NHS Commissioning Board

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.19

NHS Newborn Bloodspot Screening Programme

November 2012

DH Department of Health

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NHS Newborn Bloodspot Screening Programme

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Service specification No.19

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

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 NHS Newborn Blood Spot (NHS NBBS) screening services.

The purpose of the service specification for the NBBS Screening Programme 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 evidence base, 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 should be read in conjunction with:

- Current NHS NBBS guidance which is found on the NHS NBBS website. NHS Newborn Bloodspot Screening Programme Home Page
- Information and resources for parents of children with high risk results www.newbornbloodspot.screening.nhs.uk
- Guidance & updates on KPI indicators: http://www.screening.nhs.uk/kpi
- http://newbornbloodspot.screening.nhs.uk/standards
- Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/quality-assurance#fileid9902

1.2 Aims

The NHS NBBS Programme aims to identify newborn babies at high risk of phenylketonuria (PKU), congenital hypothyroidism (CHT), sickle cell disease (SCD), cystic fibrosis (CF) and medium-chain acyl Co-A dehydrogenase deficiency (MCADD) to improve health and reduce disability or death.

1.3 Objectives

- To offer all eligible babies timely screening
- To refer all screen positive babies to diagnostic and clinical care in accordance with standards
- To record all results on a Child Health IT system and give a copy to parents

- To ensure all those involved in care of the child also have access to the results. This is usually the GP and health visitor.

1.4 Health outcomes

The prevention of ill-health, reduction of disability and reduction of mortality in babies with screened conditions.

The NHS NBBS 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: newborn bloodspot screening.

1.5 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs,
- All those participating in the NHS NBBS 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 newborn blood spot screening is that all newborn babies in the commissioner's population, and babies who move into the area up to the age of one year, should be offered screening for the five conditions included in this specification.

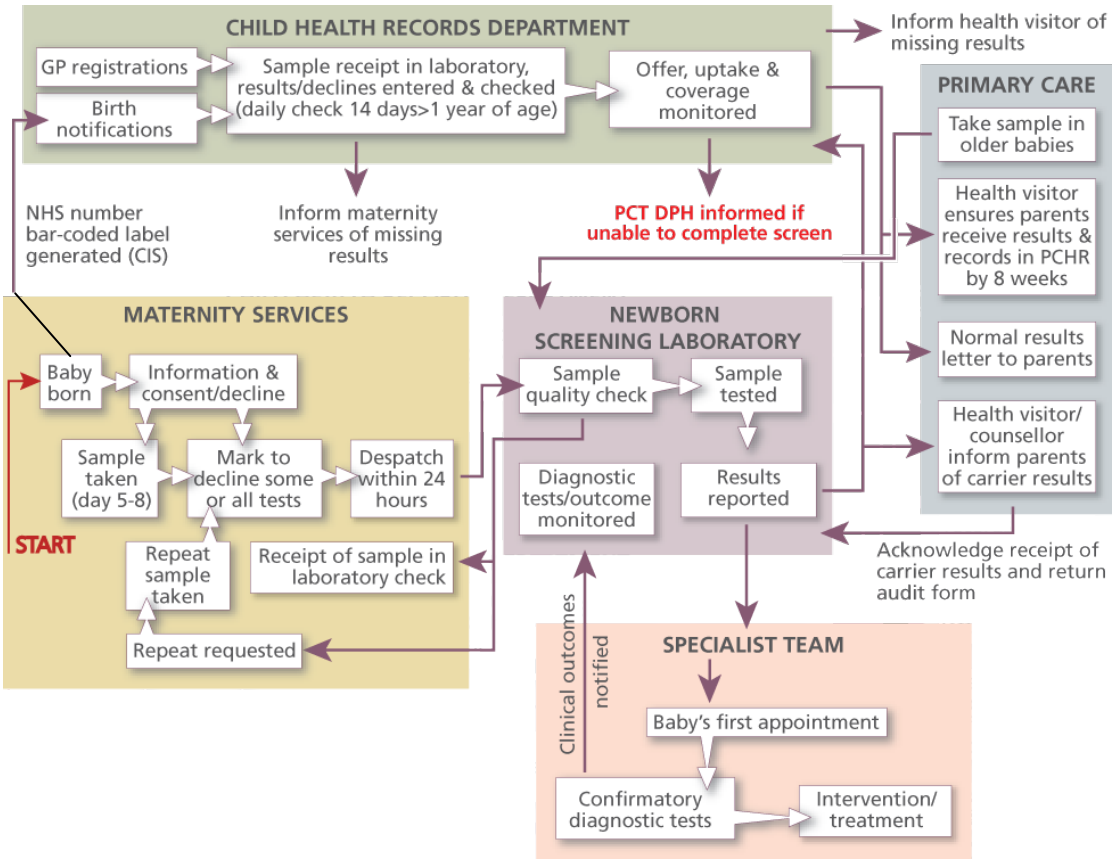
2.2 Care pathway

- 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.
- Midwives provide written information (ideally before birth) and take verbal consent.
- Screening can be offered to unscreened babies who move into a local area up to one year of age
- Samples are taken routinely on day 5 and in exceptional circumstances between days 6-8 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.
- Additional tests are offered to babies born preterm and babies at risk of blood transfusion and if required by a screening protocol to achieve a conclusive result.
- The Newborn screening laboratory tests the sample according to national policy and reports the results to the Child Health Records Department. 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 e.g. 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
- Child Health Records Departments maintain a list of the eligible population to provide a failsafe check to identify untested babies, to monitor coverage and to send results to health visitors and parents according to national policy.
- Confirmation of screen positive baby attending first clinical appointment and conclusive diagnosis, information provided and management initiated.

This can be summarised as:

- Identifying the eligible population
- Offering screening
- Taking the sample and sending to the screening laboratory
- Analysing the sample
- Timely referral of screen positive babies into diagnostic and clinical care
- Reporting results to Child Health Records Departments (CHRD)
- Recording results on CHRD IT system and ensuring conclusive result for all tests
- Reporting results to parents

Below is the newborn blood spot pathway that gives it a visual pathway. It can also be accessed at that National Screening programme website.



A full description of the pathway 'process' can be found on the Map of Medicine website at: http://eng.mapofmedicine.com/evidence/map/index.html

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 identify (i) what is going wrong and (ii) what action follows to ensure a safe outcome.

The Provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway. A complete list of the failsafe processes in the NBBS Screening Programme to be met by the Provider can be found on the National Screening Programme website
- 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

- 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

2.4 Roles and accountabilities

The NHS NBBS Programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, the screening laboratory, diagnostics laboratory and genetics services, child health records departments, health visiting services and specialist condition specific services, ie 'the screening pathway'. 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 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
- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- 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 commissioner 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 care
- links with secondary and/or 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 NHS NBBS pathway involves commissioning at different levels.

Pathway	Provider	Possible Responsibility for elements of Commissioning	Possible Responsibility for elements of Contracting	Rationale and other comments
Identify cohort in a timely manner	Maternity Services (plus occasionally through general practice)	LAT	CCG	Identification of the cohort is carried out through the midwifery service following the issuing of NN4B at birth. For those babies in the UK who are born abroad, identification takes place in primary care following registration with a GPs practice. Child Health Records Departments (CHRD) and health visitors have some responsibility to identify part of this cohort. CCGs/NHSCB Area *team* will have responsibility for commissioning maternity care. The NHSCB will have responsibility for holding primary care

				contracts, commissioning health visiting services until 2015 and commissioning CHRDs.
Inform/ Maximise uptake in a timely manner	Maternity Services (plus occasionally through general practice and health visiting services)	LAT	CCG	Informing the cohort and maximising uptake in a timely manner takes place during routine midwifery-led antenatal and postnatal care, and sometimes through primary care. Health visitors may inform families moving into the area.
Screening test: sample taking	Midwifery services (plus health visiting services)	LAT	CCG	Initial sample taking is carried out as part of broader routine midwifery care. Neonatal care services will be responsible for taking the sample if a newborn baby is in their care at the time of the test. Midwives or health visitors (depending on the time after birth when the

				repeat sample is taken), phlebotomy services or neonatal services may take repeat samples and first samples from babies moving into the area.
Screening test: analysis	Newborn Screening Laboratories	LAT with specialised commissioning	NHS CB	There are 13 newborn laboratories. In addition there are specialist laboratories carrying out second line testing for cystic fibrosis (CF) and sickle cell and thalassaemia (SCT). Laboratories store and retain residual dried blood spots.
Screening test: results reporting	Child Health Records Department	LAT	NHS CB	Blood test results are reported to the Child Health Records Department (CHRD). The CHRD send results to the health visitor or direct to parents.
	Health visiting	LAT (including specialised	NHS CB	Carrier results: SCT - Linked

	services, specialised genetics services, cystic fibrosis services	commissioning)		health visitors or specially trained counsellors give SCT carrier results to parents. Cystic fibrosis – Specially trained health visitors or specialist genetic counsellors or CF nurses will inform parents
	Designated specialist service	LAT Specialised commissioning	NHS CB	Positive results: All conditions – a designated specialist service informs the parents of the result

The commissioning of the NHS NBBS pathway involves commissioning at different levels. The NHS NBBS 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 the Department of Health 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 be 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 the Department of Health 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

Pre-screening information is provided to the pregnant woman and a medical/family history ascertained at booking. The midwife provides information on the NHS NBBS Programme to the pregnant woman at the booking visit, and in the 3rd trimester with the aid of the pre-screening leaflet. Additional communication and consent is taken at least 24 hours before testing. This includes explaining what happens to the card after screening and that parents can opt out of being contacted for research on the sample. The routine day 5 sample is taken. Additional tests are offered to babies born preterm and 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. Information on how to access the test if they change their mind is provided. Screening is largely embedded within the routine maternity pathway. Taking of the sample should be recorded in the maternity notes and Personal Child Health Record (PCHR).

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. Screening results status codes and electronic messaging of results between laboratory and CHRD needs implementing. Child health information system (CHIS) to be reviewed and commissioning action to ensure they meet national information requirements specified in Information Requirements for Child Health Information Systems (DH, February 2012). Conclusive results are recorded on a CHIS 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. For all conditions, screen positive babies should enter into appropriate care as part of a clinical network.

All parents of babies with carrier results should be notified and the options/implications explained. This is delivered by a variety of models, for CF specially trained health visitors or CF specialists fulfil this duty. Carriers for MCADD are not detected until the diagnosis protocol has been fulfilled and the result is given by a specialist clinician. Linked health visitor or specially trained counsellor give SCD carrier results to parents.

It is important that the links between the end of screening and enrolment in care are made explicit and the transfer from “screening responsibility” to “care responsibility” works seamlessly, if the benefits delivered by a screening programme are to be achieved and optimal outcomes delivered.

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

3.2 Programme co-ordination

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, so that, collectively, the aims and objectives of the Screening programme are met.

The Provider will provide one or more named individuals who will be responsible for the coordination of the delivery of the programme and the 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 the programme.

In accordance with UK NSC standards and protocols the provider and commissioner 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,
- 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 the screening programme standards found on the National Screening programme 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
    - ongoing risk management
    - insurance and liability
    - health and safety
    - waste management
    - protection of children and vulnerable adults
    - communications
    - ensure the programme is delivered by trained workforce
    - commission newborn screening and diagnostic laboratories that are CPA accredited
    - commission molecular genetics laboratories who are members of the UK Genetic Testing Network (UK GTN) and comply with the quality criteria laid down by the UK GTN Steering Group
    - cooperate with UK NSC QA

3.4 Definition, identification and invitation of cohort/eligibility

The target population to be offered screening is all newborn babies and infants moving in to the country up to one year of age.

The provider will make every effort to maximise screening uptake for the whole eligible population including the vulnerable and hard-to-reach groups.

3.5 Location(s) of programme delivery

See 2.2 Care pathway.

3.6 Days/Hours of operation

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

3.7 Entry into screening programme

See section 3.4 above.

3.8 Working across interfaces

The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are essential to reduce the potential for errors and ensure a seamless pathway for service users. It is essential that there

remains clear named clinical responsibility, at all times, and, at handover of care, the clinical responsibility is clarified. The Provider will 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 NBBS Programme standards covering managing interfaces which can be found on the National Screening programme website

Interfaces:

- Midwife notifies a new birth and NHS number is issued, automatic notification to local CHRD usually but must be able to receive hard and electronic copy from independent/community midwives via post/generic NHSmail account
- Midwife responsible for care sends blood spot card to newborn screening laboratory with the NHS number
- Failsafe system to ensure laboratory receipt of sample
- Laboratory requests midwifery services for a repeat (this will include where NHS number is missing)
- Laboratory sends results to Child Health Record Department, using screening status results codes and ideally electronically
- Child Health Record Department checks for untested babies within effective timeframe 14-17 days
- Laboratory refers screen positive results to specialist teams
- Specialist teams report, to the newborn screening laboratory, diagnostic tests/outcome result
- Child Health Record Department send normal results letter (all 5 conditions) to health visitor and to parents
- Child Health Record Department informs maternity or health visiting services of missing 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
- A process for communicating all results if baby has a 'suspected' or 'carrier' result

In addition, see 2.2 Care pathway.

3.9 Information on test/screening programme

In accordance with UK NSC standards and protocols the provider will ensure that during pregnancy, after birth, and at other relevant points throughout the screening pathway, parents/carers are provided with approved information on newborn blood spot screening. Where English is not the parent's fluent language, a trained appropriate interpreter should be used during all appointments and appropriate written information provided. A wide range of information available for local use with parent/carers has been developed in a variety of formats and languages.

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

Laboratories are expected to follow the policy guidance and standards laid out in condition specific laboratory handbooks covering screening for the appropriate conditions

Laboratories are required to provide routine data on the screening programme in a timely manner to commissioners and the UK NSC screening programme. This includes:

- data on samples analysed
- notification of screen positive results
- notification of outcome data where possible

3.11 Results reporting and recording

In accordance with UK NSC standards and protocols

- The laboratory will send results to the Child Health Record Department, ideally electronically using nationally approved status codes
- The Child Health Record Department will record conclusive results on a child health information system for all the eligible population and for all 5 conditions
- The Child Health Record Department will inform maternity or health visiting services of null/incomplete results
- The clinician will inform the CHRD, if unable to complete screen so recorded on babies record

There is a requirement for child health records departments to provide routine data to the screening programme in a timely manner.
This includes coverage data.

3.12 Results giving

In accordance with UK NSC standards and protocols the provider

- The Child Health Record Department 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 Personal Child Health Record by 8 weeks
- CF carrier results will be given according to a specified protocol

- All condition suspected results will be given to parents by a trained health professional, preferably face-to-face, following local protocols that meet recommended NHS NBBS Programme standards

3.13 Transfer of and discharge from care obligations

Babies identified as carriers, following screening, are discharged from screening once parents/carers have been notified of the results, and any follow-up referral required has been offered.

Babies in whom conditions are not suspected are discharged from screening once parents/carers have been notified of the results.

Babies in whom a condition is suspected are discharged from the screening programme once the laboratory has made the appropriate clinical referral which is accepted by the specialist, and parents have been informed of the result.

3.14 Parent/carer information

All parents, including those with special requirements, should be fully informed of the choices regarding the screening programme. Where a high risk result / diagnosis of any of the conditions is identified, appropriate further information should be provided. Information and resources are available from www.newbornbloodspot.screening.nhs.uk

3.15 Exclusion criteria

- Babies stillborn or who died before day 8
- Babies >56 days old are ineligible for CF screening
- 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 competent and appropriately trained staff in place to deliver a high quality screening programme in line with best practice guidelines and NHS NBBS Programme national policy.

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 NHS NBBS Programme are required to keep up to date with nationally approved training programmes and comply with safeguarding requirements.

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 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 Commissioner on request. It may be efficient to include in the annual report

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
- automated lancet devices appropriate for newborns are used according to the blood sampling guidelines.
- blood spot cards, equipment and laboratory reagents meet National specifications.
- IT systems should be able to support the programme and supply data for the purpose of national standards and KPIs as well as performing failsafe checks
- there are appropriate and secure premises for left over spots in line with the current guidance in the Code of Practice for Retention and Storage of Residual Spots. Details are available from the NHS NBBS Programme website.
- There is a contingency plan to maintain service

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 NHS NBBS Programme standards found in *"Standards and Guidelines for Newborn Blood Spot Screening.* The standards are available on the NHS NBBS Programme website http://newbornbloodspot.screening.nhs.uk/standards

The NHS NBBS Programme supports health professionals to meet these standards and deliver a high quality blood spot screening programme. A number of resources to support health professionals are available on the NHS NBBS Programme website.

4.2 Risk assessment of the screening pathway

Providers are expected to have an internal quality assurance process that assures commissioners of their ability to manage the risks of running a screening programme. Providers may use the Failures Modes and Effects Analysis (FMEA) method which is recommended by the NHS National Patient Safety Agency's risk assessment 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 commissioners 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 commissioner, and plans put in place to mitigate against them.

The NHS NBBS Programme has identified risk areas and these are presented visually on the Map of Medicine (http://healthguides.mapofmedicine.com/choices/map/newborn_blood_spot_screening1.html). The Screening programme maintains a national programme risk register used to identify risks and monitor progress 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 QA processes and respond in a timely manner to recommendations made
- make available data and reports from external quality assurance programmes and accreditation services to screening programmes, national team and commissioners
- collect and submit minimum data sets as required to assure the Commissioner 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
- address any non-conformities/deviations from recommended performance thresholds

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 assessments 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 if it and of their responsibilities within it
- inform the Commissioner, within 24 hours, in the event of a serious adverse event and provide all reasonable assistance to the Commissioner 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'* http://www.screening.nhs.uk/quality-assurance#fileid9902
- review their procedures and processes against the National Screening programme for the NHS NBBS Programme Standards 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 acceptable and/or 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 Commissioner, 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 commissioner.

Section 5: Data and Monitoring

5.1 Key Performance Indicators

In accordance with UK NSC standards and protocols the provider will adhere to the requirements specified in the document 'Key Performance Indicators for Screening. The National Screening programme website must be checked for the latest version (http://www.screening.nhs.uk/kpi). Three of the KPIs relate to the NHS NBBS Programme and Providers are expected to report on these as specified.

5.2 Data collection, monitoring and reporting

There will be a requirement for maternity services to provide routine data to the screening programme in a timely manner. This includes data on test offer/accepted/decline/avoidable repeats

They will also contribute to national data collection exercises where required and will provide annual data measuring performance against standards and the Key Performance Indicator data

The UK Newborn Screening programme (UKNSPC) is responsible for reporting UK performance against the standards for newborn blood spot screening to the UK NSC. It is of paramount importance to the NHS NBBS Programme that:

1. All eligible babies are offered newborn blood spot screening
2. Where parents accept the offer, that babies are actually tested
3. That each process is performed effectively and the newborn screening pathway is capable of achieving timely referral of screen positive babies (for PKU, MCADD and CHT (detected on 1st sample) this is by 14 days of age)
4. That failsafe systems exist to identify, as early as possible, babies that may have been missed or where screening results are incomplete

In addition to the annual data collection to measure performance against national standards, there are three KPIs for newborn blood spot screening two of which require data to be submitted by Child Health Record Departments. This is a pre-requisite for sending a normal results letter from the CHRD direct to parents.

Data is reported from CHRDs and laboratories to UKNSPC. There will be a requirement for maternity services to provide routine data to the screening programme in a timely manner. This includes data on test offer/accepted/decline/avoidable repeats

They will also contribute to national data collection exercises where required and will provide annual data measuring performance against standards and the Key Performance Indicator data mentioned in 5.1.