Newborn and Infant Physical Examination Screening Programme Standards 2016/17

Publication Date: April 2016
Review Date: March 2017

Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000   www.gov.uk/phe
Twitter: @PHE_uk   Facebook: www.facebook.com/PublicHealthEngland

About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH
www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening   Blog: phescreening.blog.gov.uk

For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

Corporate member of
Plain English Campaign
Committed to clearer
communication
339

Contents

1. Introduction

This document presents the revised national standards for the NHS Newborn and Infant Physical Examination (NIPE) Screening Programme. These revised standards replace 'Newborn and Infant physical examination – standards and competencies, 2008' and has an implementation date of April 2016.

The NHS NIPE Screening Programme aims to:

- identify and refer all babies born with congenital abnormalities of the heart, hips, eyes or testes, where these are detectable, within 72 hours of birth
- further identify abnormalities that may be detected, at the second physical examination performed between 6 to 8 weeks of age

Quality assurance (QA) is the process of checking that these standards are met and encouraging continuous improvement. QA covers the entire screening pathway; from identifying who is eligible to be invited to screening, through to referral and treatment where required/appropriate.

2. The NHS Newborn and Infant Physical Examination Screening Programme

The UK National Screening Committee (UK NSC) policy for NIPE is that all eligible babies will be offered the NIPE screen. The screen should be offered within 72 hours of birth and then again at 6-8 weeks of age.

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

The four components of the NIPE are:
1. **Heart**: around 1 in 200 babies may have a heart problem.
2. **Hips**: about 1 or 2 in 1,000 babies have hip problems that require treatment.
3. **Eyes**: about 2 or 3 in 10,000 babies have problems with their eyes that require treatment.
4. **Testes**: about 1 in 100 baby boys have problems with their testes that require treatment.

3. Format of the standards

The format of screening standards has been revised. Development of this format has been an iterative process, based on work with providers, users, English screening programmes and quality assurance teams. The changes were made to ensure stakeholders have access to:

- reliable and timely information about the quality of the screening programme
- data at local, regional and national level
- quality measures across the screening pathway without gaps or duplications
- a consistent approach across screening programmes
- any burden of data collection is proportionate to the benefits gained

4. Scope and terminology - process standards

The scope is standards that assess the screening process and allow for continuous improvement. This enables providers and commissioners to identify where improvements are needed.

To clarify what is being measured each process standard has three parts:

- **objective**: the aim of the standard
- **criteria**: what is being assessed
- **measure**: two thresholds (acceptable and achievable) are specified. These thresholds, definitions and reporting levels are approved by the NHS screening programmes Data Analysts Quality Assurance (DAQA) group.

  1. The **acceptable** threshold is the lowest level of performance which programmes are expected to attain to ensure patient safety and programme effectiveness. All programmes are expected to exceed the acceptable threshold and to agree service improvement plans that develop performance towards an achievable level. Programmes not meeting the acceptable threshold are expected to implement recovery plans to ensure rapid and sustained improvement.

  2. The **achievable** threshold represents the level at which the programme is likely to be running optimally; screening programmes should aspire towards attaining and maintaining performance at this level.

Example

Using a standard that assesses coverage for the NIPE:

- **objective**: to maximise timely coverage in those who want the screen
- **criteria**: the proportion screened by 72 hours
- **measure**: the acceptable and achievable levels set for the population screened are 95% and 99%, respectively

Exclusions

Some standards that are not included here:

1. **Structural standards**: these describe the structure of the programme and must be fully met. Examples of structural standards are "provision of information to all participants" and "adequate numbers of appropriately trained staff to deliver the screening programme". Structural standards are included in screening service specifications and monitored through commissioning and other quality assurance routes. The service specifications should be reviewed by providers and commissioners to ensure structural standards are met by all screening programmes.

2. **Outcome standards**: assessment of screening outcomes is currently under review by the NHS screening programmes.

3. **Treatment standards**: although included in earlier versions of the NIPE standards, these are outside the screening pathway and therefore excluded. The screening programme would refer to treatment standards, clinical guidance and treatment pathways published by other professional bodies.

4. **Cardiac standards**: will be developed at a later date and will include the findings and outcomes of the newborn pulse oximetry pilot study currently in progress.

5. **6-8 weeks infant physical examination standards**: although included in earlier versions of the NIPE standards, these have been removed from this version. Standards relating to the 6-8 week infant physical examination will be included in the NIPE programme handbook as good practice guidelines until there is a robust method of measuring and reporting the standards. The absence of an item from the list of standards does not mean it is not important, rather that it is not currently measurable or that performance is already excellent.

5. Screening pathway

The standards are based on ten themes that assess the whole pathway:

1. Identify population (to accurately identify the population to whom screening is offered).

2. Inform (to maximise informed choice across the screening pathway).
3. Coverage/Uptake (to maximise uptake in the eligible population who are informed and wish to participate in the screening programme).
4. Test (to maximise accuracy of screening test from initial sample or examination to reporting the screening result).
5. Diagnose (to maximise accuracy of diagnostic test).
6. Intervention/Treatment (to facilitate high quality and timely intervention in those who wish to participate).
7. Outcome (to optimise individual and population health outcomes in the eligible population).
8. Minimising Harm (to minimise potential harms in those screened and in the population).
9. Staff: Education and Training (to ensure that the screening pathway is provided by a trained and skilled workforce, with the capacity to deliver screening services as per service specification).
10. Commissioning/Governance (to ensure effective commissioning and governance of the screening programme).

6. Relationship between standards and key performance indicators (KPIs)

KPIs are a subset of standards that are collated and usually reported quarterly (unless numbers are small, in which case aggregate data is reported annually) compared to annual reporting for standards. There are 2-3 KPIs per screening programme. The KPIs focus on areas of particular concern. Once a KPI consistently reaches the achievable level, the KPI will revert to being a standard and allow entry of another KPI to focus on additional areas of concern or a change to the threshold of the existing standard to promote continuous improvement. Standards 1 and 3 are the current NIPE KPIs.

7. Reporting standards

Standards will be reported annually unless they are also a key performance indicator in which case they are usually reported on quarterly and annual figures are aggregated. Data will be collated between two and three months after fiscal year (April to March) end with a submission deadline of 30 June.

8. Revising standards

These standards should be viewed as developmental in nature, they focus on some key aspects of the NIPE screening pathway that are currently measurable predominantly but not exclusively by use of the NIPE SMART IT system (IT system currently being implemented across England). They are a minimum set that the NIPE programme aims to develop further in the future when more robust data becomes available. The current formal implementation of NIPE programme and roll out NIPE SMART IT system provides a mechanism for monitoring and assessing more robust data.

It is anticipated that standards will be reviewed in line with the service specifications on an annual basis.

9. Other resources to support providers and commissioners

This document focuses on process standards to enable providers and commissioners to continuously improve the quality of the screening programme. Additional NIPE operational guidance is included in the following documents which are accessible online.

1. Service specification (No. 21) including the NIPE screening pathway. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/02/serv-spec-21.pdf
2. Screening programme handbook. https://www.gov.uk/topic/population-screening-programmes/newborn-infant-physical-examination

10. The NIPE Standards

10.1. NIPE Standard 1: Identify the population and coverage

NIPE Standard 1	Identify the population and coverage.
Rationale	This standard is needed to provide assurance that screening is offered to parents of all eligible babies and each baby (where the offer is accepted) has a conclusive screening result.
Objective	To maximise timely screening in the eligible population who are informed and wish to participate in the screening programme.
Criteria	The proportion of babies eligible for the newborn physical examination who are tested for all four components (three components in female infants) of the newborn examination within 72 hours of birth.
Definitions	$\dfrac{\text{complete screens}}{\text{eligible babies}}$ expressed as a percentage, where: *tested babies* (numerator) is the total number of eligible babies for whom a decision about referral (including a decision that no referral is necessary as a result of the newborn physical examination) for each of the four conditions screened was made within an effective timeframe. *eligible babies* (denominator) is the total number of babies born within the reporting period whose mother was registered with a GP practice within the clinical commissioning group (CCG), or (if not registered with any practice) resident within the CCG area, excluding any baby who died before an offer of screening could be made. The effective timeframe for the newborn physical examination is that a conclusive screening result should be available within 72 hours of birth.
Performance thresholds	Acceptable: ≥ 95.0% Achievable: ≥ 99.5%

Mitigations	Screening may be delayed if a baby is too premature or too unwell to have the examination (for example, it is not the clinical priority at that given point in time). Screening should be completed as and when the baby's condition allows. These babies should be accounted for and the reason explained in the commentary as mitigations against performance thresholds.
	In terms of a failsafe all babies will be eligible for the NIPE examination at some point, unless the baby dies. It is recommended that the newborn examination is undertaken prior to discharge from hospital (unless home delivery). This maximises the opportunity for the examination to be completed within the 72 hour target. Babies who are identified as not having a newborn physical clinical examination should be followed up locally.
	The NIPE programme recognises that further work is needed in the future to ensure thresholds are appropriate for neonatal intensive care units and in particular those that are tertiary referral centres.
Reporting	Reporting focus: CCG. This standard will also be reported by maternity service (See NIPE programme handbook). Data source: NIPE Screening, management and reporting tool SMART (where providers have not implemented NIPE SMART, local processes will need to be in place to enable reporting of this standard).
Reporting period	Quarterly: data to be collated between two and three months after each quarter end. Deadlines: 30 September (Q1), 31 December (Q2), 31 March (Q3), 30 June (Q4).
Equity impact	Review of performance at a local level by population group may indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools that can be used to help local services and commissioners consider how to improve equity of access are NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.

10.2. NIPE Standard 2: Timeliness of intervention (abnormality of the eye)

NIPE Standard 2	Timeliness of intervention (abnormality of the eye).
Rationale	To provide assurance of timely interventions.
Objective	To maximise timeliness of diagnostic tests and entry into a clinical pathway where relevant.
Criteria	The proportion of babies who have a positive screening test (with or without risk factors) on newborn physical examination and undergo assessment by a specialist within two weeks of age.
Definitions	$$\frac{timely\ assessment}{referral\ for\ assessment\ indicated}\quad \text{expressed as a percentage}$$ *timely assessment* (numerator) is the number of babies with an abnormality of the eye attending an assessment appointment by 2 weeks of age. This first assessment should be with a consultant ophthalmologist/paediatric ophthalmology service. *referral for assessment indicated* (denominator) is the total number of babies with an abnormality of the eye identified on newborn physical examination (in the reporting period) irrespective of risk factors.
Performance thresholds	Acceptable: ≥95% Achievable: 100%
Mitigations	
Reporting	Reporting focus: Maternity service. Data source: NIPE SMART (where providers have not implemented NIPE SMART, local processes will need to be in place to enable reporting of this standard). Where NIPE SMART is implemented, local processes need to be in place to ensure outcome of the referral/ assessment is recorded on the system. Robust referral pathways, communication and feedback to the referring unit/clinician are necessary to enable local units to report on this standard.
Reporting period	Annually: data to be collated between two and three months after fiscal year end. Deadline: 30 June.
Equity impact	Review of performance at a local level by population group may indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools

	that can be used to help local services and commissioners consider how to improve equity of access are NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.

10.3. NIPE Standard 3: Timeliness of intervention (Developmental Dysplasia of Hips-DDH)

NIPE Standard 3	Timeliness of intervention (Developmental Dysplasia of Hips-DDH).
Rationale	To provide assurance of timely interventions.
Objective	To maximise the timeliness of diagnostic tests and entry into a clinical pathway where relevant.
Criteria	The proportion of babies who have a positive screening test on newborn physical examination and undergo assessment by specialist hip ultrasound within two weeks of age.
Definitions	$$\frac{timely\ assessments}{referral\ for\ assessment\ indicated}\ expressed\ as\ a\ percentage$$ *timely assessments* (numerator) is the number of babies with a positive screening test on newborn physical examination who attend for specialist hip ultrasound within two weeks of age. *referral for assessment indicated* (denominator) is the total number of babies with a positive screening test of the hips on newborn physical examination (in the reporting period). Inclusion: Babies who are found to have dislocated or dislocatable hips on newborn physical examination should be included. Exclusions: • babies who have previously noted risk factors but normal physical examination should **NOT** be included (as referral timescales are different) • babies who are found to have 'clicky hips' on physical examination should **NOT** be included (be managed and referred as per local arrangement)
Performance thresholds	Acceptable: ≥ 95.0% Achievable: 100%
Mitigations	
Reporting	Reporting focus: Maternity Service. Data source: NIPE SMART (where providers have not implemented NIPE SMART, local processes will need to be in place to enable reporting of this standard).

	Where NIPE SMART is implemented, local processes need to be in place to ensure outcome of the ultrasound scan is recorded on the system. Robust referral pathways, communication and feedback to the referring unit/clinician are necessary to enable local units to report on this standard.
Reporting period	Quarterly: data to be collated between two and three months after each quarter end. Deadlines: 30 September (Q1), 31 December (Q2), 31 March (Q3), 30 June (Q4).
Equity impact	Review of performance at a local level by population group may indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools that can be used to help local services and commissioners consider how to improve equity of access are NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.

10.4. NIPE Standard 4: Timeliness of intervention (Developmental Dysplasia of Hips-DDH- risk factors)

NIPE Standard 4	Timeliness of intervention (Developmental Dysplasia of Hips-DDH-risk factors).
Rationale	To provide assurance of timely interventions.
Objective	To maximise the timeliness of diagnostic tests and entry into a clinical pathway where relevant.
Criteria	The proportion of babies who have a negative screening test on newborn physical examination but have identified risk factors and undergo assessment by specialist hip ultrasound within six weeks of age.
Definitions	<table><tr><td>*timely assessments*</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>*referral for assessment indicated*</td></tr></table> *timely assessments* (numerator) is the number of babies with an indication for specialist hip ultrasound based on risk factors **only** who attend for specialist hip ultrasound within 6 weeks of age. *referral for assessment indicated* (denominator) is the total number of babies who have negative screening test on newborn physical examination in the reporting period) but have identified risk factors for developmental dysplasia of the hip (DDH) specified as: Risk factors: • first degree family history of hip problems in early life as defined by a positive response to the question, "Is there anyone in the baby's close family, that is, mother, father, brother or sister, who has had a hip problem that started when they were a baby or young child that needed treatment with a splint, harness or operation?" If the answer is 'yes', an ultrasound examination should be arranged, unless DDH has been definitely excluded in that particular relative. If there is any doubt, an ultrasound examination should be offered and performed • breech presentation at or after 36 completed weeks of pregnancy, irrespective of presentation at delivery or mode of delivery, or breech presentation at delivery if this is earlier than 36 weeks. In the case of a multiple birth, if any of the

	babies is breech presentation, all babies in this pregnancy should have an ultrasound examination Exclusion: Any baby with a hip abnormality identified on newborn physical examination, that is babies found to have dislocated or dislocatable hips on physical examination with or without risk factors (screen positive)
Performance thresholds	Acceptable: ≥90% Achievable: ≥95%
Mitigations	
Reporting	Reporting focus: Maternity Service. Data source: NIPE SMART (where providers have not implemented NIPE SMART, local processes will need to be in place to enable reporting of this standard). Where NIPE SMART is implemented, local processes need to be in place to ensure outcome of the ultrasound scan is recorded on the system. Robust referral pathways, communication and feedback to the referring unit/clinician are necessary to enable local units to report on this standard.
Reporting periods	Annually: data to be collated between two and three months after fiscal year end. Deadline: 30 June
Equity impact	Review of performance at a local level by population group may indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools that can be used to help local services and commissioners consider how to improve equity of access are NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.

10.5. NIPE Standard 5: Timeliness of intervention (bilateral undescended testes)

NIPE Standard 5	Timeliness of intervention (bilateral undescended testes).
Rationale	To provide assurance of timely interventions.
Objective	To maximise timeliness of diagnostic tests and entry into a clinical pathway where relevant.
Criteria	The proportion of babies identified with bilateral undescended testes detected on newborn physical examination and are seen by a consultant paediatrician/ associate specialist within 24 hours of the newborn examination.
Definitions	<table><tr><td>*timely assessments*</td><td rowspan="2">*expressed as a percentage*</td></tr><tr><td>*referral for assessment indicated*</td></tr></table> *timely assessments* (numerator) is the number of babies with bilateral undescended testes who attend for assessment by a consultant paediatrician/ associate specialist within 24 hours of the newborn examination. *referral for assessment indicated* (denominator) is the total number of babies who are identified with bilateral undescended testes on the newborn physical examination (in the reporting period).
Performance thresholds	Acceptable: 100% One threshold is set for this standard.
Mitigations	
Reporting	Reporting focus: Maternity Service. Data source: NIPE SMART (where providers have not implemented NIPE SMART, local processes will need to be in place to enable reporting of this standard). Where NIPE SMART is implemented, local processes need to be in place to ensure outcome of the referral/assessment is recorded on the system. Good referral pathways, communication and feedback to the referring unit/clinician are necessary to enable local units to report on this standard.
Reporting period	Annually; data to be collated between two and three months after fiscal year end. Deadline: 30 June.
Equity impact	Review of performance at a local level by population group may

	indicate inequity in whether or not babies enter, complete the screening pathway or access services within optimal timescales. Tools that can be used to help local services and commissioners consider how to improve equity of access are NHS England's Equality Diversity System and PHE's Health Equity Assessment Tool.