Clinical Guideline for the Newborn Blood Spot Screening Test

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7	21/10/2020	Alison Evans Pam Sizer	Checking details of the card with someone else - page 4 updated.
7.1	24/11/2020	Alison Evans Pam Sizer	Amendments of "Evidence of Practical Skill" on page 19. Record of Observed and Supervised Practice added to page 20.
8	19/04/2023	Charlotte Aldous	Inclusion of parental SCD status on NBBS card, process for declined NBBS, Antenatal/Newborn Screening email address updated, NHSE Key Performance Indicators, NNST competency pack criteria, updated STFYAYB hyperlinks

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Joint Clinical Guideline for the Newborn Blood Spot Screening Test (Guideline is no longer joint with JPUH or QEHKL)	July 2018

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:
Antenatal Screening Coordinator, Antenatal Screening Midwives, Lead Consultant Obstetrician for Antenatal and Newborn Screening, Community/Antenatal Clinic Matron).

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to individual Trust; please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

Contents Page

Introduction

Rationale

This guideline aims to provide a consistent approach to newborn blood spot sampling. It aims to support staff by outlining the procedure for gaining parental consent and describes best practice in sample collection technique. This will promote collection of good quality samples which will reduce the need for repeat samples. The guideline is in line with NHSE Standards and the UK National Screening Committee recommendations.

Objective

In health terms, screening is a method for identifying apparently well persons who may be at increased risk of a specific disorder/disease. Early detection of affected infants reduces long-term damage and improves morbidity. In addition, early diagnosis offers parents and family members more reproductive choice by identifying their carrier status prior to subsequent pregnancies. Newborn blood spot screening identifies babies who may have rare but serious conditions. The UK National Screening Committee (UKNSC) recommends that all babies are offered screening for 9 conditions:

- Congenital Hypothyroidism (CHT).
- Sickle Cell Disease (SCD).
- Cystic Fibrosis (CF).
- Medium Chain Acyl-Coa Dehydrogenase Deficiency (MCADD).
- Phenylketonuria (PKU).
- Maple Syrup Urine Disease (MSUD).
- Isovaleric Acidaemia (IVA).
- Glutaric Aciduria Type 1(GA1).
- Homocystinuria (Pyridoxine Unresponsive) (HCU).

The latter 6 are collectively known as Inherited Metabolic Disorders.

The screening programme aims to achieve early detection, referral and treatment of babies thought to be affected by any of these conditions with the aim to improve health and prevent severe disability, even death. Some of these conditions require treatment to commence by day 21 of age so it is imperative that the test is performed correctly at the right time.

Broad recommendations

The newborn blood spot screening programme consists of a series of stages and involves a number of different health professionals. This guideline provides important information associated with the screening test and outlines the role and responsibilities of the health professional offering and performing the test.

The health professional will need to assess individual requirements of those in her care to ensure advice is appropriate and understandable taking into account any translation requirements and/or sensory/cognitive impairment.

Scope

The purpose of document is to provide direction on the management and act of performing the Neonatal Screening Test (NNST). The scope of the document covers patients who are eligible for NNST screening at the Norfolk and Norwich Hospital or transfer their care to this trust. This guideline should be reviewed by all medical staff and implemented to prevent incidents occurring.

Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
CF	Cystic Fibrosis
CHT	Congenital Hypothyroidism
GA1	Glutaric Aciduria Type 1
HCU	Homocystinuria (Pyridoxine Unresponsive)
IVA	Isovaleric Acidaemia
MCADD	Medium Chain Acyl-Coa Dehydrogenase Deficiency
MSUD	Maple Syrup Urine Disease
NBBS	Newborn Bloodspot
NNST	Neonatal Screening Test
PKU	Phenylketonuria
SCD	Sickle Cell Disease

Responsibilities

All health care professionals to fully comply with this guideline to ensure timely review and management of results.

Policy Principles

Process

Information and consent

It is important to offer parents an informed choice about screening for their baby, to gain consent and to prepare them for the blood sampling procedure, when booking for maternity care, women should be directed to an electronic version "*Screening tests for you and your baby"* Screening tests for you and your baby (STFYAYB) - GOV.UK (www.gov.uk). This document discusses both antenatal and newborn screening tests including the Newborn Blood Spot and is available in English, a number of different languages in HTML versions and other formats including Easy

read versions and audio downloads. Paper copies can be provided to those with no internet access.

At least 24hrs before the test the parents should be reminded of the "*Screening tests for you and your baby"* document and advised to access and read.

These National pre-screening leaflets have been developed to enable parents to make informed decisions about all tests offered, including blood spot screening. A separate UKNSC leaflet is available on NICU, *"Babies in special care units: screening tests for your baby"* Screening tests for you and your baby: babies in special care units - GOV.UK (www.gov.uk).

- Explain fully to parents and then record in the maternity record or the baby's notes if being cared for on NICU, that newborn blood spot screening has been discussed and recommended, written information received and consent sought.
- Verbal consent is adequate.
- Parents should be asked if they consent to being contacted in the future for research linked to the screening programme, if not **"No research contact"** should be documented clearly on the card.
- Residual blood spots, the blood spots that are not used at time of screening, are kept by the laboratory for 5 years, they cannot be returned to the parents.
- Any baby having the NNST performed whose mother or father have a confirmed relevant medical history (e.g. Sickle cell disease) should have this clearly specified on the NNST card under 'Additional Information'.
- Ensure parents are aware that identifiable data may be stored by the National Sickle cell and Thalassaemia Screening Programme.

The blood spot sample should be taken on day 5 (date of birth is counted as day 0). It should only be taken after this day under particular circumstances i.e. if baby undergoing a blood transfusion.

Pre-arrange a convenient time to take the blood spot sample. At this stage, advise on keeping the baby, and particularly its feet warm prior to the test.

If the parents decline all or part of the screening

Since the introduction of the expanded inherited metabolic disorders parents can only accept or decline all of these conditions (PKU, MCADD, MSUD, IVA, GA1, HCU), not each one separately. They can decline the other conditions individually.

Record that screening has been declined on the electronic maternity record and personal child health record (PCHR) if it is available. Send the completed card marked as DECLINED to the NNUH as per usual process. The Antenatal Screening Team will forward this on to the screening laboratory. Complete 'birth details' section in the PCHR. Inform parents to contact their GP or Health Visitor if they change their minds or want further information. The NNST can be performed up to one year of age (however babies >56 days old are ineligible for Cystic Fibrosis screening).

screening laboratory will inform Child Health who will record the refusal on the system. The midwife should inform the child's GP (mother's GP if the child is not yet registered) and Health Visitor of any decline.

Completion of the card

It is imperative to firstly check the expiry date on the card prior to use. The clinician is responsible for confirming the baby's name, date of birth, NHS number and parents' contact details. Due to the potential for labelling/demographic errors it is recommended that the completed card details are checked with another person at the time of sampling, this is usually the mother or other parent/guardian. On NICU the sample may be taken, following consent, at a time when the parent or guardian is not present. The process for checking on NICU should include checking the card with another member of staff and signing on the "daily weight chart" to evidence this has been done.

Baby barcode labels should be printed at the time of delivery and are yellow to distinguish them from the mother's labels. The label includes the baby's NHS number and must be checked that it is complete and that the details are correct before giving them to the mother to take home. One is placed on each sheet of the card.

If a baby is fast tracked to NICU due to prematurity or requiring urgent care/assessment it is not possible to print the baby bar code labels immediately. As soon as they are printed they will be given to the NICU team who will check the details are correct and document on the admission checklist.

Where a baby has been transferred after delivering at another Unit, if there are no baby bar code labels available, these can be printed from the National Newborn Screening Bloodspot Failsafe IT system by the Antenatal Screening Team.

Using legible handwriting, the fields on the card not included on the bar code label must be completed.

All bloodspot samples taken by NNUH staff (whether maternity or NICU/Children's services) are required to have the **3-digit organisational code** for the Trust documented on the form under the heading "sample takers trust/org.name or mat code"**.** The code for the Norfolk and Norwich University Hospital NHS Trust is **RM1.**

The use of the code will enable the newborn laboratory to easily identify the maternity/neonatal unit in order to help:

- Accurately identify where requests for repeat tests/missing information should be sent.
- Create accurate acknowledgement lists to enable maternity units to track the samples taken and sent having been received in the screening laboratory, in order for timely identification of 'missing' or 'lost' samples.
- Allow laboratories to report 'avoidable repeat' rates by Trust.

If there is no bar code label available all boxes on the card must be completed in legible handwriting.

If a Maternity Care Assistant is taking the sample, she should document “MCA” where the “sample taker’s ID/PIN no” is requested.

The comments box should be completed with any known medical condition of the baby, relevant family history e.g. PKU, CF etc., mother’s carrier status for sickle cell and thalassaemia and reason if not taken on day 5 e.g. pre-transfusion, preterm CHT.

When completing the card, care must be taken to avoid contamination from a dirty surface or through touch.

Taking the Newborn blood spot sample

Explain the procedure to parents, record the parents’ consent to screening in the maternity record and the PCHR, if it is available, then proceed with test.

The baby can be cuddled during the procedure but must be held in a secure position for taking the sample. Engaging the baby through face-to-face contact, voice and touch may be beneficial. Analgesia in the form of breast feeding or non-nutritive sucking is recommended.

Clean the heel by washing thoroughly with plain tepid water. If faecal matter cannot be removed from the foot with water, use a mild, unperfumed soap to clean away the faecal matter and then rinse the foot thoroughly. **Do not use alcohol wipes.** The heel should be allowed to completely air-dry before taking the sample. The heel should be warm – if it feels cold gentle massage may be helpful. Additional warming of the foot is not required. Wash hands and apply gloves.

Allow the foot to hang down to increase blood flow. Before activation, place the automated lancet device against the heel in accordance with manufacturers’ instructions. Perform the test using an automated lancet device designed for use on newborns, a smaller lancet for preterm babies is available for use on NICU. **Manual lancets must not be used.**

The external and internal limits of the calcaneous are the preferred puncture site marked by the shaded areas in Diagram A. Where a baby has had repeated heel punctures the areas marked in Diagram B may also be used.

Skin puncture must be no deeper than 2.0 mm.

Adapted from Jain & Rutter [37]

Diagram A
For full-term and preterm infants

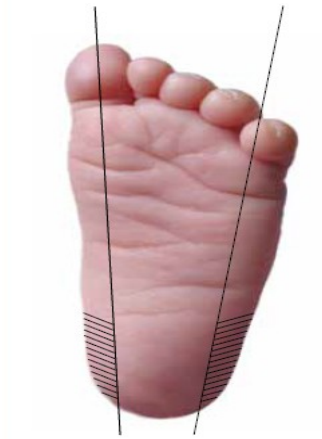
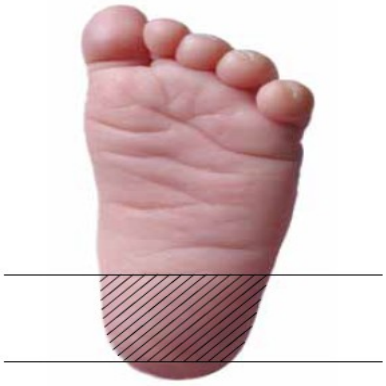
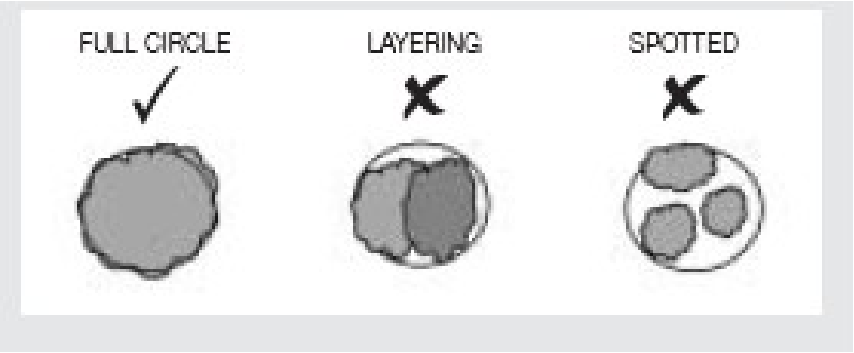


Diagram B
For infants who have had repeated heel punctures



Each circle on the Newborn Blood Spot Card must be filled completely using a **single** drop of blood. Allow blood to flow naturally, do not squeeze the foot. Direct one drop into each of the circles on the card allowing it to drip so it spreads evenly.

- The blood must seep completely through to the back of the card. There must be no layering of blood.
- **Do not** compress the bloodspot to ensure the blood has soaked through to the reverse of the card.
- **Do not** allow the heel to make contact with the card. Wipe excess blood from the heel and apply gentle pressure to the wound with cotton wool or gauze.



If the blood flow ceases:

The foot must not be squeezed as this may damage the blood cells to be tested and may cause bruising. The congealed blood should be wiped away firmly with cotton wool or gauze. Gently 'massage' the foot and drip the blood onto the card.

If the baby is not bleeding a second puncture is necessary: The second puncture should be performed on a different part of the same foot or on the other foot. Apply a spot plaster if required and remind the parent to remove in a few hours.

If more than 2 punctures are required consideration should be made as to whether the test should be completed at another time by a different member of staff.

After taking the Blood Sample

Allow blood spots to air-dry away from direct sunlight or heat before placing in the glassine envelope. NNST samples must be placed in printed envelopes to "Newborn Screening Midwives, via Pathology reception, level 1 East Block, NNUH. It is a national requirement that all NNSTs performed must reach screening laboratory within 3 working days of the sample being taken. Samples are tested at Addenbrookes Hospital Newborn Screening Laboratory. Therefore, the blood spot sample card must be taken to a GPs surgery and placed in green sample bag **the same day.** No NNST cards should ever be stored in a fridge as this will compromise the sample. Record the card's serial number and date and place of despatch of card in the baby's neonatal records or hospital buff folder, as well as the PCHR if available. Record date and time of sample on Badgernet if baby on NICU.

NNST samples will be delivered initially to the NNUH Pathology Laboratory via a specified courier service. These samples are collected Monday – Friday by the Antenatal and Newborn Screening team to quality check the documented data on the NNST card and complete audit trail. Following quality checking and auditing they are then couriered daily to Addenbrookes.

It is imperative that the laboratory receives the NNST sample promptly to ensure speedy detection of babies with possible conditions. Inform parents that results can be expected within 6-8 weeks and how they will receive them. If the baby screens positive they will be notified sooner.

The midwife must inform the health visitor at transfer of the screening status (i.e. tests completed, tests declined and any repeat testing required - See sections 5- Repeat Samples and 7- Special circumstances).

Results

Results are sent electronically by the Laboratory to the Child Health Department (Provide) for recording on the child health information system. Where all results are "condition not suspected" an automatically generated letter is sent to the parents from Child Health.

The Child Health Department regularly check the child health system to ascertain if the test had been done and contact the Midwifery team if no result or "decline" status is available by day 17. This allows a retest to be offered if a screening has been omitted or specimen lost. Communication is via the Antenatal & Newborn Screening generic email address – antenatal.newbornscreening@nnuh.nhs.uk

The National Newborn Bloodspot IT Failsafe system is in place in the Trust and is checked Monday – Friday as part of the screening failsafe process. If no sample or decline card received the system highlights a baby as amber from day 12, changing to red at day 14. The screening team print off a copy of any highlighted babies on the

tracking page daily to keep as an audit trail, documenting actions taken. Actions are also documented on the system's notes facility.

Repeats

Laboratory staff record receipt of the sample. The samples are checked for adequacy, if inadequate or for any other repeat required, a sample is requested via the Antenatal and Newborn Screening generic email address antenatal.newbornscreening@nnuh.nhs.uk

For all repeats ensure that the repeat sample box is ticked on the blood spot card.

If results are equivocal initially the laboratory will repeat the test using another spot on the original card. If it remains equivocal, a repeat sample is requested.

For CHT, babies born at less than 32 weeks (equal to or less than 31 weeks + 6 days) require a second blood spot sample to be taken in addition to the day 5 sample (counting day of birth as day 0). These babies are to be tested when they reach 28 days of age (counting day of birth as day 0) or day of discharge home, whichever is the sooner. Complete the details on the blood spot card as described in section 2 recording 'CHT preterm' on the card. Write the gestational age on the card. Two spots on the card should be filled with blood.

A one week interval between samples is recommended for borderline TSH results. Take a four blood spot sample and mark the card 'CHT borderline'.

When a baby has had a blood transfusion before day 5, delay taking the sample for 72 hours (3 clear days) after the last blood transfusion - document the date and time of transfusion end and time newborn bloodspot sample taken on the request form. In the event of multiple blood transfusions an initial screening sample should be sent by day 8 at the latest and repeat the sample 72 hours post transfusion. If an intra-uterine transfusion has been performed, count DOB as date of transfusion.

Inform parents and appropriate health professionals of any outstanding screening tests when transferring care or discharge.

Laboratories will request a repeat sample due to any of the following:

- Incomplete data on the card, e.g. no date of sample recorded.
- No NHS number (or equivalent) on the card.
- Bar-coded label not complete due to misalignment of label printer.
- Insufficient blood on the card, e.g. has not soaked through to back of card.
- Layering of blood.
- Compression of the blood spot.
- NNST sample packed wet.
- Delay in laboratory receiving the sample.
- Taken before 5 days of age.

- Second samples (for CHT preterm or post-transfusion) taken at wrong time.
- Contamination of the sample card, e.g. faeces, adult blood, etc.

When a repeat sample is requested for any of the above reasons, the sample should be taken as soon as possible but within 72 hours of the receipt of the request (unless ongoing transfusion).

Where a midwife has had 2 avoidable repeats in 3 months a competency package should be completed (see Appendix 2).

Positive results

There is a named paediatric consultant responsible for providing care for each condition identified on Newborn Screening. The Laboratory contact the named consultant directly by phone with an abnormal result, followed up by a hard copy. The named consultant or one of their team (including the Health Visitor) will contact the parents directly and offer an appointment, usually the next day, to discuss the result and organise care.

Written confirmation of the positive result will be sent to the GP. The screening laboratory will inform the screening midwives by email - 'for information'.

Special Circumstances – Babies nursed in Neonatal Intensive Care Units, born preterm and those who experience multiple blood spot samples taken from the heel.

Babies admitted to Neonatal Intensive Care Units are likely to have multiple blood samples taken. Blood Spot Screening should be coordinated with other tests. Venepuncture or venous/arterial sampling from an existing line is an alternative, this is providing the sample is not contaminated with heparin and the line cleared of infusate. An automated lancet device designed for newborns with a penetrative depth of no more than 1.0 mm is recommended for **preterm** infants. Then the whole plantar surface may be used but the posterior curvature of the heel must be avoided.

All babies will have an admission Blood Spot Sample for Sickle Cell and Thalassaemia and should be marked as "Pre-transfusion sample", in case a blood transfusion is necessary. The sample is stored with the baby's medical records and sent along with the day 5 sample. All boxes on both cards should be completed.

Preterm babies and those who have received blood transfusions will require repeat tests which are described in section 5 (Repeat samples).

Outstanding newborn screening tests should be recorded in the medical records, PCHR and in transfer/discharge letters. Inform parents of any outstanding screening tests.

Babies with siblings/known family history of any inherited metabolic disorders

Where there is known family history of an inherited metabolic disorder the pregnancy **must** be discussed with the specialist metabolic team early in the pregnancy to enable careful planning of the pregnancy and what treatment will be required by the baby before testing and results are known.

For family history of PKU, MCADD, MSUD, IVA and GA1 it may be that a blood spot should be taken at 12 – 72 hrs, condition dependent (see table – appendix 1), the bloodspot card documented with the family history and sent urgently, other tests may be required so prior planning is essential.

The laboratory should be contacted after delivery with baby details. Routine newborn bloodspot screening should follow on day 5 as usual. For HCU routine day 5 screening is all that is required.

Storage of blood spot cards

The blood spot cards are stored so that if required, one or more of the screening tests can be repeated to check a particular result. The stored blood spot specimen can also be used to test for some other disorders, which are not part of the screening programme. This may be useful if the child becomes ill and the doctor requests further tests, but this would always be discussed with the child's parents first. Anonymous testing may be performed to assist in the development of new screening methods. Where a sample needs to be identifiable, parental consent will always be obtained prior to the sample being used.

Key Performance Indicators

To ensure the Newborn Screening programme is fair and equitable, nationally standards are set by NHSE. The below Key Performance Indicators and Standards form the criteria for Newborn Bloodspot Screening:

ANNB NBS S03 Test: Barcoded NHS number label is included on the blood spot card The proportion of blood spot cards received by the laboratory with the baby's NHS number on a barcoded label.	**Acceptable:** ≥ 90.0% **Achievable:** ≥ 95.0%
ANNB NBS S04 Test and Intervention /Treatment: Timely sample collection. The proportion of first blood spot samples taken on day 5.	**Acceptable:** ≥ 90.0% **Achievable:** ≥ 95.0%
ANNB NBS S05 Test and Intervention /Treatment: Timely receipt of a sample in the newborn screening laboratory The proportion of blood spot samples received less than or equal to 3 working days of sample collection.	**Acceptable:** ≥ 95.0% **Achievable:** ≥ 99.0%
ANNB NBS S06 Test and Intervention /Treatment: Quality of the blood spot sample.	**Acceptable:** ≤ 2.0% **Achievable:** ≤ 1.0%

The proportion of first blood spot samples that require repeating due to an avoidable failure in the sampling process.	
ANNB NBS S07a Test and Intervention /Treatment: Timely taking of a repeat blood spot sample for CF inconclusive result The proportion of repeat blood spot samples taken at 21 to 24 days of age following a CF inconclusive result.	**Acceptable:** ≥ 80.0% **Achievable:** ≥ 90%
ANNB NBS S07b Test and Intervention/Treatment: Timely taking of a repeat blood spot sample following a borderline CHT screening The proportion of repeat blood spot samples taken between 7 and 10 calendar days following a borderline thyroid-stimulating hormone (TSH) result for CHT.	**Acceptable:** ≥ 80.0% **Achievable:** ≥ 90.0%
ANNB NBS S07c Test and Intervention/Treatment: Timely taking of a repeat blood spot sample for CHT screening for preterm infants. The proportion of repeat blood spot samples taken for CHT screening for preterm infants taken on 28 days of age or discharge home.	**Acceptable:** ≥ 75.0% **Achievable:** ≥ 85.0%

Screening Safety Incidents

Due to the nature and characteristics of screening tests, safety incidents within screening programmes require special attention and management. (Ref. no. 25) Where an incident occurs along any of the UKNSC screening pathways the Antenatal and Newborn Screening Coordinator should be informed and the UKNSC document “Managing Safety Incidents in NHS Screening Programmes” referred to.

Training & Competencies

All staff upon qualification will be proficient in providing the NNST to service-users. However, upon rotation to the community setting, midwives and trained Maternity Care Assistants (MCA) will be provided the opportunity to have a refresher session with the Antenatal Screening Team. This will involve discussion of the physical and documentations requirements in order to mitigate risk of avoidable repeat samples being required. Any midwife or MCA who performs two avoidable repeats in a three

month period will be required to undergo a competency package (Appendix 1) to ensure skills are developed to prevent recurrence.

Related Documents

NHSE, Newborn Bloodspot Guidance: Newborn blood spot sampling guidelines: quick reference guide - GOV.UK (www.gov.uk)

References

1. Guidelines for newborn bloodspot screening: 2021, NHSE
2. Managing Safety Incidents in NHS Screening Programmes: July 2021
3. Newborn bloodspot screening: Programme Handbook 2018. NHSE
4. NHSE, Screening tests for you and your baby, August 2022
5. UNICEF. The ten steps to successful breastfeeding http://www.babyfriendly.org.uk/page.asp?page=60

Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Review of Newborn Bloodspot quality	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Use of Newborn Bloodspot barcoded label	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Newborn Bloodspot sample collected on day 5	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Newborn Bloodspot received at lab within 3 working days	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Timely taking of a second blood spot sample for CF screening (21-24 days)	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Timely taking of a second blood spot sample following a borderline CHT screening (7-10 days)	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
: Timely taking of a second blood spot sample for CHT screening for preterm infant (by 28 days)	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly

The audit results are to be discussed at relevant governance meeting such as Clinical Governance, the Antenatal and Newborn Steering Group Meeting and externally at the NHSE Antenatal and Newborn Screening Board Meetings. These groups will review the results and recommendations for further action. Then sent to the relevant committee or Sub-Board who will ensure that the actions and recommendations are suitable and sufficient.

Appendices

Appendix 1: NHSE Newborn Bloodspot Screening Programme Handbook- Family History
Appendix 2: NNUH Maternity Competency Package

Appendix 1 NHSE : Newborn Bloodspot Screening Programme Handbook

Family History; When to take the sample

If there is a family history, early NBBS samples are recommended for some conditions. The table below summarises when to take NBBS samples:

Condition	Early sample	Routine sample	Comment for NBS card
Sickle cell disease (SCD)	No specific day	Day 5	Results of both parents
Cystic fibrosis (CF)	N/A	Day 5	Family history of CF
Congenital hypothyroidism (CHT)	N/A	Day 5	Family history of CHT
Phenylketonuria (PKU)	48 to 72 hours after birth	Day 5	Family history of PKU
Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)	24 to 48 hours after birth	Day 5	Family history of MCADD
Maple syrup urine disease (MSUD)	12 to 24 hours after birth	Day 5	Family history of MSUD
Isovaleric acidaemia (IVA)	24 to 48 hours after birth	Day 5	Family history of IVA
Glutaric aciduria type 1 (GA1)	24 to 48 hours after birth	Day 5	Family history of GA1
Homocystinuria (HCU)	N/A	Day 5	Family history of HCU

Early samples should be followed by the routine day 5 sample for the other conditions. When taking the day 5 sample, write on the blood spot card that it is a second sample and the reason for the early sample.

Appendix 2: NNUH Maternity Competency Package

Assessment of Competence For:

Documentation for assessing competency in Blood Spot Screening

Practitioner's name		
Department/Ward		
Assessors Name		
Training period	From:	To:

Competency developed by	Alison Evans – Antenatal and Newborn Screening Midwife
For use by	Registered Midwives and Band 3 MCAs
Review date *dd/mm/yyyy*	

This document has been compiled to support midwives and MCA's in maintaining their knowledge and clinical skills.

Objectives	To provide a competency framework to ensure a standard approach for individuals taking newborn blood spot screening
Competence Will Be Gained Through	*Detail how the competency will be achieved below e.g. private study, taught sessions, formal education, reflection, observation, Completing the pre reading and competency framework.*
Assessment	The Assessor may be a Registered Midwife and Band 3 MCA who has previously gained their competency in newborn blood spot screening. Assessment achieved through …… Detail assessment process. This may be: • Observational. • Verbal Question and Answers. • Written exercises. • Demonstration of practical skills.
Re-Assessment	3 years
Assessor Qualifications	Registered midwife and Band 3 MCA)who has previously gained their competency in Newborn Blood Spot Screening

Policy/Document/Recommended reading	**Completed**	
	Signature	**Date** *dd/mm/yyyy*
Joint Clinical Guideline for Newborn Blood Spot Screening Test		

Conditions screened for on Newborn Bloodspot sample

Congenital Hypothyroidism (CHT) - Incidence 1: 2000 babies born in UK	• Screening for CHT has been available since 1981. • The disorder is present when a baby is born with an absence or reduced amount of active thyroid tissue, or a hormone synthesis enzyme defect. • This results in a deficiency of the hormone produced by the thyroid (thyroxine or T4). • Babies with CHT may show prolonged jaundice, dry skin, coarse features, protruding tongue, slow feeding, bradycardia and constipation. • If the condition is untreated, physical and mental delay will usually follow. Treatment consists of replacing the equivalent of thyroxine by an oral dose of this hormone which should be started by day 21 of age. • Some babies with CHT may not show any clinical symptoms but biochemical abnormality can be detected by the laboratory screening test. • Thyroid stimulating hormone (TSH) is raised in CHT and is the basis of the screening test. Screening only detects primary hypothyroidism not secondary hypothyroidism. • TSH is measured in a dried blood spot utilising a specific immunological method. Babies born at less than 32 weeks (equal to or less than 31 weeks + 6 days) require a second blood spot sample to be taken in addition to the day 5 sample (counting day of birth as day 0). – see section 5 entitled Repeat Samples
Sickle cell disease (SCD) - incidence 1:2800 babies born in UK	Sickle Cell is an inherited disorder found mostly amongst people of African and Caribbean descent although it can occur in other ethnic groups. • Carriers of the disorder (Sickle Cell Trait, HbAS) are clinically well but untreated homozygotes (SCD, HbSS) are at risk of anaemia, recurrent infections and lifethreatening sickle cell crises. • The screening diagnosis allows treatment to be started early before children may have become unwell. • Treatment includes prophylactic administration of antibiotics and pneumococcal vaccine which should be started by 2 months of age • Carriers of sickle cell disease will also be identified through this screening test as possibly, will some other haemoglobin variants. • Beta thalassaemia major may also be detected, although this is not the aim of the test.

Cystic Fibrosis (CF) - Incidence 1:2,500 babies born in UK	In CF there is a problem transporting chloride across cell membranes. This affects certain organs in the body, particularly the pancreas and lungs. In patients with CF, the thick secretions in these organs cause digestive problems and chest infections. The abnormal transport of chloride in sweat glands leads to an increased level of chloride in their sweat which is the basis of the sweat test in confirming the diagnosis. A number of studies suggest that children who are diagnosed following newborn screening might be healthier than those diagnosed later. • Newborn screening may also reduce any delays in diagnosis, reducing anxiety and uncertainty about why a child is ill. • Early diagnosis of a baby with CF through newborn screening can also alert the parents to their risk of having other affected children. • Biochemical screening for CF uses a method to detect raised levels of immuno-reactive trypsinogen (IRT). • If the IRT is raised, DNA tests are performed to look for a number of CF gene mutations. This will identify babies who are carriers of these most common CF gene mutations.
Medium chain acyl-CoA dehydrogenase deficiency (MCADD) - Incidence 1:10,000 babies born in UK	MCADD is an autosomal recessive inherited condition which results from the lack of an enzyme required to metabolise fat into energy. This becomes significant when a child is unwell or not eating and needs to break down fat quickly to produce energy. • The inability to metabolise fatty acids to medium chain lengths quickly for energy leads to the formation of toxins. • Build-up of toxins can lead to lethargy, drowsiness, vomiting, seizures and coma. • Symptoms of MCADD would not be evident at birth and only present when a baby is not feeding or unwell. Equally, some individuals have the condition but never exhibit symptoms. • If MCADD is not identified at an early stage, up to a quarter of affected children may die from the condition, with one third of survivors sustaining significant neurological damage. • Treatment is to avoid fasting and monitoring of frequency of feeds/meals. The maximum “safe fasting time” is the length of time a baby/child can go without eating and varies depending on age.

Phenylketonuria (PKU) - Incidence 1:10,000 babies born in UK	The National Newborn Screening Programme (NNSP) has screened babies in the first weeks of life for PKU since 1969. The disorder is inherited with both parents being asymptomatic carriers. Classical PKU is caused by a deficiency of the liver enzyme phenylalanine hydroxylase, which converts the amino acid phenylalanine to tyrosine. Phenylalanine accumulates in the baby's blood leading to brain damage. • The high blood phenylalanine is measured by the laboratory to detect PKU. • The laboratory method used to detect high blood phenylalanine concentrations is Tandem Mass Spectrometry. • Babies with PKU do not show any clinical signs at birth but, without treatment, those with the classical form of the disease become severely and irreversibly mentally handicapped. • Treatment is by restriction of the intake of dietary phenylalanine which enables normal development and should start by day 21 of age.
Maple Syrup Urine Disease (MSUD) – incidence approximately 1: 150,000 born in UK	MSUD is an autosomal recessive inherited condition caused by deficiency of an enzyme leading to an inability to break down the amino acids, leucine, isoleucine and valine. • Accumulation of these amino acids leads to coma and brain damage. Babies usually become unwell within a few days of life presenting with irritability, lethargy, poor feeding, vomiting and seizures, they also have sweet smelling urine. • Treatment is a strictly controlled diet for life and an emergency regimen for when the child is unwell.
Isovaleric Acidaemia (IVA) – incidence approximately 1: 150,000 babies born in UK	IVA is an autosomal recessive inherited condition caused by deficiency of an enzyme leading to an inability to break down the amnio acid leucine. • Accumulation of the resulting Isovaleric acid can lead to vomiting, lethargy and coma. • Babies can become unwell within a few days of life and can present with excessive sleepiness, rapid breathing and floppiness. • Treatment is a strictly controlled diet for life, medication to breakdown toxins and an emergency regimen for when the child is unwell.

Glutaric Aciduria Type 1 – incidence approximately 1:300,000 babies born in UK	GA1 is an autosomal recessive inherited condition caused by deficiency of an enzyme leading to an inability to breakdown the amino acids lysine, hydroxylysine and tryptophan. This results in irreversible brain damage affecting muscles and movement. • It does not commonly present in the newborn but is usually diagnosed in the first year of life following an episode of metabolic decompensation causing encephalopathy, accompanied by infection and fever. • Treatment is a strictly controlled diet for life, medication to breakdown toxins and an emergency regimen for when the child is unwell.
Homocystinuria (HCU) (pyridoxine unresponsive) – incidence 1:300,000 babies born in UK.	HCU is an autosomal recessive inherited condition caused by a defect in the enzyme that helps in the breakdown of the amino acid homocysteine. There are 2 types of HCU, Pyridoxine (vitamin B6) responsive, usually identified in later life, and Pyridoxine unresponsive (about 50% of total HCU cases) which is the only type identified by newborn bloodspot screening. • Untreated it can lead to developmental delay, osteoporosis, eye problems, blood clots and stroke. • Some types of HCU can be controlled by taking vitamin B6, 12 and folic acid supplements (pyridoxine responsive). • For HCU pyridoxine unresponsive, treatment is a strictly controlled low protein diet as well as supplements.

Formative Assessment

1. Complete the national e-learning resource and watch the national video – community midwife discusses how she reduced her avoidable repeat rate – link https://vimeo.com/199649795/3478d86583. Link to E – learning resource https://portal.e-lfh.org.uk NHS Newborn Bloodspot Screening Programme (requires logging in).
2. Complete the practical assessment and review your learning objectives to ensure you can meet these and produce the necessary written work.
3. Ensure all documentation is complete and retain your portfolio as evidence.
4. WHEN your assessments are completed your assessor and will sign you off as competent to undertake this practice.

Action Plan (How do you plan to achieve the skill?)

Date for completion *(dd/mm/yyyy)*……

Date for review of progress *(dd/mm/yyyy)*
……..

Signature of Midwife…… **Date** *dd/mm/yyyy*……..

Signature of Assessor/Mentor…… **Date** *dd/mm/yyyy*……..

Levels of Practice

Evidence of Practical Skill

You are required to perform **up to 5** screening tests **(minimum of 3)** under direct supervision of another Registered Midwife before you can be assessed as competent in this skill.

Demonstrated (D)

Carries out or takes part in the activity under direct supervision. Practical skills may be slow or limited. Applies knowledge, skills and attitudes learnt within the training setting, to the practice setting. Understands the importance of relating research to practice.

Supervised (S)

Carries out or takes part in the activity without the need for direction but still requires intermittent direct supervision and support. Practical skills are improving and skills are being performed more quickly. Research can be assessed and applied to the practice setting.

Competent (C)

Works without direct supervision and is able to transfer knowledge and skills to new situations. Performs practical skills in a capable manner with improved speed of response. Recognises how practice can be changed based on research and can reflect on own practice in the light of experience.

Record of observed and supervised practice

	Date *dd/mm/yyyy*	Level of observed/ supervised skill	Candidate's signature	Assessor's signature
Patient 1				
Patient 2				
Patient 3				
Patient 4				
Patient 5				

Competence: Assessment of baby
Competence objective: **The Midwife/MCA will demonstrate competence in performing the newborn bloods spot screening test.** **KSF. A Dimension HWB2 Assessment and care planning to meet people's health and wellbeing needs.** **HWB5 provision of care to meet people's needs.**

Competence criteria *D = Demonstrated S = Supervised* *C = Competent*	D	S	C	**Comments**
Knowledge • Performs Newborn Blood spot on babies in accordance with legal professional and policy requirements. • Understands the rationale for Newborn Blood spot. • Has knowledge of anatomy and physiology applicable to Newborn Blood spot from the heel. • Is able to describe the procedure for obtaining a Newborn Blood spot from the babies heel. • Can discuss the factors that may help or hinder the procedure. • Can discuss the risk factors associated with this procedure. • Is able to discuss the correct procedures for minimising infection, including hand washing, use of aprons, gloves and aseptic technique. • Can discuss knowledge of safe disposal of equipment. • Is able to discuss the importance of accurate labelling of samples and completing request forms. • Can discuss the importance of record keeping.				

Practice • Identifies the patient correctly. • Explains the rationale for the procedure to the parents. • Gains informed consent from the parents and document. • Selects appropriate equipment and blood collection device. • Washes hands, wears gloves. • Positions the baby appropriately, recommending comfort measures e.g. breastfeeding, engaging in face to face contact, voice and touch. • Inspects the foot and avoiding underlying nerves and bone, selects the best site on the heel. • Cleans the site with tepid plain water and leaves foot to dry for at least 30 secs. • With the non-dominant hand holds the ankle with the foot flexed. • Pierces the skin with an appropriate newborn automated lancet (penetrative depth of 2mm for term infants) and disposes of the lancet directly in the sharps bin. • Allows the blood to form into large drops then collects blood as required. • When taking blood for the blood spot the circles must be filled completely by natural flow, one spot of blood to each circle, ensuring the blood seeps through to the back of the card. Avoids layering of blood. • The blood spot card must dry completely before being placing in the glassine envelope. Despatch within 24hrs. • Applies pressure to the site using a cotton wool ball and applies a plaster if necessary. • Encourages parents to calm baby. • Documents accurately in appropriate records. • Accurately labels the samples and ensure details match the request form.				

Final Assessment Newborn Blood Spot

Once competency has been reached in all the relevant areas in the preceding pages please complete the following.

I have assessed *print* …… **and have found him/her to be competent in the skill of Newborn Blood Spot**

Assessors signature…… **Name**……
……...

Date *dd/mm/yyyy*..... **Designation**……
...

Signature …… Name…… …… Date *dd/mm/yyyy*.....
……

I am confident in my ability to perform Newborn Blood spot in accordance with the organisation's policies.

I acknowledge my accountability to maintain my competence in line with the requirements of my professional body and/or job description

Candidates signature…… **Name**……
……...

Date *dd/mm/yyyy*..... **Ward**……
……

Candidate's comments on successfully completing a final assessment.

Re-assessment date *dd/mm/yyyy*.....

Competence record held by:…….....

Please ensure the relevant members of staff are aware that competence has been achieved and recorded as agreed by the approving committee/group/directorate.

Please ensure that a signed copy of the final assessment is placed in the individuals personnel file.

Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Women and Children's	**Department**	Maternity and Gynaecology
Name of person completing form	Charlotte Aldous	**Date**	19/4/2023

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	None	N/A	No
Pregnancy & Maternity	None	None	N/A	No
Disability	None	None	N/A	No
Religion and beliefs	None	None	N/A	No
Sex	None	None	N/A	No
Gender reassignment	None	None	N/A	No
Sexual Orientation	None	None	N/A	No
Age	None	None	N/A	No
Marriage & Civil Partnership	None	None	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?		N/A		

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.