NHS public health functions agreement 2018-19
Service specification no.16
NHS Fetal Anomaly Screening Programme - Screening for Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome (Trisomy 21, 18 & 13)
NHS public health functions agreement 2018-19

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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 and those who do not share it (as required under the Equality Act 2010); and

• Given due 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 (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).
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Service specification No.16

This is a service specification to accompany the ‘NHS public health functions agreement 2018-19 (the ‘2018-19 agreement’).

This service specification is to be applied by NHS England in accordance with the 2018-19 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 2018-19 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 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

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

The 2018-19 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

A common national service specification must be used to provide, monitor and govern the NHS Fetal Anomaly Screening Programme (FASP). This enables a consistent and equitable approach across England.

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:

- Service Specification Number 17 Fetal Anomaly Screening
- FASP screening standards
- Guidance & updates on Key Performance Indicators
- FASP Ultrasound Practitioners Handbook
- FASP Laboratory Handbook
- FASP Screening Programme Handbook
- Managing Safety Incidents in the English NHS National Screening Programmes
- NHS England Serious Incident Framework
- FASP Checks and audits to improve quality and reduce risks
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline CG 129 Antenatal care for twin and triplet pregnancies
- 'Maternity Pathway Payments: Who pays for what?-Aspects of the Maternity Pathway Payment for the Screening and Immunisations Programmes
- Royal College of Radiologists. Standards for provision of an ultrasound service.

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**
The objectives of the NHS Fetal Anomaly Screening Programme are:

- to offer screening to eligible women in England to assess the chance of the baby being born with Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome; and
- to facilitate choice in appropriate diagnostic testing and pregnancy management.

1.4. **Expected health outcomes**
The expected health outcomes of the NHS Fetal Anomaly Screening Programme are that:

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

1.5. **Principles**
The principles of the NHS Fetal Anomaly Screening Programme are:

- 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; and
- 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**
Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:

- screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary;
- a Health Equity Audit 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; and
• providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow equality, health inequality and screening guidance when making such decisions.

The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure 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/equality-act-2010-guidance .

It also requires that public bodies:
• have due regard to the need to eliminate discrimination;
• advance equality of opportunity; and
• 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 Syndrome, Edwards’ Syndrome and Patau’s Syndrome is part of the NHS Fetal Anomaly Screening Programme (FASP).

In line with NICE guidance (Clinical guideline 62 Antenatal care), 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:

- Crown Rump Length (CRL) between 45.0mm and 84.0mm (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 Syndrome, Edwards’ Syndrome and Patau’s Syndrome.
- Head Circumference (HC) equal to or more than 101.0mm (between 14+2 to 20+0 weeks of pregnancy), 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 assessment of chance to the woman on the possibility that her baby/ies will have Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome. If the chance of having a term pregnancy affected with any of these syndromes is 1 in 150 or higher (1 in 2 to 1 in 150), the pregnancy is regarded as higher chance and the woman will be offered a prenatal diagnostic (PND) test.

In January 2016 the UK NSC recommended an evaluative roll out of Non-Invasive Prenatal Testing (NIPT) in singleton pregnancies to assess what impact it would have on the existing NHS Fetal Anomaly Screening Programme. If the screening test shows that the chance of having a baby with Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome is higher than 1 in 150, (between 1 in 2 and 1 in 150) from either the combined test (T21 & T18/T13) or quadruple test (T21 only), this is called a higher chance result. Currently, women who have a higher chance result have the option of having an invasive diagnostic test (amniocentesis or CVS).

The proposed change is for NIPT to be offered as an additional option to women with singleton pregnancies who are deemed at higher chance following the combined or quadruple screen. NIPT is not diagnostic and an invasive diagnostic test is still required to receive a definitive diagnosis.

Through 2018 the FASP programme will undertake work at a national level to prepare for the commencement of the evaluative roll out which is currently estimated to be autumn 2018. This Classification: official
will require procurement of laboratory services in collaboration with NHS England for provision of the NIPT component of the screening for those women eligible according to the updated NHS screening pathway, development of operational guidance for laboratories and providers and education and training of staff representatives for all providers in England to prepare for delivery of cascade training locally.

Providers and laboratories will need to ensure that:

- all staff contributing to the screening pathway attend local cascade training delivered by the staff representative attending the national events;
- local pathways and policies to meet the requirements of the national pathway are updated and developed; and
- data specified by NHS FASP to support evaluation is submitted.

For the period of the evaluative roll out, operational guidance and pathways including the additional option of NIPT will not be included in this specification but will remain separate and accessible on the FASP pages of GOV.UK.

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:

https://www.gov.uk/topic/population-screening-programmes/fetal-anomaly

- work to national screening standards;
- provide data and reports against screening standards, key performance indicators (KPIs), and other measures as requested by the national screening programme;
- provide data on screening outcomes as required by the national screening programme;
- ensure appropriate governance structures are in place;
- 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 NHS England and the screening quality assurance service (SQAS) in reporting, investigating and managing screening safety incidents;
- respond to national action/lessons for example, change of software, equipment or equipment supplier, new technologies;
- ensure all health care professionals access appropriate training to maintain continuous professional development and competency;
- use materials provided by the national screening programme, for example leaflets, e-learning resources and operational guidance; and
- implement and support national IT developments.
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\(^{\text{th}}\) weeks of pregnancy confirmed by ultrasound scan and for Edwards’ Syndrome and Patau’s Syndrome screening using biochemical markers the eligible population are women with singleton and twin pregnancies ≤14\(^{\text{th}}\) weeks of pregnancy confirmed by ultrasound scan.

- **Inform** – during the first contact or booking visit with the midwife, verbal and written information about screening is given to the woman (using the Public Health England (PHE) booklet ‘Screening Tests for You and Your Baby’) to enable her to make an informed choice.

- **Offer** – the offer of screening and subsequent acceptance or decline should be documented.

- **Test** – combined screening is performed when the CRL is between 45.0mm to 84.0mm (10+0 to 14+1 weeks of pregnancy). The maternal serum sample can be taken between 10+0 to 14+1 weeks and the nuchal translucency measured between 11+2 and 14+1 weeks. For women ≥14+2 and ≤20+0 weeks, the quadruple test is performed for the assessment of chance of the baby being affected by 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 and between 18+0 and 23+0 weeks 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 in 150
- laboratories must be able to evidence that any planned upgrades to the software used to calculate risk in Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome screening meet the criteria to ensure compliance with the FASP programme software specification
- 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**

For the period of the evaluative roll out of NIPT as an additional option following a higher chance screening result please see the operational guidance on the NHS FASP pages of GOV.UK

Lower chance 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 chance results:
- the laboratory directly informs the designated lead within maternity service (e.g. Screening Coordinator) of the higher chance result
- a local protocol should be in place between the laboratory and maternity service to log receipt of higher chance 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 –**

Classification: official
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 chance 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

**Unaffected result:**

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

**Affected result:**

- the woman is given the opportunity to discuss the results with health professionals who are knowledgeable about Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome. This will include support for either continuing the pregnancy or a termination of pregnancy

- if the woman chooses to continue 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

When a baby is born unexpectedly affected by one of the conditions, a clinical review of the screening pathway will be undertaken and any learning shared to support ongoing quality improvement of the screening programme.

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 screening quality assurance service (SQAS), 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.
2.3 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 ensure that midwifery services are supported to facilitate early booking for maternity care and access to screening scans, agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations and organisational boundaries.

The provider should:

- develop joint audit and monitoring processes;
- develop an escalation process for screening incidents;
- 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 seek to provide robust electronic links with relevant organisations;
- ensure links with primary, secondary and tertiary care; and
- have 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.

2.4 Commissioning arrangements

Down's Syndrome, Edwards' Syndrome 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 public health commissioning, 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

2.5 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. It is recommended that the meetings should include representatives from programme coordination, clinical services, laboratory services and service management and governance leads.

3.3. Governance and leadership

The provider will:

- cooperate with and have representation on local oversight arrangements as agreed with NHS England commissioners;
- identify a trust director who is responsible for the screening programme;
- ensure internal clinical oversight and governance by an identified clinical lead and a programme manager;
- provide documented evidence of clinical governance that includes:
  - compliance with the NHS Trust and NHS England information governance/records management
  - user involvement, experience and complaints
  - failsafe procedures
  - risks and mitigation plans;
- ensure that there is regular monitoring and audit of the screening programme, and as part of the organisation’s clinical governance arrangements, the board is assured of the quality and integrity of the screening programme;
- produce an annual report of screening services, which is signed off by the board; and
- ensure the programme is delivered by trained workforce that meet national requirements.
3.4. Definition, identification and invitation of cohort/eligibility

Screening for Down’s syndrome
The target population is all pregnant women up to and including 20\(^{+0}\) confirmed weeks of pregnancy.

Screening for Edwards’ Syndrome and Patau’s Syndrome
The target population is all pregnant women up to and including 14\(^{+1}\) confirmed weeks of pregnancy. For women presenting from 14\(^{+2}\) weeks gestation the screening strategy for Edwards’ Syndrome and Patau’s Syndrome 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.
3.9. Information on Test/Screening Programme

Prior to any screening offer, the midwife will provide verbal and written information regarding screening utilising the PHE booklet ‘Screening Tests for You and Your Baby’ as a guide for discussion.

Where there are specific communication requirements, for example, English is not the woman’s first language or she has a 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 accept or decline the offer of screening or to decline should be recorded.

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 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;
- to 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;
- ensure that all diagnostic ultrasound procedures are 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;
- to undertake diagnostic procedures for women with a multiple pregnancy at a tertiary Fetal Medicine Unit; and
- ensure that cytogenetic laboratories performing analysis of prenatal samples are 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 screening result:

1. when the screening result is low chance
2. when a woman has a higher chance and has a PND result which confirms an unaffected pregnancy or declines PND
3. when a woman has a higher chance result and has a PND result which confirms diagnosis a baby affected by Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome 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’ Syndrome and Patau’s Syndrome 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 requirements are detailed in the Screening programme handbook and Ultrasound Practitioner’s handbook.
Providers should ensure training is completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

All professionals involved in the provision of ultrasound screening for Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome should comply with the training requirements detailed in the FASP 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(s) 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; and
- 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; and
- ensure that ultrasound equipment used to perform the NT and CRL measurement for the combined test should meet FASP requirements as set out in the software specification, for example, recording CRL and NT to 1 decimal place and be capable of producing and storing images of appropriate diagnostic quality. Royal College of Radiologists. Providing an Ultrasound Service.
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.
Section 4: National standards, risks and quality assurance

4.1. Key criteria and standards

The provider will:

- meet the acceptable national screening standards and work towards attaining and maintaining the achievable standards adhere to specific professional standards and guidance
  

- maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and make sure these points are reviewed in contracting and peer review processes

- participate fully in national quality assurance (QA) processes which includes:
  - submitting agreed minimum data sets and reports from external quality assurance schemes
  - undertaking ad-hoc audits and reviews as requested
  - completing self-assessment questionnaires / tools and associated evidence
  - responding to SQAS recommendations within agreed timescales providing specified evidence
  - producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations

- all screening laboratories must
  - be accredited by the UK Accreditation Service (UKAS) to ISO. ‘Medical laboratories – Requirements for quality and competence (ISO 15189)’ or be CPA accredited and actively transitioning towards ISO 15189
  - participate in EQA schemes accredited to ISO. ‘Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)’
  - meet the screening programme quality assurance requirements mapped to ISO 15189
  - and use ISO 15189 accredited reference laboratories

The UK Accreditation Service (UKAS) will look at both ISO 15189 and the screening requirements on behalf of PHE Screening Quality Assurance Services and the national screening programme

The provider (the screening laboratory lead) will:

- submit specified data set on time twice a year to the Down’s syndrome Screening Quality Assurance Support Service (DQASS)
- participate in the feedback call with the lead statistician
- act on actions specified in the DQASS report
- conform to the FASP requirements as specified in the programme handbooks
The provider (the screening support sonographer) will:

- inform and respond to DQASS requests to ensure the database of ultrasound practitioners and associated identity codes are accurate and up to date
- communicate report finding of CRL/NT biases to the individual ultrasound practitioners
- ensure actions plans are put in place for any data set assigned a red flag
- conform to the FASP requirements as specified in the programme handbooks
- operate and evidence
  - check points that track individuals through the screening pathway
  - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  - have process in place to mitigate against weakness in the pathway
- have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet national screening standards
- demonstrate that there are audited procedures, policies and protocols in place to make sure the screening programme consistently meets programme requirements
- ensure business continuity - business continuity plans must be in place where required
- ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance.

4.2 Service improvement

The provider will develop and agree with commissioners a CSIP (continual service improvement plan) in cases where national recommendations and/or screening standards are not fully met. The CSIP will include the following:

- action plans specifying changes and improvements that will be made during the contracting period
- defined timescales for actions
- roles and responsibilities for actions
- performance issues highlighted by the commissioners
- concerns raised by service users

4.3 New technologies

New technologies should not be used for screening unless approved by the UK National Screening Committee.
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’. For Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome providers are required to report against the following KPIs:

FA1 – completion of the screening request information.
FA3 – coverage of screening for Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome (pending outcome of pilot).

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;
- address any data/performance issues; and
- comply with the timely data requirements of the national screening programme and screening quality assurance service. This will include reporting quarterly against the programme KPIs, annually against the screening standards (except those reported as KPIs) and 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 must be shared with the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).