

NHS Fetal Anomaly Screening Programme

T21 NATIONAL STANDARDS (v.4)

National consultation event

19 September – 24 October 2011

1.0 POLICY FRAMEWORK

STANDARDS

- 1.1 All eligible pregnant women residing in England must be offered the first trimester Combined Screening/Test for Down's syndrome (T21) by their local hospital Trust (and assessed using the specified fetal measurement parameters as in Table 1.1)
- 1.2 All pregnant women undergoing the Combined Screening/Test must have a blood sample and nuchal translucency (NT) scan undertaken.¹
- 1.3 All service providers involved in T21 screening should work collaboratively with related external agencies and bodies such as the royal colleges, social services, voluntary sector support groups, cultural and bereavement services.
- 1.4 All policies and standards must be reviewed every three years in line with national and new technological developments that are approved by the UK National Screening Committee (UK NSC)

Table 1.1 *Obstetric ultrasound parameters for T21 screening*²

Ultrasound parameter	Equivalent in weeks gestation	Measurement	Screening test
Crown rump length (CRL)	11 ⁺² to 14 ⁺¹	44.0mm to 84.0mm (inclusive)	Combined
Head circumference (HC)	14 ⁺²	Equal to or greater than (\geq) 101.0mm	Quadruple

¹ In the absence of fetal malformation, the National Programme Centre currently recommends that nuchal translucency is the only variant that should be used to screen for T21 screening. Other variants, for example the nasal bone, should not be used for this purpose unless sufficient evidence becomes available

² The fetal measurement obtained will determine the type of screening test undertaken.

2.0 SCREENING GOVERNANCE

STANDARDS

- 2.1 Accountability for screening programmes should be included in the portfolio of an Executive Director of the hospital Trust.
- 2.2 Line management and accountability of the Screening Coordinator (if not a midwife) should be to a senior manager in the Hospital Trust.
- 2.3 Line management and accountability of the Screening Coordinator/Midwife should be to the Head of Midwifery or equivalent.
- 2.4 Line management and accountability of the Screening Support Sonographer (SSS) should be to the Superintendent Sonographer or equivalent.
- 2.5 Risk within screening programmes should be included in regular reports to the hospital Trust Board in line with all other health services. (The Board may wish to establish a separate governance committee for screening delivery or integrate within existing arrangements for clinical governance in the hospital Trust ensuring representation from senior clinicians and managers leading the screening programmes).
- 2.6 All T21 'core' healthcare providers should regularly attend the screening governance committee meetings with senior Trust and PCT colleagues (see Table 2).
- 2.7 The following groups must be sent a copy of the annual report:
 - Hospital Trust Chief Executive and Board of Governors
 - Hospital Trust screening laboratory (biochemistry and cytogenetic Leads)
 - Local Commissioning Groups (LCG)
 - National Programme Director of the UK NSC (if requested)
 - NHS Fetal Anomaly Screening Programme (if requested)
- 2.8 The hospital Trust Board of Governors should sign off the annual report ensuring that all recommended actions are taken and should oversee resolution of any major risks identified within the screening programme including appropriate management of serious incidents.

Table 2: T21 screening 'core' healthcare professionals function

TITLE	FUNCTION
Antenatal Screening Coordinator/midwife (ANSC)	<ul style="list-style-type: none"> ▪ coordinating and managing the antenatal screening programme at Trust level
Screening Support Sonographer (SSS T21)	<ul style="list-style-type: none"> ▪ coordinating and managing the nuchal translucency (NT) component of the Combined Screening/Test at Trust level
Biochemistry screening laboratory lead	<ul style="list-style-type: none"> ▪ responsible for overseeing each step of the laboratory testing process ranging from specimen handling to instrument performance validation.
Lead obstetrician	<ul style="list-style-type: none"> ▪ coordinating and managing the antenatal screening programme at Trust level
Fetal medicine specialist	<ul style="list-style-type: none"> ▪ Responsible for managing the local fetal medicine service and undertaking invasive testing for pregnant women with a 'higher risk' T21 screening result
Cytogenetic laboratory lead	<ul style="list-style-type: none"> ▪ Responsible for overseeing each step of the laboratory testing process ranging from specimen handling to instrument performance validation
PCT commissioner/screening lead	<ul style="list-style-type: none"> ▪ To work closely with service providers and ensure that steps in the care pathway implemented and appropriately resourced in terms of funding and capacity.

A) ORGANIZATION AND MANAGEMENT OF SCREENING

- 2.9 All service providers, who undertake 4,000 antenatal bookings a year, should have one whole time equivalent (WTE) Screening Coordinator/Midwife with adequate deputising arrangements to oversee the T21 hospital Trust screening programme.
- 2.10 All service providers should provide administrative support to assist the midwifery, sonography and laboratory professionals with their T21 clinical and data collection work.

- 2.11 All service providers must have a Screening Support Sonographer (SSS T21) with adequate deputising arrangements to oversee ultrasound QA functions such as image review, teaching, support, assessment and audit).³
- 2.12 All service providers should have in place a dedicated competent obstetrician with time allocated in their job plan to oversee T21 screening.
- 2.13 All service providers should have in place dedicated competent, trained biochemist with support staff for each step of the laboratory testing process ranging from specimen handling, risk reporting and instrument performance validation.
- 2.14 All service providers should have in place dedicated competent, trained cytogeneticist with support staff for each step of the laboratory testing process ranging from specimen handling and reporting of PCR and karyotype results.

B) WRITTEN POLICY

- 2.14 All relevant service providers must be involved in establishing a written policy for T21 screening. These should include provider and commissioning organisations as well as user and support groups.
- 2.15 The written policy must:
- adhere to national policies, standards and recommendations set by the UK NSC
 - governance arrangements
 - set out the aims and objectives for the local pregnant population
 - include all screening and diagnostic services involved in the screening programme
 - include a clinical referral care pathway for independent sector services which access the hospital Trust's screening programme and vice versa
 - contain guidance when other abnormalities are detected
 - have a clearly defined system for informing women of their screening test results
 - include the working partnership of allied agencies such as: social services,

³ At least one hour per month is required to undertake QA functions

voluntary sector support groups, cultural and bereavement services

- include information related to the Equality Act 2010
 - be disseminated widely to all professionals involved in the provision of antenatal screening
 - be made available to pregnant women, at their request
 - include failsafe procedures.
- 2.16 All independent healthcare services for T21 screening should be supported and overseen by a medical practitioner, preferably an obstetrician.
- 2.17 All Primary Care Trusts, hospital Trusts and independent healthcare services must have in place agreed joint policies, standards and referral pathways for first and second trimester T21 screening.
- 2.18 All independent healthcare services offering a T21 screening service must be registered and comply with the regulations set out in Care Quality Commission's (CQC) 'The Scope of Registration' (2010) and the 'Statutory Instrument 2001 No.3968: The Private and Voluntary Health Care (England) Regulations' (2001)
- C) AUDIT**
- 2.19 Screening programmes are expected to have the appropriate tools to support the minimum criteria (see appendix 2) for the audit process. This must include information technology networks that link with appropriate data collection systems within the Trust
- 2.20 Laboratory and ultrasound providers for T21 screening services must provide must provide screening and outcome data in a form specified by DQASS.
- 2.21 All service providers must respond to the completion of the Care Quality Commission's (CQC) triennial survey of women's' views and experiences of antenatal screening, also cited as an indicator in the NHS Outcomes Framework.
- 2.22 All hospital Trust departments (maternity, gynaecology and local cytogenetic laboratory) should notify their screening laboratory about the pregnancy outcome of any woman who underwent T21 screening.

3.0 EQUITY AND EQUALITY

STANDARDS

- 3.1 The hospital Trust Clinical Governance Group which oversees the T21 screening programme is responsible for ensuring that inter-agency arrangements are in place and enabling equity of access for pregnant women.
- 3.2 All service providers involved in the T21 care pathway must be familiar, and comply with, the Government's Equality Act (2010) and with the recommended guidelines for Government publications.
- 3.3 Information must be available in a range of formats and languages approved by the UK NSC for example:
- Audio tapes
 - Video tape
 - Compact Disc (CD)
 - Visual (including 'easy read') and Braille aids
- 3.4 All service providers should take into account the special requirements for each woman for example, the environment and on-site facilities, appointment time and location to meet her needs.
- 3.5 All pregnant women must have access to an interpreter who is trained to discuss T21 screening and a range of communication aids if they do not:
- Speak English and/or
 - Read English and/or
 - Understand English and/or
 - Have a hearing impairment
- 3.6 All service providers should have a suitable and quiet area where T21 screening can be explained for women that have any type of impairment.
- 3.7 All pregnant women that have special requirements should be offered additional support from other agencies or support groups that are trained in T21 pregnancy screening.

4.0 COMMUNICATING RESULTS

STANDARDS

- 4.1 All pregnant women must be notified of their screening test result within two weeks from the time of sampling.
- 4.2 All service providers must document the woman's T21 screening test result in her hand held notes and ensure that it is also recorded in the hospital Trust's clinical information system.
- 4.3 All service providers should inform women about their 'higher' or 'lower risk' screening test result and specific numerical risk.
- 4.4 All pregnant women must be given the option to discuss their screening test results and if they decide to do, this should be undertaken in a suitable environment.
- 4.5 Women who receive a higher risk test result must have access, within 3 working days (of the result being issued by the laboratory) to an appropriately trained professional in order to discuss the result and options for further management.
- 4.6 All service providers must record the woman's decision following her higher risk result in the Trust's clinical information system and/or in the maternity notes.

6.0 EDUCATION AND TRAINING FOR STAFF

STANDARDS

- 5.1 All service providers involved along the screening pathway for antenatal screening for T21, should access education and training which is recognised/approved/developed by the UK National Screening Committee, ARC and the DSA at regular (at least annual) intervals
- 5.2 All pregnant women should be given up to date, unbiased and correct information about T21 screening by all healthcare professionals involved in the screening pathway to enable them to make informed choices regarding screening for T21.
- 5.3 All service providers must provide staff with the opportunity to access an educational programme to ensure that consistent, up-to-date information is being given to women to enable them to make informed choices regarding screening for T21. This training programme should include use of the NHS FASP/UK NSC freely available resources to ensure learning is up-to-date and congruent with policy and practice standards
- 5.4 The hospital Trust screening co-coordinator or equivalent should ensure that education and training for T21 screening is accessible and accessed by all relevant staff involved in the Trust's antenatal and newborn screening programmes at regular (at least annual) intervals so that the pregnant women they see are able to make decisions based on the most up to date information.⁴
- 5.5 All service providers' training should be in line with NHS FASP guidance and employers should ensure all staff gain and maintain competence.
- 5.6 All service providers must ensure that all healthcare professionals involved in T21 screening have received appropriate training and maintain competence in the skills of communication and counselling.

⁴ A UK NSC online, auditable resource which covers all antenatal and newborn programmes is available to assist with this (<http://cpd.screening.nhs.uk/elearning>). For staff directly involved in the T21 screening pathway annual completion of the NHS FASP on-line resource to support first and second trimester screening should be accessed at least annually (<http://resources.fetalanomaly.screening.nhs.uk/professional/cemt21?page=100260>). This activity should be audited and reported back to the Trust Board and the UK NSC as part of routine data reporting/annual report.

- 5.7 All new service providers involved in screening should work through an appropriate induction as part of their mandatory training and ongoing CPD portfolio regarding screening which outlines the policy and practice recommendations of the UK National Screening Committee.⁵
- 5.8 Any service provider undertaking NT measurements, and in particular those employed through an external employment agency, should have their NT competency status assessed with the national screening programme prior to undertaking screening for T21
- 5.9 All service providers (sonographers, clinicians and midwives) undertaking any type of antenatal ultrasound scan must possess the minimum qualifications as recommended and advised by the UK, NSC, NHS Fetal Anomaly Ultrasound Screening Programme and its Education and Training Sub-Group.

⁵ An on-line resource is available to support this (<http://cpd.screening.nhs.uk/induction-resource>)

6.0 INFORMING WOMEN & CONSENT

STANDARDS

- 6.1 All pregnant women at the first antenatal appointment (hospital or community setting) and must be offered up-to-date information on fetal anomaly screening based on the current available evidence (written, verbal and alternative formats) produced to a high standard outlining the purpose, condition, testing process and implication.
- 6.2 All service providers must have a care pathway to provide evidence that the UK NSC and NHS FASP leaflets are being used
- 6.3 All pregnant women must be given the time they need to consider their choices and to discuss them with others people should they wish to.
- 6.4 All pregnant women must be given the choice to discuss their decisions with a trained and competent healthcare professional about T21 screening and the possible long-term health issues of the condition.
- 6.5 Information must be provided in an accessible format that all pregnant women can understand, and if necessary, should include an interpreter who is trained to discuss T21 screening and appropriate communication aids.
- 6.6 All service providers must avoid the terms, 'screen positive' and 'screen negative' when talking about T21 screening explaining test results to pregnant women. Instead, 'higher risk' and 'lower risk' together with the laboratory numerical value (e.g. 1: 200) must be used instead.
- 6.7 All service providers must provide supplementary information (including relevant informative/supportive websites or details of support organisations) to all pregnant women who after screening receive a higher risk test result.
- 6.8 All discussions and decisions between the service provider and the woman must be clearly recorded/filed in the woman's hand held record and hospital Trust's clinical information system.

7.0 THE COMBINED SCREENING/TEST

A) ULTRASOUND

STANDARDS

- 7.1 All hospital Trust imaging departments must have an agreed written policy which adheres to national standards and defines the purpose of T21 screening.
- 7.2 All obstetric ultrasound assessment techniques, parameters, gestational tables and charts used to undertake fetal measurements must meet nationally agreed standards.
- 7.3 The findings from any type of obstetric ultrasound scan must be recorded by all healthcare professionals in the hospital Trust's clinical information system and/or in the woman's maternity notes.
- 7.4 All hospital Trust imaging departments should allocated a 25 minute time slot for the first trimester scan (i.e. fetal surveillance, CRL and NT measurements).
If a first trimester obstetric ultrasound image is compromised, then the sonographer should consider undertaking a trans-vaginal scan an attempt to obtain better views of the CRL and NT.

B) QA OF NT AND CRL MEASUREMENTS

STANDARDS

- 7.5 All CRL and NT measurements must be subjected to rigorous, valid audit and external evaluation by the DQASS.
- 7.6 To ensure satisfactory performance, all service providers involved in the Combined Screening programme, must undertake 25 paired CRL and NT measurements in any one year
- 7.7 All hospital Trust imaging departments that provide a first trimester scan (fetal surveillance, CRL and NT scan) must take part in an approved quality assurance programme, such as DQASS.
- 7.8 All hospital Trust Screening Support Sonographers (SSS) T21 leads must be given a minimum of one session a week to undertake their clinical duties (for example, image review, teaching, support, assessment and audit).

- 7.9 All hospital Trust sonographers undertaking the NT component of combined screening within the NHS should submit a minimum of 25 paired CRL and NT measurements twice a year to DQASS.
- 7.10 All hospital Trust Screening Support Sonographers (SSS) T21 leads must on a monthly basis review 3 CRL and NT images per sonographer using the agreed NHS FASP criteria and scoring system.
- 7.11 All sonographers undertaking the NT component of Combined Screening/Test within the NHS should review their distribution curves with the SSS T21 at least once within their ultrasound department's 6 monthly DQASS cycle.
- 7.12 All SSS should keep accurate records of their own training and any training delivered to their colleagues.
- 7.13 All sonographers should report and record their unique DQASS /FMF identification code and the CRL and NT component of combined screening on the biochemistry laboratory form (accurate to 0.1mm).
- 7.14 During an examination the operator should attempt to obtain three NT measurements. The largest measurement which meets the FASP criteria should be recorded and all three images and measurements archived. If three measurements are not practical, the operator should document the reason in the maternal record and/or hospital system.
- 7.15 All sonographers newly accredited with the NHS FASP should be allocated and use a unique DQASS identification code when undertaking CRL and NT measurements.
- 7.16 All hospital sonographers previously accredited with the FMF NT training programme and now undertaking NT and CRL for the NHS Combined Screening Programme must notify DQASS of this change and continue to scan using their unique FMF identification number.

8.0 MULTIPLE PREGNANCIES

Please note that NHS FASP has recommendation the standards to be included in the forthcoming NICE Multiple Pregnancy Guidelines. As such, this particular section of the document will be consulted on separately after the new NICE guidelines are released on 28 September. Information about this event will follow in due course.

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9.0 LABORATORIES

STANDARDS

- 9.1 All hospital Trust T21 laboratories must define the purpose of its T21 screening service; its policies must adhere to national standards, expectations, guidance and requirements for reporting key performance indicators.
- 9.2 All hospital Trust T21 laboratories must be part of the clinical governance framework of its host organization and be presented on a multi-disciplinary Clinical Antenatal and Child Health Screening Group. An annual report should be submitted to the Group.
- 9.3 All T21 laboratories must be accredited by an appropriate body e.g. Clinical Pathology Accreditation UK (Ltd).
- 9.4 All T21 laboratories must participate in an accredited external quality assessment scheme e.g. UK NEQAS, and be able to demonstrate their performance in an annual report.
- 9.5 All T21 laboratories must submit screening outcome data in the specified format to DQASS and the UK NSC on request.
- 9.6 All T21 laboratories shall be directed by a person or persons who have executive accountability and the competence to assume responsibility for the service. The laboratory director would be expected to have Medical Consultant status or equivalent and have competence at the level of Fellowship of the Royal College of Pathologists (RCP) or equivalent.
- 9.7 All T21 laboratories must have a defined management structure with roles and responsibilities.
- 9.8 All T21 laboratories must have a documented risk assessment policy. Risk assessments of all aspects of the laboratory's service must be carried out regularly with findings, actions taken and outcomes submitted as part of the annual report.
- 9.9 All T21 screening laboratories must audit the hospitals they serve and participate in local, regional and national audit and monitoring of the T21 screening programme. Audit reports should be submitted as part of the annual report.
- 9.10 All T21 laboratories must undertake and document appropriate internal quality assurance procedures (e.g. weekly or monthly checks of screen positive rates, results of the analysis of internal QC specimens and regular checks of median MoM marker values).

- 9.11 A stand-alone T21 screening laboratory must have a workload of at least 10,000 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.
- 9.12 All T21 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 4,000 specimens per year and identical screening policies and analytical procedures in force.
- 9.13 97% of T21 serum screening reports must be issued within 3 working days of receipt of the specimen at the laboratory
- 9.14 All service providers must assign responsibility and have a system in place to track the transfer of maternal or fetal laboratory specimens from arriving at the laboratory to reporting results to the healthcare professional.
- 9.15 The computer software used to calculate the risk for T21 screening must be CE marked and comply with EU directives. It must also comply with the current UK national specification for risk calculation software, and comply with any amendments to that specification within two years of their release.¹⁴
- 9.16 94% of results from rapid tests should be available within 3 working days
- 9.17 94% of results from karyotyping should be available within 14 calendar days

10.0 DIAGNOSTIC TESTING

STANDARDS

- 10.1 All pregnant women should be informed and offered invasive sampling (appropriate for their specific gestation in pregnancy) within 3 to 4 working days of the referral being made
- 10.2 QF-PCR should be offered to women with an increased risk from T21 screening, but where the scan is normal (for example where a nuchal translucency is less than or equal to (\leq) 3.4mm is detected in first trimester screening). In this context QF-PCR should also be used to test for Patau syndrome (trisomy 13) and Edwards's syndrome (trisomy 18) in addition to T21).
- 10.3 As a minimum, QF-PCR and karyotyping should be offered for women found to have a fetal anomaly detected by ultrasound, or where other clinical indications justify (for example, an increased nuchal translucency is more than or equal to (\geq) 3.4mm, a family history of chromosomal abnormality or chromosomal rearrangement in one parent).
- 10.4 No pregnant woman should be offered a diagnostic test for T21 based on their age-related risk alone.
- 10.5 All pregnant women should be informed that the procedure-related risks for amniocentesis and chorionic villus sampling (CVS) are similar.⁶
- 10.6 All women pregnant with a fetus affected by T21 (diagnosed by amniocentesis or CVS), should be offered the choice to discuss the findings with another healthcare professional such as a paediatrician, a fetal medicine specialist, clinical geneticist and/or external body such as ARC, DSA or Genetic Alliance UK.
- 10.7 Following a confirmed diagnosis, clear, accurate information and support should be offered to all women, no matter how they proceed with their pregnancy.

⁶ The miscarriage risk associated with amniocentesis and CVS are different for each woman because on top of the 0.5-1% risk is the 'background' risk for miscarriage that changes with gestational age. Alfirevic Z, Mujezinovic F and Sunberg K *Amniocentesis and chorionic villus sampling for prenatal diagnosis (Review)*. 2009 The Cochrane Collaboration. John Wiley and Sons

11.0 INFORMATION TECHNOLOGY

STANDARDS

11.1 All service providers should ensure that computer-based records are used by maternity, biochemistry and cytogenetic departments and that these systems should be designed to minimize data entry and transcription errors. The IT system in place must be able to link with, and audit, all T21 screening data such as:

- Screening coverage
- Screening uptake
- Pregnancy outcome

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