Office of the Nursing Services Director

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Frequently Asked Questions

relating to the

Update on the National Newborn Bloodspot Screening Programme to include the Introduction of Newborn Screening for Cystic Fibrosis

A Continuing Education Programme for

Registered Midwives, Registered Public Health Nurses, Registered Nurses in children's hospitals/units

(An Bord Altranais Post Registration Category 1 Approval)

Section 1: Rationale for the National Newborn Bloodspot Screening Programme (NNBSP)

***Question* 1 For how long has the testing/screening service been provided by the National Newborn Bloodspot Screening Laboratory (NNBSL) in the Children's University Hospital, Temple Street Hospital?**

***Answer* 1** This service has been provided for forty five years. Newborn screening for Phenylketonuria (PKU) commenced in 1966, with further conditions being added during 1971/2 and Congenital Hypothyroidism was included in 1979.

Section 2: Professional and Legal Perspectives

CONSENT

***Question* 2 a) Why is consent required for this procedure now when it was not required in the past?**

***Answer* 2a)** Verbal consent was always required in the past. The requirement for written consent from the parent / guardian (recorded) rather than verbal consent is to satisfy Data

Protection legislation. This change in practice has been endorsed by the new National Newborn Bloodspot Screening Programme Governance structure.

***Question* 2 b) Would a general consent provided by a parent/guardian for treatment of their infant within a hospital suffice for this procedure?**

***Answer* 2 b)** No. The consent that is given by a parent/guardian in a hospital is for treatment(s) of a condition, whereas consent obtained for the Newborn Bloodspot Screening Test is to consent specifically for the National Newborn Bloodspot Screening Programme. A parent/guardian who consents to their infant participating in the National Newborn Bloodspot Screening Programme, consents to their infant having the screening procedure and the storage of their infant's Newborn Screening Card (NSC). As part of the consent process, it is essential that the parent/guardian is informed of 1) the six conditions for which screening is being undertaken; 2) the procedure, that is the 'heel-prick'; and 3) the retention of the Newborn Screening Card for 10 years.

The parent consent on the NSC also verifies that a) the baby's details are correct; and b) that the parent/guardian has received and read the information leaflet for parents and guardians.

***Question* 2 c) When should the consent be signed and who should carry this out?**

***Answer* 2 c)** The consent should be obtained by the individual Registered Midwife, Registered Public Health Nurse, Registered Nurse in children's hospital / unit who will be taking the 'heel prick' sample. In order to obtain the parent's/guardian's written consent, a full explanation is given together with providing the Information Leaflet for Parents and Guardians and the top sheet of the Newborn Screening Card. It is also essential that the opportunity is provided to the parent / guardian to have any questions answered.

***Question* 2 d) Who can give consent if the mother is not available at the time the sample should be taken, i.e. between 72-120 hrs of age, e.g. if the baby is transferred to another hospital or the mother is unwell or otherwise unavailable?**

***Answer* 2 d)** In the absence of the mother, who has automatic parental responsibility for newborn, the father may sign the consent form, if he is married to the mother at the time when the sample is due to be taken.
In the absence of a parent (mother or married father),, the HSE acting as *locum parentis* must act in the best interest of the child and in accordance with hospital policy.
The mother must be informed of whatever decision and action has been taken at the earliest appropriate time. All decisions and actions must be recorded in the infant's healthcare record.

***Question* 2 e) If only the father who is unmarried to the baby's mother is available or if the baby is in foster care, what actions must be taken?**

***Answer* 2 e)** If either of these situations arise, they should be referred to the Principle Social Worker/Medical Social Worker in accordance with the policy of the hospital/unit /community care area.

***Question* 2 f) If the mother / parent has difficulties with literacy and signs the Newborn Screening Card using an 'X' to indicate her consent to having her baby screened, is it necessary ot obtain the signature of the witness, and if so where should this be recorded?**

***Answer* 2 f)** Yes. The 'witness' must sign his/her name next to the X made by the parent/ guardian at the **sign your name and date** signature section of the Newborn Screening Card. The witness must be over the age of 18 years. The sample taker cannot be the witness. Please note that the witness is only confirming the 'X' signature of the mother / parent.

***Question* 2 g) If the baby requires a repeat sample(s) taken, is consent required for this?**

***Answer* 2 g**) When the initial consent is provided, it is for the entrance into the National Newborn Bloodspot Screening Programme. This includes repeat screening test if required. It is essential that the sample taker provides the mother with all the necessary information regarding *why the repeat test is required* and answers any questions that she may ask. Should the mother decline the repeat test, then Opt-Out Form must be completed.

NEWBORN SCREENING CARD (NSC)

***Question* 2 h) Whose phone number should be recorded on the NSC – is it the sample taker's or the mother's?**

***Answer* 2 h)** It is the sample takers phone number that is recorded on the NSC. This number is recorded so that the NNBSL will be able to contact the sample taker if necessary. Should the NNBSL need to contact the mother/parent/guardian, they will obtain the relevant telephone number from the maternity hospital/unit.

***Question* 2 i) If the sample taker is neither a Midwife nor a Public Health Nurse, where should she/he sign the NSC?**

***Answer* 2 i)** If the sample taker is neither a Midwife nor a Public Health Nurse, then she/he should cross out Midwife/PHN and fill in their appropriate grade / title, e.g. self- employed community midwife/ registered children's nurse etc. It is envisaged that very few newborn screening samples will come from healthcare sites other than maternity hospitals/units and/or community care areas.

***Question* 2 j) To what does "Rank" refer on the NSC?**

***Answer* 2 j)** The term 'rank' refers to birth order, that is Singleton: 1/1; Twin 1: 1/2 etc. These are listed on the back of the Newborn Screening Card.

***Question* 2 k) What is the purpose of the section 'Alternative Name'?**

***Answer* 2 k)** This section is provided for the sample taker to enter any alternative name that the mother may be using for the baby. However, it should be stated clearly, if known, whether this alternative name is a first name / second / surname.

***Question* 2 l) What is the purpose of the Baby Chart Number underneath the Unique Perinatal Identifier section on the NSC?**

***Answer* 2 l)** The Baby Chart Number refers to the baby's Healthcare Record Number (HCRN) which will be issued in the maternity hospital/ unit in which the baby is born. The Baby Chart Number (Healthcare Record Number) on its own has no relevance for the NNBSP. The Baby Chart Number (Healthcare Record Number) is used as the second part of the Unique Perinatal Identifier (UPI), with the first part formed by the HIPE number of maternity hospital/unit in which the baby was born. If the baby is transferred to a different hospital from the one in which they are born, then this hospital will issue it's own Healthcare Record Number for the baby and this will only be relevant to that hospital.

***Question* 2 m) Why will the Newborn Screening Cards be kept for ten years?**

***Answer* 2 m)** Newborn Screening Cards will now be retained for 10 years on behalf of the HSE and with the knowledge of the Data Protection Commissioner. The NSC's will be kept for the benefit of the baby/child at a later date. Should the NSC be required to check the results of the NNBSP or is requested for further tests at the request of a Registered Medical Practitioner, then consent will be sought from the parent / guardian for this purpose.

The samples from the NSC's may be used for quality assurance purposes and to validate new tests, such as for Cystic Fibrosis. In such circumstances, all samples will be completely anonymous and the results will not be traced back to an individual baby /child.

***Question* 2 n) What has happened to the Newborn Screening Cards to date?**

***Answer* 2 n)** Since approximately 1984/85, the NSC's have been retained. As outlined in Answer 2 k), some samples have been used anonymously with Research Ethics approval to better understand some inherited conditions in Ireland. No cards have ever been used for commercial purposes. In due course, following public consultation all NSC's retained for more than 10 years will be disposed of.

***Question* 2 o) Is the Newborn Screening Card used for the Beutler test?**

***Answer* 2 o)** Yes. The Newborn Screening Card is used for the Beutler test.

OPT-OUT FORM

***Question* 2 p) If a mother decides to 'opt out' of having her baby entered on the National Newborn Bloodspot Screening Programme, can she change her decision in the future and how long can she wait to do so?**

***Answer* 2 p)** Yes. A mother has the right to change her mind. However, should she so do, it is then *her responsibility* to then contact the PHN or the baby's General Practitioner and request the screening at a future date. It would be important to stress that there is the time limit for some conditions and that there could be irreparable damage to the baby by the delay in screening.

***Question* 2 q) What is the responsibility of the midwife or PHN with regard to follow up with the mother if she chooses to opt out of the test?**

***Answer* 2 q)** As for 2 k)

***Question* 2 r) Is it reasonable that the Opt-Out Form is completed by midwifery or nursing staff only?**

***Answer* 2 r)** Yes. As Midwives/ Public Health Nurses/ Registered Nurses in children's hospitals / units are delegated to take the newborn screening sample, then accordingly they should complete the Opt-Out Form as required.

***Question* 2 s) If a baby is a patient in a hospital/unit that is a consultant lead service, is it reasonable for the Registered Midwife or Registered Nurse to complete the Opt-Out Form as it does not require a signature for the consultant?**

***Answer* 2 s)** Yes it is reasonable. The Registered Midwife or Registered Nurse **may** seek the advice of the primary consultant if a parent is considering opting-out of newborn bloodspot screening programme and would be advised to and inform his/her Nurse Manager. However, every effort should be made to encourage a parent to consent to the Newborn Bloodspot Screening Programme.

***Question* 2 t) What information and or instructions should a parent receive if they decide to opt out of the National Newborn Bloodspot Screening Programme (NNBSP)?**

***Answer* 2 t)** Information on the NNBSP is contained on the Information leaflet for Parents and Guardians and is also on the top copy of the Newborn Screening Card and this is also given to parents / guardian. There is specific information is also on the Opt-Out Form and this should be read by or read to the parent / guardian in the event that they are considering opting -out of the NNBSP.

***Question* 2 u) Is the Opt-Out Form available in other languages?**

***Answer* 2 u)** No. In light of the infrequent number of parent(s) opting out of the NNBSP historically, it was identified that these would not be required. However, should this situation arise, it would be essential to ascertain if the parents availed of translation services during antenatal visits and at the time of birth, and to utilize them in this situation.

INFORMATION for PARENTS

***Question* 2 v) When should the mother be given the information regarding the Newborn Bloodspot Screening Test?**

***Answer* 2 v)** Parent (s) should be given written information

i) during the third trimester of pregnancy, the information leaflet Newborn Bloodspot Screening Test Information for Parents and Guardians; and
ii) at the time of sample collection, the information leaflet Newborn Bloodspot Screening Test Information for Parents and Guardians and the top sheet of the Newborn Screening Card.

***Questio*n 2 w) In what other languages will the Newborn Bloodspot Screening Test Information for Parents and Guardians leaflet be available and from where can these be accessed?**

***Answer* 2 w)** Th*e* information leaflet Newborn Bloodspot Screening Test Information for Parents and Guardians leaflet will be available in 10 other languages: Arabic, Brazilian, Chinese, French, Irish, Latvian, Lithuanian, Polish, Romanian and Russian. These can be accessed from www.newbornscreening.ie

***Question* 2 x) The information on the leaflet refers only to the midwife and PHN – what are the implications of this if the sample taker is a Registered Nurse in a children's hospital/unit?**

***Answer* 2 x)** Very few samples are taken within children's hospitals/units and for that reason the text was primarily refers to midwives and PHN for the purpose of brevity and simplicity for parents. The information in the leaflet is directed to all parents regardless of where the baby is at the time the information is being given and the sample is to be taken. The purpose of the information leaflet is to complement and support the Registered Nurse or healthcare professional in their communication with parents/guardians about the NNBSP.

***Question* 2 y) Is Cystic Fibrosis (CF) classed as a rare condition**?

***Answer* 2 y)** Yes. For the purpose of the NNBSP, CF is classed as a rare condition, with an incidence of 1/1,353 in Ireland.

Section 3: Newborn Bloodspot Screening Practice

UNIQUE PERINATAL IDENTIFIER

***Question* 3 a) What is the purpose of the Unique Perinatal Identifier (UPI) number on the NSC?**

***Answer* 3 a)** From 1st July 2011 each baby born in Ireland will be issued with an individual (unique)identifying number to ensure that the Newborn Bloodspot Screening samples can be traced throughout the newborn bloodspot screening process. This number will be issued by the maternity hospital / unit in which the baby is born and will be formed by the maternity hospital / unit HIPE code (3 digits) followed by the baby's Healthcare Record Number (HCRN) issued by the maternity hospital / unit.

Babies 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 the baby's birth is registered following notification of the birth.

The UPI will then be used in maintaining the Register for the National Newborn Bloodspot Screening Programme.

***Question* 3 b) Who will inform the parent(s) about the baby's Unique Perinatal Identifier?**

***Answer* 3 b)** All service users are familiar with the concept of a healthcare record number. The mother will be familiar with having a healthcare record number on her chart and similarly that her newborn baby will also be provided by a healthcare record number /chart. The principle underpinning the UPI for the National Newborn Bloodspot Screening Programme is similar.

***Question* 3 c) Will the Unique Perinatal Identifier be used for any purpose other than the National Newborn Bloodspot Screening Programme?**

***Answer* 3 c)** The Unique Perinatal Identifier will only be used for the purpose of the National Newborn Bloodspot Screening Programme at this point in time.

***Question* 3 d)** Who is responsible for issuing the results of the Newborn Bloodspot Screening Test and informing the Public Health Nurse?

***Answer* 3 d)** The NNBSL issues the results of the Newborn Bloodspot Screening Test to the location where the sample was taken, that is the maternity hospital/ unit or to the Local Health Office (LHO). It is the responsibility of the Director of Midwifery / Nursing or Public Health Nursing to ensure that the Midwife / Public Health Nurse receive these results.

***Question* 3 e) If a mother decides to register the baby using a different first name or surname, for example the father's surname after discharge from the maternity hospital / unit and after the Newborn Bloodspot Screening Card has been completed and sent to the NNBSL, how can the result be traced?**

***Answer 3 e*)** As each baby is issued with a Unique Perinatal Identifier for the purpose of the NNBSP, this is to ensure that the Newborn Bloodspot Screening samples can be traced throughout the newborn screening process regardless of any changes in the baby's name(s) or address(es).

***Question* 3 f) If a baby is born in Northern Ireland and has his/her Newborn Bloodspot Screening Sample taken in either the hospital or the community in the North and then requires a repeat sample - would a Unique Perinatal Identifier number be generated in Ireland?**

***Answer 3 f*)** No. As the Initial screening was undertaken in the North, then the repeat sample would be sent to the Newborn Bloodspot Screening Laboratory in Northern Ireland to which the first sample was sent.

***Question* 3 g) If a baby is born in Northern Ireland but has his/her Newborn Bloodspot Screening sample taken in this jurisdiction, from where / who provides the Unique Perinatal Identifier number generated?**

Answer 3 g) In this case the UPI number would be generated by the Director, Public Health Nursing (DPHN) in the Local Health Office LHO/ Integrated Service Area to which the birth is notified. The UPI in this situation is generated using the LHO code together with a distinct, identifiable number allocated by the DPHN.

***Question 3 h)* if a mother has a home birth, from where is/who provides the Unique Perinatal Identifier number for the baby?**

***Answer* 3 h)** The UPI number for the baby born at home would be generated by the Director, Public Health Nursing (DPHN) in the Local Health Office (LHO)/ Integrated Service Area (ISA) to which the birth is notified by the Self-Employed Community Midwife /other. The UPI in this situation is generated using the LHO code together with a distinct, identifiable number allocated by the DPHN.

***Question 3 i)* What is the rationale for delaying taking the newborn screening sample when an baby has had a blood transfusion?**

***Answer* 3 i)** It the blood sample is taken immediately after a blood transfusion, then both the baby's blood and the adult transfused blood would be tested and this could provide a false negative result. However, there is a different policy with regard to excluding Galactosaemia, for

which the enzyme activity in the red blood cells is tested and there must be a delay to allow the adult cells to 'disappear' .

***Question* 3 j) What is the rational for discarding the first drop of blood as stated on the back of the Newborn Screening Card?**

Answer 3 j) As it is possible that the first drop may be diluted due to squeezing of the baby's heel to get a blood flow, it is advisable to discard the first drop. However, "alternative releasing of the pressure for several seconds between squeezes should maintain blood flow" (*A Practical Guide to Newborn Bloodspot Screening in Ireland* (2011) page 20)

***Question* 3 k) When will a parent be notified of a positive result?**

***Answer* 3 k)** Depending on the condition, parents will be notified of a positive result within 2 - 3 working days. However, in the case of Cystic Fibrosis, parents will be notified between the 3rd and 4th week of life, because this is the earliest time frame when the confirmatory sweat test can be carried out.

***Question* 3 l) What happens to the blood samples after laboratory testing is completed?**

***Answer* 3 l)** As in Answer 2 k) the sample is now stored in a secure location as part of the child's record for 10 years and disposed of during the child's 11th year.

***Question* 3 m) Are any DNA-based newborn screening or store purified DNA tests carried out on the newborn bloodspot screening sample?**

***Answer* 3 m)** DNA testing forms part of the newborn screening programme for Cystic Fibrosis. For those that have a high Immuno-Reactive Trypsin test (IRT) (which will be approximately 1%), a 38 panel CF mutational panel analysis will then be performed by the National Centre for Medical Genetics (NCMG).

DNA testing does not form part of screening for any of the other conditions. For those with a positive result DNA analysis may on occasion be performed to confirm the diagnosis. The National Newborn Bloodspot Screening Laboratory does not (and never has) stored purified DNA

ORDERING NSC'S, DRYING BOXES or LABELS

***Question* 3 n) Should the Public Health Nurse always use a drying box to facilitate the transport of the Newborn Bloodspot Screening Card from the baby's home?**

***Answer* 3 n)** Yes. The drying boxes have been designed specifically to facilitate the safe transport of the NSC from the baby's home to the PHN's car. Once the blood spots are dry, then the NSC should be transferred from the drying box and packaged according to the regulations

as specified in *A Practical Guide for Newborn Bloodspot Screening in Ireland* (2011) 5th edn.

Question 3 o) From where are Newborn Bloodspot Screening Cards ordered?

***Answer* 3 o)** The NSC's can to be ordered from the National Newborn Bloodspot Screening Laboratory (NNBSL) at the Children's University Hospital, Temple Street, Dublin 1.

***Question* 3 p) From where are the drying boxes ordered?**

***Answer* 3 p)** The drying boxes can be ordered from:

Paul McQuilkin, DGSA Dangerous Goods Packaging Advisor

Mega-Pak Ltd: *Telephone Number:* +44 (0)1753 218600; *Fax Number*: +44 (0)1753 534600

Website: www.mega-pak.com

The minimum number of boxes that can be supplied is 150 and these are packed into outer cartons in lots of 50. The cost of delivering is approximately £20.00 per pack of 50. If the more that four packs of 50 are required, these could be put on a pallet, with a flat charge of £80.00 up to a maximum of 30 packs of 50.

The drying boxes are **not** provided either by the NNBSL nor the Children's University Hospital, Temple Street, Dublin.

***Question* 3 q) From where can the i) Yellow fluorescent address label (for exempt NSC's); and ii) Label with UN3373 (for non-exempt NSC's) be sourced**

***Answer* 3 q)** The Yellow Fluorescent Labels are available from the NNBSL, Temple Street and the UN3373 label may be obtained from either from a local hospital laboratory; or Public Health Nurses can obtain it directly from the NNBSL, Children's University Hospital, Temple Street.

***Question* 3 r) What is the responsibility of the maternity hospital / unit have for ensuring that the Newborn Bloodspot Screening test is carried out if the baby is transferred to another hospital/unit?**

***Answer* 3 r)** The maternity hospital/unit is responsible for ensuring that all babies born in their hospital / unit are offered newborn bloodspot screening. If a baby is transferred from the maternity hospital prior to the Newborn Bloodspot Screening sample being taken, then it is the responsibility of the maternity hospital/unit to ensure that the appropriate information is transferred with the baby including the Unique Perinatal Identifier (UPI). The maternity hospital/unit must check that the baby has been offered to have the Newborn Bloodspot Screening Test by checking the results off against their birth register. If not then they have a

responsibility to following this up with the hospital/unit to which the baby was transferred and the Local Health Office (LHO)

The maternity hospital/unit must also inform the Director of the NNBSL if the Newborn Bloodspot Screening sample will not be exempt from the packaging postal regulations due to infection either in the mother or infant.

If the test is carried out in the community, the recording and follow-up of the baby is the responsibility of the Director of Public Health Nursing.

***Question* 3 s) If a baby is identified as an unaffected carrier of Cystic Fibrosis (CF), what will then happen?**

Answer 3 s) The CF consultant to whom parents will have been referred (in one of the six CF specialist centers) and who will have arranged for sweat testing and clinical assessment of the infant, will then meet with the parents of this infant when the result of the sweat test becomes available. This should be on the same day as the sweat test is performed.
The purpose of the meeting is to ensure that the parents understand that their infant is healthy, has a negative screening result for Cystic Fibrosis and does not have CF. The CF consultant will refer the parents to the National Centre for Medical Genetics, located in Our Lady's Children's Hospital, Crumlin for genetic counselling and will send a copy of the letter to the infant's General Practitioner.

Question 3 t) Why is testing for congenital toxoplasmosis no longer included in the National Newborn Bloodspot Screening Programme?

***Answer* 3 t**) Screening for Congenital Toxoplasmosis was discontinued in 2007 as it was a pilot project.

CONTACT INFORMATION

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