NHS public health functions agreement 2016-17

Service specification no.16

NHS Fetal Anomaly Screening Programme - Screening for Down's, Edwards' and Patau's Syndromes (Trisomy 21, 18 & 13)

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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Prepared by Public Health England

Contents

Service specification No.16

This is a service specification to accompany the ‘NHS public health functions agreement 2016-17 (the ‘2016-17 agreement’) published in December 2015.

This service specification is to be applied by NHS England in accordance with the 2016-17 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2016-17 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2016-17 agreement is available at www.gov.uk (search for ‘commissioning public health’).

All current service specifications are available at www.england.nhs.uk (search for ‘commissioning public health’).

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 Down's, Edwards' and Patau's syndromes Screening (Trisomy 21, 18 &13) as part of the Fetal Anomaly Screening Programme (FASP).

The purpose of the service specification is to outline the service and quality indicators expected by NHS England for the population for whom it is responsible and which meets the policies, recommendations and standards of the NHS Screening programmes.

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 specification should be read in conjunction with:

- current FASP guidance https://www.gov.uk/topic/population-screening-programmes/fetal-anomaly
- FASP Ultrasound Practitioners Handbook https://www.gov.uk/government/publications/fetal-anomaly-screening-ultrasound-practitioners-handbook
- FASP Laboratory Handbook https://www.gov.uk/government/publications/fetal-anomaly-screening-laboratory-handbook-downs-edwards-and-pataus-syndromes
- any separate service specifications for the screening laboratory used by the Provider for antenatal screening services
- UK NSC Guidance, Managing Safety Incidents in the English NHS National Screening Programmes https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes
- Guidance & updates on Key Performance Indicators https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting
- Clinical Excellence (NICE) Clinical guideline 62 Antenatal care June 2010 http://www.nice.org.uk/guidance/CG62
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline CG 129 Antenatal care September 2011

http://www.nice.org.uk/guidance/cg129

- Royal College of Radiologists. https://www.rcr.ac.uk/publication/standards-provision-ultrasound-service
- Service Specification Number 17 Fetal Anomaly Screening https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/02/serv-spec-17.pdf
- 'Maternity Pathway Payments: Who pays for what?-Aspects of the Maternity Pathway Payment for the Screening and Immunisations Programmes June 2015 https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf

1.2. Aims

The NHS Fetal Anomaly Screening Programme aims to ensure that there is equal access to uniform and quality-assured screening across England and that eligible women are provided with high quality information so they can make an informed choice about their screening options and pregnancy.

1.3. Objectives

- to offer screening to eligible women in England to assess the risk of the baby being born with Down's, Edwards' or Patau's syndromes
- to facilitate choice in appropriate diagnostic testing and pregnancy management

1.4. Expected health outcomes

- women are able to make informed and supported decisions about how they respond to the risk calculation given within the screening programme
- diagnostic and follow on care services are easily accessible and support a woman's decision

1.5. Principles

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

- all those participating in the Fetal Anomaly 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 with clear lines of communication between the different Providers, screening centres, primary care and secondary care

1.6. 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

The provider 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.

The provider 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. The provider will comply with safeguarding policies and good practice recommendations for such persons.

Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees
https://www.gov.uk/guidance/equality-act-2010-guidance

It also requires that public bodies:

- have due regard to the need to eliminate discrimination

- advance equality of opportunity
- foster good relations between different people when carrying out their activities

Section 2: Scope of Screening Programme

2.1 Description of screening programme

Screening for Down's, Edwards' and Patau's syndromes is part of the NHS Fetal Anomaly Screening Programme (FASP).

In line with NICE guidance (Clinical guideline 62 Antenatal care June 2010 http://publications.nice.org.uk/antenatal-care-cg62 all pregnant women should be offered an early ultrasound scan to determine gestational age. The NHS Screening programme's recommended screening tests are gestation dependent, and are as follows:

- between 10^{+0} and 14^{+1} weeks of pregnancy the combined test, which consists of a nuchal translucency scan and a blood test that measures two specific maternal biochemical markers for use in screening for Down's, Edwards' and Patau's syndromes.
- between 14^{+2} to 20^{+0} weeks the quadruple test which measures four maternal biochemical markers for use in screening for Down's syndrome only

To complete the ultrasound component of this screening strategy, the scan appointment should allocate time to incorporate pre-scan counselling, the ultrasound examination, post-scan counselling and reporting. The time allocation for appointments to meet these requirements is a minimum of twenty (20) minutes.

The results of either test give an individual risk assessment to the woman on the possibility that her baby/ies will have Down's, Edwards' or Patau's syndromes. If the risk of having a term pregnancy affected with any of these syndromes is 1 in 150 or higher, the pregnancy is regarded as higher risk and the woman will be offered a prenatal diagnostic (PND) test.

In delivering a national screening programme and to ensure national consistency the local Provider is expected to fulfill the following, in conjunction with guidance from the National Screening Programme where appropriate and as detailed in the standards and policies available on https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards

- 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, training media and protocols for their use
- be required to respond to national action/lessons such as change of software, equipment supplier, techniques
- work with NHS England in reporting, investigating and resolving screening

incidents

- provide data and reports against programme standards, key performance indicators (KPIs), and quality indicators as required by the national screening programme on behalf of the NHS Screening Programmes
- take part in quality assurance 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
- ensure all health care professionals access appropriate training to maintain continuous professional development and competency
- ensure appropriate governance structures are in place

2.2 Care pathway

A full description of the screening pathway is given below, along with a diagram of the pathway (figure1).

The screening pathway consists of the following:

- **Identify population** - the eligible population is identified through maternity antenatal care services.

  For Down's syndrome screening, the eligible population is women with singleton and twin pregnancies $<20^{+0}$ weeks of pregnancy confirmed by ultrasound scan and for Edwards' and Patau's syndromes screening using biochemical markers the eligible population are women with singleton and twin pregnancies $\leq 14^{+1}$ weeks of pregnancy confirmed by ultrasound scan
- **Inform** - during the first contact or booking visit with the midwife, verbal and written information about the dating scan and screening is given to the woman (using the NHS Screening Programmes booklet 'Screening Tests for You and Your Baby') to enable her to make an informed choice and screening offered
- **Offer** - the offer of screening and subsequent acceptance or decline should be documented
- **Test** –
- combined screening is performed between 10^{+0} to 14^{+1} weeks gestation. The maternal serum sample can be taken between 10^{+0} to 14^{+1} weeks gestation and

the nuchal translucency measured between 11^{+2} and 14^{+1} weeks. For purposes of screening the eligibility for first trimester screening using the combined test is a crown rump length (CRL) measurement of 45.0mm – 84.0mm

- for women between 14^{+2} and 20^{+0} weeks, the quadruple test is performed for the assessment of risk for Down's syndrome only in women with a singleton and twin pregnancy. The recommended screening strategy for Edwards' and Patau's syndrome for women who present for care ≥14^{+2} but between 18^{+0} and 23^{+0} weeks gestation is the fetal anomaly scan
- arrangements for the sequencing of the ultrasound component (i.e. CRL/NT) and the collection of the maternal blood sample should be defined by local protocol and are the responsibility of the Provider. Where screening in the first trimester using the combined screening strategy is accepted, the biochemical component of the test must be completed regardless of the measurement of the nuchal Translucency. Where a nuchal translucency measurement of ≥3.5 mm is recorded, referral should not be delayed to await biochemistry information but results should be forwarded to the clinician as soon as they are available to support discussion of further investigative options with the woman
- a local failsafe protocol must be in place to ensure that all women who accept screening complete the testing pathway, and specifically for women unable to complete first trimester screening for any reason who are then required to safely transfer to second trimester quadruple screening for Down's syndrome
- blood samples are taken and sent to the laboratory with completed request form (paper or electronic). It is necessary to indicate clearly the tests accepted and requested, and if relevant, those declined. The request form must also be compliant to the minimum dataset as described and measured by the Key Performance Indicator (KPI) FA1. The specimen is processed to ensure that the tests accepted and requested are undertaken. Local protocols should be in place between the laboratory and maternity service to log receipt of a fit for purpose sample, deal with incomplete information on the request form, or any unacceptable samples that require repeat specimens. This should be done as soon as practicable to ensure timely risk calculation and all requests should be tracked until completed
- analysis and testing should be undertaken in line with nationally agreed screening protocols using a cut-off at term of 1 in150
- laboratories must be able to evidence that any planned upgrades to the software used to calculate risk in Down's, Edwards' and Patau's syndromes screening meet the criteria to ensure compliance with the FASP programme software specification https://www.gov.uk/government/publications/downs-syndrome-screening-risk-calculation-software-requirements
- local protocols should be in place between the laboratory and maternity service to ensure results are communicated within nationally set timescales/standards . NHS England should check these local protocols as they are critical to ensure adequate and timely follow up of results

Management of results

Lower risk results: all women should be notified of their screening test result within two weeks of the test being taken. The results should be documented in the health record.

Higher risk results:

- the laboratory directly informs the designated lead within maternity service (e.g. Screening Coordinator) of the higher risk result
- a local protocol should be in place between the laboratory and maternity service to log receipt of higher risk results
- the woman is informed of the result within 3 working days of the receipt of result and offered a face to face discussion with a screening midwife or clinician
- the midwife/clinician and mother discuss the options available
    1. to have no further testing
    2. to have a diagnostic test. This test should be available within 3 working days of woman receiving the screening test result
- discussion should include sufficient information to ensure that the woman is aware of the purpose, benefits, limitations and implications of undergoing a diagnostic test
- if diagnostic testing is declined the woman continues with her pregnancy and the pregnancy outcome is obtained for audit purposes. A mechanism should be in place to alert the practitioners providing subsequent care (including the newborn physical examination)

Diagnose –
Diagnostic Testing

- PND is performed in accordance with RCOG and NICE Guidelines. **Note:** PND for a Multiple Pregnancy should be conducted at a tertiary Fetal Medicine Unit due to the specialised nature of the procedures and the increased risk of miscarriage
- consent is obtained and the woman's decision is documented in the health care records
- the woman is given information on how the results of PND may be communicated to her and a method agreed
- a sample is obtained by chorionic villus sampling (CVS) (from 10^{+0} weeks) or amniocentesis (after 15^{+0} weeks)
- where the indication for undertaking PND is a higher risk screening result, the

sample is sent to the cytogenetic laboratory for quantitative fluorescence polymerase chain reaction (QF-PCR) testing

- local protocols should be in place between the laboratory and maternity service to log receipt of a fit for purpose sample, deal with incomplete information on the request form, or any unacceptable samples that require repeat specimens. This should be done as soon as practicable to ensure timely processing of samples and all requests should be tracked until completed
- following referral for diagnostic testing, information should be shared between the specialist teams, maternity services and primary care to ensure appropriate pregnancy management/delivery of the baby and monitoring of screening outcomes
- local protocols should be in place to ensure multi-disciplinary links and close working relationships between maternity services and specialist services are established

Management of diagnostic test results

Normal result:

- the woman will continue with her pregnancy and outcome is obtained

Abnormal result:

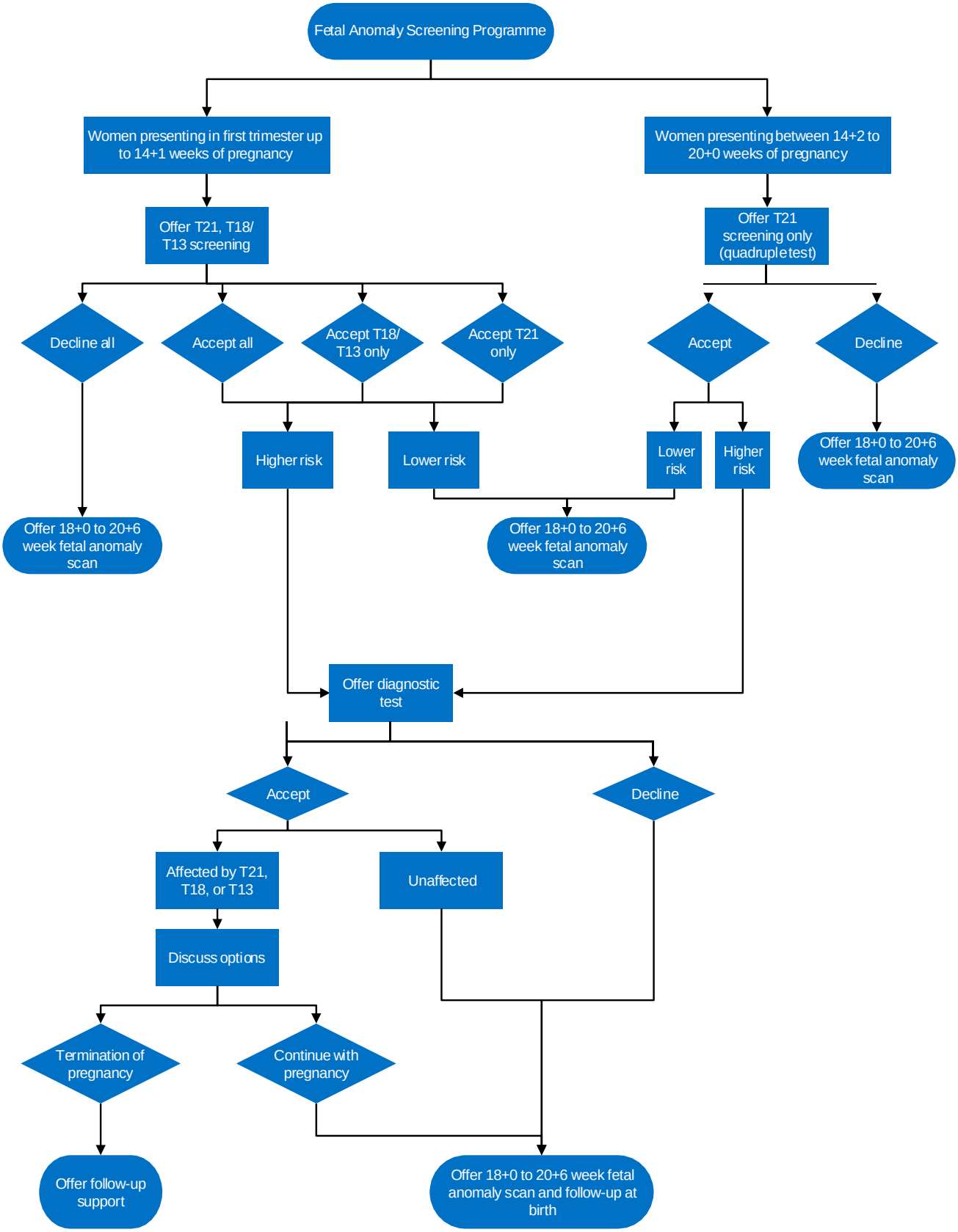
- the woman is given the opportunity to discuss the results with health professionals who are knowledgeable about Down's, Edwards' and Patau's syndromes. This will include the offer of a termination of pregnancy or continuing support through pregnancy
- if the woman chooses not to undergo termination of pregnancy and continues with her pregnancy a referral to appropriate paediatric and support services should be made
- a pregnancy outcome should be recorded and a mechanism should be in place to alert the practitioners providing subsequent care (including the newborn physical examination)
- if termination of pregnancy is accepted, this should be undertaken in line with the Abortion Act 1967

A local protocol should be in place for reporting and appropriate referral of any babies born with suspected/confirmed Down's, Edwards' or Patau's syndromes who were not identified in the antenatal period, to allow review of the woman's participation in the screening pathway.

All Providers are expected to review and risk assess local screening pathways in the light of national NHS FASP programme guidance and work with the Quality Assurance teams, and NHS England Screening and Immunisation Leads and Teams to develop, implement and maintain appropriate risk reduction measures. This should involve mechanisms to audit

implementation, report incidents, ensure staff training and development and competencies, and have appropriate links with internal governance arrangements.

Figure 1 – NHS FASP Screening Pathway for Down's, Edwards' and Patau's syndromes



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2.3 Failsafe Procedures

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 Provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway
- review and risk assess local screening pathways in the light of national SCT screening programme guidance
- work with NHS England 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 to maintain competencies; follow guidance in SCT Screening Programme Standards https://www.gov.uk/government/collections/nhs-population-screening-programme-standards and Specification for Specialised Services for Haemoglobinopathy Care (All Ages) (B08/S/a) http://www.england.nhs.uk/wp-content/uploads/2013/06/b08-speci-serv-haemo.pdf

2.4 Roles and accountabilities through the screening pathway

The NHS FASP programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, obstetric ultrasound services, the screening and diagnostic laboratories, fetal medicine and specialist services, primary care/GPs and professional bodies who set guidance for maternal and fetal medicine and management of care in pregnancy.

NHS England will be expected to ensure that the whole pathway is robust.

The Provider will be expected to fully contribute to ensuring that systems are in place to maintain the quality of the whole screening pathway in their organisation. This will include, but is not limited to:

- provision of robust screening coordination which links with all elements of the screening pathway
- ensure that midwifery services are supported to facilitate early booking for maternity care agreeing and documenting roles and responsibilities relating to

all elements of the screening pathway across organisations and organisational boundaries

- develop joint audit and monitoring processes
- agree joint failsafe mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contribute to any NHS England and public health screening lead initiatives in screening pathway development in line with NHS Screening Programmes expectations
- provide or seeking to provide robust electronic links with relevant organisations
- links with primary, secondary and tertiary care
- the need for robust IT systems across the screening pathway

All Providers should have the following posts in place:

- a screening midwife/coordinator (and deputy) to oversee the screening programme and act as a link between other members of the FASP team
- a screening support sonographer (and deputy) to specifically support the NHS FASP programme

For further specific staffing requirements refer to section 3.15. Staffing.

2.5 Commissioning Arrangements

Down's, Edwards' and Patau's syndrome screening services will be commissioned by NHS England alongside specialised services where appropriate. Commissioning of the screening pathway involves commissioning at different levels which may include NHS England screening and immunisation teams, CCGs, specialist commissioning and directly by maternity services. Refer to Who Pays for What?-Aspects of the Maternity Pathway Payment for the Screening and Immunisations Programmes June 2015 https://www.england.nhs.uk/expo/wp-content/uploads/sites/18/2015/06/who-pays-mpp-upd-06-2015.pdf

2.6 Links between screening programme and national programme expertise

PHE, through the national screening programmes, is responsible for defining high-quality,

uniform screening, providing accessible information to both the public and health care professionals, and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for ensuring training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.

PHE will be responsible for delivery of the essential elements of screening programmes best done once at national level. These include setting clear specifications for equipment, IT and data.

Section 3: Delivery of Screening Programme

3.1. Service model summary

The model of delivery for the screening programme is primarily through maternity services care. See section 2.2 Care Pathway above for further details.

3.2. Programme co-ordination

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 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 Provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

The Provider and NHS England should meet at regular intervals to monitor and review the local screening pathway. The meetings should include representatives from programme coordination, clinical services, laboratory services and service management.

3.3. Clinical and corporate governance

The Provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures e.g. screening programme boards/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 including NHS England representation 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 NHS screening programmes guidance on managing screening incidents
- have appropriate and timely arrangements in place for referral into treatment services that meet the screening programme standards
- be able to provide documented evidence of clinical governance and effectiveness arrangements on request
- 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
  - risks and mitigation plans

3.4. Definition, identification and invitation of cohort/eligibility

Screening for Down's syndrome

The target population is all pregnant women up to 20^{+0} confirmed weeks of pregnancy.

Screening for Edwards' and Patau's syndrome

The target population is all pregnant women up to 14^{+1} confirmed weeks of pregnancy. For women presenting from 14^{+2} weeks gestation the screening strategy for Edwards' and Patau's syndromes is the fetal anomaly scan. Please refer to Service specification No 17 – Fetal anomaly screening (Fetal Anomaly scan) .

3.5. Location(s) of programme delivery

The Provider will ensure appropriate accessible service provision for the population while assuring that all locations where screening occurs fully comply with the policies, standards and guidelines referenced in this service specification.

3.6. Days/Hours of operation

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

3.7. Entry into the screening programme

All women will be identified through maternity services. While there is nothing specific in the general practitioner (GP) contract regarding the screening programme, GPs have a key role in ensuring that pregnant women presenting to them are referred on as soon as possible to Midwifery Services.

Providers will ensure timely access for women to all aspects of the screening programme.

3.8. Working across interfaces between departments and organisations

The screening programme is dependent on strong functioning working relationships, both formal and informal, between primary care, the hospital trust (maternity and obstetric ultrasound services), the screening laboratory, diagnostics and molecular and cytogenetic services, paediatrics and other appropriate clinical services.

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 be expected to fully contribute to ensuring that cross organisational systems are in place to maintain the quality of the entire screening pathway. This will include, but is not limited to:

- work to nationally agreed programme standards, policies and guidance
- ensure that midwives are supported to facilitate early booking for maternity care within primary and community care settings.
- provide strong clinical leadership and clear lines of accountability
- agree and document roles and responsibilities relating to all elements of the screening pathway across organisations to assure appropriate handover arrangements are in place between services

- develop joint audit and monitoring processes
- agree jointly on the failsafe mechanisms required to ensure safe and timely processes across the whole screening pathway
- develop an escalation process for screening incidents
- contribute to any NHS England initiatives in screening pathway development in line with NHS Screening programme's expectations
- facilitate education and training both inside and outside the Provider organisation

3.9. Information on Test/ Screening Programme

Prior to any screening offer, the midwife will provide verbal and written information regarding screening utilising the approved NHS screening programmes booklet 'Screening Tests for You and Your Baby' as a guide for discussion. Where there are specific communication requirements (e.g. English is not the woman's 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 antenatal 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.

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

Providers will ensure that the ultrasound component of the screening test is performed by a health professional with at least one of the qualifications outlined in Section 3.15 Staffing.

All screening laboratories are required:

- to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service
- to follow the guidance set out in the FASP laboratory handbook
- to comply with the FASP programme standards
- to be part of the Down's Syndrome Screening Quality Assurance Support Service (DQASS)

- to have a minimum workload of at least 8,000 screening specimens per annum per testing strategy (i.e. combined screening 8,000 samples per year and Quadruple screening 8,000 samples per year). This is to ensure that screening laboratories have sufficient confidence in the quoted annual screen positive rates, and have sufficient specimens to calculate reliable, monthly median values for the biochemical markers. Laboratories with a workload of less than 8,000 specimens a year must be part of a managed network of laboratories with each having a minimum workload of 2,000 specimens per year and identical screening policies and analytical procedures in force. Further guidance regarding a managed laboratory network can be found in the FASP Laboratory Handbook at https://www.gov.uk/government/publications/fetal-anomaly-screening-laboratory-handbook-downs-edwards-and-pataus-syndromes
- use Risk Calculation software that is CE marked and complies with EU directives, and, where planned, utilise upgrades of this software to meet the criteria of the FASP software specification for risk calculation which can be found at https://www.gov.uk/government/publications/downs-syndrome-screening-risk-calculation-software-requirements
- be UKAS accredited and participate in an external quality assurance scheme (i.e. UK NEQAS)

All diagnostic ultrasound procedures should be undertaken according to RCOG and NICE guidance by health professionals who are trained to undertake these procedures under 'continuous direct ultrasound guidance' and are competent in the safe use of ultrasound equipment.

Diagnostic procedures for women with a multiple pregnancy must be undertaken at a tertiary Fetal Medicine Unit.

Cytogenetic laboratories performing analysis of prenatal samples should be UKAS accredited and participate in an external quality assurance scheme (i.e. CEQAS/UK NEQAS).

3.11. Results giving, reporting and recording

Screening results should be explained to women by appropriately trained staff and recorded in the woman's health records/IT system.

See section 2.2 Care Pathway for further detail.

3.12. Transfer of and discharge from care obligations

Active inclusion in the screening programme ends at three points depending on the woman's risk:

1. when the screening result is low risk
2. when a woman has a higher risk and has a normal PND or declines PND
3. when a woman has a higher risk and has an abnormal PND and has been provided with information on her further options.

3.13. Public Information

Providers must always use the nationally-developed public information leaflets 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 and should involve the national screening team before developing any other materials. For local awareness campaigns, local contact details must be used.

3.14. Exclusion criteria

Screening for Down's syndrome

Women presenting for maternity care at >20^{+0} weeks gestation.

Screening for Edwards' and Patau's syndrome

Women presenting for maternity care at >14^{+1} weeks gestation.

For women presenting from 14^{+2} weeks gestation the screening strategy for Edwards' and Patau's syndromes is the fetal anomaly scan. Please refer to Service specification No 17 – Fetal anomaly screening (Fetal Anomaly scan).

3.15. Staffing

Providers will have in place a dedicated screening coordinator/screening midwife and a screening support sonographer (SSS) (with appropriate deputy and administrative support arrangements to ensure continual cover), to oversee the implementation, delivery and monitoring of the screening programme in both the antenatal and ultrasound settings. These staff are also responsible for ensuring that there is an on -going educational programme for health professionals involved in screening.

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary. Training standards are detailed in the Screening programme handbook and Ultrasound Practitioner's handbook at https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook and https://www.gov.uk/government/publications/fetal-anomaly-screening-ultrasound-practitioners-handbook

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

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.

All professionals involved in the provision of ultrasound screening for Down's, Edwards' and Patau's syndromes should comply with the training requirements detailed in the FASP ultrasound practitioners handbook': https://www.gov.uk/government/publications/fetal- anomaly-screening-ultrasound-practitioners-handbook

NHS FASP recommends that any person undertaking a Fetal Anomaly ultrasound scan on pregnant women, for the purpose of screening and diagnosis of a related condition should hold, as a minimum, one of the following:

- Certificate/Diploma (as appropriate) in Medical Ultrasound (CMU/DMU) of the College of Radiographers (CoR) with evidence of appropriate continuous professional development (CPD).
- Post Graduate Certificate in Medical Ultrasound (PgCert) approved and validated by a Higher Institute of education and accredited by the Consortium for Sonographic Education (CASE) or equivalent. The qualification should be relevant to obstetric ultrasound practice.
- Royal College of Obstetricians and Gynaecologists (RCOG) Royal College of Radiologists (RCR) Diploma in Obstetric Ultrasound or the Advanced Training Skills Module (ATSM)

3.16. User involvement

The Provider will be expected to:

- demonstrate that they regularly seek out the views of service users, families and others in respect of planning, implementing and delivering services
- demonstrate how those views will influence service delivery for the purposes of raising standards
- make results of any user surveys/questionnaires available to NHS England on request

3.17. Premises and equipment

The Provider will:

- ensure that suitable premises and equipment are provided for the screening programme

- have appropriate polices in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability
- ensure that ultrasound scanning equipment meets the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use
- ensure that ultrasound equipment used to perform the NT and CRL measurement for the combined test should be capable of producing and storing images of appropriate diagnostic quality. Royal College of Radiologists. Providing an Ultrasound Service https://www.rcr.ac.uk/publication/standards-provision-ultrasound-service

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3.18. Safety & Safeguarding

The Provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2015/16 NHS Standard Contract: http://www.england.nhs.uk/nhs-standard-contract/15-16

Section 4: Service Standards, Risks and Quality Assurance

4.1. Key criteria and standards

Programme standards are available on https://www.gov.uk/government/publications/fetal-anomaly- screening-programme-standards

Providers will meet the acceptable and work towards the achievable programme standards. A number of resources to support Providers are available on the programme website.

4.2. Risk assessment of the screening pathway

Providers are expected to have an internal quality assurance and risk management process that assures the commissioners of its ability to manage the risks of running a screening programme.

Providers 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 local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the Commissioner and Quality Assurance Teams to develop, implement, and maintain appropriate risk reduction measures

High scoring risks will be identified and agreed between the Provider and the commissioners and plans put in place to mitigate against them. The Provider and commissioner will agree plans to mitigate risks.

4.3. Quality assurance

Providers will participate fully in national Quality Assurance 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 QA teams and commissioners of:

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

Laboratories undertaking Down's syndrome screening should:

- be accredited by UKAS or equivalent and list the screening tests in their repertoire of services (http://www.UKAS.com)
- participate in an accredited external quality assurance scheme for Down's syndrome screening. e.g. UKNEQAS scheme and respond within agreed timescales
- make available timely data and reports from external quality assurance programmes and accreditation services to QA, national screening programmes and commissioners within agreed timescales
- 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.

All Providers should operate failsafe systems that can identify, as early as possible, women and babies that may have been missed or where screening results are incomplete.

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

4.4. Safety concerns, safety incidents and serious incidents

Providers will comply with the national guidance for the management of safety concerns and incidents in screening programmes and NHS England guidance for the management of safety incidents (https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes)

4.5. Procedures and Protocols

The Provider 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 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 respond to any performance issues highlighted by the commissioners, 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 commissioners.

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 https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting for further details, guidance and updates on these indicators.

5.2. Data collection, monitoring and reporting

Providers 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

FASP Programme specific measures:

The following data should be provided according to the following schedule:

- Bi-annual submission to the NHS FASP monitoring arm, Down's Syndrome Screening Quality Assurance Support Service (DQASS). Data submission requirements include individual patient measurements for a set number of fields by biochemistry laboratories and NT and CRL measurements for each sonographer.

For quality and monitoring, information should be shared with the National Congenital Anomaly and Rare Disease Registration Service.