

Title: Newborn Bloodspot Screening - Service Specification

Category	Pregnancy and Newborn Screening Programmes
Programme of Care	Newborn Bloodspot screening
Date	March 2026
Revision	V 1.0

Main changes from previous version

- Information on the In Service Evaluation (ISE) for Spinal Muscular Atrophy (SMA) that will be implemented from 23rd March 2026.
- Healthcare professionals taking newborn bloodspot samples should ensure that parents are aware that SMA has been added to list of conditions screened for **on a temporary, in-service evaluation basis**
- The ISE will be for an 18-24 month period

All staff delivering the newborn screening programme should ensure they are aware of a these updated requirements/clarifications on taking samples, the management of repeat samples and the management of “movers in” and cross border babies.

Contents

1. Purpose of document	4
1.1 Aims.....	4
1.2 Objectives.....	4
1.3 Outcomes.....	4
1.4 Principles.....	4
1.4 Equality.....	5
2. Scope of the screening programme	6
2.1 Description of the screening programme.....	6
2.2 Screening Pathway.....	6
2.4 Roles and responsibilities.....	8
3. Delivery of the screening programme	9
3.1 Programme coordination	10
3.2 Clinical and corporate governance	10
3.3 Definition, identification and invitation of cohort.....	11
3.4 Location(s) of programme delivery	11
3.5 Entry and days/hours of operation.....	11
3.6 Working across interfaces between departments and organisations.....	11
3.7 Information on test/screening programme.....	13
3.8 Testing (laboratory test, performance of test by individuals).....	13
3.9 Result reporting and recording.....	13
3.10 Result giving.....	13
3.11 Transfer of and discharge from care obligations.....	14
3.12 Parent /carer information	14
3.13 Exclusion criteria.....	14
3.14 Staffing	14
3.15 User involvement.....	15
3.16 Premises and equipment.....	15
4. Service standards, risks and Quality Assurance	16
4.1 Key criteria and standards.....	16
4.2 Risk assessment of the screening pathway.....	16
4.3 Quality assurance.....	16
4.4 Safety concerns, safety incidents and screening incidents.....	17
4.5 Procedures and Protocols	17
4.6 Service improvement.....	17
5. Data and monitoring	17
5.1 Data collection, monitoring and reporting	17

1. Purpose of document

To ensure a consistent and equitable approach across Scotland a common national service specification must be used to govern the provision and monitoring of universal newborn bloodspot screening services. The purpose of the service specification is to outline the service and quality indicators expected by NHS Scotland for the population for whom it is responsible and which meets the policies, recommendations and standards of the NHS Screening programmes. Wherever possible this specification follows the English Newborn Bloodspot Screening Programme specification with relevant aspects reproduced with kind permission by the programme centre.

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This specification should be read in conjunction with:

- Newborn bloodspot screening protocols
- Newborn screening laboratory handbook
- Newborn bloodspot sampling guidance

1.1 Aims

The NHS Scotland newborn bloodspot screening programme aims to identify newborn babies at high chance of sickle cell disorder (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT) and seven (7) inherited metabolic disorders: phenylketonuria (PKU), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD), isovaleric acidaemia (IVA), glutaric aciduria type 1 (GA1) homocystinuria (HCU) AND Hereditary Tyrosinaemia Type 1 (HT1) to improve health and reduce disability or death.

From 23rd March 2026, there will also be a 18-24 month In Service Evaluation (ISE) of screening for Spinal Muscular Atrophy (SMA). The Scottish ISE will look at the feasibility and acceptability of SMA screening in a real-world NHS setting and will feed data into the ISE taking place in NHS England, the timescale for which has not yet been announced.

1.2 Objectives

To offer all eligible babies timely screening

- To refer all screen positive babies to diagnostic and clinical care in accordance with national standards
- To record all results on a Child Health IT system and give a copy to parents
- To ensure all those involved in the care of the child also have access to the results. This is usually the GP and health visiting services (or agreed alternative).

1.3 Outcomes

The prevention of ill-health, reduction of disability and reduction of mortality in babies with screened conditions.

1.4 Principles

All individuals will be treated with courtesy, respect and an understanding of their needs,

- All those participating in the NHS Scotland newborn bloodspot screening programme will have adequate information on the benefits and risks to allow an informed decision to be made before participating,
- The target population will have equitable access to screening
- Screening will be effectively integrated across a pathway including between the NHS Boards, the Scottish Newborn Bloodspot screening laboratory, primary care and secondary care.

1.4 Equality

The objectives of the screening programme should include: *Help reduce health inequalities through the delivery of the programme.*

Key deliverables:

- Screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
- A Health Equity Impact Assessment should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations
- The service should be delivered in a culturally sensitive way to meet the needs of local diverse populations
- User involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics
- Providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance when making such decisions

NHS Boards will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

NHS Boards will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. NHS Boards will comply with safeguarding policies and good practice recommendations for such persons.

2. Scope of the screening programme

2.1 Description of the screening programme

The Scottish screening policy on newborn blood spot screening is that all newborn babies resident in the NHS Board population, and babies who move into the area up to the age of one year, should be offered screening for the ten conditions included in the national newborn bloodspot screening programme, plus the offer of participation in the ISE for SMA during the evaluation period.

2.2 Screening Pathway

- The eligible population is identified through Child Health Records Departments (CHRD) or registration with a GP practice for babies born outwith Scotland moving into the area.
- Midwives check antenatal results and family history. Ideally all antenatal results obtained from antenatal SCT screening are included on the blood spot card.
- Midwives provide written information (ideally before birth) and obtain informed consent.
- Screening can be offered to unscreened babies who move into a local area up to one year of age. This will include the offer to participate in the ISE for SMA. Health visiting services (or agreed alternative) are responsible for offering screening to parents of babies with no confirmable evidence of screening results. The CHRD who note the arrival of a baby (when it is registered) alert the HV/designated health professional to unscreened babies. GPs should ensure CHRD are informed of the babies they register.
- Ideally samples are taken between 96-120 hours of life (4-5 completed days), day of birth is day 0, and sent on the day of sampling to the Scottish newborn screening laboratory. In exceptional circumstances samples can be sent between day 5 and day 8. Records are kept of all tests including those declined. If all screens are declined a card should still be completed and sent to the laboratory indicating that all screening has been declined to ensure records are complete and the family is not contacted for a missed screen in error.
- Additional tests are offered to babies born preterm and babies at risk of blood transfusion and if required by a screening protocol to achieve a conclusive result.
- The newborn screening laboratory tests the sample according to national policy and reports the results to the relevant Child Health Records Department This can result in one of five outcomes:
 - Carrier: healthcare professional informs parents of results
 - Inconclusive result: additional sample required
 - Avoidable repeat test: additional sample required e.g. insufficient blood, poor record keeping
 - Condition not suspected: parents are informed of the result
 - Condition suspected: immediate clinical referral to a specialist initiated by the laboratory and parents informed of the result, by the specialist service
- Maternity care providers ensure all babies they are responsible for are offered screening.
- Child Health Records Departments maintain a list of the eligible population to provide a failsafe check to identify untested babies, to monitor coverage and to send results to

GPs and health visiting services (or agreed alternative) and parents according to national policy.

- Confirmation of screen positive baby attending first clinical appointment and conclusive diagnosis, information provided and management initiated

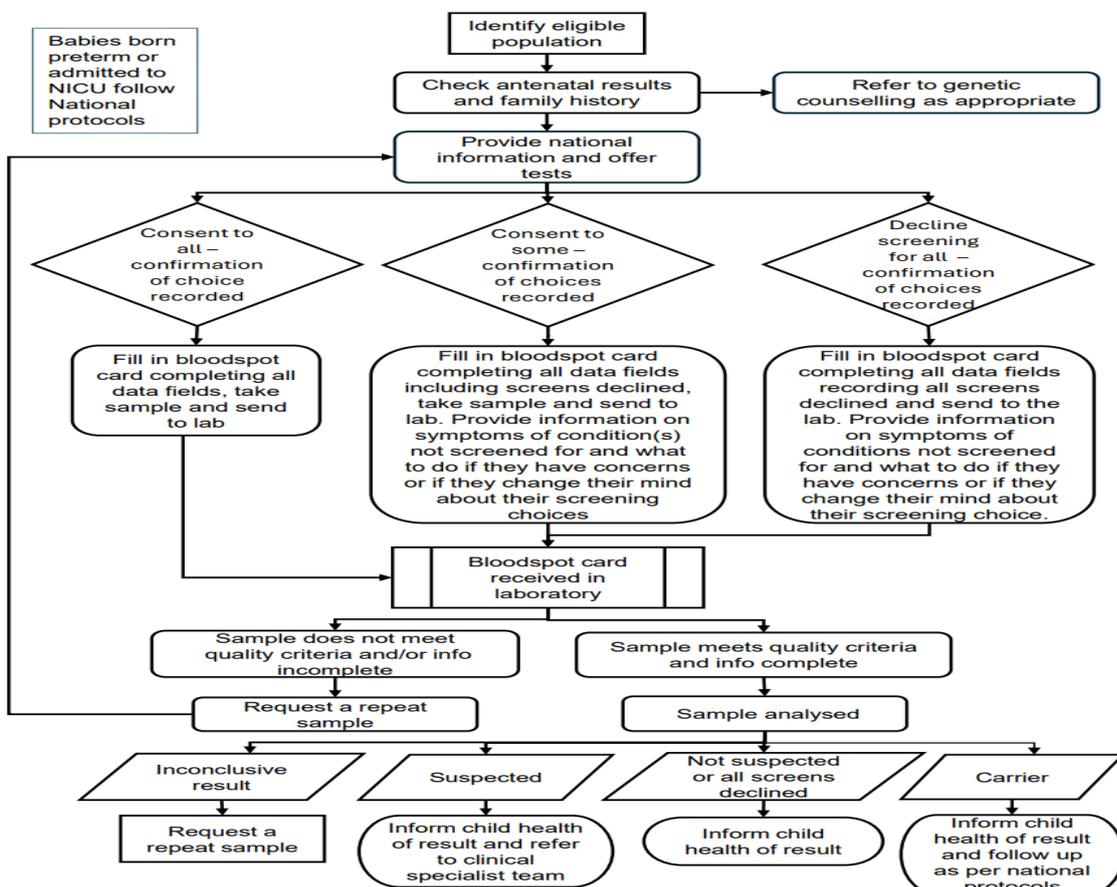
This can be summarised as:

- Identifying the eligible population
- Offering screening
- Taking the sample and sending to the screening laboratory
- Analysing the sample
- Timely referral of screen positive babies into diagnostic and clinical care
- Reporting results to Child Health Records Departments (CHRD)
- Recording results on CHRD IT system and ensuring conclusive result for all tests
- Reporting results to parent

It should be noted that the results for the ISE for SMA will not be sent to the child health record department or added to the child health information system and instead will be retained within the laboratory information management system (LIMS). No negative results will be issued but if parents are concerned about the result their Health Visitor can contact the laboratory directly for confirmation of a negative result.

A referral for any SMA positive results will be made to the paediatric neuromuscular service in Glasgow regardless of the baby's health board of residence. Clinicians will then contact the parent and arrange the baby's transfer for urgent clinical care in Glasgow.

Below is the newborn blood spot pathway for the national screening programme.



2.3 Failsafe arrangements

Quality Assurance (QA) within the screening pathway is managed by including failsafe processes. Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to (i) identify what is going wrong and (ii) what action follows to ensure a safe outcome. The NHS Boards are expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway
- review and risk assess screening pathways in the light of national screening programme guidance
- work with National screening teams and Health Improvement Scotland quality assurance teams to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that appropriate links are made with internal governance arrangements, such as risk registers
- ensure routine staff training and development to maintain competencies;
- Run regular checks through their child health department to ensure every resident baby has been offered appropriate screening and if screening has been accepted that the screening pathway has been completed.

2.4 Roles and responsibilities

The Scottish newborn bloodspot programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, the screening laboratory, diagnostics laboratory and genetics services, child health records departments, health visiting services and specialist condition specific services, i.e. 'the screening pathway'. NHS Boards will be expected to fully contribute to ensuring that cross-organisational systems are in place to maintain the quality of the whole screening pathway that provides the optimal care for families. This will include, but is not limited to:

- provision of coordinated screening that ensures all parties are clear of their roles and responsibilities, so that there is clarity of handover of responsibility throughout all elements of the screening pathway
- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any National and public health screening lead initiatives in screening pathway development in line with NHS Scotland screening programmes expectations
- providing or seeking to provide robust electronic links with relevant organisations

- links with primary care
- links with secondary and/or tertiary care
- the need for robust IT systems across the screening pathway
- joint review meetings across the screening pathway to be held on a regular basis

3. Delivery of the screening programme

Pre-screening information should be provided to the pregnant woman and a medical/family history ascertained at booking. The midwife provides national information on the newborn bloodspot programme to the pregnant woman at the booking visit, and in the 3rd trimester. Additional communication and consent is taken ideally at least 24 hours before testing. This includes explaining what happens to the card after screening and that parents can opt out of research being carried out on the sample. The routine sample is taken ideally between 96-120 hours of life. Additional tests are offered to babies born preterm and babies at risk of blood transfusion and, if required, by screening protocol to achieve a conclusive result.

Parents may decline individual conditions CHT, SCD, CF or **ALL** the Inherited Metabolic Disorders (PKU, MCADD, MSUD, IVA, GA1, HCU and HT1). Information on how to access the test if they change their mind should be provided. Screening is largely embedded within the routine maternity pathway. Taking of the sample should be recorded in the maternity record and child health record. As with all the other newborn bloodspot screening tests, Parents can also choose to participate in the SMA screening ISE or decline it. If declined they can still have screening for the other conditions.

Child health department checks should be run regularly to ensure samples are received in the laboratory and that no babies born or moving into Scotland miss being offered screening. There should be close links between the screening laboratory and the child health records departments ideally an electronic link should be established to enable rapid transmission of results and information sharing.

There needs to be a systematic notification of results and the screening results recorded in the national child Health system. All screen positive babies should enter into appropriate care which includes access to a designated clinician and relevant health professionals who confirm diagnosis and initiate appropriate clinical management and treatment. For all conditions, screen positive babies should enter into appropriate care as part of a clinical network.

All parents of babies with carrier results should be notified and the options/implications explained. This can be delivered through a range of models, dependent upon local need. Carriers for MCADD are not detected until the diagnosis protocol has been fulfilled and the result is given by a specialist clinician.

It is important that the links between the end of screening and enrolment in appropriate condition specific specialised care are made explicit and the transfer from “screening responsibility” to “care responsibility” works seamlessly, if the benefits delivered by a screening programme are to be achieved and optimal outcomes delivered.

All elements of the screening pathway should be delivered by appropriate staff and to national standards and guidelines and audited. All NHS Boards should have a lead screening midwife/coordinator (and deputies) in place to oversee the screening programme.

3.1 Programme coordination

NHS Boards will be responsible for ensuring that the part of the programme they deliver is coordinated and interfaces seamlessly with other parts of the national programme with which they collaborate, in relation to timeliness and data sharing.

The NHS Boards will ensure there are one or more named individuals responsible for the coordination of the delivery and planning of the programme with appropriate administrative support to ensure timely reporting and response to requests for information. Where there is only one named coordinator, the NHS Board will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

The NHS Board coordinators and the national screening groups should meet at regular intervals to monitor and review the national screening pathway. The meetings should include representatives from Scottish Government, National Services Division, public health, clinical services, laboratory services and service management.

3.2 Clinical and corporate governance

NHS Boards will:

- ensure co-operation with and representation on the national screening oversight arrangements/ structures e.g. screening programme steering groups
- ensure that responsibility for the screening programme lies at director-level
- ensure that there is appropriate internal clinical oversight of the programme and have its own management and internal governance of the services provided with the designation of a clinical lead, a programme coordinator/manager and the establishment of a multidisciplinary steering group/programme board and has terms of reference and record of meetings
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of the organisation's clinical governance arrangements, the organisation's board is assured of the quality and integrity of the screening programme
- comply with the national screening programme guidance on managing screening incidents
- have appropriate and timely arrangements in place for referral into treatment services that meet the national screening programme standards
- be able to provide documented evidence of clinical governance and effectiveness arrangements on request
- ensure that an annual report of their screening services is produced which is signed off by their NHS Board
- have a sound governance framework in place covering the following areas:
 - information governance/records management
 - equality and diversity
 - user involvement, experience and complaints
 - failsafe procedures

- risks and mitigation plans
 - protection of children and vulnerable adults
 - communications
- ensure the programme is delivered by trained workforce

National Services Division on behalf of Scottish Government will

- commission newborn screening and diagnostic laboratories that are UKAS accredited
- commission molecular genetics laboratories who are members of the UK Genetic Testing Network (UK GTN) and comply with the quality criteria laid down by the UK GTN Steering Group

3.3 Definition, identification and invitation of cohort

The target population is all newborn babies born in Scotland and those babies up to 1 year of age who have moved into the area. NHS Boards will make every effort to maximise screening uptake for the whole eligible population including the vulnerable and hard-to-reach groups.

3.4 Location(s) of programme delivery

NHS Boards will ensure appropriate accessible service provision for the population to be screened.

3.5 Entry and days/hours of operation

The days and hours of operation must ensure sufficient resources are in place to meet screening demand within required timescales without compromising relevant standards and guidelines. Timeliness is essential and is a key criterion of quality along all parts of the screening pathway.

3.6 Working across interfaces between departments and organisations

The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are essential to reduce the potential for errors and ensure a seamless pathway for service users. It is important that there remains clear named clinical responsibility, at all times, and, at handover of care, the clinical responsibility is clarified. NHS Boards will ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- providing strong clinical leadership and clear lines of accountability
- developing joint audit and monitoring processes
- working to nationally agreed Programme protocols, standards and policies

- agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS Scotland initiatives in screening pathway development in line with NHS screening programmes expectations
- meeting programme standards covering managing interfaces

Interfaces:

- Midwife responsible for care sends blood spot card to newborn screening laboratory with the CHI number, preferably on a label, and all fields on the card completed with four good quality blood spots or recording screening has been declined
- Laboratory requests midwifery services for a repeat (this will include where CHI number is missing)
- Laboratory sends results to Child Health Record Department using screening status results codes and subcodes ideally electronically
- Child Health Record Department checks for untested babies within agreed effective timeframe
- Child Health Record Department and the newborn screening laboratory highlight to maternity services babies where there is no sample received, repeat required or results not complete
- Laboratory refers screen positive results to specialist teams
- Specialist teams report, to the newborn screening laboratory, diagnostic tests/outcome result
- Child Health Record Department send normal results (all conditions) to the GP and health visiting services (or agreed alternative) via the 6 week health surveillance form
- Child Health Record Department informs maternity or health visiting services of missing results
- Midwife/health visitor perform screening for movers in so that Child Health Record Department can record conclusive results on the child health information system within 21 calendar days of recording the mover in on their systems
- Clinician informs CHR D if unable to complete screen so it can be recorded on the baby's record
- Health visiting services (or agreed alternative) ensure parents receive results and record results in the child health record by 8 weeks
- A process for communicating all results if baby has a 'suspected' or 'carrier' result

3.7 Information on test/screening programme

Prior to any screening offer, the NHS Board will provide verbal and written information regarding screening utilising the approved national screening programmes patient information as a guide for discussion. This will include information on any ISE. Where there are specific communication requirements (e.g. English is not the parents/carers/guardians first language, visual/hearing impairment) appropriate interpretation services should be used during the booking appointment and appropriate information provided. All women, including those with special requirements, will be fully informed of the choices regarding all newborn screening programmes.

The information should be impartially presented and should include an explanation of the limitations of the screening test. The decision to consent to screening or to decline should be recorded appropriately.

3.8 Testing (laboratory test, performance of test by individuals)

Laboratories are expected to follow the policy guidance and standards laid out in condition specific laboratory handbooks covering screening for the appropriate conditions. Laboratories are required to provide routine data on the screening programme in a timely manner to NHS Boards and the NHS Scotland screening programme. This includes:

- data on samples analysed
- notification of screen positive results
- notification of outcome data where possible
- notification of false negatives where possible

3.9 Result reporting and recording

In accordance with NHS screening programmes standards and protocols

- The laboratory will send results to the Child Health Record Department, ideally electronically using nationally approved status codes and subcodes
- The Child Health Record Department will record conclusive results on the child health information system for all the eligible population and for all screened conditions
- The Child Health Record Department will inform maternity or health visiting services/designated health professionals of null/incomplete results
- The clinician will inform the CHRD, if unable to complete screen so it can be recorded on the babies record
- The results of the ISE will be managed by the National Newborn Bloodspot Screening Laboratory and will not be sent to Child Health Record Departments and will not be added to the Child Health Information System.

3.10 Result giving

In accordance with screening programmes standards and protocols

- The Child Health Record Department will notify GPs and health visiting services (or agreed alternative) of normal results

- Health visiting services (or agreed alternative) ensure that parents receive the results from the national screening programme but not the ISE and record the results in the Child Health Record by 8 weeks
- CF and SCD carrier results will be given according to a specified protocol
- All condition suspected results will be given to parents by a trained health professional, preferably face-to-face, following national protocols that meet recommended programme standards

3.11 Transfer of and discharge from care obligations

Babies identified as carriers, following screening, are discharged from screening once parents/carers have been notified of the results, and any follow-up referral required has been offered.

Babies in whom conditions are not suspected are discharged from screening once parents/carers have been notified of the results.

Babies in whom a condition is suspected are discharged from the screening programme once the laboratory has made the appropriate clinical referral which is accepted by the specialist, and parents have been informed of the result.

3.12 Parent /carer information

All parents, including those with special requirements, should be fully informed of the choices regarding the screening programme and any ISE. Where a high risk result / diagnosis of any of the conditions is identified, appropriate further information should be provided.

3.13 Exclusion criteria

- Babies stillborn or who died before day 8
- Babies >56 days old are ineligible for CF screening
- Children over 1 year of age

3.14 Staffing

In accordance with NHS screening programmes standards and protocols NHS Boards will ensure that there are adequate numbers of competent and appropriately trained staff in place to deliver a high quality screening programme in line with best practice guidelines and national policy.

Qualifications will be specific to staff delivering the service across the care pathway. Staff must demonstrate competence (which is linked to training).

NHS Boards will have in place a workforce plan designed to maintain a sustainable programme, especially where increase in birth rate are predicted and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff.

NHS Boards are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary.

NHS Boards should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

All professionals involved in the Programme are required to keep up to date with nationally approved training programmes, maintain professional registration where appropriate and comply with safeguarding requirements.

3.15 User involvement

NHS Boards will be expected to:

- demonstrate that they have collected (or have plans in place to collect) the views of service users, families and others in respect of the services they provide
- demonstrate how those views will influence service delivery for the purposes of raising standards
- show that all families are given information about how to provide feedback about services they receive, including about the complaints procedure
- Collection of the views of service users/families will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to NHS Scotland on request. It may be efficient to include this in the annual report.

3.16 Premises and equipment

NHS Boards will ensure that:

- suitable premises and equipment are provided for the screening programme
- appropriate policies are in place for equipment calibration, maintenance and replacement
- lancet devices appropriate for newborns, preferably automated, are used and that the correct bloodspot card is available for use with expired or previous versions of the bloodspot cards destroyed
- IT systems should be able to support the programme and supply data for the purpose of national standards and KPIs as well as performing failsafe checks
- There is a contingency plan to maintain service

National Services Division (NSD) as commissioners of the Newborn laboratory service will ensure that:

- blood spot cards, equipment and laboratory reagents meet National specifications
- There is a contingency plan to maintain service

Scottish Government and NSD in conjunction with the host NHS Board of the newborn bloodspot laboratory will ensure that:

- there are appropriate and secure premises for left over spots in line with agreed national guidance

4. Service standards, risks and Quality Assurance

4.1 Key criteria and standards

NHS Boards will meet the acceptable and work towards the achievable programme standards/KPIs.

4.2 Risk assessment of the screening pathway

NHS Boards are expected to have an internal quality assurance and risk management process that assures NHS Scotland of its ability to manage the risks of running a screening programme. NHS Boards will:

- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that risks are reported through internal governance arrangements, such as risk registers
- review and risk assess national screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the pregnancy and Newborn Programme Board to develop, implement, and maintain appropriate risk reduction measures

High scoring risks will be identified and agreed between the NHS Board and the Pregnancy and Newborn Screening Programme Board and plans put in place to mitigate against them.

4.3 Quality assurance

NHS Boards will participate fully in national Quality Assurance (QA) processes, co-operate in undertaking ad-hoc audits and reviews as requested by QA teams and respond in a timely manner to their recommendations. This will include the submission to Health Improvement Scotland (HIS) and NHS Scotland of:

- agreed data and reports from external quality assurance schemes
- minimum data sets as required
- self-assessment questionnaires / tools and associated evidence

NHS Boards should operate failsafe systems that can identify, as early as possible, babies that may have been missed or where screening results are incomplete.

NHS Boards will respond to QA recommendations within agreed timescales. They will produce an action plan to address areas for improvement that have been identified in recommendations. Where HIS believe there is a significant risk of harm to the population, they can recommend to NHS Scotland to suspend a service.

Laboratories undertaking screening must:

- be accredited by United Kingdom Accreditation Service

- participate in accredited external quality assurance scheme for programme screening, e.g. United Kingdom National External Quality Assessment Service (UKNEQAS) and respond within agreed timescales
- make available timely data and reports from external quality assurance programmes and accreditation services to the Safety & Quality Assessment System (SQAS), national screening programmes and commissioners
- operate failsafe systems that can identify, as early as possible, babies that may have been missed or where screening results are incomplete
- be able to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service.

The Newborn Screening laboratory will respond to SQAS recommendations within agreed timescales. They will produce with agreement of NSD commissioners of the service an action plan to address areas for improvement that have been identified in recommendations. Where SQAS believe there is a significant risk of harm to the population, they can recommend to NSD to suspend the service.

4.4 Safety concerns, safety incidents and screening incidents

NHS Boards will comply with the national guidance for the management of safety concerns and incidents in screening programmes.

4.5 Procedures and Protocols

NHS Boards will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

4.6 Service improvement

Where national recommendations and acceptable/achievable standards are not currently fully implemented NHS Boards will be expected to indicate in service plans what changes and improvements will be made.

NHS Boards shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond to any performance issues highlighted by the quality assurance teams, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities and will be agreed with the quality assurance team.

5. Data and monitoring

5.1 Data collection, monitoring and reporting

NHS Boards should:

- ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions
- continually monitor and collect data regarding its delivery of the Service

- comply with the timely data requirements of the National Screening programme and regional Quality Assurance teams. This will include the production of annual reports. The current dataset can be accessed from the National Screening programme website

NHS Boards will ensure timely and accurate completion of data onto the screening IT system for all stages of the care pathway defined within the system.

Screening data should be made available to the national screening programme to produce performance reports for NHS Scotland.