



Public Health  
England



# NHS public health functions agreement 2019-20

**Service specification No.19  
NHS Newborn Blood Spot Screening Programme**

NHS England and NHS Improvement



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## **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 and NHS Improvement 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 due 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 2019-20 (the 2019-20 agreement)'.

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-20 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 2019-20 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-20 agreement in accordance with the procedures described in Chapter 3 of the 2019-20 agreement

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

The 2019-20 agreement is available at [www.gov.uk](http://www.gov.uk) (search for 'commissioning public health').

All current service specifications are available at [www.england.nhs.uk](http://www.england.nhs.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 and NHS Improvement for its responsible population and which meets the evidence base, policies, recommendations and standards of the UK National Screening Committee.

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 2012 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:

- Programme standards <https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>
- Programme national annual data reporting <https://www.gov.uk/government/collections/newborn-blood-spot-screening-programme-standards-and-data>
- NHS screening programmes <https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting>
- NHS population screening failsafe procedures <https://www.gov.uk/government/collections/nhs-population-screening-failsafe-procedures>
- Programme supporting publications <https://www.gov.uk/government/collections/newborn-blood-spot-screening-programme-supporting-publications>
- Safety concerns, safety incidents and serious incidents. Managing Safety Incidents in NHS National Screening Programmes <https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 37 Routine and postnatal care of women and their babies 2006 <http://www.nice.org.uk/guidance/cg37>

### The role of PHE Screening

The national screening team in Public Health England (PHE Screening) provides expert advice and support to the NHS Screening Programme. It does those things which make sense to do once rather than by each individual screening service. This includes:

- developing and monitoring standards
- producing public information leaflets
- quality assurance of local screening services
- enabling accessible training and education

Providers should subscribe to the [PHE Screening blog](#) for the latest national news and updates. [National documentation and guidance](#) is published on [GOV.UK](#).

## 1.2 Aims

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.

## 1.3 Objectives

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).

## 1.4 Expected health outcome

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

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.

## 1.5 Principles

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.



## 1.6 Addressing inequalities and ensuring equal access to screening

Screening is inherently equitable because it is offered to all individuals within the eligible population. One of the objectives of the NHS Screening Programmes is to help reduce health inequalities. The [PHE Screening inequalities strategy](#) has more information.

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 equality, health inequality and screening guidance when making such decisions

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.

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 traveller 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.

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

## Personal informed choice

All screening is an individual choice. The UK NSC has published [guidance](#) for screening programmes in the 4 UK countries to follow. Everyone must be given the opportunity to make an informed choice about whether or not to be screened. The decision should be based on an understanding of:

- why they are being offered screening
- what happens during the test
- the benefits and risks of screening
- the potential outcomes (including types of result, further tests and treatment)
- what happens to their screening records

If someone is provided with the above information about the programme and chooses not to have screening, then this is a valid choice and must be respected.

## Sharing personal information

Under the [2010 Equality Act](#), screening services are required to anticipate and prevent discrimination against people with learning disabilities.

The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals should have the confidence to share relevant information with screening services in the best interests of their patients. For example, a GP may know that an individual with a learning disability requires accessible information about screening in easy read format or needs a longer than normal appointment slot.

See [NHS England's information sharing policy](#) for more detailed guidance.

PHE Screening's [privacy notice](#) has more information about how screening data is shared within the legal requirements, including those of the General Data Protection Regulation (GDPR).

## Reasonable adjustments

Under the [2010 Equality Act](#), screening providers have a legal duty to make [reasonable adjustments](#) to make sure services are accessible to disabled people as well as everybody else.

Screening providers must follow the [Accessible Information Standard](#) by law. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information they can easily read or understand with support, so they can communicate effectively with health and social care services.

As part of the Accessible Information Standard, screening providers must do 5 things.

1. Ask people if they have any information or communication needs, and find out how to meet their needs.
2. Record those needs clearly and in a set way.
3. Highlight or flag the person's file or notes so it is clear that they have information or communication needs and how to meet those needs.

4. Share information about people's information and communication needs with other providers of NHS and adult social care, when they have consent or permission to do so.
5. Take steps to ensure that people receive information which they can access and understand, and receive communication support if they need it.

### **National accessible information materials**

PHE Screening has published national easy read versions of screening information leaflets and screening appointment letter templates.

Local screening providers should use these national materials when inviting individuals for screening who have been identified as needing information in an easy read format.

Large print and audio (MP3) versions of standard information leaflets are also available to download from GOV.UK for people with sight loss.

Local screening providers should send any individual requests for hard copy Braille versions of PHE Screening leaflets to the [screening helpdesk](#).

## Section 2: Scope of Screening Programme

### 2.1 Description of screening programme

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.

### 2.2 Care pathway

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.

This can be summarised as:

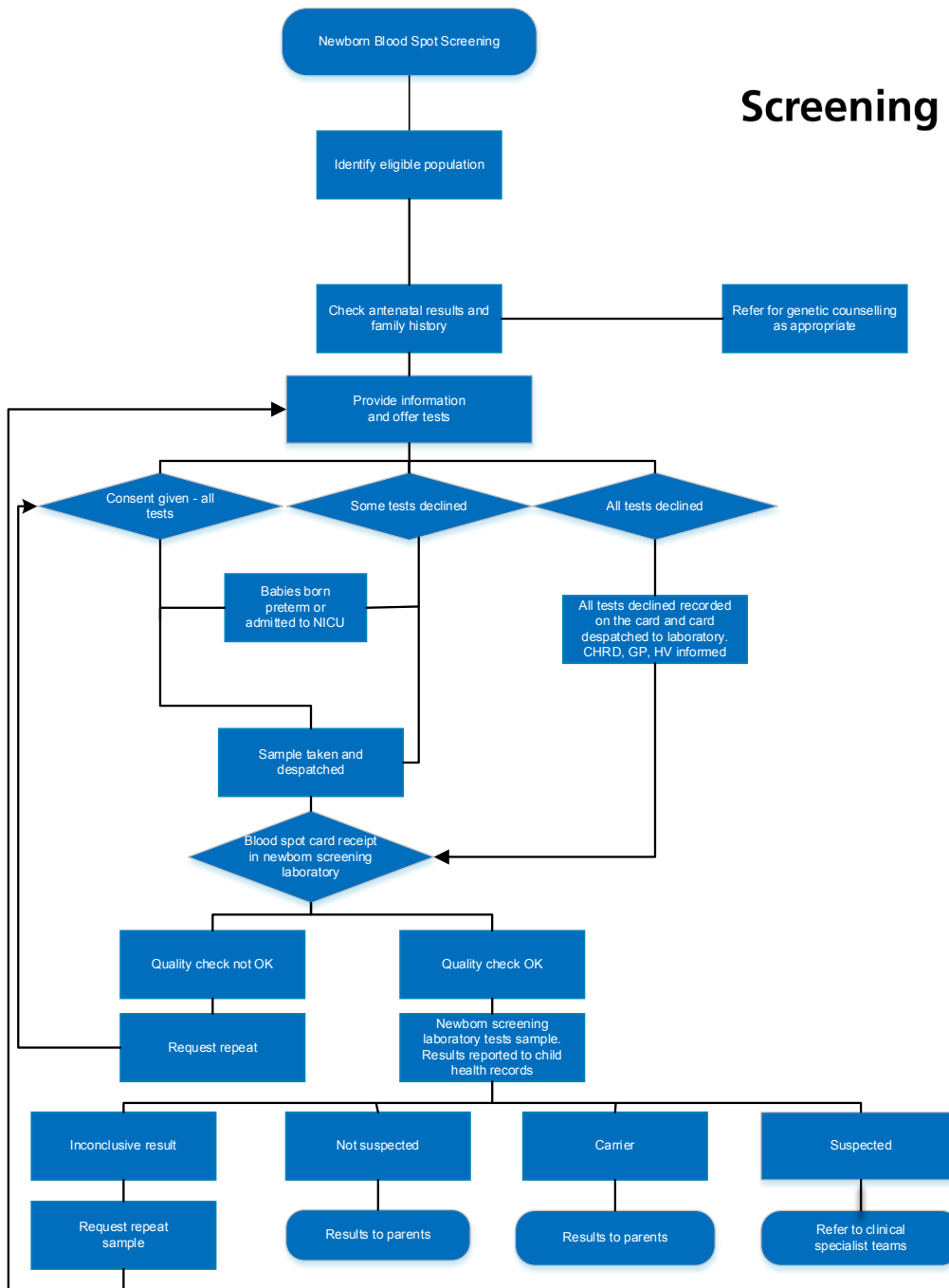
- identifying the eligible population
- offering screening
- taking the sample and sending to the screening laboratory
- analysing the sample
- timely referral of screen positive babies into diagnostic and clinical care
- reporting results to Child Health Records Departments (CHRD) and Newborn Blood 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

Below is the newborn blood spot pathway



# Screening Programmes

## Newborn Blood Spot



## 2.3 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, 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, see [Checks and audits failsafe procedures](#)
- 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

## 2.4 Commissioning arrangements

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

The NHS NBS service will be commissioned by NHS England and NHS Improvement specialised services where appropriate.

## 2.5 Links between screening programme and national programme expertise

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.

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

Public information:

Providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.



## 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 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 (see the [Code of Practice for the Retention and Storage of Residual Newborn Blood Spots](#)). Stored cards have several potential uses, including research.

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, and HCU). Information on how to access the test if they change their mind is provided. Screening is largely embedded within the routine maternity pathway.

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).

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 <https://www.gov.uk/government/collections/national-congenital-anomaly-and-rare-disease-registration-service> and <https://www.gov.uk/guidance/sickle-cell-and-thalassaemia-screening-outcome-data>.

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

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, subcodes and electronic messaging of all results from the laboratory to NBSFS and CHR 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 \(DH, February 2012\)](#) 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 the [status codes and subcodes](#) 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 healthcare 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 provided by appropriate staff and to national standards and guidelines, and audited.

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

### **3.2 Programme co-ordination**

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.

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 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.

### **3.3 Governance and leadership**

The provider will:

- cooperate with and have representation on local oversight arrangements as agreed with NHS England and NHS Improvement commissioners
- identify a suitably qualified trust laboratory Director who is responsible for the screening laboratory and the linkage of this service within the screening pathway
- provide documented evidence of clinical governance that includes:
  - compliance with NHS Trust and NHS England and NHS Improvement 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 to ensure that organisation is assured of the quality and integrity of the screening programme
- produce an annual report of screening services, which is signed off by the Trust Board or relevant sub-committee
- ensure the programme is delivered by a trained workforce that meet national requirements
- commission molecular genetics laboratories in line with the current NHS commissioning guidance for the ordering and provision of genetic tests

### **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 under a 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.

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 (this includes weekends and bank holidays).

### **3.7 Entry into the 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.

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 and NHS Improvement 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

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>
- 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

In addition, see 2.2 Care pathway.

### **3.9 Information on test/screening programme**

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

### **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 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 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

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

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 [Clinical referral: national standard protocol for cystic fibrosis](#)
- 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

### 3.12 Transfer of and discharge from care obligations

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.

Babies in whom conditions are not suspected are discharged from the screening programme 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.

### 3.13 Public information

PHE Screening uses published best practice processes to develop public information leaflets. It also works with NHS Digital to ensure that information on the [NHS.UK](#) website for the public is accurate.



Providers must:

- use the public information leaflets from PHE Screening at all stages of the screening pathway
- involve PHE in the development of any local awareness campaigns
- not duplicate clinical information on local websites
- involve PHE if they want to move from providing printed leaflets to online sources of information

Using the leaflets provided by PHE ensures accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening must be consulted and involved before developing any other supporting materials.

Providers must involve PHE in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally- developed resources. For local awareness campaigns, local contact details must be used so that the national screening helpdesk is not over.

Local provider websites must not duplicate clinical information about screening but should be restricted to contact and logistical information. Links should be provided to the national information on [NHS.UK](https://www.nhs.uk) (or the relevant programme page) and [GOV.UK](https://www.gov.uk) (or the relevant programme page).

To support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources.

### **Ordering leaflets**

Providers can order [leaflets developed by PHE Screening](#) for free for core screening purposes.

Leaflets are regularly updated so providers should not order more than 3 months' supply, or stockpile leaflets, as they could become out of date and need to be destroyed. Leaflets for non-core activities, such as local health promotion purposes, can be bought from the national print provider.

PHE can only provide one leaflet per person per screening episode. A screening episode is defined as an invitation (with any subsequent reminders) for a particular screening test. People who are referred for further assessment following a screen should get a single copy of the appropriate follow-up leaflet.

Antenatal and newborn screening is treated as a single episode, so women should get a single copy of [Screening Tests for You and Your Baby](#) to last the entire antenatal and newborn period.

This means that duplicate copies should not be provided with reminder letters or if people lose or forget their leaflet. They should be signposted to electronic sources of information instead.

### 3.14 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

### 3.15 Staffing

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.

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 resources are detailed at <http://cpd.screening.nhs.uk/newbornbloodspot>

Provider should support staff attendance at relevant organisational meetings required to maintain operational aspects of service delivery as part of a national programme.

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

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.

### 3.16 Education and training

PHE screening provides a variety of education and training for NHS screening staff. Evidence based, up-to-date e-learning resources, study days and courses can be accessed here <https://www.gov.uk/guidance/nhs-population-screening-education-and-training>

In addition each screening programme will have specific guidance for the initial training and ongoing learning for screeners. This learning should be facilitated, supported and monitored by local screening providers. In line with professional regulations individuals have a responsibility to ensure their practice is up-to-date and evidence based. Local programmes can use the national programme training guidance and resources to support this.

### 3.17 User involvement

The provider(s) should:

- demonstrate that they regularly seek out the views of service users, families and others in respect of planning, implementing and delivering services



- demonstrate how those views will influence service delivery for the purposes of raising standards
- make results of any user surveys/questionnaires available to NHS England and NHS Improvement on request

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

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.

### 3.18 Premises and equipment

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 the Retention and Storage of Residual Newborn Blood Spots \(2018\)](#).
- 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 201NHS Standard Contract: <https://www.england.nhs.uk/nhs-standard-contract/17-18/>

## Section 4: National standards, risks and quality assurance

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 NHS Improvement and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and make sure these points are reviewed in contracting and peer review process
- participate fully in national quality assurance (QA) processes which includes:
  - submitting agreed minimum data sets and reports from external quality assurance schemes
  - undertaking ad-hoc audits and reviews as requested
  - completing self-assessment questionnaires / tools and associated evidence
  - responding to SQAS recommendations within agreed timescales providing specified evidence
  - producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations
- operate and evidence
  - check points that track individuals through the screening pathway
  - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  - have process in place to mitigate against weakness in the pathway
- 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 and NHS Improvement serious incident framework
- make sure business continuity plans are in place where required
- ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance
- all screening laboratories must
  - be accredited by the [UK Accreditation Service](#) (UKAS) to ISO. 'Medical laboratories – Requirements for quality and competence (ISO 15189)'

- participate in EQA schemes accredited to ISO. 'Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)'
- meet the [screening programme quality assurance requirements](#) mapped to ISO 15189
- and use ISO 15189 accredited reference laboratories

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:
  - check points that track individuals through the screening pathway
  - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  - 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 and NHS Improvement serious incident framework <https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>
- 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:**

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:**

New technologies should not be used for screening unless approved by the UK National Screening Committee.

## Section 5: Data and Intelligence

The collection, analysis and comparison of good quality data is critical for the all NHS screening programmes in England.

PHE Screening aims to develop a consistent approach to data collection and reporting across all screening programmes and is committed to making sure that stakeholders have access to:

- reliable and timely information about the quality of the screening programme
- data at local, regional and national level
- quality measures across the screening pathway without gaps or duplications

Performance thresholds are selected to align with existing screening standards and service objectives; 1 or 2 thresholds are specified.

The acceptable threshold is the lowest level of performance which screening services are expected to attain to assure patient safety and service effectiveness. All screening services should exceed the acceptable threshold and agree service improvement plans to meet the achievable threshold. Screening services not meeting the acceptable threshold are expected to put in place recovery plans to deliver rapid and sustained improvement.

The achievable threshold represents the level at which the screening service is likely to be running optimally. All screening services should aspire to attain and maintain performance at or above this level.

### 5.1 Key performance indicators (KPIs) and screening standards

The provider should adhere to the requirements as specified on following web pages:

KPIs: "[Reporting data definitions](#)" and [Screening standards](#):

Please note that indicator definitions are updated regularly and you should always obtain the most recent version available.

### 5.2 Data collection, monitoring and reporting

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.

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 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 and results received
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

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.

Data are 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.

### **5.3 Public Health Outcomes Framework (PHOF)**

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.

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

Acceptable  $\geq 95.0\%$

Achievable  $\geq 99.0\%$

<https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016>