



Commissioning Board

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.21

NHS Newborn and Infant Physical Examination Screening Programme

November 2012

DH INFORMATION READER BOX

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NHS Newborn and Infant Physical Examination Screening Programme

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Service specification No.21

This is a service specification within Part C of the agreement “Public health functions to be exercised by the NHS Commissioning Board” dated November 2012 (the “2013-14 agreement”).

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board (“NHS CB”) under section 7A of the National Health Service Act 2006 (“the 2006 Act”) as amended by the Health and Social Care Act 2012.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2013-14 agreement including all service specifications within Part C is available at www.dh.gov.uk/publications

Section 1: Purpose of Screening Programme

1.1 Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of newborn and infant physical examination services.

The purpose of the service specification for the NHS Newborn and Infant Physical Examination (NIPE) Screening Programme is to outline the service and quality indicators expected by the NHS Commissioning Board (NHS CB) for the NHS CB's responsible population.

THE NIPE Screening Programme is in a development phase and the national service specification represents the service that should be provided when the development phase is complete. Local services will be in different stages of development and Local Area Team NHS CB commissioners should agree a pace of change with providers to deliver a service that meets the national service specification.

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This document should be read in conjunction with:

- Current NIPE guidance which is found on the NIPE website <http://newbornphysical.screening.nhs.uk/publications>
- Guidance & updates on Key Performance Indicators (KPIs) <http://www.screening.nhs.uk/kpi>
- Information and resources for parents of children with high risk results www.newbornphysical.screening.nhs.uk
- [Change in Guidance on Ultrasound Examinations of the Hips](#)
- Newborn and Infant Physical Examination Standards and Competencies <http://newbornphysical.screening.nhs.uk/publications>
- National Screening Committee 'Screening Tests for You and Your Baby'
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes <http://www.screening.nhs.uk/quality-assurance#fileid9902>
- UK NSC Quality Assurance Pilots for Antenatal and Newborn Screening Programmes, Guidance for the Quality Assurance Pilot Process

1.2 Aim

The NIPE Screening Programme's major aim is to identify and refer all children born with congenital abnormalities of the heart, hips, eyes or testes, where these are detectable, within 72 hours of birth; to further detect those abnormalities that may become detectable by 6-8 weeks of age, at the second physical examination, and thereby reduce morbidity and mortality

1.3 Objectives

The objectives for the provider are:

- To offer a NIPE to the parent of every newborn baby
- To raise standards in service performance to achieve better outcomes in screening, assessment, diagnosis and rehabilitation.
- To ensure equal access to a uniform screening programme which conforms to an agreed level of quality and reduce health inequalities
- To put in place robust failsafe checks to ensure that the full eligible population is offered, accepted screens are undertaken and that all results of screening are acted in accordance with the pathway.
- To ensure easy capture, analysis and sharing of data to inform clinical practice and provide the means to audit and monitor performance against standards.
- To provide appropriate and timely information to parents and promote family friendly integrated services that will also empower parents to make informed choices
- To ensure prompt advice and referral as appropriate for those babies with risk factors or an anomaly.
- To work with other newborn and infant screening programme, other NHS services and Government frameworks to deliver integrated approach to screening and follow-on services.
- To ensure that all staff have attained a recommended level of NIPE training suitable for their professional role and in accordance with national guidance

1.4 Expected health outcomes

The overall health outcomes are to reduce mortality and morbidity for the screened conditions, by:

- Identification of congenital abnormalities and early assessment by relevant Clinical Expert for:
 - Congenital Cardiac defects
 - Developmental Dysplasia of the Hip (DDH)
 - Ocular abnormalities
 - Undescended Testes
- Timely referral for further assessment and diagnostics leading to early treatment and intervention by relevant clinical expert / treatment centres.

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- NIPE screening contributes to the Public Health Outcomes Framework indicator on the uptake of screening for national screening programmes. Indicator 2.21v Access to non cancer screening programmes: newborn and infant physical examination screening.

1.5 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs,
- All those participating in the NIPE 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 different providers, screening centres, primary care and secondary care.

Section 2: Scope of Screening Programme

2.1 Description of screening programme

The UK National Screening Committee (UK NSC) policy on newborn infant physical screening is that all eligible newborn babies will be offered the NIPE screen. The screen is a two part screen and will be offered within 72 hours of birth and then again at 6-8 weeks of age through GP practices

This universal service facilitates early detection of congenital defects of the heart, hips, eyes and testes. Any abnormalities detected or any clinical concerns will lead to a prompt referral for early clinical assessment by the relevant clinical expert.

In delivering a national programme the provider will fulfil the following, in conjunction guidance from the UK NSC where appropriate:

- Work to nationally agreed common standards and policies
- Be required to implement and support national IT developments
- Use materials provided by the national Screening programme, e.g., leaflets, and protocols for their use
- Be required to respond to national action/lessons such as change of software, equipment supplier, techniques
- Work with the NHS CB in reporting on and resolving serious incidents
- Provide data and reports against programme standards, key performance indicators, and quality indicators as required by the Screening programme on behalf of the UK NSC
- Take part in quality assurance (QA) processes and implement changes recommended by QA including urgent suspension of services if required
- Implement and monitor failsafe procedures and continuously ensure quality
- Work with bordering providers to ensure that handover of results or patients is smooth and robust
- Participate in evaluation of the screening programme

Documents referred to above are available from the National Screening programme website.

2.2 Care pathway

Care pathways are presented in the [NSC Standards and Competencies for the Newborn and Infant Physical Examination](#). These will be read in conjunction with the [Change in Guidance on Ultrasound Examinations of the Hips](#). Please see [NHS Newborn and Infant Physical Examination Programme Home Page](#)

The care pathway

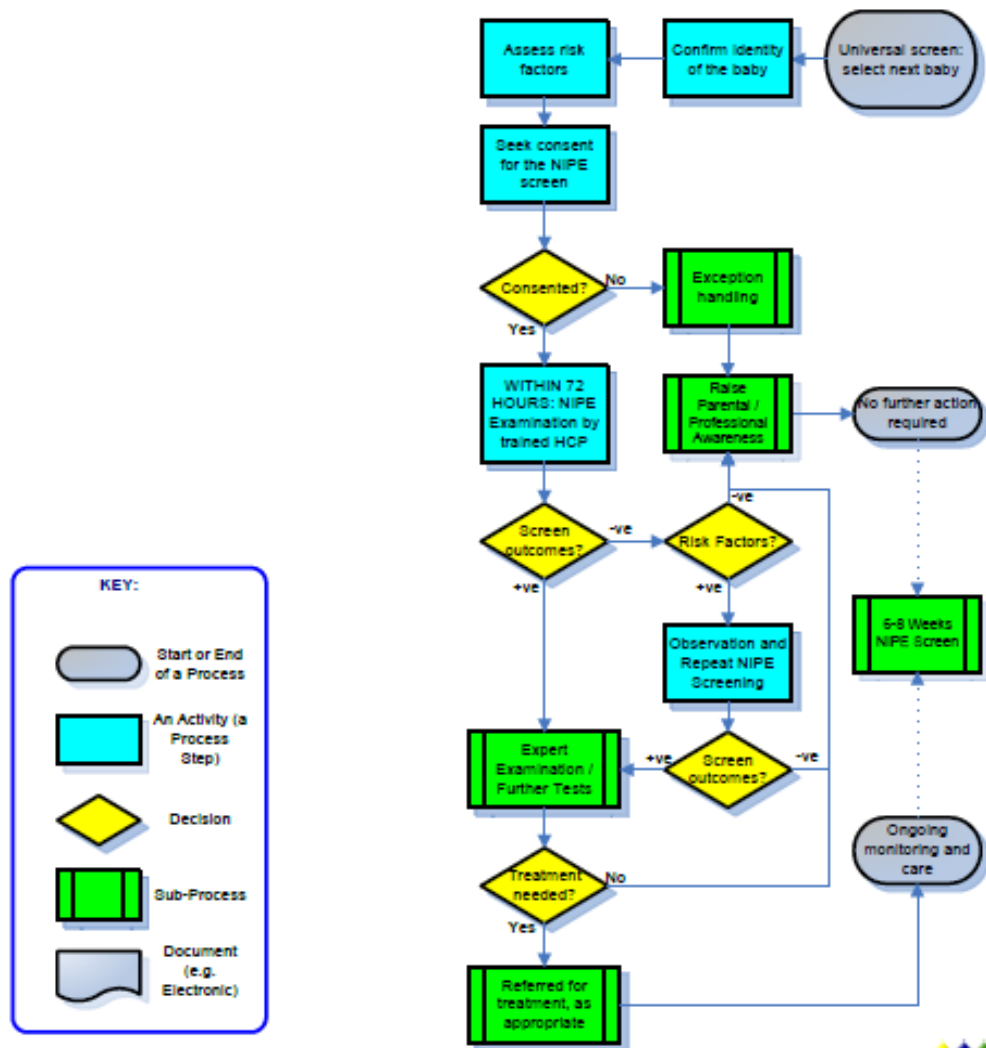
The pathway for NIPE, in newborn babies consists of the following:

- The eligible population of 'new births' or 'new registrations' is identified through a birth notification into the SMART system (or other approved IT system) or to local Child Health Record Departments.
- All eligible babies, born or resident in England, must be offered a NIPE screen (where clinically safe to do so; appropriate failsafes must be in place to ensure that any babies who aren't immediately screened due to clinical issues are followed up and screened at a more appropriate time). It is expected that all reasonable efforts will be made to ensure that babies have their screen completed by the age of 72 hours), or completed at home / in community (General Practitioner / Community Midwife). The responsibility for identifying these children remains with the birth unit until responsibility is formally passed to, another maternity service or the GP. Community care will also include the Community Midwife or Health Visitor, and will also be the responsibility of the local Child Health Records Department. The Local Co-ordinator of the screening service is responsible for ensuring that babies moving in from another area are identified and if they have not been screened, to arrange an appointment to carry out the screen.
- Written information about the NIPE screen is provided to parents as part of the parent pregnancy information that is shared antenatally. Verbal consent for the screen will be required following an informed consent model.

A description of the whole care pathway, both graphically and in text, referencing Map of Medicine and including failsafes will be available when finalised.

The following generic care pathway below is extracted from the Newborn and Infant Physical Examination Standards and Competencies March 2008. The care pathways for the individual elements of the NIPE (i.e. screening for DDH, congenital heart defects, eye abnormalities and undescended testes) are being revised.

Overall Process for Newborn Physical Examinations



For the newborn physical screening examination (72 hours), the eligible population is all live babies within the total population for the maternity service, not falling within any of the ineligible categories below. For the infant physical screening examination (6-8 weeks), this is all babies that are alive at 6 weeks of age

The provider will ensure that all women are given verbal information about screening at the booking appointment, preceded by approved written information including the UK NSC booklet, 'Screening Tests for You and Your Baby'. Where English is not a woman's fluent language, a trained interpreter will be used during the booking appointment and appropriate written information provided. Providers will always comply with the principle of '*no decision about me without me*'. Given that NIPE is directed at neonates and infants this principle would here apply to parents.

Specific and appropriate information will be provided antenatally by the provider (at around 28 weeks gestation or on booking) and again prior to the newborn and infant physical examinations. An informed consent process must be followed to enable parents to make the choice whether to accept or decline the screen. The outcome is to be clearly recorded.

Some babies may be ill at the time of the examination resulting in deferral of some aspects of the examination and some may require additional specific examinations e.g. those with antenatally diagnosed congenital heart defects, Down's syndrome and those with other syndromes. These, do not however, make a difference to how NIPE is carried out. Specific guidelines for screening, diagnosis, treatment and information as appropriate are laid down within the relevant screening programmes for these babies.

2.3 Failsafe Procedures

The provider will have appropriate failsafe mechanisms in place across the whole screening pathway and a policy, which has been agreed with the, NHS CB, relating to defining and dealing with adverse events.

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.

In accordance with UK NSC standards and protocols the provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway. (A complete list of the failsafe processes to be conducted by the Provider can be found on the National Screening programme website)
- review and risk assess local screening pathways in the light of National Screening programme guidance

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- work with the NHS CB and 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

2.4 Roles and accountability throughout the pathway

In accordance with UK NSC standards and protocols the provider is expected to have the following posts in place:

- Operational lead for the NHS newborn screening examination and nominated professional for the infant screening examination. They are responsible for the day to day management of all aspects of the programme, including responsible for being the champion of, and strategic lead for the local programme. In addition, the Local Co-ordinator is responsible for the quality and governance of the programme.
- Health care professionals who have the resources and are competent to carry out the newborn and/or infant physical examination. They or delegated members of staff are responsible for gathering and recording the outcome of the screen.
- Clinical lead - takes lead responsibility for the clinical effectiveness, quality and safety of the NIPE examinations and pathway completion for all babies in their eligible population. There will be an identified clinical lead for NIPE in each service in which NIPE is undertaken at 72 hours and at 6-8 weeks. LAT Screening Lead ensures that all commissioned services, which contribute to the NIPE pathway are commissioned in accordance with this specification and relevant national guidelines.
- Other additional roles and responsibilities may be specified.

2.5 Commissioning Arrangements

The commissioning of the NIPE screening pathway involves commissioning at different levels, as set out below.

Pathway	Provider	Responsibility for elements of Commissioning	Responsibility for elements of Contracting	Rationale
72 HOURS				
Identify cohort in a timely manner	Maternity Services (plus occasionally through general practice)	LAT	CCG	<p>Identification of the cohort is carried out through the midwifery service following the issuing of NN4B at birth.</p> <p>For those babies in the UK who are born abroad, identification takes place in primary care following registration with a GPs practice.</p> <p>Child Health Records Departments (CHRD) and health visitors have some responsibility to identify part of this cohort.</p>

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<p>Inform/Maximise uptake in a timely manner</p>	<p>Maternity Services (plus occasionally through general practice and health visiting services)</p>	<p>LAT</p>	<p>CCG</p>	<p>Informing the cohort and maximising uptake in a timely manner takes place during routine midwifery-led antenatal care, and sometimes through primary care.</p> <p>Health visitors may inform families moving into the area.</p>
<p>Screening examination and results</p>	<p>Normal baby services</p>	<p>LAT</p>	<p>CCG</p>	<p>Initial examination is carried out as part of broader routine midwifery care. Usually carried out by paediatricians, midwives or more rarely Primary Care.</p> <p>Neonatal care services will be responsible for the examination if a newborn baby is in their care at the time of the test.</p> <p>Midwives or health visitors (depending on the time after birth if the examination was delayed)</p> <p>Results are conveyed immediately after examination to parents and then entered in</p>

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				the Child Health Record and the SMART IT system (or other approved system).
Diagnose Hip abnormality (Development Dysplasia of the Hip – DDH) Eye abnormality Cardiac abnormality Undescended testes	Ultrasonography/ Paediatric Orthopaedics Paediatric Ophthalmology / Hospital Eye Service Paediatric Cardiology Paediatric Urology	LAT including specialised commissioning	CCG/NHSCB	Initial referrals may be “in house” to a neonatologist/ paediatrician. Other referrals may be made to a specialised centre.
Results reporting and counselling	As above	As above		
Intervention/Treatment	Specialist service	LAT Specialised Commissioning		
6 – 8 WEEK				
Identify cohort	Primary Care	NHS CB – part of the GP contract		If a child is still in hospital at this time then it is the Neonatal service that has responsibility to undertake the 6-8 week screen.

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				For the majority of babies the baby's GP (or nominated Primary Care examiner) will have responsibility for ensuring the 6-8 week screen is completed for all registered babies.
Inform/Maximise uptake	Primary Care – Health Visitor and GP	NHS CB – part of the GP contract		Informing the cohort and maximising uptake takes place during routine newborn Health Visitor/ GP check. This should include managing appointments and reminders and using an effective failsafe mechanism. GPs may undertake the 6-8 week screen at the same time as administering immunisations.
Screening examination and results	Primary Care – Health Visitor and GP	NHS CB – part of the GP contract		Results are conveyed immediately after examination to parents and entered in the PCHR. Results ought also to be entered on the Child Health Information System and conveyed to the GP if not carried out within primary care.

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Diagnose Hip abnormality (Development Dysplasia of the Hip – DDH) Eye abnormality Cardiac abnormality Undescended testes	Ultrasonography/ Paediatric Orthopaedics Paediatric Ophthalmology / Hospital Eye Service Paediatric Cardiology Paediatric Urology	LAT including specialised commissioning	CCG/NHS CB	Referral will be made to an appropriate specialist in a timely fashion.
Results reporting and counselling	As above	As above		Results should be conveyed to the parents, GP and CHIS in a timely fashion.
Intervention/Treatment	Specialist service	LAT Specialised Commissioning	NHS CB	

The commissioning of the NIPE Screening Programme pathway involves commissioning at different levels. The NIPE Screening Programme services will be commissioned by the NHS CB alongside specialised services where appropriate.

2.6 Links between screening programme and national programme centre expertise

Public Health England (PHE) will be responsible for delivery of the essential elements of screening programmes best done once at national level.

These include:

- developing, piloting and roll-out to agreed national service specifications of all extensions to existing screening programmes and new screening programmes;
- setting QA standards;
- setting and reviewing programme standards;
- setting and reviewing national service specifications and advising on section 7A agreements (under the direction of DH requirements);
- developing education and training strategies;
- providing patient information;
- determining data sets and management of data, for example to ensure KPIs are collected;
- setting clear specifications for equipment, IT and data;
- procurement of equipment and IT where appropriate; (Procurement may undertaken by NHS CB but will need advice from PHE screening expertise and related clinical experts);
- Collect, collate and quality assure data for cancer and non-cancer screening programmes;
- Monitor and analyse implementation of NHS commissioned screening services;
- Provide advice to DH on priorities and outcomes for the NHS CB mandate and section 7a agreement, and to lead on detailed provisions, in particular the 7a agreement on screening;
- Advise the NHS CB how to increase uptake of screening.

PHE will also be responsible for

- providing the quality assurance functions for screening programmes;
- providing Public Health expertise and advice on screening at all levels of the system, including specialist Public Health expertise being available as part of NHS CB screening commissioning teams;
- ensuring action is taken to optimise access to screening programmes, e.g. among socio-economically disadvantaged groups;
- Ensuring reports on important aspects of screening are available at various geographies (e.g. local authority) to enable population based oversight.

Section 3: Delivery of Screening Programme

3.1 Service model summary

The NIPE Screening Programme consists of two examinations of a newborn child; the first by 72 hours of age and the second 6-8 weeks of age.

The initial screen will be undertaken (subject to consent) by 72 hours of age. The ideal opportunity, and the one undertaken by most services is to ensure the Newborn Examination is undertaken prior to discharge home of the baby. This in the majority of cases ensures the examination is completed within the 72 hour target.

The NIPE Screen is undertaken as part of the wider newborn physical examination. The clinician (NIPE Examiner) undertaking the examination (usually, in the hospital Paediatric team, a midwife or an ANNP (Advanced Neonatal Nurse Practitioner) is responsible for ensuring the screen data is entered on the SMART IT system (NIPE Screening Management Tool) or other approved IT system that can ensure appropriate failsafes are in place and for any required onward referrals for areas of concern or abnormalities detected. Such referrals may, in the first instance, be to an 'in-house' neonatologist/ paediatrician. Referral to other internal or external services will be expedited as is clinically appropriate.

For those babies that are discharged without the completion of the newborn NIPE Screen, the provider must ensure that the 72 hour examination is completed within the community. The birth unit retains clinical responsibility for the examination but it may be undertaken by the GP, Community Midwife or in some cases the health visitor or more rarely a neonatal outreach service.

The 6-8 week screen is undertaken in the community setting, predominantly by GPs but in some cases other community paediatric services may be involved, such as Health Visitors or Community Paediatricians.

As above, on completion of the examination, it will be the GP's (or other examiner's) responsibility for ensuring the screen outcomes are recorded, electronically, and any relevant referrals are expedited. Any required referrals will generally be to the local paediatric team or directly to relevant tertiary services.

Note: the 6-8 week examination has been fully implemented for many years. The NIPE Screening programme are working towards a national roll out of the screening management tool (SMART IT or other approved IT system that can assure appropriate failsafes are in place) for the 6-8 week examination over the next few years (final plans to be agreed with the UK NSC) to continue to improve the ability to manage screening.

Policies and procedures are to be in place to document and report both normal and abnormal findings in an appropriate way. High quality information on the referral process and possible outcomes are to be provided including resources available to parents for further information.

Providers are to ensure that there are adequate, appropriate and joined up clinical referral pathways in place across services.

3.2 Programme co-ordination

In accordance with UK NSC standards and protocols the NHS CB will ensure that there is a named person within the provider service responsible for overseeing the strategic coordination of the screening programme across the screening pathway and who will contribute to screening programme development.

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

The Provider will provide one or more named individuals who will be responsible for the coordination of the delivery of the programme and provider contribution to planning supported by appropriate administrative support to ensure timely reporting and response to requests for information. Where there is only one named coordinator, the provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

In accordance with UK NSC standards and protocols the provider and NHS CB will meet at regular intervals (at least annually). The meetings will include representatives from programme coordination, clinical services, laboratory services and service management.

The provider will ensure that there is an appropriate level of dedicated neonatologist time for the newborn examination, and lead professional time for the 6-8 week examination, with appropriate administrative support to be responsible for the operational coordination of the NIPE screen and to contribute to strategic development.

3.3 Clinical and corporate governance

In accordance with UK NSC standards and protocols the provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures,
- ensure that responsibility for the screening programme lies at Executive-level, (or delegated responsibility)
- 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 appointment of a Clinical Lead, a Programme Manager and the establishment of a multidisciplinary steering group/programme board including NHS CB representation (that meets quarterly) as a minimum, with terms of reference
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of organisation's Clinical Governance arrangements, the organisation's Board is assured of the quality of the screening programme
- comply with the UK NSC guidance 'Managing Serious Incidents in the English NHS National Screening Programme' (or updated version).
- have appropriate and timely arrangements in place for referral into treatment services that meet programme standards found on the National Centre Website.
- provide documented evidence of clinical governance and effectiveness arrangements on request

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- ensure that an annual report of screening services is produced which is signed off by the organisation's 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
 - ongoing risk management
 - safeguarding of children and vulnerable adults

3.4 Definition, identification and invitation of cohort/eligibility

The newborn examination is offered to all live born babies in England, and the Infant examination is offered to all to babies of parents resident within England, at 6-8 weeks of age. This should not depend on GP registration.

The provider will maximise the offer and uptake of screening in vulnerable/ hard-to-reach populations (including those who are not registered with a GP).

See section 3.14 for details of ineligibility.

3.5 Location(s) of programme delivery

The NIPE programme will be delivered in locations that are accessible and acceptable to parents and their children. All locations must satisfy minimum clinical governance standards for the safe delivery of the programme.

See section 3.1: Service model summary

3.6 Days/Hours of operation

The NIPE screening programme will be offered every day for the newborn examination, and within GP core hours for the 6-8 week infant examination.

3.7 Entry into the screening programme

See section 2.2: Care pathway

3.8 Working across interfaces between departments and organisations

The screening programme is dependent on strong working relationships (both formal and informal) between the screening programmes, the SMART IT system, ultrasonography departments, child health records departments, midwifery services, paediatric services and primary care and specialist professionals. Accurate and timely communication and handover across these interfaces is essential to reduce the potential for errors and ensure a seamless pathway for service users. It is essential that there remains clear named clinical responsibility at all times and at handover of care the clinical responsibility is clarified. The Provider 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
- agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS CB Screening Lead's initiatives in screening pathway development in line with UK NSC expectations
- meeting the national screening programme standards covering managing interfaces which can be found on the National Screening programme website.

The key interfaces for NIPE are with:

- Maternity Services
- Neonatal and paediatric services
- Cardiology and Cardiac Surgical services
 - NHS Fetal Anomaly Screening Programme (NHS FASP)
 - Paediatric Cardiology
 - Paediatric Cardiac Surgery Centres
- Hip Services
 - Ultrasonography / Radiology services
 - Paediatric Orthopaedics
 - Paediatric Physiotherapy
- Eyes
 - Paediatric Ophthalmologists
- Testes
 - Paediatric Urology / Surgery
- Primary Care
- Health visiting
- Child Health Records Departments
- Parent/ Carer representation

3.9 Information on Test/ Screening Programme

The provider will ensure that during pregnancy, as part of gaining informed consent for screening, and at other relevant points throughout the screening pathway, parents are provided with information on newborn physical examination screening. For up-to-date leaflets, letter templates etc. please access the National Screening programme website.

3.10 Testing (laboratory service, performance of test by individuals)

In accordance with UK NSC standards and protocols the provider should ensure that screening examinations are carried out by appropriately trained healthcare professionals as specified by the National Screening programme.

Each individual should receive clinical audit feedback on the examinations they undertake in comparison with others in the same department.

The service is responsible for facilitating and encouraging a culture of continuous quality improvement, which enables this to take place.

The department and individual should review any cases where the target conditions were not detected by the screening test, and use this as an opportunity for case review, education and further improvements, if necessary.

3.11 Results giving, reporting and recording

In accordance with UK NSC standards and protocols the provider should ensure that screening results are explained to parents by appropriately trained newborn physical examiners. Results are given verbally and in writing on the examination screening page within the PCHR (Personal Child Health Record - 'Red Book'),

Screening data will be entered electronically on the NIPE Screening Management and Reporting Tools (SMART) IT system, or other approved system (that can assure appropriate failsafes are in place). It should also be reported on the CHIS and the GP records

3.12 Transfer of and discharge from care obligations

The provider will retain care obligations throughout the NIPE process, regardless of outcome of screening, unless formal transfer of care is made to another e.g. specialised care provider. Identification and agreement of Clinical Responsibility is essential.

3.13 Parent and Carer Information

All parents, including those with special requirements, will be fully informed of the choices regarding the screening programme and informed consent to screening recorded appropriately.

3.14 Exclusion criteria

No exclusion criteria apply. Parents need to be fully informed about the scope of the screening programme in order to make an informed choice about participation.

3.15 Staffing

In accordance with UKNSC standards and protocols the provider will ensure that there are adequate numbers of appropriately trained staff in place to deliver the screening programme in line with best practice guidelines and the competencies laid down in the UKNSC standards and competencies document (REF). The provider will also have in place a workforce plan designed to maintain a sustainable programme, especially where increases in birth rate are predicted and/or there are difficulties in recruitment of appropriately qualified healthcare staff.

The provider will ensure that all staff policies are in line with those expected across the NHS and compliance is assured for staff involved in NIPE. This will include, for example, the ability

of staff to raise concerns; personal and professional development arrangements; maintenance of professional competency; health and safety arrangements, and promoting healthy lifestyles. As an employer, the provider will ensure that all professional staff are registered with appropriate professional bodies and abide by professional codes of practice.

The provider will provide appropriate specific training for new and existing staff with regular update training where required. The provider will also actively support attendance of staff at local, regional or national training and development events relating to UK National Screening Committee.

3.16 User involvement

In accordance with UK NSC standards and protocols the provider (s) will:

- 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 the NHS CB on request. It may be efficient to include in the annual report

3.17 Premises and equipment

In accordance with UK NSC standards and protocols the provider will ensure that suitable premises and equipment are provided for the screening programme and will have appropriate policies in place for equipment calibration, maintenance and replacement to ensure programme sustainability.

The provider will ensure that appropriate IT systems are in place to support programme delivery including audit and monitoring functions. It is acknowledged that this will be subject to the roll out of the national screening management system (SMART IT).

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

Formalised Quality Assurance is currently under development to contribute to local QA for screening. Standards will ensure:

- Families are able to make informed choices about screening uptake
- Screening and diagnostic services are effective and carried out to a high standard
- Families are given comprehensive support at all stages
- Responsibilities for recording and reporting performance are clear

Providers will participate in the Quality Assurance Pilots for Antenatal and Newborn Screening Programmes as specified by the UK NSC and National Screening programme.

4.2 Risk assessment of the pathway

Providers are expected to have an internal quality assurance process that assures the NHS CB of their ability to manage the risks of running a screening programme. Providers may use the Failures Modes and Effects Analysis (FMEA) method which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks will be defined in the standard NHS format (*likelihood and severity multiplied to give a RAG score*)

Providers are expected to maintain a register of risks and work with the NHS CB and QA staff to identify key areas of risk in the screening pathway to ensure that these points are reviewed in contracting and peer review processes. On a quarterly basis high scoring risks will be identified and agreed between the provider and the NHS CB, and plans put in place to mitigate against them.

4.3 Quality assurance

The NHS CB will suspend a service on recommendation from QA.

The Provider will:

- meet national programme standards, or have plans in place to meet them where this is not the case
- participate fully in national QA processes and respond in a timely manner to recommendations made
- make available data from external quality assurance programmes to screening programmes, national team and the NHS CB
- collect and submit minimum data sets as required to assure the NHS CB and the Quality Assurance Team in Public Health England of the safety and quality of the services provided

- complete and submit the annual self-assessment tool with or without (as requested) an annual report of services to the Quality Assurance team and respond to identified areas for improvement

4.4 Serious incidents

A serious incident (SI) for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening service which exposes the programme to unknown levels of risk that screening or assessment have been inadequate, and hence there are possible serious consequences for the clinical management of patients. Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents.

In accordance with UK NSC guidance, '*Managing Serious Incidents in the English NHS National Screening Programmes*' the provider will:

- have a serious incident policy in place and ensure that all staff are aware of it and of their responsibilities within it
- inform the NHS CB within 24 hours in the event of a serious adverse event and work with the NHS CB nominated representatives to investigate and manage the serious incident.
- regularly review their procedures and processes to reduce the likelihood of incidents occurring
- have a robust system in place whereby families, other professionals and the public can raise concerns about the quality of care and where there are adequate arrangements for the investigations of such concerns.

The prime responsibility for investigating and managing a serious incident in a screening programme lies with the provider in which the serious incident occurred. In the event of a potential or actual serious incident occurring the NHS CB's representative who should be the first point of contact by email and phone is: (need a deputy for leave and absence).

A serious incident (SI) for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening service which exposes the programme to unknown levels of risk that screening or assessments have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low or high, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents.

The provider will:

- have a serious incident policy in place and ensure that all staff are aware of it and of their responsibilities within it
- inform the NHS CB within 24 hours in the event of a serious adverse event and provide all reasonable assistance to the NHS CB in investigating and dealing with the incident. Where appropriate, such incidents should also be reported to the National Screening programme to assist in the development of a national picture of risk identification and management

- comply with appropriate statutory regulations (e.g. Data Protection Act, COSHH Regulations etc) to ensure a safe working environment
- comply with the UK NSC guidance, '*Managing Serious Incidents in the English NHS National Screening Programmes*' available on the UK NSC website <http://www.screening.nhs.uk/quality-assurance#fileid9902>
- review their procedures and processes against the standards for the screening programme to reduce the likelihood of incidents occurring
- have a robust system in place whereby families, other professionals and the public can raise concerns about the quality of care and where there is adequate arrangements for the investigations of such concerns.

4.5 Procedures and protocols

The provider will be able to demonstrate that written procedures and protocols are in place to ensure best practice is consistently applied for all elements of the screening programme (these must be consistent with National Screening programme requirements). This will include policy based on best practice for the care of babies who's parents have declined to take part in the screening programme.

Where the provider undertakes screening on more than one site, they will ensure consistency of procedures and protocols across all sites, including policies for onward referral to, for example, counselling or appropriate clinical services.

The Provider shall ensure that all staff are aware of and comply with the Provider's safety, confidentiality and safeguarding policies.

4.6 Continual service improvement

Where national recommendations and core and/or developmental standards are not currently fully implemented the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period.

The Provider 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 include any performance issues highlighted by the NHS CB, 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 NHS CB.

Section 5: Data and Monitoring

5.1 Key performance indicators

The provider shall adhere to the requirements specified in the document '*Key Performance Indicators for Screening*'. Please refer to <http://www.screening.nhs.uk/kpi> for further details, guidance and updates on these indicators.

5.2 Data collection, monitoring and reporting

All providers will maintain a National Screening programme approved IT system that can assure appropriate failsafes are in place.

The Provider will ensure timely and accurate completion of data on the NIPE Screening Management and Reporting Tools or other effective data collection and analysis systems. Data needs to be delivered to the National Screening programme, on a quarterly basis.

Annually reported figures will be reported to allow the NHS CB to make informed decisions about the programme provision for the population that they are responsible for. To allow the NHS CB to carry out detailed analysis of the programme provision, the provider will supply an anonymised data set of all eligible service users at the request of the NHS CB. This dataset would not include the name but would include date of birth, postcode of residence, GP, screening clinic, as well as all other nationally agreed quality assurance data.

The provider will supply identifiable information regarding service users eligible for screening to the NHS CB in the event that a SI occurs relating to the programme, for the investigation of a complaint, for a specified quality assurance exercise or for any other reason that the NHS CB would reasonably require this information.

Activity and performance data will be shared with the NHS CB to allow benchmarking between areas within the eligible screening programme population.