NHS public health functions agreement 2018-19

Service specification no.17
NHS Fetal Anomaly Screening Programme – 18+0 to 20+6 week fetal anomaly scan
NHS public health functions agreement 2018-19

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

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

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and
- Given due regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).
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Service specification No.17

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

This service specification is to be applied by NHS England in accordance with the 2018-19 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2018-19 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

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

The 2018-19 agreement is available at www.gov.uk (search for ‘commissioning public health’).
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 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
- Guidance & updates on Key Performance Indicators
- FASP Ultrasound Practitioners Handbook
- FASP Laboratory Handbook
- FASP Screening Programme Handbook
- Managing Safety Incidents in the English NHS National Screening Programmes
- NHS England Serious Incident Framework
- FASP Checks and audits to improve quality and reduce risks
- National Institute for health and Clinical Excellence (NICE) Clinical guideline 62 Antenatal care
- National Institute for Health and Clinical Excellence (NICE) Clinical guideline CG 129 Antenatal care for twin and triplet pregnancies
- Maternity Pathway Payments: Who pays for what?-Aspects of the Maternity Pathway Payment for the Screening and Immunisations Programmes
- Royal College of Radiologists. Standards for provision of an ultrasound service.

1.2. 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^{rd} to 20^{th} 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; and
- 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

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

1.6. Equality

Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:
- screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary;
- a Health Equity Audit should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations;
- the service should be delivered in a culturally sensitive way to meet the needs of local diverse populations;
- user involvement should include representation from service users with equality characteristics reflecting the local community including those with protected
characteristics; and
- providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow equality, health inequality and screening guidance when making such decisions.

The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

The provider will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

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

It also requires that public bodies:
- have due regard to the need to eliminate discrimination;
- advance equality of opportunity; and
- foster good relations between different people when carrying out their activities.
Section 2: Scope of Screening Programme

2.1. Description of screening programme

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 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/Patau’s syndromes. Where an earlier pregnancy scan is undertaken to assess gestational age and viability, and the CRL measurement is less than 45.0mm, a repeat scan is required for women accepting screening for Down's Syndrome, Edwards’ Syndrome/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;
- Gastrochisis;
- 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:

- work to national screening standards
- provide data and reports against screening standards, key performance indicators (KPIs), and other measures as requested by the national screening programme
• provide data on screening outcomes as required by the national screening programme

• ensure appropriate governance structures are in place

• take part in quality assurance (QA) processes and implement changes recommended by QA including urgent suspension of services if required

• implement and monitor failsafe procedures and continuously ensure quality

• work with NHS England and the screening quality assurance service (SQAS) in reporting, investigating and managing screening safety incidents

• be required to respond to national action/lessons for example, change of software, equipment or equipment supplier, new technologies

• ensure all health care professionals access appropriate training to maintain continuous professional development and competency

• use materials provided by the national screening programme, for example leaflets, e-learning resources and operational guidance

• be required to implement and support national IT developments.
2.2. Care pathway

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

The fetal anomaly screening pathway consists of the following:

- **identify population** - 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

- **inform** - during the ‘first contact’ or ‘booking visit’ with the midwife, verbal and written information will be given about the fetal anomaly scan (using NHS Screening programmes booklet ‘Screening Tests for You and Your Baby’) to enable women to make an informed choice and screening offered

- **offer** - the offer of fetal anomaly screening and subsequent acceptance or decline should be documented in the woman's health records/IT system

- **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 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 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:**

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- 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 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 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 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.

Classification: official
Figure 1 Screening Pathway for fetal anomaly scan at 18+0-20+6 weeks of pregnancy

Fetal Anomaly Screening Programme

18+0 to 20+6 week fetal anomaly ultrasound screening

Screening accepted

Fetal anomaly suspected/detected

Refer as appropriate following local policy

Discuss options

Diagnostic testing accepted

Fetal anomaly confirmed

Termination of pregnancy

Offer follow-up support

Diagnostic testing declined

No abnormality suspected/detected

Follow up at delivery

Go to NIPE

Continue with pregnancy

Offer follow-up support

Follow up at delivery

Go to NIPE

Screening declined

Follow up at delivery

Go to NIPE

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Classification: official
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 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 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
- developing an escalation process for screening Incidents
- 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 NHS screening programmes expectations
- providing or seeking to provide robust electronic links with relevant organisations
- linking with primary care
- ensuring a robust IT systems across the screening pathway
- have specific staffing requirements referred to in section 3.15 Staffing.

2.4. 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 NHS England public health commissioning, CCGs, specialised commissioning and directly by maternity services.

2.5. 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. Governance and leadership

The provider will:

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

Classification: official
• ensure the programme is delivered by trained workforce that meet national requirements.

3.4. Definition, identification and invitation of cohort/eligibility

The target screening population is all pregnant women \( \leq 23^{+0} \) 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), 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.

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 NHS Screening Programmes resources as a guide for discussion. Where there are specific communication requirements

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(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 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 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.

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

3.11. Results giving, reporting and recording

Screening results should be explained to women 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

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

Providers must involve the national screening team in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed classification: official
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.

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’. 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

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• have appropriate polices in place for equipment calibration and electronic safety checks, maintenance, repair and replacement in accordance with manufacturer specification to ensure programme sustainability

• ensure that ultrasound scanning equipment meets the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use

• ensure that ultrasound equipment used to perform the NT and CRL measurement for the combined test should meet FASP requirements as set out in the software specification, for example, recording CRL and NT to 1 decimal place and be capable of producing and storing images of appropriate diagnostic quality. Royal College of Radiologists. Providing an Ultrasound Service.

3.18. Safety & Safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2015/16 NHS Standard Contract: http://www.england.nhs.uk/nhs-standard-contract/15-16.
Section 4: National standards, risks and quality assurance

4.1 Key criteria and standards

The provider will:


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

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

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

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

- 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

Classification: official
• have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet national screening standards

• demonstrate that there are audited procedures, policies and protocols in place to make sure the screening programme consistently meets programme requirements


• ensure business continuity - business continuity plans must be in place where required

• ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance

4.2 Service improvement:

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

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

4.3 New technologies:

New technologies should not be used for screening unless approved by the UK National Screening Committee.
Section 5: Data and Monitoring

5.1. Key performance indicators


For the fetal anomaly screening programme providers must report quarterly for KPI FA2 – coverage of screening for the \(18^{th} to 20^{th}\) week scan

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 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, information must be shared with the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).