Screening for Newborn Blood Spot
Clinical Guideline

V1.0

January 2019
1. **Aim and Purpose**

1.1 The purpose of this guideline is to inform midwives and clinicians about the practice of neonatal newborn bloodspot screening and current best practice process for the undertaking of newborn blood spot screening for all newborn babies. For roles and responsibilities through process see Appendix 3.

1.2 The National Screening Committee (NSC) recommend that all babies in the United Kingdom and up to one year old are offered screening for Phenylketonuria (PKU), Congenital Hypothyroidism (CHT), Sickle Cell Disease (SCD), Medium-chain acyl-CoA dehydrogenase deficiency (MCADD), Cystic Fibrosis (CF), Maple Syrup Urine Disease, Isovaleric Acidaemia (IVA), Glutaric Aciduria type 1 (GA1) and Homocystinuria. The purpose is to ensure early detection, referral and treatment for those babies found to be high risk. Babies over the age of 8 weeks cannot be screened for CF on the new born blood spot.

2. **The Guidance**

2.1 **Objectives**

2.1.1 To ensure that all mothers are given appropriate information to make informed choices regarding newborn blood spot screening.

2.1.2 To ensure that completed cards have sufficient blood and are dispatched to the laboratory in a timely manner and that they reach the laboratory as soon as possible. **NEW 2018**

2.1.3 To ensure that all test results are actioned.

2.1.4 To accurately diagnose all infants born with any of the conditions screened for.

2.1.5 To ensure that information is provided to affected families in an acceptable and accessible manner and is appropriate to the needs of the relevant communities.

2.1.6 To ensure effective and acceptable follow up, care and support for infants with any of the conditions screened and their carers.

2.1.7 To audit the service on an ongoing basis to ensure acceptability, effectiveness and adherence to guidelines.

2.2 **Key Standards**

2.2.1 These have been identified by the National Screening Committee to underpin performance management to ensure clinical quality and effectiveness of the screening programme. These standards are measured at core and developmental levels and are found in Appendix 4.

2.2.2 The NSC recommends the sample to be taken on **day 5 (NEW 2018)** following birth with the day of birth as day 0. In mitigating circumstances samples can be taken between day 6 and day 8 inclusive.
2.2.3 Written information and verbal consent must be documented in the health care records, before the sample is taken.

2.2.4 Parents and health care professionals may find the condition leaflets helpful to understand these rare conditions and by following the link below. [www.expandedscreening.org/site/home/metabolic-msud-introduction.asp](http://www.expandedscreening.org/site/home/metabolic-msud-introduction.asp)

2.2.5 Parents can opt out of screening for the conditions; However parents can only opt out of IMDs as a group and not by each condition.

2.2.6 All mothers are given verbal and written information about screening tests, where possible in the parent’s first language. 13 languages available at the link below New 2018

2.2.7 A pre-screening leaflet, ‘Screening Tests for You and Your Baby’ should be given and discussed at least 24 hours prior to testing. Ideally, this should be in the 3rd. Trimester or at postnatal discharge from the hospital or the first postnatal visit. Available at: [https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief](https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief).

An Easy guide format is available at:


2.2.8 Testing is discussed with the mother again before obtaining consent and should include information on:

- the conditions and how screening can help the babies identified
- how the sample is taken and repeats are sometimes necessary
- when parents should receive the results
- how screening for sickle cell and cystic fibrosis can identify babies who are carriers
- screening results are not 100% accurate
- a chance to ask questions should be offered

2.2.9 In addition midwives and health professionals need to ensure that parents understand:

- that they are consenting to processes that support the screening programme – this includes storage of residual blood spots for a minimum of 5 years
- that residual blood spots can be used to check screening results, for testing equipment or methods, and for training and audit
- that residual blood spots can also be used for health research that does not identify their baby
- that they may be asked if they consent to future contact about research that could identify their baby.

If parents do not consent to future research contact, the midwife or health professional seeking consent for screening must record this in the baby’s notes and in the comments box on the blood spot card as ‘no research contact’.
2.3 Verbal consent

2.3.1 Verbal consent should be obtained from parent or person with legal parental responsibility

2.3.2 Record whether consent is obtained or declined in hand held record and which tests have been taken should be entered in the Parent Held Child Record (PCHR).

2.3.3 If consent is withheld, the screening card is still filled in but ‘declined’ must be documented on it and this card must be sent to the laboratory.

2.3.4 If screening or aspects of screening are declined; parents should be given information on who to contact if they change their mind. The decline must then be documented in the hand held notes and the PCHR. Note a decline for IMD [Inherited metabolic disease] screening includes all 6 conditions. New 2018

2.3.5 Inform the GP, Health Visitor and Screening Coordinator if any tests are declined.

2.4 Sufficient blood is taken

Samples should be taken on day 5 (day 0 is day of birth). In mitigating circumstances samples can be taken between day 6 and day 8 inclusive

Follow sampling guidance (Appendix 5) or follow link: https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines

2.5 Screening card is correctly labelled

2.5.1 New blood spot cards being introduced during 2019 will contain a greyed-out area on the card. This area represents mandatory information that must be completed in full. New 2018

2.5.2 The baby’s NHS number is mandatory and should be applied to the card by way of using the newborn blood spot bar-coded labels, or by hand in exceptional circumstances.

2.5.3 The date of the sample must be identified on the card

2.5.4 The baby’s gestation and date of birth should be on the card (it is on label)

2.5.5 Ensure area code is also added: REF [in the PCT box]

2.5.6 If either parent has been identified as a sickle cell carrier, or if the pregnancy is a consequence of egg or sperm donation, this must be documented clearly on the screening card
2.5.7 Ensure all pertinent family history has been inserted including other family members affected by any of the screened conditions.

2.5.8 Check details with parent to ensure all correct.

2.6 Screening cards must reach the Bristol laboratory as soon as possible after the sample has been taken. New 2018

2.6.1 Screening cards must be posted, using our internal mail courier system, to the RCHT post room in the pre-addressed blue envelope on the same day of sample being taken, using one envelope per sample. These are available from the Screening Coordinator. New 2018

2.6.2 Do not batch samples together.

2.6.3 Records must be maintained by the professional taking the sample of the date the sample obtained and the date the sample sent.

2.7 Special circumstances

2.7.1 Sibling of baby known to have an Inherited Metabolic Disease [IMD]

2.7.1.1 It is recommended that screening for PKU, MCADD, MSUD, (New 2018) IVA and GA1, is undertaken earlier than the 5-8 day timeframe to avoid delays in diagnosis and to allay parental anxiety. New 2018

2.7.1.2 In these 5 conditions please screen at day 2 [24 – 48 hours postnatal] New 2018

2.7.1.3 However, this does not remove the need for routine screening and it is essential that the blood spot collection is undertaken on day 5 as usual to screen for the other conditions within the newborn programme. New 2018

2.7.1.4 Note on the blood spot card that an earlier test has been sent due ‘Family History’ of the identified condition [PKU/MCCAD/MSUD/IVA/GA1] New 2018

2.7.1.5 Screening for HCU can take place on day 5 as part of the routine screening, noting ‘family history of HCU’ on the blood spot card New 2018

2.7.1.6 Neonatal consultants should be alerted antenatally for pregnant women who already have a child with PKU, MCCAD, MSUD, IVA, and GA1 to provide a plan of care for the baby post birth, since these conditions can potentially have an early neonatal presentation putting a newborn at risk New 2018

For further information see PHE guidance at: https://www.gov.uk/government/publications/health-professional-handbook-newborn-blood-spot-screening/5-family-history#when-to-take-the-sample New 2018

2.8 Pre-term infants and CHT

All babies born less than 32 weeks (31+6) will need a second blood spot sample taken after the day 5 sample for CHT screening. This repeat is taken at
28 days of age [day of birth is day 0] or on the day of discharge home from hospital, whichever is sooner.

2.9 Babies undergoing blood transfusion

2.9.1 Blood spot screening should be undertaken prior to transfusion for sickle cell screening. All babies admitted to NICU must have a day 0 or “admission sample” taken. If the baby goes on to have a blood transfusion, this sample should be sent to the screening laboratory along with the day 5 fully completed sample.

2.9.2 If no day 0 sample available and a baby has had a blood transfusion by the time screening is due, blood spot screening should be taken 72 hours after transfusion (for PKU, CHT and CF) as well as at 3 months of age for sickle cell disorders.

2.10 Insufficient samples/Avoidable repeats

2.10.1 The Screening Coordinator will notify responsible clinical staff when there is an insufficient sample and repeat sampling will be undertaken by the midwife within 3 calendar days.

2.10.2 The community midwife is responsible for informing the parents that a repeat sample is required and documenting this in the hand held record when the sample has been repeated.


2.10.3 If the parents decline the test, a card must still be filled out stating that the parents have declined the test and sent to the laboratory as detailed previously.

2.11 Raised levels/borderline or inconclusive results New 2018

The screening laboratory will contact Screening Coordinators directly when raised/borderline or inconclusive levels are reported on any aspect of the test and repeat sampling will be requested from the community midwife and undertaken by them within 3 calendar days New 2018

2.12 No sample received by screening laboratory

The Screening Coordinator will notify maternity services and repeat sampling will be undertaken by the midwife. The Screening Coordinator will investigate and identify (if possible) where process erred, completing the datix processes.

2.13 Results

2.13.1 It is the responsibility of the midwife looking after the baby to ensure screening has been completed.

2.13.2 All normal results will be sent to CHRD who will forward to the parents by letter. The Health Visitor team will review that results are in the PCHR at the next planned contact.
2.13.3 Any positive results are referred on the same day as the screening result is available to the laboratory clinical liaison service who will co-ordinate local support, as per Regional Southwest Policy for Bristol Newborn Screening Laboratory [2018]. **New 2018**

https://www.nbt.nhs.uk/sites/default/files/Regional%20Policy%20template%20for%20newborn%20screening%20for%20Inherited%20Metabolic%20Disorders%20%28IMDs%29%20in%20the%20South%20West.pdf

2.13.4 The specialist teams will inform parents of positive results, provide details of planned appointments and inform the GP and Health Visiting team, who can support as necessary

2.13.5 All other results will be given by clinician at time of discussing positive result.

2.14 **Babies moving into the area up to age 1**

2.14.1 All babies moving in to the RCHT managed area should have evidence of newborn blood spot screening. If there is no evidence of screening parents should be offered screening as per health visiting guidance.

2.14.2 Babies up to 28 days old will be referred from health visiting to midwifery services where a screening sample will be taken as per guidance above.

2.14.3 Babies between 29 days and 365 days will be offered screening by the health visiting services. Babies over 8 weeks old will not be screened for cystic fibrosis. Parents should be made aware of this and the GP should be informed that this screening test has not been performed.

2.15 **Failsafe pathways**

2.15.1 There should be systems in place to ensure all babies complete screening in a timely manner.

2.15.2 The Screening Coordinator will maintain the online failsafe and monitor sample tracking as per Appendix 6.

2.15.3 The CHRD [Health Intelligence] run a daily failsafe report and inform the Health Visiting team of babies that have moved into the area where a bloodspot screen offer is required. All babies under a year of age should have documented results [or declines] for all 9 conditions screened for in England. Only results documented in English are accepted [this includes translations]. The aim is to have a conclusive result recorded on the CHIS system ≤ 21 calendar days of notifying the CHRD of movement in. **New 2018**

2.16 **Incident reporting**

Any incident resulting in delay to screening or missed screening must be recorded on the trust DATIX system and reported to the Screening Coordinator.

- All incidents will be investigated as per maternity incident management policy.
- Screening incidents will also be reported by the Screening Coordinator to the Screening and Immunization team and the Regional Quality Assurance team.

- Any incidents requiring reporting as a serious incident will be investigated using the trust guidance and the guidance: Managing safety incidents in NHS screening programmes published by Public Health England

3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Data collection, audit and quality assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Antenatal and Newborn Screening Coordinators</td>
</tr>
<tr>
<td>Tool</td>
<td>Northgate Failsafe System</td>
</tr>
<tr>
<td></td>
<td>Ongoing data collection of avoidable repeats is added to an Excel spreadsheet</td>
</tr>
<tr>
<td>Frequency</td>
<td>Daily Monitoring of failsafe solution</td>
</tr>
<tr>
<td></td>
<td>Audit of data will be quarterly</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Any recommendations will be monitored by the antenatal screening operational group which meets biannually. The results and outcome of the recommendations will be reported at the Antenatal and Newborn Screening Board and included in the Annual report</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>The results and outcome of the recommendations will be reported at the Antenatal and Newborn Screening Board and included in the Annual report.</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>A member of the screening team will be identified as the lead for implementing recommendations and sharing them with the relevant health care professional</td>
</tr>
</tbody>
</table>

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the [Equality and Diversity website](https://www.gov.uk/government/publications/newborn-blood-spot-screening-failsafe-solution-user-guide).

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1 Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Screening for Newborn Blood Spot Clinical Guideline v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>January 2019</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>January 2019</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>November 2022</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Jenny Stevenson; Screening Coordinator</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253092</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Information for staff when caring for women who are performing Newborn Blood Spot screening.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Newborn, Spot, Screening</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT CFT KCCG</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>December 2018</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>New Guideline (Extracted from 2015 Guideline Newborn BSS)</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Midwifery Guidelines Group Medical Directorate PRG</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Tunde Adewopo</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not required</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Name: Caroline Amukusana</td>
<td></td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet, ✓ Intranet Only</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical/Midwifery Obstetrics</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td>Neonatal Screening Committee</td>
</tr>
</tbody>
</table>

**Related Documents:**

- Managing safety incidents in NHS screening programmes 2018: [https://www.gov.uk/search?q=Screening+incident+guidance](https://www.gov.uk/search?q=Screening+incident+guidance)

**Training Need Identified?**

- Contained within monthly maternity update days training

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2019</td>
<td>V1.0</td>
<td>Overall review. Removed info about tests and replaced with online conditions leaflet and expanded screening links. Updated standards added and slight word changes to reflect standard changes. New information about residual blood spot consent added with link. Clarification of earlier screening for babies born with a sibling with an IMD with link. Change with Child Health governance who have now been taken over by external group, Health Intelligence who run more frequent failsafe checks. New links for professional information to support practice. Changes in some reporting processes to reflect local updates. Slight change to testing for family history of IMD. This information has been taken from a previous Guideline which had been superseded by this new encompassed guideline.</td>
<td>Jenny Stevenson Antenatal and Newborn Screening Coordinator</td>
</tr>
</tbody>
</table>
Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing.

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## Appendix 2 Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<thead>
<tr>
<th>Name of Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Screening for Newborn Blood Spot Clinical Guideline v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Directorate and service area:</strong> Obstetrics and Gynaecology</td>
<td><strong>Is this a new or existing Policy?</strong> New</td>
</tr>
<tr>
<td><strong>Name of individual completing assessment:</strong> Jennifer Stevenson, Screening Midwife</td>
<td><strong>Telephone:</strong> 01872 253092</td>
</tr>
</tbody>
</table>

1. **Policy Aim**

   Who is the strategy / policy / proposal / service function aimed at?

   To ensure that midwives understand the national screening committee guidance on Newborn Bloodspot Screening.

2. **Policy Objectives**

   To ensure that midwives understand the national screening committee guidance on Newborn Bloodspot Screening. See objectives in Guidance.

3. **Policy – intended Outcomes**

   The purpose is to ensure early detection, referral and treatment for those babies found to be high risk of the conditions screened for.

4. **How will you measure the outcome?**

   Audit tool

5. **Who is intended to benefit from the policy?**

   Maternity population cohort

6a **Who did you consult with**

   Workforce | Patients | Local groups | External organisations | Other | x |

   Please record specific names of groups

   Maternity Guidelines Group
   Obs and Gynaec Directorate

6b. **Please identify the groups who have been consulted about this procedure.**

   Guideline agreed

   What was the outcome of the consultation?
7. The Impact
Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

Are there concerns that the policy **could** have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td></td>
<td>x</td>
<td></td>
<td>To ensure that screening leaflets are available in patient first language if at all possible or arrange for an interpreter to explain.</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td></td>
<td>x</td>
<td></td>
<td>Easy read leaflets available for women with learning difficulties</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this **excludes** any policies which have been identified as not requiring consultation. **or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. **Yes** **No** x

9. If you are **not** recommending a Full Impact assessment please explain why.

Not required

Signature of policy developer / lead manager / director
Jennifer Stevenson

Date of completion and submission
December 2018
Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust's web site.

Signed ___ Sarah Jane Pedler _____________

Date __________December 2018______
## Appendix 3

### ROLES AND RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Post/Group</th>
<th>Details</th>
<th>Resources</th>
<th>Review/ Monitoring</th>
<th>Implementation</th>
<th>Records</th>
<th>Incident Reporting</th>
</tr>
</thead>
</table>
| Screening Coordinator/deputy | • Monitor on line failsafe daily to ensure all newborn babies complete screening  
• Update training of all staff involved in screening  
• Completing compliance audit | X         | X                  | X              | X       | X                  |
| Midwives                 | • Provide full written and verbal explanation of the national newborn blood spot screening program to all parents and undertake the screening process for all newborn babies  
• Undertake the day 5 blood spot screening for all newborn babies  
• Ensure fit for purpose sample posted in a timely manner | X         | X                  | X              | X       | X                  |
| NICU Staff               | • Ensure all babies admitted to NICU have a “day 0” admission sample taken  
• Provide full written and verbal explanation of the national newborn blood spot screening program to all parents and undertake the screening process for all newborn babies  
• Undertake the day 5 blood spot screening for all newborn babies  
• Ensure fit for purpose sample posted in a timely manner  
• Ensure timely scheduling of repeat samples as per guidance | X         | X                  | X              | X       | X                  |
| Health Visitors          | • Ensure all babies have a screening result, including babies moving in to the area under the age of one  
• If no screening result available offer screening to babies | X         | X                  | X              | X       | X                  |
| Maternity Guidelines Group | • Review and implementation of guidance  
• Update guidance as required | X         | X                  | X              | X       | X                  |
| Maternity Risk Management Committee | • Review any incidents reported using trust incident reporting mechanism (DATIX)  
• Instigate RCA investigation where appropriate  
• Escalate any incidents to Divisional Board as appropriate | X         | X                  |                |         |                    |
| Screening Governance Group | • Monitor compliance with standards  
• Review incident action plans  
• Implement any new standards as recommended by national programme | X         |                    |                |         |                    |
Appendix 4: Newborn Blood Spot Key Standards Summary

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Threshold acceptable</th>
<th>Threshold achievable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 1a: Completeness of coverage</td>
<td>To maximize uptake in the eligible population (PKU used as proxy)</td>
<td>95% tested</td>
<td>99.0% tested</td>
</tr>
<tr>
<td>Standard 1b: Completeness of coverage Movers In</td>
<td>To maximize uptake in the eligible population (PKU used as proxy)</td>
<td>95% tested</td>
<td>99.0% tested</td>
</tr>
<tr>
<td>Standard 2: Timely Identification of babies with a null or incomplete result recorded on the child health information system</td>
<td>To maximize uptake in the eligible population (PKU used as proxy)</td>
<td>100% records checked by 17 days to 365 days</td>
<td>100% records checked by 14 days to 365 days</td>
</tr>
<tr>
<td>Standard 3: baby's NHS number is included on the blood spot card</td>
<td>To maximize accuracy of the screening test</td>
<td>90% cards have bar coded label with NHS number</td>
<td>95% cards have bar coded label with NHS number</td>
</tr>
<tr>
<td>Standard 4: Timely sample collection</td>
<td>To maximize accuracy of the screening test</td>
<td>90% of first blood spot samples are taken on day 5</td>
<td>95% samples of first blood spot samples are taken on day 5</td>
</tr>
<tr>
<td>Standard 5: Timely receipt of a sample in the laboratory</td>
<td>To maximize accuracy of the screening test</td>
<td>95% samples received within 3 working days</td>
<td>99% samples received within 3 working days</td>
</tr>
<tr>
<td>Standard 6: Quality of the blood sample</td>
<td>To maximize accuracy of the screening test and to obtain a good quality sample first time</td>
<td>Avoidable repeat rate less than or equal to 2%</td>
<td>Avoidable repeat rate less than or equal to 1%</td>
</tr>
<tr>
<td>Standard 7a: Timely taking of a second blood spot sample for CF screening</td>
<td>To maximize accuracy of the screening test</td>
<td>Over 95% taken within defined period [day 21 – 24]</td>
<td>Over 70% taken on day 21</td>
</tr>
<tr>
<td>Standard 7b: Timely taking of second blood spot following a borderline CHT screening</td>
<td>To maximize accuracy of the screening test</td>
<td>Over 95% of second blood spot samples taken as defined</td>
<td>Over 99% of second blood spot samples taken as defined</td>
</tr>
<tr>
<td>Standard 7C: Timely taking of second blood spot for CHT screening for preterm infant</td>
<td>To maximize accuracy of the screening test</td>
<td>Over 95% of second blood spot samples taken as defined</td>
<td>Over 99% of second blood spot samples taken as defined</td>
</tr>
<tr>
<td>Standard 8: Clinical Pathology Accreditation (screening)</td>
<td>To maximize accuracy of the screening test</td>
<td>Lab CPA accredited</td>
<td></td>
</tr>
<tr>
<td>Standard 9: Timely processing of all CHT and IMD [excluding HCU] screen positive samples</td>
<td>To facilitate high quality and timely intervention</td>
<td>100% of screen positive results [excluding HCU] have clinical referral initiated within 3 working days</td>
<td>100% of screen positive results [excluding HCU] have clinical referral initiated within 3 working days</td>
</tr>
<tr>
<td>Standard 10: CPA (diagnosis)</td>
<td>To maximize accuracy of the diagnostic test</td>
<td>Lab CPA accredited</td>
<td></td>
</tr>
<tr>
<td>Standard 11: Timely receipt into clinical care</td>
<td>To facilitate high quality and timely intervention</td>
<td>Clinical appointment as defined by condition</td>
<td>Clinical appointment as defined by condition</td>
</tr>
<tr>
<td>Standard 12: Timeliness of results to parents</td>
<td>To report screen negative results in a timely manner</td>
<td>100% of babies with a not suspected result for each of the conditions for whom a not suspected results letter was despatched directly to the parents by CHRD within 6 weeks of birth</td>
<td></td>
</tr>
<tr>
<td>Standard 12b: Timeliness of results to parents [Movers in]</td>
<td>To report screen negative results in a timely manner</td>
<td>100% of babies with a not suspected result for each of the conditions for whom a not suspected results letter was despatched directly to the parents by CHRD within 6 weeks of notification of movement in</td>
<td></td>
</tr>
</tbody>
</table>

Full copy and explanation of latest standards [2017] can be found at:

Appendix 5: Blood Spot Sampling Guidance

EQUIPMENT REQUIRED

- UK NSC booklet ‘screening tests for you and your baby’ (parents should have a copy at least 24 hours pre-test)
- Baby’s NHS number/ bar code labels wherever possible
- Blood spot card (check expiry date) and glassine envelope
- Hand held maternity notes & personal child health record (PCHR)
- Tepid water for cleaning foot
- Protective gloves
- Automated incision device designed for use on newborns
- Sharps box
- Cotton wool/ gauze
- Hypoallergenic spot plaster (if required)
- Pre-addressed blue NBBS envelope

PREPARATION FOR TAKING THE SAMPLE

Ensure parents have a copy of ‘screening tests for you and your baby’ at least 24 hours prior to screening, in the appropriate language, (available in 11 languages, can be downloaded from https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief)

Gain verbal informed consent from the parent; discuss the procedure and document consent.

Parents should be asked if they wish to be contacted regarding research linked to the screening programme. If declined, write ‘no research contact’ on the blood spot card. New 2018

If parents decline screening, record declined (for all or each separate condition declined) in handheld notes, PCHR and on blood spot card. The Bloodspot card should then be sent to the laboratory, inform the GP and Health Visitor. Please note that individual metabolic disorders cannot be declined separately. Either all 6 are tested or none.

If parents decline all or part of the screening process, please request they contact the Antenatal and Newborn Screening Coordinator, if they change their mind. Screening will then be instigated.

Telephone number 01872 253092

TAKING THE BLOOD SPOT SAMPLE

- Complete details of card at time of sample. Use a bar code label if possible.
- Record the following in the comments box, if appropriate:
  1. Baby’s known medical history
2. Relevant family history e.g PKU, CF, etc
3. Mother's carrier status for Sickle Cell Disease.
4. Reasons for sample if not taken on day 5
5. Hospital code: REF

- Check all of the details on the card with the parent.
- Suggest comfort measures for baby. Ensure the baby is cuddled an in a secure position. Engaging the baby through face-to-face contact, voice and touch may be beneficial.
- Suggest the baby is breast feeding during the procedure if mother feels comfortable. If formula feeding, this may also help as a form of comforting the baby.
- Clean the heel with tepid water. Ensure the water is no warmer than if baby was going to be bathed. **DO NOT USE ALCOHOL WIPES. DO NOT USE ANY WARMING METHODS WHICH MAY INADVERTANTLY CAUSE HARM.** Allow to completely dry.
- Wash hands and apply gloves.
- Obtain sample using an automated incision device designed for newborns. For full term and pre-term infants, the external and internal limits of the calcaneus are the preferred puncture sites (see diagram A). Skin puncture must be no deeper than 2.0mm.

**Diagram A**

![Diagram A](permissions from the National Screening Committee gov.uk website.)

- Allow the heel to hang down to assist the blood flow, and place the device against the heel in accordance with manufacturers' instruction.
- Wait for the blood to flow. Allow one large spot of blood to drop onto each circle on a card. Do not allow the heel to make contact with the card. Do not squeeze the foot to increase blood flow.
- Fill each circle - do not layer the blood. Do not compress the blood onto the card- applying pressure can reduce the density of blood and can lead to a 'suspected' result being missed.
If the blood flow ceases:

The congealed blood should be wiped away firmly with cotton wool. Gently ‘massage’ foot, avoid squeezing.

If a second puncture is required:

This should be performed on a different part of the foot or on the other foot. When sample is complete wipe excess blood and apply gentle pressure. Apply a hypoallergenic plaster if required.

**AFTER TAKING THE BLOOD SPOT SAMPLE**

Allow the sample to air dry away from direct sunlight or heat, then place in glassine envelope. Dispatch sample on same day of taking. The laboratory needs to receive the sample as soon as possible or within 3 working days. **New 2018**

Document in notes and PCHR ‘red book’. Advise parents to contact their health visitor if results are not received within 6-8 weeks.
Pre-screening leaflets, “Screening Tests for You & Your Baby”, given antenatally by midwife, or at least 24 hours before screening test done

Leaflets available in 11 languages from website (https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief) or contact Screening Co-coordinator 01872 253092

Consent for screening given

Blood sample collected on day 5 and posted on day of collection to RCHT Post Room using pre-printed blue envelopes

Analysis at Bristol newborn screening laboratory. Lab sends results to CHRD

Informed choice

Screening test declined - Provide parents/carers with contact details in case of change of mind

Some tests declined - mark card, e.g., “decline CHT screening” (cannot decline individual metabolic disorders)

All tests declined – mark card “decline – all tests”

CMW informs HV, GP & Screening Co-ordinator (tel: 01872 253092) and sends card to Bristol lab (essential for failsafe procedures)

CHRD sends paper copy of result directly to parents

Newborn screening laboratory initiates the clinical referral process via Clinical Liaison Service [CLS]

Normal result

Suspected abnormal result

Repeat sample required

HV ensures results are entered into PCHR at next visit

Abbreviations
NICU – Neonatal Intensive Care Unit
CHRD – Child Health Records Department
HV – Health Visitor
PCHR – Parent Child Health Record
CLS: Clinical Liaison Service
CMW – Community Midwife
HO – Health Office

Some tests declined - mark card, e.g., “decline CHT screening” (cannot decline individual metabolic disorders)

All tests declined – mark card “decline – all tests”

CMW informs HV, GP & Screening Co-ordinator (tel: 01872 253092) and sends card to Bristol lab (essential for failsafe procedures)
Day 0

- Deliveries from elsewhere residing in Cornwall: this target to be picked by Failsafe mapped to delivery hospital
- Generation of NHS number automatically uploads to NBFSS – mapped to GP post code
- Deliveries within RCHT entered onto E3 (Links to CHRD/Health Intelligence)

Day 9

- Baby appears amber on NBSFSS list if no card arrived in lab
- Midwives send sample to RCHT and sent from Post Room Special Delivery to Bristol.
- Sample arrives in lab and processed by Screening Lab
- Sample acknowledged (01) to CHRDs in hard copy

Day 12

- Results acknowledged to CHRDs in hardcopy
- EDF completed at point of discharge and communicated to community
- Babies allocated to CMWs based on GP practice
- Visit to Mother/Baby arranged

Delivery Hospital

- Deliveries from Community entered onto E3 (Links to CHRD/Health Intelligence)
- Generation of NHS number automatically uploads to NBFSS – mapped to GP post code
- Deliveries within RCHT entered onto E3 (Links to CHRD/Health Intelligence)
Sample Tracking and Missed Babies

- Baby turns amber on Failsafe list
- Request midwife to take repeat, update excel tracker
- SCO contacts CMW of missing samples
- NBSFS updated with note to describe action
- LCO run Day 14 “Missing” Report from NBSFSS
- NBSFSS checked daily for cards not received. Lab contacted PM to check if sample arrived
- Baby turns red on Failsafe list
- Baby removed from Failsafe list
- Results acknowledged to CHRDs
- Comment added to failsafe list “sample received”
- Sample acknowledged (01) to CHRDs
- Sample processed by Screening Lab
- Sample Taken and sent to lab from RCHT using special delivery service
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Day 6
- Lab receives cards
- Sample acknowledged (01) to CHRDS in e-mail and
- Sample processed card and identifies problem with sample
- Repeat Request (03) faxed to CHRDS

Day 9
- Repeat Request (03) e-mailed to SCO
- Screening Coordinator contacts CMW to request new sample
- Screening Coordinator enters info onto failsafe database
- Visit to Mother/Baby arranged
- Baby turns amber on Failsafe list
- Baby removed from Failsafe list

Day 14
- CHRDS run Day 17 Missing Report – sent daily to SCO
- Results acknowledged to CHRDS
- Sample acknowledged (01) to CHRDS
- Sample processed by Screening lab
- Sample taken
- Midwives sends card to RCHT which are sent to Bristol using special delivery service
- Sample Taken
Moving in Day 0

**Day 0**

- **Child under 1 transfer into Cornwall:** CHIS inform CMC who open record

If born in UK and previous address known:
- CHIS chase results and input on CHIS

If no results found/ only 5 or transfer in from abroad:
- CHIS email CMC who email locality team to review if UK bloodspot completed, offer UK screen. If only 5 are recorded, offer screen for untested conditions

**Day 21**

- CHIS continue to complete daily failsafe report
- Sample processed by lab and results sent to CHIS with in 10days who record results on system: Positive results: lab follows referral pathways

Completed forms to be sent in preaddressed blue envelope through courier service

**Day 5**

- **Triage or named HCP contacts family to offer UK bloodspot screen:** refers to bloodspot rep HV to complete screen within 5 days and send to Bristol lab
  - If declined named HCP/triager completes form with declined

**OUTCOME**

All children without bloodspot results have been offered UK offer and all have results recorded by CHRD including declines