

Sickle Cell and Thalassaemia

Local Antenatal Screening Operational Guideline

2022 -2025

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Version Control Summary

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| Version | Date | Author | Status | Comment |
| 1 | 14/11/2013 | Service Manager/Specialist Nurse | Ratified |  |
| 2 | 22/05/2015 | Service Manager/Specialist NurseSpecialist Nurse | Ratified |  |
| 3 | 05/06/2018 | Service Manager/Specialist Nurse | Ratified | *Changes made in this version are below pg3,4,5* |
| 4 | 13/06/2022 | Service Manager/Specialist Nurse | Ratified | *Changes made in this version are below pg5.6.7.8* |
| 5 | 15/05/2023 | Clinical Service Lead | Ratified |  |

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| ***Changes made in version 3*** |
| Page | Subheading | Current  | Changes |
| 4 | Changes to National Screening Program- from NHS Screening Programmes | Added New | Public Health England NHS Sickle Cell and Thalassaemia Screening Programme  |
| 4 | Introduction | The local policy falls within the guidance issued by the National Programme Centre.1 | The local policy falls within the guidance issued by the Public Health England (PHE) NHS England Screening Programme Sickle Cell and Thalassaemia 2017 |
| 4 | Introduction | PHE - Sickle Cell & Thalassaemia Screening Programme. www.sct.screening.nhs.uk | PHE - Sickle Cell & Thalassaemia Screening Programme. www.gov.uk/phe/screening |
| 5 | Referral Criteria | Added new | All fathers-to-be, where antenatal screening show the mother to be a carrier |
| 5 |  |  | Guidelines for Newborn Blood Spot Sampling (2016) |
| 5 | Footnote | **Antenatal Haemoglobinopathy Screening & Follow-Up Policy****East London NHS Foundation Trust & Newham University Hospital - April 2015****NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*** [**http://www.sct.screening.nhs.uk/policy-antenatal**](http://www.sct.screening.nhs.uk/policy-antenatal) | [www.gov.uk/phe/screening](http://www.gov.uk/phe/screening) |
| 6 | National screening Policy | NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*  <http://www.sct.screening.nhs.uk/policy-antenatal>  | [www.gov.uk/phe/screening](http://www.gov.uk/phe/screening) |
| 6 | National screening Policy |  NHS Sickle Cell & Thalassaemia Programme Laboratory Handbook 3rd Edition October 2012 http://sct.screening.nhs.uk/standardsandguidelines [Accessed February 2015] | [www.gov.uk/phe/screening](http://www.gov.uk/phe/screening) |
| 7 | footnote | **Antenatal Haemoglobinopathy Screening & Follow-Up Policy****East London NHS Foundation Trust & Newham University Hospital - April 2015****NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*** [**http://www.sct.screening.nhs.uk/policy-antenatal**](http://www.sct.screening.nhs.uk/policy-antenatal) | [www.gov.uk/phe/screening](http://www.gov.uk/phe/screening) |
| 8 | footnote | **Antenatal Haemoglobinopathy Screening & Follow-Up Policy****East London NHS Foundation Trust & Newham University Hospital - April 2015****NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*** [**http://www.sct.screening.nhs.uk/policy-antenatal**](http://www.sct.screening.nhs.uk/policy-antenatal) | www.gov.uk/phe/screening |
| 8-16 | footnote | **Antenatal Haemoglobinopathy Screening & Follow-Up Policy****East London NHS Foundation Trust & Newham University Hospital - April 2015****NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*** [**http://www.sct.screening.nhs.uk/policy-antenatal**](http://www.sct.screening.nhs.uk/policy-antenatal) | www.gov.uk/phe/screening |
| 17 |  | All incidents related to the antenatal screening pathway should be reported the NHS Sickle Cell & Thalassaemia Screening Programme Centre by email to PHE.screeninghelpdesk@nhs.net.  |  |
| 19 |  | Laboratory (and counselling) support service | removed |

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| ***Changes made in version 4*** |
| **Page** | **Subheading** | **Current**  | **Changes** |
| 8 | 4.Referral Criteria | added | All women with a confirmed disease or syndrome |
| 9 | 6.National Screening Policy - What we are actually screening | added | Couples at Risk results |
| 11 | 10.Process | added | All the referrals must be reviewed within 24 to 48 hours of receipt, and the relevant process followed.The nurse must check all the results before the results are issued, and must check to see if the woman is still pregnant. In cases where the woman has had a termination or miscarriage the nurse must call the woman but remembering to be polite and empathetic and allow the woman to direct the conversation and decision for arranging the partner testing. If the woman declines partner screening the nurse MUST discharge from the service and write to the GP and midwife to inform them. |
| 11 | 10.Process- 11. The Known woman to the service | Added | The nurse MUST check the availability of the previous results, and compare them with the current results, identify any in accuracies and discuss these with the Lead nurse or Haematologist at the MDT. In the cases were the results are in accurate, the team must not contact the woman without confirmation of the correct results from the lead nurse, laboratory or Consultant Haematologist during MDT . |
| 12 | 10.Process- 12. The Unknown woman to the service | Added | In the cases were the results are in accurate, the team must not contact the woman without confirmation of the correct results from the lead nurse, laboratory or Consultant Haematologist during MDT .The administration team must negotiate the earliest appointment possible, possibly the following day and all the appointments must be booked according to the woman’s gestation. If the woman is 13-23 weeks then automatically this becomes urgent.If the woman is 13-23 weeks then partner bloods MUST be booked urgently preferably the following day. |
| 13 | 13.Antenatal Counselling - Confirmed Carrier Results / Face to Face (F2F) or Non Face toNF2F) | Added | (NF2F) If the woman is counselled virtually then the partner will attended for F2F appointment for blood test and counselling.Maternity History MUST include the following* Maternity History-She is weeks/ days. EDD-. LMP-. No terminations or Miscarriages.
* Origins : Woman partner
* Family History: Any family history of Haemoglobinopathies? Her parental blood results, siblings and offer screening
* Medical History
* Medication
* Social History
* Accommodation
* Nutrition
* Smoking, drugs, alcohol
* Anxious, stress and depression
* Employment
* Religion

Please note that it is important to label everything clearly in order to minimise delays in the process. If an error has occurred this must be reported via Datix, the couple must be informed and an apology must be issued. The partner must be recalled as soon as possible to minimise delays. The service manager MUST be informed as soon as an error has been identified. |
| 14 | Follow up after paternal screening | added | “Partner” results s must be made available to the Sickle Cell & Thalassaemia Service within 24hours to 72hours latest from the time of taking the blood sample. The administrative team must enter the woman and the partner on the specialist nurses diary in order to review the results and process. |
| 15 | -Paternal Carrier Results Positive but (baby not “at risk” of inheriting a major haemoglobin disorder) | Added | Benign Haemoglobinopathies |
| 15 | 18.Antenatal Counselling – Couples “at risk” of having a baby with a major haemoglobin disorder | Added | If the woman is past 12 weeks 5 days this becomes very urgent so the specialist nurse must call UCHL as soon as possible and arrange an earliest date possibleThe specialist nurse will complete the documentation on RiO and assessment tool. |
| 16 | 19.Following Prenatal Diagnosis (PND) | Added | The SCT team must share this letter with the Laboratory team and the Maternity unit via email.  |
| 20 | National Screening Committee (Quarterly Key Performance Indicators | added | **Monthly Data required KPIS** * No of women identified as SCT carriers
* No. of biological fathers of the baby offered screening
* No. of biological fathers of the baby accepted screening:   In this pregnancy
* No. of biological fathers of the baby accepted screening:  \*Not tested in this pregnancy. (previously tested in an NHS hospital/UK GP with documented results available)
* No. of biological father not screened (reason):    Declined
* No. of biological father not screened (reason):    unavailable for screening

**Any other reason please state:*** No. of women at increased risk of having a baby with sickle cell disease or thalassaemia
* No. of women at increased risk of having a baby with sickle cell disease or thalassaemia offered PND
* No. of couples at risk of having an infant with SCT
* No. of couples at risk of having an infant with SCT offered PND
* No. of PND performed by 12 weeks + 6 days gestation:
* No. of PND performed after 13wks
* No. of women with initial screening results before 10+0 gestation having PND offer before 12+6?
* No. of women with initial screening results before 10+0 gestation having PND offer after 13wks?
* No. of women requiring interpreters having PND offer before 12+6
* No. of women requiring interpreters having PND offer after 13wks
* No. of affected babies identified through PND
* No. of women choosing TOP

**Standard 7: Timely reporting of prenatal diagnosis (PND) results to parents*** Total Number of women who have PND (denominator)
* Total Number of women who received their PND result ≤ 5 days of test (numerator)
 |
| 21 | Laboratory Data | Added | Laboratory reporting can be simplified by considering the conditions that are likely to be encountered in the antenatal screening programme. These will comprise:* those with no evidence of a haemoglobin variant or thalassaemia
* carriers of a haemoglobin variant
* thalassaemia carriers
* homozygote and compound heterozygote conditions

The annual KPIs are for the laboratoryLaboratory reporting can be simplified by considering the conditions that are likely to be encountered in the antenatal screening programme.* Report format 0 for specimens screened by red cell indices only (low prevalence areas)
* Report format 1 for no abnormality detected.
* Report format 2 for the following haemoglobin variant carriers: HbS, HbC, HbD, HbE, HbOArab and Hb Lepore.
* Report format 3a for haemoglobin variant carriers where testing of the baby’s biological father is not required.
* Report format 3b is for haemoglobin variant carriers where testing of the baby’s biological father is required.
* Report format 4a for β thalassaemia carriers.
* Report format 4b for possible β thalassaemia carriers.
* Report format 5a for HPFH
* Report format 5b for δβthalassaemia carrier.
* Report format 6a for possible α0 thalassaemia carriers when both the biological mother and the baby’s biological father are of high risk family origins for α0.
* Report format 6b for HbH disease.
* Report format 7b for possible α thalassaemia carriers (MCH 25 to 27pg)
* Report format 8 for homozygote and compound heterozygote conditions.
* The SCT team are required to match the woman’s results to the partner results and submit the data
 |
| 22 | NHS Sickle Cell & Thalassaemia Screening Programme Annual Performance |  | There are 9 Standard KPIS that have to be ,met by all services as listed below :* Standard 1: Antenatal coverage- Achievable level: ≥ 99.0%
* Standard 2: Timeliness of antenatal screening test- Achievable level: ≥ 75.0%
* Standard 3: Completion of family origin questionnaire (FOQ)- Achievable level: ≥ 99.0%
* Standard 4: Antenatal screening test turnaround times- Achievable level: ≥ 95.0%
* Standard 5: Timely offer of prenatal diagnosis (PND) to women at risk of having an affected infant- Achievable level: ≥ 75%
* Standard 6: Timeliness of prenatal diagnosis (PND)- Achievable level: ≥ 75.0%
* Standard 7: Timely reporting of prenatal diagnosis (PND) results to parents- Achievable level: ≥ 90.0%
* Standard 8: Timely reporting of new-born screen positive results- Achievable level: ≥ 95.0%
* Standard 9: Timely receipt into Haemoglobinopathy centres- Achievable level: ≥95.0%
 |
| 22 | East London NHS Foundation Trust & Newham Sickle Cell & Thalassaemia Centre data |  | * Monthly Activity Data is collated from the RiO IT System on activity at the Newham Sickle Cell & Thalassaemia Service.
* However most data must be kept on a spreadsheet as a failsafe
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| **Executive Summary** |

The East London NHS Foundation Trust - Newham Community Services Sickle Cell and Thalassaemia Service, has a commitment, in conjunction with Newham University Hospital, to screen during the antenatal period for sickle cell, thalassaemia and other haemoglobin variants and follow up positive results for the Newham population. This is a very diverse community at high risk of inheriting haemoglobin conditions.

The aim of this policy document is to address the local screening procedures and pathways for clients affected by these haemoglobin carrier states and conditions. This policy must be read in conjunction with the NHS England National Standards for Antenatal Sickle Cell and Thalassaemia Screening Programme.

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| **Changes to National Screening Program:** |

*The NHS Screening Program is commissioned and hosted by NHS Public Health England (PHE). The NHS Sickle Cell and Thalassaemia (SCT) Screening Programme replace NHS Sickle Cell and Thalassaemia Screening Programme Standards October 2011 and have an implementation date of April 2017. There has been National Standard update from the 1st of February 2017. We have reviewed this guideline taking into consideration the National standard update.*

*The program has also moved please see contact details below:*

*PHE Screening, Floor 2 Zone B, Skipton House, 80 London Road, London SE1 6LH www.gov.uk/phe/screening Twitter: @PHE\_Screening Blog: phescreening.blog.gov.uk*

*For queries relating to Screening issues, please contact:* *phe.screeninghelpdesk@nhs.net*

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| **1.Introduction** |

Sickle cell disease and thalassaemia major syndromes (alpha and beta) are genetically inherited blood disorders, which mainly affect people whose ancestors are from Africa, Asia, the Middle East, the Mediterranean, and the Caribbean Islands, but is not exclusive to these populations.

People inherit these haemoglobin conditions in either a “carrier” or “diseased” state. The people who are carriers have usually inherited a defective gene from one parent, and are considered “healthy carriers.” It is important to identify carriers because the gene is passed from biological parent(s) to child. A couple who are both carriers of a significant Haemoglobinopathy have a 1 in 4 or 25% chance, in every pregnancy, of having a child with a major haemoglobin condition.

An individual with a major condition has inherited a defective gene from both parents and generally has a chronic lifelong condition where significant health issues are anticipated. Regular treatment is required and there is limited chance of a cure. During pregnancy, prenatal diagnosis is offered, and the woman/couple may decide to accept termination of pregnancy for an affected fetus.

Individuals with sickle cell disease have a condition, which expresses itself with bouts of severe pain; serious life-threatening infections; and varying degrees of chronic and acute anaemia. Medication to manage pain when it occurs, and prophylactically to reduce the risk of infections, is required throughout their lives. Individuals with thalassaemia major syndrome inherit a severe anaemia, which requires them to have regular blood transfusions, 4-8 weekly, for survival.

It is also possible to inherit “benign” haemoglobin, conditions that do not merit pre-natal diagnosis and where by termination of pregnancy will not offered. These conditions may cause intermittent health issues, but life-long treatment is not required. Such conditions include Hb DD, Hb EE, Hb CC, and Hb H Disease.

Screening during the antenatal period, using a simple blood test, offers an opportunity to identify women who are Haemoglobinopathy carriers, and subsequently allows screening of consenting biological fathers. Identified carrier women and partner are known as ‘**At *risk* couples**’ because they are at risk of having a baby with a major haemoglobin disorder. They are able to receive information, advice and counselling in order to make choices for the pregnancy, including the decision to have further investigations if desired.

The team at the Newham Sickle Cell and Thalassaemia Service work closely with the maternity department at Newham University Hospital, the laboratory services at Bart’s Healthcare, and liaise with primary care and other stakeholders, in order to provide quality care for this client group.

This document outlines the local processes for referrals, appointments, and follow up of women who are carriers, as well as for identified “couples at risk’, to ensure that timely reproductive choices can be made for the pregnancy.

The local policy falls within the guidance issued by the Public Health England (PHE) NHS England Screening Programme Sickle Cell and Thalassaemia 2017.[[1]](#footnote-1)

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| **2. Aims & Objectives** |

* To offer counselling and follow up to support Antenatal Screening for Sickle Cell, Thalassaemia and other Haemoglobin Variants, of all women booked within the maternity service at Newham University Hospital, Barking Birthing Centre, via the GP service or those who self-refer.
* To allow informed reproductive choice by identifying **couples “*at risk*”** of having affected infants at an early stage in pregnancy.
* Services include counselling, testing the baby’s father, referral for prenatal diagnosis and termination of affected pregnancy, as well as support for women/couples who choose to continue a pregnancy where the baby has been diagnosed as having a major haemoglobin disorder.

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| 1. **Screening Criteria**
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* The GP, Midwife or Obstetrician offer screening for Sickle Cell, Thalassaemia and other Haemoglobin Variants, via a blood test, when a woman attends to report a possible pregnancy.
* All women screened for Haemoglobinopathy and identified as a carrier, or with a haemoglobin condition, or with an inconclusive result, they will be referred to the Sickle Cell and Thalassaemia team via Barts Healthcare Laboratory.
* The screening follow up service is available to all women booked within the maternity department at Newham University Hospital, Barking Birthing Centre or via the local GP service. Known **“*at risk*” couples** may also self-refer to the Newham Sickle Cell & Thalassaemia Centre.

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| 1. **Referral Criteria**
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* All women with confirmed carrier results;
* All women with a confirmed disease or syndrome
* All fathers-to-be, where antenatal screening show the mother to be a carrier
* All women with inconclusive Haemoglobinopathy screening results;
* *“At risk”* couples known to the sickle cell and thalassaemia service who self-refer.

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| 1. **Clients that do not meet the criteria**
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* Normal results – HbAA
* Women who are **23** weeks pregnant or over, can still be seen within the context of the antenatal genetic counselling service and offered screening for the baby’s father, **BUT** prenatal diagnosis must not be offered, or referral made as the national “cut off” for termination of pregnancy is 24 weeks gestation.

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| 1. **National Screening Policy[[2]](#footnote-2)- What we are actually screening**
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**Significant maternal Haemoglobinopathies**

* Hb SS
* Hb SC
* Hb SDPunjab
* Hb SE
* Hb SOArab
* Hb S/Lepore
* Hb S/β thalassaemia
* Hb S/δβ thalassaemia
* β thalassaemia major/intermedia
* Hb Lepore/β thalassaemia
* Hb E/β thalassaemia
* Hb H Disease (--/-α)

**Carrier states in mother**

* Hb AS
* Hb AC
* Hb ADPunjab
* Hb AE
* Hb OArab
* Hb A Lepore
* β thalassaemia carrier
* δβ thalassaemia
* α0 thalassaemia carrier (--/αα)
* Hereditary persistence of fetal haemoglobin (HPFH)

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| **7. Couples at Risk results** |

**Couples at risk:** **Results that mean there is a 1 in 4 chance or higher of the fetus being affected are biological mothers who are carriers for, or affected by:**

* Hb S and baby’s biological father is a carrier or affected by Hb S, β thalassaemia, Hb DPunjab, Hb C, HbE, or Hb OArab
* β thalassaemia and baby’s biological father is a carrier or affected by Hb S, β thalassaemia, δβ thalassaemia, Hb Lepore, or Hb E
* δβ thalassaemia and baby’s biological father is a carrier or affected by β thalassaemia or Hb Lepore
* Hb Lepore and baby’s biological father is a carrier or affected by β thalassaemia, δβ thalassaemia, or Hb Lepore
* Hb DPunjab and baby’s biological father is a carrier or affected by Hb S
* Hb C and baby’s biological father is a carrier or affected by Hb S
* Hb E and baby’s biological father is a carrier or affected by β thalassaemia
* Hb OArab and baby’s biological father is a carrier or affected by Hb S

**Other results that mean there is a 1 in 4 chance or higher of the fetus being affected are if:**

* both of the baby’s biological parents are at high risk of α0 thalassaemia
* parents have any other haemoglobin variants detected which may result in a serious haemoglobin disorder
* **Calculation of gestational age may be based on last menstrual period or ultrasound scan.**

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| 1. **Screening & Referrals to Newham Sickle Cell & Thalassaemia Service**
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All bookings for all women booking for antenatal care must be offered a screening test for Sickle Cell, Thalassaemia and other Haemoglobin Variants by the GP or midwife. This sample must be accompanied by completion of a Family Origin Questionnaire Form (FOQ) Appendix 3, which assists the laboratory with processing results, and the specialist nurse with giving relevant information.

National policy supported by NICE Guidelines and NICE Quality Standards state that women must be offered screening by 10 weeks of pregnancy in order to access timely follow up care.

Samples are sent to Bart’s Healthcare Laboratory from Newham University Hospital for processing in relation to Haemoglobinopathies.

Newham Sickle Cell & Thalassaemia Service see women for counselling and offer screening of the baby’s father if they have booked for antenatal care at

* Newham University Hospital;
* Barking birthing centre;
* via their local GP service;
* Or on occasion women/couples who self-refer to the service.

All carrier (trait), affected and inconclusive results are sent to the Newham Sickle Cell & Thalassaemia Service by email (via nhs.net) on a daily basis, for follow up. The administration team will download results from cyberlab and upload the results to the woman’s RiO file.

***Women who are 23 weeks pregnant or over, can still be seen within the context of the antenatal genetic counselling service and offered screening for the baby’s father, BUT prenatal diagnosis MUST not be offered, or referral made, as the national “cut off” for termination of pregnancy is 24 weeks gestation.***

The women, who are Hb AA normal are not seen by the Sickle Cell & Thalassaemia Service. The midwife or GP will give the woman their results.

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| **9.Counselling Appointment** |

**Summary**

The nurse will complete a comprehensive assessment of the woman using the RiO IT system. This must include an assessment of the woman’s physical and mental well being, ability to make informed decisions, as well as a review of her housing situation and any other relevant social issues. Information about the baby’s father must also be included. The women and their partners are seen for antenatal genetic counselling by the Newham Sickle Cell & Thalassaemia Service between 8 weeks of pregnancy to term, and can be referred for prenatal diagnosis (PND) between 11-22 weeks of pregnancy. 24 weeks gestation is the national “cut off” for termination of pregnancy.

***If the baby’s father is not available for screening, then appropriate information and advice must be given to the woman in regards to having prenatal diagnosis (PND) and a referral must be made if the woman chooses to do so.***

**All documentation, information given and discussions MUST on RiO file:**

* On the woman’s RiO assessment which must be created prior to the counselling session;
* On the woman’s/man’s RiO progress notes;
* In the woman’s handheld antenatal records only if the appointment is face to face(F2F).

**The RiO assessment form MUST be updated:**

* With the father’s results when available;
* If the woman/couple choose to have PND, including the outcome, referral and the foetal results.

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| 1. **Process**
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The Antenatal Haemoglobinopathy referrals are received from Bart’s and the London Hospital Laboratory by the designated administrative staff at the Centre on a daily basis. All the referrals must be reviewed within 24 to 48 hours of receipt, and the relevant process followed. The administrative team at the Newham Sickle Cell & Thalassaemia Service must check **all results** to determine whether screening was done in a previous pregnancy. The nurse must check all the results before the results are issued, and must check to see if the woman is still pregnant. In cases where the woman has had a termination or miscarriage the nurse must call the woman but remembering to be polite and empathetic and allow the woman to direct the conversation and decision for arranging the partner testing. If the woman declines partner screening the nurse MUST discharge from the service and write to the GP and midwife to inform them.

**Please note:**

* Complex results must be discussed with the named Lead Specialist Nurse or Haematology Consultant (if the Lead specialist nurse is unavailable) prior to the woman’s/couples appointment.
* If the woman’s result is inconclusive and DNA performed on the sample, then the administrative team **MUST** ensure that the final confirmed result is available prior to counselling.
* Antenatal Genetic Counselling Clinics are held at least 3 days weekly at the Sickle Cell & Thalassaemia Centre via the telephone and partner invited for blood test.
* The administrative team must check whether an interpreter is required for the counselling session and book as necessary.

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| 1. **The Known woman to the service**
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**If the woman** **was screened in a previous pregnancy then the following process must be followed:**

* The nurse MUST check the availability of the previous results, and compare them with the current results, identify any in accuracies and discuss these with the Lead nurse or Haematologist at the MDT.
* In the cases were the results are inaccurate, the team must not contact the woman without confirmation of the correct results from the lead nurse, laboratory or Consultant Haematologist during MDT .
* If partner results are available partner retesting **MUST** be offered according to the National Standards and if they decline this must be documented clearly in their notes.
* The administrators must check to see if the baby’s father from the previous pregnancy was screened.
* The administrator must check to see if the paternal records are available to the team at the Sickle Cell & Thalassaemia Service.
* The nurse must contact the woman by telephone to establish whether or not the woman is aware of her previous screening result, and whether the baby’s father the same as for her previous pregnancy.
* If the baby’s father is the same, a further counselling appointment will be offered.
* If the baby’s father is different then an appointment for counselling and partner screening is required.
* The nurse will check and review all decisions and actions made by the administrative team regarding women screened in a previous pregnancy before counselling the woman to ensure that all the information collected is accurate. The woman’s RiO records must be updated to ensure that she is included in the screening cohort for statistical purposes

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| 1. **The Unknown woman to the service**
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**If there is no record that the woman was screened in a previous pregnancy or she has not previously attended the Newham Sickle Cell & Thalassaemia Centre for counselling, the following process must be followed, within 48 hours of receiving the result:**

* The specialist nurse must check the result and ensure that its accurate
* The nurse must check and confirm that the woman is pregnant prior to the administration teams calls the woman.
* In the cases were the results are inaccurate, the team must not contact the woman without confirmation of the correct results from the lead nurse, laboratory or Consultant Haematologist during MDT .
* The administrative team will contact the woman by telephone or text and inform her that her results have been received, and she is being offered a counselling and baby’s father screening appointment. **Results MUST not be disclosed over the telephone.**
* The nurse will review all letters and Haemoglobinopathy cards and sign before dispatch (or an alternative specialist nurse colleague if the named specialist nurse is unavailable).
* An appointment letter, Haemoglobinopathy card, appropriate carrier leaflet and leaflet for the baby’s father to explain the need for counselling must be sent to the woman, along with confirmation of her result and the date and time of the counselling session, by 1st class post, or via email or text if the appointment is scheduled for the following day.
* The administration team must negotiate the earliest appointment possible, possibly the following day and all the appointments must be booked according to the woman’s gestation. If the woman is 13-23 weeks then automatically this becomes urgent.
* If the woman is 13-23 weeks then partner bloods MUST be booked urgently preferably the following day.

 The national programme centre has developed a generic letter that could be adapted for local use to invite women for

 counselling <http://www.sct.screening.nhs.uk/guidance> - (Appendix 5)

 NHS Sickle Cell & Thalsseamia Screening Programme Carrier Leaflets <http://sct.screening.nhs.uk/professional-leaflets>

 Newham Sickle Cell & Thalassaemia Service Carrier Leaflets

 Tests for Dads Leaflet & letter for men to encourage screening during antenatal period

 <http://www.sct.screening.nhs.uk/guidance> - <http://sct.screening.nhs.uk/professional-leaflets> - (Appendix 6)

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| 1. **Antenatal Counselling - Confirmed Carrier Results / Face to Face (F2F) or Non Face to Face (NF2F)**
 |

* (F2F)If the woman attends for counselling with the baby’s father then consent for screening is obtained from him, prior to the counselling session.
* **(**NF2F) If the woman is counselled virtually then the partner will attend for F2F appointment for blood test and counselling the following day.
* A trained Haemoglobinopathy, competent specialist nurse must do the counselling.

The following information must be obtained or included during the counselling session:

**Assessment and history taking:**

**Maternity History MUST include the following:**

* Maternity History-She is weeks/ days. EDD-. LMP-. No terminations or Miscarriages.
* Origins : Woman partner
* Family History: Any family history of Haemoglobinopathies? Her parental blood results, siblings and offer screening
* Medical History
* Medication
* Social History
* Accommodation
* Nutrition
* Smoking, drugs, alcohol
* Anxious, stress and depression
* Employment
* Religion

**Counselling and the assessment of the woman understands:**

* The woman’s result and it’s significance to her.
* Any prior knowledge of Haemoglobinopathies?
* Relevant antenatal history (if not already known); alternately check any details that have already been recorded to ensure that they are correct.
* Obtain some background information on the baby’s father.
* Significance of the woman’s result for the baby.
* The need for screening the baby’s father.
* The potential condition (s) that the baby may be at risk of inheriting (use the maternal results and the family origins of both parents to identify the conditions which the baby is **most likely** to inherit).
* Genetic inheritance pattern.
* Pathophysiology of the condition that the baby may be at risk of inheriting.
* Offer screening to the baby’s father.
* Discuss the possible outcomes of the screening test.
* Discuss the process following screening, and reporting results to the couple.

If the baby’s father has not yet received a screening information leaflet then one must be given to him during the counselling session.vii

The blood request form sent with the paternal sample must include the man’s demographic information as well as his family origins. The antenatal woman’s details (NHS number, name, surname and date of birth), must also be included on the form to ensure that maternal and paternal results are linked by the Laboratory. The source of the sample must be written on the form so that the results are received back at the Sickle Cell & Thalassaemia Centre.

* Please note that it is important to label everything clearly in order to minimise delays in the process. If an error has occurred this must be reported via Datix, the couple must be informed and an apology must be issued. The partner must be recalled as soon as possible to minimise delays. The service manager MUST be informed as soon as an error has been identified.

A letter summarising the counselling session must be sent to the GP and antenatal screening midwife within 24 hours of the counselling session.

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| 1. **Special Notes**
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***If the baby’s father is unavailable or declines Haemoglobinopathy screening then the woman can be referred for prenatal diagnosis without a paternal Haemoglobinopathy screening result, in the same way as “at risk” couples. The test is done at University College London Hospital (UCLH) and results are returned to the Newham Sickle Cell & Thalassaemia Service.***

***If either the woman or the baby’s father is a beta thalassaemia carrier then the woman/couple must be informed that if their baby is also a beta thalassaemia carrier then this will not be identified during new-born bloodspot screening and that arrangements must be made for their baby to be screened at 1/2 years of age or older.***

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| **15. Follow up after paternal screening** |

The specialist nurse must review all “partner” results who conducted the genetic counselling clinic and linked to the woman’s results. “Partner” results must be made available to the Sickle Cell & Thalassaemia Service within 24hours to 72hours latest from the time of taking the blood sample. The administrative team, the nurse are responsible for chasing up daily progress and receipt of the partner results. The administrative team must enter the woman and the partner on the specialist nurses diary in order to review the results and process.

If there are any problems with obtaining results or they are not available within the recommended timescale, this must be reported to the nursing team lead who must escalate with the laboratory team within 24hours. If the results are not received within the National recommended timeframe of 3 days, this must be reported on Datix and the laboratory team notified directly. However it’s always advisable to initiate an investigation 1st prior to escalation.

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| **16. Normal Results (Hb AA)** |

If the paternal results are normal then this must be conveyed to the couple by letter, accompanied by a Haemoglobinopathy card for the man and the woman. If the woman specifically requested, the results may be conveyed by a telephone call. The couple must then be discharged from the Sickle Cell & Thalassaemia Service, as no further appointments will be required.

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| **17. Benign Haemoglobinopathies -Paternal Carrier Results Positive but (baby not “at risk” of inheriting a major haemoglobin disorder)** |

* If the man is identified as a Haemoglobinopathy carrier and his result is similar to the woman’s result then the couple must be invited for a follow up counselling session and the results explained “face to face” or virtually.
* If they are not “*at risk”* of having a baby with a major haemoglobin disorder (sickle cell disease or thalassaemia major syndrome). but the baby could inherit a benign haemoglobin disorder which does not require long-term treatment,
* for example a condition such as Hb EE; Hb CC; Hb DD; Hb C/Beta thalassaemia, Hb H Disease, this must be explained and the couple reassured.
* A paternal Haemoglobinopathy card and appropriate carrier leaflet must be given.
* Prenatal diagnosis is **not** required for any of these conditions and referral will not be accepted by University College London Hospital.

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| **18. Antenatal Counselling – Couples “at risk” of having a baby with a major haemoglobin disorder**  |

If the paternal result shows that the couple are “*at risk”* of having a baby with a major haemoglobin disorder (sickle cell disease, Beta thalassaemia major syndrome and Alpha Thalassaemia syndrome) then the couple must be:

* The woman must be put in the at risk couples waiting list and their counselling appointment booked in the at risk couples waiting list
* Offered an appointment for prenatal diagnosis.
* Offered an urgent follow up counselling appointment to explain the risk to their baby, details about the condition that their baby could inherit and the options for the pregnancy. An explanatory leaflet must be given to the woman. This leaflet alternatively must be sent with the appointment or can be given after attendance at the counselling session, or sent via text or email if the appointment was virtual.
* The couple must be informed of the risk of miscarriage associated with having prenatal diagnosis, even if the baby is affected by a major haemoglobin disorder or not.
* Urgently refer to University College London Hospital (UCLH) if they do decide to have prenatal diagnosis by 12 weeks 5 days. An appointment will be sent directly to the woman/couple by the UCHL team.[[3]](#footnote-3)
* If the woman is past 12 weeks 5 days this becomes very urgent so the specialist nurse must call UCHL as soon as possible and arrange an earliest date possible.
* The specialist nurse will complete the documentation on RiO and assessment tool.

**Prior to emailing the referral to UCLH, the specialist nurse at Newham Sickle Cell & Thalassaemia Service must liaise with the maternity department /antenatal screening coordinator to ensure that:**

* The nurse must check that the woman/couple do not require PND for any other condition, such as Down’s syndrome.
* All the woman’s results such as Hepatitis B & C; full blood count; HIV status, blood group and rhesus factor are available for inclusion on the referral form.
* If prenatal diagnosis is declined then the couple must be informed of the process for screening their baby after birth and how they can/ or will obtain the result, and then discharged from the service to await baby’s results.

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| **19.Following Prenatal Diagnosis (PND)** |

* Following PND, the initial result is given to the woman/couple by the team at UCLH, followed by a letter to the woman and a copy is sent to the team. The SCT team must share this letter with the Laboratory team and the Maternity unit via email.
* On receipt of the result at Newham Sickle Cell & Thalassaemia Service, the specialist nurse must contact the woman to ensure that she has a complete understanding of the result and what this means for her baby, and discuss the options for her pregnancy.
* If the baby **does not** have a major haemoglobin disorder , then no further appointments or follow up is required during pregnancy the couple is discharged.
* A record of the woman/couple results, the baby’s due date must be kept so that the new-born screening result is confirmed and conveyed to the couple as soon as it is available.
* If the couple have PND and the baby is affected, and they **choose to** have a termination of pregnancy, then the specialist nurse needs to inform the GP so that he can facilitate a referral for this procedure to be carried out. The nurse will follow up with ongoing counselling support.
* If the couple have PND, the baby is affected and they **choose not to** have a termination of pregnancy then the Newham Sickle Cell & Thalassaemia Service will offer ongoing support to the woman/couple.
* The Sickle Cell & Thalassaemia Centre must inform the parents of the new-born screening result as soon as possible after receipt. Some parents may wish to speak to the Paediatrician or a family with a child who has the same condition.
* All outcomes from PND must be documented on the woman’s RiO assessment form and progress notes. A copy of the results from UCLH must be uploaded to RiO ,and attached to her records.
* The UCHL team will send through a result outcome sheet and it’s the responsibility of the specialist nurse to complete and send back. The outcome form must also be shared with the midwifery team for they have to complete this form once the baby is born.

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| **20. Women who book late for pregnancy** |

The women who are **23** weeks pregnant or over can still be seen, within the context of the antenatal genetic counselling service and baby father must be offered screening. **BUT** prenatal diagnosis must not be offered or referral made as the national “cut off” for termination of pregnancy is 24 weeks gestation.

If they do not attend the first appointment offered, then any subsequent follow up must be in the general carrier-counselling clinic.

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| **21. Woman with a major haemoglobin disorder[[4]](#footnote-4);[[5]](#footnote-5)** |

Women who have a major haemoglobin disorder and are pregnant are considered “high risk”, must always be booked urgently and must be referred for joint obstetric/haematologist care. The specialist nurse must ensure joint care by Obstetrician & Haematologist must be initiated and continue to provide support throughout the pregnancy.

The woman must be offered an urgent appointment for counselling regarding care of her condition during pregnancy, as well as for genetic counselling and screening of the baby’s father.

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| **22. Woman with inconclusive results** |

If the woman has an “inconclusive” Haemoglobinopathy result this **MUST** be discussed with the named specialist nurse. If they are unavailable, then contact can be made with the consultant haematologist *prior* to the counselling appointment. The administrative staff must chase up the final report and inform the specialist nurse when this is available.

A counselling appointment **MUST** be offered:

* An inconclusive result means that, the laboratory has not been able to identify the genotype, therefore further investigation is required.
* The following investigations according to the National standards will be requested depending on the initial result: Capillary Electrophoresis, Mass Spectrum and DNA analysis.
* If the final confirmed result is unavailable prior to the counselling appointment, this must be explained to the woman and partner testing must proceed depending on the results and advise from the Lead Nurse or Consultant Haematologist.
* If the final confirmed result is available then this must be explained to the woman, and partner testing offered where relevant.
* If any further investigations are required then blood must be taken as requested by the laboratory.
* If the “partner” result is Hb AA then there is no risk to the baby of inheriting a major haemoglobin disorder.
* If the “partner” also has a Haemoglobinopathy, then this must be discussed with the specialist nurse and a risk assessment for the baby made, prior to any follow up appointment for the couple.

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| **23.Women with suspected alpha plus thalassaemia** **or iron deficiency anaemia[[6]](#footnote-6)’****[[7]](#footnote-7)** |

The screening result for women who may be alpha thalassaemia plus carriers or have iron deficiency anaemia may be indistinguishable.

Women who are suspected alpha plus thalassaemia carriers are not at high risk of having a baby with a major haemoglobin disorder, and the recommendation from the National Programme Centre is that there is no requirement for re-screening, follow up or partner screening in relation to Haemoglobinopathy risk.

In East London NHS Foundation Trust, particularly given the family origins of the local population groups, these inconclusive results must be referred to the GP, in writing, for investigations to exclude iron deficiency anaemia. All further follow up is via the GP.

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| **24.Woman with suspected alpha zero thalassaemia**xiii |

The Newham Sickle Cell & Thalassaemia Service have been given the responsibility to follow up women who are ***suspected alpha zero thalassaemia carriers*** as the laboratory at Barts Healthcare do not have access to information regarding family origins. Women must be routinely offered a counselling appointment and offer partner screening. The nurse must complete the FOQ with the couple to establish risk.

The local laboratory policy requests partner testing and a blood sample from the woman for both, for the following investigationsxii

* FOQ
* Full blood count,
* Ferritin levels,
* Haematinics,
* DNA testing to confirm the result.

**If both couples are at RISK**

This differs from the national policy and high prevalence-screening algorithm. Appendix 4 “Partner” testing must be offered if the man has family origins from China (including Hong Kong), Taiwan, Thailand, Cambodia, Laos, Vietnam, Indonesia, Burma, Malaysia, Singapore, Philippines, Cyprus, Greece, Sardinia, Turkey, or uncertain family origins. Then refer for PND and after confirmation of the partner DNA analysis. Its is common practice that all suspected Blood samples for Alpha Thalassaemia are sent for DNA analysis to establish the potential risk to the baby .

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| **25.Women who have had fertility treatment** |

* If a woman has had fertility treatment then it is important to establish the source of both egg and sperm to assess the potential risk of the baby inheriting a haemoglobin disorder.
* If both egg and sperm are from the baby’s biological parents then the risk to the baby can be assessed as for any other carrier woman/couple.
* If the sperm or the egg has been donated to the couple then it is not possible to do a risk assessment of the pregnancy based on the parental screening results. If the donor sperm and/or egg have been screened for a Haemoglobinopathy and the results are available then this can be discussed with the couple.
* If no screening results are available for either donor sperm or egg then the process for dealing with this situation must be locally determined with discussions between maternity services, specialist nurses, GP and consultant haematologist.
* Please note some of these women might have the donors’ results so it is advised that you ask her.

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| **26.Women who have had a bone marrow transplant** |

Women who have had a bone marrow transplant will not show their own haemoglobin genotype on routine testing. DNA will be required to confirm their haemoglobin genotype. In the interim, until the woman’s result is known, testing the baby’s father should proceed. Follow up will be based on both parental results.

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| **27.Woman who does not attend counselling appointment (DNA)[[8]](#footnote-8)** |

* The woman must be routinely contacted by telephone, prior to the first appointment being booked, to agree the date and time of the counselling session.

* A letter, text or email must be sent via first class post to confirm this appointment. If she does not attend the appointment then her GP and screening midwife must be informed by letter.
* A subsequent appointment be booked by telephone, this must be followed by writing to the woman, letter must include information about the fact that she will be discharged from the service if she fails to attend and point out the risk to their baby.
* The woman must be discharged from the service if she does not attend the second appointment. Failure to attend must be documented on her RiO file clearly and GP & maternity services must be informed of non-attendance with the option to re-refer client as necessary. This can be done via email to the midwife and a discharge letter to the GP.
* All discharges must be in line with the ELFT policy and local arrangements.

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| **28.Woman who cancels counselling appointment** |

If the woman cancels her counselling appointment, the administrative team must check:

* The reason for cancellation (for example, previous counselling? Personal reasons?).
* The woman’s must be scheduled at a suitable time for the appointment but the nurse must explain to the client for urgent reasons depending on her gestation.
* If she does not attend the rescheduled appointment then follow the process as for a woman who DNA their appointment.

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| **29.Audit & Monitoring - Data collection** |

Data is collected at three levels to support the antenatal sickle cell and thalassaemia screening programme.

* Data is populated on a spreadsheet and shared with the maternity unity and laboratory monthly
* Then data is populated on a spreadsheet and sent to NHS England quarterly
* Then Data is populated spreadsheet for Laboratory reasons yearly and sent to NHS England

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| **30. National Screening Committee (Quarterly Key Performance Indicators)[[9]](#footnote-9)** |

**National Screening Committee (Quarterly Key Performance Indicators)[[10]](#footnote-10)**

Key Performance Indicator Data (KPI) is collected quarterly (June, September, December and March) for the National Screening Committee. The Sickle Cell & Thalassaemia Screening Programme requires a report on three areas of activity related to antenatal screening:

* KPI ST1: coverage: antenatal screening
* KPI ST2: test: timeliness of antenatal screening
* KPI ST3: test: completion of family origin questionnaire (FOQ)
* KPI ST4a: referral: timely offer of prenatal diagnosis (PND) to women at risk of having an infant with sickle cell disease or thalassaemia
* KPI ST4b: referral: timely offer of prenatal diagnosis (PND) to couples at risk of having an infant with sickle cell disease or thalassaemia

**Monthly Data required KPIS**

* No of women identified as SCT carriers
* No. of biological fathers of the baby offered screening
* No. of biological fathers of the baby accepted screening:   In this pregnancy
* No. of biological fathers of the baby accepted screening:  \*Not tested in this pregnancy. (previously tested in an NHS hospital/UK GP with documented results available)
* No. of biological father not screened (reason):    Declined
* No. of biological father not screened (reason):    unavailable for screening

**Any other reason please state:**

* No. of women at increased risk of having a baby with sickle cell disease or thalassaemia
* No. of women at increased risk of having a baby with sickle cell disease or thalassaemia offered PND
* No. of couples at risk of having an infant with SCT
* No. of couples at risk of having an infant with SCT offered PND
* No. of PND performed by 12 weeks + 6 days gestation:
* No. of PND performed after 13wks
* No. of women with initial screening results before 10+0 gestation having PND offer before 12+6?
* No. of women with initial screening results before 10+0 gestation having PND offer after 13wks?
* No. of women requiring interpreters having PND offer before 12+6
* No. of women requiring interpreters having PND offer after 13wks
* No. of affected babies identified through PND
* No. of women choosing TOP

**Standard 7: Timely reporting of prenatal diagnosis (PND) results to parents**

* Total Number of women who have PND (denominator)
* Total Number of women who received their PND result ≤ 5 days of test (numerator)

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| **31. Laboratory Data**  |

Laboratory reporting can be simplified by considering the conditions that are likely to be encountered in the antenatal screening programme. These will comprise:

* those with no evidence of a haemoglobin variant or thalassaemia
* carriers of a haemoglobin variant
* thalassaemia carriers
* homozygote and compound heterozygote conditions

The annual KPIs are for the laboratory

Laboratory reporting can be simplified by considering the conditions that are likely to be encountered in the antenatal screening programme.

* Report format 0 for specimens screened by red cell indices only (low prevalence areas)
* Report format 1 for no abnormality detected.
* Report format 2 for the following haemoglobin variant carriers: HbS, HbC, HbD, HbE, HbOArab and Hb Lepore.
* Report format 3a for haemoglobin variant carriers where testing of the baby’s biological father is not required.
* Report format 3b is for haemoglobin variant carriers where testing of the baby’s biological father is required.
* Report format 4a for β thalassaemia carriers.
* Report format 4b for possible β thalassaemia carriers.
* Report format 5a for HPFH
* Report format 5b for δβthalassaemia carrier.
* Report format 6a for possible α0 thalassaemia carriers when both the biological mother and the baby’s biological father are of high risk family origins for α0.
* Report format 6b for HbH disease.
* Report format 7b for possible α thalassaemia carriers (MCH 25 to 27pg)
* Report format 8 for homozygote and compound heterozygote conditions.

The SCT team are required to match the woman’s results to the partner results and submit the data

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| **32.NHS Sickle Cell & Thalassaemia Screening Programme Annual Performance Appendix**  |

There are 9 Standard KPIS that have to be met by all services as listed below :

* Standard 1: Antenatal coverage- Achievable level: ≥ 99.0%
* Standard 2: Timeliness of antenatal screening test- Achievable level: ≥ 75.0%
* Standard 3: Completion of family origin questionnaire (FOQ)- Achievable level: ≥ 99.0%
* Standard 4: Antenatal screening test turnaround times- Achievable level: ≥ 95.0%
* Standard 5: Timely offer of prenatal diagnosis (PND) to women at risk of having an affected infant- Achievable level: ≥ 75%
* Standard 6: Timeliness of prenatal diagnosis (PND)- Achievable level: ≥ 75.0%
* Standard 7: Timely reporting of prenatal diagnosis (PND) results to parents- Achievable level: ≥ 90.0%
* Standard 8: Timely reporting of new-born screen positive results- Achievable level: ≥ 95.0%
* Standard 9: Timely receipt into Haemoglobinopathy centres- Achievable level: ≥95.0%

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| **33. East London NHS Foundation Trust & Newham Sickle Cell & Thalassaemia Centre data** |

* Monthly Activity Data is collated from the RiO IT System on activity at the Newham Sickle Cell & Thalassaemia Service.
* However most data must be kept on a spreadsheet as a failsafe

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| **34. Incident Reporting[[11]](#footnote-11) and Quality Assurance**  |

**Incident Reporting[[12]](#footnote-12)**

PHE screening gives advice on screening incidents and takes action to help prevent incidents elsewhere, including sharing lessons identified from incidents, developing new guidance and training. So all screening incidences MUST be reported to PHE. PHE.screeninghelpdesk@nhs.net.

**Purpose**

This guidance below sets out the requirements for managing safety concerns, safety incidents and serious incidents in NHS screening programmes. It is important that actions are in proportion to the risk of harm and based on accurate investigation. It is relevant to healthcare staff that may identify or manage a screening incident including those who provide and commission NHS funded services. It is for staff of NHS screening programmes who advise on screening incidents.

**Screening safety incidents- Complete local Datix and report to PHE incident desk** Incidents should also be reported using the national incident form to National Patient Safety Agency.[[13]](#footnote-13)

Screening safety incidents include: any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme

Harm or a risk of harm because one or more persons eligible for screening are not offered screening

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| **35. Serious incidents- Complete local Datix and report to PHE incident desk and follow instructions below:** |

* Some screening incidents require a heightened response. They are termed serious incidents. This is where the consequences or risks are so significant to individuals, carers and families; organisations and staff, populations, or represent significant potential learning for the NHS.
* The heightened response means that formal governance is needed around reporting, investigating, action planning, implementation, closure and learning. Principles should be defined and consistent procedures followed; It is a matter of professional judgement whether to declare a serious incident. Careful consideration of the definition is needed in each case.
* In most instances, the provider of the local screening service declares the serious incident after deciding this with the commissioner and informed by  PHE QA advice.
* In distinguishing between a screening safety incident and a serious incident, consideration should be given to: whether individuals, the public or staff would suffer avoidable severe harm or death if the root cause is unresolved or the likelihood of significant damage to the reputation of the organisations involved
* This means that a near miss can be a serious incident where there is a significant existing risk of a system failing.

**Newham Sickle Cell & Thalassaemia Centre- for queries contact**

19-21 High Street South

East Ham

E6 6EN

**Tel:** 0208 821 0800

Sending referrals & Results - Email team on : elt-tr.sickleandthal@nhs.net

Specialist lead Nurse Advise

**Bart’s Healthcare** Laboratory processes all antenatal Haemoglobinopathy samples and send the positive results to the Newham Sickle Cell & Thalassaemia Centre.-

Pathology and Pharmacy Building

4th Floor Blood Sciences

Royal London Hospital

London

E12ES

**Tel:** 0203 246 0342 **or** 0203 246 6116

**Email team on:** bartshealth.NUH-HaemoglobinopathyReferrals@nhs.net

**Prenatal Diagnosis Centre**

University College London Hospital (UCLH)

Haemoglobinopathies Genetics Centre

Ground Floor, 86-96 Chenies Mews

London

WC1E 6HX

**Tel:** 020 3447 9458 **Fax:** 020 3487 9864

**Email:** uclh.haemoglobinopathygenetics@nhs.net

**Newham University Hospital**

Glen Road

Plaistow

London

E13 8SL

**Local Antenatal Screening Co-ordinator:**

**Maternity Booking Tel:** 020 7363 8433

 For quieries or failsafe checklists send Email to - munewham@nhs.net

# NHS Sickle Cell & Thalassaemia Screening Programme

2nd Floor

Skipton House,

80 London Road,

London,

SE1 6LH

# Email: PHE.screeninghelpdesk@nhs.net

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| Standard  | Rationale | Objective |  Criteria | Definitions | Performance threshold  | Reporting | Reporting Period |
| Standard 1: Antenatal coverage | To provide assurance that screening is offered to all eligible women and each woman accepting screening has a screening result. Timely information on screening coverage is important to identify trends and monitor the effectiveness of service improvements. | To maximise the impact of the screening programme in the eligible population | The proportion of pregnant women eligible for screening who are tested | **Numerator:** ‘tested women’ is the total number of ‘eligible women’ for whom a screening result is reported, including: • known at risk couples referred directly for prenatal diagnosis (PND); repeat testing must not delay referral .**Denominator:** ‘eligible women’ is the total number of pregnant women booked | Acceptable level: ≥ 95.0%Achievable level: ≥ 99.0% | Reporting focus: maternity serviceData source: maternity serviceResponsible for submission: maternity service | Quarterly; data to be collated between 2 and 3 months after each quarter endDeadlines: 30 September (Q1), 31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 2: Timeliness of antenatal screening test | To identify carrier and affected women by 10 weeks + 0 days of pregnancy to allow the baby's biological father to be offered testing and to offer of PND to women at risk of having an affected infant by 12 weeks + 0 days of pregnancy | To maximise the opportunity for informed choice | Proportion of women tested by 10 weeks + 0 days gestation | **Numerator:** ‘women tested by 10 weeks + 0 days gestation’ **Denominator: ‘**women for whom screening sample received at laboratory’ is the total number of pregnant women | Acceptable level: ≥ 50.0%Achievable level: ≥ 75.0% | Reporting focus: maternity serviceData source: antenatal screening laboratoryResponsible for submission: maternity service | Deadlines: 30 September (Q1), 31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 3: Completion of family origin questionnaire (FOQ) | To interpret screening results in high prevalence areas and to identify women at higher risk to be offered further testing in low prevalence areas [1] | To maximise accuracy of screening test | Proportion of samples that arrive in the antenatal laboratory accompanied by a completed FOQ | **Numerator:** ‘number of antenatal samples received in the laboratory with completed FOQ’**Denominator:** ‘number of antenatal samples’ received by the laboratory | Acceptable level: ≥ 95.0%Achievable level: ≥ 99.0% | Reporting focus: maternity serviceData source: antenatal screening laboratoryResponsible for submission: maternity service | Deadlines: 30 September (Q1), 31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 4: Antenatal screening test turnaround times | To report screening outcomes promptly to help to achieve the offer of PND by 12 weeks + 0 days gestation | To maximise the opportunity for informed choice | Proportion of results reported within 3 working days | **Numerator:** ‘number of antenatal results reported ≤ 3 working days’ of receipt of sample in the laboratory **Denominator:** ‘number of antenatal samples’ received in the laboratory | Acceptable level: ≥ 90.0% Achievable level: ≥ 95.0% | Reporting focus: maternity serviceData source: antenatal screening laboratoryResponsible for submission: maternity service | Annually for samples received in the laboratory in the previous financial yearDeadline: 30 June |
| Standard 5: Timely offer of prenatal diagnosis (PND) to women at risk of having an affected infant | There is a known association between gestation at screening offer and uptake of PND, with the early offer of screening being associated with greater uptake of PND [2], [3], and [4]. The majority of PND currently takes place after 12 weeks + 6 days [5]. Approximately half of women at risk of having an affected infant decline PND; gestational age at time of decline is not known | To maximise the opportunity for women at risk of having an affected infant to make informed and timely reproductive choices | Proportion of at risk women offered PND by 12 weeks +0 days gestation | **Numerator:** ‘Number of at risk women offered PND by 12 weeks + 0 days gestation’**Denominator:** ‘Number of at risk women’ | Acceptable level: ≥ 50%Achievable level: ≥ 75% | Reporting focus: maternity service Data source: maternity service and specialist Haemoglobinopathy counsellors Responsible for submission: maternity service | Deadlines: 30 September (Q1),31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 6: Timeliness of prenatal diagnosis (PND) | There is a known association between gestation at PND offer and uptake, with the early offer being associated with greater uptake of PND. Advanced gestational age may limit reproductive choices [2], [3], [4]. | Timely intervention and choice in procedure for those who accept PND | Proportion of PND tests performed by 12 weeks + 6 days gestation | **Numerator:** ‘number of women who have PND by 12 weeks + 6 days gestation’ **Denominator:** ‘number of women who have PND’ | Acceptable level: ≥ 50.0% Achievable level: ≥ 75.0% | Reporting focus: maternity service Data source: PND laboratory Responsible for submission: PND laboratory | Deadlines: 30 September (Q1),31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 7: Timely reporting of prenatal diagnosis (PND) results to parents | To provide information about living with and supporting an affected child and if chosen, to ensure timely referral for termination of pregnancy | Maximise informed choice | Proportion of results received within 5 working days of PND procedure | **Numerator:** ‘number of women who receive their result ≤ 5 working days of PND test’ **Denominator:** ‘number of women who have PND’ | Acceptable level: ≥ 70.0%Achievable level: ≥ 90.0% | Reporting focus: maternity service Data source: maternity service and counselling services Responsible for submission: maternity service | Deadlines: 30 September (Q1),31 December (Q2), 31 March (Q3), 30 June (Q4) |
| Standard 8: Timely reporting of new-born screen positive results | To provide timely results. This includes providing information about the screening result, living with and supporting an affected child, and the care pathway | To ensure parents of screen positive infants receive results at ≤ 28 days of age | Proportion of parents informed of newborn screen positive results at ≤ 28 days of age | **Numerator:** ‘number of newborn infants with screen positive results reported to parents at ≤ 28 days of age’ **Denominator:** ‘number of newborn infants, born within the reporting period, with screen positive result’ | Acceptable level: ≥ 90.0 % Achievable level: ≥ 95.0% | Reporting focus:• SHC geographical area of responsibility• Haemoglobinopathy centre (nursing or medical) responsible for giving results• Newborn screening laboratory | Annually for infants born in the previous financial yearDeadline: June 30 |
| Standard 9: Timely receipt into Haemoglobinopathy centres | To ensure timely and appropriate management, new-born infants with positive screening results must attend a haemoglobinopathy centre (medical) by 90 days of age. | To optimise individual and population health outcomes in new-born infants born with conditions where early intervention is likely to be beneficial | Proportion of new-born infants with a positive screening result followed up and entered into care within 90 days of age | **Numerator:** ‘number of new-born infants with screen positive result seen at a Haemoglobinopathy centre (medical) ≤ 90 days of age’ **Denominator:** ‘number of new-born infants, born within the reporting period, with screen positive result’ | Acceptable level: ≥ 90.0% Achievable level: ≥95.0% | Reporting focus:• specialist Haemoglobinopathy centre with responsibility for geographical area (in development)• Haemoglobinopathy centre (medical) responsible for care• new-born screening laboratory | Deadlines: 30 September (Q1),31 December (Q2), 31 March (Q3), 30 June (Q4) |

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**Additional References**

 NHS Sickle Cell & Thalassaemia Screening Programme *Standards for the Linked Antenatal and Newborn Screening Programme 2nd Edition October 2011* [*http://sct.screening.nhs.uk/standardsandguidelines*](http://sct.screening.nhs.uk/standardsandguidelines)[Accessed

 February2015]

 National Institute for Health and Clinical Excellence *CG-62 Antenatal – NICE Guideline* (2008, modified

 December 2014) <http://guidance.nice.org.uk/CG62/NICEGuidance/pdf/English>. [Accessed February 2015]

 National Institute for Health and Clinical Excellence Quality standard for antenatal care. September 2012.

 Nice quality standard 22 <http://guidance.nice.org.uk/qs22> [Accessed February 2015]

**Reading List**

British Committee for Standards in Haematology Guidelines (2010) *significant Haemoglobinopathies: guidelines for screening and diagnosis.* British Journal of Haematology 149, 35-49

East London NHS Foundation Trust (June 2012) *Policy for service users who fail to attend appointments in children, young people, sexual and reproductive health services and CAMHS.* Trust Intranet

Healthcare staff incident reporting <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/>

East London NHS Foundation Trust (July 2012) *Screening Procedures Policy.* Trust Intranet

Map of Medicine (2010 revised 2013) *Linked Sickle Cell and Thalassaemia Screening* *- Antenatal Screening Pathway* <http://eng.mapofmedicine.com/evidence/map/linked_sickle_cell_and_thalassaemia_screening1.html>

NHS Sickle Cell & Thalassaemia Programme *Laboratory Handbook 3rd Edition October 2012*

[*http://sct.screening.nhs.uk/standardsandguidelines*](http://sct.screening.nhs.uk/standardsandguidelines)[Accessed February2015]

UK National Screening Committee (2014) *Key Performance Indicators for Screening 2014/15 Version 1.1.14*

NHS Sickle Cell & Thalassaemia Screening Programme (2012) *Guidelines for the referral of sickle cell and thalassaemia prenatal diagnosis samples to molecular Haemoglobinopathy laboratories. Version2.4* <http://www.sct.screening.nhs.uk/guidance> [Accessed March 2015]

NHS Sickle Cell & Thalassaemia Screening Programme (2015) *Data Report 2013-14.*

NHS Sickle Cell & Thalassaemia Screening Programme (2012) *Policy Framework for Antenatal Sickle Cell & Thalassaemia Screening Programme*  <http://www.sct.screening.nhs.uk/policy-antenatal> [Accessed March 2015]

NHS Sickle Cell & Thalassaemia Screening Programme (2013) *Counselling Competencies* [*http://sct.screening.nhs.uk/standardsandguidelines*](http://sct.screening.nhs.uk/standardsandguidelines)

NHS England Serious Incidents Framework

<http://www.england.nhs.uk/wp-content/uploads/2015/03/serious-incident-framwrk-15-16-faqs-fin.pdf>

NHS England <http://www.england.nhs.uk/ourwork/patientsafety/serious-incident/>

Patient Safety Serious Incident Reporting & Learning Framework <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/serious-incident-reporting-and-learning-framework-sirl/>

Royal College of Obstetricians and Gynaecologists (2010 - Reviewed December 2014) Amniocentesis and Chorionic Villus Sampling (Green top Guideline 8) <https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_8.pdf>

University of York (2014) *Involving Fathers in Antenatal Screening for Sickle Cell Disorders: Improving Informed Decision Making* <http://www.sct.screening.nhs.uk>

**Useful Websites**

Brent Sickle Cell & Thalassaemia Centre <http://sickle-thal.nwlh.nhs.uk/>

Healthtalkonline (DIPEx) <http://www.healthtalk.org/>

NHS Choices <http://www.nhs.uk/Pages/HomePage.aspx>

Sickle Cell Society <http://sicklecellsociety.org/>

UK Thalassaemia Society <http://ukts.org/>

Unit for the Social Study of Thalassaemia & Sickle Cell http://www.tascu

1. PHE - Sickle Cell & Thalassaemia Screening Programme. [www.gov.uk/phe/screening](http://www.gov.uk/phe/screening) [↑](#footnote-ref-1)
2. NHS Sickle Cell & Thalassaemia Screening Programme *Antenatal Screening Policy*

 <http://www.sct.screening.nhs.uk/policy-antenatal> 2011 [↑](#footnote-ref-2)
3. Referral Form University College London Hospital should be used [↑](#footnote-ref-3)
4. Royal College of Obstetricians and Gynaecologists (2014) *Thalassaemia in Pregnancy, Management of Beta* (Green-top

 Guideline 66) <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg66/> [↑](#footnote-ref-4)
5. Royal College of Obstetricians and Gynaecologists (2011) *Sickle Cell Disease in Pregnancy, Management of* (Green-top

 Guideline 61) Reviewed December 2014 <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg61/> [↑](#footnote-ref-5)
6. NHS Sickle Cell & Thalassaemia Screening Programme (2012) *Laboratory Handbook* <http://www.sct.screening.nhs.uk> [↑](#footnote-ref-6)
7. High Prevalence Antenatal Screening Algorithm - Appendix 4 [↑](#footnote-ref-7)
8. East London NHS Foundation Trust (2012) *Policy for Service Users Who Fail to Attend Appointments in*

 *Children, Young People, Sexual and Reproductive Health Services and CAMHS* [↑](#footnote-ref-8)
9. UK National Screening Committee (2014) *Key Performance Indicators for Screening 2014/15 Version 1.1.14* [↑](#footnote-ref-9)
10. UK National Screening Committee (2014) *Key Performance Indicators for Screening 2014/15 Version 1.1.14* [↑](#footnote-ref-10)
11. Healthcare staff incident reporting <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/> [↑](#footnote-ref-11)
12. Healthcare staff incident reporting <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/> [↑](#footnote-ref-12)
13. Healthcare staff incident reporting form <https://www.eforms.nrls.nhs.uk/staffreport/> [↑](#footnote-ref-13)