Department of Health

NHS England

NHS public health functions agreement 2015-16

Service specification no.18

NHS Sickle Cell and Thalassaemia Screening Programme

Classification: official

December 2014

Title: NHS public health functions agreement 2015-16 Service specification no.18 NHS Sickle Cell and Thalassaemia Screening Programme
Author: PHD/ IH&PHD/ PHPSU/ 10100
Document Purpose: Policy
Publication date: December 2014
Target audience: NHS England regional directors, NHS England area directors
Contact details: Public health policy and strategy unit phpsu@dh.gsi.gov.uk

Published to gov.uk, in PDF format only.

www.gov.uk/dh

NHS England Publications Gateway Reference 02591

NHS public health functions agreement 2015-16

Service specification no.18

NHS Sickle Cell and Thalassaemia Screening Programme

Prepared by Public Health England

Contents

Service specification No.18

This is a service specification within Annex C of the ‘NHS public health functions agreement 2015-16 (the ‘2015-16 agreement’) published in December 2014.

This service specification is to be applied by NHS England in accordance with the 2015-16 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 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

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

The 2015-16 agreement including all service specifications within Annex C is available at www.gov.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 England responsible population and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC).

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
- Sickle Cell and Thalassaemia Handbook for
- Laboratories http://sct.screening.nhs.uk/standardsandguidelines
- NHS Newborn Blood Spot screening programme service specification
- Specialised Haemoglobinopathy Services definition
- The National Haemoglobinopathies Project: *A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services* NICE Clinical Guideline 110. *Pregnancy and Social Complex Factors: A Model for Service Provision for Pregnant Women with Complex Social Factors.*
- Guidance and updates on KPIs http://www.screening.nhs.uk/kpi
- UK NSC guidance, Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/quality-assurance#fileid9902

1.2 Screening programme aims, objectives and health outcomes

The SCT Programme aims to:

Support people to make informed choices during pregnancy and before conception

Improve infant health through prompt identification of affected babies Ensure high quality, accessible care throughout England

Promote greater understanding and awareness of the conditions and the value of screening

1.2.1 Antenatal Sickle Cell and Thalassaemia Screening Programme

Aim:

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

Outcome to be achieved – 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

Aim:

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

1.3 Objectives

- To ensure an appropriate level of understanding about screening and these conditions among professionals involved with the programme.
- To minimise the adverse effects of screening.

1.4 Public Health Outcomes Framework

SCT screening contributes to the Public Health Outcomes Framework indicator on the uptake of screening for national screening programmes. Indicator 2.2iii Access to non-cancer screening programmes: Sickle cell and thalassaemia screening.

1.5 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.

1.6 Equality

The provider will be able to demonstrate what systems are in place to ensure equity of access to screening and subsequent diagnostic testing. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of race, culture, sexual preference, physical or learning disabilities.

The provider will have procedures in place to identify and support those women/babies who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; asylum seekers; women/babies in prison; women/babies with drug or alcohol harm issues; women with learning disabilities; women experiencing domestic abuse, with physical disabilities or women with communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such women.

Screening will be effectively integrated across a pathway with clear lines of communication between the different providers, screening centres, primary care and secondary care.

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 UK NSC policy on antenatal screening for sickle cell disease and thalassaemia is that all eligible women should be offered screening.

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

2.2. Care pathway

A description of both the antenatal SCT screening pathway and the newborn sickle cell element of the NHS Newborn Blood Spot Screening pathway are given below, along with diagrams of the pathways showing failsafe processes identified by the national screening programme. The Provider is expected to follow the pathway.

A full description of the screening pathways can be found on the Map of Medicine.

http://sct.screening.nhs.uk/carepathways

Antenatal Sickle Cell and Thalassaemia Screening Programme

The pathway for the antenatal screening for Sickle cell and Thalassaemia as part of the linked antenatal and newborn screening programme consists of the following:

- The eligible population is identified through routine midwifery-led antenatal care or primary care and offered screening by 10 weeks.

- Midwives provide written information and take consent.

- All women (in both high prevalence (HP) and low prevalence (LP) Trusts) are offered a screening blood test for thalassaemia using the initial results from routine red blood cell indices.

  - In high prevalence areas, all women are also offered a screening blood test for sickle cell and other haemoglobin variants.

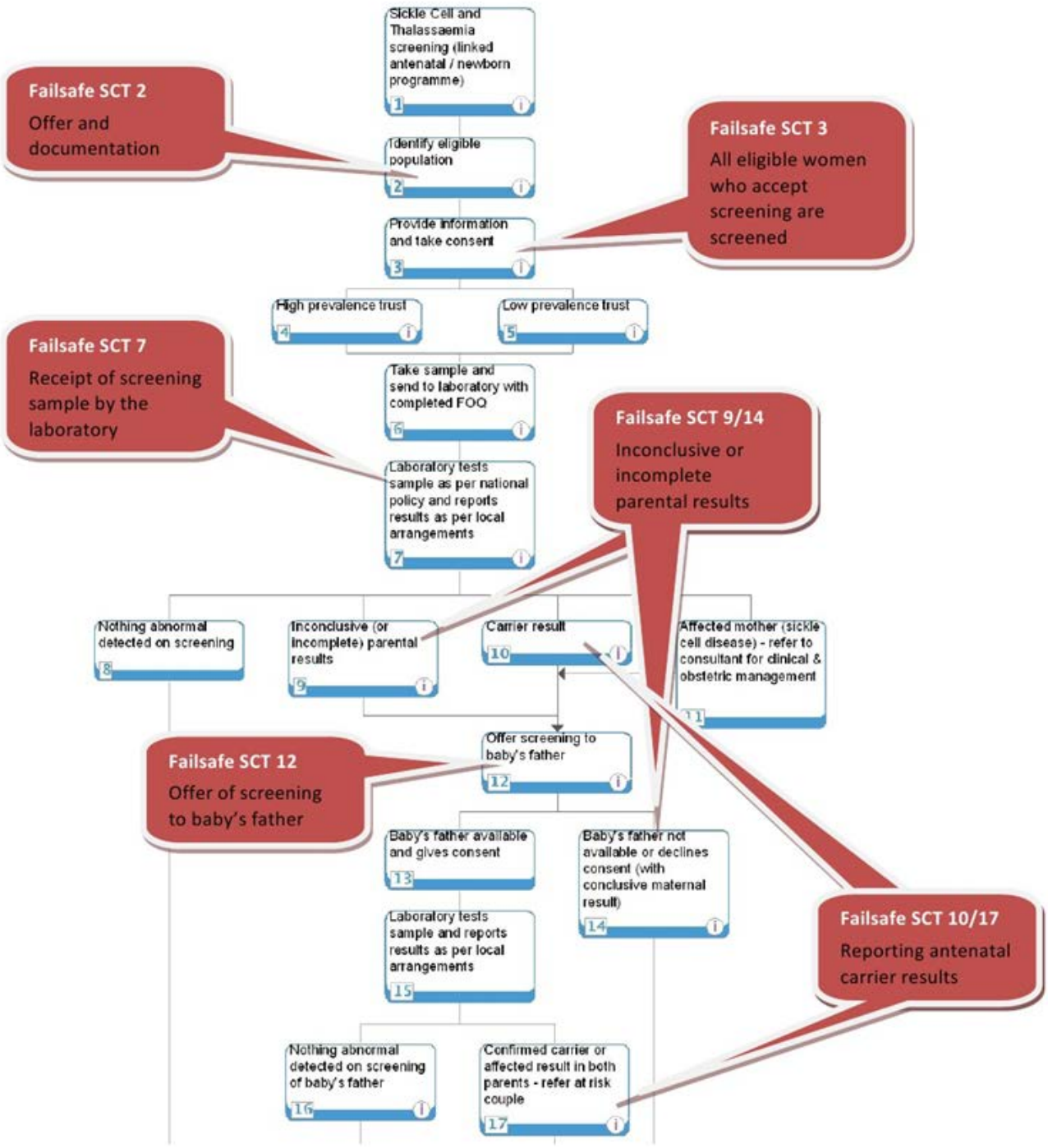
  - In low prevalence areas, the Family Origin Questionnaire (FOQ) is used as an initial screening tool to identify any woman and the baby's father who are from a high-risk group for haemoglobin variants. If the questionnaire shows that there is a risk of either parent being a carrier, a screening blood test is offered to the woman.

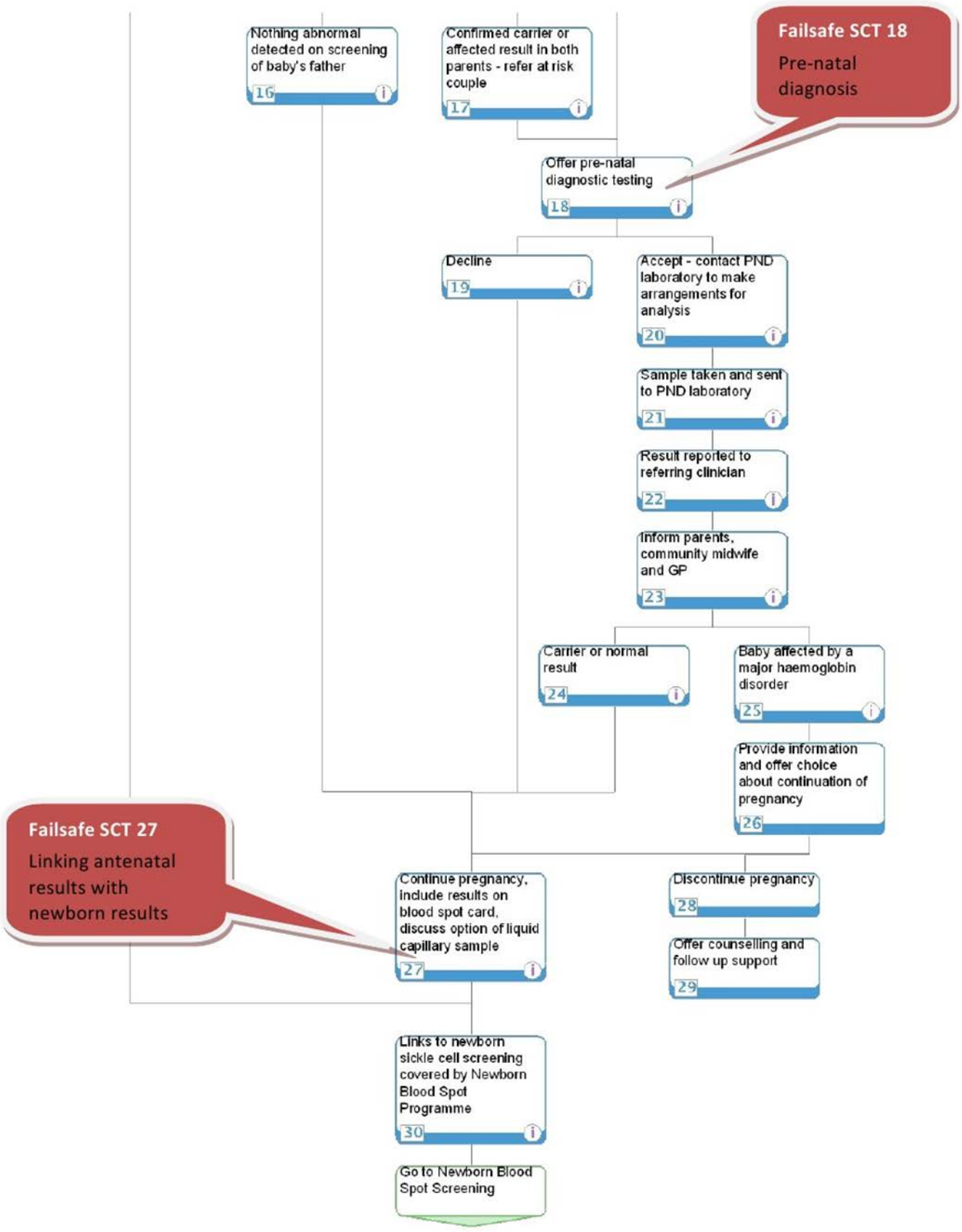
- Pathways to be in place to ensure women who are known carriers (or carrier couples) can be referred directly to appropriate counselling service immediately without being delayed by routine antenatal booking processes to ensure that PND, if wanted, can happen very early in pregnancy (this may involve additional provider contracts or referral to genetic counselling).

- Laboratory tests the sample as per national policy and reports results preferably using antenatal status codes. This can result in one of four outcomes:
  - Mother is identified as a carrier: healthcare professional informs parents of results and screening is offered to the baby's father. Results should be included on the newborn blood spot card for ongoing pregnancies.
  - Nothing abnormal is detected on screening: mother's results are included on the blood spot card.
  - Inconclusive (or incomplete) parental results: screening is offered to the baby's father
  - Affected mother (sickle cell disease): mother is referred to a consultant for clinical and obstetric management and screening is offered to the baby's father.
- If both parents are confirmed carriers and/or either is affected they are referred as an at-risk couple for pre-natal diagnostic testing and offered counselling by trained counsellors, see (http://sct.screening.nhs.uk/externaltraining).
- If the baby's father is not available for testing, prenatal diagnosis can be offered if wished on the basis of the mother's carrier status.
- Parents who decline pre-natal diagnostic testing continue with the pregnancy. Results should be included on blood spot card for ongoing pregnancies.

- If prenatal diagnosis testing is accepted, parental samples are taken and sent to the specialist laboratory for testing.
    - If PND result is normal or the fetus is identified as a carrier and the pregnancy continues, the PND result should be recorded on the blood spot card.
    - If PND testing identifies that the fetus is affected with a major haemoglobin disorder, the parents are provided with information relating to the specific disorder. Informed choice about continuation of pregnancy is offered. If they choose to continue with the pregnancy, the results are recorded on the blood spot card. If they choose not to continue with the pregnancy rapid access to termination of pregnancy services is required.
- For pregnancies resulting in a live birth, the antenatal screening pathway ends when the antenatal screening results are included on the blood spot card (screening and PND results)
- For women opting for termination of pregnancy, the antenatal screening pathway ends when the women are counselled appropriately following a termination of pregnancy

Antenatal Sickle Cell and Thalassaemia Screening, Including Failsafes




Nothing abnormal detected on screening of baby's father
16
Confirmed carrier or affected result in both parents - refer at risk couple
17
Failsafe SCT 18
Pre-natal diagnosis
Offer pre-natal diagnostic testing
18
Decline
19
Accept - contact PND laboratory to make arrangements for analysis
20
Sample taken and sent to PND laboratory
21
Result reported to referring clinician
22
Inform parents, community midwife and GP
23
Carrier or normal result
24
Baby affected by a major haemoglobin disorder
25
Provide information and offer choice about continuation of pregnancy
26
Failsafe SCT 27
Linking antenatal results with newborn results
Continue pregnancy, include results on blood spot card, discuss option of liquid capillary sample
27
Discontinue pregnancy
28
Offer counselling and follow up support
29
Links to newborn sickle cell screening covered by Newborn Blood Spot Programme
30
Go to Newborn Blood Spot Screening

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 and consists of the following:

- The eligible population is identified through NN4B issued at birth or registration with a GP practice for babies born abroad
- Midwives check antenatal results and family history. Ideally all antenatal results obtained from antenatal SCT screening are included on the blood spot card
- Midwives provide written information (ideally before birth) and take consent
- Screening can be offered to unscreened babies who move into a local area up to one year of ageHealth visiting services (or agreed alternative) is responsible offering screening to parents of babies with no written evidence of screening results. The child health record departments who note the arrival of a baby (when it is registered) alert the HV to unscreened babies. GPs need to ensure CHRD are informed of the babies they register.
- Samples are taken routinely on day 5 and in exceptional circumstances between day 5-8, (day of birth is day 0), in accordance with *Guidelines for Newborn Blood Spot Sampling*, and sent to the appropriate newborn screening laboratory. Records are kept of all tests including those declined.
- 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 before transfusion can be tested for sickle cell disease using DNA analysis. Such samples are sent by the newborn screening laboratory to one of two DNA laboratories. **This service was commissioned nationally until October 2014, responsibility has been transferred to NHS England.**

- The Newborn screening laboratory tests the sample according to national policy and reports the results to the Child Health Records Department and the Newborn Blood Spot Failsafe Solution. This can result in one of five outcomes:
- Carrier: healthcare professional informs parents of results
- Inconclusive result: additional sample required
- Avoidable repeat test: additional sample required eg insufficient blood, poor record keeping
- Condition not suspected: parents are informed of the result
- Condition suspected: immediate clinical referral to a specialist initiated by the laboratory and parents informed of the result, by the specialist service

- Maternity care providers ensure all babies they are responsible for are offered screening by utilising the Newborn Blood Spot Failsafe Solution.
    - 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 The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services* 2011), and return diagnostic results back to the newborn screening laboratories to confirm enrollment into care.

Laboratory testing 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 ideally by face- to-face discussion, or by letter with offer of a face-to-face session

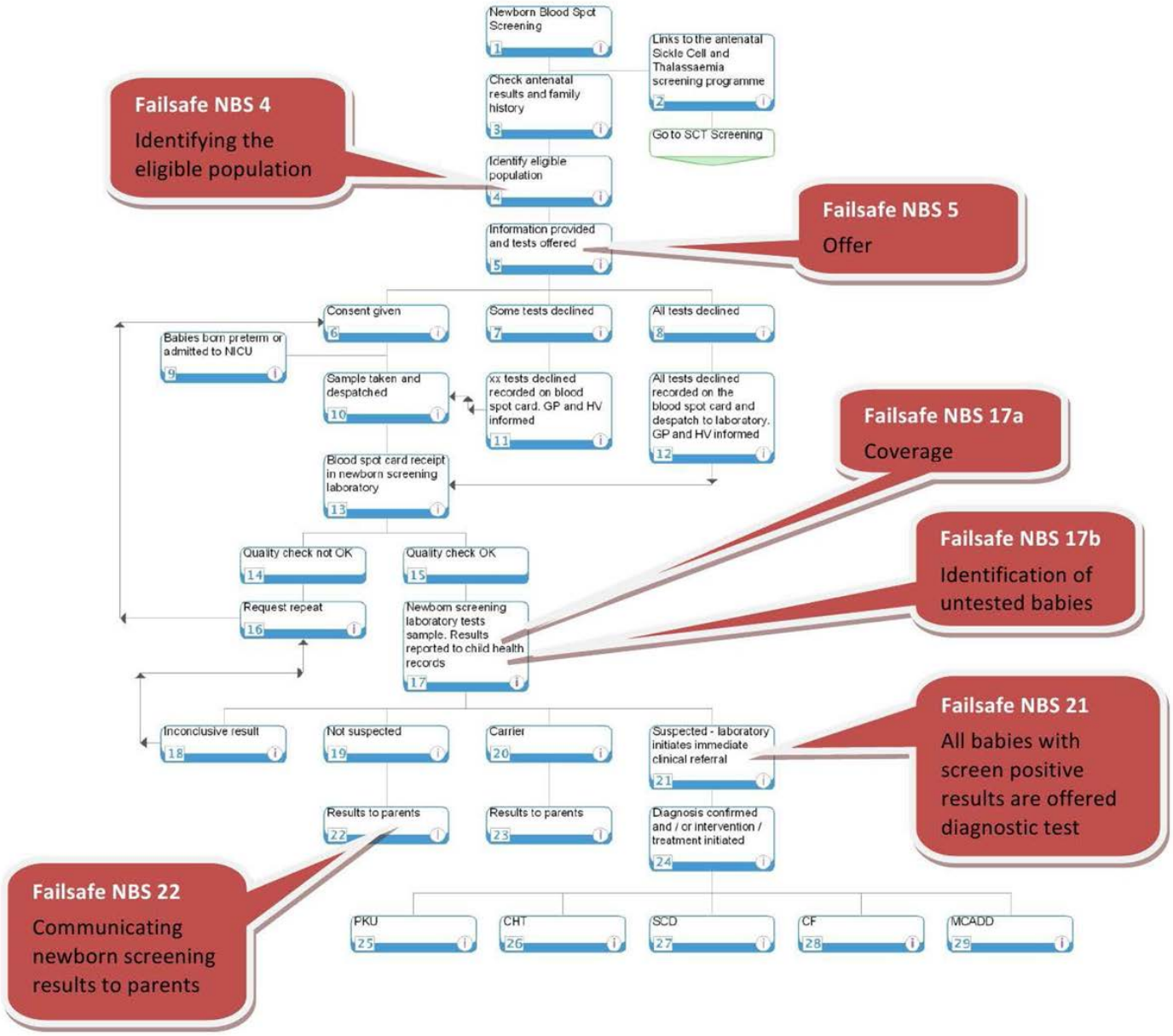
- Inconclusive result: additional sample may be required

- Condition suspected: immediate clinical referral initiated and parents informed of the result. The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services* (2011) specifies a failsafe system to ensure all screen positive babies enter the care pathway

- CHRDs maintain a list of the eligible population to provide a failsafe check to identify untested babies by 17 days, to monitor coverage and to send results to health visiting services (or agreed alternative) and parents according to national policy.

See Section 3.13 for details of the end of the screening pathway.

Newborn Sickle Cell Programme within Newborn Blood Spot Screening, Including Failsafes



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.

In accordance with UK NSC standards and protocols the provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway. A complete list of the failsafe processes in the SCT Screening Programme to be met by the Provider can be found on the national SCT screening programme website
- 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
    - follow guidance from The National Haemoglobinopathies Project *: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services* to ensure all screen positive babies enter the care pathway

2.4. Roles and accountability through the screening pathway

The linked 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. For their part the provider will be expected to fully contribute to ensuring that cross-organisational systems are in place to maintain the quality of the whole screening pathway that provides the optimal care for families. 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 community midwifery services are supported to facilitate early booking for maternity care within primary and community 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 UK NSC 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
- joint review meetings across the screening pathway to be held on a regular basis

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 Area Teams, CCGs, and directly by maternity services. Refer to 'Maternity Pathway Payments: Who pays for what' http://www.england.nhs.uk/wp-content/uploads/2014/01/who-pays-for-what-fin.pdf

2.6. Links between screening programme and national programme centre expertise

PHE, through the national screening programmes, is responsible for defining 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.

Public information:

Providers must always use the nationally-developed public information leaflets 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 and should involve the national screening team before developing any other materials.

Providers must involve the national screening team in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources.

Section 3: Delivery of Screening Programme

3.1 Service model summary

Model summary

The linked national screening programme consists of:

- Antenatal screening offered to pregnant women early in 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. Women who already know their carrier status (for example from a previous pregnancy) should be offered direct and speedy referral to counsellors for assessment of the couple risk status and prenatal diagnosis.

All women (in both high prevalence (HP) and low prevalence (LP) Trusts) are offered a screening blood test for thalassaemia using the initial results from routine red blood cell indices.

- In high prevalence areas, all women are also offered a screening blood test for sickle cell and other haemoglobin variants.

- In low prevalence areas, the Family Origin Questionnaire (FOQ) is used as an initial screening tool to identify any woman and the baby's father who are from a high-risk group for haemoglobin variants. If the questionnaire shows that there is a risk of either parent being a carrier, a screening blood test is offered to the woman.

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.

- Newborn screening offered for sickle cell disease to all newborn babies as one of five conditions now tested for on the newborn blood spot (heel prick).
  - A pre-transfusion sample should be offered to babies at risk of having a blood transfusion. Transfused babies who do **not** have a pre transfusion sample taken can be tested for sickle cell disease using DNA analysis.
  - Additional tests are offered if required by, screening protocol to achieve a conclusive result.
  - Parents may decline all or part of the test.
  - A national IT failsafe solution should be in place to ensure samples are

received in the laboratory and no babies born in England miss being offered screening. To be effective this needs central commissioning.
    - Conclusive results are recorded on a child health information system for the eligible population and for all five conditions. There needs to be a systematic notification of results to parents and the screening results recorded in the PCHR.
    - All screen positive babies should enter into appropriate care which includes access to a designated clinician and relevant health professionals who confirm diagnosis and initiate appropriate clinical management and treatment. See The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*.
    - All parents of babies with carrier results should be informed, ideally face to face, of their babies result.
- 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 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. See The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*
- 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 Service model summary

In accordance with UK NSC standards and protocols 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 provide one or more named individuals who will be responsible for the coordination of the delivery of the programme and provider contribution to planning 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 will meet at regular intervals (at least annually). The meetings will include representatives from programme coordination, clinical services, laboratory services and service management.

3.3 Clinical and corporate governance

In accordance with UK NSC standards and protocols the provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures
- ensure that responsibility for the screening programme lies at Director- level, (or delegated responsibility)
- 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 appointment of a Clinical Lead, a Programme Manager and the establishment of a multidisciplinary steering group (that meets quarterly) as a minimum
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of organisation's Clinical Governance arrangements, the organisation's Board is assured of the quality and integrity of the screening programme
- comply with the UK NSC 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.

Women do not need to be tested again in the same or subsequent pregnancy provided that:

- There are two or more previous results which are from a reputable laboratory, preferably accredited by a body in the UK, which are consistent, unequivocal and well documented. These results must be interpreted in line with recommendations in the third edition of the laboratory handbook.

And

- The red cell indices remain the same

And

- The patient identification has three or more matching data items, e.g.
  - name, date of birth and NHS number/hospital number
  - name, date of birth and address
  - NHS number/hospital number, date of birth and address (if woman confirms name change)
  - name, date of birth and haemoglobinopathy card
    For more information about the criteria please refer to the Third edition of the laboratory handbook.

The decision about re testing should be made by the laboratory who will always need to perform routine blood indices. Requests and blood samples should be taken and sent as usual to the laboratory. Known carrier women should be referred directly to counselling services without waiting for checking of the routine indices.

The target population to be offered sickle cell screening as part of the NHS Newborn Blood Spot Screening Programme is all babies between 5 and 8 days of age and babies 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 location of the offer of screening by midwives is to be locally determined.

Antenatal laboratory tests to be provided by laboratories meeting required laboratory standards which can be found on the National Screening programme website.

Pre-natal diagnostic testing is to be provided by specialist centres.

3.6 Days/Hours of operation

To be locally determined. However, timeliness is essential and is a key criterion of quality along all parts of the screening pathway.

3.7 Entry into screening programme

Antenatal: through GPs or direct referral into Maternity Services. While 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 results of newborn screening.

Newborn: through midwifery services or through 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. 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. NHS England 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:

- 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
- contributing to any NHS ENGLAND Screening Lead's initiatives in screening pathway development in line with UK NSC expectations
- meeting the SCT screening programme standards covering managing interfaces which can be found in *NHS Sickle Cell and Thalassaemia Screening Programme: Standards for the linked Antenatal and Newborn Screening Programme,* available on the National Screening programme website.

Interfaces:

- The referral of pregnant women presenting through primary care into midwifery services, or directly to a prenatal diagnosis centre if appropriate
- The sending of blood sample and FOQ (ideally electronically) from the midwifery service to the antenatal screening laboratory
- The sending of results from the antenatal screening laboratory back to the midwife (ideally using antenatal status codes)
- The referral of women/couples with confirmed carrier or affected status for counselling by the midwifery service
- The referral of women/couples with confirmed carrier or affected result to prenatal diagnosis centre by the midwifery service
- The reporting of results from the prenatal diagnosis centre to the referring clinician
- The informing of parents, community midwife and GP of prenatal diagnosis testing results by the referring clinician
- Maternity unit and newborn laboratory (maternity services and newborn sickle cell screening also covered by NHS Newborn Blood Spot Screening Programme). This may include
  - Midwife notifies a new birth and NHS number is issued, automatic notification to local CHRD
  - Midwife responsible for care sends blood spot card to newborn screening laboratory
  - Failsafe system to ensure laboratory receipt of sample
  - Laboratory requests midwifery services for a repeat if required
  - Laboratory sends results to CHRD, ideally electronically
  - CHRD checks for untested babies within effective timeframe
  - Laboratory refers screen positive results to specialist teams
  - CHRD send normal results letter to health visiting services (or agreed alternative) and to parents

  - CHRD informs maternity or health visiting services (or agreed alternative) of untested babies
  - CHRD use local pathway for reporting carrier results
  - Clinician informs CHRD if unable to complete screen so it can be recorded on the baby's record
  - Health visiting services (or agreed alternative) ensure parents receive results and record results in PCHR by 8 weeks

- Newborn laboratory and care services. This should be guided by The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*

The Map of Medicine describes these interfaces in more detail and can be found at: http://healthguides.mapofmedicine.com/choices/map/index.html

3.9 Information on test/screening programme

In accordance with UK NSC standards and protocols the provider will ensure that during pregnancy and after birth parents/carers are provided with approved information on sickle cell and thalassaemia screening by a trained workforce. The provider will ensure women have seen the written information *Screening tests for you and your baby* or had access to it in an appropriate format.

In addition, a wide range of information for the SCT Programme has been developed in a range of formats and media for women/couples that is available for local use.

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 reporting and recording

Antenatal results

- Antenatal laboratory sends results as per local arrangements, ideally using antenatal status codes
- The maternity unit notifies the newborn screening laboratory of carrier status

- It is recommended that the maternity unit keeps a log of and notifies the newborn screening laboratory of all women who are carriers and affected as well as carrier couples

Newborn results

- Newborn laboratory sends results to the newborn failsafe and CHRD, ideally electronically using nationally approved status codes
- CHRD record conclusive results on a child health information system for all the eligible population
- CHRD informs maternity or health visiting services (or agreed alternative) of null/incomplete results
- Clinician informs CHRD if unable to complete screen so it is documented in the baby's record
- 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 care commissioning guidelines (The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*

3.12 Results giving

In accordance with UK NSC standards and protocols the provider will ensure that a healthcare professional informs parents of their results.

For newborn screening results:

- the CHRD will send a normal results letter to parents and notify health visiting services (or agreed alternative)Health visiting services (or agreed alternative) will ensure that parents receive the results and record the results in the Personal Child Health Record by 8 weeks
- sickle cell carrier (and specified haemoglobin variant) results should ideally be given face to face by a trained healthcare professional
- 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

3.13 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 screening results are included on the blood spot card (This includes screening and PND results) (Node 27 on map of medicine)
- women opting for termination of pregnancy when the woman is counselled appropriately following prenatal diagnosis (nodes 26,27 and 28 on map of medicine).

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 (node 22 /23 on map of medicine)
- 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 (node 24 on map of Medicine). More detail is available in The National Haemoglobinopathies Project*: A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia Services*

3.14 Patient/carer information

A variety of national patient information materials are available from the SCT National Screening programme website.

Educating patients and carers to come to terms with their disease and how to best manage their condition is included within.

3.15 Exclusion criteria

See Section 3.4 for details of exclusion criteria in the antenatal period. Newborn:

- Babies stillborn or who died before day 8
- Children over 1 year of age

3.16 Staffing

In accordance with UK NSC standards and protocols the provider will ensure that there are adequate numbers of 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 CPD where necessary. Training standards are detailed at http://sct.screening.nhs.uk/standards

http://sct.screening.nhs.uk/training

Providers should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

The provider will ensure that counsellors for the sickle cell and thalassaemia screening programme are trained in an approved course see (http://sct.screening.nhs.uk/externaltraining).

3.17 User involvement

In accordance with UK NSC standards and protocols the provider will be required to:

- demonstrate that they have collected (or have plans in place to collect) the views of service users, families and others in respect of the services they provide
- demonstrate how those views will influence service planning and delivery for the purposes of raising standards
- show that all families are given information about how to provide feedback about services they receive, including about the complaints procedure.

Collection of the views of service users/families will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to NHS England on request.

3.18 Premises and equipment

In accordance with UK NSC standards and protocols the provider will ensure that:

- suitable premises and equipment are provided for the screening programme
- appropriate policies are in place for equipment calibration, maintenance and replacement
- appropriate IT systems are in place to support programme delivery including audit and monitoring functions and developing electronic links with other Providers in the screening pathway
- the UK NSC Laboratory Guidelines *Sickle Cell and Thalassaemia: Handbook for Laboratories'* are followed. These can be found on the SCT National Screening programme website

3.19 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/wp-content/uploads/2013/12/sec-b-cond-1415.pdf

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

Programme standards are available on the programme website (http://www.screening.nhs.uk/england).

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. See antenatal, newborn and linked SCT standards found in "*NHS Sickle Cell and Thalassaemia Screening Programme: Standards for the linked Antenatal and Newborn Screening Programme".*

4.2 Risk assessment of the screening pathway

Providers are required 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 Quality Assurance 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 against them. The provider will identify risks with high scores. The provider and commissioner will agree plans to mitigate risks.

4.3 Quality assurance

Providers will participate fully in national Quality Assurance processes, cooperate in undertaking ad-hoc audits and reviews as requested by QA teams and respond in a timely manner to their recommendations. This will include the submission to QA 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 should

- be accredited by UKAS/ CPA or equivalent and list the screening tests in their repertoire of services (http://www.UKAS.co.uk/)
- participate in an accredited external quality assurance scheme e.g. UKNEQAS scheme and respond within agreed timescales
- make available timely data and reports from external quality assurance programmes and accreditation services to QA, national screening programmes, and commissioners within agreed timescales

All providers should operate failsafe systems that can identify, as early as possible, people and babies that may have been missed or where screening results are incomplete.

Providers will respond to QA 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 QA believe there is a significant risk of harm to the population, they will 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 incidents in screening programmes and NHS England guidance for the management of serious incidents (http://www.screening.nhs.uk/incidents).

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.

It should also aspire to participate in properly conducted quality research where possible (with appropriate ethical approval).

Section 5: Data and Monitoring

5.1 Data collection, monitoring and reporting

Activity, performance and KPI data will be collected by providers and shared with NHS ENGLAND to allow benchmarking between areas within the eligible screening programme population.

- Providers should ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions.
- The Provider shall continually monitor and collect data regarding its delivery of the Service
- The Provider will 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.

For quality and monitoring, information should be shared with the National Congenital Anomaly and Rare Disease Registration Service

5.2 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 http://www.screening.nhs.uk/kpi for further details, guidance and updates on these indicators.

Public Health Outcomes Framework Indicator

2.21iii: 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%

national baseline is 98%

Providers to implement an additional KPI on coverage of untested babies (movers-in) up to one year of age.

This section outlines what data (in addition to Key Performance Indicators) the provider will be expected to collect and submit. Please refer to

http://sct.screening.nhs.uk/datacollection for further details, guidance and updates. There are two main streams of the data collection process:

Routine reporting:

- Standard annual data returns by: -
  i. all antenatal laboratories,
  ii. all newborn laboratories
- (iii) the three 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).* These data include for example:- timely referral to 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 UK NSC 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.
- Ad hoc surveys to inform screening pathway and processes
- Incident reporting

Access to data templates http://sct.screening.nhs.uk/datacollection.