

# NHS public health functions agreement 2016-17

Service specification no.18

NHS Sickle Cell and Thalassaemia Screening  
Programme

## NHS England INFORMATION READER BOX

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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 (as cited under the Equality Act 2010) and those who do not share it; and
- Given 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

# NHS public health functions agreement 2016-17

Service specification no.18  
NHS Sickle Cell and Thalassaemia  
Screening Programme

Prepared by Public Health England

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This service specification is to be applied by NHS England in accordance with the 2016-17 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 2016-17 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 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

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

The 2016-17 agreement is available at [www.gov.uk](http://www.gov.uk) (search for 'commissioning public health').

All current service specifications are available at [www.england.nhs.uk](http://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 Sick 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 England 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 <http://sct.screening.nhs.uk/standards>  
<https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>

Sickle Cell and Thalassaemia Handbook for Laboratories  
<https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-handbook-for-laboratories>

NHS Newborn Blood Spot Screening Programme service specification  
<https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016>

Specialised Haemoglobinopathy Services definition as set out in the Manual for prescribed specialised services  
<http://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf>

The Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a)  
<http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>



NICE Clinical Guideline 110. Pregnancy and Social Complex Factors: A Model for Service Provision for Pregnant Women with Complex Social Factors.

<https://www.nice.org.uk/guidance/cg110>

Guidance and updates on KPIs <https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting>

NHS Screening Programmes guidance, Managing Serious Incidents in the English NHS National Screening Programmes

<https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>

Who pays for what: Aspects of the maternity pathway payment for the screening and immunisation programmes June 2015

<https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf>

## **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 and outcomes:

To offer timely antenatal sickle cell and thalassaemia screening to all women (and couples), to facilitate informed decision-making

For those women accepting prenatal diagnosis, 50% of prenatal diagnoses to be performed before 12 weeks 6 days

### **1.2.2 Newborn Sickle Cell Screening Programme**

Objectives and outcomes:

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 Linked Antenatal and Newborn Sickle Cell and Thalassaemia Screening Programme**

Aim: to link results from antenatal tests taken by parents-to-be with their baby's test result

Objectives and outcomes

To ensure an appropriate level of understanding about screening and these 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

To prepare parents for their baby's screening result

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**

The objectives of the screening programme should include:

*Help reduce health inequalities through the delivery of the programme*

Key deliverables:

- Screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
- A Health Equity Impact Assessment 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 both equality, health inequality and screening guidance when making such decisions

The provider will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to ensure 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/guidance/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

Screening for sickle cell disease and thalassaemia is part of the NHS SCT Screening Programmes. The linked screening programme comprises two parts: sickle cell and thalassaemia screening during pregnancy and sickle cell screening in the newborn period.

- newborn screening for sickle cell disease is offered to all babies in England and is integrated into the standard newborn blood spot test. See service specification No. 19: NHS newborn blood spot screening programme  
<https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016>
- antenatal screening for sickle cell, other haemoglobin variants and thalassaemia is offered to pregnant women early in pregnancy (by 10 weeks of pregnancy) to identify women and then couples who are at increased risk (1:4) of an affected pregnancy to offer them the choice of prenatal diagnosis and the option of termination of an affected pregnancy or continuation of the pregnancy. This should ideally all take place before 12 weeks 6 days of pregnancy
- all pregnant women in the antenatal population, irrespective of high/low prevalence status are offered screening for thalassaemia using routine red blood cell indices and where appropriate by fraction quantitation
- the baby's father of any woman who is identified as affected or a carrier of significant haemoglobinopathies is offered screening for sickle cell, other haemoglobin variants and thalassaemia, irrespective of their family origin
- couples at risk of having a baby with sickle cell disease or severe thalassaemia are offered counseling and diagnostic tests for the baby
- couples who already know their carrier status (at risk couples) should be offered direct and speedy referral to counselors for assessment of the couple risk status and prenatal diagnosis

## 2.2. Care pathway (figure 1)

**Identify eligible population:** All pregnant women are eligible for screening. Screening should be offered at the antenatal booking visit by 10 weeks 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 should be recorded in the maternity records

**Known at risk couples:** couples who already know their carrier status (at risk couples) should be offered direct and speedy referral to counsellors for assessment of the couple risk status and prenatal diagnosis

**Low prevalence trust:** Low prevalence trusts are those where less than 1% of the booking bloods received by the laboratory are screen positive and high prevalence if this figure is greater than or equal to 2%. Laboratories that are between these two cut-offs would be considered borderline. 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 severe alpha thalassaemia, to identify those who need testing for haemoglobin variants. The FOQ should be completed and sent to the laboratory with the sample.

For more information on the FOQ see

<https://www.gov.uk/government/publications/family-origin-questionnaire-sickle-cell-and-thalassaemia-screening>

**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. Low prevalence trusts are those where less than 1% of the booking bloods received by the laboratory are screen positive. Laboratories that are between these two cut-offs would be considered borderline. In high prevalence trusts all pregnant women are offered screening followed by a blood test for sickle cell and other haemoglobin variants. The FOQ should 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 severe alpha thalassaemia.

For a list of high and low prevalence trusts and information on obtaining FOQ forms see

<https://www.gov.uk/government/publications/nhs-trusts-area-prevalence-for-sickle-cell-and-thalassaemia>

## 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
- There should be one prevalence per laboratory to avoid laboratories needing to follow two algorithms side-by-side. Refer to <https://www.gov.uk/government/publications/family-origin-questionnaire-sickle-cell-and-thalassaemia-screening>

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

Midwives need to include information on family origins for all women and the baby's father to accompany the full blood count (FBC) and haemoglobinopathy screen sample; complete all demographic information; and sign the FOQ form. Family origins of both the woman AND the baby's 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 father is unavailable.

If a woman declines screening, explore the reasons for this and document on the FOQ form. The completion of the FOQ in all areas is essential as part of the screening for sickle cell and thalassaemia.

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 and thalassaemia and a risk of missing an affected pregnancy resulting in the birth of an affected baby.

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 father of all carrier and/or affected women, for screening (preferably using antenatal status codes).

**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. Offer screening to baby's 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 and 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 father:** There must be documented evidence of a screening result if screening is declined because of previous test/status known. The Programme recommends that maternity units offer screening to the baby's father before 11 weeks of pregnancy to identify 'at risk couples'. Baby's fathers should be provided with written information <https://www.gov.uk/government/publications/contacting-men-for-sickle-cell-and-thalassaemia-screening> and <https://www.gov.uk/government/publications/tests-for-dads-sickle-cell-and-thalassaemia-screening>

**Baby's father available and gives consent**

**Laboratory test sample and reports results as per local arrangements**

**Nothing abnormal detected on screening of baby's 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 health 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>

<https://www.gov.uk/government/publications/baby-at-risk-of-having-thalassaemia-description-in-brief>

For more information on training see the Genetic risk assessment and counselling module at: <http://cpd.screening.nhs.uk/sct-externaltraining>

**Baby's father not available or declines consent:** If the baby's 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, being offered prenatal diagnosis in this situation if requested. Prenatal diagnosis for sickle cell disease can be undertaken without the baby's father's DNA.

Similarly, prenatal diagnosis 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 pre-natal diagnostic (PND) testing:** Prior to prenatal diagnosis test always contact the PND laboratory beforehand 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 prenatal diagnosis sample

**Decline PND:** Respect decision

The programme recommends that maternity units have a robust system for recording information on at-risk couples declining PND testing, for example recording in maternity notes, on the blood spot card and on alert forms to be sent to the newborn screening laboratory. There should be a named person in every maternity unit with the responsibility to ensure that newborn screening laboratories are informed of carrier women (or at risk couples) whose pregnancy is ongoing

**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>

**Result reported to referring clinician**

**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 guidelines 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 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.nwh.nhs.uk/information/nationalsicklecellthalassaemiacentres.aspx>

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

Alert form to be sent to the newborn screening laboratory. Maternity units to complete the short-term and long-term PND outcome form available within the guidelines for the referral of sickle cell and thalassaemia prenatal diagnosis samples to molecular haemoglobinopathy laboratories <https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-prenatal-diagnosis-guidelines>

**Links to newborn sickle cell screening covered by Newborn Blood Spot Programme**

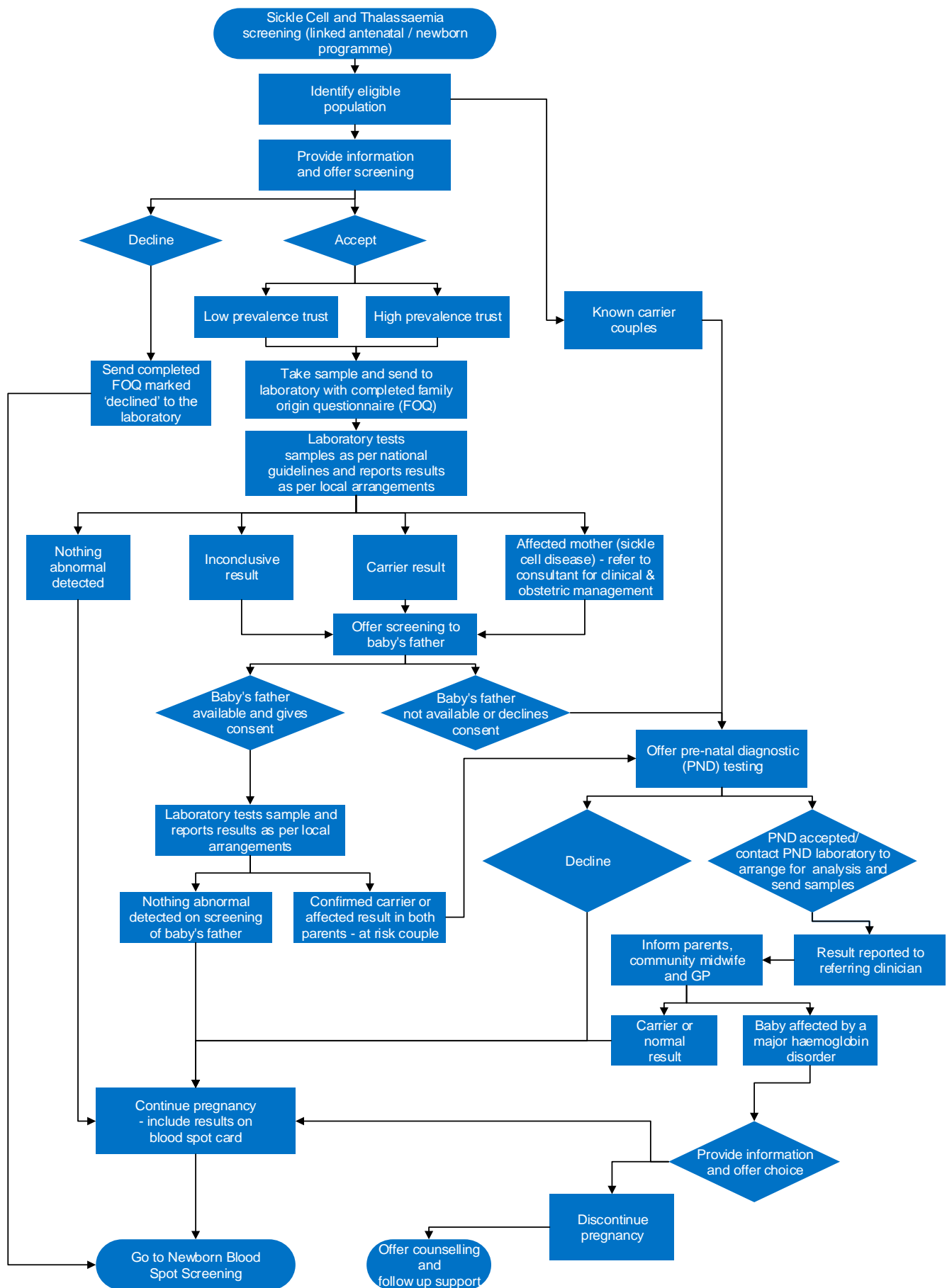
The result of an antenatal genetic test will be related to the results of a newborn baby's test for the same condition, so the linked programme provides a natural failsafe check between the mother and baby result.

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 pregnancy is on-going.

**Discontinue pregnancy:** Offer counselling and follow up support

**Women who miscarry or terminate their pregnancy following screening:**

All women should be notified of their results once they have been tested. There should be a mechanism in place to ensure that women who subsequently miscarry or terminate their pregnancy receive their results, whether negative or positive, to allow appropriate management and reproductive choice.



## Newborn Sickle Cell Screening Programme within Newborn Blood Spot Screening

The pathway for newborn screening for sickle cell is an integral part of the NHS Newborn Blood Spot Screening Programme see Service specification No. 19: NHS newborn blood spot screening programme <https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016> and [Guidelines for Newborn Blood Spot Sampling](#).

Specific issues for sickle cell and thalassaemia newborn screening

- Midwives check antenatal results and family history and record antenatal results on the blood spot card
- 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 routine 5 day 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. All screen positive results will be given to parents by a trained health professional face-to-face by four weeks of age, following local protocols and ensure that the baby enters care by eight weeks of age. See specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) <http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>.

Screen positive results are also reported to local clinician/and designated sickle cell and thalassaemia centre (under development). The designated sickle cell and thalassaemia centre ensure that affected babies enter the care pathway refer to Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) <http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf> and return diagnostic results back to the newborn screening laboratories to confirm enrollment into care

### **2.3. Failsafe arrangements**

Quality Assurance (QA) within the screening pathway is managed by including failsafe processes. Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to (i) identify what is going wrong and (ii) what action follows to ensure a safe outcome.

The provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway.
- review and risk assess local screening pathways in the light of national SCT screening programme guidance
- work with NHS England and quality assurance teams to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that appropriate links are made with internal governance arrangements, such as risk registers
- ensure routine staff training and development to maintain competencies; follow guidance in SCT Screening Programme Standards <https://www.gov.uk/government/publications/standards-for-sickle-cell-and-thalassaemia-screening> and Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) <http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>

### **2.4. Roles and accountability through the screening pathway**

The linked NHS SCT screening programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity units, the antenatal,

newborn and pre-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 coordinated 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 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
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contributing to any of NHS England 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
- 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 counselors to provide genetic risk assessment and counseling. For more information on training see the Genetic risk assessment and counseling module at: <http://cpd.screening.nhs.uk/sct-externaltraining>

## **2.5. Commissioning arrangements**

Sickle cell and thalassaemia screening services will be commissioned by NHS England alongside specialised services where appropriate. Commissioning the sickle cell and thalassaemia screening pathway involves commissioning at different levels which may include NHS England, CCGs and directly by maternity services. Refer to 'Who pays for what' <https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf>

## **2.6. Links between screening programme and national programmes expertise**

PHE, through the national screening programmes, is responsible for leading high-quality, uniform screening, providing accessible information to both the public and health care 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 as well as the possibility that testing may have already been done
- 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 PND rather than routine pregnancy care should be available
- the interface between maternity, laboratories, specialist counseling 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. See Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a)

<http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>

- 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 coordinated 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/coordinator (and deputies) 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 coordinator, 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 coordination, clinical services, laboratory services and service management.

### **3.3 Clinical and corporate governance**

The provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures e.g. screening programme boards/groups
- ensure that responsibility for the screening programme lies at director level
- ensure that there is appropriate internal clinical oversight of the programme and have its own management and internal governance of the services provided with the designation of a clinical lead, a programme coordinator/manager and the establishment of a multidisciplinary steering group/programme board including NHS England representation and has terms of reference and record of meetings
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of the organisation's clinical governance arrangements, the organisation's board is assured of the quality and integrity of the screening programme
- comply with the NHS Screening Programmes guidance on managing serious incidents
- have appropriate and timely arrangements in place for referral into treatment services that meet programme standards
- be able to provide documented evidence of clinical governance and effectiveness arrangements on request
- ensure that an annual report of screening services is produced which is signed off by the organisation's board
- have a sound governance framework in place covering the following areas:
  - information governance/records management
  - equality and diversity
  - user involvement, experience and complaints
  - failsafe procedures
  - risks & mitigation plans

### **3.4 Definition, identification and invitation of cohort/eligibility**

The target population to be offered screening antenatally is all pregnant women, and the



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.

Due to the complexities of the testing algorithm and the logistics of separating samples out new guidance recommends screening for sickle cell and thalassaemia should be repeated in every pregnancy. Trusts that opt out should assess the risks in every step of their process from identification of patients, through sample collection and transport, pathway through laboratory and getting the correct result back to the patient - along with any required referral/baby's father testing aspects. It should cover the circumstances under which the non-repeat testing policy may fail and audit evidence should be provided.

Couples who already know their carrier status (at risk couples) should be offered direct and speedy referral to counselors for assessment of the couple risk status and prenatal diagnosis.

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. 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.

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 counselors, 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
- contribute to any NHS England Screening Lead's initiatives in screening pathway development in line with NHS Screening Programmes expectations
- develop an escalation process for screening incidents (SIs)
- facilitate education and training both inside and outside the provider organisation
- Newborn laboratory and care services should be guided by The National Haemoglobinopathies Project: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services and Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) <http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>

### **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. 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 health care 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*' <https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-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

As systems are developed it is anticipated that newborn screening results should routinely be transferred to primary care in a standard format. Screen positive results are reported according to screening programme standards and Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) <http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf>

### **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 father

and PND) screening results are included on the blood spot card

- women opting for termination of pregnancy when the woman is counseled appropriately following prenatal diagnosis

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 Haemoglobinopathies Project: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/409928/NationalHaemoglobinopathiesProjectFinalV2.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/409928/NationalHaemoglobinopathiesProjectFinalV2.pdf)

### 3.13 Public information

- Providers must always use the patient 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 <http://www.nhs.uk/Conditions/pregnancy-and-baby/Pages/screening-sickle-cell-thalassaemia-pregnant.aspx> and GOV.UK (<https://www.gov.uk/topic/population-screening-programmes> or the relevant programme page)
- 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 patient surveys which contain feedback on these national resources.

### 3.14 Exclusion criteria

Newborn:

- babies stillborn or who died before day 8
- 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 and requirements, for example a screening study day or completion of national NHS Screening Programme e-learning.. Training standards are detailed at \_

<https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>

Providers must facilitate screener training in line with programme requirements/standards 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 on-going competency.

The provider will ensure that counselors for the sickle cell and thalassaemia screening programme are trained in an approved course see Genetic risk assessment and counseling module <http://sct.screening.nhs.uk/externaltraining>

### **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 England 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 policies 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 a Programme priority, in order to ensure complete data with every sample, improve the quality of KPI returns and reduce manual processes. The approach is through most common system suppliers.

### **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 2014/15 NHS standard contract <http://www.england.nhs.uk/nhs-standard-contract/>

## Section 4: Service Standards, Risks and Quality Assurance

### 4.1. Key criteria and standards

Programme standards are available on the population screening website.

<https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>

Providers will meet the acceptable and work towards the achievable programme standards. A number of resources to support providers are available on the programme website.

### 4.2. Risk assessment of the screening pathway

Providers are expected to have an internal quality assurance and risk management process that assures the commissioners of its ability to manage the risks of running a screening programme.

Providers will:

- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that risks are reported through internal governance arrangements, such as risk registers
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the Commissioner and Screening Quality Assurance Service (SQAS) teams to develop, implement, and maintain appropriate risk reduction measures

High scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate them.

### 4.3. Quality assurance

Providers will participate fully in national Quality Assurance processes, co-operate in undertaking ad-hoc audits and reviews as requested by SQAS teams and respond in a timely manner to their recommendations. This will include the submission to SQAS teams and commissioners of:

- agreed data and reports from external quality assurance schemes

- minimum data sets as required
- self-assessment questionnaires / tools and associated evidence

Laboratories undertaking screening must:

- be accredited by United Kingdom Accreditation Service
- participate in accredited external quality assurance scheme for programme screening, e.g. UKNEQAS and respond within agreed timescales
- make available timely data and reports from external quality assurance programmes and accreditation services to SQAS, national screening programmes and commissioners
- operate failsafe systems that can identify, as early as possible, women and babies that may have been missed or where screening results are incomplete
- 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.

Providers will respond to SQAS recommendations within agreed timescales. They will produce with agreement of commissioners of the service an action plan to address areas for improvement that have been identified in recommendations. Where SQAS believe there is a significant risk of harm to the population, they can recommend to commissioners to suspend a service.

#### **4.4. Safety concerns, safety incidents and serious incidents**

Providers will comply with the national guidance for the management of safety concerns and incidents in screening programmes and NHS England guidance for the management of serious incidents <https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>

#### **4.5. Procedures and Protocols**

The provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.



#### **4.6. Service improvement**

Where national recommendations and acceptable/achievable standards are not currently fully implemented the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period.

The provider shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond and any performance issues highlighted by the commissioners, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with the commissioners.

## 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 (prenatal diagnosis) including data on pregnancy outcomes for those women who have undergone prenatal diagnosis
  - (iv) anonymous data from designated clinical centres (see The National Haemoglobinopathy Project: *A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*).  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/409928/NationalHaemoglobinopathiesProjectFinalV2.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/409928/NationalHaemoglobinopathiesProjectFinalV2.pdf) These data include for example: - timely receipt into care, confirmed screening result and information about vaccination status.
  - (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:**

- Programme evaluation data collection with support from the Health Research Authority Confidentiality Advisory Group  
<https://www.gov.uk/government/publications/newborn-outcomes-project-data-collection-templates> and National Congenital Anomaly and Rare Disease Registration Service
- Ad hoc surveys to inform screening pathway and processes  
Access to data templates <https://www.gov.uk/government/collections/sickle-cell-and-thalassaemia-screening-data-collection>

### 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  $\geq 95.0\%$
- achievable  $\geq 99.0\%$
- national baseline is 98%

see

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/256502/nhs\\_public\\_health\\_functions\\_agreement\\_2014-15.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256502/nhs_public_health_functions_agreement_2014-15.pdf)