NHS Commissioning Board

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.17

NHS Fetal Anomaly Screening Programme

November 2012

DH Department of Health

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Public health functions to be exercised by the NHS Commissioning Board

Service specification No.17

NHS Fetal Anomaly Screening Programme

Contents

Service specification No.17

This is a service specification within Part C of the agreement "Public health functions to be exercised by the NHS Commissioning Board" dated November 2012 (the "2013-14 agreement").

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board ("NHS CB") under section 7A of the National Health Service Act 2006 ("the 2006 Act") as amended by the Health and Social Care Act 2012.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2013-14 agreement including all service specifications within Part C is available at www.dh.gov.uk/publications

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.

The purpose of the service specification for the NHS Fetal Anomaly Screening Programme (NHS FASP) is to outline the service and quality indicators expected by the NHS Commissioning Board (NHS CB) for the NHS CB's responsible population. This document provides details of the service specifications required to commission the Fetal Anomaly Ultrasound scan remit of the NHS FASP in England. (NOTE: There is a separate service specification covering Down's Syndrome Screening aspects of NHS FASP)

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 NHS FASP guidance which is found on the NHS FASP website. NHS Fetal Anomaly Screening Programme Home Page
- Guidance & updates on Key Performance Indicators can be found at: http://www.screening.nhs.uk/kpi
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes http://www.screening.nhs.uk/quality-assurance#fileid9902
- Best practice standards and policies can be found at: http://fetalanomaly.screening.nhs.uk/standardsandpolicies

1.2 Aim

The aim of NHS FASP is to offer all pregnant women in England a minimum of 2 ultrasound scans. The first is an early scan, undertaken after 8 weeks gestation and used mainly for dating the pregnancy and confirming viability. The second ultrasound scan is undertaken between 18+0 to 20+6 weeks of pregnancy and screens for major structural anomalies in order that women are able to exercise informed choice about their pregnancy.

1.3 Objectives

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

Ensure access to a uniform screening programme which conforms to an agreed level of quality.

- Provide information for women so that they are able to exercise informed choice.
- Identify abnormalities incompatible with life at a time when choice can operate about continuation of the pregnancy or termination.
- Identify abnormalities which may benefit from antenatal treatment.
- Identify abnormalities which require early intervention following delivery.

1.4 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs
- All those participating in the NHS FASP will have adequate information on the benefits and risks of screening 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 including between the different providers, screening centres, primary care and secondary care.

Section 2: Scope of Screening Programme

2.1 Description of screening programme

The main aim of the NHS FASP is to offer all pregnant women in England a minimum of two ultrasound scans. The programme provides policy, standards and associated information. It produces guidance on best practice relating to, counselling, diagnostic and clinical follow up services.

The first scan is an early scan taken from 8 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 screens for major structural abnormalities.

The provision of ultrasound scan appointments between 18^{+0} to 20^{+6} weeks gestation which include pre-scan counselling, the ultrasound examination, post-scan counselling and reporting. The scan will look for:
Anencephaly;
Open spina bifida;
Cleft lip;
Diaphragmatic hernia;
Gastroschisis;
Exomphalos;
Serious cardiac abnormalities;
Bilateral renal agenesis;
Lethal skeletal dysplasia;
Trisomy 13 and Trisomy 18

2.2 Care pathway

The following outlines the screening care pathway for the fetal anomaly ultrasound scan (

Figure 1):

One of the possibilities for parents as a result of choosing to be screened for fetal anomalies is that a screen positive result will be found and difficult choices offered. They should be supported through this process by skilled and experienced staff

- During the 'first contact' or 'booking visit' with the midwife, verbal and written information will be given about the dating scan and the 18^{+0} to 20^{+6} weeks fetal anomaly scan is given to the woman. The leaflet 'Screening Tests for You and Your Baby' will be given to the mother in an appropriate language as a form of written information. The provider will ensure that information will be available in appropriate formats. For example, providing a translator for those women whose first language is not English.
- The 18^{+0} to 20^{+6} week ultrasound scan is offered initially by the midwife at the 'first contact' visit and again at the 'booking' visit or just at the same visit if the first contact and booking visit is completed at the same time.
- The woman's choice to decline or accept screening is recorded in the health care records.
    - Screening declined: The woman continues with pregnancy and outcome is obtained.
    - Screening accepted: Maternal consent is obtained by the midwife during discussions at either the 'first contact' or 'booking' visit. The decision is recorded in the health care records.
- The 18^{+0} to 20^{+6} week ultrasound scan is performed with the woman's verbal consent, which is written in the notes. Women who present beyond 20^{+6} weeks will still be scanned but must be informed about the limitations of detecting structural abnormalities later in pregnancy and the conversation documented including the possibility of a late stage termination of pregnancy.
    - No anomaly identified: The woman is informed with the result recorded in the health records. The woman continues with pregnancy and outcome is obtained.
    - A single further scan will be offered at 23 weeks gestation where the image quality of the first scan is compromised for example (but not confined to) ;
        - Increased maternal body mass index (BMI)
        - Uterine fibroids
        - Abdominal scarring
        - Sub-optimal fetal position
    - Anomaly identified or suspected: The woman is informed with the result recorded in the health records. The woman is referred to a second sonographer or consultant.
- Maternal consent is obtained to have a re- scan by a second sonographer or consultant and decision is recorded in the health records.
    - Re-scan declined: The woman continues with pregnancy and outcome is obtained.
    - Re-scan accepted: Re-scan is performed with maternal consent.

- No anomaly identified: The woman is informed with the result recorded in the health records. The woman continues with pregnancy and outcome is obtained.
- Anomaly suspected: Level 3 scan, prenatal diagnosis, intra-uterine treatment, and/or termination of pregnancy may be required.
- There are three possible outcomes after an anomaly is suspected: (prenatal investigation care pathway at figure 3)
    - Declines further management: Decision is recorded in the health record. The woman continues with pregnancy and outcome is obtained.
    - Refer to a fetal medicine unit (FMU).
    - Refer to in-house consultant with fetal anomaly/ultrasound experience: Anomaly is confirmed and further prenatal investigations maybe offered. Maternal choice is then recorded in the health records.
- Prenatal investigation declined: The woman continues with pregnancy and outcome is obtained.
    - Prenatal investigation accepted: Maternal consent is explicitly obtained and maternal choice is documented in the health records.
    - Pre-counselling is completed with the midwife/clinician to ensure that the woman is aware of the purpose, benefits, limitations and implications of undergoing a prenatal diagnosis procedure.
    - A scan is performed to assess the pregnancy in preparation for the prenatal diagnostic (PND) procedure (e.g. viability of the pregnancy, accessibility for amniocentesis – liquor and/or volume, CVS placental site, Fetal Blood Sampling from the cord).
    - Sample collection for the PND test is performed by chorionic villus sampling (CVS, between 10^{+0} and 13^{+6} weeks) or amniocentesis (after 15^{+0} weeks). PND is preformed using continuous direct ultrasound guidance by an experienced clinician. Note: PND for a Multiple Pregnancy is conducted at a tertiary Fetal Medicine Unit due to the specialised nature of the procedures and the increased risk of miscarriage.
    - How the results will be given is agreed with the woman.
    - Sample is sent to the cytogenetic or molecular laboratory.
- There are four possible outcomes for a PND:
    - Inconclusive result: The woman is recalled to have a repeat test due to a mosaic or culture failure.
    - Miscarriage: A CVS or amniocentesis carries a 1-2% chance of inducing a miscarriage. The woman is offered counselling and to have fetal pathology performed. If the woman accepts to have fetal pathology, consent is obtained along with the outcome.
    - Normal result: The woman will continue with pregnancy and outcome is obtained.
    - Abnormal result: The woman is counselled and given the opportunity to discuss the results with health professionals. The woman is offered to terminate the pregnancy.
- Termination of pregnancy declined: The woman continues with her pregnancy and outcome is obtained.

- Termination of pregnancy accepted: Pre-counselling is given and maternal consent is obtained prior to procedure, in line with the Abortion Act 1967 and the Royal College of Obstetricians and Gynecologists guidance.
- Fetal pathology is offered. If accepted maternal consent and outcome is obtained.

Figure 1 Screening care pathway for the fetal anomaly scan

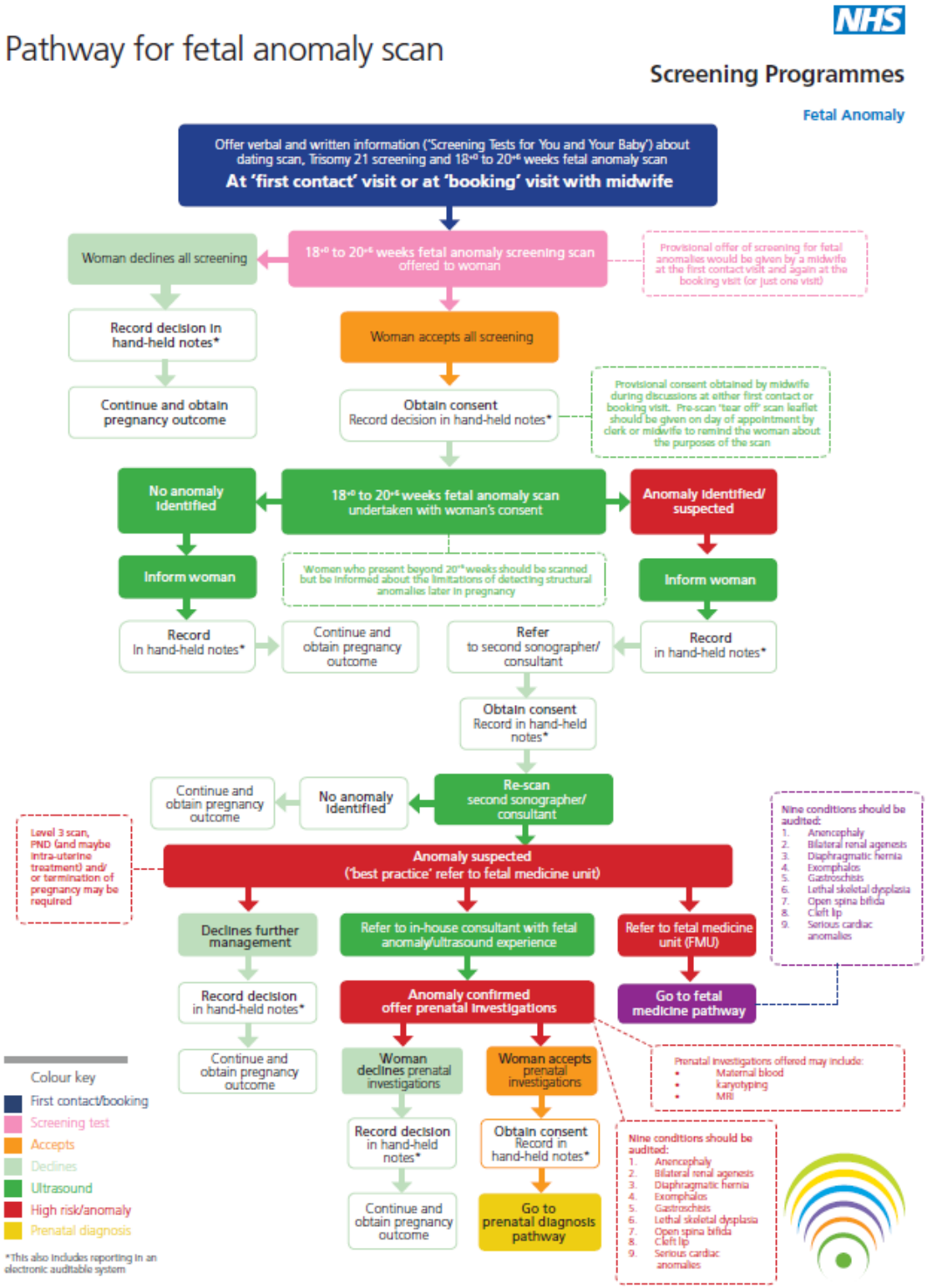


Figure 2 Map of Medicine care pathway for the fetal anomaly ultrasound scan to be commissioned

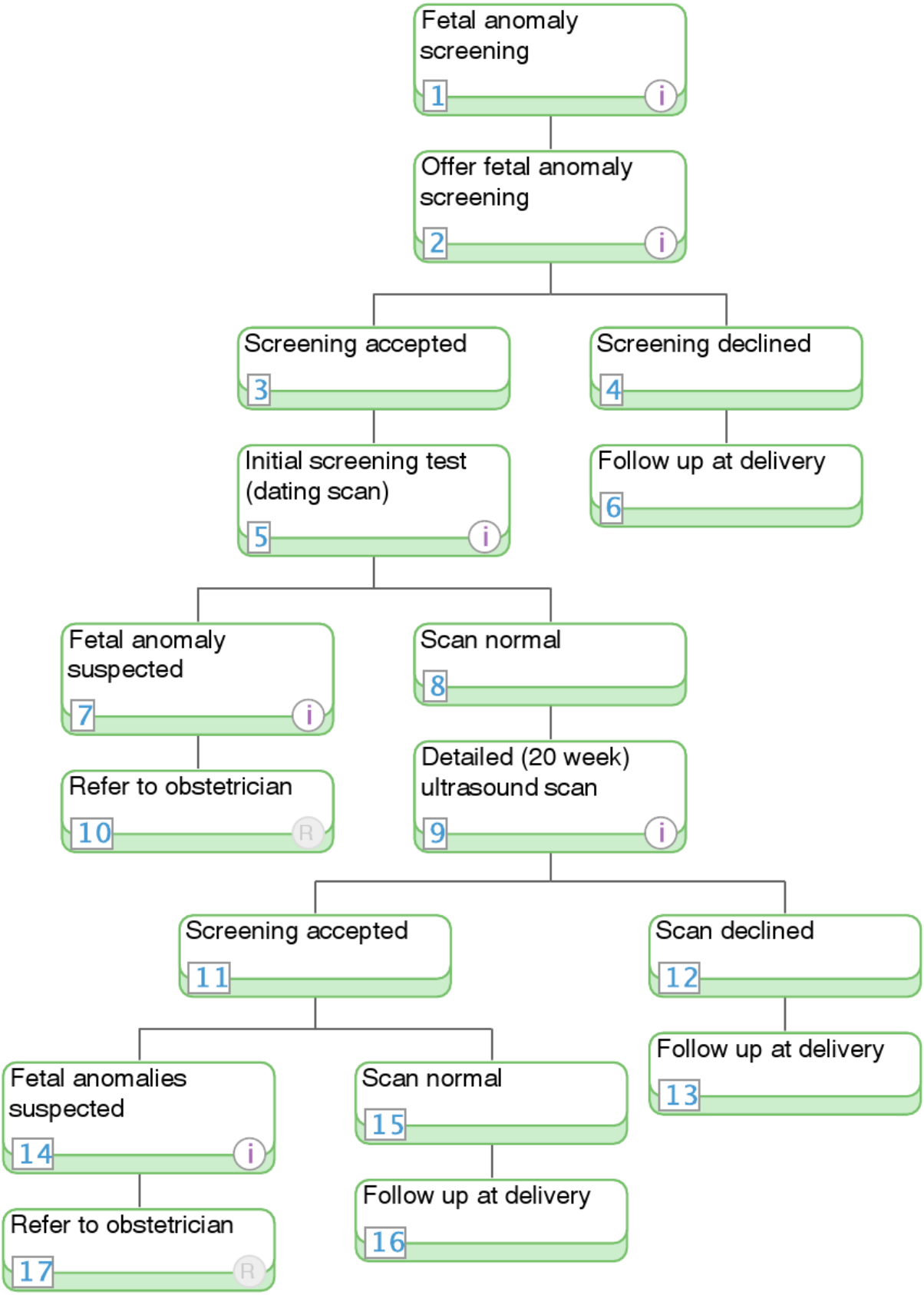
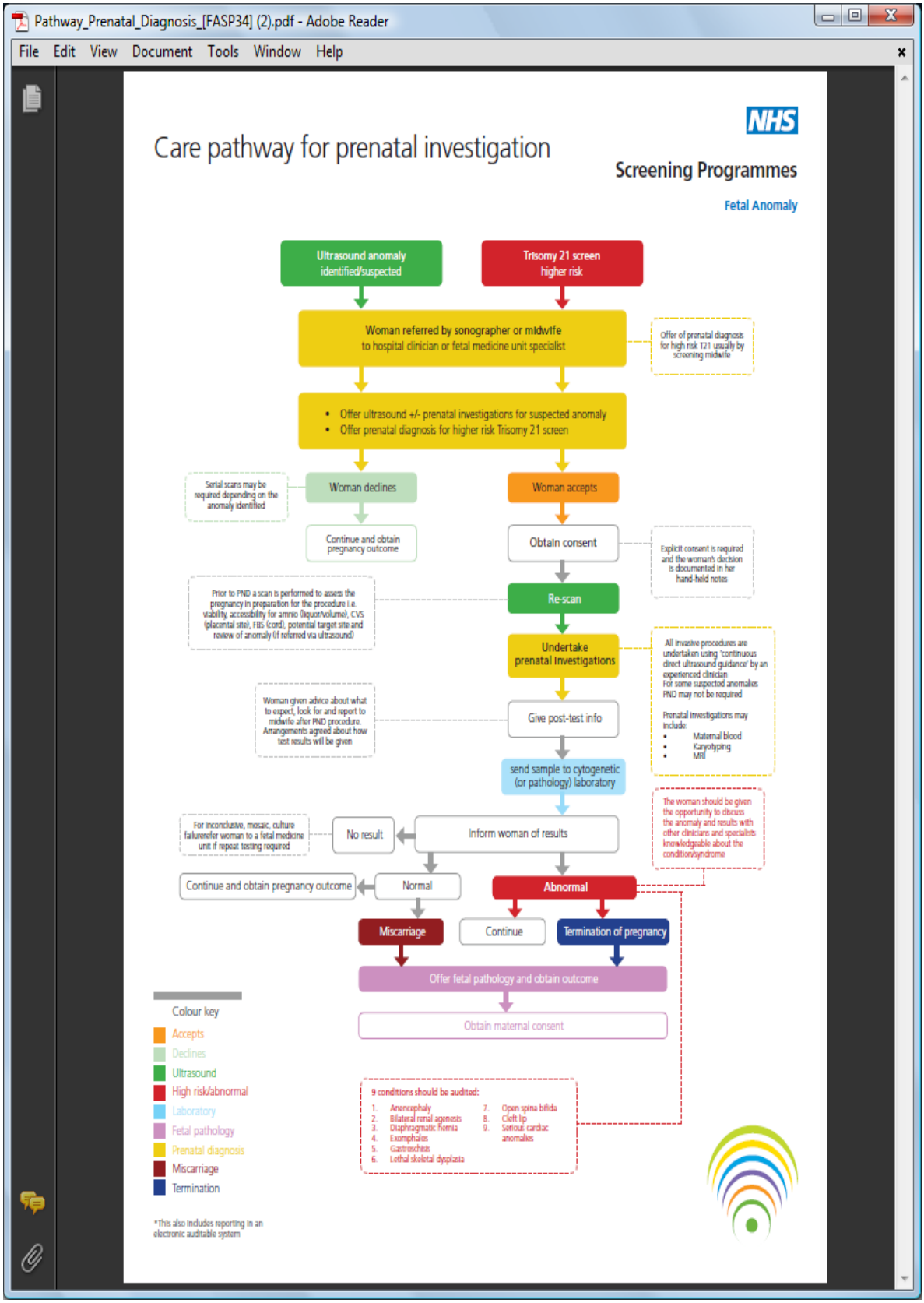


Figure 3 Care pathway for prenatal investigation



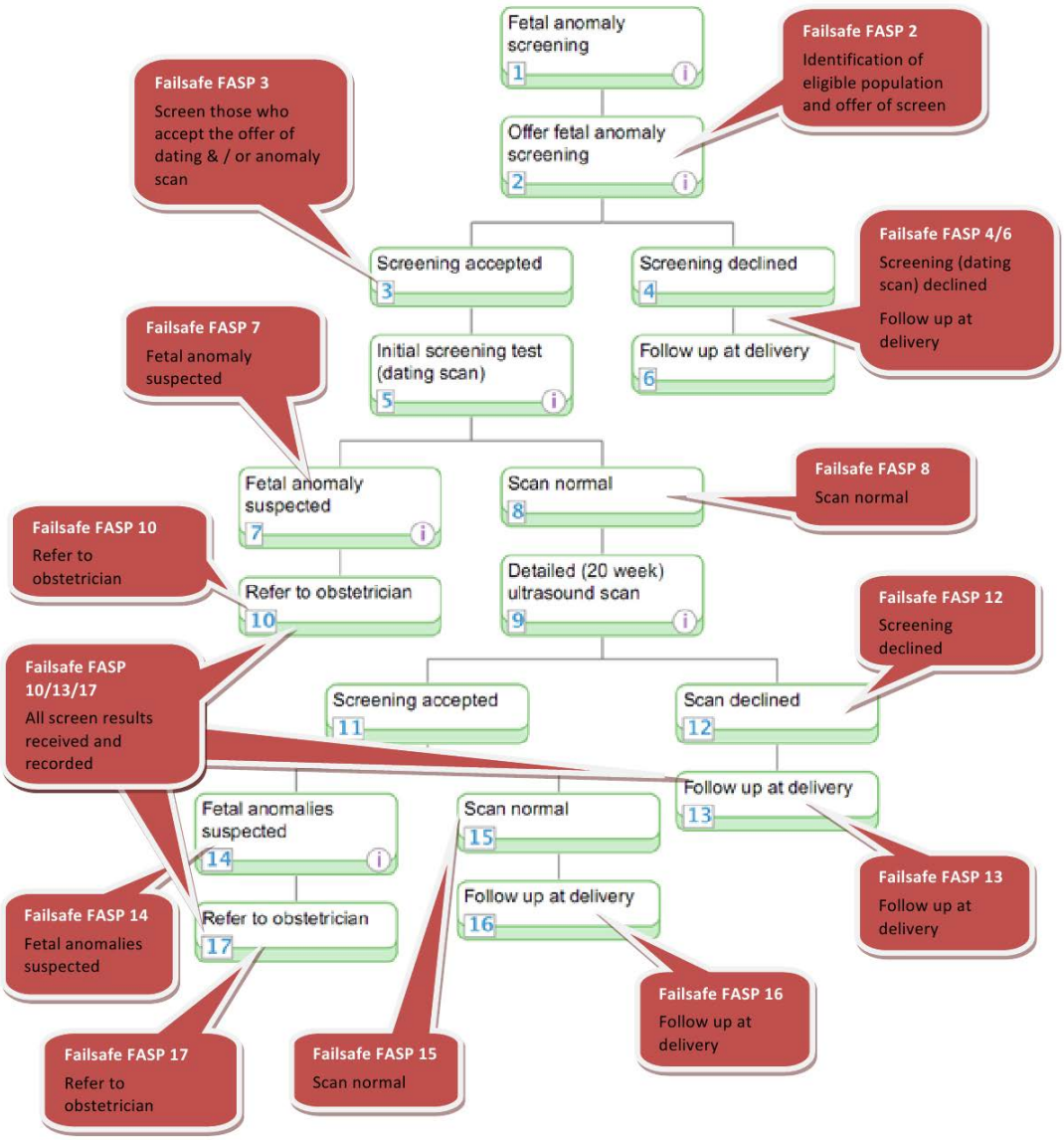
2.3 Failsafe Procedures

Quality assurance within the screening pathway is managed by including a failsafe process. 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 (i) identify what is going wrong and (ii) what action follows to ensure a safe outcome.

In accordance with UK NSC standards and protocols the providers have a duty to have adequate failsafe and also to provide assurance to the NHS CB that the failsafe is adequate. Effective implementation requires routine staff training and development and may need changes to local roles and responsibilities. Provider organisations are also expected to ensure that appropriate links are made with internal governance arrangements, such as risk registers.

Details of the failsafe procedures that must be employed for the Fetal Anomaly Ultrasound screening programme can be found on the NHS FASP website.

Figure 4 Failsafe overview of the fetal anomaly ultrasound scan care pathway



Failsafe Process	Responsibility NHS CB / Area Team
Scan normal	Screening technician
Refer to an obstetrician	Screening technician
All screen results received and recorded	Midwife
Follow up at delivery	Screening Coordinator

The NHS CB is responsible for ensuring that that all these failsafe mechanisms are working across the whole pathway

2.4 Commissioning Arrangements

The commissioning of the Fetal Ultrasound screening pathway involves commissioning at different levels. Fetal Ultrasound screening services will be commissioned by the NHS CB alongside specialised services where appropriate.

The commissioning of the Fetal Ultrasound screening pathway involves commissioning at different levels, as set out below. NHS Fetal anomaly screening services will be commissioned by the NHS CB alongside specialised services where appropriate.

Section of pathway	Provider	Possible level of commissioning	Possible level of contracting	Rationale and other comments
ANTENATAL				
Identify cohort in a timely manner	Maternity services	CCGs/ NHS CB Area team	CCGs	The eligible population is identified through routine-antenatal care
Maximise the offer to the identified cohort	Maternity service	LAT	CCG	
Screening test – sample taking (delivery of the ultrasound scan)	Obstetric ultrasonography	LAT	CCG	Carried out through routine secondary care. CCGs will have responsibility for commissioning secondary services in line with the national service specification

Results reporting	Maternity services	LAT	CCG	Results reporting is part of routine maternity care. CCGs will have responsibility for commissioning maternity care
Diagnostics	Obstetric Ultrasound Specialist/ Fetal Medicine	LAT Some elements of fetal medicine will be commissioned by specialised teams in LATs	NHS CB/CCG	Once a diagnosis has been obtained and confirmed then all options including continuation of the pregnancy or termination will be discussed and offered. Adequate services must be in place to support this in a timely manner
Sample taking for some detected abnomalities - amnio/Chorionic Villus Sampling (CVS)	Maternity services	LAT Some elements of fetal medicine will be commissioned by specialised teams in LATs	NHS CB/CCG	Sample collection of the amniotic fluid or placenta by an obstetrician consultant. CVS is in the Specialised Services National Definition Set (SSNDS). Amniocentesis where the procedure is difficult/complex (including for a multiple pregnancy) is in the SSNDS, otherwise it is not considered specialised. *CCGs* will have responsibility for commissioning maternity care NHS CB will have responsibility for commissioning specialised services
Sample analysis – Prenatal Diagnosis (PND) by QF-	Molecular/ Cytogenetic laboratories for suspected trisomy 13 and	Specialised teams in LATs	NHS CB	Molecular QF-PCR analysis delivered by the molecular/cytogenetic laboratory is under

PCR	18 only.			specialised services NHS CB will have responsibility for commissioning specialised services
Sample analysis of prenatal diagnosis for genetic mutation analysis	Molecular laboratory analysis for suspected conditions such as lethal skeletal dysplasia may be required.	Specialised teams in LATs	NHSCB	Molecular QF-PCR analysis delivered by the molecular / cytogenetic laboratory is under specialized services NHSCB will have responsibility for commissioning specialised services
Results reporting and counselling	Fetal Medicine	Specialised teams in LATs	NHS CB	Reporting of results and counselling after a positive result to discuss options delivered by specialised midwives or Consultants in Fetal Medicine under specialised commissioning. NHS CB will have responsibility for commissioning specialised services
Termination of Pregnancy	Varies from area to area	LAT	CCG	

2.5 Links between screening programme and national programme centre expertise

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

These include:

- developing, piloting and roll-out to agreed national service specifications of all extensions to existing screening programmes and new screening programmes;
- setting QA standards;
- setting and reviewing programme standards;
- setting and reviewing national service specifications and advising on section 7A agreements (under the direction of DH requirements);
- developing education and training strategies;

- providing patient information;
- determining data sets and management of data, for example to ensure KPIs are collected;
- setting clear specifications for equipment, IT and data;
- procurement of equipment and IT where appropriate; (Procurement may undertaken by NHS CB but will need advice from PHE screening expertise and related clinical experts);
- Collect, collate and quality assure data for cancer and non-cancer screening programmes;
- Monitor and analyse implementation of NHS commissioned screening services;
- Provide advice to DH on priorities and outcomes for the NHS CB mandate and section 7a agreement, and to lead on detailed provisions, in particular the 7a agreement on screening;
- Advise the NHS CB how to increase uptake of screening.

PHE will also be responsible for

- providing the quality assurance (QA) functions for screening programmes;
- providing PH expertise and advice on screening at all levels of the system, including specialist PH expertise being available as part of NHS CB screening commissioning teams.;
- ensuring action is taken to optimise access to screening programmes, e.g. among socio-economically disadvantaged groups.
- Ensuring reports on important aspects of screening are available at various geographies (e.g. local authority) to enable population based oversight

Section 3: Delivery of Screening Programme

3.1 Service model summary

The model of delivery for the screening programme is primarily through routine maternity services care.
See section 2.2 Care Pathway above for further details.

3.2 Programme Co-ordination

In accordance with UK NSC standards and protocols the NHS CB will ensure that there is a named person within the provider service responsible for overseeing the strategic coordination of the screening programme across the screening pathway within the provider service and who will contribute to screening programme development.

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 provide one or more named individuals who will be responsible for the coordination of the delivery of the programme and provider contribution to planning supported 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.

In accordance with UK NSC standards and protocols the provider and the NHS CB will meet at regular intervals (at least annually).The meetings will include representatives from programme coordination, clinical services, laboratory services and service management.

3.3 Clinical and corporate governance

In accordance with UK NSC standards and protocols the provider will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures,
- ensure that responsibility for the screening programme lies at Executive-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 appointment of a Clinical Lead, a Programme Manager and the establishment of a multidisciplinary

steering group/programme board including NHS CB representation (that meets quarterly) as a minimum and has terms of reference,
- 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 National Centre Website.
- 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

3.4 Definition, identification and invitation of cohort/eligibility

The target screening population is all pregnant women.

In accordance with UK NSC standards and protocols the provider will maximize the offer of screening in vulnerable/ hard-to-reach populations (including those who are not registered with a GP).

3.5 Location(s) of programme delivery

In accordance with UKNSC standards and protocols the provider will ensure accessible service provision for the specified population while assuring that all locations where ultrasound scanning is undertaken fully comply with the policies, standards and guidelines referenced in this service specification.

3.6 Days/Hours of operation

In accordance with UKNSC standards and protocols the provider will ensure that days and hours of operation are sufficient to meet the demand for this screening programme within the timescales indicated in relevant standards and guidelines.

3.7 Entry into the screening programme

Prior to any screening offer, in accordance with UK NSC standards and protocols the midwife will provide verbal and written information regarding screening utilising the approved UK NSC booklet 'Screening Tests for You and Your Baby' as a guide for discussion. Where English is not the woman's

first language a trained interpreter will be used during the booking appointment and appropriate information will be provided. All women, including those with special requirements, will be fully informed of the choices regarding all antenatal screening programmes and the decision to consent to screening or to decline should be recorded appropriately.

3.8 Working across interfaces between departments and organisations

The screening programme is dependent on strong working relationships (both formal and informal) between the screening programmes, the information systems, ultrasonography departments, maternity departments, child health departments and primary care and specialist professionals. 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 ensure that appropriate systems are in place to support an interagency approach to the quality of the interface between these services. This will include, but is not limited to:

- Agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- Providing strong clinical leadership and clear lines of accountability
- Developing joint audit and monitoring processes
- Agreeing jointly on what failsafe mechanisms are required to ensure safe and timely processes across the whole screening pathway
- Contributing to any NHS Commissioning Board (NHS England) Screening Lead's initiatives in screening pathway development in line with UKNSC expectations
- meeting the national screening programme standards covering managing interfaces which can be found on the National Screening programme website.

3.9 Information on Test/ Screening Programme

In accordance with UK NSC standards and protocols the provider will be able to demonstrate what systems are in place to support early contact with a health professional for midwifery services to support good quality maternity care and timely access to all aspects of the national screening programme.

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 including, but not exclusive to, 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.

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

The fetal anomaly ultrasound scan is performed by a sonographer. Any re-scans are performed by a second sonographer or consultant.

All diagnostic ultrasound procedures will be undertaken by health professionals who are fully trained to undertake intrauterine biopsies (amniocentesis or CVS) under 'continuous direct ultrasound guidance' and are competent in the safe use of ultrasound equipment.

Diagnostic procedures for Multiple Pregnancy must be undertaken at a tertiary Fetal Medicine Unit.

3.11 Results giving, reporting and recording

The result is notified to the midwife and recorded in the woman's health records.

The provider must ensure that all staff delivering any element of the screening programme is aware of and complies with the provider organisation's safety, confidentiality and safeguarding policies which will reflect all appropriate legislation.

The recording, storage and sharing of any data, including ultrasound images and reports, will comply with data protection legislation (Data Protection Act 1998).

Results giving

See section 2.2

3.12 Transfer of and discharge from care obligations

Where an abnormality is suspected or identified transfer of care will comply with referral guidance outlined within national standards.

3.13 Parent and Carer Information

Providers must ensure that all women receive information in an appropriate format about the fetal anomaly ultrasound scan which will be impartially presented and will include an explanation of the limitations of the scan.

As part of the Maternity Service, all antenatal and newborn screening programmes provide information within the booklet, 'Screening Tests for You and Your Baby'. This booklet will be given to the women during the 'first

contact' or 'booking' visit with the midwife. The booklet briefly summarises what is fetal anomaly ultrasound screening, what it can achieve, its limitation and what procedures are involved within the screening pathway. The booklet also provides contact information to organisations that can provide additional support and advice.

In addition to contributing to the standard antenatal and newborn screening booklet, the NHS FASP has developed a number of leaflets and literature that offer more detail on fetal anomaly ultrasound screening. The NHS FASP will distribute a copy of any new publication materials for patients and staff to all relevant providers. Although a set number of prints will be available, the providers will be responsible for obtaining any further required copies in order to maintain a high quality fetal anomaly ultrasound screening service.

Although the NHS FASP provides informational resources for patients, in the case of a suspected or identified fetal anomaly women will receive supplementary information that includes relevant/supportive websites or details of support organisations such as Antenatal Results and Choices (ARC).

3.14 Exclusion criteria

There are no exclusion criteria.

3.15 Staffing

In accordance with UK NSC standards and protocols 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. The NHS FASP recommends that any person undertaking a Fetal Anomaly ultrasound scan on pregnant women, for the purpose of screening and diagnosis of a related condition will 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).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.

All diagnostic ultrasound procedures will be undertaken by health professionals who are fully trained to undertake intrauterine biopsies (amniocentesis or CVS) under 'continuous direct ultrasound guidance' and are competent in the safe use of ultrasound equipment.

A Lead Screening Sonographer, with appropriate deputisation to ensure continual cover, will oversee the implementation, delivery and monitoring of the 18+0 – 20+6 weeks fetal anomaly scan standards.

The provider will also have in place a workforce plan designed to maintain a sustainable programme, especially where increases in birth rate are predicted and/or there are difficulties in recruitment of appropriately qualified healthcare staff or due to staff absences.

The provider will ensure that all staff policies are in line with those expected across the NHS and compliance is assured for staff involved in antenatal screening. This will include, for example, the ability of staff to raise concerns; personal and professional development arrangements; maintenance of professional competency; health and safety arrangements, and promoting healthy lifestyles. As an employer, the provider will ensure that all professional staff are registered with appropriate professional bodies and abide by professional codes of practice.

The provider will provide appropriate specific training for new staff with regular update training where required. The provider will also actively support attendance of staff at local, regional or national training and development events relating to UK National Screening Committee antenatal screening programmes.

Providers will have in place a dedicated screening coordinator/screening midwife and deputy who are responsible for ensuring that there is an ongoing educational programme for staff involved in screening. Furthermore, providers must have arrangements for an ongoing multidisciplinary antenatal screening educational/induction programme of a minimum of 6 hours per year and will be seen as a part of professional development.

In accordance with UKNSC standards and protocols the provider will ensure that a performance development review is undertaken on an annual basis for all health professionals involved in obstetric ultrasound.

The NHS FASP has produced leaflets for health professionals on how fetal anomaly conditions are tested during pregnancy. The leaflets are available on the NHS FASP website at http://fetalanomaly.screening.nhs.uk/fetalanomalyleafletsforprofessionals

3.16 User involvement

In accordance with UK NSC standards and protocols 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
- show that all families are given information about how to provide feedback about services they receive, including about the complaints procedure

Collection of the views of service users/families will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to the NHS CB on request.

3.17 Premises and equipment

In accordance with UK NSC standards and protocols the provider will ensure that suitable premises and equipment are provided for the screening programme and will have appropriate polices in place for electronic safety checks, equipment calibration, maintenance and replacement to ensure programme sustainability.

Suitable premises will have available height-adjustable seating and couch, variable lighting and ergonomic reporting facilities when obstetric ultrasound examinations are being performed for the NT and CRL measurement portion of the combined test. The room temperature of the ultrasound scan room will be maintained at a comfortable level, usually by air conditioning, and this will be adjusted according to the number of heat-generating units. Thus when designing ultrasound departments hospital providers will give due consideration to the floor area in relation to the potential use of the room (e.g. bed, walking, machine, cables), thereby allowing the woman and healthcare professional to move around safely.

Ultrasound scanning equipment must meet the European Council Directive, enforced by the Medicines and Healthcare Regulatory Agency, to ensure that it is safe and effective to use. Equipment will be regularly calibrated, repaired and maintained in accordance with manufacturer specifications with particular reference to calliper accuracy.

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

The NHS FASP has produced a number of standards and policies, in collaboration with the UK NSC, which recommend the best working practice for health professionals to work towards within fetal anomaly ultrasound screening and diagnostic testing. The fetal anomaly ultrasound screening and diagnostic testing standards overview all aspects of screening which include consent, best practices and data requirements for quality assurance purposes.

Providers must work towards meeting the standards and contribute to national data collection exercises where required. Providers will participate in the Quality Assurance Pilots for Antenatal and Newborn Screening Programmes as specified by the UK NSC and National Screening programme.

Key standards and criteria are outlined in the following documents available on the NHS FASP website at http://fetalanomaly.screening.nhs.uk/standardsandpolicies:

Document Title	Summary
18^{+0} to 20^{+6} weeks fetal anomaly scan – National standards and guidance for England 2010	Produced by the NHS Fetal Anomaly Screening Programme, in collaboration with the Society and College of Radiographers, Royal College of Obstetricians and Gynaecologists and the British Maternal and Fetal Medicine Society. This document provides standards and guidance relating to the care pathway for the 18^{+0} to 20^{+6} weeks fetal anomaly scan. The document also includes supplementary materials regarding the protocol when screening for the 11 conditions.

Document Title	Summary
Amniocentesis and Chorionic Villus Sampling: Policy, Standards and Protocols	The policy, standards and protocols for amniocentesis and chorionic villus sampling (CVS) is in relation to prenatal diagnosis testing. This document provides standards for consent, record keeping, testing timeframes, procedural practices, operator competence and sample processing. This document has been developed through collaboration between Antenatal Screening Wales and the NHS Fetal Anomaly Screening Programme.

4.2 Risk assessment of the pathway

Providers are expected to have an internal quality assurance process that assures the NHS of their ability to manage the risks of running a screening programme. Providers may use the Failures Modes and Effects Analysis (FMEA) method which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks will be defined in the standard NHS format (*likelihood and severity multiplied to give a RAG score*)

Providers are expected to maintain a register of risks and work with the NHS CB and QA staff to identify key areas of risk in the screening pathway to ensure that these points are reviewed in contracting and peer review processes. On a quarterly basis high scoring risks will be identified and agreed between the provider and the NHS CB, and plans put in place to mitigate against them.

4.3 Quality assurance

The NHS CB will suspend a service on recommendation from QA.
The Provider will:

- meet national programme standards, or have plans in place to meet them where this is not the case
- participate fully in national Quality Assurance processes and respond in a timely manner to recommendations made
- make available data from external quality assurance programmes to screening programmes, national team, the NHS CB and LA DsPH
- collect and submit minimum data sets as required to assure the NHS CB and the Quality Assurance Team in Public Health England of the safety and quality of the services provided
- complete and submit the annual self-assessment tool with or without (as requested) an annual report of services to the Quality Assurance team and respond to identified areas for improvement

4.4 Serious incidents

A serious incident (SI) for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening service which exposes the programme to unknown levels of risk that screening or assessment have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low or high, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as for actual serious incidents.

The provider will:

- have a serious incident policy in place and ensure that all staff are aware if it and of their responsibilities within it and comply with the UK NSC guidance Managing Serious Incidents.
- inform the NHS CB within 24 hours in the event of a serious adverse event and provide all reasonable assistance to the NHS CB in investigating and dealing with the incident. Where appropriate, such incidents should also be reported to the National Screening programme to assist in the development of a national picture of risk identification and management
- comply with appropriate statutory regulations (e.g. Data Protection Act, COSHH Regulations etc) to ensure a safe working environment
- comply with the UK NSC guidance, '*Managing Serious Incidents in the English NHS National Screening Programmes'* available on the NSC website (http://www.screening.nhs.uk/quality-assurance#fileid9902)
- review their procedures and processes against the standards for the screening programme to reduce the likelihood of incidents occurring
- have a robust system in place whereby families, other professionals and the public can raise concerns about the quality of care and where there is adequate arrangements for the investigations of such concerns.

4.5 Procedures and protocols

The provider will be able to demonstrate that written procedures and protocols are in place to ensure best practice is consistently applied for all elements of the screening programme (these must be consistent with National Screening programme requirements). This will include policy based on best practice for the care of women who have declined to take part in the screening programme.

Where the provider undertakes screening on more than one site, they will ensure consistency of procedures and protocols across all sites, including policies for onward referral to, for example, prenatal diagnostic services; counselling or appropriate clinical services.(1)

The Provider shall ensure that all staff are aware of and comply with the Provider's safety, confidentiality and safeguarding policies.

4.6 Continual service improvement

Where national recommendations and core and/or developmental 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 NHS CB, 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 NHS CB.

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

Maternity care providers and the NHS CB will make sure that sufficient clerical support, appropriate information technology (IT), equipment and software are available and that linkage is made with other data collection systems across other hospital Trust areas/departments.

Annually reported figures will be reported to allow the NHS CB to make informed decisions about the programme provision for the population that they are responsible for. To allow the NHS CB to carry out detailed analysis of the programme provision, the provider will supply an anonymised data set of all eligible babies at the request of the NHS CB. This dataset would not include the name but would included date of birth, postcode of residence, GP, screening clinic, as well as all other nationally agreed quality assurance data.

The provider will supply identifiable information regarding babies eligible for screening to the NHS CB in the event that a SI occurs relating to the programme, for the investigation of a complaint, for a specified quality assurance exercise or for any other reason that the NHS CB would reasonably require this information.

Activity, performance and KPI data will be collected by providers and shared with the NHS CB to allow benchmarking between areas within the eligible screening programme population.