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Public Health Wales

Newborn Bloodspot Screening Wales
Sgrinio Smotyn Gwaed Newydd-anedig Cymru

Newborn Bloodspot Screening Wales Policies and Standards

September 2018

Contents

NEWBORN BLOODSPOT SCREENING WALES POLICIES AND STANDARDS

INTRODUCTION

The Screening Division of Public Health Wales is responsible for the planning, preparation and delivery of the Newborn Bloodspot Screening Wales (NBSW) programme. The programme offers every newborn baby who is resident in Wales at day 5 of life bloodspot screening and every infant who becomes resident in Wales, up to one year of age.

The policies and standards in this document outline what needs to be achieved in all aspects of the programme.

The Newborn Bloodspot Screening Wales System (NBSWS) has been developed to support the management of a safe and sustainable programme across Wales. This system collects and collates information across the programme to monitor the quality of newborn bloodspot screening and provides Quality Assurance and management reports based on the policies and standards.

NBSWS also identifies babies the programme expects to receive either a bloodspot card or decline for the test(s), and initiates failsafe procedures for possible 'missed' babies.

Definitions

Eligible babies (newborn)

- A baby who is resident in Wales at day 5-8 of life
- A baby who is resident in Wales at day 5-8 of life, but is registered with an English GP
- A baby whose usual place of residence is outside Wales if they are under routine midwife care in Wales at day 5-8 of life

Babies who have been recorded as having died before the age of 5 days are not eligible.

Eligible babies (all)

- All babies up to one year of age who are resident in Wales
- A baby whose place of residence is outside Wales if they are under routine midwifery care in Wales at the time the newborn bloodspot test is due

Babies who have been recorded as having died before the age of 5 days are not eligible.

Screen positive result
Screening results are not 100% conclusive. Instead they provide presumptive results. A screen positive result is a result which shows that the child is likely to have the condition for which they are screened. Sometimes people will say that the child is affected. Positive screening results are then confirmed using diagnostic tests. For example, a screen positive result for congenital hypothyroidism (CHT) means that it is highly likely that the child has CHT, but this must be confirmed by further tests. A screen positive result will be reported as 'suspected'.

Screen negative result
Screening results are not 100% conclusive. Instead they provide presumptive results. A screen negative result is a result which suggests that the child does not have the condition for which they are being screened. Sometimes people will say that the result is 'normal'. For example, a screen negative result for cystic fibrosis (CF) means that it is highly likely that the child does NOT have CF. This screen negative result is NOT usually confirmed using further tests, but it is assumed the child is not affected. A screen negative result will be reported as 'not suspected'.

Conclusive result
A conclusive result is any of the following; not suspected, suspected, not suspected other disorder or carrier. This includes any results that were tested by DNA for sickle cell disorders. For babies greater than 8 weeks of age, not tested for CF is also a conclusive result.

Calendar Days
Calendar days are all days in a month including weekends and holidays. For some of the standards the timelines refer to calendar days because there is a clinical need for a definitive time in which an action should be taken. For example, an avoidable repeat sample should be taken within three calendar days.

Working days
For the purpose of newborn bloodspot screening working days are currently Monday to Friday with the exception of bank holidays. Working days are referred to in the standards to take into account the normal working days for the Newborn Screening Laboratory and Royal Mail.

Parent/guardian surveys
Parent/guardian surveys will be carried out to gather views of parents/guardians on their experience of newborn bloodspot screening. These surveys will also be used to monitor the performance of NBSW in

the *informed consent* and *information provision* standards. The survey will include the views of those who accept screening and also of those who decline screening.

The Conditions

Congenital hypothyroidism (CHT)

Congenital hypothyroidism (CHT) is a condition where the baby's thyroid gland fails to develop or work properly and fails to make the thyroid hormone called thyroxine. Thyroxine is needed for normal growth and development. Without thyroxine, babies do not grow properly and can develop permanent, serious physical problems and learning disabilities. Babies with CHT can be treated early with thyroxine tablets and this will allow them to develop normally.

CHT has been screened for in Wales since 1981.

Cystic fibrosis (CF)

Cystic fibrosis (CF) is one of the UK's most common inherited life-limiting diseases. CF is a disease in which abnormal movement of salt and water into and out of cells causes a build-up of thick, sticky mucous. This occurs particularly in the lungs and digestive system. Babies with CF may not gain weight well, have frequent chest infections and a limited life span. If babies with CF are treated early with a high-energy diet, medicines and physiotherapy, they may live longer, healthier lives.

CF has been screened for in Wales since December 1996.

Inherited metabolic disorders (IMDs):

-Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)

MCADD is a rare inherited condition in which there is a deficiency in the enzyme medium-chain acyl-CoA dehydrogenase which is needed for the breakdown of certain stored fats (medium-chain fatty acids). This makes it difficult for the body to break down fatty acids and produce energy, and can cause sudden death in infants.

Fatty acids are an important energy reserve during periods of poor calorie intake, prolonged periods between meals or during infections and sickness. In these situations people with MCADD have high levels of partially broken down fatty acids and low blood glucose concentrations which can result in a metabolic crisis.

Most of the time children are well, but an infection or relatively long period without food upsets their metabolism causing coma and

sometimes death. Treatment involves ensuring that children do not go for long periods without food and special management if they do get an infection. Periods of not eating can safely get longer as the child grows.

MCADD has been screened for in Wales since June 2012.

-Phenylketonuria (PKU)

Phenylketonuria (PKU) is a rare inherited condition that prevents the breakdown of a building block of protein, the amino acid phenylalanine. For people with PKU, eating normal amounts of protein can cause a harmful build-up of phenylalanine in the blood. The build-up of phenylalanine is neurotoxic and harmful to the brain. Without treatment PKU can cause severe, irreversible mental disability. If identified early, the child can be put on a restricted-protein diet with supplements and the brain can develop normally.

PKU has been screened for in Wales since 1970.

-Maple syrup urine disease (MSUD)

Maple syrup urine disease (MSUD) is a rare inherited disorder that prevents the breakdown of some of the building blocks of protein, the amino acids leucine, isoleucine and valine in the blood.

For people with MSUD, eating normal amounts of protein can cause a harmful build-up of these amino acids in the blood. Many babies with MSUD become unwell when they are a few days old. Without treatment, this leads to a coma and permanent brain damage. In older children a minor illness, such as a chest infection or a tummy upset, can lead to serious problems. As in babies, this can lead to a coma unless treated correctly.

MSUD can be treated with a protein-restricted diet. A different regime is required when the child is ill, and they may need to be hospitalised. The condition is named maple syrup urine disease because high levels of these amino acids can cause an unusual sweet smell in the urine and sweat.

MSUD has been screened for in Wales since January 2015.

-Isovaleric acidaemia (IVA)

Isovaleric acidaemia (IVA) is a rare inherited disorder that prevents the breakdown of a building block of protein, the amino acid leucine. This then causes a harmful build-up of a substance called isovaleric acid in the blood. Children with IVA can become severely unwell. Without treatment, this can lead to a coma and permanent brain

damage. Some babies with IVA have problems within a few days of birth; other children become unwell at a few months or years of age, maybe during a minor illness, such as a chest infection or a tummy upset.

IVA can be treated with a protein-restricted diet and carnitine and glycine. A different regimen is required when the child is ill, and they may need to be hospitalised.

IVA has been screened for in Wales since January 2015.

-Glutaric aciduria type 1 (GA1)
Glutaric aciduria type 1 (GA1) is a rare inherited disorder that prevents the breakdown of certain building blocks of protein, in particular the amino acids lysine and tryptophan.

For people with GA1, eating normal amounts of protein can cause harmful substances to build up in the blood and urine. In children with GA1, a minor illness, such as a chest infection or a tummy upset, can lead to serious problems. Without treatment, the child can go into a coma. Though most children come out of the coma, they usually have brain damage that affects their ability to control their muscles and movements. This means that they may be unable to sit, walk, talk or swallow.

GA1 can be treated with a protein-restricted diet and carnitine. A different regimen is required when the child is ill, and they may need to be hospitalised.

GA1 has been screened for in Wales since January 2015.

-Homocystinuria (HCU)
Homocystinuria (HCU) is a rare inherited disorder that prevents the breakdown of a building block of protein, the amino acid homocysteine. This then causes a harmful build-up of homocysteine in the blood. Without early treatment this can lead to long term health problems including learning difficulties and eye problems, osteoporosis and blood clots or strokes.

HCU can be treated with a protein-restricted diet and extra supplements and medicines.

HCU has been screened for in Wales since January 2015.

Sickle cell disorders (SCD)
Sickle cell disorders (SCD) is a term that describes a group of conditions in which haemoglobin in red blood cells is abnormal in structure. This

causes red blood cells to take up a shape like a crescent moon or farmer's sickle when de-oxygenated. Sickled red blood cells are not as flexible as normal red blood cells and can cause blockages within small blood vessels. Babies who have these conditions will need specialist care throughout their lives.

People with SCD can have attacks of severe pain, get serious, life threatening infections and are usually anaemic (their bodies have difficulty carrying oxygen). Babies with SCD can receive early treatment, including immunisations and antibiotics, which, along with support from their parents, will help reduce the chance of serious illness and allow the child to live a healthier life.

SCD has been screened for in Wales since 2013.

Further Information

Newborn Bloodspot Screening Wales website

Summary of Policies and Standards

Policy 1 – Completeness of offer and coverage

Policy 2 – Informed consent

Policy 3 – Timely sample collection

Policy 4 – Quality of bloodspot sample and information on the card

Policy 5 – Timely receipt of a sample in the newborn screening laboratory

Policy 6 - Timely processing of bloodspot cards

Policy 7 - Timely receipt into clinical care

Policy 8 - Timely despatch of results to parents

POLICY 1 - COMPLETENESS OF OFFER AND COVERAGE

Policy Statement

Every newborn baby whose usual place of residence is Wales will be offered bloodspot screening at day 5-8 of life. Every infant who becomes resident in Wales, up to the age of one year, will be offered bloodspot screening for relevant conditions (unless there is evidence that they have had appropriate screening in the UK already, or that it has been declined in the UK).

Standards

Standard 1a	**Completeness of offer (newborns)**
Description	Eligible newborn babies who have a notification of receipt of the bloodspot card in the laboratory by day 14 of life. This informs the programme of the percentage of eligible newborn babies who have and have not been offered screening.
Rationale	To ensure that eligible newborn babies are offered screening within an effective timeframe.
Data Definition	*Babies offered testing (newborn) ÷ Eligible babies (newborn)* • Expressed as a percentage • *Babies offered testing (newborn)* are the total number of eligible newborn babies for whom there is a record of screening having been accepted or declined by day 14 of life
Threshold	99%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for offering the screening test • Screening Division for monitoring

Standard 1b	**Completeness of offer (all)**
Description	All eligible babies (up to one year of age) who have a notification of receipt of the bloodspot card in the laboratory or notification of UK result or decline of screening, within 18 calendar days of being registered on the information system. This informs the programme of the percentage of eligible babies who have and have not been offered screening.
Rationale	To ensure that all eligible babies have been offered screening.
Data Definition	*Babies offered testing (all) ÷ Eligible babies (all)* • Expressed as a percentage • *Babies offered testing (all)* are the total number of eligible babies for whom there is a record, within 18 calendar days of being registered on the information system, of screening having been accepted or declined
Threshold	99%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for offering the screening test • Screening Division for monitoring

Standard 1c	**Coverage (newborns only)**
Description	Eligible newborn babies who have a conclusive bloodspot screening result for all 9 conditions by day 17 of life. This informs the programme of the percentage of eligible newborn babies who have taken up the offer of screening and for whom the laboratory has a conclusive result recorded, within this timeframe.
Rationale	To ensure that all eligible newborn babies for whom offer of screening is accepted have conclusive screening results recorded within an effective timeframe.
Data Definition	*Tested babies (newborn) ÷ Eligible babies (newborn)* • Expressed as a percentage

	• *Tested babies (newborn)* are the total number of eligible newborn babies for whom a there is a record of screening having been accepted, and for whom a conclusive result for all 9 conditions is recorded by day 17 of life • Date of birth is day 0 and tested date is the date the result is on the system
Threshold	95%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for offering the screening test • Screening Division for monitoring

Standard 1d	**Coverage (all)**
Description	Eligible babies (up to one year of age) who have a conclusive bloodspot screening result for all 9 conditions within 21 calendar days of being registered on the information system. This informs the programme of the percentage of eligible babies who have taken up the offer of screening and for whom the laboratory has a conclusive NHS bloodspot screening result recorded, within this timeframe.
Rationale	To ensure that all eligible babies for whom offer of screening is accepted have conclusive screening results recorded within an effective timeframe.
Data Definition	*Tested babies (all) ÷ Eligible babies (all)* • Expressed as a percentage • *Tested babies (all)* are the total number of eligible babies for whom there is a record of screening having been accepted, and for whom a conclusive result for all 9 conditions is recorded within 21 calendar days of being registered on the information system. • The tested date is the date the result is on the system
Threshold	95%

Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for offering the screening test • Screening Division for monitoring

POLICY 2 - INFORMED CONSENT

Policy Statement

A person with parental responsibility must receive sufficient information and have opportunity to ask questions such that they are able to give informed consent for bloodspot screening.

A person with parental responsibility must receive sufficient information and the opportunity to decline consent to be contacted for future research.

Standards

Standard 2a	**Information provision**
Description	A person with parental responsibility must receive the 'Newborn Bloodspot Screening - information for parents' leaflet and have the opportunity to ask questions to an appropriate health professional.
Rationale	A person with parental responsibility must receive the information leaflet outlining the screening process and the conditions screened for, so that they are informed as to the nature of the screening and can ask relevant questions.
Data Definition	*Received leaflets ÷ Eligible babies (sample)* • Expressed as a percentage • *Received leaflets* - core question to be asked on survey • *Eligible babies (sample)* - representative sample to be agreed
Threshold	100% of completed surveys demonstrate that the leaflet has been received and that there has been the opportunity to ask questions
Reporting	To be reported to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for providing information • Screening Division for monitoring. Survey of parents' views will be undertaken annually

Standard 2b	**Informed consent**
Description	A person with parental responsibility must give informed consent for bloodspot screening for their baby.
Rationale	Newborn bloodspot screening is an invasive medical procedure and cannot be undertaken on babies without informed consent from a person with parental responsibility.
Data Definition	*Consent informed ÷ Eligible babies (sample)* • Expressed as a percentage • *Consent informed* – core question to be asked on survey • *Eligible babies (sample)* – representative sample to be agreed
Threshold	100% of completed surveys demonstrate informed consent
Reporting	To be reported to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for gaining consent • Screening Division for monitoring. Survey of parents' views will be undertaken annually

POLICY 3 – TIMELY SAMPLE COLLECTION

Policy Statement

The newborn bloodspot sample should be taken on day 5 of life (counting day of birth as day 0) irrespective of current medical condition, prematurity or feeding status. In exceptional circumstances, such as when the baby has had a blood transfusion, the sample can be taken between day 6 and day 8 inclusive.

Standards

Standard 3a	**Timely collection of sample (day 5-8 of life)**
Description	The sample should be taken between day 5 and day 8 of life (counting day of birth as day 0).
Rationale	Taking the sample on day 5-8 of life is the UK standard to support correct outcomes of screening and for appropriate care to be initiated.
Data Definition	*Sample taken (day 5-8) ÷ All cards received (newborns)* • Expressed as a percentage • *Sample taken (day 5-8)* equals all initial routine newborn bloodspot screening cards that are received in the laboratory that have a sample recorded as taken on day 5-8 of life, counting day of birth as day 0 • *All cards received (newborns)* equals all initial routine newborn bloodspot screening cards that are received in the laboratory that are from eligible babies
Threshold	95%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and returning cards • Newborn Screening Laboratory for recording receipt of sample • Screening Division for monitoring

Data is also collated from NBSWS monthly to monitor performance in timely collection of sample (day 5). This is reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board, and is for monitoring purposes only.

Standard 3b	**Timely collection of avoidable repeat bloodspot samples**
Description	If a repeat sample is requested because of insufficient or poor quality bloodspots or incomplete/incorrect information recorded on the card (avoidable repeat sample), then this must be taken within 3 calendar days of the request.
Rationale	Minimising the time for a repeat sample to be taken and despatched increases the likelihood of correct screening outcomes, and allows appropriate care to be initiated in a timely manner.
Data Definition	*Repeat samples received (taken within 3 days of request) ÷ Repeat samples requested* • Expressed as a percentage • *Repeat samples received (taken within 3 days of request)* are those samples defined above that are received in the laboratory and indicate that the repeat was taken within 3 calendar days of the notification to the health board that a repeat was required. • *Repeat samples requested* are all samples that need to be repeated due to either insufficient/unsuitable blood on the card or insufficient information completed on the card. This does not include repeats necessary for confirmation of any of the conditions
Thres*hold*	*95%*
Reporting	*Data to be collate*d from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and returning cards • Newborn Screening Laboratory for issuing repeat sample request and for recording sample date • Screening Division for monitoring

Standard 3c	Timely CHT second sample collection for preterm babies
Description	All babies born at less than 32 weeks gestation (less than or equal to 31 weeks +6 days) should be offered a second preterm CHT test at day 28 of life (counting day of birth as day 0) or on day of discharge home, whichever is the sooner.
Rationale	Preterm infants may have lower thyroid stimulating hormone levels at the time of the first routine newborn bloodspot screening test, which would affect the screening outcome.
Data Definition	*Preterm babies second sample (CHT) ÷ Preterm babies* • Expressed as a percentage • *Preterm babies second sample (CHT) equals* all babies born at less than 32 weeks gestation who have a second bloodspot card received in the laboratory which was collected at day 28 of life or on day of discharge • *Preterm babies* equals all babies born at less than 32 weeks gestation who have an initial routine screening bloodspot card received in the laboratory
Threshold	95%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and returning cards • Newborn Screening Laboratory for recording sample dates • Screening Division for monitoring

Standard 3d	Timely second sample collection for borderline thyroid stimulating hormone (TSH)
Description	All babies with a borderline TSH result should be offered a second bloodspot sample for TSH between 7 and 10 days after the initial borderline sample. The analysis of TSH in the bloodspots is the basis for CHT screening.
Rationale	Minimising the time for the second sample to be taken

	and despatched increases the likelihood of correct screening outcomes, and allows appropriate care to be initiated in a timely manner.
Data Definition	*Second sample for borderline TSH ÷ Borderline TSH results* • Expressed as a percentage • *Second sample for borderline TSH equals* all babies with a borderline TSH result who have a second bloodspot card for TSH received in the laboratory which was collected between 7 and 10 days after the initial borderline sample • *Borderline TSH results* equals all babies who have an initial borderline TSH result
Threshold	95%
Reporting	An annual audit will be undertaken by the Newborn Screening Laboratory, to be reported to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and returning cards • Newborn Screening Laboratory for recording sample dates • Screening Division for monitoring

Standard 3e	**Appropriate repeat sample collection for transfused babies**
Description	Repeat sample collection at least 3 days after transfusion for CHT, CF and the IMDs.
Rationale	The designated timescale maximises the effectiveness of the screening test in detecting the relevant condition(s) following a blood transfusion.
Data Definition	*Transfusion repeats 3 days ÷ Transfusion repeats* • Expressed as a percentage • *Transfusion repeats 3 days* equals all repeat samples taken at least 3 days after a transfusion • *Transfusion repeats* equals all samples taken too soon after transfusions
Threshold	*95%*
Reporting	Data to be collated from NBSWS monthly, to be reported

	quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and returning cards • Newborn Screening Laboratory for recording sample date • Screening Division for monitoring

POLICY 4 – QUALITY OF BLOODSPOT SAMPLE AND INFORMATION ON THE CARD

Policy Statement

The bloodspot sample must be of good quality to maximise the accuracy of the screening test and to prevent the need for an avoidable repeat sample.

A good quality bloodspot sample is taken at the correct time, contains sufficient blood and has not been contaminated. The card must state the baby's NHS number and have complete and accurate demographic information recorded. The screening card must arrive in the laboratory within 4 working days of the sample being taken.

Standards

Standard 4a	**Avoidable repeat rate**
Description	Repeat bloodspot cards that are required because of poor quality bloodspots or incomplete/incorrect information recorded on the card.
Rationale	Minimising the need for repeat samples maximises correct and timely screening outcomes. Repeat samples requested for avoidable reasons cause delays in identification and treatment of screen positive babies, anxiety and distress to families and wastes health care resources.

Data Definition	*Avoidable repeats ÷ All cards received*
	• Expressed as a percentage
	• *Avoidable repeats* equals all repeat requests issued which are due to:
	  ○ Insufficient/poor quality bloodspot sample
	  ○ Valid NHS number for baby not recorded
	  ○ Unsuitable sample/card - sample contaminated, bloodspots compressed, sample taken when baby was too young (on or before day 4), sample in transit for >14 days
	  ○ Card expired
	• *All cards received* equals all bloodspot cards received in the laboratory except for cards stating all screening declined
	• Data to be collected by specific reason for repeat request

Threshold	≤2%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing the bloodspot card correctly • Newborn Screening Laboratory for recording repeats • Screening Division for monitoring

Standard 4b	**Quality of sample**
Description	Repeat bloodspot cards that are required because of poor quality bloodspots.
Rationale	Minimising the need for repeat samples maximises correct and timely screening outcomes. Repeat samples requested for avoidable reasons cause delays in identification and treatment of screen positive babies, anxiety and distress to families and wastes health care resources.

Data Definition	*Avoidable repeats for poor quality samples ÷ All cards received*
	• Expressed as a percentage
	• *Avoidable repeats for poor quality samples* equals all repeat requests issued which are due to:
	  ○ Insufficient bloodspot sample
	  ○ Incorrect application – poor quality samples
	  ○ Sample contaminated, compressed or damaged
	• *All cards received* equals all bloodspot cards received in the laboratory except for cards stating all screening declined
	• Data to be collected by specific reason for repeat request

Threshold	≤2%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.

Responsibility	• Health Boards for completing the bloodspot card correctly • Newborn Screening Laboratory for recording repeats • Screening Division for monitoring

Standard 4c	**NHS number on bloodspot card**
Description	Bloodspot cards received in the Newborn Screening Laboratory that have a valid NHS number for the baby recorded.
Rationale	A valid NHS number is required to properly identify the baby with whom the sample is associated, and prevents the need for a repeat sample to be taken.
Data Definition	*Cards with an NHS Number ÷ All cards received* • Expressed as a percentage • *Cards with an NHS Number* equals all bloodspot cards received in the laboratory that have a valid NHS number for the baby recorded • *All cards received* equals all bloodspot cards received in the laboratory except for cards stating all screening declined
Threshold	100%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing the bloodspot card correctly • Newborn Screening Laboratory for recording NHS numbers • Screening Division for monitoring

POLICY 5 – TIMELY RECEIPT OF A SAMPLE IN THE NEWBORN SCREENING LABORATORY

Policy Statement

The newborn bloodspot sample must be received in the newborn screening laboratory within 4 working days of being taken. To facilitate this, the sample should be sent to the Wales Newborn Screening Laboratory within 24 hours of being taken, by first class post using a prepaid envelope.

Standard

Standard 5	**Timely receipt of bloodspot card in the newborn screening laboratory**
Description	Bloodspot cards received within 4 working days of the card being completed (for samples or declines).
Rationale	Minimising the time for a sample to be received in the laboratory increases the likelihood of correct screening outcomes and allows appropriate care to be initiated.
Data Definition	*Cards received (within 4 working days) ÷ All cards received* • Expressed as a percentage • *Cards received (within 4 working days)* equals all bloodspot cards that are received in the laboratory within 4 working days of being completed • *All cards received* equals all initial routine screening bloodspot cards (including those stating decline) that are received in the laboratory
Threshold	99%
Reporting	Data to be collated from NBSWS monthly, to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for completing and despatching bloodspot cards • Newborn Screening Laboratory for recording bloodspot card receipt • Screening Division for monitoring

Data is also collated from NBSWS monthly to monitor performance in timely receipt of bloodspot card in the newborn screening laboratory within 3 working days of the sample being taken. This is reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board, and is for monitoring purposes only.

POLICY 6 – TIMELY PROCESSING OF BLOODSPOT CARDS

Policy Statement

Bloodspot cards must be analysed and the results reported in a timely manner.

Standards

Standard 6a	Timely processing of all IMD and CHT screen positive samples
Description	Samples should be analysed and clinical referral initiated within 3 working days, for babies with an IMD (excluding HCU) or CHT.
Rationale	Processing the sample and initiating clinical referral within 3 working days maximises the opportunity for prompt and appropriate intervention.
Data Definition	*Number of screen positive results and clinical referral initiated within 3 working days of sample receipt ÷ All screen positive results obtained* • Expressed as a percentage • *Number of screen positive results available and clinical referral initiated within 3 working days of sample receipt* equals those screen positive results obtained for the IMDs and CHT and where clinical referral is initiated within 3 working days of receipt of a suitable bloodspot sample into the laboratory • *All screen positive results obtained* equals all screen positive results available for the IMDs and CHT
Threshold	100%
Reporting	Data to be collated from LIMS and NBSWS annually, to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Newborn Screening Laboratory for processing samples • Screening Division for monitoring

Standard 6b	Timely processing of all CF screen positive samples
Description	Samples should be analysed and clinical referral initiated within 25 days, for babies with CF.
Rationale	Processing the sample and initiating clinical referral within 25 days maximises the opportunity for prompt and appropriate intervention.
Data Definition	*Number of screen positive results and clinical referral initiated within 25 days of sample receipt ÷ All screen positive results obtained* • Expressed as a percentage • *Number of screen positive results available and clinical referral initiated within 25 days of sample receipt* equals those screen positive results obtained for CF and where clinical referral is initiated within *25 days* of receipt of a suitable bloodspot into the laboratory • *All screen positive results obtained* equals all screen positive results available for CF
Threshold	95%
Reporting	Data to be collated from LIMS and NBSWS annually, to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Newborn Screening Laboratory for processing samples • Screening Division for monitoring

Standard 6c	Timely processing of all SCD screen positive samples
Description	Samples should be analysed and clinical referral initiated within 42 days, for babies with SCD.
Rationale	Processing the sample and initiating clinical referral within 42 days maximises the opportunity for prompt and appropriate intervention.

Data Definition	*Number of screen positive results and clinical referral initiated within 42 days of sample receipt ÷ All screen positive results obtained* • Expressed as a percentage • *Number of screen positive results and clinical referral initiated within 42 days of sample receipt* equals those screen positive results obtained for SCD and where clinical referral is initiated within 42 days of sample receipt into the laboratory • *All screen positive results obtained* equals all screen positive results for SCD
Threshold	95%
Reporting	Data to be collated from LIMS and NBSWS annually, to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Newborn Screening Laboratory for processing samples • Screening Division for monitoring

POLICY 7 - TIMELY RECEIPT INTO CLINICAL CARE

Policy Statement

Babies who have screen positive results for one or more of the conditions screened for must be received into clinical care in a timely manner.

Standards

Standard 7a	**Timely receipt of babies with screen positive results for IMDs into clinical care**
Description	Babies identified as screen positive for any of the IMDs (excluding HCU) should attend their first clinical appointment by day 14 of life.
Rationale	Receipt into clinical care by day 14 of life permits timely diagnostic confirmation and initiation of treatment.
Data Definition	*Received into clinical care ÷ Screen positive results* • Expressed as a percentage • *Received into clinical care* equals all babies that have a screen positive result for any of the IMDs and attend their first clinical appointment by day 14 of life • *Screen positive results* equals all babies that have a screen positive result for any of the IMDs • Reported individually for GA1, HCU, IVA, MSUD, MCADD and PKU
Threshold	100%
Reporting	Data to be collated from the Newborn Screening Laboratory annually, to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for collecting and returning the bloodspots to the laboratory • Newborn Screening Laboratory for processing bloodspot samples and initiating referral of babies • Health boards for receiving babies into clinical care • Screening Division for monitoring

Standard 7b	**Timely receipt of babies with screen positive results for CHT into clinical care**
Description	Babies identified as screen positive for CHT following the initial screening sample should attend their first clinical appointment by day 14 of life. Babies who have an initial borderline result that are then identified as screen positive on the repeat sample should attend their first clinical appointment by day 21 of life.
Rationale	Receipt into clinical care within the timeframes specified above permits timely diagnostic confirmation and initiation of treatment.
Data Definition	*Received into clinical care ÷ Screen positive results* • Expressed as a percentage • *Received into clinical care* equals all babies that have a screen positive result for CHT on the initial screening sample and attend their first clinical appointment by day 14 of life, and those babies that have a screen positive result for CHT following an initial borderline result and attend by day 21 of life • *Screen positive results* equals all babies that have a screen positive result for CHT
Threshold	100%
Reporting	Data to be collated from the Newborn Screening Laboratory annually , to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for collecting and returning the bloodspots to the laboratory • Newborn Screening Laboratory for processing bloodspot samples and initiating referral of babies • Health boards for receiving babies into clinical care • Screening Division for monitoring

Standard 7c	**Timely receipt of babies with screen positive results for CF into clinical care**
Description	Babies identified as screen positive for CF should attend their first clinical appointment by day 28 of life.

Rationale	Receipt into clinical care by day 28 of life permits timely diagnostic confirmation and initiation of treatment.
Data Definition	*Received into clinical care ÷ Screen positive results* • Expressed as a percentage • *Received into clinical care* equals all babies that have screen positive result for CF and attend their first clinical appointment by day 28 of life • *Screen positive results* equals all babies that have a screen positive result for CF
Threshold	95%
Reporting	Data to be collated from the Newborn Screening Laboratory annually to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for collecting and returning the bloodspots to the laboratory • Newborn Screening Laboratory for processing samples and initiating referral of babies • Medical Genetics, Cardiff & Vale UHB for processing samples for CF mutation screen • Health boards for receiving babies into clinical care • Screening Division for monitoring

Standard 7d	**Timely receipt of babies with screen positive results for SCD into clinical care**
Description	Babies identified as screen positive for SCD should attend their first clinical appointment by day 90 of life.
Rationale	Receipt into clinical care by day 90 of life permits timely diagnostic confirmation and initiation of treatment.
Data Definition	*Received into clinical care ÷ Screen positive results* • Expressed as a percentage • *Received into clinical care* equals all babies that have a screen positive result for SCD and attend their first clinical appointment by day 90 of life • *Screen positive results* equals all babies that have a screen positive result for SCD
Threshold	90%

Reporting	Data to be collated from the Newborn Screening Laboratory annually to be reported annually to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Health Boards for collecting and sending the bloodspots to the laboratory • Newborn Screening Laboratory for processing bloodspot samples and initiating referral of babies • Health boards for receiving babies into clinical care • Screening Division for monitoring

POLICY 8 – TIMELY DESPATCH OF RESULTS TO PARENTS

Policy Statement

Parents of babies who have had a newborn bloodspot screening sample tested, or a bloodspot card stating decline received in the laboratory, will be sent a letter stating the screening results or test(s) declined within 6 weeks of completion of the bloodspot card by the sample taker. An information leaflet explaining the screening results will be sent to the parents with this letter.

This system of results reporting is currently being developed and therefore this standard is not yet finalised.

Standard

Standard 8	**Communication of results to parents**
Description	A letter stating the screening test results or test(s) declined for all babies will be sent to parents within 6 weeks of completion of the bloodspot card by the sample taker.
Rationale	It is important that the results of the screening tests are made known to the parents within 6 weeks to reduce any anxiety.
Data Definition	*Results despatched (6 weeks)÷ Babies tested* • Expressed as a percentage • *Results despatched (6 weeks)* equals all babies for whom results of the screening tests are sent to the parents within 6 weeks of completion of the bloodspot card • *Babies tested* equals all babies for whom an initial routine screening bloodspot card has been received by the laboratory for testing, or stating decline of test(s)
Threshold	100%
Reporting	Data to be collated from NBSWS monthly to be reported quarterly to the NBSW Clinical Governance and Quality Assurance Group and Maternal and Child Screening Programme Board.
Responsibility	• Screening Division for sending results and for monitoring