



Public Health
England



NHS public health functions agreement 2019-20

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 England and NHS Improvement



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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement 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 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 (the '2019-2020 agreement').

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-2020 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 2019-2020 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-2020 agreement in accordance with the procedures described in Chapter 3 of the 2019-2020 agreement

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

The 2019-2020 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 and NHS Improvement 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](#)
- [Antenatal and newborn screening key performance indicators \(KPIs\)](#)
- [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](#)
- [Royal College of Radiologists. Standards for provision of an ultrasound service](#)
- [Guidelines for the safe use of diagnostic ultrasound. British Medical Ultrasound Society](#)

The national screening team in Public Health England (PHE Screening) provides expert advice and support to the NHS Screening Programme. It does those things which make sense to do once rather than by each individual screening service. This includes:

- developing and monitoring standards
- producing public information leaflets
- quality assurance of local screening services

- developing and commissioning training and education

Providers should subscribe to the [PHE Screening blog](#) for the latest national news and updates. [National documentation and guidance](#) is published on [GOV.UK](#).

1.2 Aims

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

1.3 Objectives

- to offer screening to eligible women in England to assess the chance of having a baby with Down's syndrome, Edwards' syndrome or Patau's syndrome
- to facilitate choice in appropriate diagnostic testing and pregnancy management

1.4 Expected health outcomes

- women are supported to make personal informed decisions about their screening result
- diagnostic and follow on care services are easily accessible to support a woman's decision

1.5 Principles

- individuals will be treated with courtesy, respect and an understanding of their needs
- those participating in the Fetal Anomaly screening programme will have adequate information on the benefits and limitations of screening to enable a personal informed decision to be made before participating
- the target population will have equitable access and opportunity to screening
- screening will be effectively integrated across a pathway with clear lines of communication and accountability between the different providers, screening centres, primary care and secondary care

1.6 Personal informed choice

All screening is an individual choice. The UK NSC has published guidance for screening programmes in the 4 UK countries to follow. Everyone must be given the opportunity to make an informed choice about whether or not to be screened. The decision should be based on an understanding of:

- why they are being offered screening
- what happens during the test
- the benefits and risks of screening

- the potential outcomes (including types of result, further tests and treatment)
- what happens to their screening records

If someone is provided with the above information about the programme and chooses not to attend or have screening, then this is a valid choice and must be respected.

Addressing inequalities and ensuring equal access to screening

Screening is inherently equitable because it is offered to all individuals within the eligible population. One of the objectives of the NHS Screening Programmes is to help reduce health inequalities. The PHE Screening inequalities strategy has more information.

Sharing personal information

Under the [2010 Equality Act](#), screening services are required to anticipate and prevent discrimination against people with learning disabilities.

The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals should have the confidence to share relevant information with screening services in the best interests of their patients. For example, a GP may know that an individual with a learning disability requires accessible information about screening in easy read format or needs a longer than normal appointment slot.

See [NHS England's information sharing policy](#) for more detailed guidance.

PHE Screening's privacy notice has more information about how screening data is shared within the legal requirements, including those of the General Data Protection Regulation (GDPR).

Reasonable adjustments.

Under the [2010 Equality Act](#), screening providers have a legal duty to make reasonable adjustments to make sure services are accessible to disabled people as well as everybody else.

Screening providers must follow the Accessible Information Standard by law. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information they can easily read or understand with support, so they can communicate effectively with health and social care services.

As part of the Accessible Information Standard, screening providers must do 5 things.

1. Ask people if they have any information or communication needs, and find out how to meet their needs.
2. Record those needs clearly and in a set way.
3. Highlight or flag the person's file or notes so it is clear that they have information or communication needs and how to meet those needs.
4. Share information about people's information and communication needs with other providers of NHS and adult social care, when they have consent or permission to do so.
5. Take steps to ensure that people receive information which they can access and understand, and receive communication support if they need it.

National accessible information materials

PHE Screening has published national easy read versions of screening information leaflets and screening appointment letter templates.

Local screening providers should use these national materials when inviting individuals for screening who have been identified as needing information in an easy read format.

Large print and audio (MP3) versions of standard information leaflets are also available to download from GOV.UK for people with sight loss.

Local screening providers should send any individual requests for hard copy Braille versions of PHE Screening leaflets to the screening helpdesk.

1.7 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
- 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 and opportunity 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
- foster good relations between different people when carrying out their activities

Section 2: Scope of Screening Programme

2.1 Description of screening programme

The provider is expected to follow, guidance from the national screening programme as detailed in the [standards](#) and [policies](#)

To make sure there is national consistency the provider should:

- 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
- make sure 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 [joint checks and audit](#) mechanisms where required to ensure safe and timely processes across the whole screening pathway and drive continuous quality improvement
- work with NHS England and NHS Improvement 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
- make sure 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
- implement and support national IT developments

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:

- the combined test can be performed when the crown rump length (CRL) is between 45.0mm to 84.0mm which corresponds to 11⁺² to 14⁺¹ weeks of gestation. If the ultrasound measurement shows that the CRL is less than 45.0mm, the woman should be recalled for a further scan to measure the nuchal translucency (NT)
- If the CRL is greater than 84.0mm, the second trimester quadruple test should be offered.

- the quadruple test which measures four maternal biochemical markers for use in screening for Down's syndrome only can be performed when the head circumference (HC) is equal to or more than 101.0mm (between 14⁺² to 20⁺⁰ weeks of pregnancy),

The gestational age, for the purposes of standardising marker values, should be calculated by use of crown rump length (CRL) obtained by ultrasound measurement. Combined screening can be offered (including IVF pregnancies) where the crown rump length (CRL) measurement of the baby is between 45.0mm and 84.0mm.

Maternal age in in-vitro fertilisation (IVF) pregnancies using donor eggs should be derived from the date of birth or age of the donor at the time of egg collection as this is required for calculation of prior chance.

The first trimester combined test allows earlier decision making for parents. In practice, two models are available for performing the combined test:

- a maternal blood specimen may be taken (from 10 weeks onwards) prior to the ultrasound scan. The biochemistry results can then be made available at the time of the NT scan and the combined test result can be calculated at the time of the appointment. Although the result may be calculated by the sonographer, the laboratory remains responsible for the software that calculates the screening. Midwifery and/or ultrasound departments must have a process in place to share ultrasound measurements and final screening results with the laboratory to enable timely audit of all results.
- a maternal blood specimen may be taken at the time of the ultrasound scan and the combined test result made available within a few days of the biochemistry results being authorised by the laboratory.

To complete the ultrasound component of this screening strategy, the scan appointment should allocate time to incorporate pre-scan information giving, the ultrasound examination, and post scan information giving 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 or 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 the option of a prenatal diagnostic (PND) test.

In January 2016 the [UK National Screening Committee](#) (UK NSC) recommended an evaluative roll out of Non-Invasive Prenatal Testing (NIPT).

Through 2019 the FASP programme will undertake work at a national level to prepare for the commencement of an evaluative roll out.

In preparation for this evaluative roll out Providers will make sure all staff contributing to the screening service are appropriately informed and trained in line with the national requirements.

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](#).

2.2 Screening pathway

A full description of the screening pathway is given below, along with a diagram of the [pathway](#). Providers must be familiar with the screening pathway and the timeframes in which to refer women ([figure 1](#)).

The screening pathway consists of the following:

- **Identify population** – the eligible population is identified through maternity services and screening offered.
- the combined test for Down's syndrome, Edwards' syndrome and Patau's syndrome can be performed when the crown rump length (CRL) is between 45.0mm to 84.0mm which corresponds to 11⁺² to 14⁺¹ weeks of gestation. If the ultrasound measurement shows that the CRL is less than 45.0mm, the woman should be recalled for a further scan to measure the nuchal translucency (NT)
- If the CRL is greater than 84.0mm, the second trimester quadruple test for Down's syndrome should be offered.
- the quadruple test for Down's syndrome can be offered when the head circumference (HC) is equal to or more than 101.0mm (greater than or equal to 14⁺² and less than or equal to 20⁺⁰ weeks of pregnancy),
- **Inform** – during the first contact or booking visit with the midwife, verbal and written information about screening should be given to the woman (using the Public Health England (PHE) booklet '[Screening Tests for You and Your Baby](#)') to enable her to make a personal informed choice.
- **Offer** – All eligible women should be offered screening for Down's syndrome, Edwards' syndrome and Patau's syndrome. The offer of screening and subsequent acceptance or decline must be documented in the patient held record/maternity notes (paper or electronic) and on the laboratory request (paper or electronic).

For combined screening women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only.

For quadruple screening women can choose:

- not to have screening
- To have screening for T21 only
- **Test** – combined screening is performed in singleton or twin pregnancies when the CRL is between 45.0mm to 84.0mm (11⁺² and 14⁺¹ weeks of pregnancy) for Down's syndrome, Edwards' syndrome or Patau's syndrome.
- quadruple test is performed in singleton or twin pregnancies when the CRL is greater than 84.0mm and HC is equal to or greater than 101.00mm for Down's syndrome.

- The recommended screening strategy for Edwards' syndrome and Patau's syndrome for women who present for care at greater than 14⁺² weeks of pregnancy is the fetal anomaly scan (performed up to 23⁺⁰ weeks of pregnancy).
- The timing of the ultrasound measurements (i.e. CRL/NT) and the collection of the maternal blood sample are defined locally and are the responsibility of the provider. There is evidence from screening safety incidents that completing both components (ultrasound and blood sampling) at the same time reduces the chances of incomplete screening.
- where a nuchal translucency measurement of ≥ 3.5 mm is recorded and combined screening is accepted, the blood sample must be taken and sent to the laboratory for analysis. Referral should not be delayed to await the biochemistry results. 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 result 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 chance 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 and NHS Improvement should check these local protocols as they are critical to ensure adequate and timely follow up of results.

Management of results

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 by the maternity service and offered an appointment to discuss the result 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

- Pre Natal Diagnosis (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) or amniocentesis
- where the indication for undertaking PND is a higher chance screening result, the sample is sent to the genomic laboratory for quantitative fluorescence polymerase chain reaction (QF-PCR) testing.
- In some cases a confined placental mosaicism (CPM) may be present. Confined placental mosaicism is the presence of a chromosome anomaly in the placenta of a fetus with a normal karyotype therefore, to minimize the risk of making decisions

regarding the ongoing pregnancy on the result of a CVS that reflects the cells of the placenta with an unaffected fetus, the national screening programme recommends that:

- where the QF-PCR result from a CVS sample indicates that the baby may be affected by Down's syndrome, Edwards' syndrome or Patau's syndrome and in the absence of any suspected or identified structural anomalies on ultrasound scan, the culture result should be used to confirm the QF-PCR result prior to any decisions being made regarding ongoing care or termination of the pregnancy.
- NB: there will be certain instances where the result should not be based on QF-PCR alone due to a small but significant risk of CPM and culture analysis may be appropriate. For more information refer to the [Association of Clinical Genomic Science \(ACGS\) best practice guidelines](#)
- where structural anomalies are present on ultrasound scan and the QF-PCR result indicates that the baby may be affected by Down's syndrome, Edwards' syndrome or Patau's syndrome, the clinician should discuss the options for ongoing pregnancy care with the woman.
- 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 or 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 and RCOG guidance

When a baby is born unexpectedly affected by one of the conditions screened for, 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 and NHS Improvement screening and immunisation teams to develop, implement and maintain appropriate risk reduction measures. This should involve mechanisms to audit implementation, report incidents, ensure staff training, development and competencies, and have appropriate links with internal governance arrangements.

Figure 1 – NHS FASP Screening Pathway for Down’s Syndrome, Edwards’ Syndrome and Patau’s Syndrome



NHS Fetal Anomaly Screening Programme care pathway: Down’s (T21), Edwards’ (T18) and Patau’s (T13)



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 and NHS Improvement is expected to ensure that the whole pathway is robust.

The provider is expected to make sure 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:

- providing robust screening coordination
- making sure 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
- developing joint audit and monitoring processes
- operating an escalation process for screening incidents
- joint checks and audit mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS England and NHS Improvement and Public Health England initiatives in screening pathway development in line with NHS screening programmes expectations
- providing 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.

2.4 Commissioning arrangements

Down's syndrome, Edwards' syndrome and Patau's syndrome screening services are commissioned by NHS England and NHS Improvement alongside specialised services where appropriate. Commissioning of the screening pathway involves commissioning at different levels which may include NHS England and NHS Improvement public health commissioning, CCGs, specialist commissioning and directly by maternity services.

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 is 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 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 and NHS Improvement 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, for example, screening coordinators and screening support sonographers, clinical services, laboratory services, 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 and NHS Improvement commissioners
- identify a trust director or senior nominated person who is responsible for the screening programme
- ensure internal clinical oversight and governance by an identified clinical lead and a programme manager. The clinical lead has overall clinical responsibility for the programme across the pathway.
- provide documented evidence of clinical governance that includes:
 - compliance with NHS Trust and NHS England and NHS Improvement information governance/records management
 - user involvement, experience and complaints
 - joint checks and audit mechanisms
 - 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

- 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

See section 2.2 for detailed information of the target population.

Screening for Edwards' Syndrome and Patau's Syndrome

See 2.2 for detailed information of the target population.

3.5 Location(s) of programme delivery

The provider should make sure there is 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 make sure sufficient resources are in place to meet screening demand within required timescales without compromising relevant standards and guidelines. Timeliness is essential and is a key criteria of quality along all parts of the screening pathway.

3.7 Entry into the screening programme

Women are 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 make sure there is 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 genomic 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 is expected to make sure 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 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](#)
- use chance 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 chance calculation.
- 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.
- genomic laboratories performing analysis of prenatal samples should be UKAS accredited and participate in an external quality assurance scheme (i.e. GenQA). See section 4 – national standards, risks and quality assurance for further detail.

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 lower 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 or Patau's syndrome and has been provided with information on her further options.

3.13 Public Information

PHE Screening uses published best practice processes to develop public information leaflets. It also works with NHS Digital to ensure that information on the NHS.UK website for the public is accurate.

Providers must:

- use the public information leaflets from PHE Screening at all stages of the screening pathway
- involve PHE in the development of any local awareness campaigns
- not duplicate clinical information on local websites
- involve PHE if they want to move from providing printed leaflets to online sources of information

Using the leaflets provided by PHE ensures accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening must be consulted and involved before developing any other supporting materials.

Providers must involve PHE 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 so that the national screening helpdesk is not overloaded.

Local provider websites must not duplicate clinical information about screening but should be restricted to contact and logistical information. Links should be provided to the national information on NHS.UK (<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.

Ordering leaflets

Providers can order leaflets developed by PHE Screening for free for core screening purposes.

Leaflets are regularly updated so providers should not order more than 3 months' supply, or stockpile leaflets, as they could become out of date and need to be destroyed. Leaflets for non-core activities, such as local health promotion purposes, can be bought from the national print provider.

PHE can only provide one leaflet per person per screening episode. A screening episode is defined as an invitation (with any subsequent reminders) for a particular screening test. People who are referred for further assessment following a screen should get a single copy of the appropriate follow-up leaflet.

Antenatal and newborn screening is treated as a single episode, so women should get a single copy of Screening Tests For You and Your Baby to last the entire antenatal and newborn period. (include this text for the ANNB programmes)

This means that duplicate copies should not be provided with reminder letters or if people lose or forget their leaflet. They should be signposted to electronic sources of information instead.

3.14 Exclusion criteria

Screening for Down's syndrome

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

Screening for Edwards' syndrome and Patau's syndrome

Women presenting for maternity care at greater than 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](#) .

Staffing, education and training

PHE screening makes available a variety of education and training for NHS screening staff. Evidence based, up-to-date e-learning resources, study days and courses can be accessed here <https://www.gov.uk/guidance/nhs-population-screening-education-and-training>

In addition each screening programme will have specific guidance for the initial training and ongoing learning for screeners. This learning should be facilitated, supported and monitored by local screening providers. In line with professional regulations individuals have a responsibility to ensure their practice is up-to-date and evidence based. Local programmes can use the national programme training guidance and resources to support this.

Providers must 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 make sure 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 an 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)

3.15 User involvement

The provider(s) should:

- 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 and NHS Improvement on request

3.16 Premises and equipment

The provider will:

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

- have appropriate policies in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability
- make sure 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
- make sure 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.](#)

3.17 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

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 NHS Improvement 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 process
- participate fully in national quality assurance (QA) processes which include:
 - 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
- 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
- comply with guidance on [managing safety incidents in national screening programmes](#) and [NHS England serious incident framework](#)
- make sure business continuity plans are in place where required
- ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance
- all screening laboratories, including genomics laboratories involved in the screening programme, must
 - be accredited by (or actively working towards) the [UK Accreditation Service](#)

(UKAS) to ISO. 'Medical laboratories – Requirements for quality and competence ([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 disclose these assessments to PHE Screening

The provider (the screening laboratory lead) must:

- 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) must:

- 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
- make sure 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](#)

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

New technologies:

New technologies should not be used for screening unless approved by the UK National Screening Committee.

Section 5: Data and Intelligence

The collection, analysis and comparison of good quality data is critical for the all NHS screening programmes in England.

PHE Screening aims to develop a consistent approach to data collection and reporting across all screening programmes and is committed to making sure that stakeholders have access to:

- reliable and timely information about the quality of the screening programme
- data at local, regional and national level
- quality measures across the screening pathway without gaps or duplications

Performance thresholds are selected to align with existing screening standards and service objectives; 1 or 2 thresholds are specified.

The acceptable threshold is the lowest level of performance which screening services are expected to attain to assure patient safety and service effectiveness. All screening services should exceed the acceptable threshold and agree service improvement plans to meet the achievable threshold. Screening services not meeting the acceptable threshold are expected to put in place recovery plans to deliver rapid and sustained improvement.

The achievable threshold represents the level at which the screening service is likely to be running optimally. All screening services should aspire to attain and maintain performance at or above this level.

5.1 Key performance indicators (KPIs) and screening standards

The provider should adhere to the requirements as specified on following web pages:

KPIs: “Reporting data definitions” at <https://www.gov.uk/topic/population-screening-programmes/population-screening-data-key-performance-indicators>

Screening standards: <https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>

Please note that indicator definitions are updated regularly and you should always obtain the most recent version available.

5.2 Data collection, monitoring and reporting

Providers should:

- make sure that appropriate systems are in place to support programme delivery including audit and monitoring functions
- continually monitor and collect data regarding delivery of the service
- address any data/performance issues
- 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.

FASP Programme specific measures:

For quality and monitoring of the screening pathway, data must be provided according to the following schedule or on request from PHE Screening:

- annual submission of data on [national screening standards](#).
- Bi-annual submission by screening laboratories to [Down's syndrome Screening Quality Assurance Support Service \(DQASS\)](#).

For quality and monitoring of screening programme outcomes, information must be shared with the [National Congenital Anomaly and Rare Disease Registration Service \(NCARDRS\)](#) according to the following schedule or on request from PHE Screening:

- screening laboratories for Down's syndrome, Edwards' syndrome and Patau's syndrome 3 monthly data report of all higher chance results
- follow up of specific information requests as required by NCARDRS