



**Commissioning Board**

# **Public health functions to be exercised by the NHS Commissioning Board**

*Service specification No.18*

*NHS Sickle Cell and Thalassaemia Screening Programme*

*November 2012*

## Public health functions to be exercised by the NHS Commissioning Board

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# Public health functions to be exercised by the NHS Commissioning Board

*Service specification No.18*

*NHS Sickle Cell and Thalassaemia Screening Programme*

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# Service specification No.18

**This is a service specification within Part C of the agreement “Public health functions to be exercised by the NHS Commissioning Board” dated November 2012 (the “2013-14 agreement”).**

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board (“NHS CB”) under section 7A of the National Health Service Act 2006 (“the 2006 Act”) as amended by the Health and Social Care Act 2012.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2013-14 agreement including all service specifications within Part C is available at [www.dh.gov.uk/publications](http://www.dh.gov.uk/publications)

# 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 the NHS Commissioning Board (NHS CB) for the NHS CB's 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>
- Service Specification for the Provision of Antenatal and Newborn Laboratory Screening Services (in development)
- 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:

Offer timely antenatal sickle cell and thalassaemia screening to all women and couples to facilitate informed decision making (the offer includes the offer of,

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uptake of, and reporting of results of prenatal diagnosis and any subsequent action by the end of 13 weeks of pregnancy

Outcome to be achieved – for those women accepting prenatal diagnosis , 50% of prenatal diagnoses to be performed before 12 weeks 6 days.

Mortality rate in children under 5 is less than 4 per 1000 person years of life (2 deaths per 100 affected infants).

To identify with specified sensitivity babies born with conditions where early intervention is likely to be beneficial.

### 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.

### 1.2.2 Newborn Sickle Cell Screening Programme

Aim:

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

## 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 Health outcomes

For those women accepting screening to identify 50% of couples/women at high risk of an affected pregnancy by the end of the 12<sup>th</sup> week of pregnancy. Mortality rate in children under 5 is less than 4 per 1000 person years of life (2 deaths per 100 affected infants)

To identify with specified sensitivity babies born with conditions where early intervention is likely to be beneficial (as listed in the laboratory handbook

SCT screening contributes to the Public Health Outcomes Framework indicator on the uptake of screening for national screening programmes. Indicator 2.21v 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 hearing 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.



# 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 at:

[http://eng.mapofmedicine.com/evidence/map/linked\\_sickle\\_cell\\_and\\_thalassaemia\\_screening1.html](http://eng.mapofmedicine.com/evidence/map/linked_sickle_cell_and_thalassaemia_screening1.html) and

[http://eng.mapofmedicine.com/evidence/map/newborn\\_blood\\_spot\\_screening\\_1.html](http://eng.mapofmedicine.com/evidence/map/newborn_blood_spot_screening_1.html)

### 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.

- In high prevalence NHS Trusts (where Sickle Cell diseases are estimated to affect over 1.5 pregnancies per 10,000 conceptions):
  - all pregnant women are offered screening for sickle cell, thalassaemia and other haemoglobin variants using routine blood cell indices and a completed Family Origin Questionnaire.

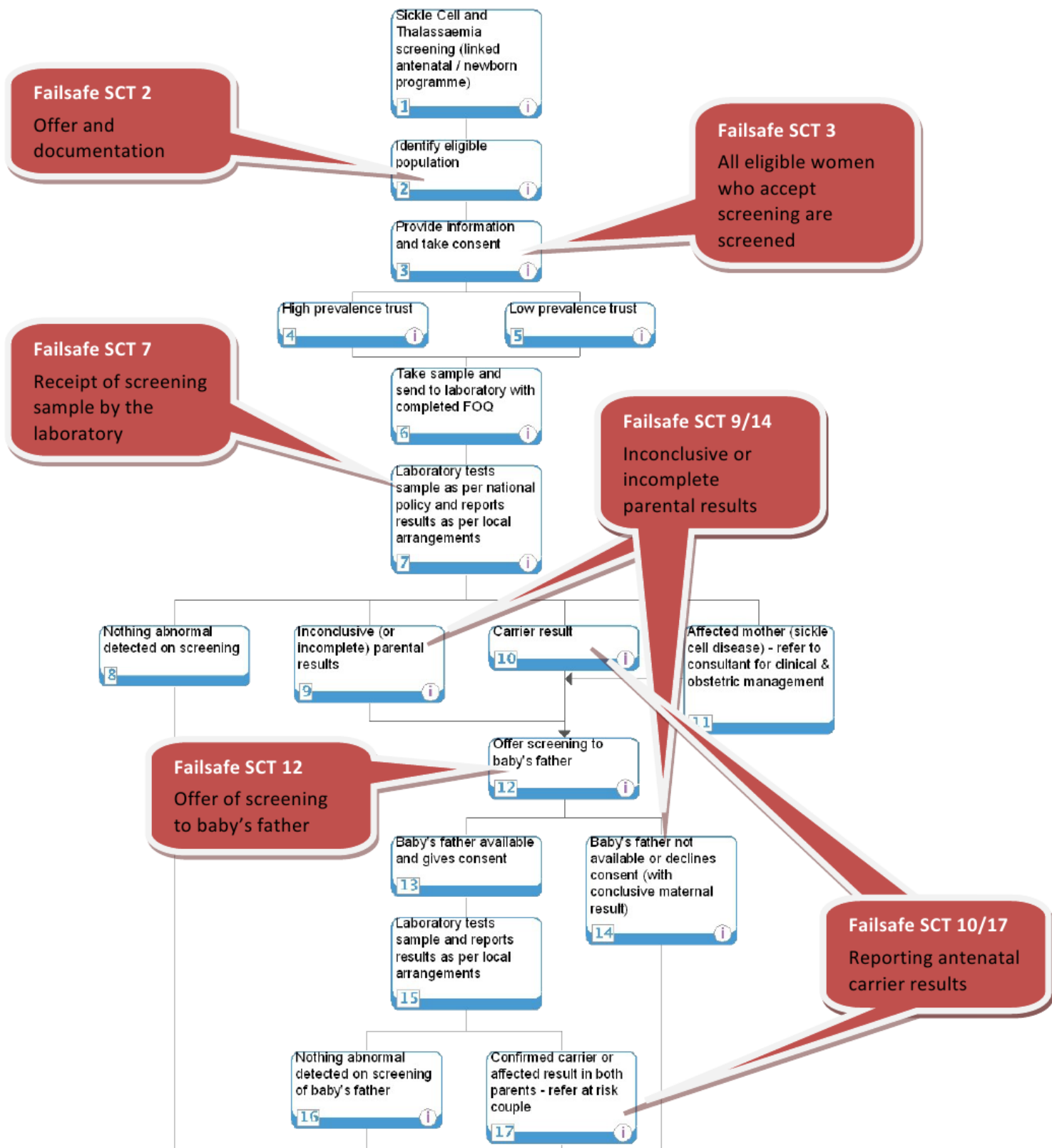
## Public health functions to be exercised by the NHS Commissioning Board

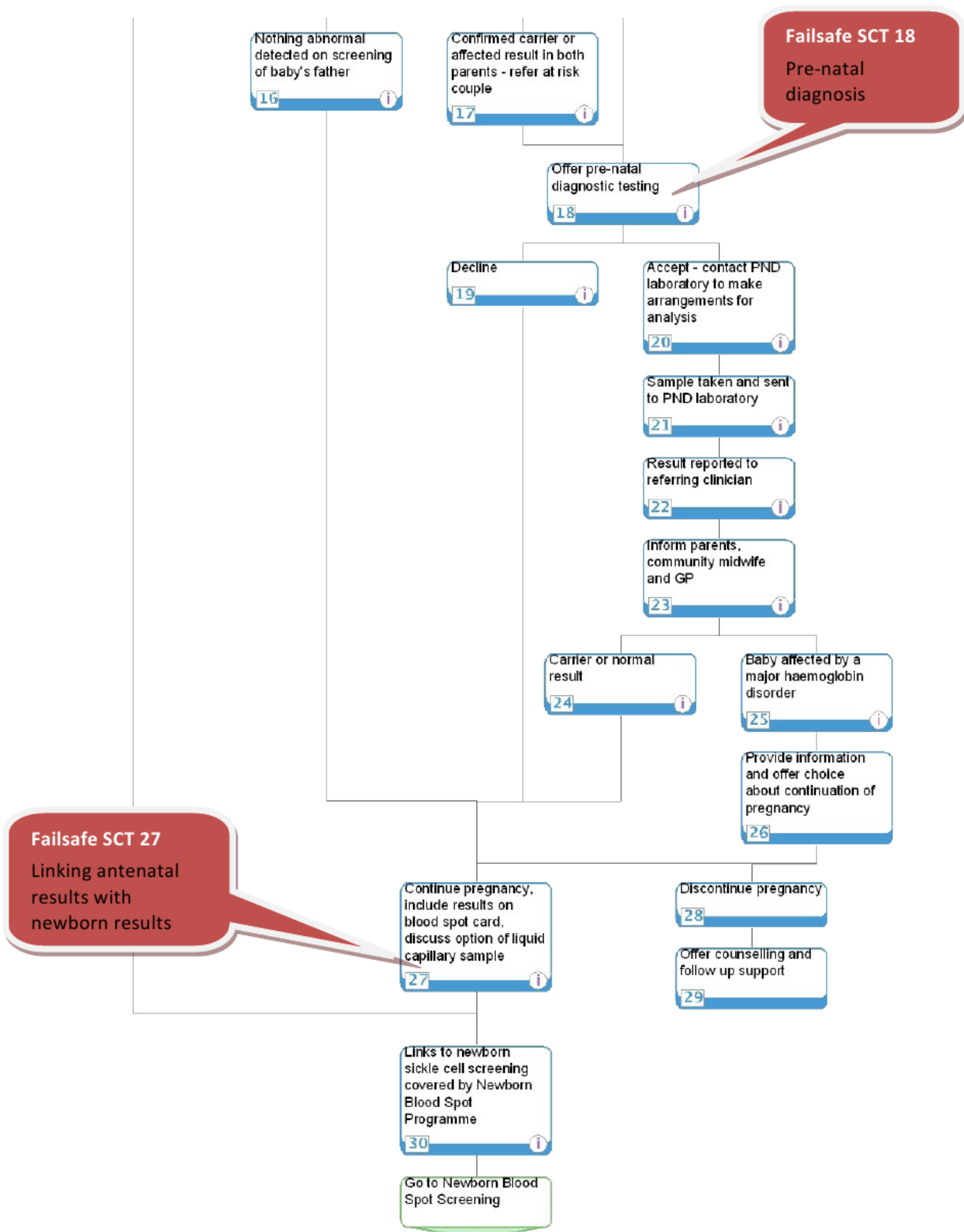
- Those who screen positive (in either part of the screen – blood test or questionnaire) will also have a specific blood test for haemoglobin variants
- For those women identified as carriers, their baby's father (irrespective of family origin) is offered testing for sickle cell, other haemoglobin variants, and thalassaemia
- In low prevalence Trusts (where sickle cell diseases are estimated to affect less than 1.5 pregnancies/10,000 conceptions):
  - all pregnant women are offered screening for thalassaemia using routine red blood cell indices and a specific blood test for haemoglobin variants
  - the Family Origin Questionnaire is used to assess the risk of the baby's mother or father being a carrier for sickle cell and other haemoglobin variants. Women in high risk groups or women whose baby's father is in a high risk group are offered laboratory testing for haemoglobin variants
  - for those women identified as carriers, their baby's father (irrespective of family origin) is offered testing for sickle cell, other haemoglobin variants, and thalassaemia
- Blood samples are taken and sent to the antenatal laboratory with completed Family Origin Questionnaires
- Pathways to be in place to ensure women who are known carriers (or couple carriers) can be referred directly to appropriate counselling service immediately without being delayed by routine booking processes to ensure that PND, if wanted, can happen very early in pregnancy (this may involve additional provider contracts or referral to genetic counseling).
- Laboratory tests sample as per national policy and reports results 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 bloodspot 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 counseling by trained counselors (PEGASUS or similar accredited course).
- 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.

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- Parents who decline pre-natal diagnostic testing continue with the pregnancy. Results should be included on bloodspot card for ongoing pregnancies.
- If pre-natal diagnosis testing is accepted, parental samples are taken and sent to the specialist laboratory for testing with nationally recommended documentation.
  - 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 appropriate termination of pregnancy services is required.
- Antenatal and PND results should be included in the blood spot card
- For pregnancies resulting in a live birth, the antenatal screening pathway ends when the antenatal screening results are included on the bloodspot card (screening and PND results)
- For women opting for termination of pregnancy, the antenatal screening pathway ends when the women are counseled appropriately following a termination of pregnancy

Antenatal Sickle Cell and Thalassaemia Screening, Including Failsafes





## 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 the issuing of NN4B 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 age. This is carried out by child health record departments who note the arrival of a baby (when it is registered) and alert the HV to visit and check the screening results.
- Samples are taken routinely on day 5-8 of age, 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 bloodspot card should be marked "pre transfusion". The "pre transfusion" bloodspot 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 is currently commissioned nationally. Newborn screening laboratory tests sample as per national policy and reports all results to Child Health Records Department (CHRD). Screen positive results are also reported to local clinician/and designated sickle cell and thalassaemia centre (under development) to 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).
- Laboratory testing results in one of four outcomes:
  - 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. This will ideally be carried out by face-to-face discussion, or by letter with offer of a face-to-face session
  - Inconclusive result: additional sample required

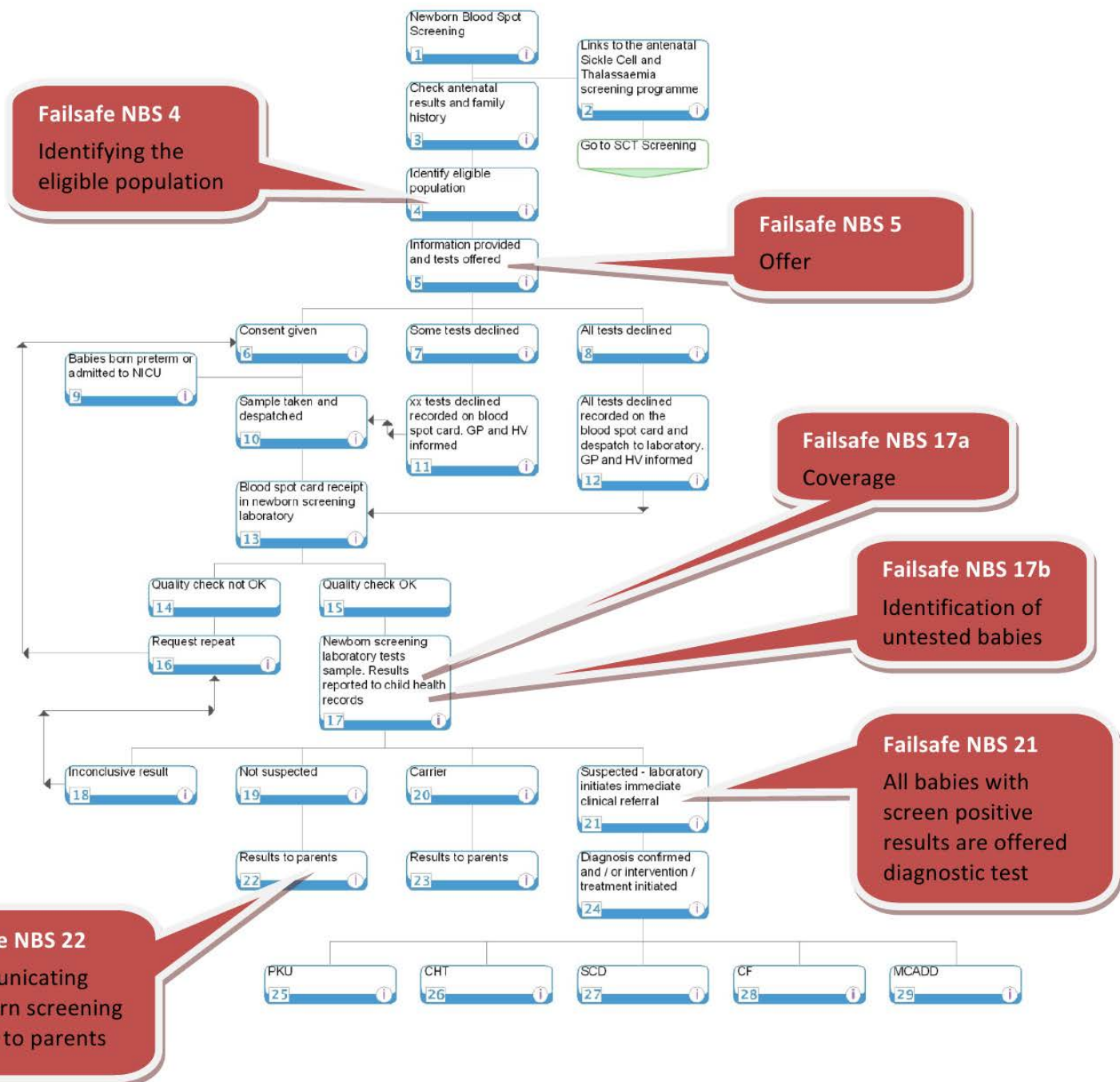
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- Not suspected: parents are informed of the result suspected: immediate clinical referral initiated and parents informed of the result. The National Haemoglobinopathies Project : *A Guide to Effectively Commissioning High Quality Sickle Cell and Thalassaemia 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 visitors 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 and the Newborn Bloodspot Programme Website
- review and risk assess local screening pathways in the light of national SCT Screening Programme guidance
- work with the NHS CB 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, CHRD, and specialist sickle cell and thalassaemia services, i.e. 'the screening pathway'. The NHS CB 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. 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

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- contributing to any of the NHS CB 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 organizations
- 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

The commissioning of the SCT screening pathway will involve commissioning different elements of the pathway at different levels.

Pathway	Provider	Possible level of commissioning	Possible level of contracting	Rationale and other comments
<b>ANTENATAL</b>				
Identify cohort in a timely manner	Maternity services / primary care	LAT	CCG	The eligible population is identified through routine midwifery-led antenatal care
Inform the cohort and maximize uptake of screening in a timely manner	Maternity services / primary care	LAT	CCG	Informing the cohort and maximizing uptake in a timely manner takes place during routine midwifery-led antenatal care and also sometimes in primary care. <i>CCGs will have responsibility for commissioning maternity care.</i>
Screening test - sample taking / Family Origin Questionnaire (FOQ) completed (antenatal)	Maternity services / primary care	LAT	CCG	Mostly carried out through routine midwifery care. Midwives take the blood sample and ensure the FOQ is completed and send to labs. GPs may

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				also take the blood sample. <i>CCGs will have responsibility for commissioning maternity care.</i>
Screening test - analysis	Antenatal labs	LAT	CCG	Level of commissioning needs to be above that of individual CCGs to allow centralisation of these services and to improve quality and efficiency as per direction of the pathology modernization agenda. (Carter Review of NHS Pathology Services (2006, 2008) made the case for consolidating pathology nationally to improve quality, patient safety and efficiency)
Results reporting	Maternity services	LAT	CCG	Results reporting as part of routine midwifery care. Negative blood test results given to mother/couple by midwife. Positive blood test results

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				given to mother/couple by specialist counsellor/midwife as it is time intensive. In some areas, especially high prevalence areas, this is carried out by specialist haemoglobinopathy counsellors. Giving of positive results includes advice about testing of partners (the baby's father ) of positive women Maternity services to be commissioned by CCGs
Counselling of "at-risk" couples	Maternity services Specialist haemoglobinopathy DNA centres (currently three in England)	LAT and Linked with specialised commissioning	NHS CB/CCG	Counselling carried out by specialist haemoglobinopathy counsellors, genetic counselors, or designated PEGASUS midwives and occasionally obstetricians who also need to be appropriately trained. Arrangements need to include couples identified from previous pregnancies as being "at risk", who would be directly referred for

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				counselling at start of pregnancy and not go through the usual 'booking process'. Two of the three specialist genetic centres provide counselling and cvs/amniocentesis for local services as well as DNA analysis of specimens.
Sample taking - amnio/ CVS sample taking	Fetal medicine specialists Specialist haemoglobinopathy DNA centres (currently three in England)	NHSCB – hub level. Linked with specialised commissioning	NHS CB	CVS is in the SSNDS. Amniocentesis where the procedure is difficult/complex is in the SSNDS Two of the three specialist genetic centres provide amnio/ CVS sample taking. <i>The NHS CB will have responsibility for commissioning specialised services (consistent with FA and Downs etc)</i>
Sample analysis – Prenatal Diagnosis (PND)	Specialist genetic centres	NHSCB – link to specialised commissioning at	NHS CB	This analysis is only carried out at three specialist genetic centres

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		hub level		(Oxford, UCH and Kings) and involves small numbers (approx 400 samples p/a). Consider commissioning through one hub to ensure consistency.
Results reporting and counselling for women undergoing PND	A range of providers – all maternity services should specify how this works for couples who have had a prenatal diagnosis either specialist haemoglobinopathy counsellor, specialist centre (where PND is done there) or obstetrician/specially trained midwife/genetic counselor	LAT	CCG	Mostly carried out by specialist haemoglobinopathy counsellor in high prevalence areas, but can be by other healthcare professionals.
<b>NEWBORN</b>				
Newborn – identify cohort	Maternity services	LAT	CCG	The eligible population is identified through the issuing of NN4B at birth (or registration with a GP

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				<p>practice for babies born abroad).  <i>CCGs will have responsibility for commissioning maternity care.</i>  <i>The NHS CB will have responsibility for holding primary care contracts.</i></p>
Inform the cohort and maximize uptake of screening	Maternity services	LAT	CCG	<p>Informing the cohort and maximizing uptake takes place during routine midwifery-led antenatal and postnatal care, and sometimes through primary care.          Health visitors may inform families moving into the area.  <i>CCGs will have responsibility for commissioning maternity care.</i></p>
Sample taking (part of Newborn Blood Spot Screening Programme)	Maternity services	LAT	CCG	<p>Midwife takes blood sample for sickle cell disease as part of New Born Blood Spot screening. Repeat samples and first</p>



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				<p>samples from babies moving into the area may be taken by midwives (up to 28 days), health visitors (up to six months) or phlebotomy services (variable)</p> <p>Neonatal care services will be responsible for taking the sample if a newborn baby is in their care at the time of the test.</p>
Screening test – analysis (for sickle cell)	Newborn labs	NHS CB specialised commissioning or Lead Area Office Commissioner for each Lab	NHS CB	Link with specialised services for 13 newborn labs (and specialist haematology laboratories carrying out second line testing specifically for sickle cell)
DNA analysis (sickle cell) for transfused babies	DNA analysis reference labs for transfused babies (currently not in the bloodspot specification)	NHS CB	NHS CB	Two labs carry out this work (Sheffield and Kings) funded nationally until 2013. Funding needs to be picked up from 2013. Proposal has been to public health leads of

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				specialist commissioners group and 'support/agreement in principle' of need – chair SCG chair from London. Note that these two labs are different to the labs that do the analysis for cystic fibrosis – although Sheffield is the same lab.
Results reporting	Child Health Records	NHS CB	NHS CB	
	Health visitors	NHS CB		<p><u>Negative results:</u> mainstream health visitor/midwife gives results to parents</p> <p><u>Carrier results:</u> linked health visitor or specially trained counsellor give SCT carrier results to parents</p> <p><u>Positive results:</u> contact by specialist counsellors (usually in high prevalence areas or local clinical service (low prevalence areas))</p> <p><i>The NHS CB will have responsibility for</i></p>

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				<i>commissioning health visiting services until 2015.</i>
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The commissioning of the SCT screening pathway involves commissioning at different levels. The SCT screening services will be commissioned by the NHS CB alongside specialised services where appropriate.

## 2.6 Links between screening programme and national programme centre expertise

Public Health England (PHE) will be responsible for delivery of the essential elements of screening programmes best done once at national level.

These include:

- developing, piloting and roll-out to agreed national service specifications of all extensions to existing screening programmes and new screening programmes;
- setting QA standards;
- setting and reviewing programme standards;
- setting and reviewing national service specifications and advising on section 7A agreements (under the direction of DH requirements);
- developing education and training strategies;
- providing patient information;
- determining data sets and management of data, for example to ensure KPIs are collected;
- setting clear specifications for equipment, IT and data;
- procurement of equipment and IT where appropriate; (Procurement may undertaken by NHS CB but will need advice from PHE screening expertise and related clinical experts);
- Collect, collate and quality assure data for cancer and non-cancer screening programmes;
- Monitor and analyse implementation of NHS commissioned screening services;
- Provide advice to DH on priorities and outcomes for the NHS CB mandate and section 7a agreement, and to lead on detailed provisions, in particular the 7a agreement on screening;
- Advise the NHS CB how to increase uptake of screening.

PHE will also be responsible for

- providing the quality assurance functions for screening programmes;
- providing Public Health expertise and advice on screening at all levels of the system, including specialist Public Health expertise being available as part of NHS CB screening commissioning teams;
- ensuring action is taken to optimise access to screening programmes, e.g. among socio-economically disadvantaged groups.
- Ensuring reports on important aspects of screening are available at various geographies (e.g. local authority) to enable population based oversight

# 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 within the first three months 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.

In high prevalence areas:

- all pregnant women should be offered screening for sickle cell, thalassaemia and other haemoglobin variants using routine blood indices and a Family Origin Questionnaire at or before 10 weeks of pregnancy
- the baby's father of all identified carrier mothers offered screening
- the Family Origin Questionnaire is used to help establish the risk of Alpha 0 thalassaemia and reduce the need for inappropriate recall of partners for this risk and thereby reduce anxiety for families (and to assist in interpretation of results)
- all women should be informed about newborn blood spot screening programme, which includes screening for sickle cell

In low prevalence areas:

- all pregnant women should be offered screening for thalassaemia by 10 weeks of pregnancy using routine red blood cell indices
  - the Family Origin Questionnaire is used to assess the risk of either the woman or the baby's father being a carrier for sickle cell and other haemoglobin variants
  - women in identified high risk groups offered laboratory testing
  - for women identified as carriers, their baby's father is offered testing for sickle cell, other haemoglobin variants, and thalassaemia
  - all women should be informed about newborn blood spot screening programme, which includes screening for sickle cell
- Newborn screening offered for sickle cell disease (a group of similar conditions) to all newborn babies as one of five conditions now tested for on the newborn bloodspot (heel prick).

- Additional tests are offered to babies at risk of blood transfusion and, 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 on the demands of the as an increasing proportion of women are aware of their carrier status before pregnancy making the need to ensure that those women and couples who already know their carrier status and wish to go direct for PND are able to exercise choice in terms of timely direct referral rather than routine pregnancy care.
- the interface between maternity, laboratories 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 the NHS CB 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 found on the National Centre Website
- 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

### 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
- The patient identification has three or more matching data items, eg:
  - name, date of birth and hospital number
  - name, date of birth and address
  - hospital number, date of birth and address (if woman confirms name change)
  - name, date of birth and haemoglobinopathy cardFor 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 counseling 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.

### 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 criteria 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 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. The NHS CB 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 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 CB 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 from the midwifery service to the antenatal screening laboratory
- The sending of results from the antenatal screening laboratory back to the midwife
- 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 Bloodspot 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
  - 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 visitor and to parents
  - CHRD informs maternity or health visiting services of missing results
  - CHRD use local reporting results for carrier results
  - Clinician informs CHRD if unable to complete screen so it can be recorded on the baby's record
  - Health visitors 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://eng.mapofmedicine.com/evidence/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 a format appropriate.

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 minimum laboratory criteria outlined in the laboratory handbook (NHS Screening Programmes) and second edition of the screening programme standards (NHS Screening Programmes), both of which can be found on the SCT National Screening programme website. See Section 5 of this service specification document on data collection requirements for screening laboratories.

### 3.11 Results reporting and recording

Antenatal results

- Antenatal laboratory sends results as per local arrangements
- The maternity unit notifies the Newborn laboratory of carrier status
- It is recommended that the maternity unit keeps a log of and notifies the Newborn laboratory of all women who are carriers and affected

Newborn results

- Newborn laboratory sends results to CHRDR, ideally electronically using nationally approved status codes
- CHRDR record conclusive results on a child health information system for all the eligible population
- CHRDR informs maternity or health visiting services of null/incomplete results
- Clinician informs CHRDR if unable to complete screen so recorded on 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 screen positive antenatal results this will either be the local specialist midwife or sickle cell counselor or occasionally an obstetrician.

For newborn screening results:

- the CHRDR will send a normal results letter to parents and notify the health visitor
- the health visitor will ensure that parents receive the results and record the results in the Parent and Child Handheld Record by 8 weeks

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- sickle cell carrier 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 generic screening objectives the programme the antenatal screening pathway ends for:

- pregnancies resulting in a live birth when the antenatal screening results are included on the bloodspot card (This includes screening and PND results) (Node 27 on map of medicine)
- women opting for termination of pregnancy when the women is counselled appropriately following a termination of pregnancy (nodes 26,27 and 28 on map of medicine) .

Based on generic screening objectives 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 to 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.

All professionals involved in the screening programme are required to keep up to date with nationally approved training programmes.

The provider will ensure that counsellors for the sickle cell and thalassaemia screening programme are trained in an approved course such as PEGASUS. Further details can be found on the SCT National Screening programme website.

### 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 the NHS CB 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

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

### 4.1 Key criteria and standards

Providers are expected to work towards meeting the acceptable and achievable antenatal, newborn and linked SCT standards found in “*NHS Sickle Cell and Thalassaemia Screening Programme: Standards for the linked Antenatal and Newborn Screening Programme*”. The standards are available on the SCT National Screening programme website <http://sct.screening.nhs.uk/standards>.

The SCT National Screening programme supports health professionals to meet these standards and deliver a high quality SCT screening programme. A number of resources to support health professionals are available on the SCT National Screening programme website.

### 4.2 Risk assessment of the screening pathway

Providers are expected to have an internal quality assurance process that assures the NHS CB of their ability to manage the risks of running a screening programme. Risks should be defined in the standard NHS format (*likelihood and severity multiplied to give a RAG score*)

Providers are expected to maintain a register of risks and work with the NHS CB and QA staff to identify key areas of risk in the screening pathway to ensure that these points are reviewed in contracting and peer review processes. On a quarterly basis high scoring risks will be identified and agreed between the provider and the NHS CB, and plans put in place to mitigate against them.

### 4.3 Quality assurance

The NHS CB will suspend a service on recommendation from QA.

The Provider will:

- meet national programme standards, or have plans in place to meet them where this is not the case
- participate fully in national Quality Assurance processes and respond in a timely manner to recommendations made
- make available data from external quality assurance programmes to screening programmes, national team and the NHS CB
- collect and submit minimum data sets as required to assure the NHS CB and the Quality Assurance Team in Public Health England of the safety and quality of the services provided

- complete and submit the annual self-assessment tool with or without (as requested) an annual report of services to the Quality Assurance team and respond to identified areas for improvement

### 4.4 Serious incidents

A serious incident (SI) for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening service which exposes the programme to unknown levels of risk that screening or assessment have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low or high, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents.

The Provider will:

- have a serious incident policy in place and ensure that all staff are aware of it and of their responsibilities within it
- inform the NHS CB within 24 hours in the event of a serious adverse event and provide all reasonable assistance to the NHS CB in investigating and dealing with the incident. Where appropriate, such incidents should also be reported to the National Screening programme to assist in the development of a national picture of risk identification and management
- comply with appropriate statutory regulations (e.g. Data Protection Act, COSHH Regulations etc) to ensure a safe working environment
- comply with the UK NSC guidance, '*Managing Serious Incidents in the English NHS National Screening Programmes*' available on the UK NSC website
- review their procedures and processes against the "*NHS Sickle Cell and Thalassaemia Screening Programme: Standards for the linked Antenatal and Newborn Screening Programme, second edition*" to reduce the likelihood of incidents occurring
- have a robust system in place whereby families, other professionals and the public can raise concerns about the quality of care and where there is adequate arrangements for the investigations of such concerns.

### 4.5 Continual service improvement

Where national recommendations and core and/or developmental standards are not currently fully implemented the provider will be expected to indicate in

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service plans what changes and improvements will be made over the course of the contract period.



## Section 5: Data and Monitoring

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 NHS CB, 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 NHS CB.

### 5.1 Data collection, monitoring and reporting

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

### 5.2 Key performance indicators

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

This section outlines what data (in addition to Key Performance Indicators) the provider will be expected to collect and submit. There are two main streams of data collection process:

#### **Routine reporting:**

- Standard annual data returns by:-
  - (i) all antenatal laboratories,
  - (ii) all newborn laboratories (jointly with the UK Newborn Screening Screening programme)
  - (iii) the three DNA laboratories (prenatal diagnosis) covering 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.
- SCT antenatal KPIs are submitted from maternity units and antenatal laboratories to the UK NSC quarterly and annually.
- Submission of newborn bloodspot KPIs by laboratories and child health information systems started in Q4 2010/11.
- Information from external Quality Assurance bodies such as UK NEQAS and CPA.

**Other:**

- Programme evaluation data collection with support from National Information Governance Board (NIGB)
- Ad hoc surveys to inform screening pathway and processes
- Incident reporting
- Regional teams maternity data collection tool (and any successor tools).

There is on-going work under development about data collection.

This includes work to inform the proposed maternity tariff, which should be confirmed for 2013/14.