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NHS public health functions agreement 2015-16

Service specification no.19

NHS Newborn Blood Spot Screening Programme

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NHS public health functions agreement 2015-16

Service specification no.19

NHS Newborn Blood Spot Screening Programme

Prepared by Public Health England

Contents

Service specification No.19

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

This service specification is to be applied by NHS England in accordance with the 2015-16 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

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

The 2015-16 agreement including all service specifications within Annex C is available at www.gov.uk (search for ‘commissioning public health’).

Section 1: Purpose of Screening Programme

1.1. Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of the NHS Newborn Blood Spot (NHS NBS) screening services.

The purpose of the service specification for the NBS Screening Programme is to outline the service and quality indicators expected by NHS England for its 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 that 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 NBS guidance which is found on the NHS NBS website. NHS Newborn Blood Spot 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 NBS Programme aims to identify newborn babies at high risk of phenylketonuria (PKU), congenital hypothyroidism (CHT), sickle cell disease (SCD), cystic fibrosis (CF), medium-chain acyl Co-A dehydrogenase deficiency (MCADD), Maple Syrup Urine Disease (MSUD), Homocystinuria (HCU), Glutaric Aciduria Type 1 (GA1) and Isovaleric Acidaemia (IVA) 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 the care of the child also have access to the results. This is usually the GP and health visiting services (or agreed alternative).

1.4. Health outcomes

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

The NHS NBS contributes to the Public Health Outcomes Framework indicator on the uptake of screening for national screening programmes. Indicator 2.21iv Access to non-cancer screening programmes: newborn blood spot screening.

1.5. Principles

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

1.6. Equality

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

It also requires that public bodies:

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

Section 2: Scope of Screening Programme

2.1. Description of screening programme

The UK NSC policy on 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 nine conditions included in this specification.

2.2. Care pathway

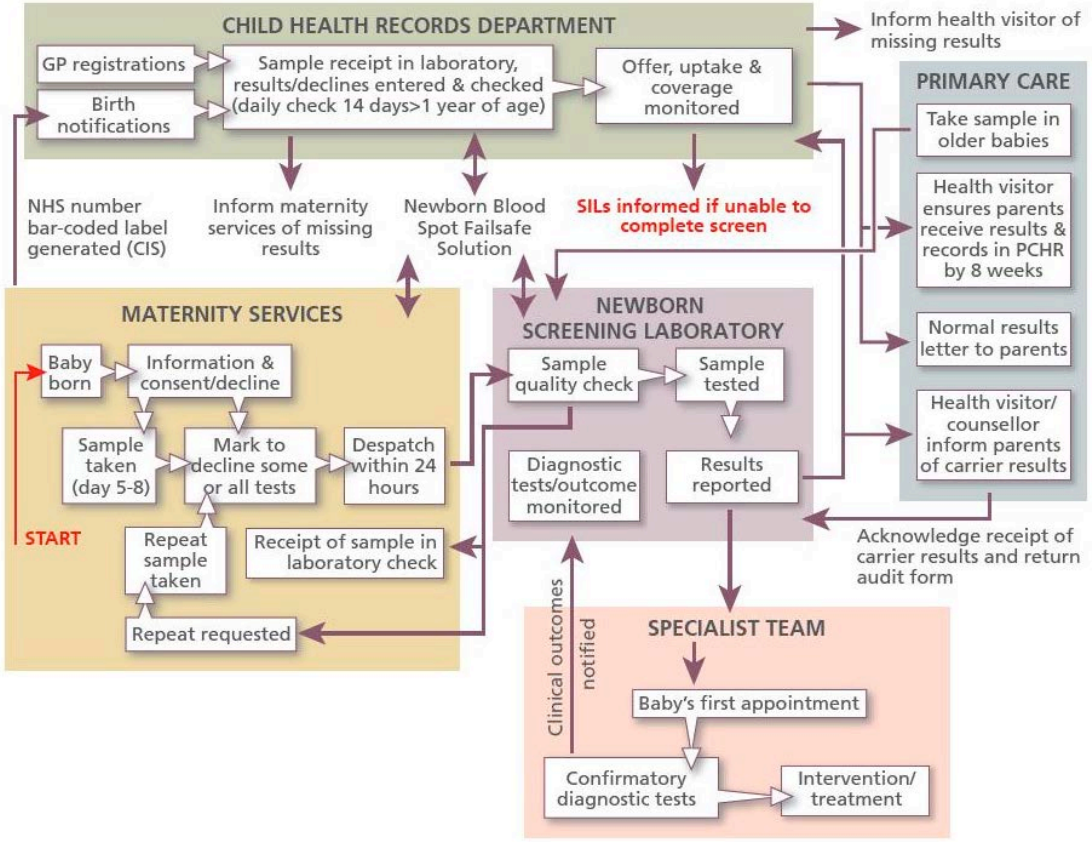
- The eligible population is identified through the issuing of NN4B at birth or registration with a GP practice for babies born abroad.
- Midwives check antenatal results and family history. Ideally all antenatal results obtained from antenatal SCT screening are included on the blood spot card.
- Midwives provide written information (ideally before birth) and take verbal consent.
- Screening can be offered to unscreened babies who move into a local area up to one year of age. Health visiting services (or agreed alternative) are responsible for offering screening to parents of babies with no written evidence of screening results. The CHRD who note the arrival of a baby (when it is registered) alert the HV to unscreened babies. GPs should ensure CHRD are informed of the babies they register.
- Samples are taken routinely on day 5 and in exceptional circumstances between day 5 and day 8, day of birth is day 0, in accordance with *Guidelines for Newborn Blood Spot Sampling*, and sent to the appropriate newborn screening laboratory. Records are kept of all tests including those declined.
- 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. For SCT please refer to No 18 NHS Sickle Cell and Thalassaemia Screening Programme Service Specification.
- The Newborn screening laboratory tests the sample according to national policy and reports the results to the Child Health Records Department and the Newborn Blood Spot Failsafe Solution. This can result in one of five outcomes:
  - Carrier: healthcare professional informs parents of results
  - Inconclusive result: additional sample required

  - Avoidable repeat test: additional sample required eg insufficient blood, poor record keeping
  - Condition not suspected: parents are informed of the result
  - Condition suspected: immediate clinical referral to a specialist initiated by the laboratory and parents informed of the result, by the specialist service
- Maternity care providers ensure all babies they are responsible for are offered screening by utilising the Newborn Blood Spot Failsafe Solution.
- 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 visiting services (or agreed alternative) 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. This pathway has been updated with failsafe and escalation steps.



A full description of the pathway 'process' can be found on the Map of Medicine website at: http://healthguides.mapofmedicine.com/choices/map/newborn_blood_spot_screening1.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 NBS Screening Programme to be met by the Provider can be found on the National Screening

Programme
website http://newbornbloodspot.screening.nhs.uk/qualityassurance

- 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
- implement and fully utilise the Newborn Blood Spot Failsafe Solution (NBSFS) as it rolls out across England

2.4. Roles and accountabilities

The NHS NBS 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, i.e. '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 that provides the optimal care for families. 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 NBS pathway involves commissioning at different levels which may include Area Teams, CCGs, and directly by maternity services. Refer to 'Maternity Pathway Payments: Who pays for what' http://www.england.nhs.uk/wp-content/uploads/2014/01/who-pays-for-what-fin.pdf. The NHS NBS services will be commissioned by NHS England alongside specialised services where appropriate.

2.6. Links between screening programme and national programme centre expertise

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

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

Public information:

Providers must always use the nationally-developed public information leaflets at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided and should involve the national screening team before developing any other materials.

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

Section 3: Delivery of Screening Programme

3.1. Service model summary

Pre-screening information is provided to the pregnant woman and a medical/family history ascertained at booking. The midwife provides information on the NHS NBS 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).

The 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 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 can be delivered through a range of models, dependent upon local need, including co-commissioning arrangements. Carriers for MCADD are not detected until the diagnosis protocol has been fulfilled and the result is given by a specialist clinician. Specially trained health care professionals give SCD carrier results to parents.

It is important that the links between the end of screening and enrolment in appropriate condition specific specialised 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.

All Trusts should have a screening midwife/coordinator (and deputies) in place to oversee the screening programme.

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
  - risks and mitigation plans
  - 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 UKAS 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
- cooperation 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 England Screening Lead's initiatives in screening pathway development in line with UK NSC expectations
- meeting the NBS 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
- Set of barcoded NHS number baby labels printed and placed in PCHR
- Midwife responsible for care sends blood spot card to newborn screening laboratory with the NHS number, preferably on a label
- Newborn Blood Spot Failsafe Solution (NBSFS) utilised to ensure laboratory receipt of sample and results recorded
- Laboratory requests midwifery services for a repeat (this will include where NHS number is missing), this can be via the NBSFS
- Laboratory sends results to Child Health Record Department and NBSFS, using screening status results codes and ideally electronically
- Child Health Record Department checks for untested babies within effective timeframe 14-17 days
- NBSFS highlights to maternity services babies where there is no sample received, repeat required or results not complete
- 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 conditions) to health visiting services (or agreed alternative) 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 visiting services (or agreed alternative) 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
- notification of false negatives where possible

3.11. Results reporting and recording

In accordance with UK NSC standards and protocols

- The laboratory will send results to the NBSFS and 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 screened 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 Child Health Record Department will send a normal results letter to parents and notify health visiting services (or agreed alternative)
- Health visiting services (or agreed alternative) ensure that parents receive the results and record the results in the Personal Child Health Record by 8 weeks
- CF and SCD 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 NBS 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 NBS 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.

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary. Training standards are detailed at http://newbornbloodspot.screening.nhs.uk/training

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

All professionals involved in the NHS NBS Programme are required to keep up to date with nationally approved training programmes, maintain professional registration where appropriate 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 NHS NBS Programme 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 NBS Programme website
- There is a contingency plan to maintain service

3.19. Safety & Safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2014/15 NHS Standard Contract:

http://www.england.nhs.uk/wp-content/uploads/2013/12/sec-b-cond-1415.pdf

Section 4: Service Standards, Risks and Quality Assurance

4.1. Key criteria and standards

Programme standards are available on the programme website (http://newbornbloodspot.screening.nhs.uk/standards). Providers will meet the acceptable and work towards the achievable programme standards. A number of resources to support providers are available on the programme website.

4.2. Risk assessment of the screening pathway

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

Providers will:

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

High scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate against them. The provider will identify risks with high scores. The provider and commissioner will agree plans to mitigate risks.

4.3. Quality assurance

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

- agreed data and reports from external quality assurance schemes

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

Laboratories undertaking screening should

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

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

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

4.4. Safety concerns, safety incidents and serious incidents

Providers will comply with the national guidance for the management of incidents in screening programmes and NHS England guidance for the management of serious incidents (http://www.screening.nhs.uk/incidents).

4.5. Procedures and protocols

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

4.6. Continual service improvement

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

The provider shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond to 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 commissioners.

Section 5: Data and Monitoring

5.1. Key Performance Indicators / Public Health Outcomes Framework

The provider shall adhere to the requirements specified in the document 'Key Performance Indicators for Screening. Please refer to http://www.screening.nhs.uk/kpi for further details, guidance and updates on these indicators.

Public Health Outcomes Framework Indicator

2.21iv: The percentage of babies registered within the local authority area both at birth and at the time of report who are eligible for newborn blood spot screening and have a conclusive result recorded on the Child Health Information System within an effective timeframe.

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

Acceptable ≥ 95.0%

Achievable ≥ 99.9%

2012-13 national baseline is 89.1%

5.2. Data collection, monitoring and reporting

- Providers should ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions.
- The Provider shall continually monitor and collect data regarding its delivery of the Service
- The Provider will comply with the timely data requirements of the National Screening programmes and regional Quality Assurance teams. This will include the production of Annual Reports. The most up to date Dataset can be accessed from the National Screening programme website.

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 NHS Newborn Blood Spot Screening Programme 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 NBS 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 as per the standards for newborn blood spot screening
4. That failsafe systems exist (including NBSFS) 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 NHS Newborn Blood Spot Screening Programme. 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 Indicators data mentioned in 5.1.

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