Public Health England

NHS

NHS Newborn Blood Spot Screening Programme Standards

Implementation date 1 April 2017

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. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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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 four 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.

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1. Introduction

This document presents the revised national standards for the NHS Newborn Blood Spot (NBS) Screening Programme. These 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).

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)

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 three 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:

1. Structural standards

These describe the structure of the programme and must be fully met. An example of a structural standard is "parents/carers are provided with approved information on NBS screening". 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. Old standards 8 and 10 that require laboratories undertaking screening to be accredited by the United Kingdom Accreditation Service (UKAS) are retained in this document in section 12 to provide detailed information on the requirements.

2. Laboratory performance standards

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

3. 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 two to three 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 two to three months after the end of the fiscal year (1 April to 31 March) with a submission deadline of 30 June for CHRDs and 15 July for newborn screening laboratories.

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 changes

General changes:

1. Reporting deadline of 15 July for all newborn screening laboratory 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 • Clarified definition • Change to achievable thresholds	CHRDs
Standard 1b: Coverage (movers in)	• PKU reported as proxy for all IMDs • Clarified definition • Change to achievable thresholds	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 • Acceptable threshold reflects data; achievable threshold remains the same • 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 • In mitigating circumstances samples can be taken between day 6 and day 8 inclusive • Numerator and denominator exclude pre-transfusion samples • 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 • Numerator and denominator exclude pre-transfusion samples • Change to thresholds to reflect data • Mitigation added	Newborn screening laboratories

Standard 6: Quality of the blood spot sample	• Clarified definition • Change to achievable threshold	Newborn screening laboratories
Standard 7a: Timely taking of a second blood spot sample for CF screening	• Only includes second samples taken for raised immunoreactive trypsinogen (IRT) – reporting mechanism under development for second samples • Change to standard to measure taking the second sample for raised IRT on day 21 to day 24 • Change to thresholds to reflect data • In mitigating circumstances the second sample for raised IRT can be taken between day 25 and day 28 inclusive	NBS programme via newborn blood spot failsafe solution (NBSFS)
Standard 7b: Timely taking of a second blood spot sample following a borderline CHT screening	• Only includes second samples taken for borderline thyroid stimulating hormone (TSH) – reporting mechanism under development for second samples	NBS programme via newborn blood spot failsafe solution (NBSFS)
Standard 7c: Timely taking of a second blood spot sample for CHT screening for preterm infants	• Only includes second samples taken for thyroid stimulating hormone (TSH) in preterm infants – reporting mechanism under development for second samples	NBS programme via newborn blood spot failsafe solution (NBSFS)
Standard 8: UKAS (screening)	• Laboratories undertaking screening must be accredited by the United Kingdom Accreditation Service (UKAS). This standard is retained in this document in section 12 to provide detailed information on the requirements.	Newborn screening laboratories
Standard 9: Timely processing of CHT and IMD screen positive samples	• Standard includes IMDs excluding HCU • Single threshold of 100% referrals within 3 working days • Updated CHT sample definition	Newborn screening laboratories
Standard 10: UKAS (diagnosis)	• Laboratories undertaking screening must be accredited by the United Kingdom Accreditation Service (UKAS). This standard is retained in this document in section 12 to provide detailed information on the requirements.	Newborn screening laboratories
Standard 11: Timely entry into clinical care	• Standard includes IMDs	Newborn screening laboratories
Standard 12a: Timeliness of results to parents (CCG	• Standard retained • Audit tool to be developed to measure standard	CHRDs

responsibility at birth)	• Updated definitions section	
Standard 12b: Timeliness of results to parents (movers in)	• New standard 12b • Audit tool to be developed to measure standard	CHRDs

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>This standard is to ensure that all eligible babies are offered NBS screening and, with verbal consent from a parent, 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
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).
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 on the last day of the reporting period.
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.
A not suspected, suspected or carrier result is one of the following newborn screening status codes:

04 condition screened for not suspected
05 condition screened for carrier
06 SCD not suspected, carrier of other haemoglobin
07 condition screened for not suspected – other disorders follow up
08 condition screened for suspected
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. 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. **Exclusions:** 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:** ≥ 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. **Achievable:** ≥ 99.0% of eligible babies have a result for the IMDs recorded on the CHIS at less than or equal to 17 days of age. ≥ 98.0% of eligible babies have a result for CF, CHT and SCD 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 **Data source:** CHRDs **Responsible for submission:** CHRDs
Reporting period	Annually for babies born in the previous fiscal year: **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>This standard is to ensure that all eligible babies are offered NBS screening and, with verbal consent from a parent, tested within an effective timeframe.

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:
• have changed responsible CCG in the first year of life; or
• have moved in from another UK country or abroad

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
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 (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.

eligible babies (denominator) is the total number of babies:

• who have changed responsible CCG, or moved in from another UK country or abroad during the reporting period; and
• for whom the CCG is responsible on the last day of the reporting period; and
• are less than or equal to 364 days of age at the point of notifying the CHRD of movement in (only if the blood spot sample can be taken before they reach a year of age)

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.

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.
notifying the CHRD of movement in – this is either:</td></tr>
</table>

	• the point of direct electronic registration on the CHIS • the point of receipt of phone/email/fax notification to the CHRD A *not suspected, suspected or carrier result* is one of the following newborn screening status codes: • 04 condition screened for not suspected • 05 condition screened for carrier • 06 SCD not suspected, carrier of other haemoglobin • 07 condition screened for not suspected – other disorders follow up • 08 condition screened for suspected • 10 haemoglobin S not suspected (by DNA) – no other haemoglobin / thalassaemia excluded *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. *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. 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. **Exclusions:** 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. See appendix 2: scenarios for examples of when babies have moved into an area and confirm if they should be in the numerator or denominator, both or neither.
Performance thresholds	**Acceptable:** ≥ 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. **Achievable:** ≥ 99.0% of eligible babies have a result for the IMDs recorded on the CHIS at less than or equal to 21 calendar days of notifying the CHRD of movement in.

	≥ 98.0% of eligible babies have a result for CF, CHT and SCD 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. 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 **Data source:** CHRDs **Responsible for submission:** CHRDs
Reporting period	Annually for babies born in the previous fiscal year: **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. 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. For the purposes of this standard, day of birth is day 0. *null or incomplete NBS result:* • no status code recorded • status code 01 (specimen received in laboratory) • 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. **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 **Data source:** CHRDs **Responsible for submission:** CHRDs
Reporting period	Annually: **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>

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).

Barcoded label output based specification available at: https://www.gov.uk/government/publications/nhs-numbers-for-newborn-screening-specification-for-the-blood-spot-card-label</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.

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
Data source: newborn screening laboratories
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:
Deadline: 15 July</td></tr>
</table>

Standard 4	Test and Intervention/Treatment: Timely sample collection
Rationale	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.
Objective	To maximise accuracy of the screening test and facilitate high quality and timely intervention in those who wish to participate.
Criteria	The proportion of first blood spot samples taken on day 5.
Definitions	*number of first blood spot samples taken on day 5* / *number of first blood spot samples taken* — expressed as a percentage For the purposes of this standard, day of birth is day 0. Pre-transfusion samples are excluded from the denominator and numerator. 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.
Performance thresholds	**Acceptable:** ≥ 90.0% of first blood spot samples are taken on day 5. **Achievable:** ≥ 95.0% of first blood spot samples are taken on day 5.
Mitigations/ qualifications	In exceptional circumstances the blood spot sample can be taken between day 6 and day 8 inclusive.
Reporting	**Reporting focus:** maternity services **Data source:** newborn screening laboratories **Responsible for submission:** newborn screening laboratories
Reporting period	Annually for samples received in the laboratory in the previous fiscal year: **Deadline:** 15 July

<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 less than or equal to 3 working days of sample collection.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>number of blood spot samples received by laboratory less than or equal to 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 less than or equal to 3 working days of sample collection.

Achievable: ≥ 99.0% of all samples received less than or equal to 3 working days of sample collection.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>Laboratories will reject samples if received more than 14 days after the sample was taken</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services
Data source: newborn screening laboratories
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:
Deadline: 15 July</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.

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.

A good quality blood spot sample is one that:

• is taken at the right time
• has all data fields completed to enable identification of the baby, analysis and reporting of results
• 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
• is not contaminated
• 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
number of first blood spot samples received by the laboratory</td><td>expressed as a percentage</td></tr>
</table>

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:

• taken when the baby was too young (on or before day 4, where day of birth is day 0) (excluding pre-transfusion samples)
• insufficient (small volume spots, blood not soaked through to the back of the blood spot card)
• unsuitable (for example incorrect blood application, compressed/damaged, missing/inaccurate details, expired card, in transit for more than 14 calendar days)

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.

Note that repeat samples requested because the previous sample was taken too soon (less than 3 clear calendar days) after transfusion are excluded</td></tr>
</table>

	from the numerator as the routine sample should be taken by day 8 at the latest. 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. See *Status codes v4.2* (see appendix 1) 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%. **Achievable:** Avoidable repeat rate is ≤ 1%.
Mitigations/ qualifications	None.
Reporting	**Reporting focus:** maternity services **Data source:** newborn screening laboratories **Responsible for submission:** newborn screening laboratories
Reporting period	Annually for samples received in the laboratory in the previous fiscal year: **Deadline:** 15 July

<table>
<tr><th>Standard 7a</th><th>Test and Intervention/Treatment: Timely taking of a second blood spot sample for CF 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 21to day 24 (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>

Exclusions:
This standard does not include the following repeat/second blood spot samples for which reporting via NBSFS is under development:
an avoidable repeat (must be taken within 3 calendar days of receipt of request)
a repeat sample for CF following a blood transfusion (must be taken at least 3 clear calendar days after the last transfusion)</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 95% of second blood spot samples taken on day 21 to day 24 (this allows for day 21 to fall on a weekend when a special visit is not warranted).

Achievable: ≥ 70% of second blood spot samples taken on day 21</td></tr>
<tr><td>Mitigations/ qualifications</td><td>In exceptional circumstances the blood spot sample for raised IRT can be taken between day 25 and day 28 inclusive.
Timeliness/method of request will affect meeting the standard.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services
Data source: NBS programme via NBSFS
Responsible for submission: NBS programme via NBSFS</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:
Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 7b</th><th>Test and Intervention/Treatment: Timely taking of a second blood spot sample following a borderline 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 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:
This standard does not include the following repeat/second blood spot samples for which reporting via NBSFS is under development:

an avoidable repeat (must be taken within 3 calendar days of receipt of request)
a repeat sample for CHT following a blood transfusion (must be taken at least 3 clear calendar days after the last transfusion)

</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 95.0% of second blood spot samples taken as defined.

Achievable: ≥ 99.0% of second blood spot samples taken as defined.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>Timeliness/method of request will affect meeting the standard.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services
Data source: NBS programme via NBSFS
Responsible for submission: NBS programme via NBSFS</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:
Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 7c</th><th>Test and Intervention/Treatment: Timely taking of a second blood spot sample for CHT screening for preterm infant</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 preterm infants (≤ 31 weeks + 6 days) taken on or before 28 days of age. Only taken earlier if baby discharged home.
———
number of second blood spot samples for preterm infants</td><td>expressed as a percentage</td></tr>
</table>
Exclusions:
This standard does not include the following repeat/second blood spot samples for which reporting via NBSFS is under development:

an avoidable repeat (must be taken within 3 calendar days of receipt of request)
a repeat sample for CHT following a blood transfusion (must be taken at least 3 clear calendar days after the last transfusion)

</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥ 95.0% of second blood spot samples taken as defined.

Achievable: ≥ 99.0% of second blood spot samples taken as defined.</td></tr>
<tr><td>Mitigations/ qualifications</td><td>Timeliness/method of request will affect meeting the standard.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: maternity services
Data source: NBS programme via NBSFS (date of discharge is not known, so as proxy, earlier than day 28 will be assumed as day of discharge)
Responsible for submission: NBS programme via NBSFS</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:
Deadline: 30 June</td></tr>
</table>

<table>
<tr><th>Standard 9</th><th>Intervention/Treatment: Timely processing of CHT and IMD (excluding HCU) 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 (excluding HCU) 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:

<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>

sample receipt is when the sample is recorded as received on the laboratory information management system. Count this as day 1.

Applies to CHT and the IMDs (excluding HCU) – 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.

This standard only applies to the CHT screen positive sample that initiated the referral</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: 100% of babies with a positive screening result (excluding HCU) 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
Data source: newborn screening laboratories
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:
Deadline: 15 July</td></tr>
</table>

<table>
<tr><th>Standard 11</th><th>Intervention/Treatment: Timely entry into clinical care</th></tr>
<tr><td>Rationale</td><td>Timely entry 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:

<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 (excluding HCU) 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) and HCU</td><td>Attend first clinical appointment by 28 days of age</td><td>Acceptable: ≥ 95.0%
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%
Achievable: 100%</td></tr>
<tr><td>SCD</td><td>Attend first clinical appointment by 90 days of age</td><td>Acceptable: ≥ 90.0%
Achievable: ≥ 95.0%</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
Data source: newborn screening laboratories (anonymised baby level data on all screen positive babies)
Responsible for submission: newborn screening laboratories</td></tr>
<tr><td>Reporting period</td><td>Annually for babies born in the previous fiscal year:
Deadline: 15 July</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 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 conditions recorded on the CHIS within 6 weeks of birth</td></tr>
</table>
not suspected result – status code 04 and 10 (see appendix 1: status codes) www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme
This standard only includes babies that:

have a not suspected result for each of the conditions; and
did not need a second screening sample to obtain the result (for example repeat IRT or TSH sample)

This standard does not include babies that:

have a not suspected result obtained on a second sample
a condition suspected or carrier result for any of the conditions tested
a declined, repeat required or screening incomplete status code

Where not suspected results letters are not sent to parents 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.
Template letters are available at: https://www.gov.uk/government/publications/newborn-blood-spot-screening-results-to-parents-template
</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: 100% of babies with a not suspected result for each of the 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/</td><td>None.</td></tr>
</table>

qualifications	
Reporting	**Reporting focus:** CCGs **Data source:** CHRDs **Responsible for submission:** CHRDs
Reporting period	Annually for babies born in the previous fiscal year: **Deadline:** 30 June

<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 conditions screened 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 conditions recorded on the CHIS within 6 weeks of notification of movement in</td></tr>
</table>
not suspected result – status code 04 and 10 (see appendix 1: status codes) www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme
This standard only includes babies that:

move in with no documented results (or declines) and are offered screening for all conditions; and
have a not suspected result for each of the conditions; and
did not need a second screening sample to obtain the result (for example repeat IRT or TSH sample).

This standard does not include babies that:

have a not suspected result obtained on a second sample
have a condition suspected or carrier result for any of the conditions tested
have a declined, repeat required or screening incomplete status code

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 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>
</table>

Mitigations/ qualifications	Babies more than 8 weeks of age are too old for CF screening but are still eligible to be screened for the other conditions.
Reporting	**Reporting focus:** CCGs **Data source:** CHRDs **Responsible for submission:** CHRDs
Reporting period	Annually for babies born in the previous fiscal year: **Deadline:** 30 June

12. Mandatory UKAS requirements

Old standards eight and 10 that require laboratories undertaking screening to be accredited by the United Kingdom Accreditation Service (UKAS) are structural standards but are retained in this document to provide detailed information on the requirements.

Old standard 8	**Test: UKAS (screening)**
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. 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. Laboratories must make reports from accreditation services available to screening programmes, the national team and commissioners. 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 **Data source:** UKAS **Responsible for submission:** newborn screening laboratories
Reporting period	Annually

Old standard 10	**Diagnose: UKAS (diagnosis)**
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. 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. 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 **Data source:** UKAS **Responsible for submission:** newborn screening laboratories
Reporting period	Annually

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

A glossary can be found within the document *PHE screening key performance indicators for 2016 to 2017* available at: https://www.gov.uk/government/publications/nhs-population-screening-reporting-data-definitions

The glossary defines terms that are consistent across NHS screening programmes. The scope of each defined term as it applies to a particular screening programme is detailed separately for each screening programme.

Appendix 1: Status codes

This table of newborn blood spot screening status codes v4.2 is available at: https://www.gov.uk/government/publications/status-codes-for-the-newborn-blood-spot-nbs-screening-programme

Status Code	Suggested term used in child health system	Sub Code	Description	Comment
01	Specimen received in laboratory	N/A	Same value applies to all screening tests (ie relates to the blood spot card) Additional data items to be provided with this status code and entered into Child Health systems. electronically or by manual means: • Date sample taken • Date sample received in laboratory • Laboratory identifier	
02	(Condition screened for) declined	0201	Declined, no history of being screened	
		0202	Declined, screened in UK (as reported by parents) with no evidence of result	
		0203	Declined, screened outside UK with evidence of result	
		0204	Declined, screened outside UK with no evidence of result	
03	(Condition screened for) Repeat/Further	0301*	Too young for reliable screening	

	sample required			
		0302	Too soon after transfusion (<72 hours)	
		0303*	Insufficient sample	(Includes not enough blood, not soaked through, small area re Card scan users)
		0304*	Unsuitable sample (blood quality): incorrect blood application	(Incorrect blood application technique – includes multi-spotted, spotted both sides)
		0305*	Unsuitable sample (blood quality): compressed/damaged	(Includes compressed, evidence incomplete drying, stained glassine, scratched/abraded/ridged , liquid/water damage/contamination, discoloured spots)
		0306*	Unsuitable sample: day 0 and day 5 on same card	
		0307*	Unsuitable sample for CF: possible faecal contamination	
		0308*	Unsuitable sample: NHS number missing/not accurately recorded	
		0309*	Unsuitable sample: Date of sample missing/not accurately recorded	
		0310*	Unsuitable sample: Date of birth not accurately matched	
		0311*	Unsuitable sample: Expired card used	

		0312*	Unsuitable sample: > 14 days in transit, too old for analysis	
		0313*	Unsuitable sample: Damaged in transit	(Includes water/liquid damage through outer postal envelope)
		0314	Sickle - Too premature for testing	
		0315	CHT - Pre-term	
		0316	CHT - Borderline result	
		0317	CF - Inconclusive	
04	(Condition screened for) Not suspected	N/A		
05	(Condition screened for) Carrier	N/A		
06	Sickle Cell Disease not suspected, carrier of other haemoglobin	0601	Result consistent with haemoglobin C carrier	
		0602	Result consistent with haemoglobin D carrier	
		0603	Result consistent with haemoglobin E carrier	
		0604	Result consistent with haemoglobin O-Arab carrier	
07	(Condition screened for) Not suspected, other disorders follow up	N/A		
08	(Condition screened for) Suspected	N/A		

09	(Condition screened for) Not screened/screening incomplete	0901	CF: > 8 weeks, too old for screening	
		0902	All screens: >1 year, too old for screening	
		0903	Moved out of area	
		0904	Not contactable, reasonable efforts made	
		0905	Baby died	
		0906	Not required, previous valid result	
10	Haemoglobin S not suspected (by DNA) No other haemoglobin /thalassemia excluded	N/A	Applies to sickle cell disease screening only	

* avoidable repeat subcodes

Appendix 2: Scenarios

The scenarios below give examples of when babies have moved into an area and confirm if they should be in the numerator or denominator, both or neither, for Standard 1b. Also see: https://www.gov.uk/government/publications/movers-in-screening-babies-with-no-available-records

Scenario	Baby moves in without evidence of conclusive results	Numerator	Denominator
1	Screening is offered but declined by parents.	Excluded	Included
2	Conclusive results are investigated, found and recorded on the CHISS equal to or less than 21 calendar days of movement in being recorded on the CHISS.	Included	Included
3	Conclusive results are investigated, found and recorded on the CHISS greater than 21 calendar days of movement in being recorded on the CHISS.	Excluded	Included
4	Baby is offered testing and screening is carried out. Conclusive results are recorded on the CHISS equal to or less than 21 calendar days of movement in being recorded on the CHISS.	Included	Included
5	Baby is offered testing and screening is carried out. Conclusive results are recorded on the CHISS greater than 21 calendar days of movement in being recorded on the CHISS.	Excluded	Included
6	Baby moves into CCG with a repeat/further sample required status. The new CCG carries out the repeat and records a conclusive result equal to or less than 21 calendar days of movement in being recorded on the CHISS.	Included	Included
7	Baby moves into CCG with a repeat/further sample required status. The new CCG carries out the repeat and records a conclusive result greater than 21 calendar days of movement in being recorded on the CHISS.	Excluded	Included
8	Screening is offered but declined by parents. Parents then reconsider the offer greater than 21 calendar days of movement in being recorded on the CHISS and baby is screened.	Excluded	Included

9	Baby moves into CCG with a conclusive result for all five original conditions (SCD, CF, CHT, PKU and MCADD) but not the four new expanded conditions (MSUD, IVA, GA1 and HCU). Baby is not offered screening for the extra conditions (following national guidance). Conclusive results for the five original conditions are recorded on the CHISS equal to or less than 21 calendar days of movement in being recorded on the CHISS. www.gov.uk/government/publications/movers-in-screening-babies-with-no-available-records	Included	Included
10	Baby is born within the reporting period but does not move into CCG until after the reporting period (in theory these babies would be in the 'CCG responsibility at birth' population of the previous CCG/country and excluded in the current CCG data return).	Excluded	Excluded
11	Baby moves into CCG within the reporting period but was born outside of the reporting period (in theory these babies would be in the 'CCG responsibility at birth' population of the previous CCG/country and excluded in the current CCG data return).	Excluded	Excluded
Scenario	**Baby moves in with evidence of conclusive results**	**Numerator**	**Denominator**
12	Conclusive results are recorded on the CHISS equal to or less than 21 calendar days of movement in being recorded on the CHISS.	Included	Included
13	Conclusive results are recorded on the CHISS greater than 21 calendar days of movement in being recorded on the CHISS.	Excluded	Included
14	Relates to both 'CCG responsibility at birth' and ‘movers in’: baby is tested in CCG but sadly dies. If the baby is less than eight days of age they are omitted from the data collection. If they are over eight days of age the tests should be recorded on the CHISS and measured against the relevant standard.	Excluded	Excluded