Public Health England

Protecting and improving the nation's health

Summary of NHS Screening Programmes service specification changes for 2016-17

Service specification no. 15

NHS Infectious Diseases in Pregnancy Screening Programme

The major change to the specification is that rubella susceptibility screening will no longer be provided from 1 April 2016.

There has been a significant update to section 2.2 (care pathway) to link with new screening pathways and the multidisciplinary approach to screening and referral for all three infections. This has been updated as a result of existing programme requirements and guidance and the results of commissioned evidence, research studies and collaborative working with PHE immunisation teams.

NHS Fetal Anomaly Screening Programme (FASP)

There are no significant changes in the FASP service specifications for 2016 to 2017. The changes mainly relate to clarifications and minor grammatical issues.

From April 2016, FASP is introducing a new KPI relating to coverage of the 18^{+0}-20^{+6} week scan.

Service specification no.16

NHS Fetal Anomaly Screening Programme – screening for Down's, Edwards' and Patau's Syndromes:

Text deleted re: 2015/16:

- 3 brief paragraphs of text highlighting the policy changes for T18/13 and Quad for T21 in twins that were included in the 2015/16 specification have been deleted as this is now business as usual for the programme (the target date for full implementation is March 2016)

Clarification of text:

- **section 2.2. Test – combined screening**: text added to clarify that eligibility for first trimester screening is on the basis of the CRL measurement which should be between 45.0mm and 84.0mm – this equates to the gestational measurements included of 11+2-14+1 but this can differ slightly according to the growth charts used. The CRL measurement is therefore the key criteria at this point and a risk should not be calculated if the measurement is outside the set parameters

Insertion of text:

- **section 2.2 Test – blood samples**: text inserted to clarify that the screening tests accepted must be clearly indicated on the request form to support the laboratory in carrying out only the accepted tests within the pathway

Change of gestation:

- **section 2.2 Diagnose:** gestation changed from 13+6-14+1 to align with the timeframe of first trimester screening

Service specification no.17

NHS FASP Screening Programme – 18^{+0}-20^{+6} week fetal anomaly scan:

There are no significant changes to this specification.

Service specification no. 18
NHS Sickle Cell and Thalassaemia Screening Programme

The most important changes to the NHS Sickle cell and Thalassaemia (SCT) Screening Programme 2016-17 service specification are:

- determining low prevalence and high prevalence areas and handling NHS Trust mergers
- repeat testing in every pregnancy

Determining low prevalence and high prevalence

New guidance on determining high or low prevalence is available on GOV.UK.

This is important as it determines which screening algorithm, or model, the trust should use. The SCT programme reviewed its recommendations and published this document following enquiries from trusts where high and low prevalence areas were merging and they required advice on which algorithm to use.

The key points from the new publication are detailed below.

There are two different screening algorithms used by the SCT programme:

1. a family origin questionnaire (FOQ), followed by a blood test for sickle cell and other haemoglobin variants for only those who are deemed at a heightened risk
2. screening by a blood test for sickle cell and other haemoglobin variants, and an FOQ

Screening algorithm number 1 is used in low prevalence trusts, while screening algorithm number 2 is used in high prevalence trusts.

When high prevalence and low prevalence trusts merge, it is recommended that low prevalence trusts move to screening algorithm number 2, the high prevalence model, as this is regarded as the gold standard.

It is **not** recommended that high prevalence trusts move to the low prevalence algorithm.

Laboratories should avoid following two algorithms simultaneously. Each laboratory should run either the high or the low prevalence algorithm.

Repeat testing in every pregnancy

Due to the complexities of the testing algorithm and the logistics of separating samples out, new guidance recommends that screening for sickle cell and thalassaemia (SCT) should be repeated in every pregnancy. The SCT programme is currently updating its laboratory handbook to give more guidance, including on testing the baby's father.

If a woman is booked for antenatal care for a subsequent pregnancy, SCT screening should be offered to the pregnant woman irrespective of previous screening. In each pregnancy, the family origin questionnaire should be completed and a routine full blood count taken and mean cell haemoglobin (MCH) and other red cell indices should be assessed.

Trusts that opt out should assess the risks in every step of their process from identification of patients, through sample collection and transport, the laboratory pathway and getting the correct result back to the patient – along with any required referral or testing of the baby's father. It should cover the circumstances under which the non-repeat testing policy may fail and audit evidence should be provided.

Service specification no. 19
NHS Newborn Blood Spot Screening Programme

Section 1.2:

The newborn blood spot (NBS) programme now screens for 9 conditions: sickle cell disease (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT) and six inherited metabolic diseases: phenylketonuria (PKU), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD), isovaleric acidaemia (IVA), glutaric aciduria type 1 (GA1) and homocystinuria (pyridoxine unresponsive) (HCU).

Section 3.1:

Parents may decline screening for the individual conditions CHT, SCD and CF or **ALL** the inherited metabolic diseases (PKU, MCADD, MSUD, IVA, GA1 and HCU).

Section 2.2:

The newborn screening laboratory tests the sample according to national policy and reports the results to the Child Health Records Department and the NBS failsafe solution (NBSFS).

Sections 2.2 and 3.8 (interfaces)

Maternity care providers ensure all babies they are responsible for are offered screening by utilising the NBSFS. This requires all screening laboratories to send receipt of sample and all results recorded (status codes and subcodes used) to the NBSFS.

Service specification no. 20
NHS Newborn Hearing Screening Programme

Sections 2.2 and 3.4:

- to align with other newborn screening programmes, wording changed to:
  *This should be completed as soon as possible after birth and prior to **any** newborn screening being performed (i.e. NIPE/NHSP/NBS)* (rather than as previously stated 'within 6 hours')

Section 2.2:

- to strengthen need for documentation, wording added:
  the screening outcome should be recorded on the NHSP IT system (eSP) and documented in the PCHR or 'Red Book'
- additional wording for clarity regarding NICU protocol, which clarifies definition of a NICU unit and a NICU baby
- wording removed (not required):
  A further test is undertaken on referred babies as part of the initial audiology assessment appointment.
- additional wording added to NICU test to provide further clarity of screening outcomes, including risk factors
- wording added for clarification in NICU protocol:
  if a clear response is obtained in both ears ***on AABR*** the…
- wording added for clarification:
  In cases of incomplete screening referral to audiology may be required
- Wording added for clarification:
  Incomplete/missed screens added in line with screening pathway

Section 2.4:

- wording added to clarify responsibility:
  paediatric medical services added into list
- wording added to clarify responsibility/role of NHS Team Leader:
  (typically from audiology/paediatrics)

Section 2.6:

- wording added:
  Evaluation and modification of changes to screening protocols

Section 3.1:

- wording added to reflect practice:
  an outpatient/***home visit***

- ***w***ording added for clarification:
  In a hospital model the majority of babies will be screened by 10 days of age.
  In a community model screening will not usually be commenced until after 10 days of age.
- *w*ording added for clarification:
  screen completion or by 44 weeks gestational age
- *w*ording amended and re-ordered for clarification:
  Audiology Services
  Audiology services should adhere to national guidance, record on eSP the audiology follow-up data on babies that refer from the screen as well as any children with later identified PCHI.

Service specification no. 21
NHS Newborn and Infant Physical Examination Screening Programme

Section 2.2 (care pathway):

- update to wording regarding newborn cohort eligibility in line with KPI definition
- additional wording to management of results to clarify required process to include recording of outcomes

Section 2.3 (failsafe arrangements):

- additional wording:
  have staff with designated responsibility for overseeing and managing the local failsafe process (ideally via use of NIPE SMART) in place

Section 3.4 (definition, identification and invitation of cohort/eligibility):

- amended wording to confirm process in line with KPI document
- wording updated to reflect current process for generation of NHS number

Section 3.11 (results giving, reporting and recording):

- additional wording:
  The clinician undertaking the examination is responsible for ensuring the results and screening outcomes are recorded. This should be undertaken by entering results on the nationally recommended (NIPE SMART) or an IT system that can ensure demonstrable failsafe mechanisms are in place, monitored and managed

Section 3.15 (staffing and training):

- minor wording changes to clarify requirement of roles and responsibilities:
  Providers will have in place one or more named individuals …… responsible for the coordination of the delivery of the programme. The designated person or persons will contribute to planning, with appropriate administrative support, to ensure timely reporting and response to requests for information

Quality assurance for antenatal and newborn laboratories

Screening laboratories must 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. See also https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes.

Service specification no. 22
NHS Diabetic Eye Screening Programme

Changes to the service specification for 2016 to 2017:

- providers should now be fully compliant with the common pathway and providing a service that meets the national service specification; further developments to the pathway may commence during 2016 to 2017 (page 8)
- inclusion of key deliverables to help reduce health inequalities (page 10)
- specific references to sending results communications to paediatrician, diabetologist and obstetrician where appropriate (page 15)
- additional emphasis on responsibility of the clinical lead to ensure failsafe activities are working effectively (page 22)
- providers should undertake a minimum of quarterly updates of lists of people with diabetes from GP practices (page 24)
- specific references to providing call/recall for routine digital screening, slit lamp biomicroscopy and digital surveillance and providing results from such to appropriate clinicians (page 24)
- requirement to always use patient information leaflets from PHE Screening and make use of national information links; to involve PHE screening and PHE Communications in the development of local publicity campaigns, to provide feedback on national resources (page 25)
- requirement to work towards recording all surveillance clinic events directly on the screening software irrespective of where clinic has taken place (page 28)
- requirement to follow new guidance on how to improve the quality of and consistency of grading and participation in Test and Training (page 30)
- specific requirement to undertake contingency planning to ensure programme resilience (page 32)
- requirement to ensure the workforce is qualified and meeting all national programme standards. Clinical lead and programme manager required to attend at least one national programme educational event each year and appropriate annual CPD for workforce is allowed (page 33, 36)
- requirement to ensure senior level IT support to support system upgrades, to quantify spend on IT systems and equipment and to provide such upon request (page 33)

Service specification no. 23
NHS Abdominal Aortic Aneurysm Screening Programme

Changes to the service specification for 2016 to 2017:

Annex A: Quality Requirements

- retirement of KPI AA1 (completeness of offer) and replacement with AA2 (coverage of initial screen)
- introduction of KPI AA3 (coverage of annual surveillance screen)
- introduction of KPI AA4 (coverage of quarterly surveillance screen)

Section 3: Scope (3.35 and 3.36)

- reworded guidance on ensuring equity of access to those men who are in secure organisations and those that are housebound

Section 4: Applicable Service Standards (4.12)

- reworded guidance on reaccreditation for screening technicians and clinical skills trainers

Section 4: Applicable Service Standards (4.24)

- introduction of paragraph stating that providers of AAA screening should have undertaken and passed the NHS Information Governance Toolkit to at least “Any Qualified Provider – Clinical Services” level

Service specification no. 24
NHS Breast Screening Programme

Sections 2.5-2.7. Administration, audit, QA, failsafe, IT (p 17)

The key change to the service specification is that, in 2016-17, NHS England will work with Public Health England to develop a single national database (Breast Screening Select) which will include registrations of all eligible women in the screening programme to allow the call:recall function to continue.

This was necessitated by the fact that the current system of registration (National Health Application Infrastructure Service; NHAIS system) is being decommissioned in 2017.

Service specification no. 25
NHS Cervical Screening Programme

There has been little change to the cervical screening service specification for 2016 to 2017.

There has been a change to the colposcopy waiting times KPI from 90% to 93%:

Appendix 1: Key Performance Indicators (pages 39-40)

- Proportion of women who are offered a colposcopy appointment within 2 weeks of referral due to cytological report of possible invasion, high-grade dyskaryosis (severe or moderate) or worse >=93%.

The rationale for this was that the service specification was not aligned with the cancer waits time and pending colposcopy guidance from the programme, so it was amended accordingly to ensure uniformity. There had previously been feedback from QA and commissioners regarding the inconsistency in the standards from the programme and the service specification. The colposcopy and programme management guidelines and specification will in future all be consistent.

Service specification no. 26
NHS Bowel Cancer Screening Programme

The key change is the production of the specification for bowel scope screening.

There has been a strengthening of the public information section:

- providers must always use the patient information leaflets from PHE Screening at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening should be consulted and involved before developing any other supporting materials

- providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources

- providers must not develop their own information about screening for local NHS websites but should always link through to the national information on NHS Choices (http://www.nhs.uk/Livewell/Screening/Pages/screening.aspx or the relevant programme page) and GOV.UK (https://www.gov.uk/topic/population-screening-programmes or the relevant programme page)

- to support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources

For local awareness campaigns, local contact details must be used:

- providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used

Equality:

- the equality sections were strengthened. This included that 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 populations
- user involvement should include representation from service users with equality characteristics
- providers should exercise high levels of diligence when considering excluding people with equality characteristics in their population from the programme and follow both equality and screening guidance when making such decisions