Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

The National Healthy Childhood Programme

Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

Is this document a:

Policy	**Procedure**	Protocol	Guideline
	x		

HSE Acute Operations *– Maternity Hospitals/Units*
HSE Community Operations Primary Care- *– Public Health Nursing, Community Midwives, Self Employed Community Midwives, Private Midwives*
National Newborn Bloodspot Screening Programme Governance Group

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4	17th May 2022	All Sections reviewed and updated	NNBSP Review Working Group

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PART A: Outline of PPPG Steps

Infant	Applicable up to one year of age
NBS	Newborn Bloodspot Screening
NBSC	Newborn Bloodspot Screening Card
NNBSL	National Newborn Bloodspot Screening Laboratory
NNBSP	National Newborn Bloodspot Screening Programme

For simplicity of language, this guideline will use the term 'female' or 'mother' throughout, and this should be taken to include people who do not identify as female but who have given birth and also for females who have given birth but the baby may not be with them due to fostering, adoption, hospitalisation of the baby and/or mother. Similarly, where the term 'parents' is used, this should be taken to include other people who are the baby's primary caregivers and single parents (NICE 2021).

A.1 Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

A 1.1 Maternity Hospital/Unit Births and NNBSP

Maternity Hospitals/Units, both within the Republic of Ireland (ROI) and Northern Ireland, notify the Local Health Office (LHO) of all infants born and who reside in the designated LHO (Appendix V). This may be notified to the Child Health Office/DPHN Office/Birth Notification Office and Primary Care Unit Management depending on local arrangements.

A 1.1.1 The Maternity Hospital/Unit ascertains if the newborn bloodspot screening (NBS) sample is scheduled to be obtained in the hospital or the community or tertiary hospital.

A 1.1.2 The Maternity Hospital/Unit:

- Maintains a birth register for all infants born in the hospital/unit.
- Issues the **Unique Perinatal Identifier (UPI)** number for all infants born in the Maternity Hospital/Unit (Appendix VI). It is noted that the UPI will be replaced by the Individual Health Identifier (IHI) when implemented.
- Maintains a Newborn Bloodspot Screening (NBS) register for infants who have their NBS sample taken while in the Maternity Hospital/Unit.
- For all samples obtained in the Maternity Hospital/Unit, the Newborn Bloodspot Screening Cards (NBSCs) must be forwarded to the National Newborn Bloodspot Screening Laboratory (NNBSL).

A 1.1.3 The Maternity Hospital/Unit is responsible for completing the NBS for all infants on the wards and in the Special Care Baby Unit (SCBU)/Neonatal ICU between 72 and 120 hours following the birth and also for any repeat NBS samples required for in-patient infants. Frequency of sampling is referred to in the Practical Guide to Newborn Bloodspot Screening in Ireland (8th Edition).

A 1.1.4 Arrangements may be put in place for the NBS to be obtained by the Maternity Hospital/Unit staff following discharge, for example outpatients, Community Midwifery team visiting in the home (e.g. domino, early transfer home teams).

A 1.1.5 If infants are being discharged without the NBS completed, the Maternity Hospital/Unit is responsible for notifying the relevant designated Local Health Office (LHO) Public Health Nursing Service of the requirement to carry out the NBS.

A 1.1.6 In the case where the Maternity Hospital/Unit wish to review the infant, the Director of Midwifery and/or Nursing (DOM/N)/designated staff member may issue an appointment for the infant to return to the hospital for follow up/review during the designated timeframe for which the NBS can be undertaken. The Public Health Nursing Service must be informed of the birth and that the NBS will be undertaken in the hospital during the review visit NBS.

A 1.1.7 The Maternity Hospital/Unit may request that mother and infant return to the Maternity Hospital/Unit at weekends/bank holidays/extended holiday periods, to facilitate early discharge and when the Public Health Nursing Service is not available. The Maternity Hospital/Unit of birth is responsible for ensuring that the NBS is taken. The Public Health Nursing Service must be informed of the birth and the plan for undertaking the NBS.

A 1.1.8 If infants are being transferred to a tertiary hospital, the transferring Maternity Hospital/Unit is responsible for notifying the relevant tertiary hospital in their transfer referral documentation of the requirement to carry out the NBS. (Refer to A 1.3).

A 1.2 Maternity Hospital/Unit Notification of NBS Request to PHN Service

A 1.2.1 If the NBS is scheduled to be obtained by the PHN service, the DOM/N/designated staff member is responsible for ensuring that:

- The designated officer in the LHO is notified of the birth.
- The DPHN/Child Health Office is informed that the infant has been discharged prior to the sample being carried out and is notified of the request for NBS to be obtained by the PHN service.
- The Maternity Hospital/Unit should provide two confirmed phone contact details of Parent(s)/legal Guardian(s) and the Eircode if known.
- Where a Parent(s)/legal Guardian(s) and infant are staying at a temporary address, e.g. grandparents house, this should be made clear on the NBS request to the PHN service.
- The date the NBS sample is due to be taken should be indicated on the NBS request.
- The following information is provided and correct:
  - Infant's UPI number
  - Time of Birth
  - Date of first feed
  - Type of feed
- The mother has been given the Parent Information Leaflet –"*What you need to know about Newborn Bloodspot Screening – heel prick"* (Appendix VII).

- Notification to the DPHN of the infection status of the child or mother if relevant; e.g. HIV, Hepatitis B (**this would necessitate Biohazard packaging for the NBSC**).

- In the case of a family and infant relocating and/or returning to reside in ROI (from outside ROI) prior to the NBS, it is the responsibility of the Maternity Hospital/Unit where the infant is born to inform the DPHN for the designated LHO that the infant and family is relocating/returning to the ROI, within the timeframe for the sample to be taken (72-120 hours). (See section A 1.7.2 – A 1.7.4)
- Maternity Hospitals/Units can use the Health Atlas address finder facility to help check the location of the appropriate LHO for the infant (https://finder.healthatlasireland.ie/)

A 1.2.2 Where a request for NBS comes from a Maternity Hospital/Unit to an incorrect LHO, the DPHN/LHO must return the NBS request to the Maternity Hospital/Unit and provide the correct LHO details. The Maternity Hospital/Unit must correct this information and send the request to the correct LHO as soon as possible to avoid delays in sample taking.

To minimise the risk of delayed screening a representative of the DPHN office should contact the correct LHO to inform them of the pending NBS request.

A 1.2.3 In addition to the above, Northern Ireland (NI) Maternity Hospitals/Units will contact the Public Health Nursing Service/LHO and request:

- The Public Health Nursing Service Office/Child Health Office to issue the Infant's **Unique Perinatal Identifier** (UPI) number (Appendix VIII). It is noted that the UPI will be replaced by the Individual Health Identifier (IHI) when implemented.

A 1.3 Maternity Hospital/Unit Notification of NBS request to Tertiary Hospital Paediatric Unit

A 1.3.1 It may be necessary for an infant to be transferred to a tertiary hospital for continuing medical and/or surgical treatment before the NNBSP has been completed.

A 1.3.2 The nurse/midwife responsible for the transfer of an infant from a Maternity Hospital/Unit to a tertiary hospital paediatric unit must inform the receiving unit that NBS is required and provide them with the infant's UPI.

- The infant's UPI issued by the Maternity Hospital/Unit must be used on all NBS samples sent to the NNBSL even when an infant is transferred to a Tertiary Hospital Paediatric Unit.

- If an infant is transferred to a Tertiary Hospital Paediatric Unit and an NBS sample (initial and/or repeat) is required the Hospital Chart Record Number (HCRN) of the transfer hospital must be included in the appropriate space on the NBSC.
  - For example if an infant is born in Midland Regional Hospital Portlaoise (MRHP) a UPI of 201-XXXXXXX is generated for that infant. If they are transferred to a Children's Health Ireland Hospital (e.g. CHI at Crumlin) and a newborn bloodspot sample is required to be taken, the MRHP UPI is recorded at the top of the screening card and the CHI Crumlin

HCRN is recorded in the 'Infant's healthcare record number (if transferred to another hospital)' field on the NBS card – See Figure 1.

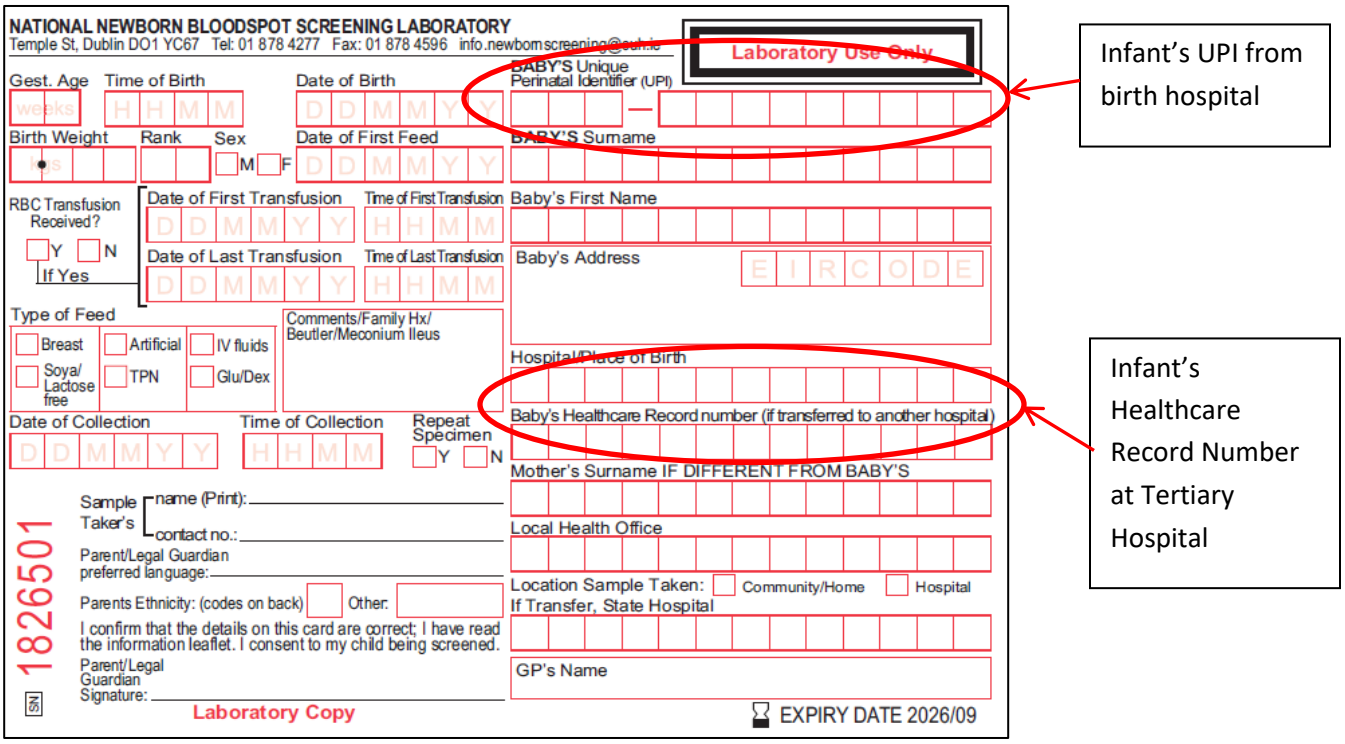


Figure 1: Newborn Bloodspot Screening Card Data Fields

A 1.3.3 The receiving Tertiary Hospital Paediatric Unit must have written procedures for:

- Performing the test between 72 and 120 hours after birth and repeat samples as recommended in the *Practical Guide to Newborn Bloodspot Screening In Ireland* (8th Edition Dec 2021) or as requested by the NNBSL.
- Sending the NBSC to the NNBSL.
- Receive the reports via eReports and post as applicable.
- Recording the results in the infant's medical records.

A 1.4 Self Employed Community Midwife (SECM) notification of birth and NBS status to PHN service

A 1.4.1 The SECM will notify the relevant DPHN of the home birth and the pending discharge from SECM service. On discharge from the SECM service, the DPHN office should receive a Discharge Summary from the SECM detailing the newborn bloodspot screening status.

A 1.4.2 The SECM is responsible for undertaking NBS for all infants in their care. The NBS sample must be taken between 72 hours and 120 hours following the birth.

A 1.4.3 If the mother was booked with a Maternity Hospital/Unit, the SECM will contact the Maternity Hospital/Unit in which the mother was booked and request them to issue the Infant's **Unique Perinatal Identifier** (UPI) number (Appendix VIII). It is noted that UPI will be replaced by the Individual Health Identifier (IHI) when implemented.

If the mother was not booked with a Maternity Hospital/Unit, the SECM should contact the nearest Maternity Hospital/Unit and request a UPI. Should there be any difficulty in obtaining a UPI this should be escalated to the relevant Designated Midwifery office/Director of Midwifery or deputy.

A 1.4.4 The Maternity Hospital/Unit and the DPHN will receive the result of the NBS via eReports.

A 1.5 Private Midwives notification of NBS status to PHN service

A 1.5.1 Private Midwives are responsible for undertaking the NBS in all women who have had a home birth under their care. The NBS sample must be taken between 72 and 120 hours following the birth.

A 1.5.2 Private Midwives will contact the DPHN for the designated LHO and request the DPHN to issue the Infant's **Unique Perinatal Identifier** (UPI) number (Appendix VIII). It is noted that the UPI will be replaced by the Individual Health Identifier (IHI) when implemented. In exceptional cases where it is difficult to obtain a UPI from the PHN service, the NNBSL can provide an emergency Laboratory number until the UPI is available.

A 1.5.3 In the event that a woman is transferred to a Maternity Hospital/Unit and the baby is born in the Maternity hospital/Unit; the Maternity Hospital/Unit will provide the UPI and inform the Private Midwife.

A 1.5.4 The Private Midwives will notify the DPHN for the designated LHO that the NBS sample has been taken and the pending discharge from the Private Midwives service. On discharge from the Private Midwife service, the DPHN office should receive a Discharge Summary from the Private Midwife detailing the newborn bloodspot screening status.

A 1.5.5 Following discharge from Private Midwife service, if a repeat is required it is the responsibility of the PHN service to take the repeat sample.

A 1.5.6 If the baby remains under the care of the Private Midwife and a repeat sample is required it is the responsibility of the Private Midwife to ensure the repeat sample is taken.

A 1.5.7 The DPHN will receive the result of the NBS via eReports. Private Midwives will receive the results via post.

A 1.6 Public Health Nursing Service and the NNBSP

A 1.6.1 The DPHN/Designated Officer will:

- Maintain the NBS register for the LHO
- Ensure on receipt of NBS request that all the relevant details of the NBS request are included and correct.
- If relevant, the infection status (e.g. HIV, Hep B) of the mother and infant is highlighted to the sample taker.
- Issue a UPI number on request for infants born outside of ROI and home births (Appendix VIII).

A 1.6.2 The DPHN or Designated Officer will:

- Notify the relevant Primary Care Teams (PCT)/Registered Public Health Nurse (RPHN)/Registered Midwife (RM)/Registered Nurse (RGN) of the request for the NBS by email/mobile phone/other local electronic means (e.g. Sharefile) as per local procedures.

A 1.6.3 The email will generate an automatic acknowledgement of read receipt. Where email read receipts are not used the RPHN/RM/RGN acknowledges receipt of the request for Newborn Bloodspot Screening as per local arrangements.

A 1.6.4 The RPHN/RM/RGN contacts the Parent(s)/legal Guardian(s) and arranges an agreed time and place for NBS to be carried out.

- Ideally the NBS is taken in the home environment.
- In exceptional circumstances, if the mother must attend a primary care facility for the NBS it is recommended that they are accompanied at the clinic visit.
- The clinical environment should be conducive to carrying out the NBS. Parents are also advised of the need to bring the infant in a buggy/car seat to the primary care facility for safety reasons.

A 1.6.5 At weekends/bank holidays/extended holiday periods and when the Public Health Nursing Service is available

- In some LHOs where there is a weekend/bank holiday period service for the NNBSP, the Designated Officer informs the weekend nurse by 12:00 midday on Friday that a NBS is requested for the infant. (Refer to section A 1.1.6 and A 1.1.7)

A 1.6.6 As per local arrangements, additional special arrangements can be organised for extended holiday periods/ urgent requests from NNBSL, to ensure the NBS is delivered from LHO to the NNBSL (For example a courier arrangement).

A 1.6.7 Red Weather alerts: In the event of a red weather alert due to adverse weather conditions, the sample taker in conjunction with the ADOM/ADPHN must assess the risk of travel of either the PHN or the parent and infant against the risk of delayed screening. Further advice can be sought from the HSE Emergency Management Team and/or NNBSL on occasions where the red weather alert progresses beyond two days.

A 1.6.8 In the case of highly mobile families, the infant may have moved out of the area before the NBS has been carried out. The DPHN must be informed of the circumstances as early as possible. Every effort should be made to ensure that the NBS is taken.

A 1.7 Other situations

A 1.7.1 In the case of infants born outside the jurisdiction when the Parent(s)/legal Guardian(s) notify the Public Health Nursing Service that they have brought their infant to this jurisdiction, the Public Health Nursing Service is responsible for ensuring that the sample is carried out if required. For

example this may occur following international adoptions, surrogacy, emigration, persons seeking asylum. Screening can be carried out up to the age of one year. The RPHN/RM may seek the advice of the NNBSL and/or Family GP.

A 1.7.2 Where an infant under one year of age has moved into the LHO (temporary or permanent), evidence of NBS must be obtained. This may take the form of email or written results or a written record in the CHR. Where no proof of screening is available it should be assumed that the infant is not screened. Sample taker and/or DPHN service should check with the NNBSL and/or eReports to confirm screening status

Screening a child who has not been screened, should be discussed with the NNBSL, and where relevant the GP, together with the parent. If recommended for screening it must be arranged.

In general, all conditions are eligible for screening in unscreened children under one year except Cystic Fibrosis where the bloodspot screening is not reliable in infants over 6 weeks of age. Please see Appendix XXI for further details regarding CF screening in children under one year who have missed the newborn bloodspot screening window.

A 1.7.3 Where an infant, up to one year of age, enters the country and has not received NBS for all the conditions screened for in the Irish NNBSP in the infant's country of origin, clarification will be sought from the NNBSL and the infant's family GP regarding the required screening for the infant.

In general, all conditions are eligible for screening in unscreened children under one year except Cystic Fibrosis where the bloodspot screening is not reliable in infants over 6 weeks of age. Please see Appendix XXI for further details regarding CF screening in children under one year who have missed the newborn bloodspot screening window.

A 1.7.4 The decision to screen children greater than one year is a local decision, made by the clinician and family GP and is dependent on the family history and the country of origin of the parents. In such circumstances the NNBSL should be contacted for advice in advance of sample taking.

A 1.8 Consent

A 1.8.1 The sample taker is responsible for ensuring that appropriate signed consent is obtained and informing the Parent(s)/legal Guardian(s) that by signing the NBSC they are confirming that:

- He/she received, read and understood the HSE Parent Guardian Information Leaflet –"*What you need to know about Newborn Bloodspot Screening – heel prick"* (Appendix VII). There are translated versions of the HSE Parent Guardian Information Leaflet available on the HSE website for download (https://www2.hse.ie/screening-and-vaccinations/heel-prick-screening/heel-prick-screening-what-it-is.html . Translators can be used if required.
- The details of the infant on the NBSC are correct.
- They consent to the NBS sample being taken
- They agree to the storage of the NBSC as per current Department of Health policy.

A 1.8.2 Who can give consent?

The HSE has published the revised National Consent Policy (2022) and Appendix 5 of the National Consent policy provides clarity as to who are a child's legal guardians.
The National Consent Policy (2022) notes that this is a complex legal position and the relevant provisions are set out in the Guardianship of Children Act 1964 as amended by the Child and Family Relationships Act 2015.

The Parent who signs the NBSC must be a legal Guardian. Please note:

- Where a child's mother and father are married at the time of birth both are the legal guardians and either can give consent to newborn bloodspot screening as per Section 6 of the *Guardianship of Infants Act 1964*.

- If Parents are not married, the birth mother is automatically the legal Guardian of the infant and can only sign the NBSC. The unmarried second parent may not be automatically the guardian of the infant, and may not be in a position within the timeframe for the NBS to have legal responsibility to sign the NBSC to provide consent.
    - The infant's father is an automatic legal guardian if from 18th January 2016 he has lived with the infant's mother for 12 consecutive months including at least 3 months with the mother and infant following the infant's birth. This may be applicable for cases of newborn bloodspot screening where a child may be screened up to the age of one year.

- If the birth mother is unavailable to sign the consent, i.e. through illness or hospital transfer, the unmarried second parent cannot sign the consent. In these cases, the sample taker should make every effort to contact the birth mother to get verbal consent and to document this in the relevant clinical notes/child health record. Written consent from the birth mother must be obtained at the earliest opportunity and forwarded to the NNBSL.

- If the birth mother is not contactable, for example due to severe illness, then the HSE must act in the best interest of the infant which would be to take the newborn bloodspot screening sample and inform the birth mother as soon as possible as to the decision taken and to record that in the child health record. If appropriate, this should ideally be in discussion with the second parent or primary care giver of the infant to ensure that they are aware of the need and benefit of newborn bloodspot screening.

  If the infant has been discharged home to the care of the second parent and the birth mother is too unwell to be discharged, the Maternity Hospital/Unit should plan on the infant's discharge that the second parent should bring the infant back into the hospital to obtain consent from the birth mother, record it in the clinical record and then proceed to take the newborn bloodspot screening sample. This is similar to bringing infants back into hospital in areas where there is no weekend public health nursing service.

- RPHNs/RMs arranging a house call to perform the newborn bloodspot screening must insist

on the birth mother being present. Grandmothers or other relatives/friends cannot provide written consent.

- If a Midwife is taking the newborn bloodspot screening sample in hospital and the birth mother is not present on the ward, the midwife should return when the birth mother is present.

- Other Circumstances
  - Where an interim care order is in place only the parent(s)/legal guardian(s), or the birth mother if unmarried, can provide consent.
  - If there is a full care order in place consent can be provided by the relevant health or social care provider. HSE National Consent Policy notes that it is good practice to seek consent of parent/legal guardian but not mandatory.

  - Other circumstances which more than likely will not apply to newborn screening due to the timing, although could be applicable for late screening up to the age of one year, but are worth noting include:
    - Adoption: Where a child has been jointly adopted, the adoptive parents are the child's legal guardians. However, adoption is unlikely to have been completed at the time that newborn bloodspot screening is due to take place (72-120 hours after birth) and the birth mother would be the legal guardian at that time.
    - Surrogacy:
      - Where a child is born through surrogacy in Ireland, the surrogate mother is the legal guardian at birth until the commissioning mother/father are appointed as legal guardians. The surrogate mother, as birth mother, has legal responsibility for the newborn until the infant is legally adopted. For infants born to surrogates in Ireland it is permissible under the National Consent Policy for consent to be obtained from the surrogate mother by the sample taker by telephone/electronic means (Part 2 Section 4.2.2) if deemed necessary.
      - If practicable, the surrogate mother may give consent prior to the infant being discharged but is must be made clear to the surrogate mother that she is consenting to the heel prick screening for the infant. The discussion that has taken place and the consent agreement must be documented in the healthcare record.
      - If the commissioning father's sperm was used in the surrogacy procedure, he may apply to the Court for a declaration of parentage; once granted, this would immediately entitle him to apply to the Court for guardianship.
      - The commissioning mother, or a commissioning father whose sperm was not used in the procedure, may apply to the Court for legal guardianship one they/she has fulfilled the relevant legal requirements (see National Consent Policy 2022, pages 140-141).
    - Surrogacy in another jurisdiction: Under current Irish legislation, the surrogate mother, as birth mother, has legal responsibility for the newborn until the infant is legally adopted. This may mean that the birth mother is resident in another

jurisdiction. There is currently no provision in Irish legislation allowing consent to be provided by the parents who bring the infant back into Ireland after birth abroad to a surrogate mother until legal adoption has taken place. This Procedure will be updated when there has been an update in the relevant Irish legislation around surrogacy abroad.

- In respect of same sex couples, the infant's biological parent is a legal guardian.
  - The biological parent's partner or spouse may apply to the Court to become a legal guardian in accordance with the requirements below.
  - Where a same-sex couple has a child through Donor Assisted Human Reproduction (not including surrogacy) after 4th May 2020 and has complied with the provisions of Part 2 of the Children and Family Relationships Act 2015, (i.e. they have used a recognised fertility clinic and have signed all the relevant consents and declarations, the spouse, civil partner or cohabitant of the mother will be the legal parent of the child. In this situation, the spouse or civil partner of the biological parent will automatically be a legal guardian. A cohabitant will be a legal guardian if they fulfil the residence requirement (i.e. have lived with the infants mother for 12 consecutive months including at least 3 months with the mother and the infant following the infants birth).

- If the parent(s)/legal guardian(s) has literacy difficulties they can be asked to make a mark on the newborn bloodspot screening card to indicate that they have been fully informed about the benefits and risks of newborn bloodspot screening.

- If parent(s)/legal guardian(s), in this case married parents, disagree as to the provision of consent for newborn bloodspot screening the HSE National Consent Policy provides guidance on this in Section 3.2.2 (National Consent Policy 2022). All reasonable efforts should be made to recognise and respect the views of parent(s)/legal guardian(s) as regard what is in the best interest of the child including when these views differ from those of the service provider. Where a second-opinion is sought by the Parent(s)/legal guardian(s), this should be facilitated as far as possible by the service provided.

  Where parent(s) or legal guardian(s) refuse to consent to an intervention which the healthcare worker reasonably believes to be in the best interests of the child, every effort should be made to reach a consensus position as regards the best interest of the child. This may require involving one or more other healthcare workers, including the provision of independent second opinions, as well as mediation or other external supports (if these are available).

  If, having taken these steps, it is not possible for the healthcare workers and the parent(s) or legal guardian(s) to reach an agreement as to what is in the best interests of the child, it may be necessary to seek legal advice as to whether an application to the Court is required.

In such a situation, the parent (s) or legal guardian(s) should be informed of their right to seek legal representation and to be heard in relation to the application. The healthcare worker has an obligation to act in the best interests of the child at all times. This means that if in the opinion of the healthcare worker the intervention is immediately required and there is no time to make an application to Court without exposing the child to an immediate risk of death or serious injury, the intervention should proceed notwithstanding the parental objection. In such a situation, the healthcare worker should record the basis for his or her evaluation that immediate intervention is required and the steps which they have taken on this basis.

- Newborn bloodspot screening should take place as it is in the infant's best interest.

A 1.9 Parent(s)/Legal Guardian(s) right to opt out of NNBSP

A 1.9.1 The Parent(s)/legal Guardian(s) have the right to opt-out from the NNBSP on behalf of their infant.

A 1.9.2 The sample taker accurately documents in the clinical record the discussion with the Parent(s)/legal Guardian(s), including the screening procedure that has been offered, the evidence base, benefits and risks, the Parent(s)/legal Guardian(s) decision to decline and the fact that the implications of this decision have been fully outlined.

A 1.9.3 The sample taker informs the DPHN/DOM/N/Paediatric Consultant on Call (Maternity Hospital/Unit only) that the Parent(s)/legal Guardian(s) is opting out of the NNBSP and will discuss further actions required.

A 1.9.4 The Parent/legal Guardian must be requested to sign the *National Newborn Bloodspot Screening Programme Opt-out form* (Appendix XII) https://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/information-for-professionals/phn/national-newborn-bloodspot-screening-programme-opt-out-form.pdf.

The Parent(s)/legal Guardian(s) can be given the opportunity to consult with other healthcare professionals if required.

A 1.9.5 The Parent (s)/legal Guardian(s) sign the *National Newborn Bloodspot Screening Programme Opt-out form* in the presence of the sample taker and the sample taker also signs the form.

- A copy of this form is given to the Parent(s)/legal Guardian(s).
- The original form is filed in the CHR/Maternity chart.

A 1.9.6 The Sample Taker will send a copy of the *National Newborn Bloodspot Screening Programme Opt-out form* to:

- The DPHN
- The NNBSL
- The infant's General Practitioner (GP)
- DOM/N/Maternity Hospital

A 1.9.7 Where the Parent(s)/legal Guardian(s) have opted out of the NNBSP, the Parent(s)/legal Guardian(s) will be informed that it is their responsibility to contact the Public Health Nursing Services and/or the infant's GP should they change their mind in the future and wish to be included in the NNBSP. The sample taker will record the discussion and decision made in the CHR.

A 1.9.8 Where Parent(s)/legal Guardian(s) decline to sign the *National Newborn Bloodspot Screening Programme Opt-out form*

- The opt-out form must be completed by the sample taker and documented on the opt-out form that the Parent(s)/legal Guardian(s) declined to sign the form.
  - For samples due to be taken in the Maternity Hospital/Unit, the sample taker will document the discussion with the Parent(s)/legal Guardian(s) and the decision made on the Maternity Chart. The Maternity Hospital/Unit will inform the infant's GP, DPHN and the NNBSL. The sample taker will discuss this case with their DOM/N and decide on further actions for example completion of a National Incident Report Form (NIRF).
  - For samples due to be taken in the community the sample taker will document the discussion with the Parent(s)/legal Guardian and record the decision made on the CHR. The sample taker will discuss this case with their ADPHN and decide on further actions for example completion of a NIRF.
- The Sample Taker will send a copy of the *National Newborn Bloodspot Screening Programme Opt-out form* to:
  - Parent(s)/legal Guardian(s)
  - The DPHN
  - The NNBSL
  - The infant's General Practitioner (GP)
  - DOM/N/Maternity Hospital

A 1.10 Information Giving

A 1.10.1 Parent(s)/legal Guardian(s) should receive information on the NNBSP antenatally in the 3rd trimester and at discharge from the Maternity Hospital/Unit.

A 1.10.2 All Parent(s)/legal Guardian(s) will be given:

- The HSE Parent /Guardian Information Leaflet –*"What you need to know about Newborn Bloodspot Screening – heel prick"* (Appendix VIII) if they have not already received this information. Information Leaflets can be obtained online at: https://www2.hse.ie/screening-and-vaccinations/heel-prick-screening/heel-prick-screening-what-it-is.html including information leaflets in a selection of other languages.
- The Parent Information Copy (Appendix X) of the *Newborn Bloodspot Screening Card* (NBSC) (Appendix X) which also contains information about the NNBSP.

A 1.10.3 All Parent(s)/legal Guardian(s) will receive the following information to indicate that this is screening and not diagnostic testing:

- The conditions which are being screened for and the reason for screening
- Advice that further samples may be required

- The NBSC will be retained for 10 years and then destroyed (as per current Department of Health policy)

A 1.11 Completion of the Newborn Bloodspot Screening Card

A 1.11.1 The Sample Taker completes the details required for the NBSC:

- *Infant's Unique Perinatal Identifier (*UPI) (see Appendix VI and Appendix VIII)
- *Infants demographic details:* Infant's surname (as given by the parents), first name, address including postal code/Eircode
- *Place of birth: Hospital or Community*
- *Infants healthcare record number/transfer to another hospital number*
- *Mother's surname (if different from infant's)*
- *Local Health Office* (e.g. Meath, West Cork, Dublin South West, Laois/Offaly) (Appendix V)
- *Location sample taken:* Please tick the relevant box 'Community' or 'Hospital'
- If a hospital transfer record the hospital name the infant is transferred to
- *GP's Name*
- *Gestational age; time of birth; date of birth, gender*
- *Birth Weight* (recorded to 3 decimal places, if available)
- *Rank* (For multiple births e.g. Twin 1 Twin 2)
- *Date of first feed*
- *Blood Transfusion* - Date and time of first transfusion, date and time of last transfusion
- *Type of Feed* at the time of sample collection (breast, artificial, Total Parenteral Nutrition (TPN), IV fluids, soya/lactose free, Glucose/Dextrose (Glu/Dex))
- Comments: (Family History, Beutler, Meconium Ileus)
- *Date and time of collection, repeat specimen (yes or no).*
- *Sample taker name and sample taker phone contact number:* This requires the phone number of the sample taker to enable the sample taker to be contacted directly should this be required. The Parent(s)/legal Guardian(s) phone number is **NOT** to be entered here.
- *Parent(s)/legal Guardian(s) Preferred language:* This field should always be completed – insert the preferred language. For any language, other than English, an interpreter could be required to communicate possible suspected screen positives and the need to attend a hospital for further samples.
- *Parent(s)/legal Guardian(s) ethnicity* (Ethnicity codes are provided on the back of the NBSC)
- *Parent(s)/legal Guardian(s) consent signature.*
- Note details on the reverse side of the NBSC will be filled in by the laboratory

A 1.11.2 The Sample Taker when completing the NBSC ensures that:

- All the data recorded on the NBSC is correct and confirmed by the parent
- NBSC is signed indicating that the Parent(s)/legal Guardian(s) is consenting to their infant being screened
- The top information sheet is removed and given to the Parent(s)/legal Guardian(s)
- The Parent/Guardian copy is given to the Parent(s)/legal Guardian(s) at the time that the sample is taken
- The 'Sample Takers' copy is filed in the CHR/Maternity chart

A 1.11.3 Parent(s)/legal Guardian(s) will be informed that results will be issued to the Maternity Hospitals/units and LHOs only and that results will not be issued to Parent(s)/legal Guardian(s) over the telephone.

A 1.11.4 Further information is available on https://www2.hse.ie/heel-prick-screening/ or by e-mailing info.newbornscreening@cuh.ie

A 1.12 Education and Training

A 1.12.1 The sample taker must have completed education and training in the procedure of taking an NBS sample and carry out this procedure within their scope of practice.

A 1.12.2 There is a training module available on HSE LAND for all staff under the suite of modules contained in the National Healthy Childhood Training Programme called '*National Newborn Bloodspot Screening Programme*'

A 1.12.3 Registered Public Health Nurses (RPHNs), Registered Midwives (RMs) Registered Children's Nurses (RCNs), midwifery students, student PHNs, and Nursery Nurses (NN) undertake NBS under their scope of professional practice/competence:

- Where a RGN undertakes NBS, the DPHN and RGN must be satisfied that additional training has been undertaken and that the nurse is working within their scope of practice.
- Where a NN undertakes NBS, the DOM/N/Maternity Hospital/Units and NN must be satisfied that additional training has been undertaken and that the NN is working within their scope of practice

A 1.13Sample Taking Timing and Special Considerations

A 1.13.1The blood sample should be taken **not earlier than 72 hours and not later than 120 hours** after the infants birth and when feeding has been established. Infants should be established on full lactose and protein containing feeds for at least 24 hours before the newborn bloodspot sample is taken unless at high risk for Classical Galactosaemia (refer to A 1.13.5).

Professional clinical judgement should be used in decision making around established feeding prior to taking the newborn bloodspot sample:

- For breastfed infants in the community, the Breastfeeding Observation Assessment Tool (BOAT) should be used to guide assessment of feeding and support professional decision making
- For breastfed infants the Maternity Hospital/Unit local individual feeding records (i.e. LATCH score) are available to guide assessment of feeding and support professional decision making
- For infants on expressed breastmilk/formula, the sample taker can review the infants intake over the previous 24 hours to aid assessment of feeding and support professional decision making

A 1.13.2 Using professional clinical judgement, if an infant has not been feeding well then:

- The sample taker should arrange to revisit the next day to take the initial sample if it is still within the 72-120 hour window.

- If the following day is outside the 72-120 hour window or the sample taker is unable to revisit, take the initial sample within the 72-120 hour window and take an additional sample on or around Day 10.

A 1.13.3 Specific concerns for infants need to be considered and stated on the NBSC. There are further details included in '*A Practical Guide to Newborn Bloodspot Screening in Ireland*' (8th Edition). Sample takers are advised to contact the NNBSL with any queries they have in relation to these.

- **Total Parenteral Nutrition (TPN):** This should be clearly indicated on the NBSC because these infants may not be on any galactose containing feed and a Beutler test will need to be performed to rule-out Classical Galactosaemia.

- **Intravenous fluid (IV Fluids):** Babies on IV fluids may not have adequate protein and galactose intake and may result in a false negative for amino acid disorders as well as Classical Galactosaemia.

- **Intravenous Glucose/Dextrose:** If a baby is on IV Glucose or Dextrose a false negative screen may be reported for MCADD. It is imperative that this is noted on the screening card and a repeat card to be collected when IV is discontinued.

- **Blood Transfusion:** If an infant requires a red blood cell (RBC) transfusion before the routine 72-120 hour sample is taken, a pre RBC transfusion should be collected to perform a Beutler test to rule out Classical Galactosaemia. (Note: a RBC transfusion invalidates the Beutler test). The routine 72-120 hour sample should be collected as normal regardless if the child has a RBC transfusion and do not delay this 72-120 hour sample due to RBC transfusions. For any further samples to be collected on a RBC transfused infant then allow 72 hours to pass before taking any more samples. If the baby received an intrauterine transfusion, this should be clearly noted on the screening card, as this will invalidate the result of the Beutler test and could give a false negative screen result.

- **Prematurity (<37 weeks):** All premature infants should have a pre-transfusion sample taken if a RBC transfusion is planned or likely to out-rule Classical Galactosaemia. A routine sample should be taken between 72 hours and 120 hours after birth.
  Further samples should be collected at regular intervals e.g. as a guideline 1 week, 2 weeks, 4 weeks and term corrected gestational age. On some occasions additional samples may be requested by the NNBSL or Clinical Team.

  Please note that preterm infants with hypothyroidism can have a delayed thyrotropin increase most likely because of immaturity of the hypothalamic-pituitary thyroid axis. These infants are at increased risk of being undetected in the screening process if repeat samples are not collected at term corrected gestational age.

- **Meconium Ileus:** Cystic Fibrosis should be considered in those infants who present with meconium ileus within the first days of life. An Ethylenediaminetetraacetic Acid (EDTA) blood sample should be sent directly to the Department of Medical Genetics, Children's Health Ireland at Crumlin for CF mutation analysis, with full clinical information (CFTR mutational analysis is undertaken as Bloodspot IRT may give a false negative result in this clinical setting). A routine NBS sample should be taken at 72-120 hours to screen for the other conditions and Meconium Ileus noted on the NBSC.

- **Maternal Phenylketonuria:** Phenylalanine is actively transported across the placenta; the blood level in the foetus is about twice that of the mother. Therefore, women who themselves have phenylketonuria, should plan conception, so that their condition is under optimum control at the time of conception. Regular and frequent monitoring of blood levels of phenylalanine and tyrosine are required throughout pregnancy in order to safeguard the well-being of the foetus. Following the birth of the infant a lithium heparin liquid sample should be taken from the infant at the same time as the NBS and a repeat sample taken at day 10 after birth.

A 1.13.4 Families who are deemed to be high risk for any of the conditions being screened for, require careful attention e.g. Traveller Families, or other Ethnic Groups, or a family history of any of the screened for conditions. Refer to *A Practical Guide for newborn Bloodspot Screening in Ireland* (8th Edition).

A 1.13.5 The Beutler Test (for Classical Galactosaemia) is completed for all infants born to parents who identify as Irish Travellers and siblings of known cases of Classical Galactosaemia:

- A NBS sample should be taken from the infant immediately after the infant is born and prior to the first feed and/or before any blood transfusion has been given.
- The NBS sample is immediately sent to the NNBSL for a Beutler test – the NBSC should be clearly marked 'FOR BEUTLER TEST'.
- Samples for Beutler testing must be in the laboratory by 12pm on weekdays and by 10am on a Saturday for same day reporting. If received after these times, samples will be analysed the next working day.
- Where the mother's expressed wish is to breastfeed the infant, all efforts must be made to ensure that the Beutler is sent to the lab as soon as possible so that breastfeeding can be initiated in the event of a negative Beutler result.
- Reporting of Beutler results can be obtained from the laboratory between 09:00-17:00 Monday to Friday and 09:00-12:00 Saturday. Christmas and Easter opening hours of the NNBSL will be circulated in advance to DOM/Ns and DPHNs.
- Following the NBS sample for the Beutler test, infants should be fed with a lactose/galactose free feed until the result of the Beutler Test result is known.
- If the result of the Beutler is negative for Galactosaemia the Parent(s)/Guardian(s) should be informed as soon as possible so as to take the infant off the lactose/galactose free feeds.
- These infants should have the routine NBS sample taken between 72 and 120 hours.

A 1.13.6 Family history must be stated clearly on the NBSC and the condition indicated. High risk family history includes: siblings of known case of any of the conditions screened for and marriage of first cousins.

A 1.14 Requirements for Sample Procedure

A 1.14.1 All sample takers must follow current National and Local Guidelines regarding infection prevention and control including hand-washing and/or use of alcohol hand gel, personal protective equipment (PPE) in the taking of the sample. Latest guidance available at www.hpsc.ie

A 1.14.2 The following are the equipment requirements:

- Latex Free Gloves
- An automated incision device of penetrative depth of no more than 2.4mm is recommended (WHO 2010), e.g. Quikheel. A slice incision is recommended as opposed to a prick/stab incision.
  - The distance for a 7 pound (3kg) infant from outer skin surface to bone is:
    - Medial and lateral heel – 3.32mm
  - For Preterm infants depth maybe smaller and will depend on the prematurity of the infant. A 0.85mm automated incision device is available for premature neonates.
- Sterile water (if required)
- Gauze
- Paper towel
- Sharps box
- Newborn Bloodspot Screening Card
- HSE Parent /Guardian Information Leaflet –"*What you need to know about Newborn Bloodspot Screening – heel prick"* (Appendix VII)
- Biohazard bag and UN3373 sticker (if required)
- For Maternity Hospital/Unit services
  - Water Resistant Tear Proof Envelope (e.g. Tyvek or equivalent)
  - Preprinted addressograph for Temple Street Lab (yellow label)
- For community services:
  - Water Resistant Tear Proof Envelope (e.g. Tyvek or equivalent)
  - Preprinted addressograph for Temple Street Lab (yellow label)
  - An Post registration label (if appropriate)
  - Transport and drying box – see Appendix XVI

A 1.14.3 The Sample Taker will check the expiry date on the Card – this can be found on the bottom right hand corner under 'GPs Name'. The cards should not be used after this date. Using expired cards may result in a request for a repeat sample. Do not detach the bloodspot portion of the card from the main card, as it is bar-coded and is required for laboratory use.

A 1.14.4 Sample takers need to note that:

- Total Parental Nutrition should be clearly indicated on the NBSC; because these infants may not be on any galactose containing feed a Beutler test will need to be performed to rule-out Classical Galactosaemia.

- If the family have a history of PKU, HCU, MCADD and GA1, an additional NBSC is taken on day 10.

A 1.14.5 Biohazards: infants whose mothers are known or suspected of being infected with HIV or Hepatitis B or other known infectious diseases; should have newborn bloodspot screening performed as normal. The NBSC must be identified as a Biohazard (Reference A 1.16.6).

A 1.14.6 NBSCs, appropriately dried and packaged, should be sent as soon as possible either by registered post or by courier.

A 1.14.7 When a number of samples are being sent in the one water resistant and tear proof envelope, ensure that all the samples are fully air dried and that the bloodspots are aligned at 180 degrees to each other so that the bloodspots do not rest on each other. Please ensure the checklist (Appendix XIV) is enclosed with:

- The details of all the infants Surname and their UPIs
- The total number of NBSCs enclosed and the date posted
- For biohazards see A1.16.6
- The name of the person compiling the checklist, their location and contact number
- Any additional comments

A 1.14.8 RPHN/RGN should notify the DPHN/designated officer that NBS is taken and record in the CHR as per local procedures.

A 1.14.9 Midwives/RGN should record that NBS is taken as per local procedures.

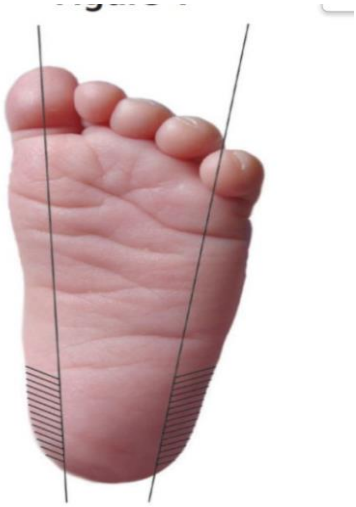
A 1.15 Sample Technique

A 1.15.1 The method used for obtaining the blood sample is by “heel prick”.

A 1.15.2 Obtain the sample using an automated incision device.

- Avoid posterior curvature of the heel; see Figure 2
- Allow the heel to hang down to assist blood flow
- Before activation, place the automated incision device against the heel in accordance with the manufacturer’s instruction.
- For full-term and preterm infants. Skin puncture must be no deeper than 2.4mm.

Figure 2: Location on heel where sample should be taken from (shaded area)



A 1.15.3 In order to encourage blood flow to the heel area, the Parent(s)/Guardian(s) should be advised on the day prior to sampling (if possible) to put two pairs of socks on the infant's feet.

A 1.15.4 Do not touch bloodspot rings on the NBSC with gloves before, during or after the sample is taken. Ensure there is no contact with Vaseline or other creams.

A 1.15.5 Latex interferes with Beutler sample and may cause a false positive result. Latex free gloves are to be used when carrying out the NBS.

A 1.15.6 Preferably take the sample from the infant while the Parent/legal Guardian holds the infant. Encourage skin to skin contact, breastfeeding or non-nutritive sucking to aid comfort. Allowing the infant's leg to hang lower than the body will encourage blood flow.

A 1.15.7 Place a paper towel on the lap of the individual holding the infant.

A 1.15.8 Ensure that the heel is visibly clean and warm**.** The skin may be gently rubbed for 1-2 minutes to increase blood supply if deemed necessary. **Never** use any external warming source (e.g. hairdryer, warm water). This introduces a risk of thermal burns and/or scalds.

A 1.15.9 Routine cleansing of the heel is not required. However, if the heel is visibly dirty or soiled it can be cleaned with gauze soaked in cool sterile water. Ensure that the heel is completely dry before taking the sample. Do not use alcohol or infant wipes as they may interfere with sample results or cause serum rings.

A 1.15.10 Encircle the heel with finger(s) and thumb and squeeze gently until the skin looks taut and suffused with blood.

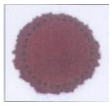
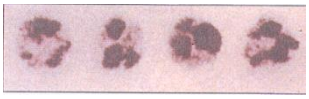
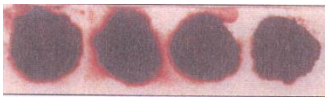
A 1.15.11 Press the automated incision device firmly against the side of the ball of the heel and trigger the device.

A 1.15.12 Hold the foot downwards and gently massage the heel to encourage blood flow.

A 1.15.13 Wipe away the first drop of blood and allow another large drop to form. (The first drop may be a diluted blood drop). Touch the circle marked on the card gently to the hanging drop so that the blood soaks through from the back of the card to the front:

- Blood drops must be soaked through from the back to the front of the card, filling all circles completely
- Check that the blood has soaked completely through the circle on the front as well as the rear of the card
- Do not press or squeeze the bloodspot to 'force' it through the NBSC
- Figure 3 outlines various types of sample quality

Figure 3: Examples of various types of sample quality

Sample Quality	Example	Comment
Valid sample		Sufficient amount of blood to completely fill all circles.
Insufficient sample		Removing card before blood has completely filled circle.
Sample not dry before posting		Posting sample before drying for up to 4 hours.
Sample appears supersaturated		Applying excess blood to card.
Sample appears diluted or contaminated		Squeezing area surrounding puncture site Allowing card to come in contact with gloved or ungloved hands Exposing blood spots to direct heat.
Sample shows serum rings.		Not wiping alcohol from puncture site before skin puncture. Squeezing area surrounding puncture site excessively. Drying specimen incorrectly.

A 1.15.14 Wipe away excess blood with gauze. Press clean gauze firmly onto the wound until bleeding stops.

A 1.15.15 The Sample Taker will ensure sufficient blood is taken to meet the requirements to completely fill the four bloodspots circles on the NBSC.

A 1.15.16 See *Flowchart for Newborn Bloodspot Screening Sample Takers* if having difficulty in obtaining a sufficient sample – Appendix XV.

A 1.15.17 It is imperative that adequate blood is supplied for analysis to reduce the incidence of repeat sample requests. Please ensure that the blood soaks through fully from the back through to the front of the card to avoid an **insufficient** sample.

A 1.15.18 Ensure the sample is **fully dried** before placing in the water resistant and tear proof envelope.

- Drying time is dependent on the environment
- **Wet samples** cause the production of 'serum rings' which could result in a false negative result and ultimately increases the risk of missing a case.
- Do not dry in direct sunlight or near a heating source, e.g. a radiator

A 1.15.19 The sample taker must remove their gloves and PPE if used and perform hand hygiene.

A 1.15.20 The sample taker in the LHO will use a transport/drying box for the NBSC following the procedure to facilitate the transport of the NBSC from the infant's home to the Nurse's/Midwife's car in a safe manner (Appendix XVI).

A 1.16 Transporting the NBSC to the NNBSL

A 1.16.1 If the NBS is taken in the Maternity Hospital/Unit, the Nurse/Midwife/Nursery Nurse transfers the NBSC to the NNBSL through hospital arrangements for blood sampling products.

A 1.16.2 If the NBS is taken in the community, the RPHN/Nurse/Midwife in LHO will:

- Transfer the NBSC from the drying box and package according to the NNBSL regulations.
- A water resistant and tear proof envelope (e.g. Tyvek or equivalent) is used with the yellow fluorescent address label (Appendix XVII).
- It must be noted that a maximum of three NBSCs can be put into one water resistant and tear proof envelope. The samples must be fully air dried and assembled opposite ends to each other i.e. to prevent blood circles from each card touching each other.
- In the community; send the NBSC by registered post (or by courier/hand deliver in exceptional circumstances i.e. emergency situations/extended holiday periods) to the NNBSL. Evidence of posting is attached to the CHR.

A 1.16.3 In the Maternity Hospital/Unit; details of samples sent by courier are recorded as per local procedure.

A 1.16.4 If more than a single NBSC is being dispatched together please include summary list of names/UPIs (Appendix XIV).

A 1.16.5 Dispose of the automated incision device according to the local protocol for clinical waste – do not include the automated incision device(s) in the package with the NBSC.

A 1.16.6 If a Biohazard e.g. HIV, Hepatitis A, B, C is identified the NBSC must be managed in accordance with infection control practice.

- The general principle is that the NBSC is placed in an inner sealed biohazard plastic bag/water proof envelope when the blood spot has completely dried.
  - The word 'Biohazard' must be noted on the NBSC, but the nature of the biohazard should not be noted as it is not relevant to screens being performed
  - If an official biohazard bag is not available, the NBSC can be put in a sealed plastic bag/water proof envelope and 'biohazard' written on the plastic bag/envelope to alert laboratory staff that precautions are required.
  - This inner plastic bag/water proof envelope is then placed in an outer water resistant and tear proof envelope. The outer envelope is **not** marked 'Biohazard'.

A 1.16.7 Laboratory opening hours and requirements around weekend/bank holidays (Appendix XV):

- Laboratory opening hours are:
  - 09:00 – 17:00 Monday-Friday
  - 09:00 – 12:00 Saturday
- To ensure samples reach the NNBSL in a timely manner and to minimise a delay in reporting over weekends, samples due to be taken on a Thursday should be collected early Thursday morning if infant is 72 hours old, allow sample to dry fully, **and post on Thursday afternoon** to arrive in our laboratory on Friday morning for analysis**.**
- At weekends, where possible, samples taken on a Saturday are posted by 13:00 by registered post. Samples taken on Saturday afternoon/Sunday are posted on a Monday morning.
- At bank holiday weekends, where possible, samples taken on a Saturday are posted by 12midday by registered post. Samples taken on Saturday afternoon/Sunday/Monday are posted on a Tuesday morning.
- At extended holiday periods, a courier/taxi service may be used from a designated centre to the NNBSL for the NBSC to be transported directly to NNBSL.
- A memo will issue from the NNNBSL each year outlining Christmas/New Year and Easter opening arrangements

A 1.17 Record Keeping

A1.17.1 The Midwife/Nurse/Nursery Nurse in the Maternity Hospital/Unit will record in the maternal healthcare record – child care section either:

- Completion of the procedure.
- Or issue a request for NBS to the relevant LHO or tertiary paediatric hospital.

A 1.17.2 The RPHN/Midwife/Nurse working in the LHO will record in the child health record the following:

- Yes, No or Refused (opt-out)
- Location: Hospital or Community
- Date
- Evidence of posting attached and filed in the CHR
- Is repeat required?

- The sample taker's copy of the NBSC should be filed in the CHR

A 1.18 Amendments to Newborn Bloodspot Screening Cards

A 1.18.1 If there are any amendments required to be made to any details recorded on the NBSC, the **Patient Details Amendment Form** should be completed (Appendix XIII) and forwarded to the NNBSL by email or post.

A 1.18.2 Where there is an error in recording the 'type of feed' identified, the NNBSL needs to be notified immediately by emailing info.newbornscreening@cuh.ie identifying the service e.g. Maternity Hospital/Unit, LHO; stating the infant's clinical details and the amendment to be made

A 1.19 Managing Inaccessible Visits

A 1.19.1 On failing to gain access to the mother's home:

- The RPHN/RM must phone the maternity hospital/unit to confirm the discharge details, discharge address and additional contact details of nominated support person.
- The RPHN/RM can telephone the of nominated support person to request the mother makes contact with the RPHN/RM as soon as possible.
- If the above is not productive, the RPHN/RM should phone the GP. Under article 9 (2) h of GDPR concerning the provision of health and social care services, data concerning health may be requested from the Data Controller (GP). The Data Controller determines if and what information is given
- All of the above steps should be documented, dated, timed and signed appropriately using the child health record.
- The RPHN/RM will inform the ADPHN of the above and discuss actions. An NIRF should be completed if discharging address/contact numbers are incomplete or inaccurate and this causes a delay in the sample taking
- Following confirmation that it is the correct address the RPHN/RM should leave a PHN visiting card requesting the Parent(s)/legal Guardian(s) to contact the RPHN/RM as soon as possible to arrange for a sample to be taken.
- In the event the address cannot be confirmed (e.g. a rural address without an Eircode) then the RPHN/RM is not in a position to leave a PHN visiting card, contact should be made with the Maternity Hospital/Unit /Midwife/GP for further details and records same in the maternal postnatal record.

A 1.19.2 The RPHN/RM contacts the Maternity Hospital/Unit with notice of the inaccessible visit. Every effort must be made to ensure that the sample is taken in collaboration with appropriate services (e.g. the Maternity Hospital/Unit, GP, Garda Síochána, other PHN Departments etc.) The RPHN/RM records this in the CHR.

A 1.19.3 If the sample is successfully taken it is the responsibility of the sample taker to ensure that the relevant services are informed that the sample has been taken.

A 1.19.4 If the sample is subsequently late or missed a NIRF should be completed. Learning from such an incident is circulated to relevant colleagues as appropriate.

A 1.20 Newborn Bloodspot Screening Sample Results

A 1.20.1 NNBSL notifies the Maternity Hospital/Units/ DPHN of NBS Result by eReports™

- Each Maternity Hospital/Unit and Local Health Office must nominate a NBS Management Lead and two authorised eReports™ users. This ensures eReports™ access is available at local level for authorised users.
- The NNBSL also notify Private Midwives by post.

A 1.20.2 The NNBSL provides each authorised user with:

- User Name.
- User ID
- URL for eReports™ access.
- Handbook for eReports™ users
- Training as needed for authorised users.

A 1.20.3 Ereports™ allow:

- Verification of receipt of samples before results are available.
- Requests for repeat samples can be made electronically.
- Results of Samples become available 2-3 days after receipt of sample in the laboratory.
- Result codes are supplied which indicate interim stages of results analysis and investigations for some conditions.
- A search facility which can be used to find and link results, this includes searching by infant name, date of birth (DOB), or range of birth dates, mothers name, UPI etc.
- Results available online to authorised users in the LHO and the Maternity Hospitals/Units for up to 60 days following the issuing of a result.
- Individual reports can be printed locally for healthcare records and for parent/guardian information requests.

A 1.20.4 The NNBSL approves screening results normally within 48 hours of receipt of sample, which are made available via eReports™ to authorised users.

A 1.20.5 The NNBSL phones the DOM/N or designated officers and/or DPHN or designated officers with results requiring urgent action for example screen positives, admission to hospital, sweat test.

A 1.20.6 The NNBSL forwards a list via eReports™ indicating the results of the screening to both:

- The DOM/N/Maternity Hospital/Unit – designated officers.
- The DPHN/LHOs – designated officers.
- Where relevant to Children's Hospital Ireland.

A 1.21 Checking NNBSP Sample Results

Maternity Hospital/Units Checking NBS Register – sample results

A 1.21.1 The DOM/N/designated officer (Outpatient Midwife Manager and/or Postnatal Midwife Manager) oversees and monitors NBS results for infants where a NBS has taken place in the Maternity Hospital/Unit.

A 1.21.2 The Designated Officer undertakes daily monitoring of the eReports™ for initial requests for NBS and for any repeat NBS requests and arranges appropriate sampling and resampling for any infant who remains in hospital at that point.

A 1.21.3 The Designated Officer undertakes weekly monitoring procedures as follows:

- Identifying and eliminating duplication.
- Identifying infants without UPI and ensuring all infants have a UPI issued.
- Monitoring on the newborn screening register those infants 12 days old where there are no eReport results identified. For those infants check the following:
  - That the sample has reached NNBSL (eReports™).
  - That the hospital/ward has a record of the NBSS been taken.
  - Or that a record of the "*National Newborn Bloodspot Screening Programme Opt-out form*" form (Appendix XII) is in the maternal chart – infant section.
- Record closure of screening episode where information received identifies:
  - Confirmation that an infant has died.
  - The family have refused the service and a "*National Newborn Bloodspot Screening Programme Opt-out form*" form is completed (Appendix XII).
- If sample has not been taken for other reasons, arrange sampling and continue to follow up until screening episode is closed.
- The designated officer signs/initials the entries to indicate that he/she has undertaken the exercise (note: manual format).

A 1.21.4 Conclusive results will normally be available within 18 days of birth for most conditions screened. Cystic Fibrosis results may not be available for up to 30 days after birth.

A 1.21.5 If results are not available by day eighteen, the designated officer should contact the NNBSL and request the result (Appendix XVIII).

A 1.21.6 The designated officer will continue to follow up on results that are pending until all results are made available.

A 1.21.7 The Maternity Hospital/Unit is responsible for ensuring that omissions are notified to the DPHN where results have not been received from the NNBSL.

A 1.21.8 The Maternity Hospital/Unit /Designated Officer:

- Works with the CHO/LHO Child Health Lead, DPHN and/or their designated officers as required to ensure that all infants have a result recorded.

A 1.21.9 The DPHN and their designated officers maintains an electronic/paper NBS register based on the full Birth Register (Immunisation/PHR/Child Health Information ICT System) and ensures all infants for the LHO have received the NNBSP and have a result recorded.

Tertiary Paediatric Hospitals – sample results

A 1.21.10 As per section A 1.3.3 the Tertiary hospital must have written procedures in place for:

- Performing the test between 72 and 120 hours after birth and repeat samples as recommended in the *Practical Guide to Newborn Bloodspot Screening In Ireland* (8th Edition Dec 2021) or as requested by the NNBSL.
- Sending the NBSC to the NNBSL.
- Receive the reports via eReports and post as applicable.
- Recording the results in the infant's medical records.

DPHN/LHO Checking NBS Register - sample results

A 1.21.11 DPHN Office/Designated Officer has direct access to the Immunisation/PHR/Child Health ICT system/database as an electronic full Birth Register for all infants in the LHO.

A 1.21.12 The DPHN Office/Designated Officer ensures homebirths and infants born outside the ROI are included in the Birth Register.

A 1.21.13 The DPHN/Designated Officer checks all NBS results against the Birth Register for the designated LHO area to ensure that <u>all infants</u> residing in the designated area have an NBS outcome status recorded by day 18.

A 1.21.14 The Designated Officer undertakes a <u>daily</u> monitoring of the eReports™ for initial requests for NBS and for any repeat NBS requests and informs the relevant ADPHN and/or PHN who arranges appropriate sampling and resampling for any infant who has returned home.

A 1.21.15 The Designated Officer undertakes "failsafe"[1] <u>weekly</u> monitoring procedures as follows:

- Confirmation that sample reached NNBSL through checking the eReports™ (i.e. check through "Patient Search" that the name of the infant is on eReports™ although results may not be available)
- If not reported within 4 days of sample collection (or by Day 12 if sample collection date is unknown), check that:
  - the Maternity Hospital/Unit of birth or SECM has completed the NBS
  - the RPHN/RM/RGN has taken the NBS
  - a record of the "*National Newborn Bloodspot Screening Programme Opt-out form*" form (Appendix XII) is in the CHR
  - the infant is known to have "moved out" of the area
  - infant has died

[1] Failsafe means in this context a system designed to ensure that if one part of the system does not work, the whole system does not become dangerous.

- Record closure of screening episode where information received identifies:
  - Confirmation that an infant has died
  - The family have refused the service and a "*National Newborn Bloodspot Screening Programme Opt-out form*" is completed (Appendix XII)
  - The family moved to another area, which has taken over responsibility for NBS
- If the NBSS has not been taken for other reasons, arrange sampling and continue to follow up until screening episode is closed
- Conclusive results will normally be available within 18 days of birth for most conditions screened. Cystic Fibrosis results may not be available for up to 30 days after birth.
- The designated officer signs/initials the entries to indicate that he/she has undertaken the exercise (Note: manual format).

A 1.21.16 Where confirmation is obtained through the eReports™ search that a sample has reached the NNBSL and no results or repeat request are received by Day 18, the designated officer makes a request for the results to the NNBSL (Appendix XVIII).

A 1.21.17 Where reports are received which do not belong to the LHO; the designated officer will inform the NNBSL (Appendix XIX).

A 1.21.18 The NBS Register should match the Immunisation/PHR/Child Health System. The designated officer will:

- Where infants have moved into the area and an eReport™ is received, the designated officer will inform the Immunisation/PHR/Child Health ICT system and add the infant to the NBS register
- Where infants are on the NBS register which is aligned to the Immunisation/PHR/Child Health ICT system and an eReport™ is not received, the designated officer will contact the NNBSL (telephone or email) to ascertain is there a change of address or detail.
  - If the infant is residing in the area, the designated officer will request the result (Appendix XXI) and notify the Immunisation/PHR/Child Health ICT system of any change in details of the child
  - If the infant is not residing in the area, the infant is ineligible for screening and the designated officer will notify the Immunisation/PHR/Child Health ICT system of any change in details of the child

A 1.21.19 Where issues are identified by the designated officer in the monitoring procedures the designated officer will inform the Nurse Manager (DPHN/ADPHN) as appropriate.

A 1.21.20 This Procedure does not mandate that all reports must be issued to RPHNs for filing. Work is in progress to centralise informing parents of results directly from the NNBSL. If required, the RPHN can obtain the NBS results from the DPHN/designated officer. Individual results can be printed out from the eReport™ system (Appendix XX) and sent to the RPHN to be filed in the CHR.

A.1.21.21 Where results are pending the DPHN/designated officer monitors the results which are pending via the eReports system until confirmation of final results are received.

A 1.21.22 The RPHN should discuss the results with the Parent(s)/legal Guardian(s) at the next child health check (3 months PHN child health assessment) as prompted by the CHR; i.e. not suspected/in treatment.

A 1.21.23 Parent(s)/legal Guardian(s) can request a written copy of the sample result from the DPHN and /or NNBSL:

- Where the results are normal the DPHN can issue the results to the Parent(s)/legal Guardian(s) via the DPHN office.
- Screen positive results will be notified as per Section A 1.26. The DPHN can liaise with the NNSBL and/or medical team before issuing the written copy to the Parent(s)/legal Guardian(s).

A 1.22 Repeat Screening Requests

A 1.22.1 Repeat samples are requested by the NNBSL and reasons for the repeat request are outlined, for example:

- Insufficient blood on card for all or some of the screens to be performed.
- Unsatisfactory sample quality – compressed/diluted sample, serum rings or contaminated
- Abnormal, borderline or equivocal test result.
- Baby too young when blood sample was collected, sample collected before 72 hrs after birth.
- Blood on the card not dried properly before being put into a plastic coated Tyvek® envelope, thus causing serum rings or a diluted sample.
- There is a query about the identification of the baby or babies if multiple births.
- The sample was taken on an expired card.
- The card was delayed, greater than 14 days getting to the NNBSL and is too old for analysis which can result in a false negative.
- The bloodspot portion of the NBS card and demographic portion were re-attached but NBS card barcodes do not match up.
- The name on the bloodspot portion does not match that on the demographic portion of the card; the identity of the baby may need clarification or a repeat sample.
- Sample is unsuitable for analysis if taken within 72hrs of a RBC transfusion.

A 1.22.2 The NNBSL will inform the DOM/N/designated officer in hospital services and the DPHN/ designated officer in community services that a repeat NBS is required by eReports.

A 1.23 Repeat Sampling

A 1.23.1 The DOM/N/Maternity Hospital/Unit and DPHN/LHO will establish the location of the infant:

- where the infant remains in Maternity Hospital/Unit care, the Maternity Hospital/Unit will complete the request
- where the infant has been discharged to the LHO, the repeat sample will be completed by Public Health Nursing Service

- If the infant is in a tertiary hospital see section A.1.3.

Repeat Newborn Bloodspot Screening for babies who remain in the Maternity Hospital/Unit/Tertiary Paediatric Hospital

A 1.23.2 The DOM/N/Designated Officer in hospital services will ensure the request for the repeat NBS is forwarded to the relevant ward on the day of receipt of request for repeat NBS and ensure that it is completed as soon as possible.

A 1.23.3 The RM/Nursery Nurse in the relevant ward will inform the Parent(s)/legal Guardian(s) of the reason for repeat sample taking and obtain consent.

A 1.23.4 Where the infant has been discharged from hospital care, the DPHN will be requested to complete the repeat NBSS.

A 1.23.5 In the event that the infant has been discharged from hospital care and the DPHN office cannot be contacted, for example outside of normal office hours (9-5 Mon-Fri), arrangements are made by the Maternity Hospital/Unit for the Parent(s)/legal Guardian(s) and the infant to return to the hospital for sample taking.

Repeat Newborn Bloodspot Screening for babies who have been discharged home (Public Health Nursing)

A 1.23.6 The DPHN/Designated Officer will ensure that the request for the repeat NBS is forwarded to and received by the appropriate RPHN/RM/RGN on the day of receipt of request for repeat NBS.

A 1.23.7 The RPHN/RM/RGN will contact the Parent(s)/legal Guardian(s) to arrange for sample taking as soon as possible either at a home visit or at a clinic visit.

A 1.23.8 The repeat NBSS will be completed as soon as possible.

A 1.23.9 If the repeat sample is due to be taken at a weekend, the sample may need to be taken in the local, Maternity Hospital/Unit if community services not available at the weekend – see Section A 1.6.5

A 1.24 Procedure for Repeat Sampling

A 1.24.1 The sample taker must:

- explain to the Parent(s)/legal Guardian(s) why a repeat sample has been requested
- assure the Parent(s)/legal Guardian(s) that if the repeat sample should prove screen positive, that they will be contacted immediately by a liaison nurse /Clinical Nurse Specialist from the relevant maternity hospital/unit programme
- be aware that the Parent(s)/legal Guardian(s) can decide to opt out of the repeat sample being taken. Section A 1.10 covers this in detail

A 1.24.2 The sample will be taken in the same way as the initial sample (Section A 1.10 – A 1.15).

A 1.24.3 The sample taker must clearly indicate on the NBSC that the sample is a Repeat Sample by ticking the box 'Yes'.

A 1.24.4 The sample should then be sent immediately to the NNBSL either by registered post or by courier or fast track services as appropriate.

A 1.24.5 The sample taker informs the DOM/N/DPHN/designated officer and/or NNBSL where relevant that the sample is taken and gives details of how the sample is sent to the laboratory.

A 1.24.6 The sample taker will keep a record of the NBS in the infant section of the maternal chart or the neo-natal infant chart for hospital services and/or the Child Health Record for community services.

- For community services the sample taker documents in the CHR that a repeat was required and the date the repeat sample was taken.
- The relevant designated officer records in the newborn bloodspot screening register that a request for a repeat sample has been received and that the NBS sample has been taken and submitted to the NNBSL.

A 1.25 NBS Repeat Sample Results

NNBSL notify Maternity Hospital/Unit/Community of repeat sample results

A 1.25.1 The NNBSL informs the DOM/N/ Maternity Hospital/Unit and the DPHN/LHO of the repeat sample results (individual report) of the repeat screening via eReports™.

A 1.25.2 The NNBSL follows up on all children where a result is not normal and/or requires clarification and further follow up.

A 1.25.3 The NNBSL liaises with the designated liaison nurse in the relevant maternity hospital/unit who refers the infant and their Parent(s)/legal Guardian(s) to the appropriate pathway if required.

A 1.25.4 The Clinical Team/Clinical Nurse Specialist for the appropriate care pathway makes contact with the family and arranges a hospital /outpatient visit for infants with a suspected screen positive result (See section A 1.25).

A 1.25.5 The designated officer for the DOM/N/Maternity Hospital/Unit and/or LHO DPHN for the designated LHO continues to follow up on repeat sample results until screening is closed.

A 1.26 Procedure for management of screen positive results and repeat Newborn Bloodspot Screening samples

Screen Positive Results

A1.26.1 The response to query screen positive result is immediate and direct.

A 1.26.2 The Clinical Liaison Nurse/Clinical Director of the NNBSL contacts the designated liaison midwife or paediatric registrar (depending on the disorder) in the Maternity Hospital/Unit and:

- informs of the name, UPI, date of birth and address of the infant
- the medical condition suspected and the result of the screen

- requests the designated liaison midwife in the Maternity Hospital/Unit to locate the infant and Parent(s)/legal Guardian(s)

A 1.26.3 The designated liaison Midwife/Paediatric Registrar in the Maternity Hospital/Unit contacts the Parent(s)/legal Guardian(s) to:

- explain why the infant has to be referred to hospital
- explain what medical condition is suspected in their infant, including the screening result and any other test results such as the Beutler
- explain why a further blood sample is required
- arrange with the Parent(s)/ legal Guardian(s) for the infant to be brought directly to the Children's University Hospital, Temple Street or to the local Paediatric Unit as requested by the Newborn Bloodspot Screening Laboratory
- advise the Parent(s)/legal Guardian(s) that their infant might be kept in hospital for a number of days depending on the result of the repeat investigation. Therefore they should go prepared for a hospital stay.

A 1.26.4 The designated liaison midwife in the Maternity Hospital/Unit may give the contact details of the Clinical Director of the National Newborn Bloodspot Screening Laboratory or their deputy to parents if they wish to obtain more information before they arrive in the hospital.

A 1.26.5 Special arrangements have been put in place to contact Parent(s)/legal Guardian(s) with suspected CF where the Clinical Liaison Officer in the NNBSL will contact the CF Nurse Specialists in the appropriate HSE designated paediatric CF centres to give them the full contact details, relevant information and results of the mutational screen. The CF Nurse Specialist will book a sweat test appointment if it is required and then contact the Parent(s)/legal Guardian(s) to arrange for the infant to attend the appropriate CF centre.

PART B: PPPG Development Cycle

B1 INITIATION

B 1.1 Purpose

To provide a standardised approach for the implementation of the National Newborn Bloodspot Screening Programme (NNBSP) in all hospitals and community settings.

B 1.2 Scope

This procedure and its appendices apply to all staff working directly and indirectly in the provision of the National Newborn Bloodspot Screening programme in all hospitals and community settings.

B 1.2.1 Target users of this procedure include all staff working directly and indirectly in the provision of the NNBSP.

B 1.2.2 The population to whom the NNBSP applies is all infants in the Republic of Ireland.

B 1.3 Objectives

B 1.3.1 To ensure a standardised approach in the delivery of the NNBSP to all infants in Ireland.

B 1.3.2 To promote the delivery of a safe and effective NNBSP by all Registered Public Health Nurses (RPHNs), Registered Midwives (RMs), Registered General Nurses (RGNs), Registered Children's Nurses (RCNs), Self Employed Community Midwives (SECMs), Private Midwives, midwifery students, student PHNs and Nursery Nurses who are providing the NNBSP in hospital or community settings.

B 1.3.3 To guide administrative/clerical officers who have delegated roles from the Director of Midwifery and/or Nursing (DOM/N) and Director of Public Health Nursing (DPHN) in supporting the processes of the NNBSP in Maternity Hospitals/Units, tertiary paediatric hospitals and Public Health Nursing services within CHOs/LHOs.

B 1.3.4 To provide information to Consultant Neonatologists, Consultant Paediatricians, Non Consultant Hospital Doctors (NCHD), Public Health Doctors, Community Medical Doctors and General Practitioners (GPs) who are working in Maternity Hospitals/Units and CHOs/LHOs on supporting best practice in relation to the delivery of the NNBSP.

B 1.4 Outcome(s)

B 1.4.1 Parent(s)/Legal Guardian(s) of all infants who are born in Ireland, or who become Irish residents in the first year of life without having been screened for the conditions in the NNBSP in their country of origin, should be offered newborn bloodspot screening as per the NNBSP.

B 1.4.2 Any infants suspected of having any of the conditions screened for should be referred to the appropriate clinical care pathway.

B 1.5 PPPG Development Group

See Appendix II for Membership of the PPPG Development Group.
See Appendix III for PPPG Conflict of Interest Declaration Form.

B 1.6 PPPG Governance Group

B 1.6.1 See Appendix IV for Membership of the Approval Governance Group.

B 1.7 Supporting Evidence

B 1.7.1 Relevant Legislation

- Department of Health and Children (1966) Circular 27/66 District Nursing Service
- Department of Health and Children (2000) Circular 41/2000
- General Data Protection Regulation (2016) European Commission
- Government of Ireland
  - Notification of Births Act (1907)
  - Notification of Births Extension Act (1915)
  - Guardianship of the Infant Act (1964)
  - Health Act (1970)
  - Data Protection Acts (1988, 2003)
  - Child Care Act (1991)
  - Civil Registration Act (2004) and Civil Registration (Amendment Act (2014)
  - Nurse and Midwives Act (2011)
  - Children First Act (2015)
  - Child and Family Relationship Act (2015)

B 1.7.2 Relevant Guidelines/Policy

- Children's Health Ireland at Temple Street (2021) A Practical Guide to Newborn Bloodspot Screening in Ireland (8th Edition)
- Health Information and Quality Authority (2012) National Standards for Safer Better Healthcare
- Health Information and Quality Authority (2016) Supporting Peoples Autonomy: a Guidance Document
- Health Information and Quality Authority (2017) National Standards for the Prevention and Control of Healthcare Acquired Infections
- Health Services Executive (2011) Standards and Recommended Practices for Healthcare Records Management
- Health Service Executive (2016) National Framework for developing policies, procedures, protocols and guidelines (PPPGs)
- Health Service Executive (2019) National Consent Policy
- Health Service Executive (2019) Data Protection Guidelines
- Health Service Executive (2019) Child Protection and Welfare Policy
- Health Service Executive (2019) National Infant Feeding Policy for Maternity and Neonatal services
- Health Service Executive (2019) National Infant Feeding Policy for Primary Care Teams and Community Health Organisations. Health Service Executive: Dublin.
- Health Service Executive(2020) National Healthy Childhood Programme Child Health Assessment Manual for Registered Public Health Nurses
- Health Service Executive (2021) Interim Guidance on Infection Prevention and Control for the Health Service Executive 2021 (HSE V1.3)
- National Institute for Health and Clinical Excellence (2021) *Guideline postnatal care of women and infants*. National Institute for Health and Clinical Excellence, London
- Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice Professional Guidance

- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework
- Nursing and Midwifery Board of Ireland (2021) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives
- World Health Organisation (2010) WHO Guidelines on Drawing Blood Best Practices in Phlebotomy
- World Health Organisation (WHO) (2013) *Recommendations on Postnatal care of the Mother and Newborn*

B 1.8 Glossary of Terms

B 1.8.1 Abbreviations

ADOM/N	Assistant Director of Midwifery and/or Nursing
ADPHN	Assistant Director of Public Health Nursing
CF	Cystic Fibrosis
CGAL	Classical Galactosaemia
CHIS	Child Health Information System
CHO	Community Healthcare Organisation
CHR	Child Health Record
CHT	Congenital Hypothyroidism
DOM/N	Director Of Midwifery and/or Nursing
DPHN	Director of Public Health Nursing
GA1	Glutaric Aciduria Type 1
GDPR	General Data Protection Regulations
GP	General Practitioner
HCU	Homocystinuria
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
IHI	Individual Health Identifier
LHO	Local Health Office
MCADD	Medium Chain Acyl-CoA Dehydrogenase Deficiency
MSUD	Maple Syrup Urine Disease
MN-CMS	Maternal and Newborn Clinical Management System
NBS	Newborn Bloodspot Screening
NBSC	Newborn Bloodspot Screening Card
NHCP	National Healthy Childhood Programme
NI	Northern Ireland
NIRF	National Incident Report Form
NICHIS	National Immunisation and Child Health Information System
NMBI	Nursing and Midwifery Board of Ireland
NN	Nursery Nurse
NNBSL	National Newborn Bloodspot Screening Laboratory
NNBSP	National Newborn Bloodspot Screening Programme
PCT	Primary Care Team
PHR	Personal Health Record
PKU	Phenylketonuria
PPPGs	Policies, Procedures, Protocols and Guidelines
RCN	Registered Children's Nurse

RGN	Registered General Nurse
RM	Registered Midwife
ROI	Republic of Ireland
RPHN	Registered Public Health Nurse
SECM	Self Employed Community Midwife
TOR	Terms of Reference
UPI	Unique Perinatal Identifier

B 1.8.2 Definitions

Appropriate	Matching the circumstances, meeting the needs of the individual, groups or situation (NMBI, Glossary of Terms)
Consent	Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a processof communication in which the service user has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention (HSE National Consent Policy, 2019)
Infant	Applicable up to one year of age
Must	Commands an action a nurse of midwife is obliged to take from which no deviation whatsoever is allowed (NMBI, 2021)
Professional Judgment	A nurses professional judgment is based on the principles of responsibility, accountability and autonomy as outlined within their professional scope of practice (NMBI, 2015)
Referral	An act of referring someone for consultation, review or further action if the required intervention is outside the scope of practice of the nurse or midwife's competence to provide safe, quality care (NMBI, Glossary of Terms)
Should	Indicates a strong recommendation to perform a particular action from which the deviation in particular circumstances must be justified (NMBI, 2021)

B 2 DEVELOPMENT OF PPPG

B 2.1 List the questions (clinical/non-clinical)

This is a review of the current national procedure. Review and development of this national procedure will provide a standardised procedure to the provision of the NNBSP by all hospital and community services.

What is the evidence-based guidance on newborn bloodspot screening that should be included in this procedure to assist services in providing the NNBSP.

B 2.2 Describe the literature search strategy

The NNBSP has been operational since 1966. The NNBSL developed a "*Practical Guide to Newborn Bloodspot Screening in Ireland*" which formed the basis for how the programme operated. This national procedure has been developed to compliment the '*Practical Guide to Newborn Bloodspot Screening in Ireland'* and offer more detailed guidance for relevant staff. Information from the relevant international screening and national guidance documents has been used to update this procedure.

B 2.3 Describe the method of appraising evidence

This update was informed by the Practical Guide to Newborn Bloodspot Screening in Ireland. National guidelines supported the development of this procedure and as such quality appraisal of those national documents did not take place.

B 2.4 Describe the process the PPPG Development Group used to formulate recommendations

A draft of the procedure was forwarded to representatives of all key stakeholders. All feedback submissions were analysed and reviewed by the PPPG development group. The final draft was submitted to the NNBP Governance Group.

B 2.5 Provide a summary of the evidence from the literature

Newborn bloodspot screening commenced in Ireland in 1966 with the development of a national screening programme for phenylketonuria (PKU). Currently in Ireland the National Newborn Bloodspot Screening Programme (NNBSP) screens for nine conditions and more may be added in the future. Participation in the NBS programme in Ireland is high, with an estimated uptake of 99.9%. This indicates considerable confidence in the programme, with the programme acknowledged as one of the most successful national public health initiatives. Each year, the NNBSP identifies approximately 110 infants in Ireland with one of the conditions screened for through the programme.

What is Newborn Bloodspot Screening?

Newborn bloodspot screening, also known as the 'heel-prick test' screens all newborn infants for nine rare conditions. A sample of blood is taken from the newborn infant's heel between 72 and 120 hours after birth and is sent to the National Newborn Bloodspot Screening Laboratory for analysis. The nine conditions screened for are:

- Phenylketonuria (PKU)
- Maple Syrup Urine Disease (MSUD)
- Homocystinuria (HCU)
- Classical Galactosaemia (GAL)
- Cystic Fibrosis (CF)
- Congenital Hypothyroidism (CHT)
- Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCADD)
- Glutaric Aciduria Type 1 (GA1)
- Adenosine Deaminase Deficiency Severe Combined Immunodeficiency (ADA-SCID)

Why is it important?

Newborn bloodspot screening ensures that any infants with any these rare conditions are identified and treated as early as possible. All conditions that form part of the NNBSP have been selected because they all have a relatively high incidence within the Irish population and they fulfil, in part or in full, the criteria that have been set out internationally for newborn screening. These include:

- The conditions screened for are treatable
- There is a screening test available which is easily applied to large population groups
- There are few false positives and false negative results; i.e. the test is reliable
- The incidence of the conditions in the community is sufficiently high to warrant screening
- The cost of screening makes the process cost-effective

Other issues of note

General Data Protection Regulations (GDPR)

The HSE Data Protection Officer has produced a number of guidance documents in relation to GDPR.

- HSE Data Protection Policy (https://www.hse.ie/eng/gdpr/hse-dataprotection-policy/hse-data-protection-policy.pdf)
- HSE Privacy Notice - Patients and Service Users (https://www.hse.ie/eng/gdpr/hse-data-protection-policy/hse-privacynoticeservice-users.pdf)
- HSE GDPR Frequently Asked Questions (https://www.hse.ie/eng/gdpr/gdprfaq/hse-gdpr-faqs-public.pdf)

Sharing information within the HSE

Within the HSE, the clinical information collected by a doctor or other healthcare professional or staff member authorised to process a service users' data is not passed on to others within the HSE, unless it is considered necessary for their health or social care needs or for one of the other reasons set out in the Data Privacy Notice.

Freedom of Information

The 2014 Freedom of information Act provides every person with the legal right to access official records held on them by the HSE. The relevant staff should ensure that information regarding the mother is documented only in the maternal postnatal record and not in the child health record. Only the mother or her designate should have access to her personal data in the maternal postnatal record.

Documentation

Professional record keeping and the documentation and interactions between the patient and healthcare professional are key features in clinical practice. The maintenance of accurate records is also essential given the professional and legal requirements on healthcare practitioners to ensure high standards of practice in this area (NHCP 2020). The Nursing and Midwifery Board of Ireland (NMBI highlights the importance of appropriate and high-quality documentation in the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI 2021).
NMBI advise that the maintenance of good clinical records is essential for nurses and midwives. Refer to Recording Clinical Practice Professional Guidance (NMBI 2015) for more detailed guidance if required.

Infection prevention and control considerations (IPC)

All staff should refer to the Health Protection Surveillance Centre website (www.hpsc.ie) for updated IPC publications. Standard Precautions and Transmission Based Precautions are detailed in the IPC guidance. They include advice regarding hand hygiene, use of Personal Protective Equipment (PPE), handling and disposing of sharps, precautions regarding droplet transmission, cleaning of equipment etc. Refer to HSE's Guidance on Infection Prevention and Control for further details.

B 2.6 Detail resources necessary to implement the PPPG recommendations

The NNBSP is already in operation using the "*Practical Guide to Newborn Bloodspot Screening in Ireland*" as a basis for its operation. Additional resources may be required in particular geographic areas and requirements for any additional resources should be escalated operationally through line management structures.
Changes will be required to the HSE Land online elearning module.
Briefing memos and/or sessions maybe required to highlight to staff that the procedure has been revised.

B 2.7 Outline of PPPG steps/recommendations - See Part A

B 3 GOVERNANCE AND APPROVAL

B 3.1 Outline Formal Governance Arrangements

B 3.1.1 The National Newborn Bloodspot Screening Programme Governance Group will oversee the operation of the NNBSP and this supporting procedure. The aim of the NNBSP Governance Group is to oversee the development and implementation of an effective and efficient quality assurance framework for the NNBSP to ensure that all infants are offered newborn bloodspot screening in accordance with agreed protocols and standard operating procedures.

This procedure was approved by the National Community Operations: Primary Care and the Office of the Chief Clinical Officer.

B 3.2 List method for assessing the PPPG in meeting the Standards outlined in the HSE National Framework for developing PPPGs.

This procedure was prepared by the Procedure Development Group using the HSE National Framework for developing PPPGs. This PPPG was developed in line with the HSE 2016 National Framework for PPPG Development which incorporates the NCEC Standards for Clinical Practice Guidance (2015).

B 3.3 Attach any copyright/permission sought

Not applicable.

B 3.4 Insert approved PPPG Checklist

Standards for developing Clinical PPPG	Checklist
Stage 1 Initiation	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	✔
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	✔
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	✔
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	✔
The views and preferences of the target population have been sought and taken into consideration (as required).	**Not Required**
The overall objective(s) of the PPPGs are specifically described.	✔
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	✔

Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	✔
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	✔
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	✔
There is service user/lay representation on PPPG Development Group (as required).	N/A
Information and support is available for staff on the development of evidence-based clinical practice guidance.	✔
Stage 2 Development	**Checklist**
The clinical question(s) covered by the PPPG are specifically described.	✔
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	Not Required – Programme already in operation
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	Not Required – Programme already in operation
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	Not Required – Programme already in operation
There is an explicit link between the PPPG and the supporting evidence.	✔
PPPG guidance/recommendations are specific and unambiguous.	✔
The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.	Not Required – Programme already in operation
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	Not Required – Programme already in operation
Budget impact is documented (resources required).	Not Required – Programme

	already in operation
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	Not Required
Three additional standards are applicable for a small number of more complex PPPGs: Cost effectiveness analysis is documented. A systematic literature review has been undertaken. Health Technology Assessment (HTA) has been undertaken.	Not Required
Stage 3 Governance and Approval	**Checklist**
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	Previous draft SOP was approved in 2016 – no change
The PPPG has been reviewed by independent experts prior to publication (as required).	Not Required
Copyright and permissions are sought and documented.	Not Required
Stage 4 Communication and Dissemination	**Checklist**
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	✔
Plan and procedure for dissemination of the PPPG is described.	✔
The PPPG is easily accessible by all users e.g. PPPG repository.	✔
Stage 5 Implementation	**Checklist**
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	Already in place
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	Not Applicable
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	Not Required
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	Already in place
Stage 6 Monitoring, Audit, Evaluation	**Checklist**
Process for monitoring and continuous improvement is documented.	Already in place
Audit criteria and audit process/plan are specified.	Already in place
Process for evaluation of implementation and (clinical) effectiveness is specified.	Not required
Stage 7 Revision/Update	**Checklist**
Documented process for revisions/updating and review, including timeframe is provided.	✔
Documented process for version control is provided.	✔

I confirm that the above Standards have been met in developing the following:

Title of PPPG: Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

Name: Paul Marsden	**Signature:** Paul Marsden
Title: Project Manager	**Date: 16/05/2022**

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved

B 4 COMMUNICATION AND DISSEMINATION

B 4.1 Describe communication and dissemination plans

This national procedure was commissioned by the NNBSP governance group. A development group was established with representatives from hospital and community services. A draft of the procedure developed. Feedback was sought on the consultation draft from key stakeholder groups such as DPHNs, DOMs, NNBSL, Office of Nursing and Midwifery Services Director (ONMSD), Higher Education Institutions, Midwifery Schools, SECMs, Private Midwives, National Healthy Childhood Programme, National Clinical Programme for Children and the INMO. The Development Group reviewed all feedback received and a final draft of the procedure was prepared. The final draft of the procedure was submitted to the NNBSP Governance Group for recommendation for approval to HSE National Community Operations and the Office of the Chief Clinical Officer.

The approved document will be circulated to all Maternity Hospitals/units and DPHNs and Tertiary Paediatric Hospitals nationally for dissemination to their respective nursing departments and to other key stakeholders involved in providing the NNBSP. A copy of the procedure is available on the HSE website to download at https://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/information-for-professionals/national-newborn-bloodspot-screening-programme.pdf.The procedure will be submitted to the National Central Repository of the HSE.

Communication in relation to this procedure will clearly identify that it supersedes all previous NNBS procedures.

B 5.0 IMPLEMENTATION

B 5.1 Describe implementation plan listing actions, barriers and facilitators and timelines

The NNBSP is already in operation using the "*Practical Guide to Newborn Bloodspot Screening in Ireland*" (8th Edition, Dec 2021) as a basis for its operation. Therefore there will be no requirement for an implementation plan. This Procedure will be disseminated as per Communication and Dissemination plan (Section 4) to alert all users to the updated version of the procedure. The HSE Land online training module on newborn bloodspot screening will reference this latest version of the procedure

B 5.2 Describe education/training plans required to implement the PPPG

The NNBSP is already in operation using the "*Practical Guide to Newborn Bloodspot Screening in Ireland*" (8th Edition, Dec 2021) as a basis for its operation. The HSE LanD online training module has been updated and will be offered to relevant staff in conjunction with the communication and dissemination of this procedure.

B 5.2.1 The DOM/N, DPHN/DON Designated Midwifery Officer (SECM)/Team Leader (Private Midwives) will ensure that:

- Nursing and Midwifery staff members will be informed of this updated procedure.
- All relevant administrative and clerical staff members will be informed of this updated procedure.
- The online module on HSE LAND will be updated to reflect any changes
- The online version will be available at https://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/information-for-professionals/national-newborn-bloodspot-screening-programme.pdf
- While this document may be printed the electronic version on the website is the controlled copy and can only be guaranteed for 24 hours after downloading.

B 5.3 Identify lead person(s) responsible for the implementation of the PPPG.

Project Manager National Childhood Screening Programmes

B 5.4 Outline specific roles and responsibilities

The **NNBSP Governance Group** is responsible for developing and recommending this national procedure for use to Primary Care Operations and Chief Clinical Officer for approval. On approval the NNBSP Governance Group will ensure the final approved copies are circulated to all DPHNs and DOM/Ns nationally. The NNBSP Governance Group will agree a review date for this procedure and in the event of amendments to legislation, HSE policy or other related PPPGs will initiate an earlier review as required.

The NNBSP Governance Group will ensure:

- This document is available online at https://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/information-for-professionals/national-newborn-bloodspot-screening-programme.pdf
- The update, if necessary, to the HSE Land Newborn Bloodspot Screening Module

DOM/Ns, DPHNs and DONs of Tertiary Paediatric Hospitals

Within the Maternity Hospitals/Units, the community services and the Tertiary Paediatric Hospitals, the DOMN/DPHN /DON will be responsible for ensuring that:

- Nursing and Midwifery staff members will be informed of this revised procedure
- All relevant administrative and clerical staff members will be informed of this revised procedure
- Nursing and Midwifery staff will be informed of the educational module available on HSE Land of the educational update on the NNBSP
- It is the responsibility of Line Managers to ensure that staff members working under their remit have read and signed the policy (on paper or electronic format) in each clinical area.
- This version of the document will be made available in an electronic format.

Designated Midwifery Officer

The Designated Midwifery Officer for SECMS who are employed under the Memorandum of Understanding and Contractual Agreement (2014) will ensure that:

- SECMS will be informed of this revised procedure.
- All relevant administrative and clerical staff members will be informed of the approval of this revised procedure.
- Nursing and Midwifery staff will be informed of the educational module available on HSELanD of the educational update on the NNBSP
- It is the responsibility of Line Managers to ensure that staff members working under their remit have read and signed the policy (on paper or electronic format) in each clinical area.
- This version of the document will be made available in an electronic format

Private Midwives Team Leader

The Team Leader of Private Midwives who are contracted by the Parent(s)/Guardian(s) will ensure that:

- Private Midwives will be informed of this revised procedure.
- All relevant administrative and clerical staff members will be informed of the approval of this revised procedure.
- Nursing and Midwifery staff will be informed of the educational module available on HSELanD of the educational update on the NNBSP

Role of nurses and Midwives

It is every nurse and midwives' responsibility to ensure they are working within their "Scope of Practice" at all times and that they identify their training needs to their manager to maintain standards of care (NMBI, 2015).

Each nurse/midwife is responsible for adhering to this procedure and to use it to guide their practice in the delivery of the service they provide. Each nurse/midwife is responsible for ensuring that they read and understand the document and sign the attached signature sheet or have confirmed this through the MAPS policy portal where it is in use. When areas of concern are identified, where legislation is known to have changed or where a health and safety risk is identified, it is the responsibility of each nurse/midwife to ensure that their line manager is informed in order to ensure appropriate review and amendments are made to the guideline.

B 6.0 MONITORING, AUDIT AND EVALUATION

B 6.1 Describe the plan and identify lead person(s) responsible for the following processes:

B 6.1.1 Monitoring of the implementation of this procedure will be through the DPHN/DOM/N/DON/Designated Midwifery Officer

B 6.1.2 Audit

Midwifery/Nursing/Public Health Nursing management team will conduct an annual audit. The objectives of the audit will be:

- to provide evidence of compliance to the national procedure
- to ensure standardisation of application of the procedure
- to identify areas for improvement, make recommendations and prioritize actions

B 6.1.3 Evaluation

Evaluation of the procedure will be initiated by the Project Manager, Child Health Screening Programmes and will occur through feedback at professional team meetings, direct patient feedback and through reviews of National Incident Report Forms (NIRFs) to monitor any Near-Misses/Adverse Incidents. Feedback from Your Service Your Say and through local formal complaints processes will be considered in any revision of the procedure.

B 7.0 REVISION/UPDATE

B 7.1 Describe procedure for the update of the PPPG (including date for revision)

A formal review of this version will be carried out on a three yearly basis unless there is a change required informed by legislation, best practice or any relevant EU Directives which may indicate a requirement to update this procedure sooner.

The responsibility for this review lies with the NNBSP Governance Group. Any learnings that arise from the ongoing monitoring and evaluation of the NNBSP that may impact on this procedure will be used to amend, update and change Version 4. If there are no amendments to the PPPG following the review process, the date and detail on the version tracking box on the front cover of the PPPG will be updated anyway.

Where another condition(s) is added to the NNBSP this version will be updated to reflect the addition.

B 7.2 Identify method for amending PPPG if new evidence emerges

When areas of concern are identified, where legislation is known to have changed or where a health and safety risk is identified, it is the responsibility of each nurse/midwife to ensure that their line manager is informed in order to trigger an appropriate review and amendments if necessary are made to the guideline nationally. Practitioners will assist in the revision of the guideline and also request an earlier review of this guideline where required if new evidence-based practice is recommended.

B 7.3 Complete version control update on PPPG Template cover sheet.

This is version 4 of the procedure. See version control document on the cover sheet for updated sections.

B 8.0 REFERENCES

European Commission (2016) General Data Protection Regulations https://ec.europa.eu/info/law/law-topic/data-protection/eu-data-protection-rules_en

Health Service Executive (2016) National Framework for Developing Policies, Procedures, Protocols and Guidelines (PPPGs). Health Service Executive: Dublin.

Health Service Executive (2019) National Infant Feeding Policy for Primary Care Teams and Community Health Organisations. Health Service Executive: Dublin.

Health Service Executive (2019) National Infant Feeding Policy for Maternity & Neonatal Services

Health Service Executive (2020) National Healthy Childhood Programme Child Health Assessment Manual for Registered Public Health Nurses

Health Service Executive (2021) Guideline on the Observation of a Breastfeed and use of the Breastfeeding Observation Assessment Tool (BOAT) resource. Health Service Executive: Dublin.

Health Service Executive (2022) National Consent Policy 2022 V1. Health Service Executive: Dublin.

Children's Health Ireland (2021) A Practical Guide to Newborn Bloodspot Screening in Ireland – 8th Edition. National Newborn Bloodspot Screening Laboratory, Children's University Hospital Temple Street

National Institute for Health and Care Excellence (NICE) (2021) Postnatal Care: NICE Guideline www.nice.org.uk/guidance/ng194

Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice Professional Guidance. Nursing and Midwifery Board of Ireland: Dublin.

Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Nursing and Midwifery Board of Ireland: Dublin.

Nursing and Midwifery Board of Ireland (2021) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Nursing and Midwifery Board of Ireland: Dublin.

World Health Organisation (2010) WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. https://apps.who.int/iris/handle/10665/44294

B 9.0 APPENDICES

Appendix I: Signature Sheet

Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

Signature Sheet

I have read, understand and agree to adhere to this Policy, Procedure, Protocol or Guideline:

Print Name	Signature	Area of Work	Date

Appendix II: Membership of the PPPG Development Group

Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

Please list all members of the development group (and title) involved in the development of the document.

Sinead Lawlor National Practice Development Co-Ordinator Public Health Nursing Services	Signature: Sinead Lawlor Date: 17/05/2022
Grace O'Neill Regional Child Health Training/Development Officer/Immunisation Co-Ordinator	Signature: Grace O'Neill Date: 17/05/2022
Jan Flanagan Director Public Health Nursing (Roscommon)	Signature: Jan Flanagan Date: 17/05/2022
Sheila Heery Practice Development Co-Ordinator Public Health Nursing Services (Kerry)	Signature: Sheila Heery PHN PDC CKC# Date: 17/05/2022
Fiona Hanrahan Director of Midwifery, Rotunda Maternity Hospital	Signature: Fiona Hanrahan Date: 17/05/2022
Paula Power Director of Midwifery, St Luke's Hospital Kilkenny	Signature: Power Date: 17/05/2022
Mary Dwyer/Siobhan Mulvany Clinical Midwifery Manager II, Rotunda Maternity Hospital	Signature: MDwyer Siobhan Mulvany Date: 17/05/2022
Niamh Murphy Public Health Nurse, Clonaslee	Signature: *Niamh Murphy* Date: 17/05/2022
Chairperson: Paul Marsden Project Manager Child Health Screening Programmes National Healthy Childhood Programme	Signature: Paul Marsden Date: 17/05/2022

Appendix III: Conflict of Interest Declaration Form

CONFLICT OF INTEREST DECLARATION

This must be completed by each member of the PPPG Development Group as applicable

Title of PPPG being considered: Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP)

Please circle the statement that relates to you

1. I declare that I DO NOT have any conflicts of interest.

2. I declare that I DO have a conflict of interest.

Details of conflict (Please refer to specific PPPG)

_____

_____

_____

_____

(Append additional pages to this statement if required)

Signature

Printed name

Registration number (if applicable)

Date

The information provided will be processed in accordance with data protection principles as set out in the Data Protection Act. Data will be processed only to ensure that committee members act in the best interests of the committee. The information provided will not be used for any other purpose.

A person who is covered by this PPPG is required to furnish a statement, in writing, of:

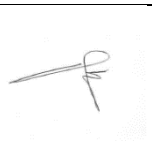
(i) The interests of the person, and

(ii) The interests, of which the person has actual knowledge, of his or her spouse or civil partner or a child of the person or of his or her spouse which could materially influence the person in, or in relation to, the performance of the person's official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold from, the person, or the spouse or civil partner or child, a substantial benefit.

Appendix IV:

Membership of the Approval Governance Group

Please list all members of the relevant approval governance group (and title) who have final approval of the PPPG document: **Procedure for all Community and Hospital Services Providing the National Newborn Bloodspot Screening Programme (NNBSP).**

T.J. Dunford Head of Operations/Assistant National Director, Primary Care Operations	Signature:  Date: 17/05/2022
Angela Dunne Director of Midwifery National Women and Infant Health Programme	Signature:  Date: 17/05/2022

Appendix V: Local Health Office Areas

Community Healthcare Organisation (CHO) Area	Local Health Office (LHO) Area
1	Donegal
	Sligo/Leitrim/West Cavan
	Cavan/Monaghan
2	Galway
	Mayo
	Roscommon
3	Limerick/North Tipperary
	Clare
4	Kerry
	North Cork
	North Lee
	South Lee
	West Cork
5	Carlow/Kilkenny
	South Tipperary
	Waterford
	Wexford
6	Dublin South East
	Dun Laoghaire
	Wicklow
7	Dublin South City
	Dublin South West
	Dublin West
	Kildare/West Wicklow
8	Laois/Offaly
	Longford/Westmeath
	Louth
	Meath
9	Dublin North
	Dublin North Central
	Dublin North West

Appendix VI: DOM/N/Maternity Hospital/Unit Unique Perinatal Identifier (UPI)

National Newborn Bloodspot Screening Programme - Unique Perinatal Identifier

What is the Unique Perinatal Identifier (UPI)

From 1st July 2011 each infant born in Ireland will be issued with an individual (unique) identifying number to ensure that Newborn Bloodspot Screening samples can be traced throughout the screening process.

Why is the UPI being introduced now?

This date has been chosen to coincide with the introduction of Newborn Screening for Cystic Fibrosis (CF) on 1st July 2011. CF screening will be added to the conditions for which screening already takes place through the 'heel-prick' method and will be carried out on the same bloodspot sample.

How will the UPI be issued?

The UPI will be formed by the 3 digit hospital HIPE code (see list of maternity hospitals/units below) of the birth hospital followed by the Healthcare Record Number (HCRN) of the infant.

Will an infant who is not born in an Irish Maternity Hospital/Unit receive a UPI?

Infants born either at home or in a maternity hospital/unit outside Ireland will be issued a UPI by the Director of Public Health Nursing in the area in which their birth is registered following notification of birth.

How will the UPI work?

The number will be used on all information relating to the National Newborn Bloodspot Screening Programme (NNBSP) including the following:

- On all Newborn Screening Cards sent to the National Newborn Screening Laboratory in the Children's University Hospital Temple Street including repeat samples
- On maternity hospital/unit Newborn Bloodspot Screening Registers
- On requests from maternity hospital/unit to Public Health Nursing Services to undertake Newborn Bloodspot Screening
- On requests from maternity hospitals/unit to a Children's hospital/unit to undertake Newborn Bloodspot Screening on infants transferred prior to completion of the NNBSP
- On LHO/ISA community child health service Newborn Bloodspot Screening Registers
- On NNBSL reports
- On all notifications of births from maternity hospitals/units to LHO/ISA community child health services (This may not be possible in all areas until the new Maternal and Newborn Clinical Management System is in place).

Will there be a space to put the UPI on the NBS card?

The Newborn Bloodspot Screening Cards have been modified to include a space for UPI.

What happens with maternity hospitals/unit where infant does not have its own healthcare record number?

For the small number of hospitals/units where this is the case, support has been provided through the Newborn Screening for Cystic Fibrosis Implementation process over recent months to assist in addressing the changes required prior to 1st July 2011.

HIPE Code	Maternity Hospital / Unit
201	Midland Regional Hospital Portlaoise
202	Midland Regional Hospital Mullingar
301	University Hospital Limerick
402	Cavan General Hospital
500	Letterkenny General Hospital
501	Sligo University Hospital
600	University Hospital Waterford
601	St Luke's General Hospital Kilkenny
605	Wexford General Hospital
607	South Tipperary General Hospital
724	Cork University Hospital
726	University Hospital Kerry
800	Galway University Hospitals
802	Mayo University Hospital
919	Portiuncula Hospital Ballinasloe
922	Our Lady of Lourdes Hospital Drogheda
930	Coombe Women and Infants University Hospital
931	National Maternity Hospital Holles Street
932	Rotunda Hospital Dublin

Appendix VII: Information for Parents and Guardians

Copies of the leaflet are available to order from www.healthpromotion.ie

Appendix VIII: DPHN/LHO Unique Perinatal Identifier for NNBSP

Unique Perinatal Identifier (UPI) for non-Irish hospital births.

The first 3 digits of the UPI for non-Irish hospital births will be as follows:

L01	Dublin Area 1
L02	Dublin Area 2
L03	Dublin Area 3
L04	Dublin Area 4
L05	Dublin Area 5
L06	Dublin Area 6
L07	Dublin Area 7
L08	Dublin Area 8
L09	Wicklow
L10	Kildare
L11	Louth
L12	Meath
L13	Cavan
L14	Monaghan
L15	Longford/Westmeath
L16	Laois/Offaly
L17	Wexford
L18	Waterford
L19	South Tipperary
L20	Carlow/Kilkenny
L21	Cork South
L22	Cork North
L23	Cork West
L24	Kerry
L25	Limerick
L26	Clare
L27	Tipperary North/East Limerick
L28	Galway
L29	Roscommon
L30	Mayo
L31	Sligo/Leitrim
L32	Donegal

The remaining digits of the identifier will then commence with the year (i.e. 2011 followed by a unique 4 digit number given by the LHO (e.g. 0001 for the first non-Irish hospital birth notified each year, 0002 for the second).

These will be allocated by the DPHN (or her/his nominee) and recorded in a file held locally (either electronically or in a manual file).

- Therefore the third infant recorded in such a manner in Dublin Area 5 in 2012 would have the following UPI **L05 20120003**
- The third infant recorded in such a manner in Longford/Westmeath in 2012 would have the following UPI **L15 20120003**

Appendix IX: Newborn Bloodspot Screening Card Parent Information Copy

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Information for Parent/Legal Guardian

The Newborn Bloodspot (heel-prick) screen helps identify babies who may be at high risk of having a rare but serious condition. Most babies who are screened will not have any of the conditions, but for the small number of babies who do, the benefits of screening are enormous.

Early treatment can improve health, prevent disability and early death. However, unfortunately, not all cases of these rare conditions may be detected by newborn bloodspot screening.

You are asked to sign the newborn bloodspot screening card to confirm that the information about your baby is correct and that you agree to the screen. If you do not want your baby screened you should speak with your public health nurse or midwife, and you will be asked to sign a different form. The newborn bloodspot screening card is sent for analysis to the National Newborn Bloodspot Screening Laboratory, Temple Street, Dublin. Occasionally, the public health nurse or midwife may contact you and ask to take a second blood sample from your baby's heel. This may be because not enough blood was collected, or because the result was not clear.

Depending on the screening result, your child's sample may be sent for a specific confirmatory genetic test relevant only to a condition included in the newborn bloodspot screening programme, to complete the screening process.

Following screening a bloodspot may be used:

- For checking your baby's results or for other tests that your doctor recommends, but only after you give permission
- For quality control purposes and to help improve the screening programme. In such circumstances all samples will be completely anonymised and it will not be possible to trace any results back to an individual child.

If you would like a copy of the screening results, please ask your public health nurse.

For further information on all aspects of the newborn bloodspot screening programme including the conditions, the screen and the bloodspot sample, see the Information Leaflet for Parents or visit www2.hse.ie/heel-prick-screening or www.newbornscreening.ie

The newborn bloodspot screening card and results are stored securely as part of your baby's health record by the National Newborn Bloodspot Screening Laboratory. The newborn bloodspot screening card will be stored securely for at least 10 years, after which it will be destroyed as per current policy.

Appendix X: Newborn Bloodspot Screening Card

NATIONAL NEWBORN BLOODSPOT SCREENING LABORATORY
Temple St, Dublin D01 YC67 Tel: 01 878 4277 Fax: 01 878 4596 info.newbornscreening@cuh.ie

Laboratory Use Only

Gest. Age (weeks) | Time of Birth (H H M M) | Date of Birth (D D M M Y Y)

Birth Weight (kg) | Rank | Sex ☐M ☐F | Date of First Feed (D D M M Y Y)

RBC Transfusion Received? ☐Y ☐N
If Yes: Date of First Transfusion (D D M M Y Y) | Time of First Transfusion (H H M M)
Date of Last Transfusion (D D M M Y Y) | Time of Last Transfusion (H H M M)

Type of Feed
☐Breast ☐Artificial ☐IV fluids
☐Soya/Lactose free ☐TPN ☐Glu/Dex

Comments/Family Hx/ Beutler/Meconium Ileus

Date of Collection (D D M M Y Y) | Time of Collection (H H M M) | Repeat Specimen ☐Y ☐N

Sample Taker's name (Print): _____
contact no.: _____

Parent/Legal Guardian preferred language: _____

Parents Ethnicity: (codes on back) ☐ Other: ☐

I confirm that the details on this card are correct; I have read the information leaflet. I consent to my child being screened.

Parent/Legal Guardian Signature: _____

Laboratory Copy

1826501

BABY'S Unique Perinatal Identifier (UPI) — —

BABY'S Surname

Baby's First Name

Baby's Address | EIRCODE

Hospital/Place of Birth

Baby's Healthcare Record number (if transferred to another hospital)

Mother's Surname IF DIFFERENT FROM BABY'S

Local Health Office

Location Sample Taken: ☐ Community/Home ☐ Hospital
If Transfer, State Hospital

GP's Name

EXPIRY DATE 2026/09

Appendix XI: Patient Details Amendment Form

This form is to gather only required information to complete infants' newborn bloodspot screen and to comply with GDPR regulations. Amend incorrect details that were recorded by sample taker or in the laboratory and comply with GDPR regulations.

Re: Lab sample no. YY - XXXXXX

Infant's surname:

DOB:

Infant's Unique Perinatal Identifier:

Address:

Hospital of birth:

Dear NNBSL please amend the following details on infant noted above:

Signed by: **PRINT NAME:**

Position: Phone no**:**

Please forward to one of the following

- Secure email info.newbornscreening@cuh.ie
- Secure fax 01 8784596
- Post to Newborn Screening Laboratory CHI , Temple St., D01 YC67

NOTE: If attaching additional documentation please ensure it only contains required information on infant, not mother in order to comply with GDPR regulations, e.g. birth notification not suitable as mums history attached and not appropriate to share outside Maternity unit.
All documents received will be attached to patient record and stored permanently.

Lab use only

Source of error: Laboratory/LHO/Maternity unit /Other (please **circle)**

Details checked on LIMS:	Disclaimer added:
Sample quality checked:	Results reviewed:
Amended by:	PC action complete:
	Sign:

Appendix XII: National Newborn Bloodspot Screening Programme Opt-Out Form

Download the opt-out form via:
https://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/information-for-professionals/phn/national-newborn-bloodspot-screening-programme-opt-out-form.pdf

Seirbhís Sláinte Health Service Executive

NATIONAL NEWBORN BLOODSPOT SCREENING PROGRAMME

OPT-OUT FORM

Baby's Unique Perinatal Identifier (UPI): _____ - _____ Gender: *(Please circle)* M F

Baby's Surname: _____ Gest Age: *(Weeks)* _____

Baby's First Name: _____ Rank: _____

Baby's Address: _____ Hospital/Birth Place _____

Mother's Surname: _____

Time of Birth: H H M M Date of Birth: D D M M Y Y Birth Weight *(kgs):* _____ . _____

RBC Transfusion Received? Y / N *If Yes* Date of First Transfusion: D D M M Y Y Time of First Transfusion: H H M M

Date of First Feed: D D M M Y Y Local Health Office: _____

- I_____being the parent/legal guardian of Baby _____ do not consent to allow the Newborn Bloodspot Screen (Heel-Prick) to be carried out on my baby.
- I have read the Newborn Bloodspot Screening information leaflet and the screen has also been explained to me.
- I fully understand the importance of the decision that I am taking by not allowing my baby to be screened.
- I understand that not detecting or treating one of the conditions, should my baby have one, may result in severe intellectual or physical disability which could require long term care or result in premature death.

Signed (Parent/Legal Guardian): _____

Full Name (PRINT):_____ **Date:** _____

Signed by potential sample taker:_____ **Date:** _____

Position/Job Title:_____ **Health Area Office:** _____

Ensure copies of opt-out form are sent to all locations below

Six copies of this completed form, signed by parent/legal guardian and sample taker should be made.
A copy to be given to the parent/legal guardian and a copy kept by the sample taker, plus a copy posted to each of the following:- • The Director of Nursing/Midwifery • Director of Public Health Nursing • National Newborn Bloodspot Screening Laboratory • The baby's General Practitioner

	Director of Nursing/Midwifery	Director of Public Health Nursing	National Newborn Bloodspot Screening Laboratory (NNBSL)	General Practitioner
Name				
Address			NNBSL, Children's University Hospital, Temple Street, Dublin D01 YC67	
Date Sent				

Signed *(Potential Sample taker)*:_____ Date: _____

Name (*Block Capitals)*: _____

Parents/Legal Guardians may change their mind and 'opt back in' to have their baby screened, until their baby reaches one year of age, but it is their responsibility to inform their GP or Public Health Nurse. The Cystic Fibrosis 'heel prick' screen is not suitable if a baby is over six weeks of age and a different test is necessary, separate to the heel prick, for this component of the screening programme.

LF-NNS-0116 ver.2 ***www.newbornscreening.ie***

Appendix XIII: National Newborn Bloodspot Screening Laboratory Contact Details

Contact Details	
Children's University Hospital **Temple Street, Dublin 1, D01 YC67**	(01) 878 4200
Newborn Screening Laboratories	
Enquiries	(01) 878 4277
Fax	(01) 878 4596
Email Address	info.newbornscreening@cuh.ie
Director: Dr Jennifer Brady	(01) 878 4277
Chief Medical Scientist: (Ms Loretta O' Grady)	(01) 878 4277
Clinical Liaison Officer: (Ms Catherine Harvey)	(01) 8921804
National Centre for Inherited Metabolic Disorders	
Enquiries	(01) 878 4317
Laboratory Opening Hours	
Monday to Friday Analysis including Beutler samples and reporting of results	**09:00-17:00**
Saturday Morning Analysis including Beutler samples and reporting of results Beutler samples must be in the NNBSL before 10:00	**09:00-12:00**
Christmas and Easter Holidays:	Opening hours will be circulated well in advance and/or posted on the website

All samples received in the laboratory up to 12:00 will be analysed that day, samples received after that will be analysed the next working day. The 12:00 deadline may change on Christmas Eve or Good Friday, sample takers will be notified in advance.

Appendix XIV: Newborn Bloodspot Screening Card Checklist for Sending Samples Together

Newborn Bloodspot Screening Card Checklist

IMPORTANT

Ensure samples are dry, envelopes are sealed and no automated incision devices enclosed

Please complete this form and list each infant's name and UPI as written on the screening cards.

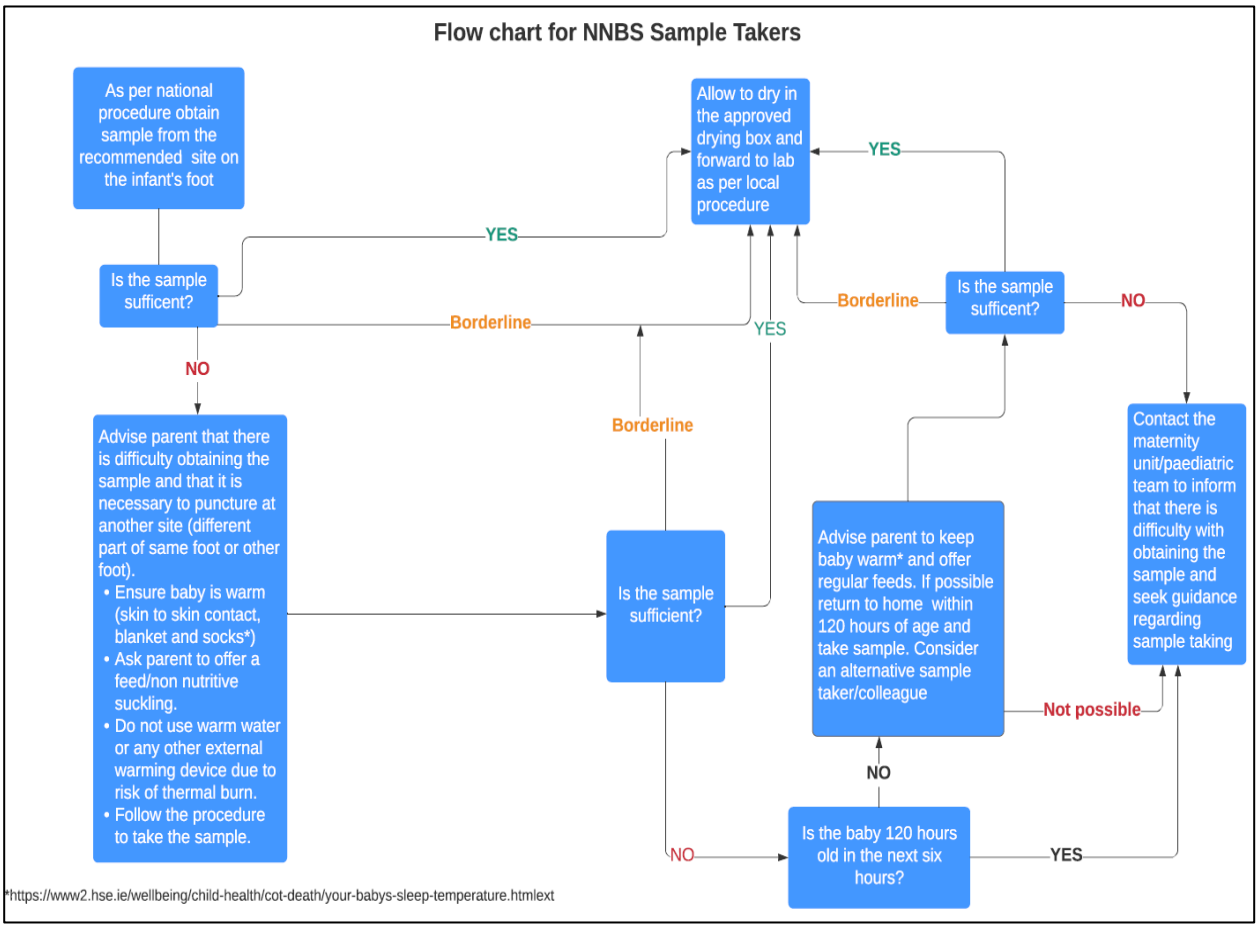
This form should be included in all envelopes containing more than one screening card (maximum of 3 samples)

The National Newborn Bloodspot Screening Laboratory
Children's University Hospital, Temple Street, Dublin 1, D01 YC67
Ph: 01 8784610/4277

Location:		**Contact No.:**
Total number of cards:	**Date Posted:**	**Checked by:**

Infant's Surname (as on card)	**Infant's UPI (as on card)**	**Additional Comment** *if relevant*

Appendix XV: Flow chart for Newborn Bloodspot Screening Sample Takers



Appendix XVI: Transport/Drying Box – Procedure for Transporting Samples

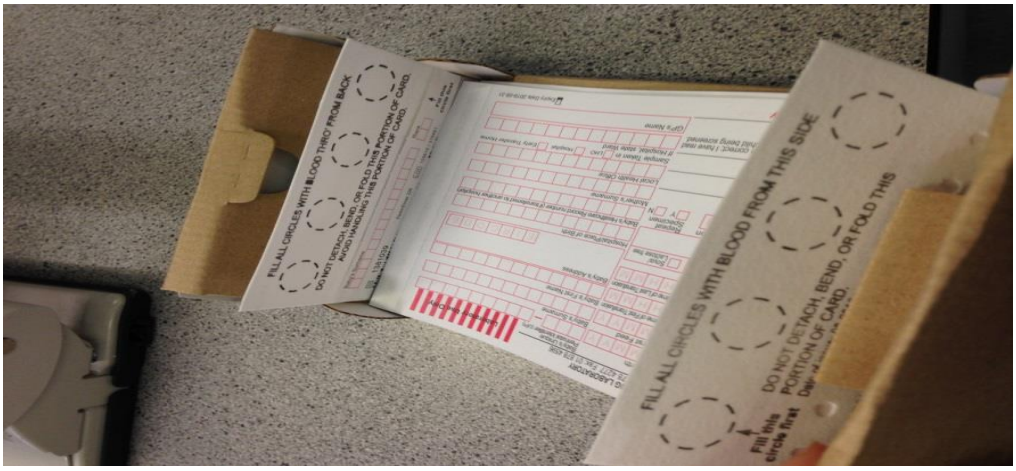
Transport/Drying Boxes

- The National Newborn Bloodspot Screening Laboratory has designed drying/transport boxes in conjunction with Mega Pak to facilitate the transport of NBSCs from the infant's home to the PHNs car in a safe manner. Once the bloodspot has dried, the NBSC should be removed from the box and packaged according to the regulations. These drying boxes can contain two NBSCs.

- The boxes are reusable. However, if they become contaminated with blood they should be disposed of either by incineration or through the accepted procedure for disposable of hazardous waste.

- These boxes can be ordered directly from Mega Pak Ltd by the Public Health Nursing Department. The minimum order is 150 boxes, flat packed in batches of 50 from Mega Pak Ltd (Irish Office), 16 Highfield Green, Swords, Co Dublin. Tel: 01 8402063, email megapakireland@eircom.net, website www.mega-pak.com

Drying box for two NBS cards: top and tail samples, blood spots should not come in contact



Procedure for transporting samples

The sender of NBSCs by registered post or by courier is responsible for ensuring that the packaging and transportation of the sample complies with current transport regulations regarding Health and Safety as laid down in the European Directive (ADR 2015) Packaging Regulations P650.

Dried bloodspots must be packaged appropriately. NNBSL recommends that once the blood has dried, the NBSC should be inserted into a water-resistant, tear-proof Tyvek® envelope or equivalent. The yellow fluorescent address label should be fixed to the outer envelope.

Pre-printed registered envelopes

Pre-printed plastic envelopes may be purchased directly from An Post by e-mailing customer service at irishstamps@anpost.ie and copying both Brian Beehan (brian.beehan@anpost.ie) and Noreen Hudson (noreen.hudson@anpost.ie)

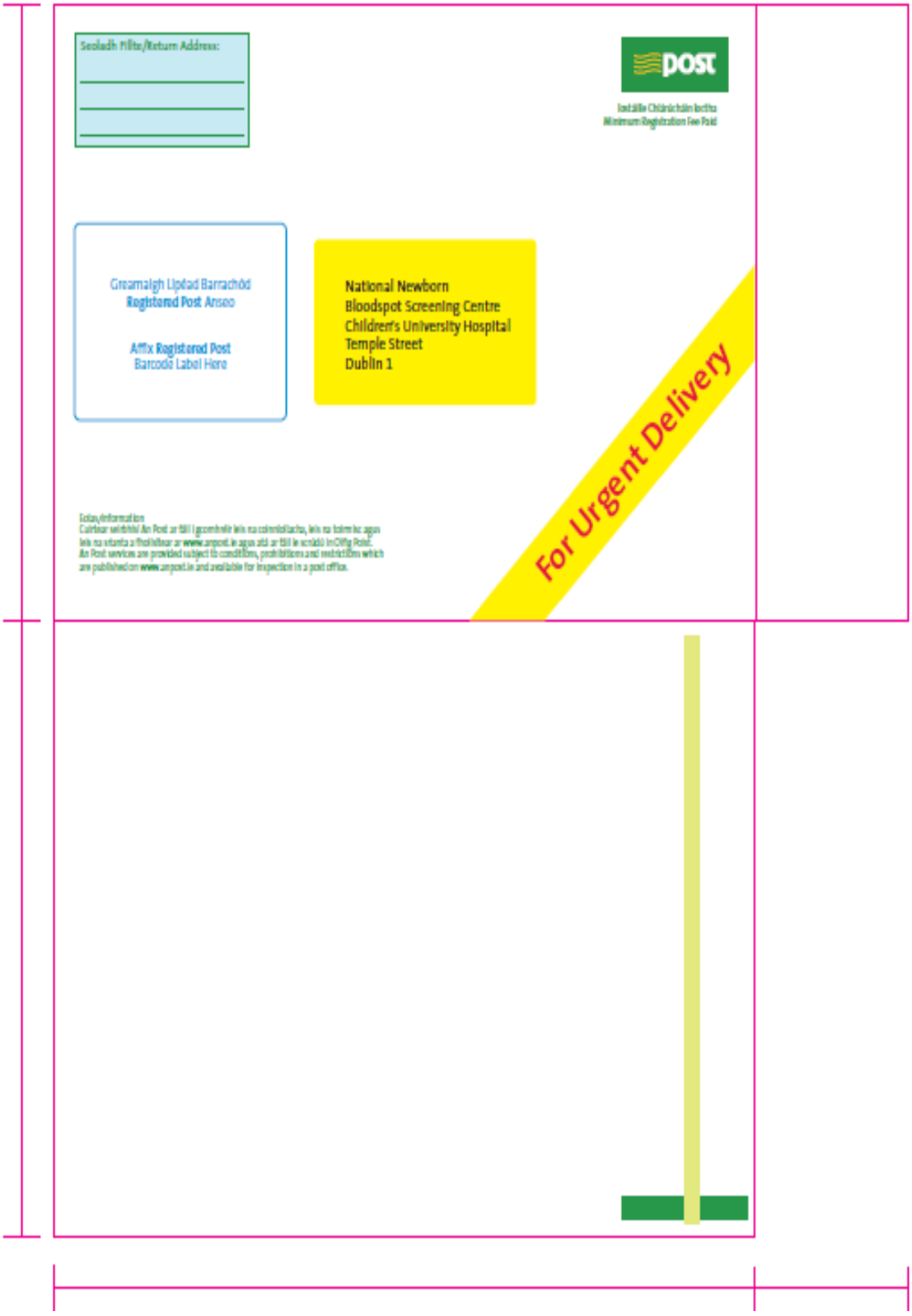
Please send an email for the envelopes to the email addresses above, stating the amount of envelopes required and quoting an HSE purchase order number. A Pro Forma invoice, with the HSE purchase order number as reference, will then be returned to enable payment by EFT. Once the EFT payment has reached An Post's bank account the Philatelic Section will dispatch the order.

Responsibility of sender

If more than one NBSC is put in an envelope, they should be placed at 180° to each other (i.e. the bloodspots should not overlap and therefore not touch). The sender should state in writing how many NBS cards are in each envelope and include a list of the names of the infants on a separate page, a sample checklist is available to download from www.newbornscreening.ie

NBSCs, appropriately packaged, should be sent daily and not batched. It is the responsibility of the sender to dispatch the sample as soon as possible after collection, either by registered post or by courier. It is not appropriate to put the package into the post knowing that there may be a delay in it arriving at the NNBSL due to either a postal dispute (local or national) or over the Christmas period when the post is delayed. Alternative arrangements should be made by maternity hospitals/units and LHOs to ensure NBSCs are dispatched to NNBSL without delay. Parents should never be asked to post or deliver NBSCs to the NNBSL. This is the responsibility of the sample taker.

Appendix XVII: Waterproof and Tear Proof Envelope for Registered Post



Appendix XVIII: Temple Street Children's University Hospital – Copy Result Request Form

No.	Infant	Mother	DOB	Infant	Mother	Address	Hospital of Birth	Unique Identifier (UPI)	NNBSL Office Use/ Comments
	Surname			Forename					
1									
2									
3									
4									
5									
6									

N.B.: Please ensure e-reports have been checked prior to sending this form requesting copy reports.

Requested by: _____ **Address:** _____

_____ **Tel No.:** _____

Issued by (NNBSL use only): _____ **Date** (NNBSL use only):_____

Appendix XIX: Informing NNBSL of reports received that do not belong to LHO Area

Please complete details of this form:
For infants on whom you have received reports who do not belong to your Area
Return the Form to NNBSL. Please indicate correct LHO (if known).
Please email or FAX (on headed paper) to NNBSL as soon as possible

Location (LHO):	**Date:**
Reported By: (Print name and provide signature)	**Position:**

UPI	Lab Number	Infant's Surname	Infant's First Name	Date of Birth	Mothers Surname	Old Address	New Address	Correct LHO (if known)

Comment:

Appendix XX: Individual Sample Results – Print Out

National Newborn Bloodspot Screening Laboratory

An INAB accredited testing Laboratory Reg. No.374MT
Children's Health Ireland at Temple Street, D01 YC67

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Tel: 01 878 4277 Fax: 01 878 4596 Email: info.newbornscreening@cuh.ie: www.newbornscreening.ie

Newborn Bloodspot Screening Report **Report date:** 11/01/2022

Location: Paediatric OPD Rotunda Hospital (RH)

Baby Details

Name:	**TEST SAMPLE, TEST SAMPLE**	**UPI:**	**932-H0000000**	**Sex:** Male
Mother's Surname:				
Address:	123 TEMPLE ST, DUBLIN 1, D01 YC67			
DOB:	01/12/2021	**Lab number:**	22-001001	
Date of collection:	05/12/2021	**Time of collection:**	14:00	
Date received:	06/12/2021	**Sample type:**	Initial	

Sample taker name: MARY SMYTH **Contact number:** 01 8784200
Location sample taken: Hospital place of birth

Screening results

Condition	Result	Result Codes NNBSL	Result Codes HSE
GA1 (Glutaric aciduria type 1)	Not Suspected	N	2
MCADD (Medium-chain acyl-CoA dehydrogenase deficiency)	Not Suspected	N	2
PKU (Phenylketonuria)	Not Suspected	N	2
HCU (Homocystinuria)	Not Suspected	N	2
MSUD (Maple Syrup Urine Disease)	Not Suspected	N	2
GAL (Classical Galactosaemia)	Not Suspected	N	2
CHT (Congenital Hypothyroidism)	Not Suspected	N	2
CF (Cystic Fibrosis)	Not Suspected	N	2

Appendix XXI: Standard Operating Procedure for infants who have missed the newborn screening window for cystic fibrosis (CF)

Children who have missed the 72-120 hour window for newborn bloodspot screening for logistical or other reasons (e.g. clinical condition, lost screening card, mix up in identification, etc.) can have the bloodspot repeated for immunoreactive trypsinogen (IRT) up to six weeks of age (day 42 of life). This applies to premature infants as well as term infants.

Beyond six weeks of age the IRT values are not interpretable with respect to cystic fibrosis (CF) newborn bloodspot screening (NBS) and a bloodspot screening sample should **not** be taken for the purpose of newborn bloodspot screening (NBS) for CF.

Infants and children greater than six weeks of age who were not screened, or where issues with the sample, or testing resulted in no result for CF NBS available in the correct timeframe, should have a sweat test performed. This approach is applicable up to one year of age to align it with the upper age limit for repeating newborn bloodspot screening for the other conditions (not CF) in the newborn bloodspot screening programme.

Parents who opt out of screening initially and decide to opt in at a later date, providing the child is under one year of age at the time of opt in will have a sweat test performed to complete the screening process. If the child is over one year of age at the time of opt in, no sweat test will be offered unless there are clinical suspicions to warrant same.

The sweat test should be performed in one of the six HSE designated specialist CF centres involved in accepting infants for assessment as per the CF NBS programme. The six centres are:

- Our Lady's Children's Hospital Crumlin
- Temple Street Children's University Hospital
- Tallaght University Hospital
- University Hospital Galway
- University Hospital Limerick
- Cork University Hospital

The following steps should be undertaken:

1. The individual aware of, or concerned that, a child has not been screened for CF as part of the newborn bloodspot screening programme should inform the National Newborn Bloodspot Screening Laboratory (NNBSL) in the Children's University Hospital, Temple St, Dublin.

2. The NNBSL should collect the relevant details of the infant involved, and the details of why screening was missed, and then contact the specialist CF centre (based on the geographic catchment areas covered by the CF NBS programme) to request a sweat test.

3. The NNBSL will contact the designated newborn bloodspot screening liaison person in the Maternity Unit/Hospital in which the infant was born to inform them that the infant has not been screened to date and that a newborn bloodspot screen is required for all other conditions on the screening programme and a sweat test should be performed to out rule CF.

   The Clinical Liaison Officer in the NNBSL will contact the newborn bloodspot liaison person in the Maternity Unit/Hospital to obtain parent and infant information and to inform them that the infant has not been screened to date.

4. PLEASE NOTE: If the infant was **NOT** born in a maternity unit in Ireland (e.g. a home birth, or an infant born outside the Republic of Ireland) then the NNBSL does **NOT** contact the newborn bloodspot screening liaison person in the Maternity Unit/Hospital, but links directly with the Assistant Director of Public Health Nursing (ADPHN) and the CF specialist centre, to make the arrangements outlined below.

5. The Clinical Liaison Officer in the NNBSL will contact the relevant ADPHN based on the family's address, to inform them that the newborn bloodspot screening is required for all the other conditions on the newborn bloodspot screening programme (if not already screened) and a sweat test should be performed to out rule CF.

6. The newborn bloodspot screening liaison person in the Maternity Unit/Hospital or ADPHN/Public Health Nurse (PHN) will inform the parents that the sweat test needs to be done and explain why. It will be made clear that the Public Health Nurse (PHN) will take the newborn bloodspot screening sample for all the other conditions on the newborn bloodspot screening programme (with the exception of CF) and the specialist CF centre will contact them to arrange the sweat test. It is also advisable that the PHN provides the parents with the contact details for the Clinical Liaison Officer in the NNBSL.

7. Contact with the specialist CF centre should use the existing lines of communication for the CF newborn bloodspot screening programme; i.e. a telephone call to the CF Clinical Nurse Specialist (CNS) followed by faxed written details.

8. The NNBSL will provide the specialist CF centre with the ADPHN contact details.

9. It is important that the parents have been informed by the PHN or Maternity Unit/Hospital that a sweat test needs to be performed PRIOR to the parents been contacted by the CF CNS.

10. The CF CNS will organise a sweat test and review by a CF Consultant as per the usual procedure for the CF NBS programme.

11. The specialist CF centre will provide the results to the NNBSL as soon as they are available.

12. The NNBSL will report the results of the CF screen via eReports once the sweat test result is available from the CF centre.

13. The NNBSL will inform the individual who highlighted the case that the infant has been assessed and will inform the Maternity Unit/Hospital and the DPHN in that area via eReports.

The procedure as described above does not apply to infants who had newborn bloodspot screening performed in another country which did not include screening for CF, and then moved to Ireland at a later date. These children should not be screened for CF, but should have a sweat test performed only if clinically indicated, such as if they develop clinical features, or have a strong family history, of CF.

Appendix XXII: NNBSP Governance Group

Name	Position
Dr Abigail Collins	Director of Public Health, Clinical Lead Child Health Public Health (Chairperson)
Paul Marsden	Project Manager Child Health Screening and Surveillance Programmes
Dr Jennifer Brady	Consultant Clinical Biochemist, Clinical Director, National Newborn Bloodspot Screening Laboratory, Children's Health Ireland at Temple Street
Loretta O'Grady	Chief Medical Scientist, National Newborn Bloodspot Screening Laboratory, Children's Health Ireland at Temple Street
Prof Ahmed Monavari	Clinical Director, National Centre for Inherited Metabolic Diseases, Children's Health Ireland at Temple Street
Bernie Quirke	Laboratory Manager, Children's Health Ireland at Temple Street
Dr Barry Linnane	Paediatric Respiratory Consultant, University Hospital Limerick
Jan Flanagan	Director of Public Health Nursing, Roscommon
Rachel McKevitt	Assistant Director of Public Health Nursing, Cavan/Monaghan
Catherine Harvey	Clinical Liaison Nurse, National Newborn Bloodspot Screening Laboratory, Children's Health Ireland at Temple Street
Grace O'Neill	Regional Child Health Training/ Development Officer/Immunisation Co-Ordinator, HSE South East
Angela Dunne	Director of Midwifery, National Women and Infants Health Programme
Sarah Hensey	Project Support, National Healthy Childhood Programme