NHS public health functions agreement 2018-19
Service specification no.19
NHS Newborn Blood Spot Screening Programme
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Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).
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Service specification No.19

This is a service specification to accompany the ‘NHS public health functions agreement 2018-19 (the ‘2018-19 agreement’).

This service specification is to be applied by NHS England in accordance with the 2018-19 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 2018-19 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

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

The 2018-19 agreement is available at www.gov.uk (search for ‘commissioning public health’).

All current service specifications are available at www.england.nhs.uk (search for ‘commissioning public health’).
1. Purpose of Screening Programme

Purpose of the specification

1.1. 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.

1.2. 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.

1.3. 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.

1.4. This specification should be read in conjunction with:

- Who pays for what: Aspects of the maternity pathway payment for the screening and immunisation programmes June 2015
Section 1: Purpose of Screening Programme


Aims

1.5 The NHS NBS Programme aims to identify newborn babies at high risk of sickle cell disease (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT) and six inherited metabolic diseases: phenylketonuria (PKU), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD), isovaleric acidaemia (IVA), glutaric aciduria type 1 (GA1) and homocystinuria (pyridoxine unresponsive) (HCU) to improve health and reduce disability or death.

Objectives

1.6 The objectives of the programme are:

- 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).

Health outcomes

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

1.8 The NHS NBS Programme 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.

Principles

1.9 The principles of the programme are that:

- 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.
Equality

1.10 Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:
- screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary;
- a Health Equity Audit should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations;
- the service should be delivered in a culturally sensitive way to meet the needs of local diverse populations;
- user involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics;
- providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance when making such decisions.

1.11 The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

1.12 The provider will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP, homeless people and rough sleepers, asylum seekers, gypsy traveler groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

1.13 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.

1.14 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.

Classification: official
2 Scope of Screening Programme

Description of screening programme

2.1. The NHS screening programmes policy on newborn blood spot screening is that all newborn babies in the commissioner’s population, and babies under a year of age that move into the area, should be offered screening for the nine conditions included in this specification.

Care pathway

2.2. The care pathway follows that:

- the eligible population is identified through the issuing of an NHS number at birth or registration with a GP practice for babies born abroad;
- registered health care professionals check antenatal results and family history. Ideally all antenatal results obtained from antenatal SCT screening are included on the blood spot card;
- registered health care professionals provide written information (ideally before birth) and take verbal consent;
- screening is offered to unscreened babies who move into a local area under a year of age. Health visiting services (or agreed alternative) are responsible for offering screening to parents of babies with no documented screening results in English. The CHRD who record the arrival of a baby should alert the HV to unscreened babies. GPs should ensure CHRD are informed of the babies they register;
- samples are taken on day 5 (day of birth is day 0), in accordance with Guidelines for Newborn Blood Spot Sampling (2016), and sent on the day of sampling 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 Service specification No. 18: NHS sickle cell and thalassaemia screening programme;
- 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, for example, insufficient blood, missing/inaccurate details on the card

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 using 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.

2.3. 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) and Newborn Blood Spot Failsafe Solution (NBSFS)
- Recording results on Child Health Information System (CHIS) and making sure that every baby has conclusive result for all tests
- Reporting results to health care professional and parent

2.4. Below is the newborn blood spot pathway.
Roles and accountabilities

2.5 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, that is, ‘the screening pathway’. The provider will be expected to fully contribute to making sure 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 NHS NBS programmes expectations
- providing or seeking to provide suitable electronic links with relevant organisations
- links with primary care
- links with secondary and/or tertiary care
- the need for appropriate IT systems across the screening pathway
- joint review meetings across the screening pathway to be held on a regular basis

Commissioning arrangements

2.6 The commissioning of the NHS NBS pathway involves commissioning at different levels which may include NHS England public health commissioning, CCGs, and directly by maternity services.

2.7 Refer to Who Pays for What? Aspects of the Maternity Pathway Payment for the Screening and Immunisations Programmes June 2015. The NHS NBS services will be commissioned by NHS England specialised services where appropriate.

Links between screening programme and national programme expertise

2.8 Public Health England (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.

2.9 PHE will be responsible for delivery of the essential elements of screening programmes best done once at national level.

2.10 Public information:
- Providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent

Classification: official
messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.
3 Section 3: Delivery of Screening Programme

Service model summary

3.1. 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 by a healthcare professional at least 24 hours before testing. A healthcare professional must inform parents that blood spot cards are stored by the laboratory after screening. Stored cards have several potential uses, including research.

3.2. Parents must be asked for their consent to future contact about research that could identify their baby. 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 individual conditions CHT, SCD, CF or ALL the Inherited Metabolic Diseases (PKU, MCADD, MSUD, IVA, GA1, HCU). Information on how to access the test if they change their mind is provided. Screening is largely embedded within the routine maternity pathway.

3.3. Identifiable data on babies who have suspected or confirmed sickle cell disease or thalassaemia is sent to the National Congenital Anomaly and Rare Diseases Registration Service (NCARDRS). NCARDRS has permission from the National Information Governance Board under section 251 the NHS Health ACT 2006 and the authority of the Health Service (Control of Patient Information) Regulations 2002, to collect patient-identifiable data without the need for individual informed consent on all suspected and confirmed congenital anomalies and rare diseases in England (CAG ref: CAG 10-02(d)/2015).

3.4. To comply with CAG requirements, providers must confirm that mothers undergoing screening are made aware of data sharing with NCARDRS and the right to opt out of the register at any time. For more information see www.gov.uk/phe/ncardrs and gov.uk/phe/newborn-outcomes.

3.5. Consent and taking of the sample should be recorded in the maternity/professional record and Personal Child Health Record (PCHR).

3.6. The Newborn Blood Spot Failsafe Solution (NBSFS) should be used to make sure 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, sub codes and electronic messaging of all results from the laboratory to NBSFS and CHRD needs implementing. Child health information system (CHIS) is 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) and Service Specification No.28 Child Health Information Systems (CHIS, November 2013) and Child Health Information Services (CHIS) Provider Service Specification (NHS England, August 2015). Conclusive results are recorded on a CHIS for the eligible population using Classification: official.
the status codes and subcodes for all conditions.

3.7 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.

3.8 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 healthcare professionals give SCD carrier results to parents.

3.9 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.

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

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

**Programme coordination**

3.12 In accordance with NHS screening programmes standards and protocols the provider will be responsible for ensuring that the part of the programme they provide is coordinated. This must interface 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.

3.13 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.

3.14 In accordance with NHS screening programmes 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.

**Governance and leadership**

3.15 The provider will:
• cooperate with and have representation on local oversight arrangements as agreed with NHS England commissioners;

• identify a Trust director who is responsible for the screening programme;

• ensure internal clinical oversight and governance is overseen by an identified clinical lead and a programme manager;

• provide documented evidence of clinical governance that includes:
  - compliance with the NHS Trust and NHS England information governance/records management
  - user involvement, experience and complaints
  - failsafe procedures
  - risks and mitigation plans;

• ensure that there is regular monitoring and audit of the screening programme, and as part of the organisation’s clinical governance arrangements, the board is assured of the quality and integrity of the screening programme;

• produce an annual report of screening services, which is signed off by the board;

• ensure the programme is delivered by trained workforce that meet national requirements;

• 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;

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

3.16 The target population to be offered screening is all newborn babies and infants moving into the country under a year of age.

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

**Location(s) of programme delivery**

3.18 See 2.2 Care pathway.

**Days/Hours of operation**

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

3.20 Newborn blood spot screening laboratories should check and report positive results for medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD) or isovaleric acidaemia (IVA) within 24 hours of being analysed successfully.

Classification: official
Entry into screening programme

3.21 See section 3.4 above.

Working across interfaces

3.22 The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway.

3.23 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.

3.24 The provider will be responsible for ensuring that the pathway is well managed. For their part the provider will ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- providing strong clinical and managerial leadership and clear lines of accountability
- developing joint audit and monitoring processes
- working to nationally agreed programme standards and policies
- agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway, see Checks and audits failsafe procedures.
- contributing to any NHS England initiatives in screening pathway development in line with NHS screening programmes expectations
- develop an escalation process for screening safety incidents
- facilitate education and training both inside and outside the provider organisation

3.25 Interface is where:

- 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 approved barcoded NHS number baby labels printed and placed in PCHR
- maternity staff responsible for care send blood spot card to newborn screening laboratory with the barcoded NHS number label, and all fields on the card completed with four good quality blood spots. If screening is
declined the completed card should still be sent to the laboratory with the blood spots section blank

- Newborn Blood Spot Failsafe Solution (NBSFS) is used to confirm laboratory receipt of sample and all results recorded (status codes and subcodes used)
- laboratory requests midwifery services for a repeat (this will include where NHS number is missing), this can be via the NBSFS when enabled
- laboratory sends results to Child Health Record Department and NBSFS, using screening status results codes and subcodes and ideally electronically
- Child Health Record Department checks for untested babies within effective timeframe, all babies over 14 (17) days and 365 days are checked.
- 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
- laboratory communicates carrier screening results via locally agreed pathway
- specialist teams report, to the newborn screening laboratory, diagnostic tests/outcome result
- Child Health Record Department send screen negative results letter to health visiting services (or agreed alternative) and to parents. This principle applies to babies where all nine results are negative and it applies for babies where one result is suspected or the baby is too old for CF. [https://www.gov.uk/government/publications/newborn-blood-spot-screening-results-to-parents-template](https://www.gov.uk/government/publications/newborn-blood-spot-screening-results-to-parents-template)
- Child Health Record Department informs maternity or health visiting services of missing results
- midwife/health visitor perform screening for movers in so that Child Health Record Department can record conclusive results on the child health information system (CHIS) within 21 calendar days of recording the mover in on CHIS
- the health care professional responsible for screening informs CHRD if unable to complete screen or screening declined so it can be recorded on the baby’s record. This is in addition to sending a completed card to the laboratory writing ‘declined’ where the spots should be
- health visiting services (or agreed alternative) ensure parents receive results and record results in PCHR by 6 weeks
- a process for safely communicating all results if baby has a ‘suspected’ or ‘carrier’ result and helping parents to access further information and support when necessary

Classification: official
In addition, see 2.2 Care pathway.

Information on test/screening programme

3.26 In accordance with NHS screening programmes 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.

Testing (laboratory service, performance of test by individuals)

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

3.28 Laboratories are required to provide routine data on the screening programme in a timely manner to commissioners and the 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

Results reporting and recording

3.29 In accordance with screening programmes standards and protocols, the:

- laboratory will send results to the NBSFS and Child Health Record Department, ideally electronically using nationally approved status codes and subcodes;

- Child Health Record Department will record conclusive results on a child health information system for all the eligible population and for all screened conditions;

- Child Health Record Department will inform maternity or health visiting services of incomplete results;

- health care professional responsible for screening will inform the CHRD, if unable to complete screen or screening declined so it can be recorded on the baby’s record.

3.30 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, CCG responsibility at birth and movers in.
Results giving

3.31 In accordance with NHS screening programmes 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 6-weeks;
- CF and SCD carrier results will be given according to a specified protocol, see CF Initial Clinical Referral Guidelines;
- all condition suspected results will be given to parents by a trained health professional, preferably face-to-face, following local protocols that meet recommended NBS programme standards.

Transfer of and discharge from care obligations

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

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

3.34 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.

Parent/carer information

3.35 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

Exclusion criteria

3.36 The exclusion criteria are:

- babies stillborn or who died before day 8;
- babies >56 days old are ineligible for CF screening;
- children over 1 year of age.
Staffing

3.37 In accordance with NHS screening programmes standards and protocols the provider will make sure 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 programme and laboratory guidelines.

3.38 Qualifications will be specific to staff delivering the service across the care pathway. Staff must demonstrate competence (which is linked to training).

3.39 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.

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

3.41 Providers should make sure training has been completed satisfactorily and recorded and that there is a system in place to assess ongoing competency.

3.42 All professionals involved in the screening programme are required to keep up to date with nationally approved training programmes, maintain professional registration where appropriate and comply with safeguarding requirements.

User involvement

3.43 In accordance with the screening programmes 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

3.44 Collection of the views of service users/families will often be via surveys or questionnaires, and not disadvantage those with literacy issues or for whom English is not their first language. 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.

Premises and equipment

3.45 In accordance with NHS screening programmes standards and protocols, the provider will make sure that:

- suitable premises and equipment are provided for the screening programme
• appropriate policies are in place for equipment calibration, maintenance and replacement

• age appropriate automated incision devices are used according to the programme guidelines for newborn blood sampling

• 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 (2005).

• there is a contingency plan to maintain service

**Safety & safeguarding**

3.46 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 2017-18 NHS Standard Contract: [https://www.england.nhs.uk/nhs-standard-contract/17-18/](https://www.england.nhs.uk/nhs-standard-contract/17-18/)
4 National standards, risks and quality assurance

4.1 The provider will:

- meet the acceptable national screening standards and work towards attaining and maintaining the achievable standards
- adhere to specific professional standards and guidance
- maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and make sure that these points are reviewed in contracting and peer review processes
- participate fully in national quality assurance (QA) processes which includes:
  o submitting agreed minimum data sets and reports from external quality assurance schemes
  o undertaking ad-hoc audits and reviews as requested
  o completing self-assessment questionnaires / tools and associated evidence
  o responding to SQAS recommendations within agreed timescales providing specified evidence
  o producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations
- all screening laboratories must:
  o be accredited by the UK Accreditation Service (UKAS) to ISO. 'Medical laboratories – Requirements for quality and competence (ISO 15189)' or be CPA accredited and actively transitioning towards ISO 15189
  o participate in EQA schemes accredited to ISO. 'Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)'
  o meet the screening programme quality assurance requirements mapped to ISO 15189
  o use ISO 15189 accredited reference laboratories

4.2 The UK Accreditation Service (UKAS) will look at both ISO 15189 and the screening requirements on behalf of PHE Screening Quality Assurance Services and the national screening programme.
- operate and evidence:
  o check points that track individuals through the screening pathway
  o identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  o have process in place to mitigate against weakness in the pathway
- implement and fully utilise the Newborn Blood Spot Failsafe Solution (NBSFS)
- have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet national screening standards
- demonstrate that there are audited procedures, policies and protocols in place to make sure the screening programme consistently meets programme requirements
- comply with guidance on managing safety incidents in national screening programmes and NHS England serious incident framework

- make sure there is business continuity - business continuity plans must be in place where required
- make sure sub-contracts and/or service level agreements with other providers meet national standards and guidance

**Service improvement:**

4.3 The provider will develop and agree with commissioners a CSIP (continual service improvement plan) in cases where national recommendations and/or screening standards are not fully met. The CSIP will include the following:
- action plans specifying changes and improvements that will be made during the contracting period
- defined timescales for actions
- roles and responsibilities for actions
- performance issues highlighted by the commissioners
- concerns raised by service users

**New technologies**

4.4 New technologies should not be used for screening unless approved by the UK National Screening Committee.
5 Data and Monitoring

Key Performance Indicators / Public Health Outcomes Framework


Public Health Outcomes Framework Indicator

5.2. The NBS screening programme contributes to the Public Health Outcomes Framework. Indicator 2.20xi: The percentage of babies registered within the CCG both at birth and on the last day of the reporting period who are eligible for newborn blood spot screening and have a conclusive result recorded on the Child Health Information System by 17 days of age.

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

- Acceptable ≥ 95.0%
- Achievable ≥ 99.0%

The 2015-16 England baseline is 94.25:


Data collection, monitoring and reporting

5.4 Providers should:
- make sure that appropriate systems are in place to support programme delivery including audit and monitoring functions;
- continually monitor and collect data regarding its delivery of the Service;
- comply with the timely data requirements of the national screening programmes and regional quality assurance teams. This will include the production of an Annual Report.

5.5 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.

5.6 The NHS Newborn Blood Spot Screening Programme is responsible for reporting UK performance against the standards for newborn blood spot screening to the NHS screening programmes. 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. 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. failsafe systems exist (including NBSFS) to identify, as early as possible, babies that may have been missed or where screening results are incomplete

5.7 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.

5.8 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.

5.9 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.

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