Public Health England

NHS

# NHS Newborn Blood Spot Screening Programme

## Standards 2017 to 2018

**DRAFT DOCUMENT FOR CONSULTATION**

**Public Health England leads the NHS Screening Programmes**

# About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

## About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the 4 UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH
www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk

For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net



Published Month 20XX
PHE publications gateway number: 201XXXX

# Contents

# 1. Introduction

This document presents the revised national standards for the NHS Newborn Blood Spot (NBS) Screening Programme. These annual standards replace *Standards for Newborn Blood Spot Screening August 2013* and have an implementation date of April 2017. A summary of the main changes is available on page 11. They should be read in conjunction with the standards for the NHS Sickle Cell and Thalassaemia Screening Programme (www.gov.uk/government/publications/standards-for-sickle-cell-and-thalassaemia-screening – currently under revision).

The NBS programme aims to support health professionals and commissioners in providing high quality NBS screening services. This involves the development and regular review of quality standards against which data is collected and reported annually. The standards provide a defined set of measures that providers have to meet to ensure local programmes are safe and effective.

Quality assurance (QA) is the process of checking that these standards are met and encouraging continuous improvement. QA covers the entire screening pathway; from identifying who is eligible to be invited for screening, through to referral and intervention where required/appropriate.

# 2. The NHS Newborn Blood Spot (NBS) Screening Programme

The UK National Screening Committee (UK NSC) has responsibility for setting screening policy. It recommends that all babies are offered screening for the following 9 conditions:

- sickle cell disease (SCD)
- cystic fibrosis (CF)
- congenital hypothyroidism (CHT)
- phenylketonuria (PKU)
- medium-chain acyl-CoA dehydrogenase deficiency (MCADD)
- maple syrup urine disease (MSUD)
- isovaleric acidaemia (IVA)
- glutaric aciduria type 1 (GA1)
- homocystinuria (pyridoxine unresponsive) (HCU)

PKU, MCADD, MSUD, IVA, GA1 and HCU are all inherited metabolic diseases (IMDs). Screening for MSUD, IVA, GA1 and HCU was introduced in England in January 2015.

NBS screening is offered up to a year of age. For the small number of babies affected, early detection, referral and treatment can help to improve their health and prevent severe disability or even death. Parents can also receive support and education about their child's condition.

Please note that movers in under a year of age will not be offered NBS screening for MSUD, IVA, GA1 and HCU if they have documented results (or declines) for the 5 conditions screened for in England prior to expansion of the programme (SCD, CF, CHT, PKU and MCADD) (www.gov.uk/government/publications/movers-in-screening-babies-with-no-available-records).

The NBS programme has responsibility for implementing this policy and setting standards in England. It is a complex programme delivered by a range of different organisations working together. The service specification (No. 19) for providers is available as part of the public health functions exercised by NHS England (www.england.nhs.uk/commissioning/pub-hlth-res/).

The NBS programme aims to ensure that there is equal access to uniform and quality assured screening across England and that families are provided with high quality information so they can make an informed choice about NBS screening for their baby. Review of performance at a local level by population group may indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools that can be used to help local services and commissioners consider how to improve equity of access are the NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.

# 3. Format of the standards

The format of the screening standards has been updated. Development of this format has been an iterative process, based on work with providers, users, English screening programmes and QA teams. The changes were made to ensure 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
- a consistent approach across screening programmes
- data collection that is proportionate to the benefits gained

# 4. Scope and terminology

## Process standards

This document presents annual standards that assess the screening process and allow for continuous improvement. This enables providers and commissioners to identify where improvements are needed.

To clarify what is measured, each process standard has 3 parts:

- objective – the aim of the standard
- criteria – what is being assessed
- measure – 2 thresholds (acceptable and achievable):
  - the **acceptable threshold** is the lowest level of performance which programmes are expected to attain to ensure patient safety and programme effectiveness
  - the **achievable threshold** represents the level at which the programme is likely to be running optimally

All programmes should aspire towards attaining and maintaining performance at the achievable threshold. All programmes are expected to exceed the acceptable threshold and to agree to service improvement plans that develop performance towards an achievable level. Programmes not meeting the acceptable threshold are expected to implement recovery plans to ensure rapid and sustained improvement. These thresholds, definitions and reporting levels are approved by PHE's Screening Data Group.

The process standards are accompanied by clinical guidelines that should be followed to deliver high quality screening processes and to meet the standards (see section 9).

## Exclusions

The following standards and information are not included in this document:

### Structural standards

These describe the structure of the programme and must be fully met. Examples of structural standards are "parents/carers are provided with approved information on NBS screening" and "laboratories undertaking screening must be accredited by United

Kingdom Accreditation Service (UKAS)". Structural standards are included in screening service specifications and monitored through commissioning and other QA routes. Providers and commissioners should review the service specifications to ensure structural standards are met by all screening programmes.

## Laboratory performance standards

Laboratory performance standards are available in the condition-specific laboratory handbooks (see section 9).

## Information on clinical outcomes

Outcomes of the screening pathway are influenced by factors beyond the screening programme. The NBS programme reports summary data on screen positive results, clinical outcomes and false negative screening results where possible. This information is used to monitor performance of the programme. Details of the data fields required are not given in this document but are circulated annually to newborn screening laboratories.

# 5. Screening pathway

The standards are based on 10 generic themes that assess the whole pathway:

1. **Identify population** (to accurately identify the population to whom screening is offered)
2. **Inform** (to maximise informed choice across the screening pathway)
3. **Coverage/Uptake** (to maximise uptake in the eligible population who are informed and wish to participate in the screening programme)
4. **Test** (to maximise accuracy of the screening test from initial sample or examination to reporting the screening result)
5. **Diagnose** (to maximise accuracy of the diagnostic test)
6. **Intervention/Treatment** (to facilitate high quality and timely intervention in those who wish to participate)
7. **Outcome** (to optimise individual and population health outcomes in the eligible population)
8. **Minimising Harm** (to minimise potential harms in those screened and in the population)
9. **Staff: Education and Training** (to ensure that the screening pathway is provided by a trained and skilled workforce, with the capacity to deliver screening services as per service specification)
10. **Commissioning/Governance** (to ensure effective commissioning and governance of the screening programme)

# 6. Relationships between standards and key performance indicators (KPIs)

KPIs are a subset of standards that are collated and usually reported quarterly (unless numbers are small, in which case aggregate data is reported annually) compared to standards, which are reported annually. There are 2 to 3 KPIs per screening programme. The KPIs focus on areas of particular concern. In general, once a KPI consistently reaches the achievable level, it will revert to being a standard. This allows entry of another KPI to focus on additional areas of concern or a change to the threshold of the existing standard to promote continuous improvement.

NBS has 3 KPIs that are derived from standards 1a, 1b and 6 – see www.gov.uk/government/publications/nhs-population-screening-reporting-data-definitions.

# 7. Reporting standards

NBS process standards are reported annually (NBS KPIs are reported quarterly and annual KPI figures are aggregated). The NBS programme coordinates an annual collection and analysis of process standards data from child health records departments (CHRDs) and newborn screening laboratories. The organisations collating the data are responsible for ensuring the data is accurate, timely and complete. An output and information requirements specification is available to support collection of CHRD data from child health information systems (CHISs) (www.gov.uk/government/publications/newborn-blood-spot-screening-data-and-reporting-specifications).

The data should be collated 2 to 3 months after the end of the fiscal year (1 April to 31 March) with a submission deadline of 30 June.

The cohort of responsibility for CHRDs is clinical commissioning groups (CCGs) (standards 1a, 1b, 2 and 12) and for newborn screening laboratories is maternity services (standards 3 to 7). PHE is responsible for ensuring that reports on important aspects of screening are available at various geographies (for example local authority) to enable population-based oversight.

# 8. Revising standards

It is anticipated that the standards will be reviewed in line with the service specification on an annual basis.

# 9. Other resources to support providers and commissioners

This document focuses on process standards to enable providers and commissioners to continuously improve the quality of the screening programme. Additional operational guidance is available in the following documents:

- Service specification (No. 19) including the NBS screening pathway: www.england.nhs.uk/commissioning/pub-hlth-res/
- Condition-specific laboratory handbooks:
  - CF laboratory handbook (2014): www.gov.uk/government/publications/cystic-fibrosis-screening-laboratory-handbook
  - CHT laboratory handbook (including initial clinical referral guidelines) (2014): www.gov.uk/government/publications/congenital-hypothyroidism-screening-laboratory-handbook
  - IMD laboratory handbook (including initial clinical referral guidelines) (2015): www.gov.uk/government/publications/newborn-blood-spot-screening-laboratory-guide-for-imds
- CF initial clinical referral guidelines (2005): www.gov.uk/government/publications/clinical-referral-national-standard-protocol-for-cystic-fibrosis
- Guidelines for Newborn Blood Spot Sampling (2016): www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines
- Status codes v4.2 (2014): www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme

# 10. Summary of proposed changes

**General changes:**

1. Reporting deadline of 30 June for all standards as required by PHE's Screening Data Group

2. Clarified whether timeframes refer to working days or calendar days

| Standard | Changes | Data collected by |
|---|---|---|
| **Standard 1a:** Coverage (CCG responsibility at birth) | • PKU reported as proxy for all IMDs<br>• Clarified definition<br>• Change to achievable threshold (please note evidence is being reviewed) – note different threshold for CF and CHT due to need for a second sample for some babies | CHRDs |
| **Standard 1b:** Coverage (movers in) | • PKU reported as proxy for all IMDs<br>• Clarified definition<br>• Change to achievable threshold (please note evidence is being reviewed) – note different threshold for CF and CHT due to need for a second sample for some babies | CHRDs |
| **Standard 2:** Timely identification of babies with a null or incomplete result recorded on the CHIS | • No change | CHRDs |
| **Standard 3:** Barcoded NHS number label is included on the blood spot card | • Change to standard to drive improvement in the use of barcoded NHS number labels as NHS number is mandatory<br>• Acceptable threshold reflects data; achievable threshold remains the same<br>• Denominator excludes samples received from places with no NHS number | Newborn screening laboratories |
| **Standard 4:** Timely sample collection | • Change to standard to measure taking the sample on day 5 only<br>• In mitigating circumstances samples can be taken between day 6 and day 8 inclusive<br>• Change to thresholds to reflect data | Newborn screening laboratories |
| **Standard 5:** Timely receipt of a sample in the newborn screening laboratory | • Change to standard to drive improvement in timely receipt of samples<br>• Numerator and denominator exclude pre-transfusion samples<br>• Change to thresholds to reflect data | Newborn screening laboratories |

| | | |
|---|---|---|
| **Standard 6:** Quality of the blood spot sample | • Clarified definition | Newborn screening laboratories |
| **Standard 7:** Timely taking of a second blood spot sample for CF and CHT screening | • Only includes second samples taken for raised immunoreactive trypsinogen (IRT) or borderline thyroid stimulating hormone (TSH) – reporting mechanism under development for other repeat/second samples<br>• Change to standard to measure taking the second sample for raised IRT on day 21 only<br>• In mitigating circumstances the second sample for raised IRT can be taken between day 22 and day 28 inclusive | NBS programme via newborn blood spot failsafe solution (NBSFS) |
| **Standard 8:** UKAS (screening) | • Propose removing standard – see consultation survey | Newborn screening laboratories |
| **Standard 9:** Timely processing of CHT and IMD screen positive samples | • Standard includes all IMDs<br>• Single threshold of 100% referrals within 3 working days<br>• Updated CHT sample definition | Newborn screening laboratories |
| **Standard 10:** UKAS (diagnosis) | • Propose removing standard – see consultation survey | Newborn screening laboratories |
| **Standard 11:** Timely receipt into clinical care | • Standard includes all IMDs<br>• Single threshold of 100% attended first clinical appointment for CHT and IMDs<br>• SCD standards removed – see consultation survey | Newborn screening laboratories |
| **Standard 12a:** Timeliness of results to parents (CCG responsibility at birth) | • Propose removing standard – see consultation survey<br>• Updated definitions section | CHRDs |
| **Standard 12b:** Timeliness of results to parents (movers in) | • If retain standard 12a, propose new standard 12b | |

# 11. The NBS standards

<table>
<tr><th>Standard 1a</th><th>Identify the population and coverage: Coverage (CCG responsibility at birth)</th></tr>
<tr><td>Rationale</td><td>A key objective of the programme is to ensure that all eligible babies are offered NBS screening and, with verbal consent, tested within an effective timeframe.</td></tr>
<tr><td>Objective</td><td>To accurately identify the population to whom screening is offered and to maximise coverage in the eligible population who are fully informed and wish to participate in the screening programme.</td></tr>
<tr><td>Criteria</td><td>The proportion of babies registered within the CCG both at birth and on the last day of the reporting period who are eligible for NBS screening and have a not suspected, suspected or carrier result recorded on the CHIS for each of the 9 conditions at less than or equal to 17 days of age.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>tested babies<br>eligible babies</td><td>expressed as a percentage</td></tr>
</table>
tested babies (numerator) is the total number of eligible babies that have a not suspected, suspected or carrier result for each of the 9 conditions recorded on the CHIS at less than or equal to 17 days of age (day of birth is day 0).<br><br>
eligible babies (denominator) is the total number of babies born within the reporting period, excluding any baby who died before the age of 8 days. For this standard, the cohort includes only babies for whom the CCG was responsible at birth and is still responsible on the last day of the reporting period.<br><br>
responsible CCG refers to all babies that are registered with a GP within the CCG; the data should be grouped and reported per CCG responsible population or UK equivalent using the baby’s, or if not available, mother’s GP practice code. If neither the baby nor mother’s GP is known, responsibility is determined by place of residence.<br><br>
A not suspected, suspected or carrier result is one of the following newborn screening status codes:<br><br>
• 04 condition screened for not suspected<br>
• 05 condition screened for carrier<br>
• 06 SCD not suspected, carrier of other haemoglobin<br>
• 07 condition screened for not suspected – other disorders follow up<br>
• 08 condition screened for suspected<br>
• 10 haemoglobin S not suspected (by DNA) – no other haemoglobin / thalassaemia excluded
</td></tr>
</table>

| | |
|---|---|
| | *each of the 9 conditions* – PKU will serve as a proxy indicator for each of the IMDs. This is because screening for the IMDs can only be accepted or declined as a group. Data should be returned for PKU, SCD, CF and CHT.<br><br>Declines (status code 02) should be recorded on the CHIS and included in the denominator but not the numerator – decline data is collected and reported alongside coverage data to help interpretation.<br><br>**Exclusions:**<br>This standard does not measure babies who change responsible CCG since birth or move in from another UK country or abroad (movers in) even though these babies are eligible for screening – this is measured using standard 1b. |
| **Performance thresholds** | **Acceptable:**<br>≥ 95.0% of eligible babies have a result for each of the 9 conditions recorded on the CHIS at less than or equal to 17 days of age.<br><br>**Achievable:**<br>≥ 99.0% of eligible babies have a result for the IMDs and SCD recorded on the CHIS at less than or equal to 17 days of age.<br><br>≥ 98.0% of eligible babies have a result for CF and CHT recorded on the CHIS at less than or equal to 17 days of age. |
| **Mitigations/ qualifications** | For a small number of babies the screening pathway for CF and CHT requires a second sample to be taken before a not suspected, suspected or carrier result can be arrived at – this could delay timeliness of the result. |
| **Reporting** | **Reporting focus:** CCGs<br>**Data source:** CHRDs<br>**Responsible for submission:** CHRDs |
| **Reporting period** | Annually for babies born in the previous fiscal year:<br>**Deadline:** 30 June |

<table>
<tr><th>Standard 1b</th><th>Identify the population and coverage: Coverage (movers in)</th></tr>
<tr><td>Rationale</td><td>A key objective of the programme is to ensure that all eligible babies are offered NBS screening and, with verbal consent, tested within an effective timeframe.<br><br>This standard focuses on children that move in and become the responsibility of the CCG within the reporting period.</td></tr>
<tr><td>Objective</td><td>To accurately identify the population to whom screening is offered and to maximise coverage in the eligible population who are fully informed and wish to participate in the screening programme.</td></tr>
<tr><td>Criteria</td><td>The proportion of all babies eligible for NBS screening who:<br><br>• have changed responsible CCG in the first year of life; or<br>• have moved in from another UK country or abroad<br><br>and have a not suspected, suspected or carrier result for each of the 9 conditions (or 5 conditions if not eligible for expanded screening) recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement in.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>tested babies<br>eligible babies</td><td>expressed as a percentage</td></tr>
</table>
<br>tested babies (numerator) is the total number of eligible babies that have a not suspected, suspected or carrier result for each of the 9 conditions (or 5 conditions if not eligible for expanded screening) recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement in.<br><br>eligible babies (denominator) is the total number of babies:<br><br>• who have changed responsible CCG, or moved in from another UK country or abroad during the reporting period; and<br>• for whom the CCG is responsible on the last day of the reporting period; and<br>• are less than or equal to 364 days of age at the point of notifying the CHRD of movement in<br><br>responsible CCG refers to all babies that are registered with a GP within the CCG; the data should be grouped and reported per CCG responsible population or UK equivalent using the baby’s, or if not available, mother’s GP practice code. If neither the baby nor mother’s GP is known, responsibility is determined by place of residence.<br><br>changed responsible CCG – baby was born out of the CCG but has become its responsibility because he/she moved and was notified to CHRD within the reporting period.</td></tr>
</table>

| | |
|---|---|
| | *notifying the CHRD of movement in* – this is either:<br><br>• the point of direct electronic registration on the CHIS<br>• the point of receipt of phone/email/fax notification to the CHRD<br><br>A *not suspected, suspected or carrier result* is one of the following newborn screening status codes:<br><br>• 04 condition screened for not suspected<br>• 05 condition screened for carrier<br>• 06 SCD not suspected, carrier of other haemoglobin<br>• 07 condition screened for not suspected – other disorders follow up<br>• 08 condition screened for suspected<br>• 10 haemoglobin S not suspected (by DNA) – no other haemoglobin / thalassaemia excluded<br><br>*each of the 9 conditions* – PKU will serve as a proxy indicator for each of the IMDs that the baby is eligible for at the time of movement in (see *not eligible for expanded screening*). This is because screening for the IMDs can only be accepted or declined as a group. Data should be returned for PKU, SCD, CF and CHT.<br><br>*not eligible for expanded screening* – movers in under a year of age will not be offered screening for MSUD, IVA, GA1 and HCU if they have documented results (or declines) for the 5 conditions screened for in England prior to expansion of the programme (SCD, CF, CHT, PKU and MCADD) – see www.gov.uk/government/publications/movers-in-screening-babies-with-no-available-records.<br><br>Declines (status code 02) should be recorded on the CHIS and included in the denominator but not the numerator – decline data is collected and reported alongside coverage data to help interpretation.<br><br>**Exclusions:**<br>Note that this standard does not measure babies who are already the responsibility of the CCG at birth and transfer within the same CCG. Standard 1a captures babies registered within the CCG both at birth and on the last day of the reporting period. |
| **Performance thresholds** | **Acceptable:**<br>≥ 95.0% of eligible babies have a result for each of the 9 conditions (or 5 conditions if not eligible for expanded screening) recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement in.<br><br>**Achievable:**<br>≥ 99.0% of eligible babies have a result for the IMDs and SCD recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement in.<br><br>≥ 98.0% of eligible babies have a result for CF and CHT recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement |

| | |
|---|---|
| | in. |
| **Mitigations/ qualifications** | CF can only be screened for up to 8 weeks of age.<br><br>For a small number of babies the screening pathway for CF and CHT requires a second sample to be taken before a not suspected, suspected or carrier result can be arrived at – this could delay timeliness of the result. |
| **Reporting** | **Reporting focus:** CCGs<br>**Data source:** CHRDs<br>**Responsible for submission:** CHRDs |
| **Reporting period** | Annually for babies born in the previous fiscal year:<br>**Deadline:** 30 June |

| Standard 2 | Coverage: Timely identification of babies with a null or incomplete result recorded on the CHIS |
|---|---|
| **Rationale** | The NBS programme relies on regular checks of the CHIS to identify babies with a null or incomplete result within an effective timeframe. Reports are produced to identify these babies and action is taken to follow them up, according to local protocols. |
| **Objective** | To maximise coverage in the eligible population who are fully informed and wish to participate in the screening programme. |
| **Criteria** | The CHRD has a process in place to identify babies with a null or incomplete NBS result that meets the standard. |
| **Definitions** | CHRDs are asked to report whether they have a system in place that meets the standard for identifying babies with a *null or incomplete NBS result* for any of the 9 conditions.<br><br>There can be flexibility in the frequency and age range of reports providing the method complies with the acceptable performance threshold – for example daily check of babies equal to or more than 17 days of age and equal to or less than 364 days of age; weekly check of babies equal to or more than 11 days of age and equal to or less than to 364 days of age.<br><br>For the purposes of this standard, day of birth is day 0.<br><br>*null or incomplete NBS result:*<br><br>• no status code recorded<br>• status code 01 (specimen received in laboratory)<br>• status code 03 (repeat/further sample required) |
| **Performance thresholds** | **Acceptable:** CHRD performs regular checks (ideally daily, minimum weekly) to identify babies ≥ 17 days and ≤ 364 days with a null or incomplete result.<br><br>**Achievable:** CHRD performs regular checks (ideally daily, minimum weekly) to identify babies ≥ 14 days and ≤ 364 days with a null or incomplete result. |
| **Mitigations/ qualifications** | None. |
| **Reporting** | **Reporting focus:** CHRDs<br>**Data source:** CHRDs<br>**Responsible for submission:** CHRDs |
| **Reporting period** | Annually:<br>**Deadline:** 30 June |

<table>
<tr><th>Standard 3</th><th>Test: Barcoded NHS number label is included on the blood spot card</th></tr>
<tr><td>Rationale</td><td>Use of the NHS number on the baby's blood spot card is mandatory in England. Use of a barcoded NHS number label will reduce the risk of an inaccurate NHS number on the blood spot card which would require a repeat sample to be taken.</td></tr>
<tr><td>Objective</td><td>To maximise accuracy of the screening test from initial sample to reporting the screening result.</td></tr>
<tr><td>Criteria</td><td>The proportion of blood spot cards received by the laboratory with the baby's NHS number on a barcoded label.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of blood spot cards received by the laboratory with the baby's NHS number on a barcoded label</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of blood spot cards received by the laboratory</td></tr>
</table>
<br>number of blood spot cards received by the laboratory (denominator) is the total number of all blood spot cards received, including repeats and second samples (with the exception of samples received from places that do not use an NHS number – for example Jersey and Guernsey).
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 90.0% of blood spot cards are received by the laboratory with the baby's NHS number on a barcoded label.<br><br>Achievable: ≥ 95.0% of blood spot cards are received by the laboratory with the baby's NHS number on a barcoded label.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services<br>Data source: newborn screening laboratories<br>Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for samples received in the laboratory in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 4</th><th>Test and Intervention/Treatment: Timely sample collection</th></tr>
<tr><td>Rationale</td><td>It is essential to begin the screening process promptly to give each screen positive baby the best possible chance of receiving early treatment. The blood spot sample should be taken on day 5.</td></tr>
<tr><td>Objective</td><td>To maximise accuracy of the screening test and facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of blood spot samples taken on day 5.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of first blood spot samples taken on day 5</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of first blood spot samples taken (excludes pre-transfusion samples)</td></tr>
</table>
<br>For the purposes of this standard, day of birth is day 0.<br><br>Pre-transfusion samples are excluded from the denominator.<br><br>The sample should be taken in accordance with the Guidelines for Newborn Blood Spot Sampling: www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines.</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 90.0% of first blood spot samples are taken on day 5.<br><br>Achievable: ≥ 95.0% of first blood spot samples are taken on day 5.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>In exceptional circumstances the blood spot sample can be taken between day 6 and day 8 inclusive.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services<br>Data source: newborn screening laboratories<br>Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for samples received in the laboratory in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 5</th><th>Test and Intervention/Treatment: Timely receipt of a sample in the newborn screening laboratory</th></tr>
<tr><td>Rationale</td><td>All samples must arrive within the screening laboratory as soon as possible after the sample has been taken. This enables the laboratory to analyse the sample at the earliest opportunity and also reduces the risk of sample deterioration due to prolonged despatch.</td></tr>
<tr><td>Objective</td><td>To maximise accuracy of the screening test and to facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of blood spot samples received within 3 working days of sample collection.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of blood spot samples received by laboratory within 3 working days of sample collection (excludes pre-transfusion samples)</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of blood spot samples received by laboratory (excludes pre-transfusion samples)</td></tr>
</table>
sample received is when the sample is recorded as received on the laboratory information management system.
For the purposes of this standard, day of sample collection is day 0.
Pre-transfusion samples are excluded from the numerator and the denominator.
The sample should be taken in accordance with the Guidelines for Newborn Blood Spot Sampling: www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines.
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 95.0% of all samples received within 3 working days of sample collection.<br><br>Achievable: ≥ 99.0% of all samples received within 3 working days of sample collection.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services<br>Data source: newborn screening laboratories<br>Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for samples received in the laboratory in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 6</th><th>Test and Intervention/Treatment: Quality of the blood spot sample</th></tr>
<tr><td>Rationale</td><td>Good quality blood spot samples are vital to ensure that babies with rare but serious conditions are identified and treated early.<br><br>Good quality samples should be obtained first time to prevent the need for avoidable repeats. Avoidable repeat samples can cause anxiety for parents, distress to babies and delays in the screening process. They are also a waste of resources.<br><br>A good quality blood spot sample is one that:<br><br>• is taken at the right time<br>• has all data fields completed to enable identification of the baby, analysis and reporting of results<br>• contains sufficient blood to perform all tests (each circle filled and evenly saturated by a single drop of blood that soaks through to the back of the blood spot card)<br>• is not contaminated<br>• arrives in the laboratory in a timely manner</td></tr>
<tr><td>Objective</td><td>To maximise accuracy of the screening test and facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of first blood spot samples that require repeating due to an avoidable failure in the sampling process.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of avoidable repeat requests</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of first blood spot samples received by the laboratory</td></tr>
</table>
<br>avoidable repeat requests (numerator) is the total number of repeat (second or subsequent) samples requested by the laboratory during the reporting period because the previous sample was:<br><br>• taken when the baby was too young (on or before day 4, where day of birth is day 0) (excluding pre-transfusion samples)<br>• insufficient (small volume spots, blood not soaked through to the back of the blood spot card)<br>• unsuitable (for example incorrect blood application, compressed/damaged, missing/inaccurate details, expired card, in transit for more than 14 calendar days)<br><br>first blood spot samples received by the laboratory (denominator) is the total number of first blood spot samples received by the laboratory during the reporting period.<br><br>Note that repeat samples requested because the previous sample was taken too soon (less than 3 clear calendar days) after transfusion are excluded from the numerator as the routine sample should be taken by day 8 at the latest.</td></tr>
</table>

| | |
|---|---|
| | The sample should be taken in accordance with the *Guidelines for Newborn Blood Spot Sampling:* www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines.<br><br>See *Status codes v4.2* for further details on avoidable repeat categories: www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme. |
| **Performance thresholds** | **Acceptable:** Avoidable repeat rate is ≤ 2.0%.<br><br>**Achievable:** Avoidable repeat rate is ≤ 0.5%. |
| **Mitigations/ qualifications** | None. |
| **Reporting** | **Reporting focus:** maternity services<br>**Data source:** newborn screening laboratories<br>**Responsible for submission:** newborn screening laboratories |
| **Reporting period** | Annually for samples received in the laboratory in the previous fiscal year:<br>**Deadline:** 30 June |

<table>
<tr><th>Standard 7</th><th>Test and Intervention/Treatment: Timely taking of a second blood spot sample for CF and CHT screening</th></tr>
<tr><td>Rationale</td><td>Timely taking of a second blood spot sample is vital to maximise accuracy of the screening test and ensure that clinical referral and treatment targets are met.</td></tr>
<tr><td>Objective</td><td>To maximise accuracy of the screening test and facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of second blood spot samples taken as defined for individual tests.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of second blood spot samples for raised IRT taken on day 21 (day of birth is day 0)</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of second blood spot samples for raised IRT requested</td></tr>
</table>
<table>
<tr><td>number of second blood spot samples for borderline TSH taken between 7 and 10 calendar days after the initial borderline sample</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of second blood spot samples for borderline TSH requested</td></tr>
</table>
Exclusions:<br>This standard does not include the following repeat/second blood spot samples for which reporting via NBSFS is under development:
<ul>
<li>an avoidable repeat (must be taken within 3 calendar days of receipt of request)</li>
<li>a repeat sample for CF, CHT and the IMDs following a blood transfusion (must be taken at least 3 clear calendar days after the last transfusion)</li>
<li>a second blood spot sample for TSH for babies born at less than 32 weeks gestation (≤ 31 weeks + 6 days) (must be taken when they reach 28 days of age or day of discharge home, whichever is sooner (day of birth is day 0))</li>
</ul>
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 95.0% of second blood spot samples taken as defined.<br><br>Achievable: ≥ 99.0% of second blood spot samples taken as defined.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>In exceptional circumstances the blood spot sample for raised IRT can be taken between day 22 and day 28 inclusive.<br><br>Timeliness/method of request will affect meeting the standard.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services<br>Data source: NBS programme via NBSFS<br>Responsible for submission: NBS programme via NBSFS</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

| Standard 8 | Test: UKAS (screening) PROPOSE REMOVING STANDARD – SEE CONSULTATION SURVEY |
|---|---|
| **Rationale** | To support maintenance of quality, clinical laboratories must participate in a recognised laboratory accreditation process that addresses structure, process and outcome characteristics when providing a clinical laboratory service. |
| **Objective** | To maximise accuracy of the screening test from initial sample or examination to reporting the screening result. |
| **Criteria** | Laboratories undertaking NBS screening tests are accredited by UKAS. This includes the NBS specialist assessment. |
| **Definitions** | UKAS accredits pathology laboratories against a set of defined standards. These standards are allied to international standards for competence in medical laboratories – ISO 15189. During the NBS specialist assessment UKAS looks at both the ISO standards and the UK screening specific laboratory standards, as an integrated process.<br><br>The assessment comprises a main visit to the laboratory by a team of independent assessors at intervals of every 4 years, with a surveillance visit by a regional assessor within 2 years of the main visit. Other visits may be undertaken to assess resolved non-compliances as part of continuing surveillance of enrolled laboratories.<br><br>Laboratories must make reports from accreditation services available to screening programmes, the national team and commissioners.<br><br>Laboratory accreditation can be checked at www.ukas.com/browse-accredited-organisations/?org_cat=855&parent=Medical%20Laboratories&type_id=7. |
| **Performance thresholds** | **Acceptable:** The laboratory is UKAS accredited (with the specialist assessment of NBS screening by the next full visit). |
| **Mitigations/ qualifications** | None. |
| **Reporting** | **Reporting focus:** newborn screening laboratories<br>**Data source:** UKAS<br>**Responsible for submission:** newborn screening laboratories |
| **Reporting period** | Annually<br>**Deadline:** 30 June |

<table>
<tr><th>Standard 9</th><th>Intervention/Treatment: Timely processing of CHT and IMD screen positive samples</th></tr>
<tr><td>Rationale</td><td>Timely processing of all screen positive samples is vital to ensure that health benefits are achieved by reducing morbidity/mortality.</td></tr>
<tr><td>Objective</td><td>To facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of CHT and IMD screen positive results available and clinical referral initiated within 3 working days of sample receipt by the screening laboratory.</td></tr>
<tr><td>Definitions</td><td>For each condition:<br><br>
<table>
<tr><td>number of positive screening results available and clinical referral initiated within 3 working days of sample receipt by screening laboratory</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of positive screening results available</td></tr>
</table>
<br>sample receipt is when the sample is recorded as received on the laboratory information management system.<br><br>Applies to CHT and the IMDs – laboratories shall notify positive screening results in accordance with the initial clinical referral guidelines for each condition. This notification initiates the clinical referral of screen positive cases.<br><br>This standard only applies to the CHT screen positive sample that initiated the referral (i.e. first sample if TSH ≥ 20 mU/L or repeat sample following borderline TSH).</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: 100% of babies with a positive screening result have a clinical referral initiated within 3 working days of sample receipt by screening laboratory.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: newborn screening laboratories<br>Data source: newborn screening laboratories<br>Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for samples received in the laboratory in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

| Standard 10 | Diagnose: UKAS (diagnosis) PROPOSE REMOVING STANDARD – SEE CONSULTATION SURVEY |
|---|---|
| **Rationale** | To support maintenance of quality, clinical laboratories must participate in a recognised laboratory accreditation process that addresses structure, process and outcome characteristics when providing a clinical laboratory service. |
| **Objective** | To maximise accuracy of the diagnostic test. |
| **Criteria** | Laboratories undertaking NBS screening and diagnostic tests are accredited by UKAS. Following up screening and diagnostic tests shall be undertaken in line with the diagnostic protocols. |
| **Definitions** | UKAS accredits pathology laboratories against a set of defined standards. These standards are allied to international standards for competence in medical laboratories – ISO 15189.<br><br>The assessment comprises a main visit to the laboratory by a team of independent assessors at intervals of every 4 years, with a surveillance visit by a regional assessor within 2 years of the main visit. Other visits may be undertaken to assess resolved non-compliances as part of continuing surveillance of enrolled laboratories.<br><br>Laboratory accreditation can be checked at www.ukas.com/browse-accredited-organisations/?org_cat=855&parent=Medical%20Laboratories&type_id=7. |
| **Performance thresholds** | **Acceptable:** The laboratory is UKAS accredited. |
| **Mitigations/ qualifications** | None. |
| **Reporting** | **Reporting focus:** newborn screening laboratories<br>**Data source:** UKAS<br>**Responsible for submission:** newborn screening laboratories |
| **Reporting period** | Annually<br>**Deadline:** 30 June |

<table>
<tr><th>Standard 11</th><th>Intervention/Treatment: Timely receipt into clinical care</th></tr>
<tr><td>Rationale</td><td>Timely receipt into clinical care of all screen positive babies is vital to ensure that health benefits are achieved by reducing morbidity/mortality.</td></tr>
<tr><td>Objective</td><td>To facilitate high quality and timely intervention in those who wish to participate.</td></tr>
<tr><td>Criteria</td><td>The proportion of babies referred to specialist services that are seen by the condition-specific standard.</td></tr>
<tr><td>Definitions</td><td>For each condition:<br><br>
<table>
<tr><td>number of screen positive babies referred to specialist services that are seen by the condition-specific standard</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of screen positive babies referred</td></tr>
</table>
</td></tr>
<tr><td>Performance thresholds</td><td>
<table>
<tr><th>Condition</th><th>Intervention /treatment</th><th>Thresholds</th></tr>
<tr><td>IMDs and CHT (suspected on first sample)</td><td>Attend first clinical appointment by 14 days of age</td><td>Acceptable: 100%</td></tr>
<tr><td>CHT (suspected on repeat following borderline TSH)</td><td>Attend first clinical appointment by 21 days of age</td><td>Acceptable: 100%</td></tr>
<tr><td>CF (2 CFTR mutations detected)</td><td>Attend first clinical appointment by 28 days of age</td><td>Acceptable: ≥ 95.0%<br>Achievable: 100%</td></tr>
<tr><td>CF (1 or no CFTR mutation detected)</td><td>Attend first clinical appointment by 35 days of age</td><td>Acceptable: ≥ 80.0%<br>Achievable: 100%</td></tr>
</table>
</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None (reasons that standard is not met should be included in an exception report).</td></tr>
<tr><td>Reporting</td><td>Reporting focus: newborn screening laboratories<br>Data source: newborn screening laboratories (anonymised baby level data on all screen positive babies)<br>Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 12a</th><th>Minimising harm: Timeliness of results to parents (CCG responsibility at birth)</th></tr>
<tr><td>Rationale</td><td>To report not suspected NBS screening results to parents in a timely manner.</td></tr>
<tr><td>Objective</td><td>To optimise individual and population health outcomes in the eligible population.</td></tr>
<tr><td>Criteria</td><td>The proportion of babies with a not suspected result for each of the 9 conditions for whom a not suspected results letter was despatched directly to parents by the CHRD within 6 weeks of birth.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of not suspected results letters despatched directly to parents by the CHRD within 6 weeks of birth</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of babies with a not suspected result for each of the 9 conditions recorded on the CHIS within 6 weeks of birth</td></tr>
</table>
not suspected result – status code 04<br>www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme
This standard only includes babies that:
<ul>
<li>have a not suspected result for each of the 9 conditions; and</li>
<li>did not need a second screening sample to obtain the result (for example repeat IRT or TSH sample)</li>
</ul>
This standard does not include babies that:
<ul>
<li>have a not suspected result obtained on a second sample</li>
<li>a condition suspected or carrier result for any of the conditions tested</li>
<li>a declined, repeat required or screening incomplete status code</li>
</ul>
Where not suspected results letters are not sent by CHRDs, area teams should provide evidence that the health visitors have given the results to parents and documented this in the personal child health record (‘red book’). This could be achieved through local audit.
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: 100% of babies with a not suspected result for each of the 9 conditions for whom a not suspected results letter was despatched directly to parents by the CHRD within 6 weeks of birth.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: CCGs<br>Data source: CHRDs<br>Responsible for submission: CHRDs</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:<br>Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 12b</th><th>Minimising harm: Timeliness of results to parents (movers in)</th></tr>
<tr><td>Rationale</td><td>To report not suspected NBS screening results to parents in a timely manner.</td></tr>
<tr><td>Objective</td><td>To optimise individual and population health outcomes in the eligible population.</td></tr>
<tr><td>Criteria</td><td>The proportion of babies with a not suspected result for each of the 9 conditions for whom a not suspected results letter was despatched directly to parents by the CHRD within 6 weeks of notification of movement in.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of not suspected results letters despatched directly to parents by the CHRD within 6 weeks of notification of movement in</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>number of babies with a not suspected result for each of the 9 conditions recorded on the CHIS within 6 weeks of notification of movement in</td></tr>
</table>
not suspected result – status code 04<br>www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme
This standard only includes babies that:
<ul>
<li>move in with no documented results (or declines) and are offered screening for all 9 conditions; and</li>
<li>have a not suspected result for each of the 9 conditions; and</li>
<li>did not need a second screening sample to obtain the result (for example repeat IRT or TSH sample).</li>
</ul>
This standard does not include babies that:
<ul>
<li>have a not suspected result obtained on a second sample</li>
<li>have a condition suspected or carrier result for any of the conditions tested</li>
<li>have a declined, repeat required or screening incomplete status code</li>
<li>are too old to be screened for CF</li>
</ul>
Where not suspected results letters are not sent by CHRDs, area teams should provide evidence that the health visitors have given the results to parents and documented this in the personal child health record (‘red book’). This could be achieved through local audit.
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: of babies with a not suspected result for each of the 9 conditions for whom a not suspected results letter was despatched directly to parents by the CHRD within 6 weeks of notification of movement in.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>None.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: CCGs</td></tr>
</table>

| | |
|---|---|
| | **Data source:** CHRDs<br>**Responsible for submission:** CHRDs |
| **Reporting period** | Annually for babies born in the previous fiscal year:<br>**Deadline:** 30 June |

# Abbreviations

| | |
|---|---|
| CCG | clinical commissioning group |
| CF | cystic fibrosis |
| CHIS | child health information system |
| CHRD | child health records department |
| CHT | congenital hypothyroidism |
| GA1 | glutaric aciduria type 1 |
| HCU | homocystinuria |
| IMD | inherited metabolic disease |
| IRT | immunoreactive trypsinogen |
| ISO | International Organization for Standardization |
| IVA | isovaleric acidaemia |
| KPI | key performance indicator |
| MCADD | medium-chain acyl-CoA dehydrogenase deficiency |
| MSUD | maple syrup urine disease |
| NBS | newborn blood spot |
| NBSFS | Newborn Blood Spot Failsafe Solution |
| PHE | Public Health England |
| PKU | phenylketonuria |
| QA | quality assurance |
| SCD | sickle cell disease |
| TSH | thyroid stimulating hormone |
| UKAS | United Kingdom Accreditation Service |
| UK NSC | UK National Screening Committee |

# Glossary

**To be completed**

# Status codes

**To be completed**