Healthcare Improvement Scotland

Newborn blood spot screening

Standards

November 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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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(1) for review in 2025. 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 blood spot screening between 96-120 hours (4-5 days old).(5) Screening is done by taking a blood sample from the baby's heel. The sample is screened for nine inherited and metabolic disorders. If the screening test is positive, or high risk, the baby is referred for specialist care which will include further diagnostic testing.(5, 6) For some diseases, it is possible to identify if the baby is a healthy carrier of the disease.

These standards cover 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:

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

Scottish pregnancy and newborn screening programme: governance

The Scottish pregnancy and newborn screening programme board(1) is:

- accountable for the newborn blood spot 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 blood spot 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.

Related guidance and policy

All Healthcare Improvement Scotland standards are mapped to key national legislation, policy and standards.(7-10) They support the implementation of person-centred and trauma informed principles, and human rights and equality legislation.(11-13)

These standards should be read alongside the following:

- Healthcare Improvement Scotland: Core screening standards
- Healthcare Improvement Scotland: Maternity care 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 in Scotland. The eligibility criteria can be found on NHS Inform.

The standards cover:

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

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

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 may look like in practice.

Implementation

These standards have been developed by key stakeholders from across the newborn blood spot screening pathway (see Appendix 1 for further information). The standards support and inform organisational self-evaluation and improvement.

Implementation of the standards by the newborn blood spot 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.

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 newborn blood spot screening

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

Standard 3: Newborn blood spot sampling and results

NHS boards ensure that newborn blood spot sampling is high-quality with 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

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

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 at the recommended timeframe after birth for the following conditions:(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. This is usually provided during pregnancy. Information should include the aim of screening, benefits and limitations and potential results. 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 baby. There should also be discussion about the time limitations for the screening tests. Parents and carers should be informed that all six inherited metabolic disorders are tested at once and it is not possible to test for some metabolic disorders and not others. 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.(14)

Where the blood spot test 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 be provided on any signs or symptoms relating 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 leaflet, 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 any or all of the screening tests
- when and how the results will be received
- what the results and possible incidental findings mean
- contact details for a named midwife, other healthcare professional or specialist organisations to ask questions
- what happens if repeat blood tests, further testing or specialist referral are required.

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

- decision to accept or decline all or any part of the screening test
- who to contact if parents and carers have any questions or concerns, including their named midwife, other healthcare professional or specialist organisation.

1.3 Staff supporting parents and carers to make informed decisions about screening:

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

What does the standard mean for parents and carers?

- You will be offered newborn blood spot screening for your baby.
- 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.
- You will be able to decide if you want to test for some or all the screened for 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 decisions
- take a person-centred approach to newborn blood spot screening that enables choice and supports informed decision making, with opportunities for discussion and questions
- ensure decisions to accept or decline newborn blood spot screening are recorded and shared appropriately.

What does the standard mean for the NHS board?

NHS boards:

- ensure appropriate, accurate and timely national information leaflet is easily accessible
- have arrangements in place to record and share informed decision making and consent for newborn blood spot screening
- have clear protocols in place to support parents and carers to opt into newborn blood spot screening, if they change their mind later
- ensure staff have time, resources and training to support parents and carers in decision making.

Examples of what meeting this standard might look like
• Use of tools and frameworks to support informed decision making by parents and carers, including obtaining consent or declining tests. • Use of national information leaflet about newborn blood spot screening including provision of information in alternative formats and languages. • Signposting of parents and carers to specialist support organisations. • Local protocols describing staff responsibility for provision of information on newborn blood spot screening including opting out.

Standard 2: Offer of newborn blood spot screening

Standard statement

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

Rationale

NHS boards have protocols in place to ensure every registered newborn baby, resident in their NHS board, is invited for newborn blood spot screening, in line with national guidance. Screening is offered between 96-120 hours after birth. Newborn babies are recorded on the Child Health Information Systems within their board of residence. Exceptions to this timeframe should be recorded, for example, when the baby is pre-transfusion or preterm congenital hypothyroidism, and babies should be offered screening when appropriate in line with national guidance. NHS boards should have processes and protocols outlining staff roles and responsibilities to review records for screening results by day 15, and 'escalate/follow-up' for further action as appropriate

For a child under one year who has transferred into the board area, NHS boards should have local protocols for confirming if newborn blood spot screening has taken place. If previous screening results are not available or verifiable, newborn blood spot screening is offered in line with the national protocols.

Parents and carers may decline or opt-out of all or some of the newborn blood spot tests. Staff should record all decisions in the baby's notes, including where any part of screening including specific blood spot tests has been declined. This information should be shared on the relevant systems.

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

Criteria

2.1 NHS boards offer high-quality, safe and timely newborn blood spot screening in line with national timeframes and protocols, including to all:

- registered newborn babies, ideally between 96–120 hours after birth
- babies where there is a clinical reason the sample was not taken 96–120 hours after birth, for example babies who are pre-transfusion or preterm
- babies who have transferred into the NHS board area within one year of birth.

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 Child Health Information System.

2.3 NHS boards have processes to identify babies under one year of age who have transferred into their area who have no health records or verifiable results for previous blood spot screening. All identified babies will be offered screening.

2.4 NHS boards have systems and protocols in place to monitor babies with no screening results recorded by day 15, which includes:

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

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 ensure systems and processes are in place to audit data and develop improvement plans for offering blood spot screening, which cover uptake and opt-out of newborn blood spot screening adherence to failsafe protocols.

2.7 NHS boards ensure effective and timely reporting of KPIs to local governance groups and the national blood spot screening programme board.

2.8 NHS boards have systems and processes in place to ensure that parents 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?

- You will be offered newborn blood spot screening for your baby at an appropriate time.
- You can be confident that staff routinely monitor records to ensure all babies are offered newborn blood spot screening. If there are any delays to people being offered screening, this will be reviewed and acted on.
- If you move to a new area, and your baby has not been screened, you will be able to have your baby tested up to their first birthday.
- If you change your mind about having your baby screened, you will know who to contact to talk through your options.
- 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 newborn 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 blood spot 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
• Local protocols detailing staff responsibilities for identifying babies with no blood spot screening results. • Local protocols for the management of babies transferring into the NHS board including those with no health visitor records. • Audit and improvement plans for delivery of newborn blood spot screening, including KPI adherence and timeframes for providing screening. • Reports to the local governance committee on newborn blood spot screening outcomes. • Standard operating procedures to ensure babies are registered on the CHI and Child Health Information Systems.

Standard 3: Newborn blood spot sampling and results

Standard statement

NHS boards ensure that newborn blood spot sampling is high-quality with 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. The sample can be taken in the community or in hospital.(5) Newborn blood spot sample taking for babies who are premature, unwell or have had a blood transfusion, should follow the relevant national guidance.(5)

Staff undertaking newborn blood spot sampling are trained in the preparation and collection of the sample.(5) High-quality sample taking minimises parental and carer anxiety or potential delay for treatment. The baby should be made as comfortable as possible. It is essential that a sufficient, high-quality sample is taken to avoid any unnecessary repeat sampling. Staff should ensure the correct information is captured on the blood spot card. Blood spot sample cards should be checked to ensure they are in-date.

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 blood spot screening sample may not give a clear result for cystic fibrosis or congenital hypothyroidism and a second blood spot sample may be 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 cover sampling and staff responsibilities for all babies, including those who are:

- 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.

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

- providing information and obtaining parental or carer consent (see Standard 1)
- checking the expiry dates on blood spot cards
- accurately completing all data fields on the blood spot card
- collecting a high-quality sample in line with Scottish newborn screening laboratory guidance
- using the appropriate packaging and labelling and dispatching the sample in line with agreed national timelines, guidance and protocols.

3.3 Staff ensure the baby is as comfortable as possible, and support the parent or carer to provide a calm environment.

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 cover:

- quality of blood spot sampling
- minimising avoidable repeat sampling
- effective transportation and delivery of samples, in line with agreed timeframes
- monitoring the expiry date of blood spot cards, the recall and discard out-of-date cards.

3.6 Staff undertake timely repeat samples when requested by the SNSL.

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

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

What does the standard mean for parents and carers?
• 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 their roles, responsibilities and workplace setting: • undertake accurate and high-quality blood spot sampling in line with national guidance • check the blood spot card is in-date • complete all necessary fields of the blood spot card • ensure timely transportation of the sample to the laboratory • ensure the baby is as comfortable as possible.
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 blood spot sample cards are available and expired cards are discarded • have protocols in place to ensure timely transportation of samples to the laboratory.

Examples of what meeting this standard might look like
• Training records and evidence of ongoing continued professional development related to newborn blood spot sampling and second sampling. • Audit frequency of, reasons and timelines for repeat testing. • Audits and improvement plans relating to transportation and packaging of samples. • Child Health Information System reports detailing results at the six–eight week child health review. • Monitoring of outcomes from second sampling for cystic fibrosis and congenital hypothyroidism. • Evidence that the screening has taken place if the parents and carers have consented.

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.(15) The SNSL should have a designated clinical lead and service manager with responsibility for newborn blood spot laboratory processes. Laboratory staff should have access to ongoing training, education, supervision and assessment.

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, 16) The SNSL is responsible for informing staff where a repeat sample is required.

It is important that results are reported in line with national timeframes and protocols. This ensures accurate monitoring and review of screening outcomes, screening incidents, failsafe processes and missed tests.(16)

If a screening result is positive, the SNSL will contact the appropriate specialist team in the relevant NHS board, providing the screening result and patient information to allow the specialist to contact the parent or carer (see Standard 5).(16)

Criteria

4.1 The SNSL can demonstrate:

- successful participation in relevant quality assurance and regulatory frameworks
- adherence to national standards and procedures for results reporting and monitoring quality, including screening incident 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.(16)

4.6 SNSL staff also 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 of and competence in 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 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.

4.10 The SNSL ensures that it initiates appropriate referrals for all babies with a positive screening result in line with national timelines.

What does the standard mean for parents and carers?
• 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 cared for 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 screening incidents or 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 robust governance structure. • 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 a positive screening result are offered multidisciplinary specialist support and care planning.

Rationale

Specialist support and care planning is offered when the newborn blood spot test results confirm 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 and be in line with the principles outlined in Standard 1.

NHS boards ensure pathways are in place for timely specialist care and advice where required.(1) Where further care is required, the parent or carer should be contacted by the most appropriate healthcare 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 of a baby 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
- signposting to peer support or specialist support organisations.

5.3 Parents and carers are supported by skilled and knowledgeable specialist staff:

- who are compassionate, respectful and non-judgemental
- who provide opportunities to raise any concerns and questions about ongoing care, support or treatment
- who help them to develop personalised care plans.

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

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

What does the standard mean for parents and carers?
• You can be confident that if your baby has a positive result, you 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 to 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 • provide information and support to parents and carers that is sensitive and respects their decisions • 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 • have referral pathways for specialist services and support • provide reports to the SNSL on diagnostic outcomes for screening positive babies.
Examples of what meeting this standard might look like
• Local care and referral 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 SNSL detailing diagnostic outcomes from newborn blood spot screening. • Personalised care plans developed with parents and carers.

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.(17) 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 the 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
- review panel and editorial panel meetings in June and October 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.

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 for Healthcare Improvement Scotland and the Scottish Government (2022), 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 the Scottish Newborn Screening Laboratory	NHS Greater Glasgow and Clyde
Lorna Allen	Senior Involvement Manager	Cystic Fibrosis Trust
Sarah Campbell	Midwife	NHS Grampian
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
Liz Rennie	Programme Manager - Child Health and Screening Dept	NHS Greater Glasgow and Clyde
Tasmin Sommerfield	National Clinical Advisor for Screening	NHS National Services Scotland

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[1]	Senior Programme Manager	NHS National Services Scotland
Jen Layden	Programme Manager	Healthcare Improvement Scotland
Safia Qureshi[2]	Director of Evidence and Digital	Healthcare Improvement Scotland
Sarah Smith	Director of the Scottish Newborn Screening Laboratory	NHS Greater Glasgow and Clyde
Fiona Wardell	Team Lead	Healthcare Improvement Scotland

[1] Attendance at review panel only.
[2]Attendance at editorial panel only.

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.
Incidental findings	findings identified other than the primary condition being screened for.(18)
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.

Term	Definition
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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