



Commissioning Board

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.16

NHS Down's Syndrome Screening (Trisomy 21) Programme

November 2012

Public health functions to be exercised by the NHS Commissioning Board

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Service specification No.16

NHS Down's Syndrome Screening (Trisomy 21) Programme

Contents

Public health functions to be exercised by the NHS Commissioning Board	3
Contents	4
Service specification No.16	5
Section 1: Purpose of Screening Programme	6
Section 2: Scope of Screening Programme	8
Section 3: Delivery of Screening Programme	19
Section 4: Service Standards, Risks and Quality Assurance	26
Section 5: Data and Monitoring	29

Service specification No.16

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 Down's Syndrome Screening (Trisomy 21) Programme.

The purpose of the service specification is to outline the service and quality indicators expected by the NHS Commissioning Board (NHS CB) for the NHS CB's responsible population and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC).

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This specification should be read in conjunction with:

- any separate service specifications for the screening laboratory used by the provider for antenatal screening services
- NHS FASP (2011) Screening for Down's syndrome: UK Policy recommendations 2011 – 2014 Model of Best Practice
- NHS FASP Amniocentesis and Chorionic Villus Sampling: Policy, Standards and protocols
- UK NSC Guidance, Managing Serious Incidents in the English NHS National Screening Programmes <http://www.screening.nhs.uk/quality-assurance#fileid9902>
- Antenatal Screening – Working Standards: National Down's Syndrome Screening Programme for England
- Standard & policy documents including recommended criteria for CRL & NT can be found at: <http://fetalanomaly.screening.nhs.uk/standardsandpolicies>
- Guidance & updates on Key Performance Indicators can be found at <http://www.screening.nhs.uk/kpi>

1.2 Aims

The NHS Down's syndrome screening programme aims to:

- Offer all women a screening test for Down's syndrome and
- to provide information for women so that they are able to exercise informed choice.

1.3 Objectives

- To offer to all eligible women a screening test for Down's syndrome which complies with the UK NSC Model of Best Practice 2011 – 2014.
- To provide appropriate, accessible information in a range of formats for women so that they are able to make an informed choice about their screening options and pregnancy management.

1.4 Expected health outcomes

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

- The screening test should achieve a detection rate (DR) and screen positive rate (SPR) recommended by the UKNSC. The current UK NSC Model of Best Practice standard from April 2011 is a DR greater than 90% of affected pregnancies with a SPR of less than 2% of unaffected pregnancies for those undergoing first trimester combined screening. For the second trimester quadruple test the standard is a DR greater than 75% for a SPR of less than 3%.
- Women are able to make informed and supported decisions about how they respond to the risk calculation given within the screening programme.
- Diagnostic and follow on care services are easily accessible and support a woman's decision, including paediatric and social services support.

1.5 Principles

- All individuals will be treated with courtesy, respect and an understanding of their needs.
- All those participating in the Down's syndrome 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 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 Down's syndrome screening programme is part of the NHS FASP.

The recommended screening test for Down's syndrome in the first trimester is the combined test which consists of a nuchal translucency scan and a test that measures two specific maternal biochemical markers. The recommended screening test in the second trimester is a quadruple test which measures four maternal biochemical markers. The results of either test give an individual risk assessment to the woman on the possibility that her baby will have Down's syndrome. If the risk of having a term pregnancy affected with Down's syndrome is 1 in 150 or higher, the pregnancy is regarded as higher risk and the woman will be offered a diagnostic test.

Down's syndrome screening is undertaken between 10 weeks + 0 days and 20 weeks + 0 days.

2.2 Care pathway

The care pathways for the Down's syndrome screening programme differ depending on the stage in her pregnancy when the women had her first contact or booking with a midwife. In addition, the prenatal investigation care pathway is applied when the result of a screening test is a higher risk.

The following outlines the screening care pathway for the first and second trimester Down's syndrome screening

- During the first contact or booking visit with the midwife, verbal and written information about the dating scan, Down's syndrome screening and 18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan is given to the woman.
- First trimester combined screening is offered between 10⁺⁰ to 14⁺¹ weeks gestation. The maternal serum sample can be taken between 10⁺⁰ to 14⁺¹ weeks gestation and the nuchal translucency measured between 11⁺² and 14⁺¹ weeks gestation. For women presenting late, between 14⁺² and 20⁺⁰ weeks, the quadruple test is offered.
- The woman's choice to decline or accept screening is recorded in the health care records.
- Screening declined: The woman continues with pregnancy and the outcome is recorded.
- Screening accepted:
 - Combined test: Once the woman has chosen to be screened, a dating scan, maternal blood collection and NT scan is performed, ideally within the same visit. If the NT measurement is greater than or

- equal to 3.5mm, referral for specialist scanning and counseling should be considered as good clinical management in all cases.
- Quadruple test: Once the woman has chosen to be screened maternal blood is collected.
 - The midwife/clinician will complete a laboratory request form. The form will include the following essential information that will aid in correctly identifying the woman and determining a risk calculation: correct maternal demographics, gestational age determined by ultrasound, smoking status (if yes or formerly, how many and date stopped), maternal weight on the day sample was taken, family origin or ethnicity, diabetic (yes/no), single or multiple pregnancy and note of any fertility treatment (e.g. donor egg or IVF).
 - Sample and form are dispatched to the biochemistry laboratory for validation and analysis.
 - Sample is analysed and a risk that is high or low is determined using a cut-off of 1:150.
 - Lower risk:
 - The midwife/clinician is informed of the result which is recorded in the health records.
 - The result is communicated, usually by issuing a letter. All women should be notified of their screening test result within two weeks of the test being taken. The results are then be documented in the Trusts clinical information system and/or in the woman's maternity notes.
 - Prenatal diagnosis (PND) is not offered. The woman continues with her pregnancy and outcome is obtained.
 - Higher risk result:
 - The midwife/clinician is informed of the result which is recorded in the health records.
 - The woman is informed of the result (usually by telephone) within 3 working days of the sample being received by the laboratory and is recalled.
 - The midwife and mother discuss the options available.
 1. To have no further testing;
 2. To have an additional diagnostic test. This option should be offered within three working days of receiving the screening test results.
 - Woman is referred by the sonographer or midwife to a hospital clinician or fetal medicine unit specialist.
 - If the mother decides to have a prenatal diagnosis test (PND) either quantitative fluorescence polymerase chain reaction (QF-PCR) or full karyotyping is offered. Sample collection for the test is performed by chorionic villus sampling (CVS, between 10⁺⁰ and 13⁺⁶ weeks) or amniocentesis (after 15⁺⁰ weeks).
 - Note: Multiple pregnancy PND must be conducted in accordance with the NICE clinical guideline 129.
 - PND declined: The woman continues with her pregnancy and outcome is obtained.
 - PND accepted: Consent is explicitly obtained and the woman's decision is documented in the health care records.

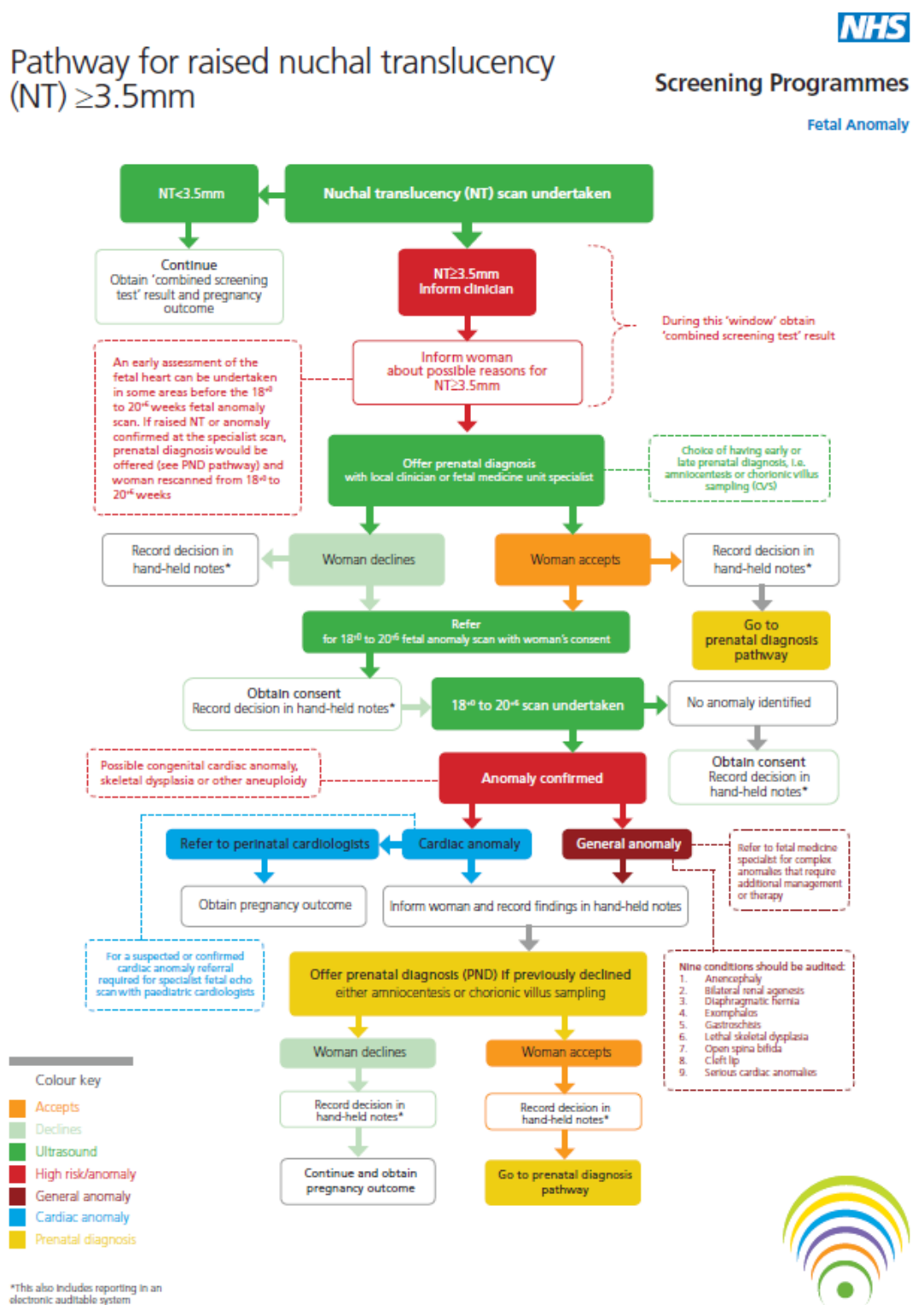
Public health functions to be exercised by the NHS Commissioning Board

- Pre-counselling is completed with the clinician to ensure that the woman is aware of the purpose, benefits, limitations and implications of undergoing a PND.
- PND is preformed using continuous direct ultrasound guidance by an experienced clinician.
- The woman is given information on how the results may be communicated to her and a method agreed.
- Sample is sent to the molecular/cytogenetic or pathology 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(very rare)
 - Miscarriage: A CVS or amniocentesis carries a 1-2% chance of inducing a miscarriage.
 - Normal result: The woman will continue with pregnancy and outcome is obtained.
 - Abnormal result: The woman is provided with all the information about the result and given the opportunity to discuss the results with health professionals who are knowledgeable about Down's syndrome This will include the offer of a termination of the pregnancy.
- Termination of pregnancy declined: The woman continues with her pregnancy and outcome is obtained.
- Termination of pregnancy accepted: This is undertaken in line with the Abortion Act 1967.
- Fetal pathology is offered. If accepted maternal consent is attained and outcome is obtained.

The complete care pathway for T21 screening can be found on the Map of Medicine website at:

http://eng.mapofmedicine.com/evidence/map/down_s_syndrome_screening1.html

Figure 1 Pathway for raised nuchal translucency greater than 3.5m



2.2 Figure 2 Care pathway for prenatal investigation

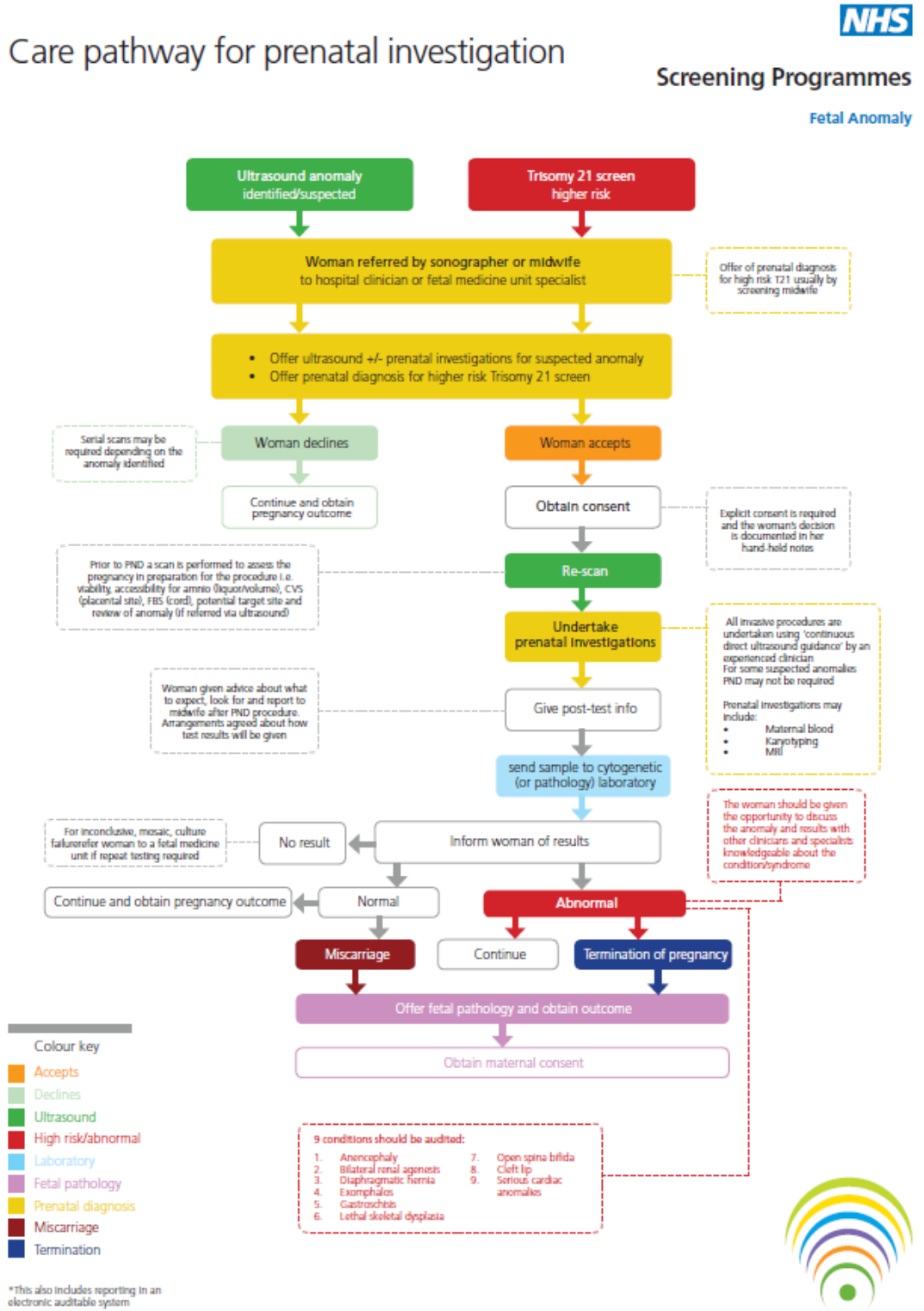
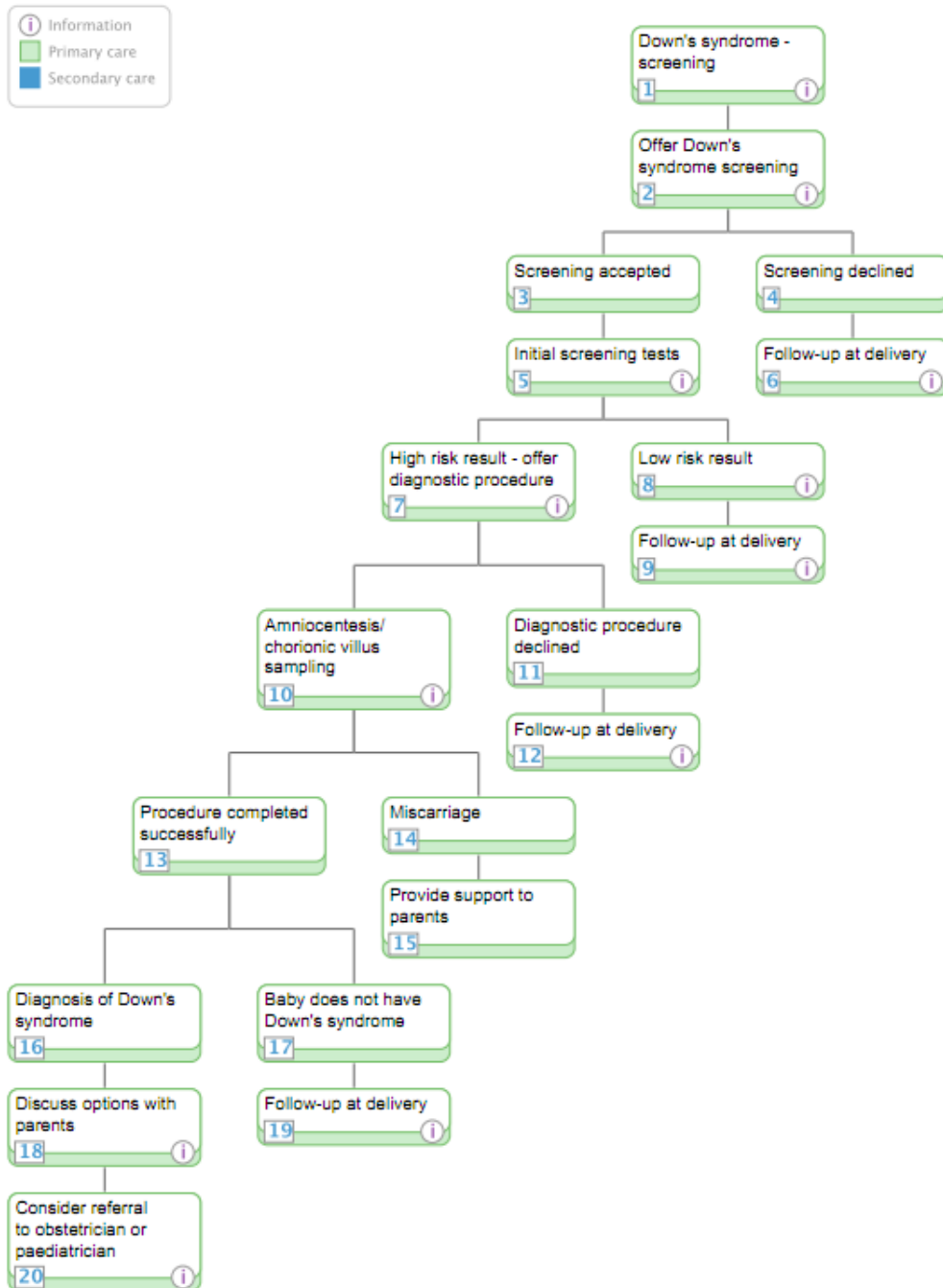


Figure 3 Map of Medicine care pathway for Down's syndrome screening

http://eng.mapofmedicine.com/evidence/map/down_s_syndrome_screening1.html
 This care map has been locally developed and approved by The UK National Screening Committee for use in England.

Down's syndrome screening



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Page 1 of 8

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.

In accordance with UKNSC standards and protocols the provider is expected to:

- have appropriate failsafe mechanisms in place across the whole screening pathway. A complete list of the failsafe processes in the Down's syndrome screening programme to be met by the provider can be found on the national NHS FASP screening programme website
- 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 NHS CB 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 routine staff training and development

2.4 Roles and accountability throughout the pathway

Antenatal Screening – Working Standards for the Down's Screening Programme outlines the various roles and accountabilities that must be adhered to. The most recent version of this document can be accessed from NHS Fetal Anomaly Screening Programme Website.

2.5 Commissioning Arrangements

The commissioning of the Down's syndrome screening pathway involves commissioning at different levels. Down's syndrome screening services will be commissioned by the NHS CB alongside specialised services where appropriate. Commissioning the Down's syndrome screening pathway involves commissioning at different levels as set out in the following table.

Public health functions to be exercised by the NHS Commissioning Board

Section of pathway	Provider	Possible level of commissioning		Rationale and other comments
ANTENATAL				
Identify cohort in a timely manner	Maternity services / primary care	LAT	CCG	The eligible population is identified through routine midwifery-led antenatal care or via primary care (GPs and pharmacy). CCGs will have responsibility for commissioning maternity care. The NHS CB will have responsibility for commissioning pharmacy services and holding primary care contracts.
Maximise the offer to the identified cohort	Maternity services / primary care	LAT	CCG	Informing the cohort and maximizing uptake in a timely manner takes place during routine midwifery-led antenatal care and also sometimes in primary care. CCGs will have responsibility for commissioning maternity care. The NHS CB will have responsibility for holding primary care contracts.
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.
Screening test – sample taking (maternal blood test)	Maternity services	LAT	CCG	Carried out through routine maternity antenatal care. CCGs will have responsibility for commissioning maternity care.

Public health functions to be exercised by the NHS Commissioning Board

Screening test – analysis (first and second trimester)	Biochemistry laboratories	LAT	CCG	There are currently 23 biochemistry labs carrying out first trimester testing for Trisomy 21, and approximately 10 carrying out second trimester testing. This numbers of laboratories is likely to be reduced still further. The level of commissioning needs to be through the NHS CB to allow centralisation of these services and to improve quality and efficiency as per direction of the pathology modernization agenda. (Carter Review of NHS Pathology Services (2006, 2008) made the case for consolidating pathology nationally to improve quality, patient safety and efficiency)
Results reporting	Maternity services	LAT	CCG	Results reporting (higher and lower risk) is part of routine midwifery care. CCGs will have responsibility for commissioning maternity care
Counselling of higher risk couples undergoing pre-natal diagnosis	Maternity services	NHSCB – specialised commissioning	NHSCB	Counselling of higher risk couples is part of pre-natal diagnosis and is under specialised commissioning NHS CB will have responsibility for commissioning specialised services
Sample taking for higher risk couples - amnio/Chorionic Villus Sampling (CVS)	Maternity services	CCGs NHS CB – specialised commissioning	NHS CB	Sample collection of the amniotic fluid or chorionic villus sampling (CVS) by a specialist obstetric consultant. CVS is in the Specialised Services National Definition Set (SSNDS). Amniocentesis where the procedure is difficult/complex is in the SSNDS, otherwise it is

Public health functions to be exercised by the NHS Commissioning Board

				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)	Cytogenetic/ molecular laboratories	NHS CB – specialised commissioning	NHS CB	QF-PCR /Karyotyping analysis delivered by the molecular/cytogenetic laboratory is under specialised services NHS CB will have responsibility for commissioning specialised services
Results reporting and counselling	Maternity services	NHS CB – specialised commissioning	NHS CB	Reporting of results and counselling after a positive result to discuss options delivered by specialised midwives under specialised commissioning. NHS CB will have responsibility for commissioning specialised services

2.6 Links between screening programme and national programme centre expertise

PHE will be responsible for delivery of the essential elements of screening programmes 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 Key Performance Indicators (KPI)s 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

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.

The provider and NHS CB will meet at regular intervals (at least quarterly). 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 providers will:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures
- 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 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 and integrity of the screening programme
- comply with the UK NSC guidance on managing serious incidents.

Public health functions to be exercised by the NHS Commissioning Board

- have appropriate and timely arrangements in place for referral into treatment services that meet the screening programme standards found on the NHS 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

3.4 Definition, identification and invitation of cohort/eligibility

All pregnant women.

3.5 Location(s) of programme delivery

The provider will ensure accessible service provision for the population while assuring that all locations where Down's syndrome screening requires biochemistry analysis and prenatal diagnostic testing 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.

3.7 Entry into the screening programme

While there is nothing specific in the GP contract regarding the Down's syndrome screening programme, general practitioners have a key role in ensuring that pregnant women referred to them are referred on as soon as possible to Midwifery Services and for holding results of newborn screening.

3.8 Working across interfaces between departments and organisations

The screening programme is dependent on strong functioning working relationships, both formal and informal, between Primary Care, the Hospital Trust (maternity and obstetric ultrasound services), the Screening Laboratory, Diagnostics and Molecular and Cytogenetic services, and appropriate Clinical Services, i.e. The Screening Pathway. 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:

- ensuring that midwives and obstetric sonographers are supported to facilitate early booking for maternity care within primary and community care settings.
- agreeing 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.
- 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.
- developing an escalation process for Serious Incidents (SIs)
- contributing to any NHS CB's initiatives in screening pathway development in line with UKNSC expectations.
- facilitating, providing or supporting education and training both inside and outside the provider organisation.

3.9 Information on Test/ Screening Programme

Prior to offering any test or procedure, the woman must be given verbal and written information. A variety of materials in a number of formats are available to help health professionals communicate information about Down's syndrome screening.

In accordance with UK NSC standards and protocols the providers must ensure that all women receive information in an appropriate format about the screening tests for Down's syndrome as early as possible with at least 24 hours before being asked to make any decision. The information should be impartially presented and should include an explanation of the limitations of the screening test.

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

In accordance with UK NSC standards and protocols the providers will ensure that the ultrasound portion of the screening test must be performed by a health professional with any of the qualifications outlined in Section 3.177

All T21 screening laboratories are required to be part of the Down's Syndrome Screening Quality Assurance Support Service (DQASS). A stand-alone screening laboratory must have a workload of at least 10,000 Down's syndrome screening specimens per annum to have sufficient confidence in the quoted annual screen positive rates, and to have sufficient specimens to calculate reliable, monthly median values for the biochemical markers. Laboratories with a workload of less than 10,000 specimens a year must be part of a managed network of no less than 3 laboratories, with each having a minimum workload of 5,000 specimens per year and identical screening policies and analytical procedures in force.

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.

Laboratories are expected to follow the standards laid out in guidance described in introduction

Results reporting and recording

T21 screening results are determined by the following provisions:

T21 screening result	Action
< 1:150	All women should be notified of their screening test result within two weeks of the test being taken. The results must then be documented in the Trust's clinical information system and/or in the woman's maternity notes. All women should be informed of their screening test result by a method that is flexible and acceptable to them.
> 1:150	The midwife is notified and the result is recorded in the woman's health records. The woman is recalled and a diagnostic test should be offered within 3 working days of the report being issued.

Results for the prenatal diagnostic testing should be available within 3 working days from the date the sample is received for the QF-PCR

Diagnostic test result	Action
Negative	The result is notified to the midwife and recorded in the health records. The woman is notified within the recommended period of 3 working days for the QF-PCR analysis. No further follow up is required and the woman can continue with her pregnancy.
Positive	The midwife is notified and the results are recorded in the health records. The woman is recalled and counselling is offered to discuss how the pregnancy can be managed.

3.11 Results giving

The provider will give low risk results either verbally or in written form.

The provider will give high risk results verbally to the woman. See section 2.2.

3.12 Transfer of and discharge from care obligations

Active inclusion in the screening programme ends at three points depending on the woman's risk

1. when the Down's syndrome screening result is low risk or
2. when a woman has a high risk and has a normal PND or
3. when a woman has a high risk and has an abnormal PND and has been provided with information on her further options.

3.13 Parent and Carer Information

A variety of national service user information materials are available from the National Screening programme website, including information for parents on how to support a child with Down's syndrome. Providers will be responsible for obtaining sufficient required copies in order to maintain a high quality Down's syndrome screening service.

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. A Lead Screening Sonographer (SSST21) together with a Screening Midwife/Coordinator (with appropriate deputy arrangements) to ensure continual cover, will oversee the implementation, delivery and monitoring of the 'combined screening programme' in both the antenatal and ultrasound settings.

All professionals involved in the provision and delivery of antenatal screening for Down's syndrome should undergo training recognised by the UK NSC.

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 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). The qualification should be relevant to obstetric ultrasound practice.
- Royal College of Obstetricians and Gynaecologists (RCOG) Royal College of Radiologists (RCR) Diploma in Obstetric Ultrasound.

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.

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.

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.

3.16 User involvement

All 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. It may be efficient to include in the annual report

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

Ultrasound equipment used to perform the NT and CRL measurement for the combined test should be capable of producing images of appropriate diagnostic quality. Standards for ultrasound equipment can be found in "*NHS Fetal Anomaly Screening Programme: 18⁺⁰ to 20⁺⁶ Weeks Fetal Anomaly Scan National Standards and Guidance for England*" available on the National [NHS Fetal Anomaly Screening Programme Home Page](#).

Public health functions to be exercised by the NHS Commissioning Board

Biochemistry laboratories must comply with the current National Specification for Risk Calculation Software published by the UK NSC, be CE marked and comply with EU directives with any computer software used to calculate the T21 risk.

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 National Screening Committee, which recommend the best working practice for health professionals to work towards in Down's syndrome screening and diagnostic testing. The Down's syndrome screening and diagnostic testing standards provide an overview all aspects of screening which include consent, best practices and data requirements for quality assurance purposes.

4.2 Risk assessment of the pathway

Providers are expected to have an internal quality assurance process that assures the NHS CB of its ability to manage the risks of running a screening programme.

Providers are expected to use the Failures Modes and Effects Analysis (FMEA) method, which is recommended by the NHS National Patient Safety Agency's risk assessment programme, to identify all possible risks along the Down's syndrome screening pathway and to ensure that there are control arrangements in place to minimise the occurrence of the possible risks.

Risks should 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.

In accordance with UK NSC standards and protocols 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 and the NHS CB

- 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 of it and of their responsibilities within it
- 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 UK NSC website (<http://www.screening.nhs.uk/quality-assurance#fileid9902>)
- review their procedures and processes against the standards for the Down's 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 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 Data collection, monitoring and reporting

Providers should ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions. In addition, providers should, as a minimum, be able to provide the detection and false positive rates of their screening population.

Data collection through routine reporting is obtained through the following processes:

- Annual returns from antenatal biochemistry and cytogenetic laboratories.
- KPI for Down's syndrome screening is submitted quarterly by local maternity units and antenatal laboratories.
- Audit of the working standards upon request by the NHS FASP. The audit may require data regarding timeframe for the return of screening and diagnostic test results and
- Bi-annual submission to the NHS FASP monitoring arm, Down's Syndrome Screening Quality Assurance Support Service (DQASS). Data submission requirements include individual patient measurements for a set number of fields by biochemistry laboratories and NT and CRL measurements for each sonographer.
- Information required from external quality assurance bodies such as National External Quality Assurance Scheme (UK NEQAS).
- Performance indicators will be agreed by the NHS CB. Providers will also be required to supply any future Key Performance Indicator data agreed by the UKNSC and the NHS CB.

5.2 Quality

All Trusts should have a lead screening sonographer and screening midwife/coordinator (and deputies) in place to oversee the screening programme.