NHS public health functions agreement 2018-19

Service specification no.18
NHS Sickle Cell and Thalassaemia Screening Programme
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Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and

- Given due regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).
Contents

ServicespecificationNo.18.................................................................................................................6

Section 1: Purpose of Screening Programme.....................................................................................7
  1.1. Purpose of the Specification........................................................................................................7
  1.2 Aims .............................................................................................................................................8
  1.2.1 Antenatal Sickle Cell and Thalassaemia Screening Programme ...........................................8
  1.2.2 Newborn Sickle Cell Screening Programme ...........................................................................9
  1.2.3 Linked Antenatal and Newborn Sickle Cell and Thalassaemia Screening Programme ..........9
  1.3 Principles ...................................................................................................................................9
  1.4 Equality ...................................................................................................................................9

Section 2: Scope of Screening Programme..........................................................................................11
  2.1. Description of Screening Programme.......................................................................................11
  2.2. Care pathway (figure 1) .............................................................................................................11
  Newborn Sickle Cell Screening Programme within newborn blood spot screening...........18
  2.3. Roles and accountability through the screening pathway.........................................................20
  2.4. Commissioning arrangements...................................................................................................21
  2.5. Links between screening programme and national programmes expertise .21
  3.1 Service model summary see section 2.2 care pathway above for further details...22
  3.2 Programme co-ordination .........................................................................................................22
  3.3 Governance and leadership .......................................................................................................22
  3.4 Definition, identification and invitation of cohort/eligibility....................................................23
  3.5 Location(s) of programme delivery .............................................................................................24
  3.6 Days/hours of operation .............................................................................................................24
  3.7 Entry into screening programme ...............................................................................................24
  3.8 Working across interfaces .........................................................................................................24
  3.9 Information on test/screening programme................................................................................25
  3.10 Testing (laboratory service, performance of test by individuals) .............................................26
  3.11 Results giving ..........................................................................................................................26
  3.12 Transfer of and discharge from care obligations......................................................................26
  3.13 Public information ....................................................................................................................27
  3.14 Exclusion criteria .....................................................................................................................27
  3.15 Staffing ....................................................................................................................................27
  3.16 User involvement .....................................................................................................................28
  3.17 Premises and equipment ...........................................................................................................29
  3.18 Safety & safeguarding ..............................................................................................................29

Section 4: National standards, risks and quality assurance.................................................................30

Section 5: Data and Monitoring.........................................................................................................32
  5.1 Key performance indicators / Public Health Outcomes Framework ........................................32
  5.2 Data collection, monitoring and reporting ................................................................................32
Other: ........................................................................................................................................32
5.3 Public Health Outcomes Framework Indicators.................................................................32
Service specification No.18

This is a service specification to accompany the ‘NHS public health functions agreement 2018-19 (the ‘2018-19 agreement’).

This service specification is to be applied by NHS England in accordance with the 2018-19 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2018-19 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2018-19 agreement is available at www.gov.uk (search for ‘commissioning public health’).

All current service specifications are available at www.england.nhs.uk (search for ‘commissioning public health’).
Section 1: Purpose of Screening Programme

1.1. Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of the linked antenatal and newborn NHS Sickle Cell and Thalassaemia (SCT) Screening Programme.

The purpose of the service specification is to outline the service and quality indicators expected by NHS England (NHS E) for NHS E responsible population and which meets the policies, recommendations and standards of the NHS Screening Programmes.

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This specification needs to be read in conjunction with the following:

SCT Screening Programme Standards, 2017 http://sct.screening.nhs.uk/standards

NHS Sickle Cell and Thalassaemia Programme Handbook 2017

Checks and audits to improve quality and reduce risks 2017

Sickle Cell and Thalassaemia Handbooks for Laboratories 2017

NHS Newborn Blood Spot Screening Programme service specification.

Specialised Haemoglobinopathy Services definition as set out in the Manual for prescribed specialised services

The Specification for Specialised Services for Haemoglobinopathy Care (All Ages)


### 1.2 Aims

The NHS SCT Programme aims to:

- Ensure a high quality, accessible screening programme throughout England
- Support people to make informed choices during pregnancy and ensure timely transition into appropriate follow up and treatment
- Improve infant health through prompt identification of affected babies and timely transition into clinical care
- Promote greater understanding and awareness of the conditions and the value of screening

#### 1.2.1 Antenatal Sickle Cell and Thalassaemia Screening Programme

Objectives:
To offer timely antenatal sickle cell and thalassaemia screening to all women (and couples), to facilitate informed decision-making.
Outcome:
For those women accepting prenatal diagnosis (PND), at least 50% of PNDs to be performed before 12 weeks 6 days.

1.2.2 Newborn Sickle Cell Screening Programme

Objectives:
To identify babies born with conditions where early intervention is likely to be beneficial.

Outcome:
To achieve the lowest possible childhood death rate and to minimise childhood morbidity from sickle cell diseases.

1.2.3 Linkage between Antenatal and Newborn Sickle Cell and Thalassaemia Screening Programme

Objectives:
- to promote an appropriate level of understanding about screening for these genetically inherited conditions among professionals involved with the programme;
- to review the results from antenatal testing before, during and after the newborn test is offered, and to check that the results are congruent; and
- to prepare parents for their baby’s screening result.

Outcome:
To minimise the adverse effects of screening

1.3 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs
- All those participating in the sickle cell and thalassaemia screening programme will have adequate information on the benefits and risks to allow an informed decision to be made before participating
- The target population will have equitable access to screening
- Screening will be effectively integrated across a pathway including between the different providers, screening centres, primary care and secondary care

1.4 Equality section

Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:
- screening should be delivered in a way which addresses local health
inequalities, tailoring and targeting interventions when necessary

- a Health Equity Audit should be undertaken as part of both the commissioning and review of this screening programme; including equality characteristics, socio-economic factors and local vulnerable populations
- the service should be delivered in a culturally sensitive way to meet the needs of local diverse populations
- user involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics
- providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow equality, health inequality and screening guidance when making such decisions.

The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

The provider will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees https://www.gov.uk/equality-act-2010-guidance.

It also requires that public bodies:

- have due regard to the need to eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities
Section 2: Scope of Screening Programme

2.1. Description of Screening Programme

The linked screening programme comprises two parts: sickle cell and thalassaemia screening during pregnancy and sickle cell screening in the newborn period.


Antenatal screening for sickle cell, other haemoglobin variants and thalassaemia is offered to pregnant women early in pregnancy, (women should be tested by 10 weeks + 0 days of pregnancy) to identify women and couples who are at increased risk (1:4 or higher) of an affected pregnancy to offer them the choice of PND and the option of termination of an affected pregnancy or continuation of the pregnancy. For those women and couples at risk of having an affected baby PND to be offered by 12 weeks 0 days. PND test should ideally all take place before 12 weeks 6 days of pregnancy.

The provider must ensure:

- that if risk status is known pre-pregnancy a prompt referral for counselling and offer of PND is made at the first appointment in pregnancy
- all pregnant women, are offered screening for sickle cell, other haemoglobin variants and thalassaemia
- where a woman is identified as affected or a carrier of significant haemoglobinopathy the baby's biological father is offered screening for sickle cell, other haemoglobin variants and thalassaemia, irrespective of their family origin
- women and couples at risk of having a baby with sickle cell disease or thalassaemia major are offered counselling and diagnostic tests for the baby.

2.2. Care pathway (figure 1)

**Identify eligible population:** All pregnant women are eligible for screening. Women should be tested at the first antenatal appointment by 10 weeks and 0 days of pregnancy. In each pregnancy, the family origin questionnaire should be completed and a routine full blood count taken and mean cell haemoglobin (MCH) and other red cell indices should be assessed. In rare circumstances molecular techniques may be used to confirm their haemoglobinopathy status.
Provide information and take consent: Consent and reference to the provision of written information including *Screening Tests For You And Your Baby* should be recorded in the maternity records.

Known at risk couples: women and couples who already know their carrier status must be offered prompt referral for counselling and offer of PND (Figure 2).

Low prevalence trust: Low prevalence trusts are those where less than 1% of the booking bloods received by the laboratory are screen positive. In low prevalence trusts a family origin questionnaire (FOQ) is used to assess the risk of either the woman or the baby’s father being a carrier for sickle cell or other haemoglobin variants, or alpha thalassaemia major, to identify those who need testing for haemoglobin variants. The FOQ should be completed and sent to the laboratory with the sample.


High prevalence trust: High prevalence trusts are those where greater than or equal to 2% of the booking bloods received by the laboratory are screen positive.

In high prevalence trusts all pregnant women are offered screening followed by a blood test for sickle cell and other haemoglobin variants. The FOQ must also be completed and sent to the laboratory with the sample to facilitate interpretation of results by laboratory staff and identify those at risk of alpha thalassaemia major.

Laboratories that are between these two cut-offs would be considered borderline and should continue to use their current algorithm.


Trust mergers

- The high prevalence algorithm is viewed as the gold standard, low prevalence trusts are recommended to move to the high prevalence algorithm rather than the other way around

Take sample and send to laboratory with completed family origin questionnaire (FOQ): Information on the family origins of women and the baby’s biological father must accompany the full blood count (FBC) and haemoglobinopathy screen sample. Family origins of both the woman AND the baby’s biological father (where available) going back at least 2 generations (or more if possible) need to be assessed and documented.
Screening for sickle cell and thalassaemia should still be offered even if information about the baby’s biological father is unavailable.

If a woman declines screening, explore the reasons for this and document.

In low prevalence trusts, if a sample is received in the laboratory without a completed FOQ there is a risk that the woman will not be screened for sickle cell disease and a risk of missing an affected pregnancy.

There should be a local policy in place to ensure that FOQ information on any women whose samples are received without an FOQ, are obtained.

Screening laboratories must be able to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service.

**Laboratory tests sample as per national policy and reports results as per local arrangements:** All laboratories and maternity units should have a written policy and process for reporting results to all women, and for obtaining a blood sample from the baby’s biological father for all carrier and/or affected women for screening.

**Nothing abnormal detected:** All women should be notified of their screening test result before or at the next antenatal visit, according to local protocol. The result should be recorded in the health records and on the newborn blood spot card.

**Inconclusive results:** Some haemoglobin variants are difficult to identify and analysis may take longer. Rather than waiting for a long period of time for a conclusive maternal result, offer screening to the baby’s biological father and if nothing abnormal is detected on father’s result, then the risk to the baby can be excluded.

**Result for carrier or affected mothers:** A healthcare professional informs parents of carrier/affected results in accordance with programme guidelines and local pathway. Women should be provided with information about their carrier status along with a leaflet specific to their carrier status: https://www.gov.uk/government/collections/adult-carriers-sickle-cell-thalassaemia-unusual-haemoglobin

Refer affected mothers to consultant care for clinical and obstetric management.

The programme recommends the maternity units keep a log of, and inform the newborn laboratory of, all women who are carriers or affected, including results from PND, and have systems in place to check the screening result of babies born to screen positive women.

**Offer screening to baby’s biological father:** the offer must be made in every pregnancy, irrespective of previous screening results.
Baby’s biological fathers should be provided with written information: https://www.gov.uk/government/publications/tests-for-dads-sickle-cell-and-thalassaemia-screening

**Baby’s biological father available and gives consent.**

**Laboratory tests sample and reports results as per local arrangements.**

**Nothing abnormal detected on screening of baby’s biological father:** Offer information and advice about the possibility of the child being a carrier based on the mother’s carrier or affected result.

**Confirmed carrier result in both parents - refer at risk couple:** Parents are referred for counselling by a trained healthcare professional. Written information should be provided along with written confirmation of carrier status. https://www.gov.uk/government/publications/baby-at-risk-of-having-sickle-cell-disease-description-in-brief

**Baby’s biological father not available or declines consent:** If the baby’s biological father is unavailable for testing or his haemoglobinopathy status is unknown, then a risk assessment should be done. The programme supports women who are carriers or affected being offered PND in this situation. PND for sickle cell disease can be undertaken without the baby’s biological father’s DNA. Similarly, PND for thalassaemia can be undertaken without the baby’s father’s DNA, although the diagnosis cannot be given with as high a degree of certainty if samples from both parents are not known or tested.

**Offer PND testing:** Prior to the PND test always contact the PND laboratory to make arrangements for sending the sample. Fresh blood samples from both parents (where available) are to be sent to the DNA referral laboratory with appropriate consent for molecular analysis along with the PND sample.

**Decline PND:** Respect decision
The programme recommends that information on women who decline PND is recorded in the maternity notes.

**Accept PND - contact PND laboratory to make arrangements for analysis:** For additional information on DNA testing and contact details of PND laboratories see laboratory handbook at https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-handbook-for-laboratories
Inform parents, community midwife and GP: The responsibility for reporting results is as per local arrangements / practice. To find out what your local arrangements for reporting results are, contact your local antenatal and newborn screening coordinator.

Carrier or normal result: A designated healthcare professional informs and counsels parents of PND results in accordance with local policy and in a timely manner as per Programme standards i.e. within 5 days of having the PND procedure.

Baby affected by a major haemoglobin disorder: Parents to be referred for counselling and follow up by trained healthcare professionals. There should be a local protocol in place. Specialist midwives, Sickle Cell and Thalassaemia Centres and Regional Genetic Centres (RGCs) provide counselling services, information and advice for families with, or ‘at risk’ of, genetic conditions.

For a list of specialist centres refer to:
http://www.sickle-thal.nwlh.nhs.uk/information/nationalsicklecellthalassaemiacentres.aspx

Continue pregnancy; include results on blood spot card: Maternity units should notify newborn screening laboratories of women continuing with affected pregnancies and parental results are to be included on newborn blood spot card. Parents must be informed that their child will be referred to paediatrician / haematologist / specialist counsellor as per local policy and programme standards.

An alert form should be sent to the newborn screening laboratory. Maternity units to complete the short-term and long-term PND outcome form.

Links to newborn sickle cell screening covered by Newborn Blood Spot Programme
The result of an antenatal genetic test will be related to the results of a newborn baby’s test for the same condition, so the linked programme provides a check between the mother and baby result.

The postnatal report given to women following the birth of the baby should contain all antenatal screening results for communication to primary care and allow linkage to newborn screening results where relevant. There should be systems in place to inform newborn screening laboratories of all antenatal screening and diagnostic results. There should be a named person in every maternity unit with responsibility to ensure that newborn screening laboratories are informed of carrier or affected women whose pregnancies are ongoing.

Discontinue pregnancy: Offer counselling and follow up support.

Women who miscarry or terminate their pregnancy following screening: There should be a mechanism in place to ensure that women who subsequently miscarry or terminate their pregnancy receive their antenatal screening results to allow appropriate management and reproductive choice.

The postnatal report should contain all antenatal and PND screening results for
communication to primary care.

Known at risk women should be given a direct contact to ensure early access to counselling in future pregnancies and given information on pre-implantation genetic diagnosis.
Figure 1

Sickle Cell and Thalassaemia screening (linked antenatal / newborn programme)

Identify eligible population

Provide information and offer screening

Decline

Accept

Low prevalence trust

High prevalence trust

Known carrier couples

Send completed FOQ marked ‘declined’ to the laboratory

Take sample and send to laboratory with completed family origin questionnaire (FOQ)

Laboratory tests samples as per national guidelines and reports results as per local arrangements

See ‘counselling and referral for known at-risk couples and women where father’s result is unavailable’ pathway

Nothing abnormal detected

Inconclusive result

Carrier result

Affected mother (sickle cell disease) - refer to consultant for clinical & obstetric management

Offer screening to baby’s father

Baby’s father available and gives consent

Laboratory tests sample and reports results as per local arrangements

Nothing abnormal detected on screening of baby’s father

Confirmed carrier or affected result in both parents - at risk couple

Offer pre-natal diagnostic (PND) testing

Decline

PND accepted - contact PND laboratory to arrange for analysis and send samples

Inform parents, community midwife and GP

Result reported to referring clinician

Carrier or normal result

Baby affected by a major haemoglobin disorder

Provide information and offer choice

Discontinue pregnancy

Go to Newborn Blood Spot Screening

Offer counselling and follow up support

Continue pregnancy - include results on blood spot card

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Figure 2

NHS Sickle Cell & Thalassaemia Screening Programme
counselling and referral to prenatal diagnosis (PND)
for known carrier couples and women where father's result is unavailable

Known carrier woman

Take the woman's sample and send to laboratory with completed FOQ
Offer screening to baby's biological father

Father not a carrier

Offer woman/couple counselling and PND

Father a carrier or unavailable

Refer to counselling and PND
Take samples and send to laboratory with completed FOQ

ASAP or ideally by 10 weeks 0 days gestation

Decline PND

Accept PND

Organise PND
Contact DNA laboratory to inspect the sample

Perform PND
Send parental and fetal samples to DNA laboratory for analysis

ASAP or ideally by 12 weeks 0 days gestation

Give PND results to parents and discuss options

At or less than 5 days of PND procedure

Unaffected carrier baby

Affected baby

Continue pregnancy
Inform HCPs of screening/PND result or known at risk couple
Send alert form to inform newborn screening laboratory of at risk couple

Newborn blood spot screening

Termination of pregnancy declined

Termination of pregnancy accepted

Terminate pregnancy

Offer counselling and follow up
Newborn Sickle Cell Disease Screening within Newborn Blood Spot Screening Programme


Specific issues for newborn screening for sickle cell disease:

- Registered health care professionals check antenatal results (including results from baby’s biological father) and family history and record antenatal results on the blood spot card.

- Identifiable data on babies who have suspected or confirmed sickle cell disease or thalassaemia is sent to the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).

- A pre-transfusion sample to screen for sickle cell disease is taken on all babies admitted to a neonatal unit. The blood spot card should be marked “pre-transfusion”.

- The “pre-transfusion” blood spot card should be stored with the baby's medical record in line with local protocols and dispatched to the newborn screening laboratory together with the day 5 sample if the baby has received a blood transfusion in the interim.

- As a failsafe, transfused babies who did not have a pre-transfusion sample taken can be tested for sickle cell disease using DNA analysis. Such samples are sent by the newborn screening laboratory to the DNA laboratory.

Newborn screening results in one of four outcomes:

- condition not suspected: parents are informed of the result

- baby is identified as a carrier: results are reviewed against maternal and paternal results where these are available (to assist communication and identify any cases where misdiagnosis or non-paternity could be an issue); then parents are informed by a trained health care professional, ideally by face-to-face discussion, or by letter with offer of a face-to-face session

- inconclusive result: additional sample may be required

- condition suspected: immediate clinical referral initiated and parents informed of the result face to face. All screen positive results must be given to parents by a trained healthcare professional, by 28 days of age. The baby must enter care by 90 days of age.
Newborn screening laboratory scientists and clinicians responsible for the care of screen positive infants should complete the newborn outcomes data collection template. The completed form is sent to NCARDRS via scts.evaluation@nhs.net from an NHS.net email address; this manual data collection process will soon be replaced by the newborn outcomes system.

In 2018, NHS England will work with PHE to implement a new system for referring SCT screen positive infants from newborn screening laboratories into treatment services (the newborn outcomes system). This system will improve patient safety by allowing users to view the status of patients along the care pathway and alert clinicians when important milestones are breached; it will automate the gathering and reporting of newborn outcome data and KPIs and integrate with the National Haemoglobinopathy Registry (NHR) and with NCARDRS. System to be fully implemented by 31 March 2019.

2.3. Roles and accountability through the screening pathway

The linked NHS SCT screening programme is dependent on systematic specified relationships between stakeholders. Stakeholders include staff from maternity units, the antenatal, newborn and pre-natal diagnosis screening laboratories, diagnostics laboratory and genetics services, child health records departments, and specialist sickle cell and thalassaemia services, i.e. ‘the screening pathway’. NHS England will be responsible for ensuring that the pathway is robust.

The provider will be expected to fully contribute to ensuring that systems are in place to maintain the quality of the whole screening pathway in their organisation.

This will include, but is not limited to:

- provision of robust co-ordinated screening that ensures all parties are clear of their roles and responsibilities, so that there is clarity of handover of responsibility throughout all elements of the screening pathway

- ensuring that midwifery services are supported to facilitate early booking and testing for maternity care within primary, community and hospital care settings

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations including CHRDs


- contributing to any of NHS E and public health screening lead initiatives in screening pathway development in line with NHS Screening Programmes expectations

- providing or seeking to provide robust electronic links with relevant organisations

20
• links with primary, secondary and tertiary care

• the need for robust IT systems across the screening pathway

All providers should have the following posts in place

• screening midwife/coordinator (and deputy) to oversee the screening programme and act as a link between others members of the SCT multidisciplinary team

• health care professionals/SCT counsellors to provide genetic risk assessment and counselling.

2.4. Commissioning arrangements

Sickle cell and thalassaemia screening services will be commissioned by NHS E alongside specialised services where appropriate. Commissioning the sickle cell and thalassaemia screening pathway involves commissioning at different levels which may include NHS E, CCGs and directly by maternity services. Refer to ‘Who pays for what’

2.5. Links between screening programme and national programmes expertise

PHE, through the national screening programmes, is responsible for leading high-quality, uniform screening, and providing accessible information to both the public and healthcare professionals, and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for ensuring training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.

PHE will be responsible for delivery of the essential elements of screening programmes best done once at national level. These include setting clear specifications for equipment, IT and data.
Section 3: Delivery of Screening Programme

3.1 Service model summary see section 2.2 care pathway above for further details.

As with all newborn and antenatal screening the process of the offer of screening is largely embedded within the routine maternity and newborn pathway and not as a separate service.

There are key points about this programme which make it different, and also are relevant to effective commissioning. The key points for the SCT Programme are:

- the importance of early testing in pregnancy to enable women to exercise choice
- recognition of the impact of lifetime genetic information. As an increasing proportion of women and their partners are aware of their carrier status before pregnancy, the choice of direct access for counselling and offer of PND rather than routine pregnancy care should be available
- the interface between maternity, laboratories, specialist counselling service and specialist diagnostic services
- the importance of timely and reliable communication by newborn screening laboratories of screen positive results to the local clinician and the designated sickle cell and thalassaemia centre to ensure that affected babies enter the clinical care pathway
- linkage with primary care and CHRDs.

All elements of the screening pathway should be delivered by appropriate staff and to national standards and guidelines.

3.2 Programme co-ordination

The provider will be responsible for ensuring that the part of the programme they deliver is co-ordinated and interfaces seamlessly with other parts of the programme with which they collaborate, in relation to timeliness and data sharing.

The provider will ensure that they have a screening midwife/co-ordinator (and deputy) in place to oversee the screening programme, supported by appropriate administrative support to ensure timely reporting and response to requests for information. Where there is only one named co-ordinator, the provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

The provider and NHS England should meet at regular intervals to monitor and review the
local screening pathway. The meetings should include representatives from programme co-
ordination, clinical services, laboratory services, service management and screening QA.

3.3 Governance and Leadership

The provider will:

- cooperate with and have representation on local oversight arrangements as agreed with 
  NHS England commissioners
- identify a Trust director who is responsible for the screening programme
- ensure internal clinical oversight and governance by an identified clinical lead and a 
  programme manager
- provide documented evidence of clinical governance that includes:
  o compliance with the NHS Trust and NHS England information governance/records 
    management
  o user involvement, experience and complaints
  o failsafe procedures
  o compliance with checks, audits and failsafe procedures 
    https://www.gov.uk/government/publications/sct-checks-and-audits-to-improve-
    quality-and-reduce-risks
- ensure that there is regular monitoring and audit of the screening programme, and as part 
  of the organisation’s clinical governance arrangements, the board is assured of the quality 
  and integrity of the screening programme
- produce an annual report of screening services, which is signed off by the board
- ensure the programme is delivered by trained workforce that meet national requirements

3.4 Definition, identification and invitation of cohort/eligibility

The target population to be offered screening antenatally is all pregnant women, and the 
biological fathers of babies whose mothers are carriers or affected.

In each pregnancy, the family origin questionnaire should be completed and a routine full 
blood count taken and mean cell haemoglobin (MCH) and other red cell indices should be 
assessed.

Women and couples who already know their carrier status (at risk couples) should be offered 
direct and speedy referral to counsellors/antenatal screening coordinators for assessment of 
the couple risk status and PND.

The target population to be offered sickle cell screening as part of the NHS Newborn Blood 
Spot Screening Programme is all newborn babies and infants moving in to the country up to 
one year of age.
The provider will make every effort to maximise screening uptake from vulnerable and hard-to-reach groups within the eligible population. This includes babies born abroad who move into the country up to one year of age.

3.5 Location(s) of programme delivery

The provider will ensure appropriate accessible service provision for the population whilst assuring that all locations where SCT screening occurs fully comply with the policies, standards and guidelines referenced in this service specification.

3.6 Days/hours of operation

The provider will ensure that days and hours of operation are sufficient to meet the national programme standards.

3.7 Entry into screening programme

**Antenatal:** through GPs or direct referral into maternity services/SCT specialist centres. Whilst there is nothing specific in the GP contract regarding the SCT programme, general practitioners have a key role in ensuring that pregnant women referred to them are referred on as soon as possible to midwifery services and for holding previous antenatal results and results of newborn screening.

All maternity units should provide a publically available and advertised direct dial and/or email address for women, GPs and midwives.

**Newborn:** through midwifery services or through HVs/GPs/CHRDs for babies born abroad.

3.8 Working across interfaces

The screening programme is dependent on strong working relationships (both formal and informal) between professionals and organisations along the screening pathway. These include maternity services, the screening and PND laboratories, SCT counsellors, health visiting and specialist haematology clinical services.

Accurate and timely communication and handover across these interfaces is essential to reduce the potential for errors and ensure a seamless pathway for service users. It is essential that there remains clear named clinical responsibility at all times and at handover of care the clinical responsibility is clarified.

The provider will be responsible for ensuring that the pathway is robust. For their part the provider will ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:
- ensuring that midwives are supported to facilitate early booking for maternity care within all care settings

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations

- providing strong clinical and managerial leadership and clear lines of accountability

- developing joint audit and monitoring processes

- working to nationally agreed programme standards and policies

- agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway and implement checks and audits to improve quality and reduce risks

- contribute to any NHS E Screening Lead's initiatives in screening pathway development in line with NHS Screening Programmes expectations

- develop an escalation process for screening safety incidents

- facilitate education and training both inside and outside the provider organisation


### 3.9 Information on test/screening programme

Prior to any screening offer, the midwife will provide verbal and written information regarding screening utilising the approved NHS Screening Programmes booklet ‘Screening Tests for You and Your Baby’ as a guide for discussion. This must include information about data sharing with NCARDRS for women at risk of having a baby affected by SCT who accept PND and if a baby is suspected sickle cell disease or thalassaemia major. Information must include how to opt out of the register for more information see www.gov.uk/phe/ncardrs

Where there are specific communication requirements (e.g. English is not the woman's first language, visual/hearing impairment) appropriate interpretation services should be used during the booking appointment and appropriate information provided. All women, including those with special requirements, will be fully informed of the choices regarding all antenatal screening programmes.
The information should be impartially presented and should include an explanation of the limitations of the screening test. The decision to consent to screening or to decline should be recorded appropriately.

A wide range of information, in a range of formats and media are available to support healthcare professionals to ensure parents/carers are provided with approved information on sickle cell and thalassaemia screening.

3.10 Testing (laboratory service, performance of test by individuals)

Antenatal, newborn and DNA referral laboratories are expected to follow the policy guidance and standards laid out in ‘Sickle Cell and Thalassaemia: Handbook for Laboratories’ and meet the programme standards.

3.11 Results giving

Screening results should be explained to women by appropriately trained staff and recorded in the woman’s health records/IT systems.

See section 2.2 for further detail

Newborn screening results should routinely be transferred to primary care in a standard format.

3.12 Transfer of and discharge from care obligations

Based on the generic screening objectives of the programme the antenatal screening pathway ends for:

- pregnancies resulting in a live birth when the antenatal (including baby’s biological father and PND) screening results are included on the blood spot card
- women opting for termination of pregnancy when the woman is counselled appropriately following PND.

Based on the generic screening objectives of the programme the newborn screening pathway ends for:

- condition not suspected and carrier results when parents and GPs are informed of the result
- screen positive results when the parents are informed of the result and the baby is seen and tested and diagnosis confirmed by a clinician and registered in the designated clinical network. More detail is available in The National
3.13 Public information

- providers must always use the public information leaflets from PHE Screening at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening should be consulted and involved before developing any other supporting materials.

- providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.

- providers must not develop their own information about screening for local NHS websites but should always link through to the national information on NHS Choices and GOV.UK.

- to support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local user surveys which contain feedback on these national resources.

3.14 Exclusion criteria

Newborn:

- babies stillborn or who died before day 5
- children over 1 year of age.

3.15 Staffing

In accordance with NHS Screening programmes standards and protocols the provider will ensure that there are adequate numbers of competent and appropriately trained staff in place across the screening pathway to deliver the screening programme in line with best practice programme and laboratory guidelines.

Qualifications will be specific to staff delivering the service across the care pathway. Staff must demonstrate competence (which is linked to training).
The provider will have in place a workforce plan designed to maintain a sustainable programme, especially where increase in birth rate are predicted and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff.

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including appropriate annual CPD in line with programme requirements, for example a screening study day or completion of national NHS Screening Programme e-learning.

Providers must facilitate screener training in line with programme requirements as detailed in each NHS screening programme specification. Providers should ensure training has been completed satisfactorily and recorded and that they have a system in place to assess ongoing competency.

The provider will ensure that counsellors / antenatal screening coordinators for the sickle cell and thalassaemia screening programme meet Sickle Cell & Thalassaemia counselling competences https://cpdscreening.phe.org.uk/sct-counselling-competences.

**Education and training resources**

Information on all education and training resources is available [here](#). Courses have been developed in collaboration with King’s College London (KCL). The genetic risk assessment and counselling module and SCT screening: specialist counselling update are intended to provide a benchmark of professional competence to health professionals involved in counselling women and couples ‘at risk’ of having a child with a haemoglobinopathy.

### 3.16 User involvement

The provider(s) will be expected to:

- demonstrate that they regularly seek out the views of service users, families and others in respect of planning, implementing and delivering services

- demonstrate how those views will influence service delivery for the purposes of raising standards

- make results of any user surveys/questionnaires available to NHS E and screening QA teams on request.
3.17 Premises and equipment

The provider will:

- ensure that suitable premises and equipment are provided for the screening programme
- have appropriate polices in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability
- ensure that equipment meets the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use.

Electronic provision of the FOQ information with the antenatal order for sickle cell and thalassaemia screening is recommended in order to ensure complete data with every sample.

3.18 Safety & safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS standard contract. As an example, please see link below for 2016/17 NHS standard contract [http://www.england.nhs.uk/nhs-standard-contract/](http://www.england.nhs.uk/nhs-standard-contract/).
Section 4: National standards, risks and quality assurance

4.1 The provider will:

- meet the acceptable national screening standards and work towards attaining and maintaining the achievable standards adhere to specific professional standards and guidance

- maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and make sure these points are reviewed in contracting and peer review processes

- participate fully in national quality assurance (QA) processes which includes:
  - submitting agreed minimum data sets and reports from external quality assurance schemes
  - undertaking ad-hoc audits and reviews as requested
  - completing self-assessment questionnaires / tools and associated evidence
  - responding to SQAS recommendations within agreed timescales providing specified evidence
  - producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations

- all screening laboratories must
  - be accredited by the UK Accreditation Service (UKAS) to ISO. "Medical laboratories – Requirements for quality and competence (ISO 15189)" or be CPA accredited and actively transitioning towards ISO 15189
  - participate in EQA schemes accredited to ISO. "Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)"
  - meet the screening programme quality assurance requirements mapped to ISO 15189
  - and use ISO 15189 accredited reference laboratories

The UK Accreditation Service (UKAS) will look at both ISO 15189 and the screening requirements on behalf of PHE Screening Quality Assurance Services and the national screening programme

- operate and evidence
  - check points that track individuals through the screening pathway
  - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  - have process in place to mitigate against weakness in the pathway

- have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet national screening standards
• demonstrate that there are audited procedures, policies and protocols in place to make sure the screening programme consistently meets programme requirements

• comply with guidance on managing safety incidents in national screening programmes and NHS England serious incident framework

• ensure business continuity - business continuity plans must be in place where required

• ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance

4.2 Service improvement:

The provider will develop and agree with commissioners a CSIP (continual service improvement plan) in cases where national recommendations and/or screening standards are not fully met. The CSIP will include the following:

• action plans specifying changes and improvements that will be made during the contracting period
• defined timescales for actions
• roles and responsibilities for actions
• performance issues highlighted by the commissioners
• concerns raised by service users.

4.3 New technologies:

New technologies should not be used for screening unless approved by the UK National Screening Committee.
Section 5: Data and Monitoring

5.1 Key performance indicators / Public Health Outcomes Framework

The provider shall adhere to the requirements specified in the document ‘Key Performance Indicators for Screening’. Please refer to https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting for further details, guidance and updates on these indicators.

5.2 Data collection, monitoring and reporting

Providers should:

- ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions
- continually monitor and collect data regarding its delivery of the service
- comply with the timely data requirements of the national screening programmes and regional quality assurance teams. This will include the production of annual reports. The most up to date dataset can be accessed from the national screening programme website
- collect and submit
  - Annual data returns by:
    i. all antenatal laboratories,
    ii. all newborn laboratories
  - (iii) the DNA laboratories (PND) including data on pregnancy outcomes for those women who have undergone PND
  - (v) two DNA laboratories (newborn screening) for babies who have had a blood transfusion
  - SCT antenatal KPIs are submitted from maternity units and antenatal laboratories to the NHS Screening Programmes quarterly and annually (submission of KPI data began in Q4 of 2010/11).

Other:
For quality and monitoring, completed newborn outcome data templates must be shared with the NCARDRS.

In 2018, NHS E will work with PHE to implement a new system for referring SCT screen positive infants from newborn screening laboratories into treatment services (the newborn outcomes system). This system will automate the gathering and reporting of newborn outcome data and KPIs and integrate with the NHR and with NCARDRS. System to be fully implemented by 31 March 2019.

5.3 Public Health Outcomes Framework Indicators

The SCT Programme contributes to the Public Health Outcomes Framework. Indicator iii: The
percentage of pregnant women eligible for antenatal sickle cell and thalassaemia screening for whom a conclusive screening result is available at the day of report.

Key deliverable: The acceptable level should be achieved as a minimum by all services

- acceptable ≥ 95.0%
- achievable ≥ 99.0%

see: