Department of Health

NHS England

NHS public health functions agreement 2015-16

Service specification no.17

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

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

Prepared by Public Health England

Contents

Service specification No.17

This is a service specification within Annex C of the ‘NHS public health functions agreement 2015-16 (the ‘2015-16 agreement’) published in December 2014.

This service specification is to be applied by NHS England in accordance with the 2015-16 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 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

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

The 2015-16 agreement including all service specifications within Annex C 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 for the population for whom it is responsible and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC).

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:

- current FASP guidance www.fetalanomaly.screening.nhs.uk.
- National Ultrasound Guidance and Standards: 18^{+0}-20^{+6} week fetal anomaly scan' at: http://fetalanomaly.screening.nhs.uk/standardsandpolicies
- FASP Ultrasound Practitioners Handbook http://www.fetalanomaly.screening.nhs.uk/combinedscreeningresources
- FASP Laboratory Handbook www.fetalanomaly.screening.nhs.uk
- any separate service specifications for the screening laboratory used by the provider for antenatal screening services
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/incidents
- Failsafe Processes www.screening.nhs.uk/failsafe
- Guidance & updates on Key Performance Indicators can be found at http://www.screening.nhs.uk/kpi

- Antenatal Screening – Working Standards: National Down's Syndrome Screening Programme for England (2007)
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/quality-assurance
- Antenatal Screening – Working Standards: National Down's Syndrome Screening Programme for England (2007)
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care June 2010 http://www.nice.org.uk/guidance/CG62
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline CG 129 Antenatal care September 2011 http://www.nice.org.uk/guidance/CG129
- Royal College of Radiologists. Standards for Ultrasound Equipment
- https://www.rcr.ac.uk/docs/radiology/pdf/StandardsforUltrasoundEquipmentJan2005.pdf
- Service specification No17, fetal Anomaly Screening
- http://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016
- 'Maternity Pathway Payments: Who pays for what' http://www.england.nhs.uk/wp-content/uploads/2014/01/who-pays-for-what-fin.pdf

1.2. Aim

The NHS Fetal Anomaly Screening Programme aims to ensure that there is equal access to uniform and quality-assured screening across England and that eligible women are provided with high quality information, so that they can make an 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 abnormalities incompatible with life
- identify abnormalities which may benefit from antenatal treatment
- identify abnormalities which require early intervention following delivery

- to facilitate choice in appropriate diagnostic testing and pregnancy management

1.4. Expected health outcomes

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

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

1.5. Principles

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

1.6. Equality

The provider will be able to demonstrate what systems are in place to ensure equity of access to screening and subsequent diagnostic testing. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of race, culture, sexual preference, physical or learning disabilities.

The provider will have procedures in place to identify and support those women who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; asylum seekers; women in prison; women with drug or alcohol harm issues; women with learning disabilities; women experiencing domestic abuse, with physical disabilities or women with communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such women.

Screening will be effectively integrated across a pathway with clear lines of communication between the different providers, screening centres, primary care and secondary care.

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 Fetal Anomaly screening Programme recommend 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 (Anatomical Base Menu and Fetal Cardiac Protocol (www.fetalanomaly.screening.nhs.uk/standards)

The first scan is an early pregnancy scan performed from 8^{+0} weeks gestation and is used mainly for dating the pregnancy and confirming viability. 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 counselling, the ultrasound examination, post-scan counselling 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.

In delivering a national screening programme and to ensure national consistency the local provider is expected to fulfil the following, in conjunction with guidance from the National Programme where appropriate and as detailed in the standard and policies available on www.fetalanomaly.screening.nhs.uk/standards

- work to nationally agreed common standards and policies
- be required to implement and support national IT developments
- use materials provided by the national screening programme, e.g. leaflets, training media and protocols for their use
- be required to respond to national action/lessons such as change of software, equipment supplier, techniques
- work with NHS England in reporting on and resolving serious incidents
- provide data and reports against programme standards, key performance indicators (KPIs), and quality indicators as required by the national screening programme on behalf of the UK NSC
- take part in quality assurance processes and implement changes recommended by QA including urgent suspension of services if required
- implement and monitor failsafe procedures and continuously ensure quality
- work with bordering providers to ensure that handover of results or patients is smooth and robust
- participate in evaluation of the screening programme
- ensure all health care professionals access appropriate training to maintain continuous professional development and competency
- ensure appropriate governance structures are in place

2.2. Care pathway

A description of the fetal anomaly screening pathway is given below, along with a diagram of the pathways showing failsafe processes (Figure 1)

A full description of the screening pathway can be found on the Map of Medicine at: www.mapofmedicine.com

The fetal anomaly screening pathway consists of the following:

- the eligible population is identified through maternity antenatal care services. For fetal anomaly screening the eligible population are women <23^{+0} weeks of pregnancy confirmed by ultrasound scan
- during the ‘first contact’ or ‘booking visit’ with the midwife, verbal and written information will be given about the fetal anomaly scan is given to the woman (using UK NSC booklet ‘Screening Tests for You and Your Baby’) to enable her to make an informed choice and screening offered

- the offer of fetal anomaly screening and subsequent acceptance or decline should be documented in the woman's health records/IT system
- the fetal anomaly ultrasound scan should be performed between 18^{+0}-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 fetal anatomical survey and fetal cardiac protocol which are detailed in the programme standards at: www.fetalanomaly.screening.nhs.uk/standards, Note: an additional view (3 Vessel & trachea view) has been added to the Fetal Cardiac Protocol and plans to commence training of sonographers and introduction of the viewing and reporting of this view should be developed and commenced during 2015/16 with the aim for full compliance by Mid-2016.
- a local 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 health record/IT system.

Anomaly suspected: the woman is informed at the time of the scan the sonographer/midwife/clinician and mother 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 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 (insert ref). 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
  - 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
  - **Normal PND result**: the woman will continue with pregnancy and outcome is obtained.
- 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
- 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 or continuing support through pregnancy
- if the woman chooses not to undergo termination and continues with her pregnancy a referral to appropriate paediatric and support services should be made
- a pregnancy outcome should be recorded and a mechanism should be in place to alert the practitioners providing subsequent care (including the newborn physical examination)
- if termination of pregnancy is accepted, this should be undertaken in line with the Abortion Act 1967 and RCOG guidance

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

All providers are expected to review and risk assess local pathways in the light of national FASP programme guidance and work with the Quality Assurance teams, and NHS England Screening and Immunisation Leads and Teams to develop, implement and maintain appropriate risk reduction measures. This should involve mechanisms to audit implementation, report incidents, ensure staff training and development and competencies, and have appropriate links with internal governance arrangements.

A full description of the screening pathway can be found on the map of medicine at http://healthguides.mapofmedicine.com

A pathway for Fetal Anomaly screening with identification of failsafe points is shown in figure 1 in section 2.3 below.

2.3. Failsafe Procedures

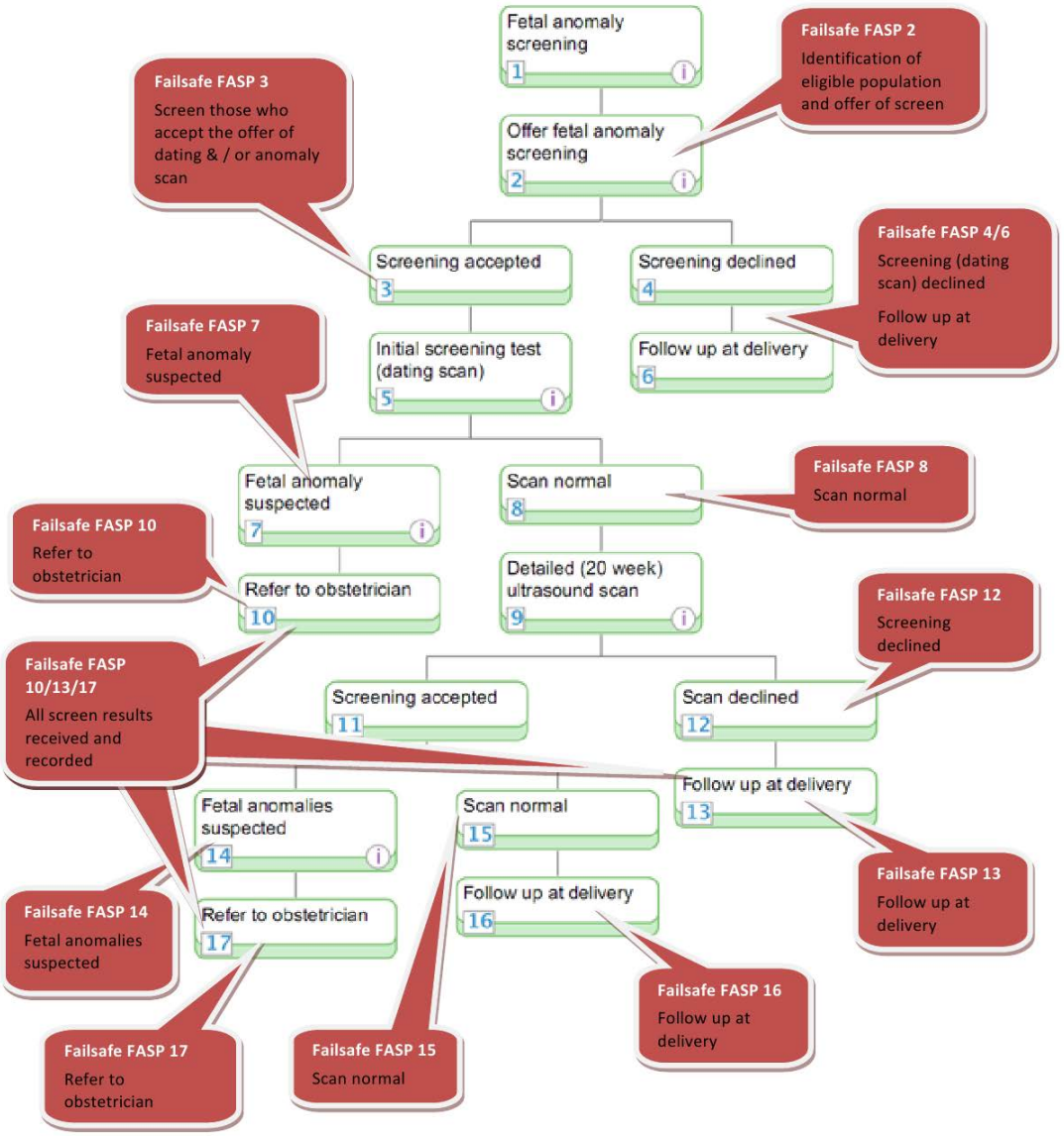
Quality assurance within the screening pathway is managed by including failsafe processes. Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to identify (i) what is going wrong and (ii) what action follows to ensure a safe outcome.

The provider is expected to:

- have and evidence appropriate failsafe mechanisms in place across the whole screening pathway
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with NHS England and Quality Assurance Teams to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that appropriate links are made with internal governance arrangements, such as risk registers
- ensure staff have access to appropriate training and development to maintain competencies

A Map of Medicine screening pathway for the 18^{+0}-20^{+6} week fetal anomaly scan with failsafe points is available on the Map of Medicine website and in Figure 1 below.

Figure 1 Map of Medicine screening pathway with failsafe points



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

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

- provision of robust screening coordination which links with all elements of the screening pathway
- ensuring that community midwifery services are supported to facilitate early booking for maternity care agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations and organisational boundaries
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms where required to ensure safe and timely processes across the whole screening pathway
- contributing to any NHS England and public health screening lead initiatives in screening pathway development in line with UK NSC 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.

2.5. Commissioning Arrangements

Fetal anomaly screening services will be commissioned by NHS England alongside specialised services where appropriate. Commissioning the fetal anomaly screening pathway involves commissioning at different levels which may include Area Teams, CCGs, and directly by maternity services. Refer to ‘Maternity Pathway Payments: Who pays for what’ See section 1.1.

2.6. Links between screening programme and national programme centre expertise

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

PHE will be responsible for delivery of the essential elements of screening programmes best done once at national level.

These include setting clear specifications for equipment, IT and data.

Section 3: Delivery of Screening Programme

3.1. Service model summary

The model of delivery for the screening programme is primarily through maternity services care.

See section 2.2 Care Pathway above for further details.

3.2. Programme Co-ordination

The provider will be responsible for ensuring that the part of the programme they deliver is coordinated and interfaces seamlessly with other parts of the programme with which they collaborate, in relation to timeliness and data sharing.

The provider will ensure there are one or more named individuals responsible for the coordination of the delivery and planning of the programme 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 will meet at regular intervals (at least annually) to monitor and review the local screening pathway. The meetings will include representatives from programme coordination, clinical services, laboratory services and service management.

3.3. Clinical and corporate governance

The providers will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures e.g. screening programme boards/groups
- ensure that responsibility for the screening programme lies at Director-level
- ensure that there is appropriate internal clinical oversight of the programme and have its own management and internal governance of the services provided

with the designation of a Clinical Lead, a programme coordinator/manager and the establishment of a multidisciplinary steering group/programme board including NHS England representation (that meets quarterly) as a minimum and has terms of reference and record of meetings

- ensure that there is regular monitoring and audit of the screening programme, and that, as part of organisation's Clinical Governance arrangements, the organisation's Board is assured of the quality of the screening programme
- comply with the UK NSC guidance Managing Serious Incidents
- have appropriate and timely arrangements in place for referral into treatment services that meet programme standards found on the FASP website
- be able to provide documented evidence of clinical governance and effectiveness arrangements on request
- ensure that an annual report of screening services is produced which is signed off by the organisation's Board
- have a sound governance framework in place covering the following areas:
    - information governance/records management
    - equality and diversity
    - user involvement, experience and complaints
    - failsafe procedures
    - Risks and Mitigation plans

3.4. Definition, identification and invitation of cohort/eligibility

The target screening population is all pregnant women up to 23^{+0} confirmed weeks of pregnancy.

3.5. Location(s) of programme delivery

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

3.7. Entry into the screening programme

All women will be identified through maternity services. While there is nothing specific in the general practitioner (GP) contract regarding the 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 ensure timely access for women to all aspects of the screening programme.

3.8. Working across interfaces between departments and organisations

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

Accurate and timely communication and handover across these interfaces is essential to reduce the potential for errors and ensure a seamless pathway for service users. It is essential that there remains clear named clinical responsibility at all times and at handover of care the clinical responsibility is clarified.

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

- work to nationally agreed programme standards, policies and guidance
- ensure that midwives and obstetric sonographers are supported to facilitate early booking for maternity care within primary and community care settings
- provide strong clinical leadership and clear lines of accountability
- agree and documenting roles and responsibilities relating to all elements of the screening pathway across organisations to assure appropriate handover arrangements are in place between services
- develop joint audit and monitoring processes
- agree jointly on what the failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway
- develop an escalation process for Serious screening Incidents (SIs)
- contribute to any NHS England’s initiatives in screening pathway development in line with UKNSC expectations

- facilitate, provide or support education and training both inside and outside the provider organisation

3.9. Information on Test/ Screening Programme

Prior to any screening offer, the midwife/sonographer will provide verbal and written information regarding screening utilising the approved UK NSC resources as a guide for discussion. Where there are specific communication requirements (e.g. English is not the woman's first language, visual/hearing impairment) appropriate interpretation services should be used during the booking appointment and appropriate information provided. All women, including those with special requirements, will be fully informed of the choices regarding all antenatal screening programmes.

The information should be impartially presented and should include an explanation of the limitations of the screening test. The decision to consent to screening or to decline should be recorded appropriately 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 will ensure that the fetal anomaly ultrasound scan is performed by a health professional with at least one of the qualifications outlined in Section 3.15.

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

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

Cytogenetic laboratories performing analysis of prenatal samples should be CPA accredited and participate in an external Quality assurance scheme (i.e. NEQAS).

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 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

Providers must always use the nationally-developed public information leaflets at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided and should involve the national screening team before developing any other materials.

Providers must involve the national screening team in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources.

3.14. Exclusion criteria

Women presenting for maternity care at >23^{+0} weeks gestation.

3.15. Staffing

The provider will 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 standards are detailed at http://fetalanomaly.screening.nhs.uk/training

The provider will ensure that there are adequate numbers of appropriately trained staff in place to deliver the screening programme in line with best practice guidelines.

All professionals involved in the provision of ultrasound screening for fetal anomaly screening should comply with the training requirements detailed in the FASP 'Ultrasound Practitioners handbook' (http://www.fetalanomaly.screening.nhs.uk/combinedscreeningresources)

The 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) will be expected to:

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

3.17. Premises and equipment

The provider will:

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

- have appropriate polices in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability
- ensure that ultrasound scanning equipment meets the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use
- ensure that ultrasound equipment should be capable of producing and storing images of appropriate diagnostic quality
- Royal College of Radiologists. Standards for Ultrasound Equipment. https://www.rcr.ac.uk/docs/radiology/pdf/StandardsforUltrasoundEquipmentJan2005.pdf

3.18. Safety & Safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2013/14 NHS Standard Contract: http://www.england.nhs.uk/nhs-standard-contract

Section 4: Service Standards, Risks and Quality Assurance

4.1. Key criteria and standards

Programme standards are available on the programme website www.fetalanomaly.screening.nhs.uk/standards

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

4.2. Risk assessment of the screening pathway

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

Providers will:

- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that risks are reported through internal governance arrangements, such as risk registers
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the Commissioner and Quality Assurance Teams to develop, implement, and maintain appropriate risk reduction measures

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

4.3. Quality assurance

Providers will participate fully in national Quality Assurance processes, co-operate in undertaking ad-hoc audits and reviews as requested by QA teams and respond in a timely

manner to their recommendations. This will include the submission to QA teams and commissioners of:

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

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

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

4.4. Safety concerns, safety incidents and serious incidents

Providers will comply with the national guidance for the management of safety concerns and incidents in screening programmes and NHS England guidance for the management of serious incidents (http://www.screening.nhs.uk/incidents)

4.5. Procedures and Protocols

The provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

4.6. Service improvement

Where national recommendations and acceptable/achievable standards are not currently fully implemented the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period.

The provider shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond and any performance issues highlighted by the commissioners, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with the commissioners.

Section 5: Data and Monitoring

5.1. Key performance indicators

The provider shall adhere to the requirements specified in the document ‘Key Performance Indicators for Screening”. Please refer to http://www.screening.nhs.uk/kpi for further details, guidance and updates on these indicators.

5.2. Data collection, monitoring and reporting

Providers should:

- ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions
- continually monitor and collect data regarding its delivery of the Service
- comply with the timely data requirements of the National Screening programme and regional Quality Assurance teams. This will include the production of annual reports. The current dataset can be accessed from the National Screening programme website.

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