



Public Health
England



NHS public health functions agreement 2019-20

**Service specification No.17
NHS Fetal Anomaly Screening Programme –
18⁺⁰ to 20⁺⁶ week fetal anomaly scan**

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.17

This is a service specification to accompany the 'NHS public health functions agreement 2019-2020 (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')

Section 1: Purpose of Screening Programme

1.1 Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of fetal anomaly ultrasound screening services as part of the Fetal Anomaly Screening Programme (FASP).

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

This specification is not designated to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. of 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 16 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 role of PHE Screening

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](https://www.gov.uk).

1.2 Aims

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

1.3 Objectives

The objectives of the 18⁺⁰ to 20⁺⁶ weeks ultrasound scan are to:

- offer screening to eligible women in England to identify anomalies that are life limiting
- identify anomalies which may benefit from antenatal treatment
- identify anomalies which require early intervention following delivery
- to facilitate choice in appropriate diagnostic testing and pregnancy management

1.4 Expected health outcome

The following are expected in accordance to the programme's overall aims and objectives:

- women are supported to make personal informed choices about how they respond to the identification of a fetal anomaly
- diagnostic and follow on care services are easily accessible and 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 to allow a personal informed choice to be made before participating
- the target population will have equitable access to screening
- screening will be effectively integrated across a pathway with clear lines of communication 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 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 and NHS Improvement 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](https://www.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 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

In delivering a national screening programme the Provider is expected to follow guidance from the national screening programme and 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

The Fetal Anomaly Screening Programme (NHS FASP) recommends the offer of a mid-pregnancy scan which is undertaken between 18⁺⁰ to 20⁺⁶ weeks of pregnancy to screen for major fetal anomalies. The examination should be undertaken in accordance with the requirements of the FASP guidance in the [screening programme handbook](#) (Anatomical Base Menu and Fetal Cardiac Protocol).

The first screening scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for Down's syndrome, Edwards' syndrome and Patau's syndrome. Where an earlier pregnancy scan is undertaken to assess gestational age and viability, and the Crown Rump Length (CRL) measurement is less than 45.0mm, a repeat scan is required for women accepting screening for Down's syndrome, Edwards' syndrome and Patau's syndrome.

The second scan is undertaken between 18⁺⁰ to 20⁺⁶ weeks of pregnancy and screens for major structural abnormalities.

The [11 auditable conditions](#) currently screened for are:

- Anencephaly;
- Open spina bifida;
- Cleft lip;
- Diaphragmatic hernia;
- Gastroschisis;
- Exomphalos;
- Serious cardiac abnormalities;
- Bilateral renal agenesis;
- Lethal skeletal dysplasia;
- Edwards' syndrome (Trisomy 13)
- Patau's syndrome (Trisomy 18)

The ultrasound scan appointment should incorporate pre-scan information giving, the ultrasound examination, post-scan information giving and reporting. The time allocation for appointments to meet these requirements for a singleton pregnancy is a minimum of thirty (30) minutes and for a multiple pregnancy is forty five (45) minutes.

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 fetal anomaly screening pathway consists of the following:

- **identify population** - the eligible population is identified through maternity services. For fetal anomaly screening the eligible population are women less than or equal to 23⁺⁰ weeks of pregnancy confirmed by ultrasound scan
- **inform** - during the 'first contact' or 'booking visit' with the midwife, verbal and written information should be given about the fetal anomaly scan (using NHS Screening programmes booklet '[Screening Tests for You and Your Baby](#)') to enable women to make a personal informed choice.
- **offer** - the offer of screening and subsequent acceptance or decline must should be documented in the patient held record/maternity notes (paper or electronic)
- **test** - the fetal anomaly ultrasound scan should be performed between 18⁺⁰ to 20⁺⁶ weeks gestation. Where the image quality of the first scan is compromised a single further scan should be offered by 23⁺⁰ weeks gestation
- the fetal anomaly ultrasound scan should be performed to comply with the requirements of the anatomical base menu and fetal cardiac protocol which are detailed in the [programme handbook](#).

- a local failsafe protocol must be in place to ensure that all women who accept fetal anomaly screening complete the testing pathway

Management of results:

No anomaly suspected: all women should be notified of their scan findings at the time of the screen. The results should be documented in the patient held record/maternity notes (paper or electronic).

Anomaly suspected: the woman is informed at the time of the scan and the sonographer/midwife/clinician and woman discuss the options available

1. to have no further investigations
2. accept referral for a further scan/investigation i.e. to a second sonographer/obstetrician/fetal medicine department as per local protocol. The result should be recorded in the health record/IT system

Discussion should include sufficient information to ensure that the woman is aware of the purpose, benefits, limitations and implications of undergoing further investigations.

- if further investigation 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).

Following **further scan/investigation** there are the following possible outcomes:

- **No anomaly identified:** all women should be notified of their scan findings at the time of the screen. The results should be documented in the health record/IT system and the pregnancy outcome obtained.
- **Anomaly suspected/identified:** the woman is informed at the time of the scan. The sonographer/midwife/clinician and mother discuss the findings and the two options available
 - Declines further management: decision is recorded in the health record. The woman continues with pregnancy and outcome is obtained. A mechanism should be in place to alert the practitioners providing subsequent care (including the newborn physical examination).
 - Accepts referral to either an in-house consultant with fetal anomaly/ultrasound experience or a fetal medicine unit (FMU) depending on the condition suspected and local protocol

Diagnostic Testing

Some fetal anomalies will be confirmed by scan alone and others will require prenatal diagnostic testing.

- Where **prenatal diagnostic testing** (PND) is required discussion should include sufficient information to ensure that the woman is aware of the purpose, benefits, limitations and implications of undergoing a diagnostic test
 - 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
- 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.
- where the indication for undertaking PND is a suspected fetal anomaly the sample is sent to the cytogenetic laboratory for full karyotype
- **Unaffected PND result:** the woman will continue with pregnancy and outcome is obtained.
- local protocols should be in place to ensure multi-disciplinary links and close working relationships between maternity services and specialist services are established and function well

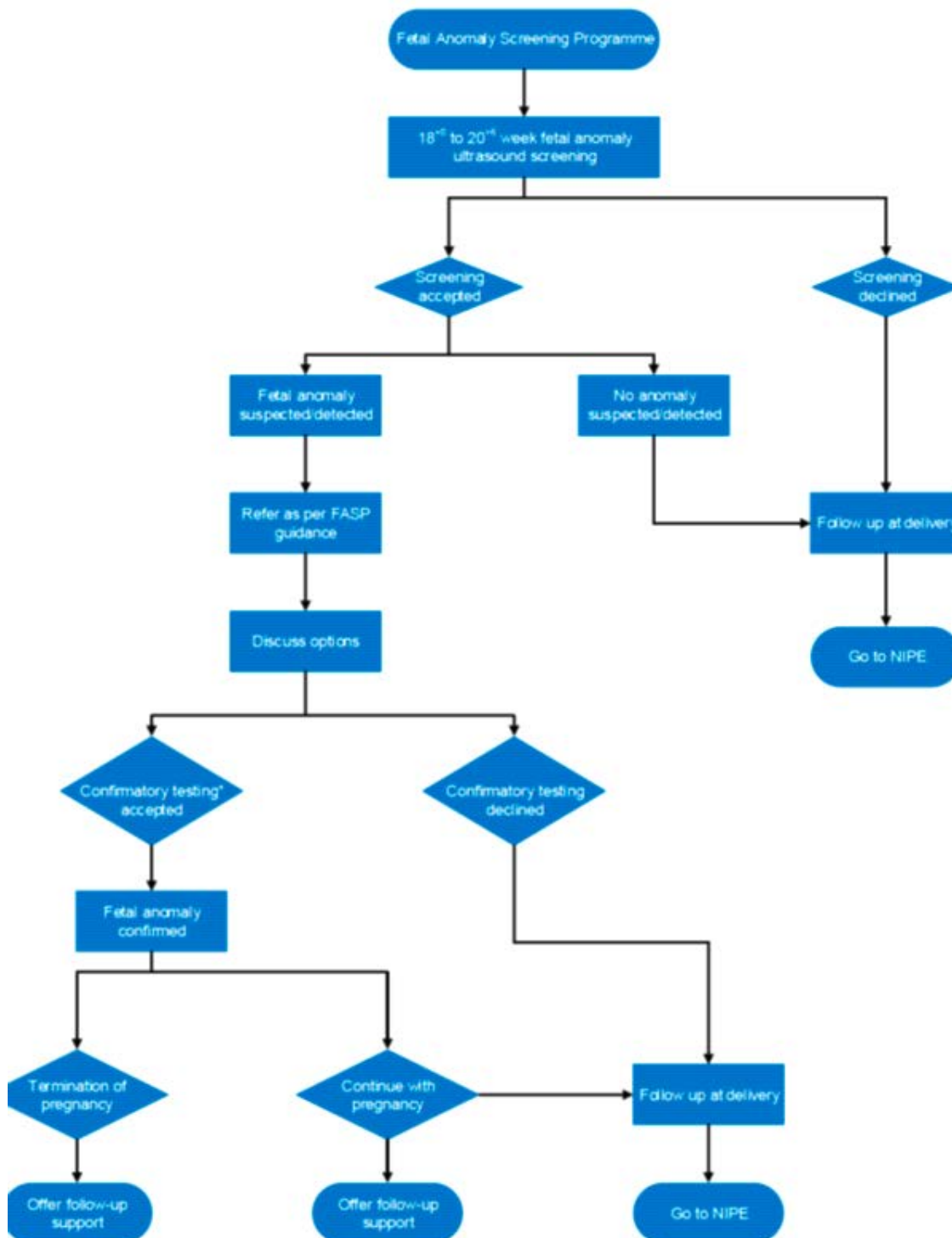
Confirmation of fetal anomaly:

- the woman is given the opportunity to discuss the results with health professionals who are knowledgeable about the identified fetal anomaly. This will include the offer of a termination of pregnancy or continuing support through pregnancy
- if the woman chooses to continue with her pregnancy a referral to appropriate paediatric and support services should be made
- following diagnosis of a **fetal anomaly** (either by ultrasound or PND), 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
- 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 11 auditable conditions, a clinical review of the screening pathway should 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 pathways in the light of national FASP programme guidance and work with the screening quality assurance service 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 Screening Pathway for fetal anomaly scan at 18⁺⁰ to 20⁺⁶ weeks of pregnancy



*Confirmatory testing may include a further ultrasound scan for confirmation of anomaly plus or minus Invasive Prenatal Diagnosis?

2.3 Roles and accountability throughout the pathway

The FASP programme is dependent on systematic specified relationships between stakeholders. Stakeholders include maternity services, obstetric ultrasound services, the 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 which links with all elements of the screening pathway
- making sure 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
- 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 care
- the need for robust IT systems across the screening pathway
- For further specific staffing requirements refer to section 3.15.

2.4 Commissioning arrangements

Fetal anomaly screening services are commissioned by NHS England and NHS Improvement alongside specialised services where appropriate. Commissioning the fetal anomaly screening pathway involves commissioning at different levels which may include NHS England and NHS Improvement public health commissioning, CCGs, specialised 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 aided by 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 will meet at regular intervals (at least annually) to monitor and review the local screening pathway. The meetings will 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 meets national requirements

3.4 Definition, identification and invitation of cohort/eligibility

The target screening population is all pregnant women less than or equal to 23⁺⁰ confirmed weeks of pregnancy.

3.5 Location(s) of programme delivery

The provider should make sure there is appropriate accessible service provision for the specified population while assuring that all locations where fetal anomaly 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 Fetal Anomaly 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), fetal medicine, genomic laboratory and medicine 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 (e.g. English is not the woman's first language, visual/hearing impairment) appropriate interpretation services should be used during the booking appointment and appropriate information provided. All women, including those with special requirements, will be 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 to decline screening should be recorded appropriately by the midwife at booking and confirmed by the sonographer prior to the fetal anomaly scan being undertaken.

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

Providers should make sure that the fetal anomaly ultrasound scan is performed by a health professional with at least one of the qualifications outlined in Section 3.15 Staffing.

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).

3.11 Results giving, reporting and recording

Screening results should be explained to women at the time of the scan by appropriately trained staff and recorded in the woman's health record/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 when:

- no fetal anomaly is identified
- a fetal anomaly is confirmed and the woman 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) (<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) (<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

Women presenting for maternity care greater than or equal to 23⁺¹ weeks gestation

3.15 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.

The provider must have in place a dedicated screening coordinator/screening midwife and a lead screening sonographer (with appropriate deputy 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 make sure training is completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

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 will 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 Skills Training Module.

3.16 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

3.17 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.](#)

3.18 Safety and 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 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
- 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 be 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.

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](#)

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:

- notification of all suspected and confirmed anomalies from screening undertaken in pregnancy at the time of scan
- follow up of specific information requests as required by NCARDRS