Tower Hamlets GP Care Group
Blood Spot Screening of the Newborn policy

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Title	Blood Spot Screening of the Newborn
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Approved by		

Blood Spot Screening of the Newborn Policy

Contents

1. Introduction

The GP Care Group have a vision to respond to the health and social care needs of its population by providing high quality, accessible services which meets individual and family needs. It aims to provide guidance to the highest standards to ensure regulated and efficient practice within the organisation.

The aim of this policy is to outline the roles and responsibilities of all Tower Hamlets GP Care Group staff involved in the National Bloodspot Screening Programme (1) (March 2016). Clear guidance is required to ensure that all local procedures act in accordance to the national standards set out by Public Health England.

Purpose

The Newborn bloodspot screening (NBS) programme is offered to all children under the age of one year in the UK and aims to screen them for a series of rare but potentially serious conditions. Screening is necessary to ensure early detection, rapid diagnosis and treatment to improve the health and wellbeing of all babies and avoid serious ill health or death.

It is also offered to babies under the age of 1 who are born overseas but become residents in the UK, if there is no document to suggest that screening has been carried out. When babies are between 5-8 days of age, the midwife or other health professional will prick their heel and collect 4 blood samples on to the newborn bloodspot card. In instances where the child is older but it has been made known that screening has not taken place, the blood spot is taken as soon as possible. The bloodspot card, once completed is then sent to Great Ormond Street Hospital for processing in line with the UK National Screening Committee (UK NSC), which recommends that all babies are offered screening for the following nine conditions;

- Cystic fibrosis (CF)
- Congenital hypothyroidism (CHT)*
- Glutaric Aciduria Type 1 (GA1)
- Homocystinuria (HCU)
- Isovaleric Acidaemia (IVA)
- Maple syrup urine disease (MSUD)
- Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)
- Phenylketonuria (PKU)
- Sickle cell disease (SCD)

Screening is important for the early detection of these nine conditions. Without treatment and intervention, there can be serious implications which clinicians should be aware of and are highlighted in the table below;

SCD	severe pain, life-threatening infections and anaemia (symptoms can be present even with treatment)
CF	poor weight gain, frequent chest infections and reduced life expectancy (symptoms can be present even with treatment)
CHT	permanent, serious physical problems and learning disabilities
PKU	permanent brain damage and serious learning disabilities
MCADD	serious illness and possible death
MSUD	coma, permanent brain damage and possible death
IVA	coma, permanent brain damage and possible death
GA1	coma and neurological damage
HCU	learning difficulties, eye problems, osteoporosis, blood clots or strokes

Consent

All babies in the UK are offered screening but parents can make an informed choice and are within their rights to decline. Clinicians should ensure that they explain to parents why the blood spot screening test needs to be carried out and provide them with a copy of the booklet; *Bloodspot tests. An easy guide to screening tests for your new baby* (Public Health England, 2017). Should a parent decline for one or some conditions, a bloodspot card should be completed accordingly or if all tests are refused, a bloodspot card should still be completed and sent off to complete the process.

The NHS Bloodspot Screening Standards (PHE, 2017), replaces the standards for newborn bloodspot screening (PHE, August 2013). 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 must meet to ensure local programs are safe and effective.

Quality assurance 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.

Information for Parents

Public Health England has developed a series of publications for health professionals to provide to families about blood spot screening. These information leaflets are available in several different languages and can be accessed on:
https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief

Parents Who Decline Retesting

If a positive result is identified and parents decline retesting, the practitioner should explore the reason for their decision and offer further information. However, parents should not be pressured to carry out a repeat test and should be allowed to make an informed choice.

Health visitors must document on the child's EMIS records and personal child health record (PCHR, 'red book') when a parent has declined retesting. It should also be recorded on the newborn screening blood spot test card. Practitioners must ensure that the parents are informed of the risks to the child should they decline retesting and be offered further information as well as contact details/processes should they change their minds. The General Practitioner (GP) should also be informed in writing when parents decline retesting.

Sample letter templates for GPs, Parents and movers in for parents who decline newborn blood spot screening are available at;
https://www.gov.uk/government/publications/declined-newborn-blood-spot-screening-template-letters

Looked After Children

Children who are under the care of the Local Authority, the practitioner must obtain consent from the person who has parental responsibility (PR) and must be documented on the child's EMIS record.

2. UK Newborn Blood Spot Screening Standards

The 12 key national standards for the NHS Newborn Blood Spot (NBS) Screening Programme have been revised and the changes are highlighted in Table 1 below.

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	Newborn screening laboratories

	Change to thresholds to reflect data	
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 responsibility at birth)**	▪ Standard retained ▪ Audit tool to be developed to measure standard	CHRDs
Standard 12b: **Timeliness of results to parents (movers in)**	▪ New standard 12b ▪ Audit tool to be developed to measure standard	CHRDs

3. The Process Standards

Table 2 summarizes the 12 national standards for the New Born Blood Spot Screening Programme. These standards are a set of measures used to ensure safety and efficacy of local programmes and are used by commissioners to assess processes and highlight further developments for future performance. Each standard consists of three key areas which determine what is measured. These are; objective- aim of the standard, criteria- what is assessed, measure- two thresholds (acceptable & achievable). The acceptable threshold defines the minimum level of performance which programmes are expected to meet. The achievable threshold represents the best level at which the programme can run.

Standard	Criteria	Performance Threshold	Data Source	Reporting Focus
Standard 1a: **Identify the population and coverage: Coverage (CCG responsibility at birth)**	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.	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.	CHRDs	CCGs
	The proportion of all babies eligible for NBS screening who: -have changed responsible CCG in the first year of life; or -have moved in	Acceptable: ≥ 95.0% of eligible babies have a result for each of the 9 conditions (or 5 conditions if not eligible for expanded screening)	CHRDs	CCGs

Standard 1b: **Identify the population and coverage: Coverage (movers 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.	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.		
Standard 2 Coverage: **Timely identification of babies with a null or incomplete result recorded on the CHIS**	The CHRD has a process in place to identify babies with a null or incomplete NBS result that meets the standard	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	CHRDs	CHRDs

		days with a null or incomplete result.		
Standard 3 **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% 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.	Newborn screening laboratories	Maternity services
Standard 4: **Test and Intervention/Treatment: Timely sample collection**	The proportion of first blood spot samples taken on day 5.	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.	Newborn screening laboratories	Maternity services
Standard 5: **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% 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.	Newborn screening laboratories	Maternity services
	The proportion of first blood	Acceptable: Avoidable repeat	Newborn screening	Maternity services

Standard 6: **Test and Intervention/Treatment: Quality of the blood spot sample**	spot samples that require repeating due to an avoidable failure in the sampling process.	rate is ≤ 2.0%. Achievable: Avoidable repeat rate is ≤ 1%.	laboratories	
Standard 7a: **Test and Intervention/Treatment: Timely taking of a second blood spot sample for CF screening**	The proportion of second blood spot samples taken as defined for individual tests.	**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	NBS programme via NBSFS	Maternity services
Standard 7b: **Test and Intervention/Treatment: Timely taking of a second blood spot sample following a borderline CHT screening**	The proportion of second blood spot samples taken as defined for individual tests.	**Acceptable:** ≥ 95.0% of second blood spot samples taken as defined. **Achievable:** ≥ 99.0% of second blood spot samples taken as defined.	NBS programme via NBSFS	Maternity services
Standard 7c: **Test and Intervention/Treatment: Timely taking of a second blood spot sample for CHT screening for preterm infant**	The proportion of second blood spot samples taken as defined for individual tests.	**Acceptable:** ≥ 95.0% of second blood spot samples taken as defined. **Achievable:** ≥ 99.0% of second blood spot samples taken as defined.	NBS programme via NBSFS (date of discharge is not known, so as proxy, earlier than day 28 will be assumed as day of discharge)	Maternity services
	The proportion	**Acceptable:** 100%	Data source:	Newborn

Standard 9: **Intervention/Treatment: Timely processing of CHT and IMD (excluding HCU) screen positive samples**	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.	of babies with a positive screening result (excluding HCU) have a clinical referral initiated within 3 working days of sample receipt by screening laboratory	Newborn screening laboratories	Screening laboratories
Standard 11: **Intervention/Treatment: Timely entry into clinical care**	The proportion of babies referred to specialist services that are seen by the condition-specific standard.	*N.B. Performance thresholds are condition specific. *See Table 3 below*	Newborn screening laboratories (anonymized baby level data on all screen positive babies)	Newborn screening laboratories

Condition	Intervention/Treatment	Thresholds
IMDs (excluding HCU) and CHT (suspected on first sample)	Attend first clinical appointment by 14 days of age	**Acceptable:** 100%
CHT (suspected on repeat following borderline TSH)	Attend first clinical appointment by 21 days of age	**Acceptable:** 100%
CF (2 CFTR mutations detected) and HCU	Attend first clinical appointment by 28 days of age	**Acceptable:** ≥ 95.0% **Achievable:** 100%
CF (1 or no CFTR mutation detected)	Attend first clinical appointment by 35 days of age	**Acceptable:** ≥ 80.0% **Achievable:** 100%
SCD	Attend first clinical appointment by 90 days of age	**Acceptable:** ≥ 90.0% **Achievable:** ≥ 95.0%

4. Roles and Responsibilities

Midwives

Midwives are responsible for obtaining the newborn blood spot sample from babies around day 5-8 and have a duty up until day 28 for newborn blood spot screening. If a repeat sample is needed for infants under the age of 28 days, the onus of responsibility remains with midwifery services.

Neonatal Unit

When a baby is born preterm (<37 weeks) it is the responsibility of neonatal staff to ensure a blood spot sample is taken before discharge. For babies born before 32 weeks' gestation (≤31 weeks + 6 days) will not require a repeat test after 28 days. Transfused infants no longer require repeat testing at 4 months.

Child Health

Child Health Information Service (CHIS) are responsible for reporting newborn blood spot to NHS England. They are required to inform health visiting teams of infants who transfer in where the new born blood spot result is not known/recorded.

The following list highlights the roles and responsibilities of the child health department:

- The coordination of all blood spot screening requests.
- Repeat blood spot samples when;
- Insufficient blood sample
- Babies born prematurely and reach 36 weeks of age
- Results from the first sample is borderline for a condition
- Babies have had a blood transfusion
- Babies up to the age of 1 who have moved into the area and have no record or an incomplete record of blood spot screening recorded.
- Notifying health visiting team for babies who are carriers of sickle cell and cystic fibrosis disorders
- Reporting and discussing incidents or near misses to the strategic implementation group and operational managers
- Keeping a database for audit purposes as part of the clinical governance process to feedback at regional and local level.

Health Visitors

Health Visitors are responsible for all newborn blood spot screening for all babies from 29 days and up to 1 year of age.

- Health visitors should establish at the new birth visit that the newborn blood spot sample has been carried out by the Midwife by reading the notes within the Personal Child Health Record (PCHR or 'red book') and then document this on EMIS. Where this is missing, the Health Visitor should contact the Midwives to discuss this further and refer to midwifery services if required.

- If a repeat test is required when the infant is under the age of 28 days, this should be referred to Midwifery services.

- The health visitor will discuss with the parents/carers at the new birth visit, when they will receive the results of the screening test.

- If a baby is over the age of 28 days and has not been screened, the health visitor/community staff nurse should contact the Child Health department. They should then undertake the repeat blood spot screening as per procedure.

- Health visitors who receive results that a baby is a healthy carrier for sickle cell disease or cystic fibrosis, should document this on the child's EMIS record and Personal Child Health Record (PCHR/red book).

- For all 'not suspected' results received from Child Health, will be recorded on the child's EMIS records. Health visitors should inform parents/carers at the 6-8 week contact and record this in the PCHR (red book).

- There may be an instance where sickle cell results are identified as 'not suspected', however abnormal levels have been detected and therefore a repeat test will be required at 6 months of age to determine whether abnormal bands are still present. The screening laboratory will notify the Child Health Department when the repeat test is due and Child Health will inform the Health Visiting Team. Health visitors should ensure they keep parents/carers updated on all results and notify them if further testing is necessary. All results should be recorded on the child's EMIS record and PCHR (red book).

- If there are no results received by the 6-8 weeks' appointment, health visitors/staff nurse will need to contact the Child Health Department to follow up the results.

Movement/Transfer In

Health Visitors who come across infants under one year of age who have moved into the area and who are reported to have been screened must ensure they provide evidence in the form of a written confirmation of results. For infants born within the UK, evidence can be obtained from Child Health or from documented evidence within the PCHR.

If there is no proof of screening, the health visitor should assume the baby has not been tested and discuss re-testing with parents and complete the newborn blood spot screening test if consent is given. If the baby is older than 8 weeks of age, blood spot screening should be offered for MCADD, PKU, CHT and sickle cell disorders. Health visitors/staff nurse should inform parents/carers that screening will not identify cystic fibrosis as serum levels return to normal after 8 weeks. This process also applies to babies under the age of one year, born outside of the UK.

5. Positive Results

The Newborn screening laboratory will contact the appropriate specialist services once a positive result has been identified. The health visitor will be notified of suspected abnormal result by CHIS. If there is a positive result for cystic fibrosis, the health visiting team will be contacted by the specialist nurse in the hospital to request for the health visitor to arrange a joint visit to discuss the results and care plan with the family. The purpose of this is to enhance partnership working and provide support to the child and family on a long-term basis.

6. Blood Sampling Guidelines

The procedures for carrying out the newborn blood spot sampling can be downloaded at:
https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines

A short film guide demonstrating the discussion practitioners should have with parents/carers around the blood spot sampling procedure can be accessed on:
https://cpdscreening.phe.org.uk/cms.php?folder=5295

An e-learning resource which provides clinicians with a practice interactive blood spot card can be found on the following link:
https://cpdscreening.phe.org.uk/interactivecard.php

7. Performing the Heel Prick

1. Parents should give verbal consent which should also be documented on the child's EMIS records.

2. Blood spot sampling card should be completed with the baby's name and barcode label (if barcode label is unavailable, NHS number should be handwritten on the card).

3. Verbally confirm with parents the baby's name, date of birth, parents/carers contact details and any relevant medical history i.e. parent's carrier status.

4. Explain the procedure to the parents/carers.

5. Recommend measures to comfort the baby and reduce pain. This can be done through feeding, sucking, stimulating the baby through voice and touch to ensure they are calm.

6. Ensure the infant is suitably positioned/cuddled to take the sample securely.

7. Before the sample can be taken, practitioners must ensure that the heel is clean. The use of alcohol wipes/disinfecting the skin prior to the procedure is not necessary. Health professionals are advised to clean the heel with plain water and cotton wool gauze. The water should not be heated and the baby's foot should not be immersed. Allow the heel to dry thoroughly before taking the sample.

8. Clinicians should wash and dry hands thoroughly and then wear gloves.

9. Warming of the foot is not required.

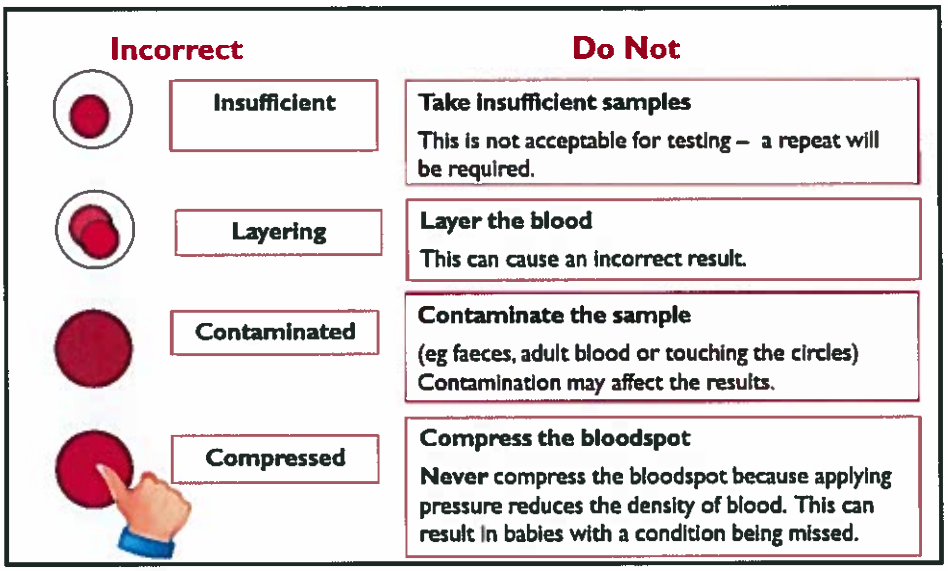
10. Perform the test using age appropriate automated incision device (manual lancets must not be used). An arched shape incision device is recommended. Depth of incision should be less than or equal to 2.0mm.

11. Allow the heel to hang down to increase blood flow to the foot. Before activation, place the automated incision device against the heel. Heel puncture should be performed on the plantar surface of the heel, beyond the lateral and medial limits of the calcareous. N.B See shaded area on the image below.

Figure 1

1. For baby's who have had repeated heel punctures, an automated incision device with a penetrative of no more than 1mm is recommended.

2. Puncture the heel and wait up to 15 seconds to allow blood to flow. The aim is to fill each circle on the blood spot card using a single drop of blood for each circle. Apply the blood drop to one side of the card, allow the blood to fill the circle by natural flow and seep through to the back of the card. Fill the circle completely and AVOID layering blood. See image below.



1. Repeat procedure for each circle, ensuring that each sample permeates to the back of the card.

2. There is no need to discard the first blood drop.

3. Do not allow the heel to make contact with the card.

4. Do not squeeze or apply pressure to the foot in an attempt to increase the blood flow.

5. Wipe excess blood from the heel and apply gentle pressure to the wound with a cotton wool ball.

6. If the blood flow ceases the following steps apply:

   - Congealed blood should be wiped away firmly with cotton wool or gauze.
   - Gently massage the foot, avoid squeezing and drop the blood on to the card.
   - If the baby is not bleeding, perform a second puncture on a different part of the same foot or the other foot.

7. Apply a hypoallergenic spot plaster if required and remind parents to remove the plaster after a few hours.

8. Allow blood spots to air dry before placing the card in the glassine envelope.

9. Dispatch the blood spot card in the pre-paid/stamped addressed envelope (first class) on the same day (if not using a courier). If this is not possible, dispatch within 24 hours as dispatch should not be delayed in order to batch blood spot cards together for postage.

10. For further information on dispatch guidance, see Standard 4 in the guidelines for newborn blood spot sampling quick reference guide; https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines

11. Record the completion of the test in the PCHR ('red book') and child's EMIS.

Clinical Incidents

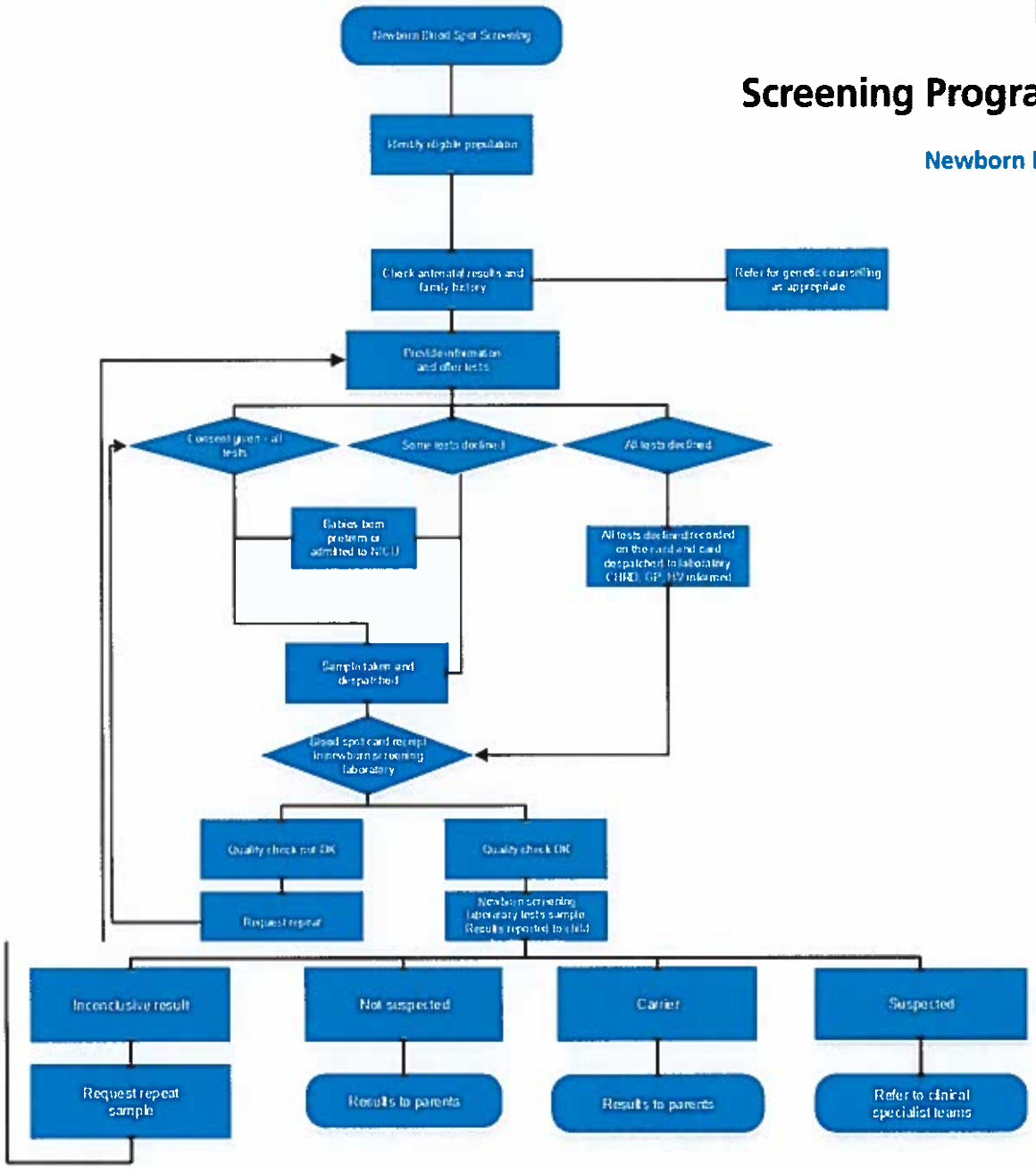
Any related incidents from carrying out these procedures, which may involve clinical error or near miss, must be reported following the Tower Hamlets GP Care Group Incident Reporting Policy.

Appendix 1

NHS

Screening Programmes

Newborn Blood Spot



Appendix 2


Flowchart for Repeat Blood Spot Tests
Laboratory will contact Bloodspot Screening Link Coordinator at Child Health Department if a repeat test is required.
Screening Coordinator will contact relevant Health Visiting Team/Health Visitor informing them that a repeat blood spot test is needed and will give details of the Child.
Health Visitor/Staff Nurse will contact the family, informing them that a repeat test is required, informing the family of the reason for the request. A visit will then be arranged in line with the Lone Worker Policy.
Informed consent for the repeat blood spot sample must be obtained and documented in the personal child health record (PCHR, 'red book') and child's EMIS record. Newborn Screening procedure for performing the heel prick test, must be followed.
Health Visitor/Staff Nurse to record the sample taken in the PCHR and child's EMIS record. Sample should then be sent by post on the same day that the sample was taken. Samples should NOT be sent in internal post.
Health Visitor/Staff Nurse to e-mail Screening Link Coordinator, informing them that the blood spot test has been completed and posted.

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