Healthcare Improvement Scotland

Newborn blood spot screening

Draft standards

July 2025

NHS SCOTLAND

We are committed to advancing equality, promoting diversity and championing human rights. These standards are intended to enhance improvements in health and social care for everyone, regardless of their age, disability, gender identity, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic status or any other status. Suggested aspects to consider and recommended practice throughout these standards should be interpreted as being inclusive of everyone living in Scotland.

We carried out an equality impact assessment (EQIA) to help us consider if everyone accessing health and social care services will experience the intended benefits of these standards in a fair and equitable way. A copy of the EQIA is available on request.

Healthcare Improvement Scotland is committed to ensuring that our standards are up-to-date, fit for purpose and informed by high-quality evidence and best practice. We consistently assess the validity of our standards, working with partners across health and social care, the third sector and those with lived and living experience. We encourage you to contact the standards and indicators team at his.screeningstandards@nhs.scot to notify us of any updates that might require consideration.

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www.healthcareimprovementscotland.scot

Contents

Introduction

Healthcare Improvement Scotland published the Pregnancy and Newborn Screening: Newborn blood spot standards in 2019. In Autumn 2024, these standards were prioritised by the National Screening Oversight Board for review in 2025.[1] The standards have been updated to:

- align with the UK newborn blood spot screening programme
- support benchmarking and audit
- prepare for the implementation of screening for tyrosinaemia as part of the newborn screening programme, as recommended by the UK National Screening Committee.[2]

The national pregnancy and newborn screening programme covers a range of screening tests for specific conditions.[3, 4] The aims of the programme are to:

- enable early identification of screened for conditions
- ensure treatment is started as soon as possible.

All newborn babies are offered a blood spot screening test between 96-120 hours (4-5 days old).[5] The test is done by taking a blood sample from the baby's heel. The sample is checked to find out whether the baby is unaffected or has the screened for condition.[5, 6] For some diseases it is possible to pick up if the baby is a healthy carrier of the disease.

These standards relate to newborn blood spot screening for:

- cystic fibrosis
- sickle cell disease
- congenital hypothyroidism
- six inherited metabolic disorders. These are phenylketonuria, medium-chain acyl-CoA dehydrogenase deficiency, maple syrup urine disease, isovaleric acidaemia, glutaric aciduria type 1 and homocystinuria.

NHS boards and staff involved in newborn blood spot screening should ensure they are following up-to-date national guidance and protocols, which reflect any changes to the national screening programme.

Information and resources

To support parents and carers to make informed decisions about newborn blood spot screening, information should be provided in a format and language that suits their needs. Support should be provided to enable informed decision making with opportunities for questions. Care and communication should be compassionate, understanding and non-judgmental. Parents and carers should always be respected and supported in their choices and decisions.

The following resources and organisations are available to support parents and carers, their families and staff:

- Your baby! Tests offered
- NHS Inform: Newborn screening
- Ready steady baby
- British Thyroid Foundation
- Cystic Fibrosis Trust - Newborn blood spot screening
- Metabolic Support UK
- National Society for Phenylketonuria
- Thyroid UK – Congenital hypothyroidism

Scottish pregnancy and newborn screening programme: governance

The Scottish pregnancy and newborn screening programme board[1] is:

- accountable for the newborn screening pathway, screening assessment, diagnosis and referral
- responsible for monitoring the effectiveness of the programme, including the offer of screening and performance against key performance indicators (KPIs).

The national newborn screening programme collects data on the performance of the programme, including coverage and outcomes. The KPIs are available from the pregnancy and newborn screening programme board. NHS boards should ensure regular reporting through appropriate national databases and forums. These newborn blood spot screening standards do not include the specifics of each KPI but should be read alongside the KPIs.

NHS boards deliver newborn blood spot screening for all babies registered within their locality. NHS boards are responsible for ensuring that the test is offered in line with national protocols. Whilst specialist support and care is not part of the screening pathway, it has been included in the standards to align with the participant pathway.

The Scottish Newborn Screening Laboratory (SNSL) provides a national screening service funded by the National Services Division of NHS National Services Scotland, with the appropriate accreditations.

These standards apply to NHSScotland services and staff delivering newborn blood spot screening services.

Related guidance and policy

All Healthcare Improvement Scotland standards are mapped to key national legislation, policy and standards.[7-9] They support the implementation of person-centred and trauma informed principles, and human rights and equality legislation.[10-12]

These standards should be read alongside the following:

- Healthcare Improvement Scotland: Core screening standards
- Healthcare Improvement Scotland: Pregnancy and newborn screening standards
- Maternity pathway and schedule of care: clinical guidance and schedule
- National Services Scotland: A guide to national population screening in Scotland
- Public Health Scotland: Your baby - tests offered
- Scottish Equity in Screening Strategy 2023-26
- Scottish Perinatal Network.

Scope of the standards

These standards apply to all newborn babies registered with a GP in Scotland. The eligibility criteria can be found on NHS Inform.

The standards cover:

- information provision and informed decision making
- offer of the newborn blood spot screening
- newborn blood spot screening and results
- laboratory processes and results reporting
- specialist support and care planning following a positive result.

Format of the standards

Healthcare Improvement Scotland standards follow the same format. Each standard includes:

- an overarching standard statement
- a rationale explaining why the standard is important
- a list of criteria describing what is needed to meet the standard
- what the standards mean if you are a parent or carer
- what the standard means if you are a member of staff
- what the standard means for organisations
- examples of what meeting the standard looks like in practice.

Implementation

These standards have been developed by key stakeholders from across the newborn blood spot screening pathway. The standards support and inform organisational self-evaluation and improvement.

Implementation of the standards by the screening programme board and NHS boards will ensure the delivery of safe, effective, person-centred and trauma informed services across the screening pathway.

These standards are a key component in supporting the programme board's approach to quality assurance. Monitoring performance against these standards, at a local and national level, aims to improve the quality of the programme.

External quality assurance (EQA) of screening programmes will be delivered using the Healthcare Improvement Scotland quality of care approach and the quality framework. This approach specifies how Healthcare Improvement Scotland will design and deliver EQA activity to support improvement in healthcare.

The approach emphasises the importance of regular, open and honest self-evaluation of programmes using the quality framework as a basis, combined with other relevant data and intelligence, including performance against these standards.

Terminology

Wherever possible, we have used generic terminology which can be applied across all health and social care settings. All terminology is included in the glossary.

How to participate in the consultation process

We welcome feedback on the draft standards and will review every comment received. We are using different methods in our consultation, including:

- targeted engagement with people who use services (and representatives) and service providers (including staff at the point of care)
- circulation of the draft standards to relevant professional groups, pregnancy screening staff and third sector organisations
- an online survey.

Submitting your comments

Responses to the draft standards should be submitted using our online survey.

The consultation closes on **Tuesday 12 August 2025**. If you would like to submit your comments using a different format, please contact the project team on his.screeningstandards@nhs.scot.

Please note, consultation comments will not be accepted after the closing date, or in an alternative format, unless previously agreed with the project team.

Consultation feedback

Feedback on the draft standards will be reviewed and themed by the project team. The development group will reconvene following consultation to review feedback on the draft standards and agree on amendments to the standards.

A summary of the responses to the consultation will be made available on request from the project team at his.screeningstandards@nhs.scot.

The final standards will be published in Winter 2025.

Standards summary

Standard 1: Information provision and informed decision making

Parents and carers are supported to make informed decisions about newborn blood spot screening.

Standard 2: Offer of the newborn blood spot screening

NHS boards ensure newborn blood spot screening is offered to all registered babies.

Standard 3: Newborn blood spot screening and results

NHS boards ensure that newborn blood spot sampling is high-quality with the timely reporting of results.

Standard 4: Laboratory processes and results reporting

The Scottish Newborn Screening Laboratory undertakes sample testing and reporting of results in line with nationally agreed standards and protocols.

Standard 5: Specialist support and care planning following a positive result

NHS boards ensure babies with positive screening results are offered multidisciplinary specialist support and care planning.

Standard 1: Information provision and informed decision making

Standard statement

Parents and carers are supported to make informed decisions about newborn blood spot screening.

Rationale

Blood spot screening is offered to all registered newborn babies to identify specific conditions at the recommended timeframe after birth. The blood spot screening tests for the following:[6]

- cystic fibrosis
- sickle cell disease
- congenital hypothyroidism
- six inherited metabolic disorders. These are phenylketonuria, medium-chain acyl-CoA dehydrogenase deficiency, maple syrup urine disease, isovaleric acidaemia, glutaric aciduria type 1 and homocystinuria.

Parents and carers should be provided with tailored information prior to newborn blood spot screening. Information should include the aim of screening, benefits and limitations and potential results. Parents and carers should be given information in advance of the screening and time to understand the screening process. Staff should provide opportunities for parents and carers to discuss the screening tests, including the risks and benefits of screening, and what the results might mean for their newborn. There should also be discussion about the time limitations for the screening tests. Parents should be aware that the test for all six inherited metabolic disorders is undertaken as a single test and these disorders cannot be screened for separately. The principles of informed consent and shared decision making are central to the screening programme. Consent for newborn blood spot testing should be obtained in line with national guidance and protocols.

Where screening for one or all conditions has been declined, parents and carers should be given information on how to opt back into the screening process. Information should also be provided on any signs or symptoms which may relate to conditions that may have been picked up at screening.

NHS boards should ensure that staff are appropriately trained in person-centred and trauma informed communication approaches. Parents and carers should be respected and supported in their decisions. Signposting to specialist support organisations should be made as appropriate.

Criteria

1.1 To support informed decision making, parents and carers are provided with evidence-informed, accessible and timely national information, which includes:

- the conditions being screened for
- the aim, benefits and limitations of newborn blood spot screening
- consent to screening and that screening (any or all tests) can be declined
- how to opt in to screening following an initial decline of any or all tests,
- the timeframes and time limitations of the screening
- when and how the results will be received
- what the results and possible incidental findings mean
- contact details for a named midwife and specialist organisations to ask questions
- what happens if repeat blood tests, further testing or specialist referral is required.

1.2 NHS boards ensure that systems and processes are in place for the recording and sharing of information, including:

- the parent and carer's decision to accept or decline all or any part of screening
- the parent and carer's contact details for communication of a positive result.

1.3 Parents and carers are supported to make informed decisions about screening by staff who:

- are trained and knowledgeable in newborn blood spot screening including eligibility criteria
- offer evidence-informed, accessible and timely national information
- take consent in line with guidance and protocols
- provide empathetic, respectful and compassionate care and support
- provide opportunities to discuss what screening and results mean
- signpost to specialist support organisations, where required.

What does the standard mean for parents and carers taking part in newborn blood spot screening?

- You will be offered newborn blood spot screening to find out if your baby may have a health condition.
- Staff will provide information about the tests and the conditions being tested for.
- The information you receive will support you to make an informed decision about whether you would like your baby to be tested or if you only want to test for some health conditions. If you later change your mind, staff will support you to understand what your options are.
- All your decisions will be respected.
- You will be offered the opportunity to discuss newborn blood spot screening and results with an appropriate healthcare professional.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- provide information and support to parents and carers that is evidence based, tailored, sensitive and respects their choices
- take a person-centred approach to blood spot screening that enables choice and supports informed decision making, with opportunities for discussion and questions
- ensure decisions to accept or decline screening are recorded and shared appropriately.

What does the standard mean for the NHS board?

NHS boards:

- ensure appropriate, easily accessible and timely national information is readily available and relevant to when the test is being offered
- have arrangements in place to record and share informed choice and consent for screening
- have clear protocols in place to support parents and carers to opt in to screening, if they change their mind
- ensure staff have time, resources and training to support parents and carers in decision making.

Examples of what meeting this standard might look like
• Evidence of parent and carer involvement in decision making for screening. • Evidence of information provision provided in alternative formats and languages. • Signposting of parents and carers to specialist support organisations. • Evidence of protocols for parents to request blood spot screening for up to one year. • Local protocols describing staff responsibility for provision of information.

Standard 2: Offer of the newborn blood spot screening

Standard statement

NHS boards ensure newborn blood spot screening is offered to all registered babies.

Rationale

Newborn blood spot screening is offered to every registered baby in line with national guidance. NHS boards should have protocols in place to ensure babies in their resident population are identified and offered screening within agreed timelines. Newborn babies are recorded on the Child Health Information Systems within their board of residence. NHS boards should offer blood spot screening to all registered newborn babies between 96–120 hours after birth. Newborn blood spot screening can also be offered to all babies who have moved into the area within 12 months of birth and the parent or carer has registered with a GP.

NHS boards ensure processes are in place to review records to ensure screening has taken place within agreed timeframes. It is also the responsibility of NHS boards to check available records to determine if screening has taken place for babies who have transferred into their board area. Where no records are available or verifiable, blood spot screening is offered in line with the national protocols. Local protocols should outline staff roles and responsibilities to review records to ensure screening has been offered.

Parents and carers may decline all or some of the newborn blood spot tests. Staff should record all decisions, including a decline of all or some of blood spot screening, in the baby's notes. This information should be shared on the relevant systems.

NHS boards should ensure systems and process are in place to monitor newborn blood spot screening. This includes screening attendance and uptake and failsafe protocols.

Criteria

2.1 NHS boards offer high-quality, safe and timely blood spot screening in line with national timeframes and protocols. This includes offering blood spot screening to:

- all registered newborn babies, ideally between 96–120 hours after birth, but up to their first birthday
- all babies who have moved into the area within 12 months of birth and the parent has registered with the GP.

2.2 NHS boards have systems and protocols in place to ensure all newborn babies within their board area are registered on:

- Community Health Index (CHI)
- local and national Child Health Information Systems.

2.3 NHS boards have processes to identify registered babies up to one year who have moved into the area.

2.4 NHS boards have processes to ensure babies who have no health records or verifiable results for previous blood spot screening will be offered screening.

2.5 NHS boards ensure processes are in place to record and share information with relevant staff where any part of screening including specific blood spot tests has been declined.

2.6 NHS boards have systems and protocols in place to review records for babies with no screening results recorded by day 15, which includes:

- clear roles and responsibilities of staff in monitoring
- frequency of monitoring reports in line with national protocol
- timely follow up to determine whether the baby requires blood spot testing
- a timely appointment for blood spot tests, where required.

2.7 NHS boards ensure systems and processes are in place to audit data and develop improvement plans for offering blood spot screening, which covers:

- uptake and opt-out of newborn blood spot screening
- KPIs for attendance and uptake
- adherence to failsafe protocols.

2.8 NHS boards ensure effective and timely reporting on KPIs to local governance groups and the national programme board.

2.9 NHS boards have systems and processes in place to ensure that families and carers are aware of how they can opt in or make an appointment if their decision changes.

What does the standard mean for parents and carers taking part in newborn blood spot screening?

- You will be offered newborn blood spot screening for your baby at the appropriate time.
- Staff will explain clearly that there are different tests for different conditions and that you can decide that you do not wish your baby to be screened or if you only want some of the tests.
- Babies can be tested until their first birthday. If you change your mind and decide you want your baby to be tested, you will be informed about which tests are available and who to contact.
- Staff will respect your decision.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- understand the eligibility criteria for newborn blood spot screening
- review records to ensure babies have been offered screening within national timeframes
- apply the process for recording opting out of screening.

What does the standard mean for the NHS board?

NHS boards:

- have an effective system in place to ensure all registered babies are offered blood spot screening within the agreed timescales
- have a primary and failsafe mechanism in place to ensure that all babies are offered newborn screening in line with national guidance
- regularly check the national Child Health Information System to identify babies where no screening has taken place and ensure testing is offered without delay
- monitor current processes to deliver the newborn blood spot screening pathway
- undertake audit and implement changes to improve processes and outcomes.

Examples of what meeting this standard might look like
- Protocols for eligibility and invitation to the newborn blood spot screening service. - Local protocols detailing roles and responsibilities for identifying babies with no screening results. - Documentation demonstrating discussions, decision making and how information is shared appropriately between teams. - Audit and improvement plans for delivery of newborn blood spot screening. - Reports to local governance committee on screening outcomes. - Standard operating procedures to ensure babies are registered on the CHI and Child Health Information Systems.

Standard 3: Newborn blood spot screening and results

Standard statement

NHS boards ensure that newborn blood spot sampling is high-quality with the timely reporting of results.

Rationale

Obtaining high-quality and timely blood spot samples ensures that babies with a positive screen are identified, referred and treated early.[5] For babies who are premature, unwell or have had a blood transfusion, staff should follow national guidance. The sample can be taken in the community or in hospital.

Staff undertaking blood spot sampling are trained in the preparation and collection of the sample.[5] This includes ensuring the correct information is captured on the blood spot card. It is essential that a high-quality and sufficient sample is taken to avoid any unnecessary repeat sampling. High-quality sample taking enables timely referral and treatment where there is a positive result. It minimises parental anxiety or potential delay for treatment.

Staff undertaking the test should ensure that the sample is transported in a timely manner to the laboratory and in line with local protocols. For further information on laboratory processes and results reporting, see Standard 4.

In some circumstances, the first blood spot screening sample may not be able to give a clear result for cystic fibrosis or congenital hypothyroidism, therefore a second blood spot sample is required for further testing. It is important that the second blood spot sample is taken within the agreed timescales in line with national guidance.[5]

Criteria

3.1 NHS boards have local protocols in place which covers sampling and staff responsibilities for babies:

- born prematurely
- being cared for in neonatal units both in and outwith board of residence
- born at home
- who have moved into the NHS board area including from across the UK.

3.2 Staff undertaking blood spot sampling (including repeat tests) are trained and competent to:

- provide information and obtain parental consent (see Standard 1)
- accurately complete all data fields on the blood spot card
- collect a high-quality sample in line with guidance from the SNBL
- collect and transport the sample in line with agreed timelines and protocols.

3.3 Staff ensure that blood spot samples are packaged, labelled and dispatched in line with national guidance and protocols.

3.4 NHS boards ensure local protocols and contingency plans are in place to ensure the timely delivery of blood spot cards to the laboratory.

3.5 NHS boards audit processes and implement improvement plans, which covers:

- quality of blood spot sampling
- minimising avoidable repeat sampling
- effective transportation and delivery of samples, in line with agreed timeframes.

3.6 Laboratories have protocols in place to alert the staff who take samples of the need for a repeat sample and this is acted on in timely manner.

3.7 Where a repeat test is required, staff ensure parents and carers understand the reasons and provide opportunities to ask questions and make informed decisions.

3.8 Where second blood spot screening samples for cystic fibrosis and congenital hypothyroidism are required, these are taken in line with national guidance.

What does the standard mean for parents and carers of the baby?

- Staff will explain how the sample will be taken and make sure your baby is as comfortable as possible.
- Your baby's newborn blood spot test will be completed within agreed timescales.
- Staff will do everything they can to ensure they only need to take one sample.
- If a repeat sample is required, you will be informed and supported by staff.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- undertake accurate and high-quality blood spot sampling in line with national guidance
- complete all necessary fields of the blood spot card
- ensure timely transportation of the sample to the laboratory.

What does the standard mean for the NHS board?

NHS boards:

- ensure staff are trained and competent in accurate blood spot sampling
- monitor and review accuracy of blood spot sampling
- develop protocols to monitor missed samples
- have an effective system in place to make sure a high-quality second blood spot sample is taken from babies at the correct time period if required
- have protocols in place to ensure timely transportation of samples to the laboratory.

Examples of what meeting this standard might look like

- Local contingency plans to ensure transportation of samples in the event of a postal strike or severe weather.
- Training records and evidence of ongoing continued professional development.
- Monitoring reports of repeat testing.
- Audits and improvement plans relating to transportation and packaging of samples.
- Child Health Information System reports detailing results at the 6–8 week child health review.
- Monitoring of outcomes from second sampling.
- Evidence that the screening has taken place if the parents and carers have consented.
- Training records relating to second sampling.

Standard 4: Laboratory processes and results reporting

Standard statement

The Scottish Newborn Screening Laboratory undertakes sample testing and reporting of results in line with nationally agreed standards and protocols.

Rationale

The Scottish Newborn Screening Laboratory (SNSL) processes and analyses all newborn blood spot screening samples in line with national guidance and protocols. The SNSL will have the appropriate accreditation to perform analysis.[13]

Robust clinical governance ensures that screening tests are processed within an environment that delivers high reliability and accuracy. The role of the SNSL is to ensure the accurate reporting of results and referral of screen positive results for further testing and treatment.[1, 14] The SNSL is responsible for informing staff where a repeat sample is required.

Laboratory staff should have access to ongoing training, education, supervision and assessment.

It is important that results are reported in line with national timeframes and protocols, allowing for accurate monitoring and review of screening outcomes and missed tests.[14]

If a screening result is positive, the SNSL will contact the appropriate specialist team in the relevant geographical area, providing the screening result and patient information to allow the specialist to contact the parents/carers (see Standard 5).[14]

Criteria

4.1 The SNSL can demonstrate:

- participation in the relevant quality assurance and regulatory frameworks
- adherence to national standards and procedures for results reporting and monitoring quality, including adverse events management
- reporting against relevant newborn blood spot screening KPIs
- learning from the detection, review and reporting of any issues relating to laboratory processes.

4.2 There is a designated clinical lead and service manager with responsibility for newborn blood spot laboratory processes.

4.3 Samples are processed using equipment and techniques which meet national standards and protocols.

4.4 SNSL staff are trained to the required standards of competence and undertake regular training, continued professional development, education, supervision and assessment appropriate to their roles and responsibilities.

4.5 Results from screening are issued by the SNSL in line with national timeframes.[14]

4.6 SNSL staff communicate with the appropriate NHS board where:

- a repeat blood sample is required and provide reasons for this
- results are inconclusive or there was a process error.

4.7 SNSL staff can demonstrate:

- understanding and competence of laboratory processes
- up to date knowledge of screening through validation and verification.

4.8 The SNSL has systems and processes in place to ensure quality assurance and monitoring of key aspects of sampling, including sample quality and timely sample delivery.

4.9 The SNSL, NHS boards and national programme board have systems and processes are in place to:

- collate and monitor activity and outcome data
- undertake audit and review of activity and outcome data
- implement actions and improvement plans
- work collaboratively to promote the exchange of information and shared learning.

What does the standard mean for parents and carers taking part in newborn blood spot screening?

- You can be confident that blood spot samples have been analysed accurately and by appropriately trained staff.
- You will receive your baby's results in a timely manner.
- You will receive information on what your baby's results mean and what will happen next.
- You can be confident that if your baby has a positive result, they will be on the correct care pathway.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- understand and work within the relevant national standards, protocols and guidance
- work collaboratively as part of a wider multidisciplinary team
- are supported to attend regular training, continued professional development and education.

What does the standard mean for the Scottish Newborn Screening Laboratory?

The SNSL will:

- ensure standards and requirements for safe and effective laboratory services are in place
- provide data monitoring in line with national and relevant audit returns
- review internal and external monitoring and quality reports to ensure the identification of issues in a timely manner.

Examples of what meeting this standard might look like

- Evidence of relevant laboratory accreditation.
- Evidence of laboratory staff qualifications and continued professional development.
- Evidence of timely laboratory processes.
- Protocols for requesting repeat samples.
- Demonstrate lessons learned from screening incidents or adverse events.

Standard 5: Specialist support and care planning following a positive result

Standard statement

NHS boards ensure babies with positive screening results are offered multidisciplinary specialist support and care planning.

Rationale

Specialist support and care planning is offered when the blood spot tests results confirms the baby has one of the screened for conditions.[1] The referral process is initiated by the laboratory (see Standard 4). Parents and carers are informed about their baby's results, prognosis, referral and treatment. This supports informed decision making and effective planning. Information should include details of condition specific specialist organisations.

NHS boards ensure pathways are in place for timely specialist care and advice where required.[1] If a condition is suspected, the family will be contacted by the most appropriate health professional for that condition. Multidisciplinary care planning should be available. For some conditions there may be need for an urgent review. Treatment may start whilst awaiting the outcome of diagnostic tests.

Staff are appropriately trained and knowledgeable in line with relevant condition specific professional guidance and frameworks. This includes further diagnostic testing and management guidance, where relevant.

Criteria

5.1 NHS boards have pathways in place for specialist support and care following confirmation of a screened for condition, in line with national guidance and protocols.

5.2 NHS boards provide information and support to parents and carers that is responsive to individual needs, which may include:

- options for care and management of the condition
- further testing, where required
- onward referral for counselling or wellbeing support
- peer and third sector support.

5.3 Parents and carers are signposted to condition specific specialist staff and support including third sector organisations, where appropriate.

5.4 NHS boards monitor and report on diagnostic pathway outcomes to the SNSL.

What does the standard mean for parents and carers taking part in newborn blood spot screening?

- You can be confident that if your baby has a positive result, they will be able to access the care and support that is right for them.
- Your baby's care and support will be clearly explained and you will be given time to ask questions and think about your options.
- You will be able to access specialist staff and services that support you.
- You will know who to contact if you have any concerns or questions.
- You will be listened to and you will be supported by compassionate, respectful and non-judgemental staff.
- You will be supported by staff who are skilled and knowledgeable.
- Staff will signpost you to specialist support organisations, if that is right for you.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- are appropriately trained and knowledgeable in the relevant condition specific care and treatment pathways
- can provide information and support to parents and carers that is sensitive and respects their choices
- provide empathetic, respectful and compassionate care and support
- refer to specialist staff and services, as required
- signpost to relevant information and appropriate additional support, as required.

What does the standard mean for the NHS board?

NHS boards:

- ensure pathways are in place to provide timely access to specialist services in line with national guidance and protocols
- monitor outcomes from screening
- have referral pathways for specialist services and support
- provide reports to the newborn blood spot laboratory on diagnostic outcomes for screening positive babies.

Examples of what meeting this standard might look like
• Local pathways to specialist teams. • Monitoring reports detailing completion of the blood spot screening pathway within an agreed defined reporting period. • Provision of reports from NHS boards to the laboratory detailing diagnostic outcomes.

Appendix 1: Development of the newborn blood spot screening standards

Healthcare Improvement Scotland has established a robust process for developing standards, which is informed by international standards development methodology.[15] This ensures the standards:

- are fit for purpose and informed by current evidence and practice
- set out clearly what people who use services can expect to experience
- are an effective quality assurance tool.

The standards have been informed by current evidence, best practice recommendations, national policy and are developed by expert group consensus. The standards have been cocreated with key stakeholders and people with lived experience from across Scotland.

Evidence base

A review of the literature was carried out using an explicit search strategy developed by Healthcare Improvement Scotland's Research and Information Service. Additional searching was done through citation chaining and identified websites, grey literature and stakeholder knowledge. Searches included Scottish Government, Public Health Scotland, NICE, SIGN, NHS Evidence and Department of Health and Social Care websites. This evidence was also informed equalities impact assessments. Standards are mapped to a number of information sources to support statements and criteria. This includes, but is not limited to:

- government policy
- approaches to healthcare delivery and design, such as person-centred care
- clinical guidelines, protocols or standards
- professional or regulatory guidance, best practice or position statements
- evidence from improvement.

Standards development

A standards development group, chaired by Dr Sarah Smith, Director of Scottish Newborn Screening Laboratory, was convened in April 2025 to consider the evidence and to review the 2019 standards for newborn blood spot screening.

Membership of the development group is outlined in Appendix 2.

Each standard is underpinned by the views and expectations of healthcare staff, third sector representatives, people participating in screening and the public. Information has been gathered from several sources and activities, including:

- two development group meetings in April and May 2025
- a six-week consultation period including a survey and stakeholder workshops
- a final development group meeting held in October 2025
- a review panel meeting and an editorial panel meeting in June 2025.

Consultation feedback and finalisation of the standards

Following consultation, the standards development group reconvened to review the comments received on the draft standards and make final decisions and changes. More information can be found in the consultation feedback report, which is available on request from the standards and indicators team.

Quality assurance

All standards development group members were responsible for advising on the professional aspects of the standards. Clinical members of the standards development group advised on clinical aspects of the work. The Chair had lead responsibility for formal clinical assurance and sign off on the technical and professional validity and acceptability of any reports or recommendations from the group. Membership of the editorial review panel is available in Appendix 3.

All standards development group members made a declaration of interest at the beginning of the project. They also reviewed and agreed to the standards development group's terms of reference. More details are available on request from his.screeningstandards@nhs.scot.

The standards were developed within the Operating Framework: Healthcare Improvement Scotland and Scottish Government, which highlights the principles of independence, openness, transparency and accountability.

For more information about HIS's role, direction and priorities, please visit: Healthcare Improvement Scotland.

Appendix 2: Membership of the standards development group

Name	Position	Organisation
Sarah Smith (Chair)	Director of Scottish Newborn Screening Laboratory	NHS Greater Glasgow and Clyde
Lorna Allen	Senior Involvement Manager	Cystic Fibrosis Trust
Sarah Campbell	Midwife	NHS Grampian
Alison Cozens	Consultant in Paediatric Inherited Metabolic Medicine	NHS Lothian
Rosemary Davidson	Consultant Geneticist	NHS Greater Glasgow and Clyde
Jonathan Gibson	Campaigns Lead	Metabolic Support UK
Lyn Hutchinson	Senior Programme Manager	NHS National Services Scotland
Tamasin Knight	Consultant in Public Health	NHS Tayside
Jane Oliver	Health Improvement Manager (Screening confidence and equity)	Public Health Scotland
Alison Potts	Consultant in Public Health	NHS Greater Glasgow and Clyde
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Name	Position	Organisation
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The standards development group, review and editorial panels were supported by the following members of Healthcare Improvement Scotland's standards and indicators team:

- Stephanie Kennedy – Administrative Officer
- Jen Layden – Programme Manager
- Carolyn Roper – Project Officer
- Fiona Wardell – Team Lead

Appendix 3: Membership of the editorial and review panel

Name	Position	Organisation
Lyn Hutchinson	Senior Programme Manager	NHS NSS
Jen Layden	Programme Manager	Healthcare Improvement Scotland
Safia Qureshi	Director of Evidence and Digital	Healthcare Improvement Scotland
Sarah Smith	Director of Scottish Newborn Screening Laboratory	NHS Greater Glasgow and Clyde
Fiona Wardell	Team Lead	Healthcare Improvement Scotland

Glossary

Term	Definition
Accessible and timely	ensuring people can access care when and where they need it.
Effective	providing care based on evidence and which produces a clear benefit.
Eligibility criteria	refers to the criteria that means someone should be invited for screening. Each national screening programme has defined eligibility criteria. Criteria include age and/or sex, or if the person has any conditions (for example diabetes) that may mean they are more likely to develop an illness or condition (such as diabetic eye disease).
Failsafe	refers to processes designed to ensure that all aspects of the screening process are safe and effective, and that there are appropriate mechanisms where an issue or screening incident occurs.
Person-centred and personalised care	is care that responds to individual needs and preferences, and ensures individuals are partners in their planning and delivery.
Registered babies	are babies who are registered with a general practice or on the Child Health Information System. Babies who are registered can access screening. It is the responsibility of the NHS board of residence to ensure systems are in place to monitor and review screening outcomes for registered babies.
Safe	ensures people using health and care services feel safe and the care they receive does not harm them.
Screening incident	an adverse event that could have caused, or did result in, harm to a person or a group of people.

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