Lothian NHS Board

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131 536 9000
www.nhslothian.scot.nhs.uk

Date 17/06/2024
Your Ref
Our Ref 8711

Enquiries to Richard Mutch
Extension 35687
Direct Line 0131 465 5687
loth.freedomofinformation@nhs.scot
richard.mutch@nhs.scot

Dear

FREEDOM OF INFORMATION – FETAL ULTRASOUND SCREENING

I write in response to your request for information in relation to fetal ultrasound screening.

Question:

1. All policies, procedures, protocols, guidance, standard operating procedures held by or on behalf of Edinburgh Royal Infirmary relating to (1) fetal ultrasound screening in general, and (2) testing and screening for fetal abnormalities (including Down's Syndrome).

   We would be grateful if you could please provide us with the above information in force between **December 2019 and May 2020.**

Answer:

Please see enclosed all documentation that was used during the period in question, for fetal ultrasound screening.

Attachments:

- Informing your midwife (Sonographers will have a conversation with the patient and will fill in this bright orange form which is stapled to the front of the patient's blue notes, to remind them to contact the midwife - in the event that bloods/screening could not be performed at the time of examination).
- Antenatal Screening - Working Standards for Down's Syndrome Screening 2007
- FASP (Fetal Anomaly Screening Programme) Handbook
- FASP Ultrasound Handbook
- Guide to screening tests - provided by the midwife to patients on the first appointment
- Relevant section of local Ultrasound Protocols in use Dec 2019 - May 2020

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information

Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing, Midwifery and AHPs
Cc: Chief Executive
Enc.

NHS

Antenatal and Newborn Screening Programmes

Antenatal Screening - Working Standards for Down's Syndrome Screening 2007

National Down's Syndrome Screening Programme for England

These standards are intended to improve the quality of the screening process and enable women to exercise informed choice along the Down's syndrome screening pathway.

If you have any comments on these standards, please write to:

NSC
UK National Screening Committee

National Programme Centre
NHS Fetal Anomaly Screening Programme
UK National Screening Committee
Unit G1, The Innovation Centre, University of Exeter,
Rennes Drive, EXETER EX4 4RN

Provided by the

NSC
UK National Screening Committee

http://www.screening.nhs.uk/home.htm
http://www.screening.nhs.uk/downs/home.htm

First Publication March 2003
Revised Publication April 2007

The 2003 standards were reviewed and revised by Rachel Honor Miller, Assistant to the National Screening Programme, under the guidance of Pat Ward, Programme Director, and with the assistance of those acknowledged in appendix 1.

07
Antenatal Screening - Working Standards for Down's Syndrome Screening

'The National Programme Centre wishes to express its thanks to everyone who has contributed to the compilation of these standards.'

Contents

Page Number	Section Number	Section Title
06		Abbreviations
07		Introduction
11	1.0	Policy Framework:
		Written Policy
		Audit
		The Clinical Antenatal Screening - Steering Group
		Screening Co-ordinator
19	2.0	Private Sector Screening Services
23	3.0	Clinical Governance
27	4.0	Equity
29	5.0	Clinical Arrangements
33	6.0	Education and Training for Staff
37	7.0	Consent
41	8.0	Informing Women
45	9.0	Women with Special Requirements
49	10.0	Ultrasound Scanning
55	11.0	Nuchal Translucency Measurements
59	12.0	Multiple Pregnancies
61	13.0	Laboratories
65	14.0	Diagnostic Testing
69	15.0	Information Technology

Page Number	Section Title	
71	References	
75	Bibliography	
79	Annex 1	Useful Websites
83	Appendix 1	Expert Groups
87	Appendix 2	Audit Requirements
99	Appendix 3	Training Resources
103	Appendix 4	Pathway for Down's Syndrome Screening
105	Appendix 5	Minimum Qualifications required for performing Ultrasound Scans

Abbreviations

AFP	Alpha-fetoprotein
BMUS	British Medical Ultrasound Society
CASE	Consortium for the Accreditation of Sonographic Education
CNST	Clinical Negligence Scheme for Trusts
CPD	Continuous Professional Development
DIPEx	Database of Individual Personal Experiences
DMU	Diploma of Medical Ultrasound
DNA	Deoxyribo-Nucleic Acid
DoSySP	Down's Syndrome Screening Programme
DQASS	Down's Syndrome Screening Quality Assurance Support Service
EU	European Union
FISH	Fluorescent In Situ Hybridisation
MoM	Multiple of the Median
NT	Nuchal Translucency
PEGASUS	Professional Education for Genetic Assessment and Screening
QC	Quality Control
QF-PCR	Quantitative Fluorescent-Polymerase Chain Reaction
T	Trisomy
UK NEQAS	United Kingdom, National External Quality Assessment Scheme
UK NSC	United Kingdom, National Screening Committee

Introduction

These standards (2007) are core to the National Down's Syndrome Screening Programme

Introduction

The National Health Service (NHS) Down's Syndrome Screening Programme was implemented following a statement from the Health Minister, Yvette Cooper, in 2001, which set out that:

'All women would be offered screening for Down's syndrome as part of new initiatives to modernise neonatal and antenatal screening.'

This was followed by a statement in the Chief Medical Officer's Update[1].

The remit to implement this over England was given to the UK National Screening Committee (UK NSC) which was set up in 1996 by the Department of Health to advise Ministers on population screening issues - www.nsc.nhs.uk.

The standards were originally collated in 2002 following professional and public consultation. The comments[2] from this process culminated in a publication of working standards in 2003, after a series of reviews by the relevant expert groups relating to the Down's syndrome screening programme, and the Antenatal Sub-Group of the UK National Screening Committee.

This was complemented by a statement from the Department of Health in November 2003, which set out

The Model of Best Practice[3] to which all Trusts should aspire. In October 2003, guidance on Down's syndrome screening was issued from the National Institute of Clinical Excellence on the Routine Antenatal Care of the Pregnant Woman[4].

The initial working standards set out in 2003 were base standards and reflected the stage of implementation.

The core standard of the Programme is that all Down's syndrome screening programmes must meet a target detection rate of greater than 75%, for a false positive rate of less than 3%, by 2007.

The work of the National Programme Centre is to assure the quality of the screening programme and benchmark Trusts against set standards. This reflects the statements set out in the Department of Health (2004) The NHS Improvement Plan – Putting People at the Heart of Public Services:

'Patient safety will be a central focus of health care delivery: caregivers will act to further reduce risks and learn from things that go wrong,'
and:
'In the next stage (up to 2008), there will be a stronger emphasis on quality and safety alongside a continuous focus on delivering services efficiently, fairly, and in a way that is personal to each of us[5].'

Revised Standards
As with all services, assessment and review of standards are an integral part of improvement and quality assurance. They set out what is expected of the service and provide users with knowledge of the level of care they should receive.

The 2003 standards have been reviewed to reflect progress in the service and now incorporate new areas such as private sector screening services, consent, and multiple pregnancies.

They were revised after a thorough consultation with the expert groups* of the UK NSC, allied national bodies, professionals involved in the provision of screening services and relevant support groups (see appendix 1).

It is intended that all standards will be reviewed in accordance with changes to the screening service.

***The annual report which sets out the membership of these groups can be seen on the website: http://www.screening.nhs.uk/downs/documents.htm (Website visited on 22/02/07)**

1.0 Policy Framework

1.0 Policy Framework

The National Programme Centre supports the Healthcare Commission's standard that patients should not experience any unnecessary delay at any stage of the service pathway, and that everything should be measured by its impact upon them[6].

Standards:

1.1 Screening tests for Down's syndrome should be offered to all pregnant women presenting for maternity care, before twenty weeks of gestation.

1.2 The overall standard of the National Programme is for all Down's syndrome screening programmes to meet a target detection rate of greater than 75%, for a false positive rate of less than 3%, by 2007[3]. All screening programmes must have this core objective written in their policy.

The National Programme Centre (2007) expects that Trusts* have achieved these rates as part of the minimum requirement (core standard) put forward by the Model of Best Practice 2003[3].

***N.B. Standards referring to Trusts also refer to hospitals which have been granted foundational status, i.e. Foundation Hospitals.**

1.3 All relevant stakeholders must be involved in developing a written policy for Down's syndrome screening within the Trust. This must include: Strategic Health Authorities, service providers, commissioners, quality programme managers*, clinical staff, cytogenetic services, fetal medicine centres, Primary Care Trusts and user/support groups.

***N.B. The National Down's Syndrome Screening Programme is moving towards quality assurance within its services. This has implications for managers at the service and the departmental level. To reflect this, managers within these standards are referred to as 'quality' managers.**

Written Policy

1.4 The written policy should be performance managed by the Strategic Health Authority.

The written policy must:

- adhere to national standards and recommendations set by the UK National Screening Committee
- set out the aims and objectives for the local population
- include all screening and diagnostic services involved in the screening programme
- include a clinical referral pathway for private sector

services which access the Trust's screening programme

- include a risk assessment policy for each service provider
- 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, voluntary sector support groups, religious bodies and bereavement services
- be disseminated widely to all professionals involved in the provision of antenatal screening
- be made available to pregnant women, at their request

Audit

1.5 Audit and monitoring of the screening programme should be performance managed by the relevant Strategic Health Authority.

1.6 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.

1.7 Providers of laboratory and ultrasound services for Down's syndrome screening must be able to give (as a minimum) the detection rates, and screen positive rates, of their locally screened population.

1.8 A survey of womens' views and experiences of the Trust's screening programme should be conducted at least once a year.

The Clinical Antenatal Screening Steering Group

1.9 A multidisciplinary Clinical Antenatal Screening Steering Group should be in place to oversee the clinical management, governance and quality of the Trust's Down's syndrome screening programme.

1.10 The Chair of the Clinical Antenatal Screening Steering Group should preferably be a lead clinician involved in the Down's syndrome screening service, supported by a quality programme manager.

1.11 The Clinical Antenatal Screening Steering Group should have representatives from the departments and services responsible for

providing the Trust's antenatal screening programme, for instance: the midwifery service, ultrasound department, Primary Care Trust, educational lead, local screening co-ordinator and laboratory service.

1.12 The Clinical Antenatal Screening Steering Group must:

- set out a comprehensive strategic plan for improving quality in accordance with the Trust's overall service developments
- develop policies aimed at managing and reducing risk
- ensure inter-agency arrangements are in place to support women through the screening pathway
- examine the audit report from the screening services, which must be based on the UK National Screening Committee's minimum audit criteria (see appendix 2)

1.13 The Clinical Antenatal Screening Steering Group must assist in the compiling of an annual report, which reflects the UK National Screening Committee's minimum audit criteria.

The annual report must include – as a minimum:

- a summary of the minimum audit information requested by the UK National Screening Committee (see appendix 2)
- findings of the survey (see standard 1.8)

The report must be forwarded to the appropriate regulatory bodies, for instance: the Strategic Health Authority, the Primary Care Trust, Regional Antenatal Screening Co-ordinator and the Trust's Governance Board, which should forward a copy to the Chief Executive of the Trust.

N.B. Foundation Trusts must forward their report to Monitor: The Independent Regulator of NHS Foundation Trusts.

Screening Co-ordinator

1.14 There should be a dedicated antenatal screening co-ordinator/midwife and a deputy appointed by the Trust, responsible for:

- implementing the Trust's written policy on Down's syndrome screening
- assisting in the implementation of policies to achieve the UK National Screening Committee's standards

- assisting in the development of care-pathways
- overseeing the clinical management of the antenatal screening programme for Down's syndrome
- ensuring arrangements are in place for audit and monitoring of the programme, which link to the agreed quality assurance mechanism (see appendix 2)
- assisting in the compilation of an annual report (see also standard 1.13), which reflects the minimum audit criteria (see appendix 2)
- ensuring there are arrangements in place for the education and training of local staff who provide NHS screening services
- supporting women and their families in issues about screening
- advising and supporting staff
- communicating with the Primary Care Trust and its staff
- ensuring timely liaison with Primary Care staff

2.0 Private Sector Screening

2.0 Private Sector Screening

Statement from the UK National Screening Committee:

The UK National Screening Committee aims to protect the health of the population, not simply to advise the NHS. Although screening policy and quality in the private sector is more difficult to regulate than in the NHS, the UK National Screening Committee will continue to consider it.

It also needs to be recognised that a possible conflict of interest may occur in the advice given to the local providers or commissioners, especially if the clinicians also provide screening to the private sector.

Standards:

2.1 The private sector services offering antenatal screening must comply with the Statutory Instrument 2001 No.3968: The Private and Voluntary Health Care (England) Regulations (2001) (refer to annex 1).

2.2 It is expected that the Public Health Department will assess and ascertain the quality of the private antenatal screening services within its population, especially when they access a NHS diagnostic facility.

2.3 Primary Care Trusts and Hospital Trusts must have an agreed clinical referral pathway (see standard1.4) for private sector services which access their screening programmes.

2.4 All private services for Down's syndrome screening should be supported and overseen by a medical practitioner, preferably an obstetrician.

2.5 It is expected that all private screening services for Down's syndrome will be assessed by their local Public Health Department to ascertain the quality of the service being offered, particularly if they use NHS diagnostic facilities.

2.6 Providers of private services for Down's syndrome screening should ensure that they meet the same quality standards, and targets set for the NHS, by the UK National Screening Committee.

2.7 Private services for Down's syndrome screening should participate in an external quality assurance programme e.g. UK NEQAS and DQASS (see also section 13.0).

2.8 The private sector screening services for Down's syndrome should be able to provide their detection rates and screen positive rates, based on their own data.

2.9 Private sector screening services for Down's

syndrome should produce an annual report which allows their performance to be assessed against national standards. This report should contain a summary of the following information:

- the number of women accessing the private service
- the number of screening tests being performed
- the chosen method of screening
- the screen positive rate and detection rate for the service
- the number of women who are referred to, and undergo, a NHS diagnostic test

The National Programme Centre stipulates that women undergoing any screening must be able to assure themselves of the quality and effectiveness of the tests being offered.

3.0 Clinical Governance

(See also section 1.0)

3.0 Clinical Governance (see also section 1.0)

The National Programme Centre supports Government policy aimed at improving quality and accountability in the NHS[7].

Standards:

3.1 Governance arrangements must be put in place by the Trust for their screening programme.

3.2 The Clinical Antenatal Screening Steering Group must be included in the Trust's clinical governance framework.

3.3 The Clinical Antenatal Screening Steering Group is responsible for governance of the Trusts' Down's syndrome screening programme, and should identify individuals responsible for overall quality, performance, and management of the screening programme.

The following tables display a suggested framework for governance within a programme.

Table 1 Governance Framework

Governance of the Down's Syndrome Screening Programme	
Position:	Responsible for:
Antenatal Screening Co-ordinator	• co-ordinating and managing the screening programme at Trust level
Quality Service Managers* of departments and senior laboratory and ultrasound staff involved in delivering the Down's syndrome screening programme	• quality of the service being provided within the department • risk assessment i.e. preventing and dealing with errors in the department • continually improving and managing the service
Quality Programme Manager of the Trust's Down's syndrome screening programme	• quality of the screening programme • quality assurance of the programme • ensuring that the programme is benchmarked against UK national standards
Chief Executive of the Trust	• overall quality and management of the Trust's programme
Director of Public Health for a Primary Care Trust	• ensuring that the local population is covered by a screening programme which adheres to the UK National Screening Committee's standards
Regional Antenatal Screening Co-ordinator	• co-ordinating and managing the screening programme at regional level
Strategic Health Team	• responding to quality assurance issues at regional and local level • overseeing the Trust's screening programme • overseeing the Trust's quality assurance mechanisms

Table 2 Accountability Framework

Accountability Framework for the Down's syndrome Screening Programme	
Position:	Accountable to:
Antenatal Screening Co-ordinator	• Clinical Antenatal Screening Steering Group • Directorate Manager
Quality Service Managers, senior laboratory and ultrasound staff	• Medical Directors • Quality Programme Manager
Quality Programme Manager	• Clinical Antenatal Screening Steering Group • Chief Executive of the Trust
Clinical Antenatal Screening Steering Group	• The Trust's Governance Board • Chief Executive of the Trust
The Trust's Governance Board	• Chief Executive of the Trust • Medical Director for the Strategic Health Authority
Regional Antenatal Screening Co-ordinator	• Primary Care Trusts • Regional Public Health Lead • UK National Screening Committee

***N.B. The National Down's Syndrome Screening Programme is moving towards quality assurance within its services. This has implications for managers at the service and the departmental level. To reflect this, managers within these standards are referred to as 'quality' managers.**

4.0 Equity

4.0 Equity

The National Programme Centre is working towards the reduction of inequalities in womens' experiences of screening.

Standards:

4.1 The Clinical Antenatal Screening Steering Group is responsible for ensuring that inter-agency arrangements[8] are in place to support vulnerable women as they go through the screening pathway (see standard 1.12 and appendix 4).

4.2 The Trust's policy and inter-agency support network must accommodate the needs of those women who are considered vulnerable, for instance: teenagers, asylum seekers, women whose first language is not English, those who have experienced or are experiencing domestic violence, women who have sensory impairments, disabilities or special needs.

4.3 Staff involved in the delivery of the Trust's screening programme should be familiar with the Equality Act 2006 (refer to annex 1).

5.0 Clinical Arrangements

5.0 Clinical Arrangements

The National Programme Centre is working towards women receiving well co-ordinated, quality screening, in appropriate settings[9].

Standards:

5.1 A multidisciplinary Clinical Antenatal Screening Steering Group must be in place to examine and assist in the composition of audit reports (see appendix 2 for minimum criteria), and oversee the clinical management and quality of the Trust's Down's syndrome screening programme (see also standards 1.9 - 1.13).

5.2 A dedicated screening co-ordinator/midwife and deputy should be appointed to oversee the antenatal screening programme at Trust level; this responsibility must be included in their job description (N.B. standard 1.14).

5.3 Adequate clerical support must be provided to assist the screening co-ordinator/midwife and deputy with their clinical duties and with audit and monitoring work.

5.4 The screening and diagnostic tests the woman accepts or declines, must be documented in the Trust's clinical information system and/or in the woman's maternity notes.

5.5 Clear systems must be in place for tracking samples, i.e. from the test being taken to the reporting of the result.

5.6 All women should be notified of their screening test result within two weeks of the test being taken. The result must then be documented in the Trust's clinical information system and/or in the woman's maternity notes.

5.7 All women should be informed of their screening test result by a method that is flexible, feasible and acceptable to them.

5.8 Results on screening tests should be given to women when support concerning the result can be provided, and when further options of the screening pathway can be discussed.

5.9 Women who wish to discuss their screening options, or test results, should be able to do so in an environment which is private and comfortable.

5.10 Women who receive a higher risk* test result must have access, within 3 working days, to an appropriately trained professional, in order to discuss the result(s) and options for further management.

***Higher risk refers to pregnancies, which according to the Trust's screening methods employed, are deemed to be at a higher risk of being affected by Down's syndrome.**

5.11 Following a higher risk test result the woman's decision must be recorded in the Trust's clinical information system and/or in the maternity notes.

5.12 All pregnancies should be followed up by audit, after delivery, to ascertain outcomes for the screening programme.

5.13 There must be a system in place for the cytogenetic department to notify the quality programme manager (see footnote p.26), and the Down's syndrome screening laboratory, of pregnancy outcomes involving an affected fetus/baby: subject to the Trust's policy on confidentiality and data protection.

6.0 Education and Training for Staff

6.0 Education and Training for Staff

The National Programme Centre supports educational programmes which provide staff involved in screening, with unbiased and accurate information about Down's syndrome and screening tests.

Standards:

6.1 All professionals involved in the provision and delivery of antenatal screening for Down's syndrome, should undergo education which is recognised by the UK National Screening Committee. This includes training offered by: Professional Colleges, Institutes of Higher Education, allied institutions and national/local support organisations (see appendix 3).

6.2 The Trust must provide staff with a recognised, ongoing educational programme to ensure that consistent, up-to-date information is being given to women as they make decisions along the Down's syndrome screening pathway (appendix 4).

6.3 The dedicated screening co-ordinator/ midwife and deputy are responsible for ensuring a programme of education is accessible to all staff, involved in the Trust's Down's syndrome screening programme.

6.4 The local screening co-ordinator/midwife must ensure that the educational programme is reviewed and evaluated regularly by the regional antenatal screening co-ordinator.

6.5 All new staff involved in screening should work through an appropriate induction programme which follows the recommendations of the UK National Screening Committee (see appendix 3).

6.6 The ongoing education and training of staff involved in Down's syndrome screening must be seen as an integral part of their continuous professional development.

7.0 Consent

7.0 Consent

Women must understand what they are being screened for, and the implications when being screened, of receiving a higher risk or a lower risk result.

Standards:

7.1 Women must be informed of the purposes, possible outcomes and the limitations of the screening test.

7.2 When women are offered a screening test for the detection of Down's syndrome they must not be made to feel that they should accept the screening tests as part of their antenatal care.

7.3 Only the woman has the right to consent* to (or decline) the screening tests.

7.4 Consent must be obtained prior to any screening/diagnostic tests, and documented in the Trust's clinical information system and/or in the woman's maternity notes.

(For further guidance refer to Gillick Competence - Fraser Guidelines [10] see annex 1: website on consent).

***Consent to screening must be given voluntarily, by a legally competent person, which is a person of any age who can understand the information being given to them[11] to make an informed decision.**

7.5 The screening and diagnostic tests the woman accepts or declines must be documented in the Trust's clinical information system and/or in the woman's maternity notes.

7.6 The right to decline tests or further investigations should be made clear and any such decision, including withdrawal of consent, must be respected.

7.7 Only the woman and those providing the antenatal care have the right to receive the results.

7.8 All professionals must respect a woman's wishes regarding the sharing with her husband/partner of her decision to either accept or decline the screening tests.

8.0 Informing Women

8.0 Informing Women

The National Programme Centre supports women having access to information and counselling which enables them to make an informed choice about screening.

Standards:

8.1 All women must be given clear information about the choices available along the screening and diagnostic pathway (see appendix 4).

8.2 All women must be informed of the tests available within the Trust for Down's syndrome screening, irrespective of any assumptions as to how individuals may choose to proceed through the screening pathway.

8.3 All professionals involved in the screening process must be impartial and supportive towards women, as they make decisions along the screening and diagnostic pathway.

8.4 All women must receive information about Down's syndrome and the availability of a screening test, as early as possible in pregnancy, and at least 24 hours before they are asked to make any decisions.

8.5 Prior to being tested, women must be given an opportunity to discuss, with their support network, their decision about being screened.

8.6 Verbal information given to women about the screening tests for Down's syndrome should be supported with a national leaflet, and when appropriate, a local one.

8.7 The verbal/written information given must include an explanation of the limitations of the screening tests.

8.8 All women must be given an opportunity to discuss their screening decision with a professional trained in screening, who can provide them with information on Down's syndrome and the possible long-term health and social issues.

8.9 All professionals involved in screening should be aware that some women have conditions that make it difficult for them to access the choices available. Information should therefore be given in an appropriate form, which may involve the use of interpreters and communication aids.

8.10 When explaining individual results to women, screen negative and screen positive must not be used to explain higher risk and lower risk results.

8.11 Upon request, Trusts must provide a copy of their written policy on Down's syndrome screening, which must include (as a minimum), the detection rates and screen positive rates of their screened population.

8.12 Supplementary information, including relevant informative/supportive websites or details of support organisations, should be offered to all women receiving a higher risk test result.

8.13 Professionals involved in antenatal screening for Down's syndrome should work collaboratively with appropriate agencies such as: social services, voluntary sector support groups, religious bodies and bereavement services; in order to provide a comprehensive support network that is centred on the woman's needs and requests.

The decision whether to undergo screening belongs to the woman: however the National Programme Centre supports and encourages her to seek the views of her husband/partner.

9.0 Women with Special Requirements

9.0 Women with Special Requirements

Information about screening tests should be provided in a form that is accessible to pregnant women who have additional needs such as: physical, cognitive or sensory disabilities, or women who do not speak or write English[12].

Standards:

9.1 All professionals involved in the screening process should be aware that some women have conditions that make it difficult for them to access the choices available. Information should therefore be given in an appropriate form, and when necessary, audio tapes, videos, digital video discs, visual and braille aids, should be used.

9.2 A woman's special requirements should be taken into account when appointments are made to discuss screening, which should include the timing of appointments, their location, the physical environment and the facilities that are available on-site.

9.3 Non-English speaking women must have access to an interpreting facility that is acceptable to them; this may be literature in their own language.

9.4 Women who have difficulties with verbal communication, for example those with hearing difficulties, should be given the opportunity to discuss the screening tests in an environment that is conducive to confidentiality and privacy.

9.5 Women who have special requirements should be offered additional support from other agencies, and when appropriate, this should include social services.

9.6 Staff involved in the delivery of the Trust's screening programme should be familiar with the Race Relations Act 2000 (refer to annex 1).

10.0 Ultrasound Scanning

10.0 Ultrasound Scanning

Statement regarding recalculation of Down's syndrome screening risk following ultrasound examination at the mid-pregnancy ultrasound scan:

'The National Down's Syndrome Screening Implementation Advisory Group and the Fetal Anomaly Ultrasound Steering Group, recommend that at the time of a mid-pregnancy fetal anomaly ultrasound scan, a Down's syndrome risk generated by a nationally accepted screening method, in either the 1st or 2nd trimester, should not be recalculated up or down due to the presence or absence of a single ultrasound marker of less predictive power than increased nuchal fold[13].'

Standards:

10.1 All pregnant women undergoing screening for Down's syndrome must have a dating scan:

- sometime after 8 weeks of gestation
- before serum screening is done
- between 11 to 13 weeks and 6 days gestation, if the nuchal translucency is to be measured

10.2 All ultrasound departments must have an agreed written policy which adheres to national standards and defines the purpose of antenatal screening using ultrasound scans.

10.3 There must be a senior member of the ultrasound department at superintendent level, taking overall responsibility for the quality of the scanning department's screening service.

10.4 All ultrasound departments' quality service managers (see footnote p.26) should continuously assess and monitor the quality of their ultrasound screening through their operator's performances.

10.5 All women should receive information about ultrasound scans as early as possible in pregnancy, and at least 24 hours before one is performed.

10.6 The information given to women about ultrasound scans should be supported by a national leaflet and, when appropriate, a local leaflet should also be given.

10.7 The clinician requesting a scan must ensure that all relevant medical and social issues, which may affect screening outcomes, are made available to the person performing the scan.

10.8 Women should be given information on the purpose and limitations of the ultrasound scan they are about to have, and its outcome.

10.9 Ultrasound scanning in pregnancy should, in the first instance, be performed transabdominally.

10.10 Assessment techniques and biometric charts used for fetal measurements must meet nationally agreed standards.

10.11 The British Medical Ultrasound Society (BMUS) recommended technique* for scanning for gestational age is by:

- measurement of the crown rump length (CRL) when scanning is performed before 13 weeks and 6 days
- measurement of the head circumference (HC) or biparietal diameter (BPD) when scanning is performed after 13 weeks

10.12 All sonographers/clinicians undertaking any antenatal ultrasound scan must possess the minimum qualifications detailed in appendix 5, as recommended by the UK NSC and advised by the Expert and Training Sub-Group of the National Fetal Anomaly Ultrasound Screening Programme.

10.13 All sonographers/clinicians performing antenatal ultrasound scans must be able to communicate results effectively, and should attend an appropriate communication/counselling session as part of their training and ongoing professional development.

***For further information on ultrasound scanning measurements, please refer to the BMUS website (see annex 1).**

10.14 The findings from the ultrasound scan must be recorded in the Trust's clinical information system and/or in the woman's maternity notes.

10.15 In order to demonstrate the satisfactory performance of the ultrasound department to the UK National Screening Committee, it must take part in an approved internal and external quality assurance programme, such as the Down's Syndrome Screening Quality Assurance Support Service (DQASS).

10.16 Ultrasound scanning machines used for antenatal screening must adhere to National and European standards for their specifications, maintenance schedules and upgrading.

11.0 Nuchal Translucency Measurements

11.0 Nuchal Translucency

In the absence of fetal malformation, the National Programme Centre currently recommends that nuchal translucency is the only ultrasound marker that should be used to screen for Down's syndrome. Other markers, for example the nasal bone, should not be used for this purpose unless sufficient evidence becomes available[14].

Standards:

11.1 The scanning department must have an agreed written policy which adheres to national standards and defines the purpose of screening for Down's syndrome, by measurement of the nuchal translucency.

11.2 When calculating a risk for Down's syndrome, the nuchal translucency measurement must be used in combination with a maternal serum screening test. **N.B. The measurement of the nuchal translucency must not be used in isolation, for this purpose.**

11.3 All sonographers/clinicians performing nuchal translucency measurements must have received appropriate training through an accredited training course.

11.4 All sonographers/clinicians performing nuchal translucency measurements must have their results subjected to rigorous, valid audit and to external evaluation by the National Programme Centre.

11.5 To ensure satisfactory performance, each sonographer must perform a minimum of 50 nuchal translucency measurements per year.

11.6 In order to demonstrate the satisfactory performance of the service, the scanning department must take part in an approved internal and external quality assurance programme, such as DQASS, for nuchal translucency measurements.

11.7 The ultrasound scanning equipment used should have a cineloop function and callipers that have a precision to one decimal point, i.e. 0.1 mm.

11.8 The computer software used to calculate the Down's syndrome risk must comply with the current national specification for risk calculation software[15]. It must also be CE marked and comply with EU directives.

12.0 Multiple Pregnancies

12.0 Multiple Pregnancies

The National Programme Centre maintains that for multiple pregnancies biochemical screening alone should not be used[16] for the detection of Down's syndrome.

Standards:

12.1 Women with a multiple pregnancy must receive adequate information prior to being screened; this information must include the implications and limitations of the test, the risks from an invasive diagnostic procedure and the potential for selective feticide.

12.2 The recommended method of screening for multiple pregnancies is by measurement of the nuchal translucency, preferably in combination with biochemistry.

13.0 Laboratories

13.0 Laboratories

A 'laboratory' is defined for the purposes of the screening standards as any facility which produces biochemical results which are used for the calculation of a Down's syndrome screening risk. This will include centralised laboratories; satellite laboratories remote from a central laboratory and biochemical testing equipment that is attached to a stand-alone screening service. Private laboratories are also expected to comply with these standards.

Standards:

13.1 Laboratories must have an agreed written policy which adheres to national standards and defines the purpose of serum screening for Down's syndrome.

13.2 The laboratories must be represented on a Clinical Antenatal Screening Steering Group and be part of a clinical governance framework.

13.3 The laboratory must be accredited by an appropriate body e.g. Clinical Pathology Accreditation UK (Ltd).

13.4 The laboratory must participate in an accredited external quality assessment scheme e.g. UK NEQAS, and be able to demonstrate satisfactory performance.

13.5 The laboratory must submit screening data to DQASS at least twice a year.

13.6 There must be a senior member of the laboratory staff at consultant level, or a medical scientist with relevant experience in screening, taking overall responsibility for all laboratory aspects of the Down's syndrome screening service.

13.7 There must also be a defined managerial structure for the responsibilities of other members of staff involved in the screening work.

13.8 There must be a documented risk assessment policy for the laboratory aspects of the Down's syndrome screening service, showing an analysis of the possible areas where mistakes may occur and the steps that have been taken to minimise their occurrence.

13.9 Appropriate internal quality assurance procedures must be undertaken and documented, 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.

13.10 The laboratory must participate in audit of the screening service at local and regional level and provide an annual report, or the necessary data for the preparation of an annual report, to the Trust's Clinical Antenatal Screening Steering Group.

13.11 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.

13.12 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.

13.13 A managed network should have a consultant biochemist who is responsible for monitoring the performance of each of the screening laboratories, and has the authority to effect change, when necessary.

13.14 The computer software used to calculate the Down's syndrome risk must comply with the current national specification for risk calculation software[15]. It must also be CE marked and comply with EU directives.

13.15 Laboratories undertaking Down's syndrome serum screening must comply with the national standards in force at any particular time, regarding detection rates, screen positive rates and the cut-off used to define the higher risk population.

13.16 97% of Down's syndrome serum screening reports must be issued within 3 working days of receipt of the specimen at the laboratory.

14.0 Diagnostic Testing

14.0 Diagnostic Testing

The UK National Screening Committee's recommended policy on diagnostic tests offered to women, as identified through screening tests, as being at high risk of having a pregnancy affected by Down's syndrome, is that local NHS bodies and interested groups should give consideration to the following recommendation:

Policy Recommendations

Where a high quality 18-20 week ultrasound scan is offered as part of routine antenatal care, the UK NSC recommends that the following policy should be considered:

- QF-PCR alone to women of increased risk of Down's syndrome, but where the scan is normal (for example where a nuchal translucency <3mm is detected in first trimester screening). In this context QF-PCR should also be used to test for Patau syndrome and Edwards syndrome in addition to Down's syndrome

- QF-PCR and karyotyping to investigate fetal anomalies detected by ultrasound (for example when an increased nuchal translucency >3mm is detected in first trimester screening), or where other clinical indications justify, for example, a family history of chromosomal abnormality or chromosomal rearrangement in one parent

Standards:

14.1 Pregnant women should not be offered a diagnostic test for Down's syndrome based on their age-related risk alone.

14.2 97% of results from rapid tests should be available within 3 working days.

14.3 97% of results from karyotyping should be available within 14 working days.

14.4 A woman whose diagnostic test result confirms her fetus has Down's syndrome, should then be given the opportunity to discuss the syndrome with a paediatrician, a fetal medicine specialist or a geneticist.

14.5 Following a confirmed diagnosis, appropriate information and support should be given to all women, no matter how they decide to proceed with the pregnancy.

Invasive Diagnostic Procedures*

The invasive procedure of choice for diagnostic sampling in a pregnancy between 11 to 15 weeks is chorionic villus sampling. After 15 weeks the usual method of sampling is by amniocentesis.

Statement on acetyl cholinesterase gel test

Following a raised AFP, a routine acetyl cholinesterase gel test on amniotic fluid is not necessary to detect neural tube defects. Instead, the diagnostic test of choice is an ultrasound scan.

***For further information on amniocentesis and chorionic villus sampling, please refer to the Royal College of Obstetricians and Gynaecologists guidelines[17].**

15.0 Information Technology

15.0 Information Technology

In accordance with Connecting for Health (CfH), the National Programme Centre supports departments working towards computer-based records, for their screening services.

Standards:

15.1 Trusts are responsible for ensuring that information technology used by departments involved in Down's syndrome screening is capable of interfacing with hospital information system(s).

15.2 The information system should include appropriate tools to support the audit process (see appendix 2).

15.3 The information technology networks used in screening should link with appropriate data collection systems.

References

References

1. CMO's *Update Number 31*: *Down's Syndrome Screening* October 2001

2. UK National Screening Committee *Antenatal Screening Service for Down's Syndrome in England: 2001* Published August 2002 ISBN 09543684 0 1

3. Department of Health *Model of Best Practice* November 2003 http://www.screening.nhs.uk/downs/model_best practice.pdf (website visited on 22/02/07)

4. National Institute for Clinical Excellence (NICE) *Antenatal Care: Routine Care for the Healthy Pregnant Woman; Clinical Guideline* National Collaborating Centre for Womens' and Childrens' Health RCOG Press October 2003 ISBN 1900364913

5. Department of Health *The NHS Improvement Plan; Putting People at the Heart of Public Services* June 2004 p.27

6. Department of Health *Tackling Health Inequalities; A Programme for Action* 2003

7. Department of Health *National Standards, Local Action, Health and Social Care Standards and Planning Framework 2005/06 – 2007/08:* Published July 2004

8. Antenatal Screening for Wales *Policy and Standards to Support the Provision of Antenatal Screening in Wales* December 2005 p.7:2.2

9. Department of Health *Education and Skills: Disabled Children and Young People and those with Complex Health Needs* October 2004 p.20:14.3

10. Department of Health *Best Practice Guidance for Doctors and other Health Professionals; on the Provision of Advice and Treatment to Young People under 16: on Contraception* Sexual and Reproductive Health July 2004 p.4

11. Nursing Midwifery Council (NMC) *The NMC Code of Professional Conduct: Standards for Conduct, Performance and Ethics:* NMC London November 2004 p.6:3.4

12. National Patient Safety Agency *Understanding the Safety Issues for Vulnerable Groups of Women known to be at Higher Risk of Maternal Death or Morbidity* February 2005

13. Smith-Bindman R., Hosmer W., Feldstein V.A., Deeks J.J., Goldberg J.D., *Second Trimester Ultrasound, to Detect Fetuses with Down Syndrome: A Meta-Analysis* JAMA 2001:285(8) p.1044-1055

14. UK National Screening Committee *National Down's Syndrome Screening Programme for England - A Handbook for Staff* 2004

15. UK National Screening Committee *National Down's Syndrome Screening Programme for England: National Specification for Risk Calculation Software and Guidance on Implementation* October 2004

16. Spencer K., *Screening for Trisomy 21 in Twin Pregnancies in the First Trimester using Free ß-hCG and PAPP-A, combined with Fetal Nuchal Translucency Thickness*
Prenatal Diagnosis 2000 20: p.91-95

17. Royal College of Obstetricians and Gynaecologists *Clinical Green Top Guideline No. 8: Amniocentesis and Chorionic Villus Sampling (Revised)*
January 2005

Bibliography

Bibliography

All Wales Multi-Professional Management Group *Making Decisions (Wales) A Consultation Document* October 2004

British Medical Ultrasound Society *Fetal Size and Dating: Charts Recommended For Clinical Obstetric Practice* December 2006

Department of Health *Education and Skills: National Service Framework for Children, Young People and Maternity Services* March 2005

Healthcare Commission *Assessment for Improvement: The Annual Health Check: Criteria for Assessing Core Standards* April 2005

House of Commons Health Committee *Choices in Maternity Services:* The Stationery Office Limited: London July 2003

Murray S., Bachus L., *Factors Contributing to Patient Safety and Adverse Maternal Outcomes for Five Minority Groups of Women in the UK:* A scoping review of current knowledge undertaken for the National Patient Safety Agency London 2004

National Health Service Litigation Authority *Clinical Negligence Scheme for Trusts: Maternity Clinical Risk Management Standards* April 2005

National Health Service Quality Improvement Scotland *Clinical Standards: Pregnancy and Newborn Screening* October 2005

Royal College of Obstetricians and Gynaecologists - Supplementary Working Group *Ultrasound Screening – Supplement to Ultrasound Screening for Fetal Abnormalities* RCOG 2000

Royal College of Radiologists *Standards for Radiological Equipment* November 2004

UK National Screening Committee *Antenatal Ultrasound Survey of England 2002:* Published April 2005

UK National Screening Committee *The Development of a Management Safety Case for the Laboratory Serum Screening Process* 2005

Annex 1
Useful Websites

Annex 1

Useful Websites

Antenatal Results and Choices
http://www.arc-uk.org

British Medical Ultrasound Society
http://www.bmus.org

Contact a Family
http://www.cafamily.org.uk

Continuous Professional Development: Induction Programme
http://www.screening.nhs.uk/cpd/induction.htm

Database of Individual Personal Experiences
http://www.dipex.org/antenatalscreening

Department of Health
http://www.dh.gov.uk/Home/fs/en

Department of Health: Guidance on Consent
http://www.dh.gov.uk/consent

Down's Syndrome Association
http://www.dsa-uk.com/

Equality Act 2006
http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060003_en.pdf

Freedom of Information Act
http://www.opsi.gov.uk/acts/acts2000/20000036.htm

Healthcare Commission
http://www.healthcarecommission.org.uk

Mencap
http://www.mencap.org.uk

Monitor; Regulator of NHS Foundation Trusts
http://www.monitor-nhsft.gov.uk/

National Institute for Health and Clinical Excellence
http://www.nice.org.uk

NHS Connecting for Health
http://www.connectingforhealth.nhs.uk

Private and Voluntary Health Care (England) Regulations 2001
http://www.opsi.gov.uk/SI/si2001/20013968.htm

Race Relations (Amendment) Act 2000
http://www.opsi.gov.uk/ACTS/acts2000/20000034.htm

Royal College of Obstetricians and Gynaecologists
http://www.rcog.org.uk

Support Organisation for Families affected by Trisomy 13 and 18
http://www.soft.org.uk

UK NHS Down's Syndrome Screening Programme
http://www.screening.nhs.uk/downs/home.htm

(Websites visited on 22/02/07)

Appendix 1
Expert Groups

Appendix 1

Expert Groups

The orginal standards (2003) for Down's Syndrome screening were revised following a period of consultation with professionals and the following organisations:

National Programme Directors and members of the Screening Programmes:

- Fetal Anomaly Ultrasound Steering Group
- Fetal, Maternal and Child Health Sub-Group
- Regional Antenatal Screening Co-ordinators
- Regional Education Training Facilitators
- UK National Screening Committee
- Working Groups of the Down's Syndrome Screening Programme

Antenatal Screening Wales
Northern Ireland Executive: Department of Health
Scottish Executive: Department of Health

Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Radiologists
Association of Clinical Cytogeneticists
British Fetal Maternal Medicine Society
British Medical Ultrasound Society
Genetics Department: Department of Health
Society of Radiographers
The Association for Clinical Biochemistry

Calderdale Down's Syndrome Group
Down's Syndrome Association (DSA)
Down's Syndrome Association – Greater Manchester
Down's Syndrome Association – London Branch
Down's Syndrome Extra 21
Down's Syndrome Heart Group
Down's Syndrome Medical Interest Group (DSMIG)
Down's Syndrome North East Group
The Clinic for Down's Children
The Sarah Duffen Centre

Antenatal Results and Choices (ARC)
Antenatal Screening Web Resource (AnSWer)
Association for Spina Bifida and Hydrocephalus (ASBAH)
Council for Disabled Children
Database of Individual Patient Experiences (DIPEx)
Disability Action North East
Local All Faiths Group
Local Opportunities & Awareness of Down's Syndrome (LOADS)
Suffolk Support Group
Sure Start
Values into Action

Appendix 2
Audit Requirements

Appendix 2

Audit Requirements

The National Programme's audit and monitoring requirements for the Trusts Down's Syndrome Screening Programme:

Initial specifications and criteria (C) to be included in the audit report:

(a) The preferred method of screening adopted by the Trust.

(b) The cut off/threshold level used by the programme.

(c) Contact details of the Trust and the Strategic Health Authority.

(d) The number of women delivered within the maternity unit(s) under the jurisdiction of the Trust, to include:

- home confinements
- the total number of women actually delivering within the jurisdiction of the Trust and its maternity facilities

All figures to relate to annual totals within the financial year.

Basic requirements and criteria (C):

(1) The number of women booked for antenatal care before 20 weeks of pregnancy.

C The total number of women seeing a midwife/GP for an antenatal booking history/visit regardless of the intended place of delivery. (This group is termed the **eligible population***).

(2) The number of women offered screening for Down's syndrome regardless of the technique employed e.g. by serum screening, nuchal translucency or combined/integrated testing before 20 weeks of pregnancy. This must not include late diagnosis made as a result of fetal anomaly ultrasound screening after 20 weeks of pregnancy.

C The total number of women booked to deliver under the jurisdiction of the Trust who are made aware of the option of screening for Down's syndrome and receive appropriate information leading up to a decision to accept or decline the test, i.e. the **informed offer**.

To ensure accuracy this information must be collated as soon as possible after the informed offer has been made and preferably by 20 weeks of pregnancy. **N.B. Collection of this data should not take place after delivery**.

***The eligible population refers to the total number of women booked for antenatal care before 20 weeks of pregnancy, regardless of the intended place of delivery.**

Figures in (2) to relate to annual totals within the financial year and expressed as a percentage of (1).

(3) The number of women accepting the informed offer of screening for Down's syndrome by (a) the Trust's chosen method, or (b) other methods (i.e. the relevant screening uptake rates).

C (a) The total number of women having a specific screening test by the Trust's chosen method.

(b) The total number of women having a specific screening test by an alternative method.

Above figures to relate to annual totals within the financial year and expressed as a percentage.

(4) The number of women who do not complete the screening test.

C Women who according to the Trust's policy are offered screening in stages, for example, contingency/integrated screening, who do not complete the test.

The following questions relate to the Trust's own screening method unless stated otherwise:

(5) The number of women undergoing risk assessment by serum screening alone who have had a dating scan carried out prior to sampling.

C The total number of women undergoing serum screening alone in whom the risk assessment has been based on the accuracy of an early dating scan. Screening methods which inherently involve early scanning (in particular nuchal translucency), are excluded from this requirement.

(6) The number of women accepting screening in the context of the Trust's own method who receive a lower risk result, i.e. the **screen negative rate**.

C The total number of eligible women accepting the offer of the Trust's own screening method who are allocated as being at lower risk of their pregnancies being affected by Down's syndrome.

(7) The number of women accepting screening in the context of the Trust's own method who receive a higher risk result, i.e. **screen positive rate**.

C The total number of eligible women accepting the offer of the Trust's own methods who are allocated as being at higher risk of their pregnancies being affected by Down's syndrome.

(8) The number of women defined as higher risk as a result of the Trust's own screening method and are then offered a diagnostic test.

C The number of women classified as screen positive using the Trust's own method who are followed up and offered a diagnostic test. This does not include diagnostic offer rates for other available screening methods.

(9) The number of women accepting the offer of a diagnostic procedure:

(a) after a higher risk result using the Trust's own screening method, i.e. the diagnostic uptake rate

(b) as a consequence of other screening methods employed

or,

(c) as a result of other indications, e.g. past history, maternal request, late ultrasound indications.

C The total number of eligible women proceeding with an invasive diagnostic test, firstly on the basis of the Trust's higher risk screening results and secondly as a consequence of other factors.

The above figures to be subdivided into amniocentesis or chorionic villus sampling groups.

(10) The cytogenetic method used by which a diagnosis is made.

C Initial methodology, e.g. QF-PCR/Karyotyping/FISH or DNA, to be listed, i.e. method employed when diagnosis first made.

(11) The overall pregnancy loss rate following invasive diagnostic procedures for Down's syndrome screening.

C The total miscarriage and pregnancy loss rate at any stage of pregnancy following invasive diagnostic procedures for Down's syndrome, to include method of testing and individual practitioner's pregnancy loss rate.

(12) The total number of identified Down's syndrome cases in the total pregnant population.

C The total number of all cases of Down's syndrome identified in all women receiving antenatal care under the jurisdiction of the Trust.

(13) The total number of identified Down's syndrome cases in the eligible population.

C The total number of cases of Down's syndrome identified in women who book for antenatal care under 20 weeks of pregnancy.

(14) The total number of identified Down's syndrome cases in the **ineligible population.**

C The total number of pregnancies affected by Down's syndrome in women who book for antenatal care after 20 weeks.

(15) The total number of identified Down's syndrome pregnancies in the eligible population, screened using the Trust's screening method, subdivided into those designated as higher and lower risk.

C The total number of women in the eligible population screened using the Trust's own method who are diagnosed as having a pregnancy affected by Down's syndrome divided into:

(a) those classified as higher risk

and,
(b) those classified as lower risk.

(16) The total number of Down's syndrome affected pregnancies in the eligible population who were not offered screening.

C The total number of affected pregnancies diagnosed in the eligible population where screening was not

N.B. The ineligible population refers to women who book for antenatal care after 20 weeks of pregnancy.

offered, the gestational age at which diagnosis was made and the diagnostic method employed.

(17) The total number of Down's syndrome affected pregnancies in the eligible population who were offered but declined screening.

C The total number of affected pregnancies in the eligible population who were offered screening using the Trust's chosen method, but where this was declined.

(18) The total number of identified Down's syndrome pregnancies in the eligible population not screened using the Trust's own screening method.

C The total number of women in the eligible population who were not screened using the Trust's own method and are diagnosed as having a pregnancy affected by Down's syndrome. The gestational age at which diagnosis was made, reasons for not screening and the method whereby the diagnosis was made.

(19) The total number of identified Down's syndrome pregnancies diagnosed as a result of late interventions, such as fetal anomaly scanning after 20 weeks of pregnancy in the eligible group.

C The total number of affected pregnancies diagnosed in the eligible population within a financial year, where the screening/diagnostic method was employed after 20 weeks gestation; regardless of the method of screening/diagnosis. This would include fetal anomaly ultrasound screening. The gestational age at which diagnosis was made and the diagnostic method employed.

(20) The total number of cases of Down's syndrome diagnosed prenatally by whichever method employed, as a percentage of the total identified Down's syndrome cases in the relevant pregnant population.

C The actual detection rate of Down's syndrome for the Trust regardless of the mechanism of the screening or diagnosis employed (i.e. the **overall detection rate**).

(21) The Trust should explore womens' experiences and levels of satisfaction with their screening programme.

C Conduct an annual confidential survey of 10% of annual deliveries: to explore womens' experiences of the screening process, focusing particularly on issues that are pertinent to the Trust's screening programme.

Additional UK NSC objectives and criteria:

(22) The proportion of higher risk results issued by the laboratory within three working days of the last phase of the Trust's screening programme, following receipt of a sample acceptable for processing.

C All screening results of the Down's Syndrome Screening Programme available to women, and communicated to them by the agreed method discussed at their previous antenatal visit.

The minimum standard being 97% of all higher risk results from the last phase of the screening programme, being made available within 3 working days of receipt by the laboratory, with the Trust's screening programme being notified of the result within 7 working days.

(23) The proportion of women with higher risk results, who are seen and offered a diagnostic test within 3 working days of the report being issued by the laboratory.

C All women who have a higher risk result, and are offered a diagnostic test and given verbal and written information to assist them in making a decision. Minimum standard set is 97% of women classified as being at higher risk, being seen and offered a diagnostic test within 3 working days of the report being issued.

(24) The proportion of women receiving the result of their diagnostic test within 14 working days of receipt of the specimen at the laboratory.

C Minimum standard set of 97% of diagnostic Down's syndrome results, being available to women within 14 working days of receiving specimens in the laboratory, and all information and services being available in support of that decision.

Appendix 3 Training Resources

Appendix 3

Training Resources

The Down's Syndrome Screening Educational Training Pack 2005
This pack consists of printed slides and notes to support an enclosed digital presentation on various aspects of screening for Down's syndrome.

For more details log on to:
http://www.screening.nhs.uk/downs/training.htm

Professional Education for Genetic Assessment and Screening (PEGASUS)
PEGASUS is a national network of centres commissioned by the NHS Sickle Cell and Thalassaemia Screening Programmes. Using sickle cell and thalassaemia as a model, PEGASUS aims to facilitate training in basic genetics for professionals involved in antenatal and newborn screening.

For more details log on to:
http://www.screening.nhs.uk/cpd/pegasus.htm

Screening Choices
Screening Choices was commissioned by the UK National Screening Committee to address the priority area of facilitating informed screening choices. It is an interactive, flexible, open-learning programme for professionals involved in antenatal and newborn screening.

For more details log on to:
http://www.screening.nhs.uk/cpd/choices

Database of Patients' Experiences (DIPEx)
The UK National Screening Committee supports this charity website which examines patient's experiences of illness and health-related and antenatal screening issues. The website is for patients, their carers, families and friends, and for professionals working in the healthcare sector.

For more details log on to:
http://www.dipex.org/antenatalscreening

Induction Resource
This is a multidisciplinary induction resource for new staff involved in antenatal screening.

For more details log on to:
www.screening.nhs.uk/cpd/induction.htm

Down's Syndrome Screening Quality Assurance Support Service (DQASS)
This is a statistical support service for Down's syndrome screening laboratories. It aims to provide an independent audit of laboratory data in a standardised and statistically valid way. The analyses will help laboratories to check their baseline median values, risk algorithm, parameter

values and population measures, such as age-adjusted follow up rates.

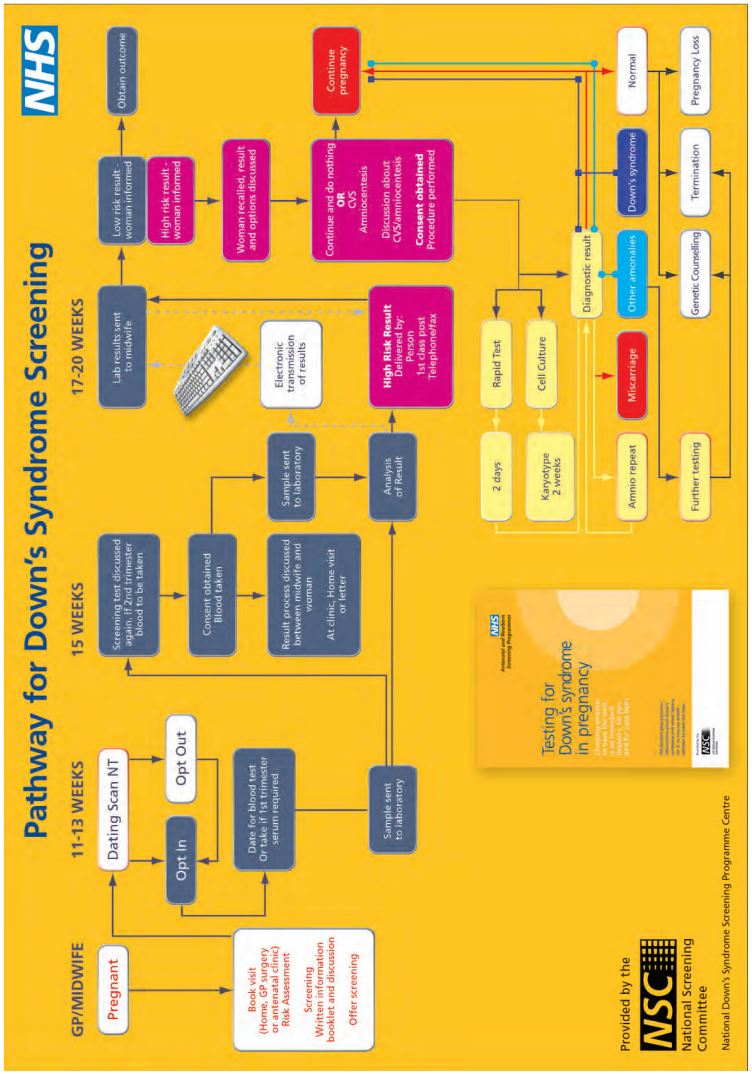
For more details log on to:
http://www.screening.nhs.uk/downs/dqass.htm

(Websites visited on 22/02/07)

Appendix 4 Pathway for Down's Syndrome Screening

Appendix 4

Pathway for Down's Syndrome Screening



Appendix 5 Minimum Qualifications Required for Performing Ultrasound Scans

Appendix 5

Minimum Qualifications Required for Performing Ultrasound Scans

The National Programme Centre, with advice from the Expert Education and Training Sub-Group of the National Fetal Anomaly Ultrasound Screening Programme, has issued the following recommendation for employers, or employing organisations, and any person undertaking fetal anomaly screening on pregnant women.

The Group 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.

Guidance to Managers

Where individuals, including those from overseas, do not hold any of the above listed qualifications then the employing organisation should ensure that the ultrasound qualification held is equivalent in competencies to those attained in the above.

In addition, the employing organisation should ensure that the individual is supervised until they are satisfied that the individual's practice is at a standard, congruent with competencies acquired in the above qualifications.

NHS

Screening Programmes

Fetal Anomaly

Fetal Anomaly Screening Programme

Programme handbook

June 2015

About the NHS Screening Programmes

NHS Screening Programmes identify apparently health people who may be at increased risk or a disease or condition, enabling earlier treatment and better informed decisions. They are implemented on the advice of the UK National Screening Committee (UK NSC), which oversees screening policy in all four nations, and works with the different implementation bodies to support delivery.

Public Health England (PHE) is responsible for the NHS Screening Programmes. PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

NHS Screening Programmes
Floor 2, Zone B
Skipton House
80 London Road
London SE1 6LH
Tel: 020 368 20890
www.gov.uk/topic/population-screening-programmes

Twitter: @PHE_Screening

You can download this publication from
www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook

Gateway ref: 2015002

Contents

1 Introduction 5

1.1 Conventions 5
1.2 Related documents 5

2 The Fetal Anomaly Screening Programme (FASP) 6

2.1 General principles of screening 6
2.2 Background 6
2.3 The policy 6

3 Markers used in screening tests 8

3.1 Maternal age 8
3.2 Biochemical markers 9
3.3 Effect of vaginal bleeding on biochemical markers 9
3.4 Effect of 'vanished twin' on biochemical markers 9
3.5 Ultrasound markers 10

4 Down's, Edwards' and Patau's syndromes 11

4.1 Down's syndrome 11
4.2 Edwards' and Patau's syndromes 11

5 Screening tests 12

5.1 The early pregnancy scan 12
5.2 First trimester combined test 12
5.3 Second trimester quadruple test 13
5.4 Screening in twin pregnancies 13
5.5 National standards for T21/T18/T13 screening 13
5.6 The 18^{+0} to 20^{+6} week fetal anomaly ultrasound scan 14
5.6.1 18^{+0} to 20^{+6} FASP ultrasound scan base menu (See Appendix 1) 15
5.6.2 Fetal cardiac protocol 16
5.6.3 Normal variant 16
5.6.4 Image capture, storage and archiving 17
5.6.5 Training and professional competence 17
5.6.6 Safety of ultrasound 17

6 Diagnostic testing 18

6.1 Results of diagnostic testing 18
6.2 Audit 18

7 Non-invasive prenatal testing (NIPT) 20

7.1 Current availability of NIPT 20

7.2 Additional considerations 20

8 Quality Assurance (QA) 21

9 Key performance indicators (KPIs) 22

10 Screening safety incidents 23

Glossary 24

Resources 27

Appendix 1 – 18^{+0} to 20^{+6} FASP ultrasound scan base menu 28

Appendix 2 – Ultrasound images and schematics 30

Appendix 3 – Stakeholder and support groups 36

1 Introduction

The purpose of this handbook is to bring together in one publication the Fetal Anomaly Screening Programme's (FASP) guidelines and recommendations that relate to the screening pathway and are not covered in detail in the other handbooks.

1.1 Conventions

Throughout the document the following are used interchangeably:

- Down's syndrome is referred to as T21
- Edwards' syndrome as T18
- Patau's syndrome as T13

1.2 Related documents

a. Handbook for laboratories

This sets out the requirements for laboratory staff involved in the pathways for first trimester screening for Down's, Edwards' and Patau's syndromes and second trimester biochemical screening for Down's syndrome.

https://www.gov.uk/government/publications/fetal-anomaly-screening-laboratory-handbook-downs-edwards-and-pataus-syndromes

b. Ultrasound Practitioner's Handbook

This sets out the requirements for ultrasound practitioners involved in the pathway for first trimester screening for Down's, Edwards' and Patau's syndromes.

www.gov.uk/government/publications/fetal-anomaly-screening-ultrasound-practitioners-handbook

c. Department of Health / NHS England Service – Specification for Screening for Down's, Edwards' and Patau's syndromes (No. 16) and Specification for 18^{+0} to 20^{+0} fetal anomaly scan (No.17)

These outline the service and quality indicators expected by NHS England for the population for whom it is responsible and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC). It is relevant for both commissioners and providers of the screening service to enable an understanding of the care pathway pregnant women should expect and how that service should be delivered.

Both documents should be read in full to gain a better understanding of the expected roles and responsibilities for the various healthcare professionals involved in providing the screening pathway. These are updated annually and new versions posted to the website.

www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016

d. Standards

These define a set of standards relating to screening for Down's, Edwards' and Patau's syndromes and the 18^{+0} to 20^{+6} week fetal anomaly scan.

www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards

2 The Fetal Anomaly Screening Programme (FASP)

2.1 General principles of screening

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition.

Further information regarding the general principles of screening can be found at:

screening.nhs.uk

2.2 Background

NHS FASP, based in Public Health England, is an expert team that ensures national consistency and provides expertise. They support and manage on-going roll out, technical and professional development of the programme and ensure quality and safety standards are maintained and continuously improved.

The screening programme has evolved from its establishment in 2001 when the majority of screening was performed using maternal biochemistry in the second trimester. The recommended method of screening is now first trimester screening, combining maternal age, biochemistry and ultrasound measurement of fetal nuchal translucency to provide a pregnant woman with the risk of having a baby with Down's, or Edwards'/Patau's syndromes.

The offer of a fetal anomaly scan is recommended and where accepted should be undertaken between 18^{+0} to 20^{+6} weeks of pregnancy. The fetal anomaly scan base menu sets out the fetal anatomy to be examined. The fetal anomaly scan screens for 11 conditions. For further information see section 5.6 of this handbook.

FASP has established standardisation of the following to enable commissioners and quality assurance teams to assess the quality of the service provided. These include:

- national standards, guidance and risk cut-off for Down's, Edwards' and Patau's syndromes screening programme in the light of emerging evidence
- a statistical service to ensure that laboratories have access to the best advice in maintaining their population medians
- specifications for risk calculation software to make sure that all laboratories calculate risks in a uniform way
- use of a base menu and fetal cardiac protocol to enable consistency in the structures examined as part of the 18^{+0} to 20^{+6} week fetal anomaly scan

2.3 The policy

FASP offers screening to all eligible pregnant women in England to assess the risk of the baby being born with Down's, or Edwards'/Patau's syndromes or a number of fetal anomalies (structural abnormalities of the developing fetus).

FASP aims to ensure there is equal access to uniform and quality-assured screening across England and women are provided with high quality information so they can make an informed choice about their screening and pregnancy options. Education and training resources are available for staff covering all stages of the process, from informing women of test availability, through to understanding and supporting their decisions.

The screening policy is to offer screening to assess the risk of the baby being born with Down's or Edwards'/Patau's syndromes. The test

of choice for both singleton and twin pregnancies is first trimester combined screening. Women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only

The first scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for Down's, Edwards'/Patau's syndromes, with a second scan for fetal anomalies between 18^{+0} to 20^{+6} weeks. The timing of the scans allows for further diagnostic tests if required and ensures women have time to consider decisions about continuing their pregnancy.

The second scan is designed to identify abnormalities which indicate the baby may die shortly after birth, conditions that may benefit from treatment before birth, to plan delivery in an appropriate hospital/centre and/or to optimise treatment after the baby is born. Some women may choose not to be screened at all, or only for some conditions and it is important that this choice is respected.

3 Markers used in screening tests

3.1 Maternal age

All women have a chance of having a baby with Down's, Edwards' or Patau's syndrome and this chance increases with age. The older a mother, the more chance she has of having a baby with the condition.

Table 1: Example for a woman who is 16 weeks pregnant

Maternal age	Chances of having a pregnancy affected by Down's syndrome	Probability
20 years	1 in 1500	0.07%
30 years	1 in 900	0.1%
40 years	1 in 100	1%

Figure 1: Graph to illustrate the likelihood of a pregnancy affected by Down's, Edwards' or Patau's syndromes according to maternal age showing T21 (black line), T18 (blue line), T13 (green line). Risks are at the time of the 12 weeks scan

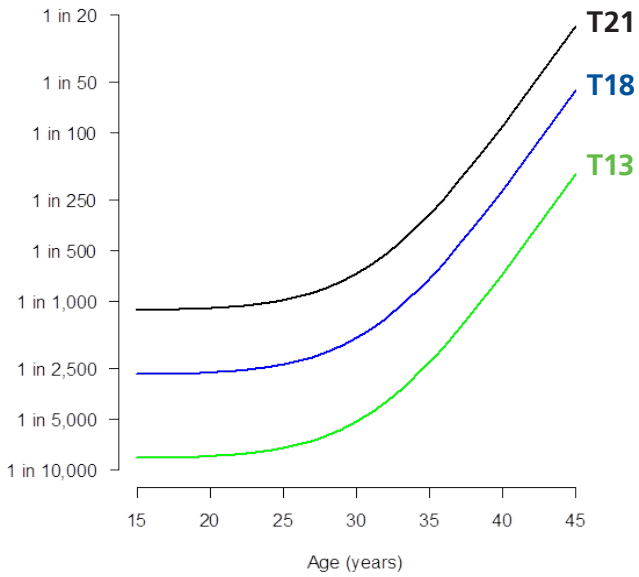


Table 2: Reframing risk

Chance of an affected pregnancy		Chance of an unaffected pregnancy	
1 in 4	25%	3 in 4	75%
1 in 5	20%	4 in 5	80%
1 in 10	10%	9 in 10	90%
1 in 20	5%	19 in 20	95%
1 in 30	3%	29 in 30	97%
1 in 50	2%	49 in 50	98%
1 in 100	1%	99 in 100	99%
1 in 200	0.5%	199 in 200	99.5%

Can be applied to any screening test where the result is reported as a probability

3.2 Biochemical markers

There are five analytes (commonly referred to as markers) measured by the laboratory that are used to calculate the likelihood of a pregnancy being affected by Down's, Edwards' or Patau's syndromes – six if human chorionic gonadotropin (hCG) and its free beta subunit are considered as two separate analytes. Please refer to the laboratory handbook for more information on biochemical markers see:

www.gov.uk/government/publications/fetal-anomaly-screening-laboratory-handbook-downs-edwards-and-pataus-syndromes

3.3 Effect of vaginal bleeding on biochemical markers

There are concerns that a history of significant maternal vaginal bleeding might change the levels of biochemical markers used in the combined test. FASP recommends women are offered the combined test in the normal way (calculating the risk based on maternal age, NT, free beta hCG and PAPP-A levels), as current evidence suggests that the biochemical marker levels are not significantly different in women with this history.

3.4 Effect of 'vanished twin' on biochemical markers

When ultrasound shows there is an empty second pregnancy sac, the biochemical markers appear no different to those in a singleton pregnancy and the combined test of NT, PAPP-A and free beta HCG can be used to calculate the risk.

When ultrasound shows that there is a second sac containing a non-viable fetus (sometimes called 'vanished' twin), it is possible there could be a contribution to the maternal biochemical markers for many weeks. It is recommended that in this event services undertake the risk calculation based on the maternal age and nuchal translucency only (ie without biochemistry).

3.5 Ultrasound markers

Please refer to the laboratory and ultrasound practitioner's handbooks for more detailed information on ultrasound markers:

fetalanomaly.screening.nhs.uk/publications

FASP aims to ensure there is equal access to uniform and quality-assured screening across England and women are provided with high quality information so they can make an informed choice about their screening and pregnancy options. Education and training resources are available for staff covering all stages of the process, from informing women of test availability, through to understanding and supporting their decisions.

The screening policy is to offer screening to assess the risk of the baby being born with Down's or Edwards'/Patau's syndromes. The test of choice for both singleton and twin pregnancies is first trimester combined screening. Women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only

The first scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for Down's, Edwards'/Patau's syndromes, with a second scan for fetal anomalies between 18^{+0} to 20^{+6} weeks. The timing of the scans allows for further diagnostic tests if required and ensures women have time to consider decisions about continuing their pregnancy.

The second scan is designed to identify abnormalities which indicate the baby may die shortly after birth, conditions that may benefit from treatment before birth, to plan delivery in an appropriate hospital/centre and/or to optimise treatment after the baby is born. Some women may choose not to be screened at all, or only for some conditions and it is important that this choice is respected.

4 Down's, Edwards' and Patau's syndromes

Inside the cells of our bodies there are tiny structures called chromosomes. These chromosomes carry the genes that determine how we develop. There are 23 pairs of chromosomes in each cell. Problems can occur when the sperm or egg cells are produced which can lead to a baby having an extra chromosome.

4.1 Down's syndrome

People with Down's syndrome (T21) have extra chromosome 21 in the cells of their body . A baby born with T21 will have a learning disability. They may have communication problems and difficulty managing some everyday tasks. It is impossible to know what level of learning disability a baby with T21 will have. It can vary from mild to severe.

Some health problems are more common in people with T21, for example, heart conditions, and problems with the digestive system, hearing and vision. Some problems can be serious but many can be treated. With good healthcare, someone with Down's syndrome is expected to live to around 60 years. People with Down's syndrome have distinctive facial features including almond shaped eyes. Like all children, they also inherit features from their parents. T21 affects 1 in every 1000 births.

www.gov.uk/topic/population-screening-programmes/fetal-anomaly

4.2 Edwards' and Patau's syndromes

Sadly, most babies with T18 or T13 will die before they are born, be stillborn or die shortly after birth. Some babies may survive to adulthood but this is rare.

In Edwards' syndrome (T18) there is an extra copy of chromosome 18 in each cell. All babies born with T18 will have a wide range of problems, which are usually extremely serious - these may include major brain abnormalities. Babies affected by T18 can have heart problems, unusual head and facial features, growth problems and be unable to stand or walk. T18 affects about 3 of every 10,000 births.

In Patau's syndrome (T13) there is an extra copy of chromosome 13 in each cell. All babies born with T13 will have a wide range of problems, which are usually extremely serious - these may include major brain abnormalities. Babies affected by T13 can have heart problems, a cleft lip and palate, growth problems, poorly formed eyes and ears, problems with their kidneys and are unable to stand or walk. T13 affects about 2 of every 10,000 births.

5 Screening tests

5.1 The early pregnancy scan

The scan has several purposes. It is to:

- confirm viability
- ascertain if it is a singleton or multiple pregnancy
- estimate gestational age
- detect major structural anomalies that may be identified in early pregnancy eg anencephaly

If the woman accepts screening for T21, T18/T13 syndromes the scan is one component of the screening test. Ultrasound scanning in pregnancy should, in the first instance, be performed transabdominally.

Assessment techniques and biometric charts used for fetal measurements must meet nationally agreed standards. ***British Medical Ultrasound Society (BMUS, 2009) - Fetal size and dating: charts recommended for clinical obstetric practice, Loughna et al Ultrasound 2009; 17(3):161–167***

5.2 First trimester combined test

The combined test uses maternal age, the nuchal translucency measurement (NT) and two biochemical tests, free beta hCG and PAPP-A, together with the gestational age calculated from the crown rump length (CRL) measurement, to calculate the risk of the pregnancy being affected by T21or T18/T13. The optimal time to perform the combined test is between 11 weeks 2 days to 14 weeks 1 day of gestation, which corresponds to a CRL of 45.0 mm to 84.0 mm.

In cases where screening is accepted but it is not possible to obtain the NT measurement at the first appointment, at least one other attempt should be offered, this may be on the same day or at a later date. If it is not possible to obtain an accurate NT measurement despite 'twice on the couch' then further attempts do not have to be offered and the woman should be referred in to the second trimester screening pathway.

If the ultrasound measurement shows that the CRL is less than 45.0 mm, the woman should be recalled for a further scan to measure the NT. If the CRL is greater than 84.0 mm, the second trimester quadruple test should be offered.

The first trimester combined test allows earlier decision making for parents. In practice, two models are available for performing the combined test:

- a maternal blood specimen may be taken (from 10 weeks onwards) prior to the ultrasound scan. The biochemistry results can then be made available at the time of the NT scan and the combined test result can be calculated at the time of the appointment. Although the result may be calculated by the sonographer, it is recommended that the laboratory take primary responsibility for the risk calculation software and audit all results
- a maternal blood specimen may be taken at the time of the ultrasound scan and the combined test result made available within a few days of the biochemistry results being authorised by the laboratory

When calculating a risk for T21 and/or T18/T13 syndromes, the nuchal translucency measurement must be used in combination with a maternal serum screening test.

The nuchal translucency measurement must not be used in isolation.

Where women have chosen not to accept screening for Down's, Edwards' and Patau's syndromes, but choose to accept an early pregnancy scan, structural anomalies may still be identified, including an NT of ≥ 3.5mm. It is not within FASP's remit to provide guidance regarding the clinical care of women who have declined screening but they should be aware that any such anomaly will be reported and signposted as per local clinical guidelines for care and management.

FASP recommends that the Down's and/or Edwards'/Patau's screening risk generated from first trimester combined screening must not to be recalculated up or down following the initial screening test or at the 18^{+0} to 20^{+6} fetal anomaly ultrasound scan due to the presence or absence of a single ultrasound marker of less predictive power than increased nuchal fold (Smith-Bindman et al, 2001).

For further information regarding the scan element of the combined screening test please see the Ultrasound practitioner's handbook.

www.gov.uk/government/publications/fetal-anomaly-screening-ultrasound-practitioners-handbook

5.3 Second trimester quadruple test

The quadruple test uses maternal age and four biochemical markers measured from 14 weeks 2 days until 20 weeks 0 days - AFP, hCG (total, intact or free beta subunit), uE3 and Inhibin-A. Although this combination of markers has a lower detection and standardised screen positive rate than the combined test, it is the nationally recommended screening strategy in the second trimester. The optimum time for testing in the second trimester is around 16 week's gestational age.

There will always be a need for a screening test in the second trimester for those women who book too late for first trimester testing or when an NT measurement cannot be obtained (despite twice on the couch) in the first trimester. An ultrasound scan will be required to date the pregnancy and a fetal head circumference is the recommended measurement used for women presenting in the second trimester. Further information regarding the practicalities of a solution to combining dating and screening requirements at the early pregnancy scan are explored in more detail in the following article: ***Chudleigh et al (2011), A practical solution to combining dating and screening for Down's syndrome.***

5.4 Screening in twin pregnancies

Women with a twin pregnancy are eligible for combined screening or quadruple screening dependent on gestational age. For detailed information regarding screening in twin pregnancies please see section 6 of the Laboratory Handbook at:

www.gov.uk/government/publications/fetal-anomaly-screening-laboratory-handbook-downs-edwards-and-pataus-syndromes

5.5 National standards for T21/T18/T13 screening

The national standards seen in Table 3 state the threshold for the national programme and will be reported on each year by the Down's syndrome screening Quality Assurance Support Service (DQASS).

Screening strategy	Thresholds	
	Acceptable	Achievable
T21	Standardised DR 85%	
	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
T18/T13	Standardised DR 80%	
	Standardised SPR 0.1-0.2%	Standardised SPR 0.13-0.17%
T21/T18/T13	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
Quadruple (T21)	Standardised DR 80%	
	Standardised SPR 2.5-3.5%	Standardised SPR 2.7-3.3%

*The DR and SPR for the quadruple test relate to singleton pregnancies only

5.6 The 18^{+0} to 20^{+6} week fetal anomaly ultrasound scan

FASP recommends a mid-pregnancy scan which is undertaken between 18^{+0} to 20^{+6} weeks of pregnancy to screen for major fetal anomalies. The examination should be undertaken in accordance with the 18^{+0} to 20^{+6} FASP ultrasound scan base menu and fetal cardiac protocol.

Some providers are able to arrange the fetal anomaly scan later within the recommended window ie closer to 20 weeks as opposed to 18 weeks - where this occurs services must be able to facilitate referrals for further investigations and options for pregnancy choices in a timely manner and within the required national timeframes. Ongoing audit of practice should be in place to monitor conformity. FASP recommends the screening pathway must be completed by 23^{+0} weeks of pregnancy.

Women who wish to have a fetal anomaly ultrasound scan, but do not wish to be informed if abnormalities are found, should be advised that all significant findings seen on scan will be reported and therefore should consider not having fetal anomaly ultrasound screening.

The main structures to be assessed at the 18^{+0} to 20^{+6} week scan are defined. Abnormalities of these structures can indicate a number of specific conditions. Other conditions may be detected using this ultrasound screening test, but there are insufficient data to confidently predict the standard which should be achieved.

11 conditions are specified that indicate that:

- the baby may die shortly after birth
- are conditions that may benefit from treatment before birth
- to faciliate planned delivery in an appropriate hospital/centre
- and/or to optimise treatment after the baby is born
- and have detection rates (DR) which exceed 50%.

(Fetal Anomaly Ultrasound Screening Programme Study: Literature Survey June 2007 Bryant L, Fisher A and Vicente F Social Research and Regeneration Unit A University of Plymouth Centre)

Table 4: The conditions screened for as a minimum in England

Conditions	Detection rate (%)
Anencephaly	98
Open spina bifida	90
Cleft lip	75
Diaphragmatic hernia	60
Gastroschisis	98
Exomphalos	80
Serious cardiac anomalies includes the following: • Transposition of the Great Arteries (TGA) • Atrioventricular Septal Defect (AVSD) • Tetralogy of Fallot (TOF) • Hypoplastic Left Heart Syndrome (HLHS)	50
Bilateral renal agenesis	84
Lethal skeletal dysplasia	60
Edwards' syndrome (Trisomy 18)	95**
Patau's syndrome (Trisomy 13)	95**

**Detections rates will be reviewed following implementation of screening as part of the combined screening strategy

It is accepted that an ultrasound scan at this time can also constitute part of general clinical practice and management as well as screening. The two are closely linked.

Although it is not the remit of the screening programme to set out standards or guidance on the management of these areas, it is acknowledged that by not incorporating a reference to them in the 18^{+0} to 20^{+6} FASP ultrasound scan base menu, it may give the impression that they should not be noted during the ultrasound scan. The examination of placental position and amniotic fluid whilst not part of the screening protocol is good clinical practice.

There is no requirement to determine fetal gender within the FASP in England; it is not part of the 18^{+0} to 20^{+6} FASP ultrasound scan base menu. There is no programme requirement to recall the woman if the fetal sex is not identified due to poor visualisation or difficult fetal position.

5.6.1 18^{+0} to 20^{+6} FASP ultrasound scan base menu (See Appendix 1)

The 18^{+0} to 20^{+6} FASP ultrasound scan base menu specifies measuring techniques and defines the anatomical structures to be assessed. This promotes consistency in the examination.

The fetal anatomy to be examined is:

1. head circumference demonstrating HC measurement and measurement of the atrium of the lateral ventricle
2. suboccipito-bregmatic view demonstrating measurement of the transcerebellar diameter
3. coronal view of lips with nasal tip
4. abdominal circumference demonstrating AC measurement
5. femur length demonstrating FL measurement
6. sagittal view of spine including sacrum and skin covering

Six specific fetal anatomical sections should be identified at examination. A hard copy image and report should be recorded and appropriately stored in any combination of the following formats:

- ultrasound clinical information storage system
- auditable electronic hospital information system
- ultrasound request/report form
- in the woman's hand-held notes

The head circumference (HC), abdominal circumference (AC) and femur length (FL) measurements should be taken to assess growth velocity in a pregnancy where the expected date of delivery (EDD) was previously assigned in line with nationally approved charts and tables.

If the EDD was not previously assigned, the pregnancy should be dated by HC or FL. ***Loughna P, Chitty L, Evans T and Chudleigh T - 'Fetal size and dating: charts recommended for clinical obstetric practice' Ultrasound (2008)***

5.6.2 Fetal cardiac protocol

The views required are:

1. Situs/Laterality
2. Four-Chamber: Transverse section of the thorax including a complete rib and crux of the heart
3. Aorta/Left Ventricular Outflow Tract: This view shows the outflow tract of the left ventricle
4. Pulmonary/Right Ventricular Outflow Tract: This view shows the outflow tract of the right ventricle only or the Three-Vessel View (3VV): This view shows the outflow tract of the right ventricle including the pulmonary artery
5. The 3 vessel and trachea view (3VT): a transverse view of the fetal upper mediastinum; it depicts the main pulmonary artery in direct communication with the ductus arteriosus, the transverse aortic arch and the superior vena cava

A single repeat scan must be offered and completed by 23^{+0} weeks gestation. In cases where the image quality of the first examination is compromised by one of the following:

- increased maternal body mass index (BMI)
- uterine fibroids
- abdominal scarring
- sub-optimal fetal position

The woman should be rescanned on the same day or offered a new appointment according to local clinical assessment.

If first examination is sub-optimal and the sonographer is suspicious of a possible fetal abnormality, a second opinion should be sought. This should be documented.

Where an adequate assessment of the fetal anatomy remains compromised after the repeat scan, the woman should be told that the screening is incomplete and this should be recorded.

5.6.3 Normal variant

The introduction of a national Down's, Edwards' and Patau's syndromes screening programme in early pregnancy has changed the way in which the 18^{+0} to 20^{+6} fetal anomaly scan findings are interpreted. FASP recommends that an established screening test result should not be recalculated at this time.

The screening programme is increasingly delivering higher detection rates for lower screen positive rates. Therefore, women who are found to be 'lower risk' through testing in either first or second trimesters, or who have declined screening for Down's, Edwards' and Patau's syndromes should not be referred for further assessment of chromosomal abnormality even if normal variants such as the examples below (whether one or more are identified) are seen at the 18^{+0} to 20^{+6} week fetal anomaly screening scan. The term ultrasound "soft marker" should no longer be used.

1. Choroid plexus cyst(s)
2. Dilated cisterna magna
3. Echogenic foci in the heart
4. Two vessel cord

However, the appearances listed below (previously classified as "markers") are examples of findings which should be reported and the woman referred for further assessment and treated as for any other suspected fetal anomaly.

1. Nuchal fold (greater than 6mm)
2. Ventriculomegaly (atrium greater than 10mm)
3. Echogenic bowel (with density equivalent to bone)
4. Renal pelvic dilatation (AP measurement greater than 7 mm)
5. Small measurements compared to dating scan (significantly less than 5th centile on national charts)

5.6.4 Image capture, storage and archiving

The required images are detailed on the 18^{+0} to 20^{+6} FASP ultrasound scan base menu (see appendix 1). Ultrasound images should be captured, stored and archived on an electronic reporting system. There should be a permanent electronic record of all imaging studies. All imaging studies should be accompanied by an electronic report available with the images. Every provider should be able to upload ultrasound scan reports and images on an auditable electronic reporting system in order to provide minimum audit data. All required images should be captured, stored and archived for the purposes of a complete maternal record and to fulfil medico-legal requirements.

5.6.5 Training and professional competence

All ultrasound practitioners must hold minimum certification as specified by FASP in Service Specification No 17:

www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016

All providers should have multidisciplinary education and training programmes for health professionals involved in obstetric ultrasound and antenatal screening.

All diagnostic ultrasound procedures must be undertaken by health professionals who are fully trained in the use of the specialised equipment and in the safe use of ultrasound.

All practitioners undertaking ultrasound screening should be funded by the provider to attend relevant continuous professional development (CPD) training.

5.6.6 Safety of ultrasound

All health professionals working with ultrasound equipment should be aware of the Royal College of Radiologists (RCR) and Society and College of Radiographer's (SCoR) standards for the provision of an ultrasound service:

www.rcr.ac.uk/standards-provision-ultrasound-service

All health professionals should adhere to the British Medical Ultrasound Society (BMUS) recommended scanning time limits for obstetric scanning. British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment November 2009. BMUS

bmus.org

Ultrasound machinery used for the 18^{+0} to 20^{+6} weeks fetal anomaly scan should be capable of producing images of diagnostic quality and include the following features (as a minimum):

- adequate display/screen size for sufficient clear visualisation
- magnification facility
- cineloop function
- callipers that have a precision to one decimal point (ie 0.1 mm)
- adjustable signal processing facilities
- tissue-specific pre-sets for individual clinical applications
- appropriate probe relevant to gestational age
- doppler and harmonic function

6 Diagnostic testing

Pregnant women should not be offered a diagnostic test for Down's, Edwards' and Patau's syndromes based on their age-related risk alone.

Diagnostic testing can include Chorionic Villus Sampling or amniocentesis. The procedure should be performed by specially trained health professionals and women may be required to attend a tertiary centre for the procedure.

Chorionic Villus Sampling (CVS) is an abdominal or sometimes cervical invasive procedure performed under continuous ultrasound guidance. The CVS can be performed from 10 weeks but is usually only performed from 11 weeks of pregnancy to obtain a sample of placental tissue for chromosomal or genetic analysis. For every 100 women who have this test one will miscarry.

Amniocentesis is an invasive procedure undertaken from about 15 completed weeks (15^{+0}) onwards to obtain a sample of amniotic fluid surrounding the fetus. Using an aseptic technique whilst under continuous ultrasound guidance, a sterile needle is passed through the mother's abdomen, uterus and amniotic sac. A sample of amniotic fluid is aspirated and sent for chromosomal or genetic analysis. For every 100 women who have this test one will miscarry.

The reason for offering the woman the test should be explained, for example:

- a history of an inherited disorder
- a previous pregnancy or a child with a chromosome disorder
- a raised chance of Down's and/or Edwards'/ Patau's syndromes following screening
- suspected anomaly following an ultrasound scan

In twin pregnancies invasive prenatal diagnosis should be conducted at a tertiary fetal medicine unit due to the specialised nature of the procedures and the increased risk of miscarriage and in line with Royal College of Obstetrics and Gynaecology and National Institute for Health and Care Excellence (NICE) guidelines.

If karyotyping is offered, the woman should be informed that subtle chromosomal changes and single gene defects will not normally be detected. The implications of this should be explained, ie not all inherited conditions will be identified.

The woman should be informed of the usual reporting times for karyotyping and/or QF-PCR before the procedure.

Further information regarding the procedure for diagnostic testing can be found at

www.rcog.org.uk/globalassets/documents/guidelines/gtg_8.pdf

6.1 Results of diagnostic testing

All providers should have a written pathway for communication of results. The process for communicating results should be discussed and agreed with the woman before the procedure. All women must be informed of the CVS or amniocentesis result by an appropriately trained person. When a CVS or amniocentesis is performed at a tertiary centre, that centre should provide written results to the referring clinician. The woman should be informed of the results of diagnostic testing as per local policy.

6.2 Audit

Each department performing amniocentesis and CVS procedures should maintain a register of CVS and amniocentesis procedures performed and outcome of pregnancy. To facilitate audit, pregnancy outcome forms should be completed and returned to the screening laboratory, or other locally agreed collating centre, at the end of the pregnancy. The provider should develop a written pathway for the completion and return of pregnancy outcome forms to the centre collecting the data.

Patient evaluation of service provision is an integral aspect of overall service audit and should be included as part of the audit and performance management framework. Information should be shared with the National Congenital Anomaly and Rare Disease Registration Service for quality and monitoring.

7 Non-invasive prenatal testing (NIPT)

NIPT is a new way of identifying pregnant women who are at higher risk of having a baby with Down's, Edwards' and Patau's syndromes. The test detects DNA from a baby in a sample of blood taken from the mother.

The UK NSC will review the use of NIPT as a screening test against the agreed criteria.

www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes

7.1 Current availability of NIPT

NIPT is currently only available privately in the UK. Most studies conducted so far have been in high risk women and further work in larger groups of pregnant women is required to evaluate the accuracy of the new test, in particular the false positive rate (that is the number of women incorrectly identified as being at risk).

The UK NSC is supporting a study to assess the performance of the test in an NHS setting. Women in five hospitals are offered screening as normal, with those who have a medium-to-high risk then being offered NIPT as a second stage test. If that confirms the woman is at high risk then a diagnostic test would be offered. The introduction of NIPT should mean that fewer women are offered invasive diagnostic tests.

The study aims to discover whether the test can perform as accurately in the general population as previous studies and to determine information needs for both women and health care professionals. The research will report in 2015.

7.2 Additional considerations

As NIPT is a blood test and women have many blood tests in pregnancy, one of the important aspects of the new pilot is looking at ways to ensure women understand the test and the implications of the results. Only then will they be able to make an informed decision about whether the test is right for them. Furthermore, it will be important to ensure that test results can be provided in a timely fashion without causing anxiety or distress.

The current research shows that a percentage of the tests do not produce results at all because there is not enough of the baby's DNA present in the mother's blood sample. This outcome is more common among larger women and can range from as few as 1% to as many as 12% of results. This is one of the reasons why NIPT is likely to work best as a second stage of the screening process, for women already found to be at higher risk.

8 Quality assurance (QA)

Each NHS screening programme has a defined set of standards that providers have to meet to ensure that local programmes are safe and effective. Quality assurance (QA) is the process of checking that these standards are met and encouraging continuous improvement and includes:

- advising on the development of national quality standards
- monitoring of how services meet (or fail to meet) standards
- providing expert screening advice for incident management
- facilitating quality review of services, including peer advice
- supporting on a day-to-day basis, those involved in commissioning or providing screening services

QA covers the entire screening pathway; from identifying who is eligible to be invited to screening, through to referral and treatment where required/appropriate.

The aim of QA is to maintain minimum standards and drive continuous improvement in the performance of all aspects of screening to ensure that all women and their babies have access to high quality screening wherever they live. QA is essential in order to minimise harm and maximise benefits of screening.

Formal QA visits to local screening programmes provide the forum for a peer review of the whole multidisciplinary screening pathway, and an assessment of the effectiveness of team working within the local screening programme and associated referral sites.

- regional teams advise providers and commissioners about reducing risks in local screening programmes
- they assess the robustness of local arrangements through audit, as part of peer review and in the investigation of any incidents as they occur
- they act as a conduit for information and dialogue at national, regional and local levels, additionally sharing good practice
- participation in a formal process of QA is the responsibility of each local screening programme
- the performance of the local programmes is monitored in a variety of ways such as review of statistics, regional meetings or informal visits, all of which offer a valuable insight into the activity of a local programme

9 Key performance indicators (KPIs)

Key performance indicators (KPIs) for the NHS screening programmes were introduced to provide a way of measuring how well the screening programmes are doing in important areas. They contribute to the quality assurance of screening programmes but are not, in themselves, sufficient to quality assure or performance manage screening services. They help local screening services to identify potential problems so they can be put right and have led to changes in practice and implementation of measures to prevent errors occurring in the screening pathway.

There is currently one KPI for the fetal anomaly screening programme, but work is currently ongoing to develop additional KPIs.

More information on KPIs can be found at **www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting**

10 Screening safety incidents

A screening safety incident is any unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening; or to staff working in the screening programme.

A screening safety incident can affect populations as well as individuals. It is an actual or possible failure in the screening pathway and at the interface between screening and the next stage of care. Although the level of risk to an individual in an incident may be low, because of the large numbers of people offered screening, this may equate to a high corporate risk. It is important to ensure that there is a proportionate response based on an accurate investigation and assessment of the risk of harm. Due to the public interest in screening, the likelihood of adverse media coverage with resulting public concern is high even if no harm occurs.

More information about managing screening safety incidents is available at

www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

cpd.screening.nhs.uk/incident-resource

Glossary

Amniocentesis

An invasive procedure undertaken from about 15 completed weeks (15^{+0}) onwards to obtain a sample of amniotic fluid (liquor) surrounding the fetus. Using an aseptic technique whilst under continuous ultrasound guidance, a sterile needle is passed through the mother's abdomen, uterus and amniotic sac. A sample of amniotic fluid is aspirated with a syringe and sent for analysis to test for a range of chromosomal and inherited disorders. Out of 100 women who have this test from 15 weeks it is likely that one will miscarry as a direct consequence of the procedure.

Amniotic fluid

Also known as 'liquor', this is the fluid surrounding the fetus during pregnancy. It contains substances and cells from the fetus, which can be removed by amniocentesis and examined.

Anomaly

An aberration or change often used related to a gene or physical structure that may or may not result in a disease or condition.

Biochemical markers

Analytes (commonly referred to as markers) measured by the laboratory that are used to calculate the likelihood of a pregnancy being affected by a condition or syndrome.

Chorionic Villus Sampling (CVS)

An abdominal or cervical procedure performed under continuous ultrasound guidance after 10 completed weeks in pregnancy to obtain a sample of placental tissue for chromosomal or genetic analysis. The range of chromosomal and genetic conditions that can be detected is similar to those for amniocentesis. For every 100 women who have this test one will miscarry.

Combined test

Between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy, a combination of the nuchal scan measurement and a blood sample from the mother which measures the concentration of pregnancy associated plasma protein-A (PAPP-A), and free beta human chorionic gonadotrophin (Free beta hCG). Together with the mother's age and the gestation of the pregnancy, these are used to estimate the chances that the fetus is affected with Down's syndrome.

Crown rump length (CRL)

Ultrasound measurement between the top of the head (crown) to the bottom of the buttocks (rump)

Detection rate

The proportion of affected individuals with a positive screening result.

Diagnostic test

Refers to the process involved in obtaining a definite diagnosis. For example the diagnostic test on an amniocentesis sample (invasive procedure) is the full karyotype or QF-PCR.

Down's Syndrome (trisomy 21)

A disorder caused by the presence of an extra copy (three instead of two) of chromosome 21. It affects all population groups and is distinguished by a number of features occurring together including low muscle tone, a face that appears flatter with eyes slanting upward, small ears and an unusually wide neck and a deep crease across the palm of the hand. Some may have heart problems or visual problems or may develop Alzheimer's disease. Although people with Down's syndrome have learning difficulties, these vary in severity.

Edwards' Syndrome (trisomy 18)

A syndrome caused by the presence of an extra copy (three instead of two) of chromosome 18. The combination of features present in babies affected with trisomy 18 can lead to many different problems including growth deficiency, feeding and breathing difficulties, developmental delays, learning difficulties, undescended testes in males, kidney malformations, heart defects. They may also have malformations in the bones.

Survival of infants with trisomy 18 depends on how severely they are affected. Most do not survive the first year of life.

Fetal anomaly

Structural abnormalities with how the fetus has developed.

Fetal anomaly ultrasound scan

A screening test offered to pregnant women to monitor the growth and development of the fetus before birth by producing a real-time visual image. Scans before 16 weeks are useful for dating and assessing the viability of the pregnancy (and are able to detect some major malformations). Detailed scanning at 18 weeks, 0 days to 20 weeks, 6 days should show up most malformations as well as some minor ones.

Gestational age

The duration of an ongoing or completed pregnancy, measured from the first day of the last menstrual period (usually about two weeks longer than that measured from conception). Gestational age is usually measured in weeks and days.

Invasive diagnostic procedure

A method used to obtain a sample used to aid diagnosis , for example, amniocentesis or chorionic villus sampling.

Marker

An identifiable physical location on a chromosome whose inheritance can be monitored. Markers can be expressed regions of DNA (genes) or some segment of DNA with no known coding function but whose pattern of inheritance can be determined.

Nuchal scan (Nuchal transluscency scan NT)

Between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy the thickness of fluid in the tissue space within the nape of the fetal neck, the nuchal translucency can be measured. An increased amount of fluid may indicate that the fetus has Down's syndrome, structural or genetic anomaly. By combining the mother's age and the gestation of the pregnancy with information from the scan an individual statistical chance of an anomaly can be given for that particular pregnancy. If the chance is one in 150 or higher a diagnostic test, such as CVS, will be offered.

Patau's Syndrome (trisomy 13)

A disorder caused by the presence of an extra copy (three instead of two) of chromosome 13. The disorder is characterised by low birth weight, cleft lip or palate, defects of the heart, eye structure, spine, scalp and abdomen, abnormal genitalia, low set ears, abnormal palm pattern, extra digits and overlapping of fingers over thumb. Between 80 per cent and 90 per cent of babies do not survive infancy and those that do survive have learning disabilities.

Prenatal

Relating to the period before birth

Quadruple test

Second trimester test to calculate the risk of Down's syndrome, usually based on the measurement of AFP, uE3, free b-hCG (or total hCG), and inhibin-A together with the woman's age.

Quality assurance (QA)

A system for monitoring and maintaining high standards in every aspect of a screening programme.

Risk

Risk is usually taken to mean the chance of an event happening. It can be be expressed in a number of ways, see diagrams in the UK NSC Resource Cards for Midwives Nos 3 and 5.

Risk cut-off

Determines those women who are in the 'higher risk' group and considered 'screen positive'.

Screen positive rate (SPR)

The number of women who receive a higher risk result.

Screening

Testing people who do not have or have not recognised the signs or symptoms of the condition being tested for, either with the aim of reducing risk of an adverse outcome, or with the aim of giving information about risk.

Screening pathway

The whole system of activities needed to deliver high quality screening. It ranges from identifying and informing those to be offered screening through to the treatment and follow up of those found to have abnormality, and support for those who develop disease despite screening

Screening programme

The whole system of activities needed to deliver high quality screening. It ranges from identifying and informing those to be offered screening through to the treatment and follow up of those found to have abnormality, and support for those who develop disease despite screening

Screening safety incident

An unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening; or to staff working in the screening programme.

Screening test

A test or inquiry used on people who do not have or have not recognised the signs or symptoms of the condition being tested for. It divides people into low and higher risk groups.

Syndrome

Combination of symptoms and signs grouped together to form a disorder.

Throughput

Number of samples undertaken per cycle

Trisomy

Three copies of a particular chromosome rather than the usual pair.

Ultrasound scan

A ultrasound scan is a safe and painless test that uses sound waves to make images. It is like radar.

Resources

Pathway for screening for Down's, Edwards' and Patau's syndromes
www.gov.uk/government/publications/fetal-anomaly-screening-care-pathways

Pathway for the 18^{+0} to 20^{+6} week scan
www.gov.uk/government/publications/fetal-anomaly-screening-care-pathways

Having a mid-pregnancy scan – Tear off pad
www.gov.uk/government/collections/fetal-anomaly-screening-providing-services

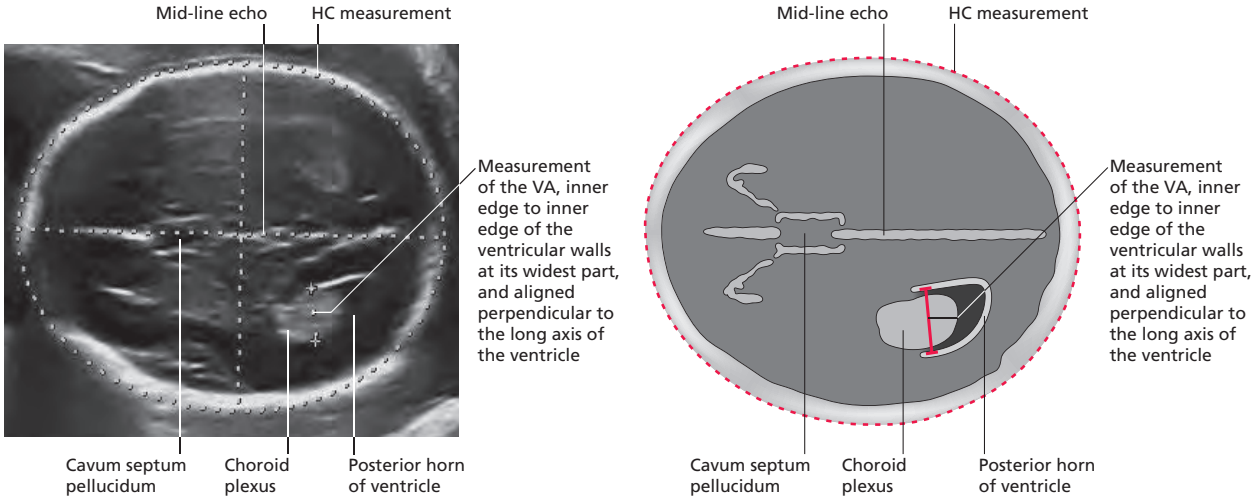
Appendix 1 – 18^{+0} to 20^{+6} FASP ultrasound scan base menu

Structure/Area	Detail	Fetal Measurements*	Images/measurements to capture/archive
Head and neck • **Skull** • **Brain** • **Neck**	Head shape	*Head circumference (HC)	Yes, to include HC measurement, CSP, posterior horn and measurement of the ventricular atrium at the level of the glomus of the choroid plexus
	Cavum septum pellucidum (CSP)	Measurement not required	
	Ventricular Atrium (VA)	*Atrium of the lateral Ventricle	
	Cerebellum	*Transcerebellar diameter (TCD)	Yes, to include measurement of the TCD in the suboccipitobregmatic view
	Nuchal Fold (NF) Measure if appears large	Distance between the outer border of the occipital bone and the outer skin edge	Yes, if measurement ≥ 6mm
• **Facial Features**	Coronal view of lips & nasal tip	Measurement not required	Yes
• **Lungs** • **Heart**	Visceral situs/laterality of heart	Measurement not required	Annotate "LT" and "RT" on archived images to denote visceral situs/ laterality
	a) Four chamber view (FCV)		No
	b) Aorta (Ao) arising from left ventricle		No
	c) Pulmonary artery (PA) arising from right ventricle, or the 3 vessel view (3VV)		No
	d) 3 vessel and trachea view (3VT)		No

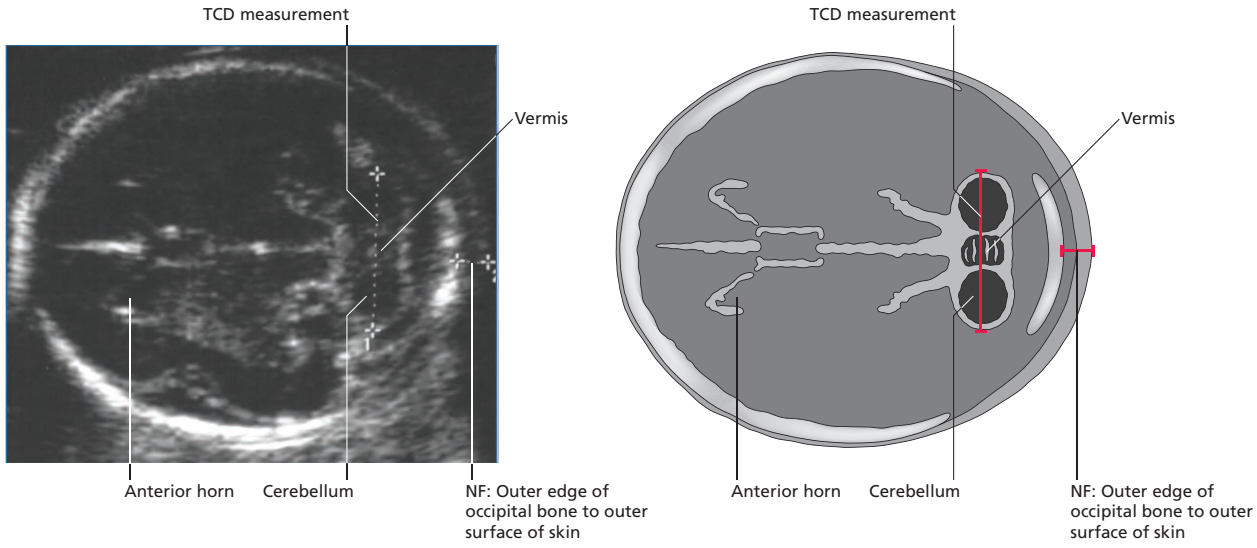
Structure/Area	Detail	Fetal Measurements*	Images/measurements to capture/archive
Abdominal content	Stomach & position	Measurement not required *Abdominal circumference (AC)	Yes
	Short intra-hepatic section of the umbilical vein (UV)		
	Abdominal wall and cord insertion		
	Diaphragm	Measurement not required	
	Kidneys Measure AP renal pelvis diameter if it appears large	Measurement not required unless renal pelvis AP diameter >7mm	Yes, if AP renal pelvis diameter measures >7mm
	Bladder	Measurement not required	
Spine • **Cervical** • **Thoracic** • **Lumbar** • **Sacral**	Vertebrae Skin covering	Measurement not required	Yes, image either sagittal or coronal plane
Limbs • **Upper & lower**	Femur, tibia & fibula (both legs)	*Femur length	Yes, image and measure a single femur only
	Metatarsals (both feet)	Digit count not required	
	Radius, ulna, humerus (both arms)	Measurement not required	
	Metacarpals (both hands)	Digit count not required	
Uterine cavity • **Uterine content**	Placenta	According to local policy/protocol	
	Amniotic fluid	According to local policy/protocol	

Appendix 2 – Ultrasound images and schematics

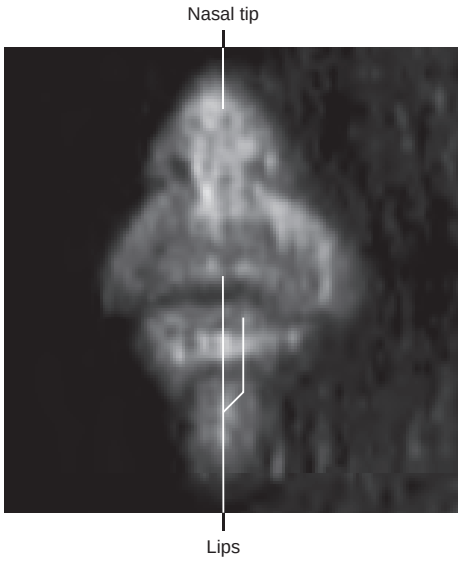
Head circumference (HC) and ventricular atrium (VA)

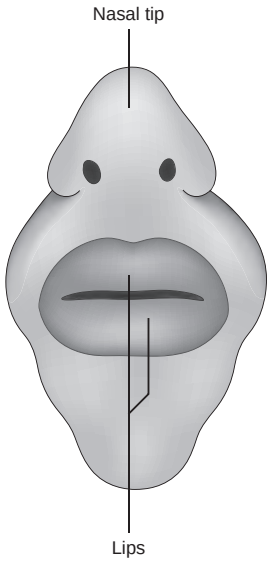


Transcerebellar diameter (TCD) and nuchal fold (NF)

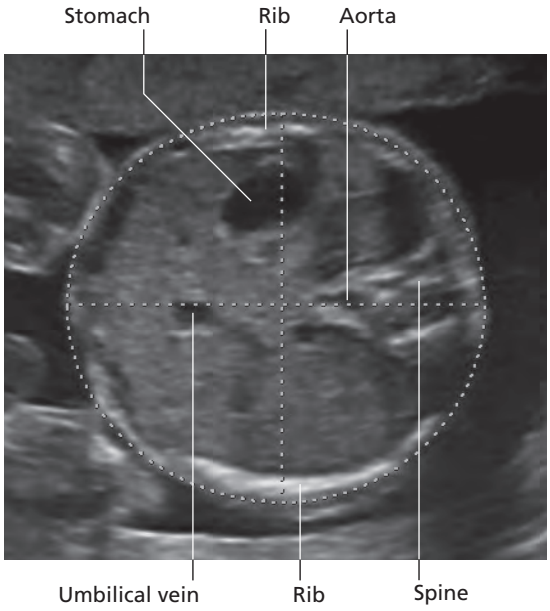


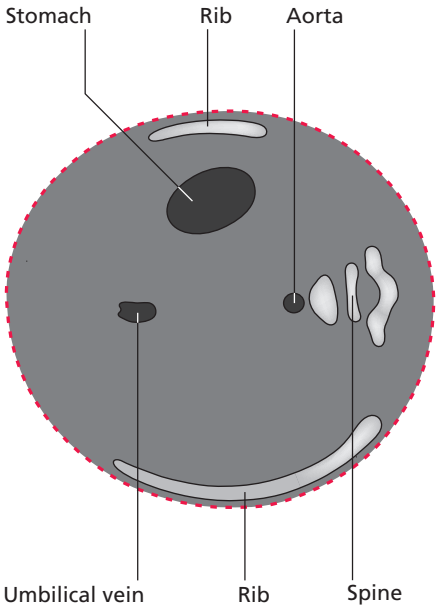
Lips and nasal tip



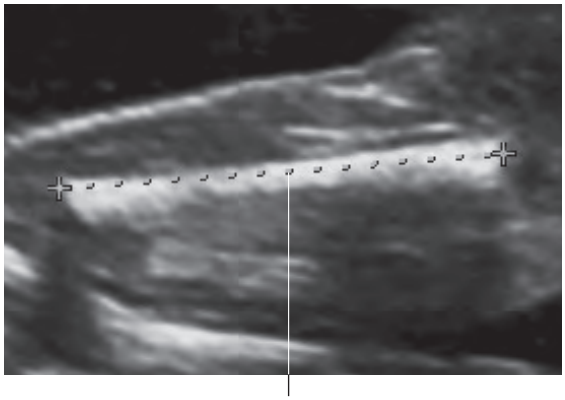


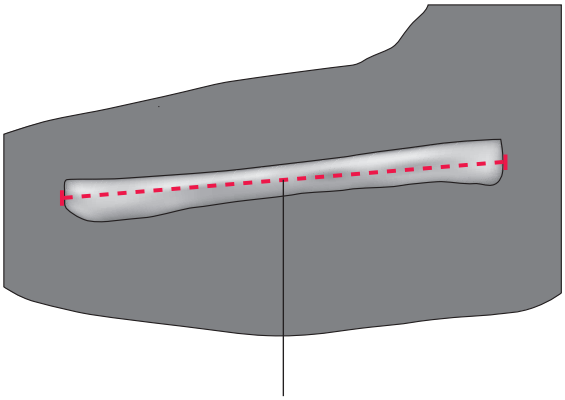
Abdominal circumference (AC)



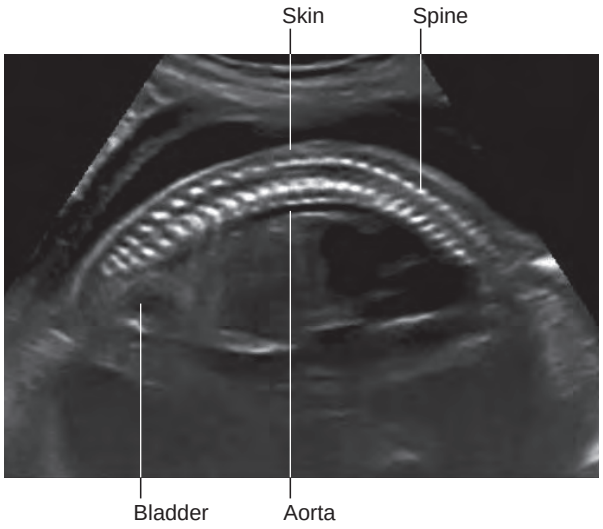


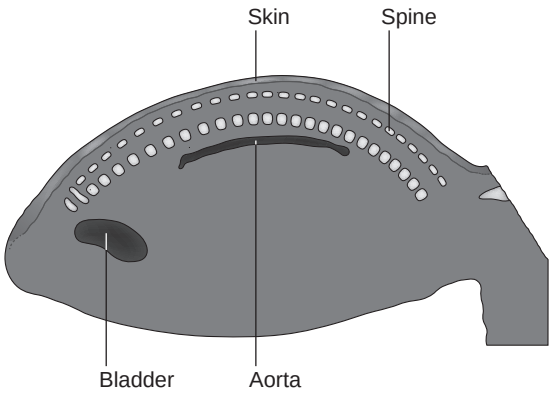
Femur length (FL)



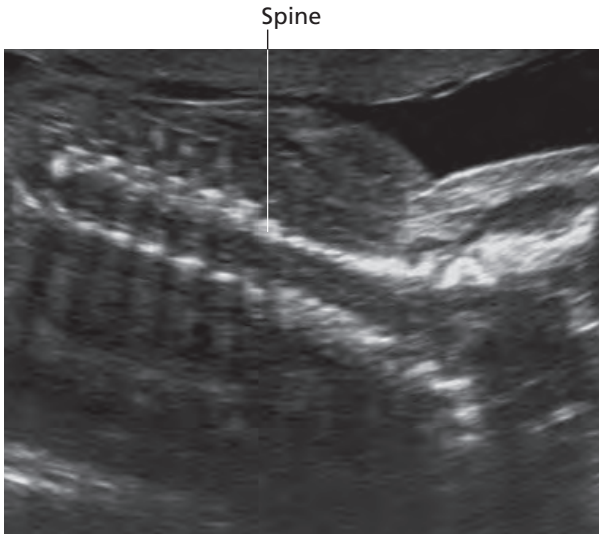


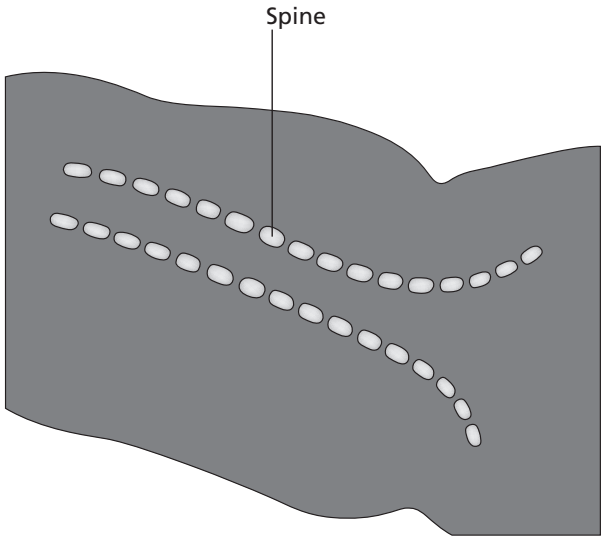
Sagittal spine



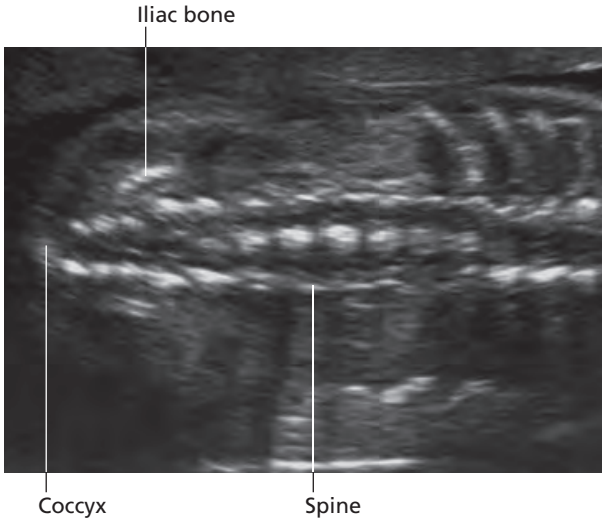


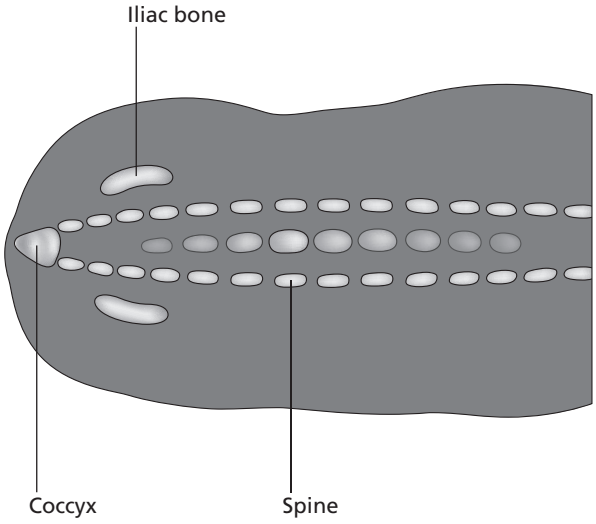
Coronal upper spine



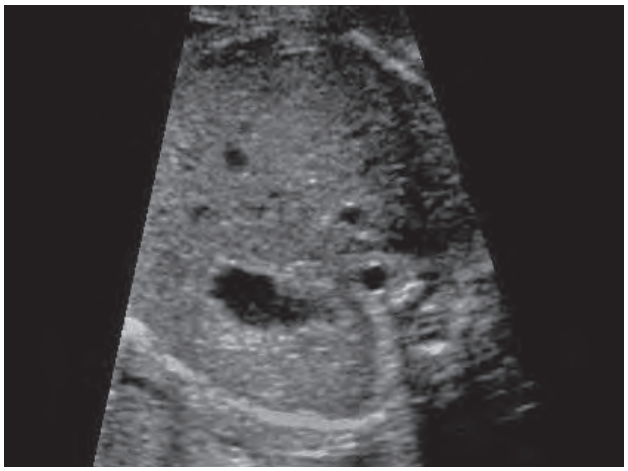


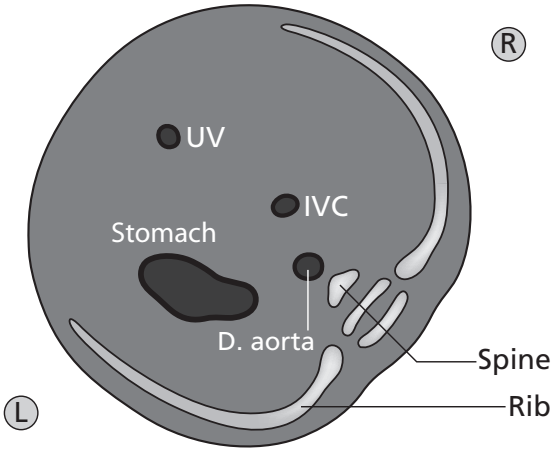
Coronal lower spine



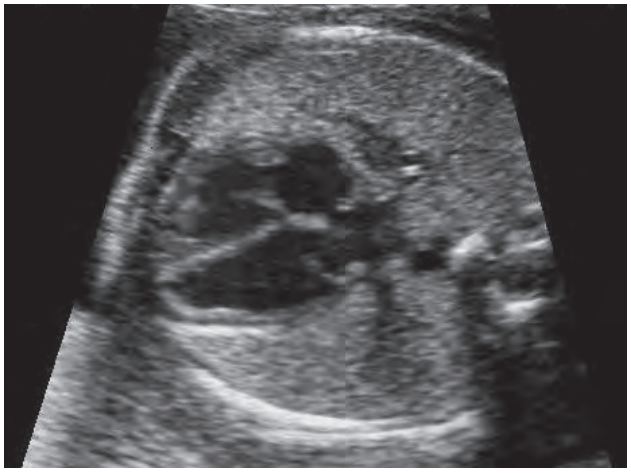


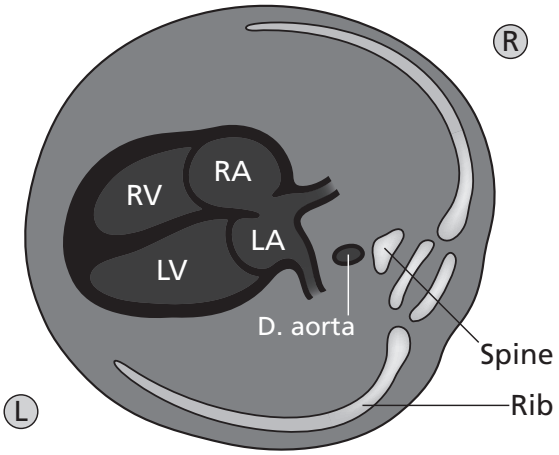
Visceral situs/laterality



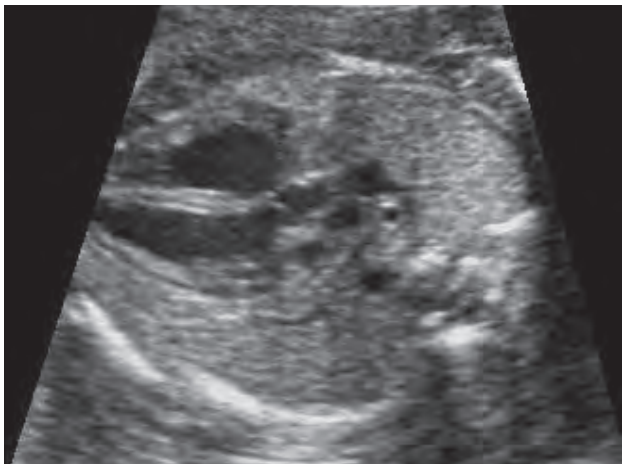


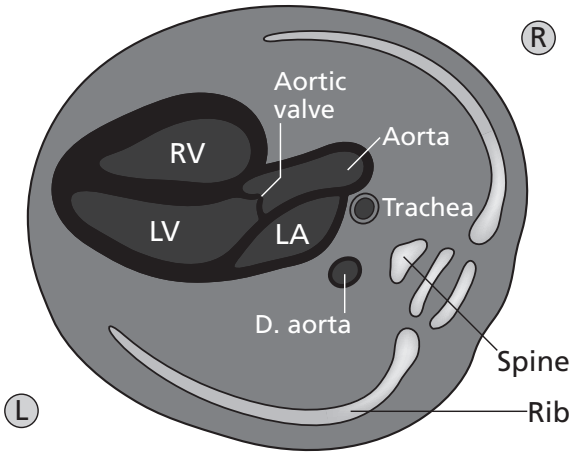
4 chamber view (4CH)



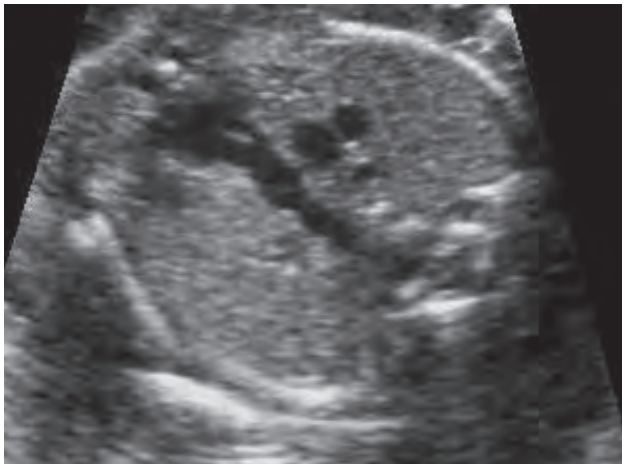


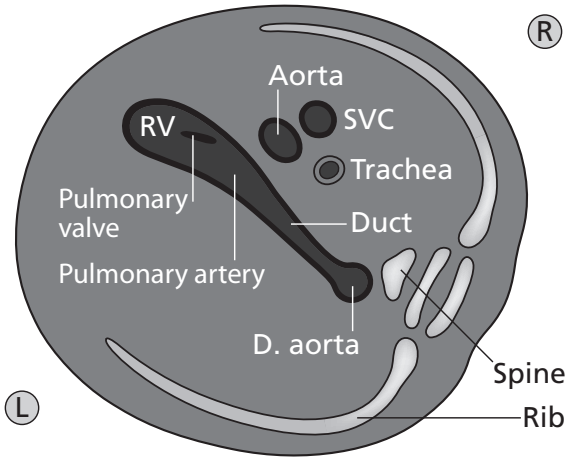
Aorta (AO)/left ventricular outflow tract



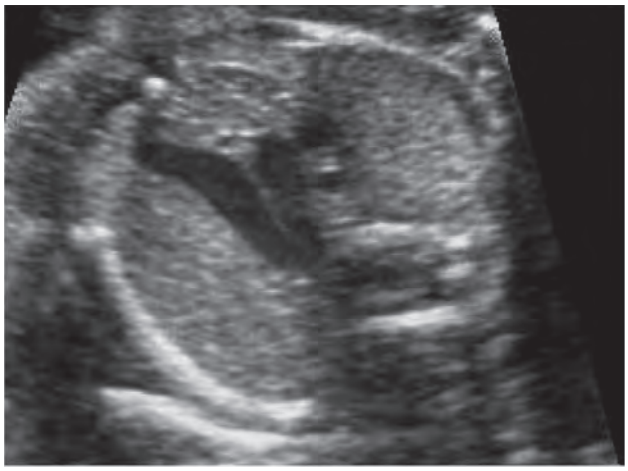


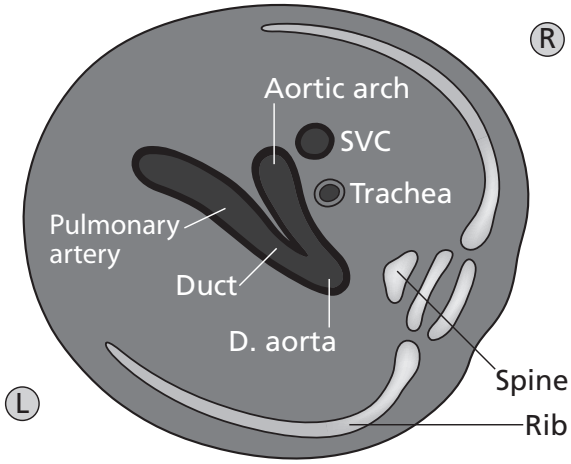
Pulmonary artery (PA)/right ventricular outflow tract or 3 vessel view (3VV)





3 vessel and trachea view (3VT)





Appendix 3 – Stakeholder and support groups

Antenatal Results and Choices (ARC)
www.arc-uk.org

Antenatal Screening Wales
www.antenatalscreening.org

Association of Congenital Diaphragmatic Hernia Research, Advocacy and Support (CHERUBS)
www.cherubs-cdh.org

AXrEM Associations of Healthcare Technology Providers for Imaging, Radiotherapy and Care
www.axrem.org.uk

British Heart Foundation
www.bhf.org.uk

British Maternal and Fetal Medicine Society (BMUS)
www.bmus.org

Care Quality Commission (CQC)
www.cqc.org.uk

Cleft Lip and Palate Association (CLAPA)
www.clapa.com

Clinical Negligence Scheme for Trusts (CNST)
www.nhsla.com/Claims/Pages/Clinical.aspx

Contact a Family
www.cafamily.org.uk

Department of Health
www.gov.uk/government/organisations/department-of-health

Down's Syndrome Association
www.downs-syndrome.org.uk

Down's Syndrome Screening Quality Assurance Service (DQASS)
www.gov.uk/downs-syndrome-screening-quality-assurance-support-service

Genetic Interest Group
www.gig.org.uk

Healthtalk.org
www.healthtalkonline.org

Health Professions Council
www.hpc-uk.org

MBRRACE-UK: Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
www.npeu.ox.ac.uk/mbrrace-uk

Medicines & Healthcare products Regulatory Agency (MHRA)
www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Miscarriage Association
www.miscarriageassociation.org.uk

National Institute for Health and Clinical Excellence (NICE)
www.nice.org.uk

National Patient Safety Agency (NPSA)
www.npsa.nhs.uk

UK National Screening Committee
www.gov.uk/guidance/nhs-population-screening-explained

NHS Fetal Anomaly Screening Programme
www.gov.uk/topic/population-screening-programmes/fetal-anomaly

Nursing and Midwifery Council
www.nmc-uk.org

Royal College of Midwives (RCM)
www.rcm.org.uk

Royal College of Nursing (RCN)
www.rcn.org.uk

Royal College of Obstetrics and Gynaecology (RCOG)
www.rcog.org.uk

Royal College of Paediatrics
www.rcpch.ac.uk

Royal College of Radiologists
www.rcr.ac.uk

Shine (previously the Association of Spina Bifida and Hydrocephalus)
www.shinecharity.org.uk

Skills for Health
www.skillsforhealth.org.uk

Society and College of Radiographers (SCoR)
www.sor.org

SOFT UK (Support Organisation for Trisomy 13/18 and related disorders)
www.soft.org.uk

Tiny Tickers
www.tinytickers.org

United Kingdom Accreditation Service
www.ukas.com

NHS Screening Programmes
Floor 2, Zone B
Skipton House
80 London Road
London SE1 6LH

Tel: 020 368 20890
Email: PHE.screeninghelpdesk@nhs.net
Web: www.gov.uk/topic/population-screening-programmes/fetal-anomaly
Twitter: @PHE_Screening

NHS

Screening Programmes

Fetal Anomaly

Fetal Anomaly Screening Programme

Handbook for ultrasound practitioners

April 2015

About the NHS Screening Programmes

NHS Screening Programmes identify apparently health people who may be at increased risk or a disease or condition, enabling earlier treatment and better informed decisions. They are implemented on the advice of the UK National Screening Committee (UK NSC), which oversees screening policy in all four nations, and works with the different implementation bodies to support delivery.

Public Health England (PHE) is responsible for the NHS Screening Programmes. PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

NHS Screening Programmes
Floor 2, Zone B
Skipton House
80 London Road
London SE1 6LH
Tel: 020 368 20890
www.screening.nhs.uk

Twitter: @PHE_Screening

Image sources: PHE photo library

You can download this publication from **www.screening.nhs.uk**

Gateway ref: 2015002

Contents

1 Introduction 5

1.1 Conventions 5
1.2 Related documents 5

2 The Fetal Anomaly Screening Programme (FASP) 6

2.1 General principles of screening 6
2.2 Background 6
2.3 The policy 6

3 Screening tests 8

3.1 First trimester combined test 8
3.2 Second trimester quadruple test 8
3.3 National standards 8

4 Markers used in screening tests 10

4.1 Maternal age 10
4.2 Biochemical markers 10
4.3 Ultrasound markers 11

5 Screening risk 12

5.1 Risk cut-off 12
5.2 Risk calculation software 12

6 Role of the Screening Support Sonographer 13

6.1 Functions 13

7 Criteria for measuring NT and CRL 14

8 Departmental review of images 16

8.1 Rationale 16
8.2 Local quality assurance 16
8.3 Supplementary audit activities 16
8.4 The scoring process for departmental review of images 16

9 DQASS 26

9.1 Aims of DQASS 26
9.2 Information DQASS needs from laboratories 26
9.3 DQASS reports 27

9.4 Contacting DQASS 27
9.5 Completing blood test forms 28
9.6 Flag status 29
9.7 Managing red flags 34
9.8 Throughput (number of scans undertaken per cycle) 35
9.9 Guidance for managing red flag for throughput 36
9.10 Scenarios 36

10 Education and Training 37

10.1 NHS model of training in NT and CRL measurements 37
10.2 Theory component 37
10.3 Practical component 38

11 Quality Improvement and Assurance 41

11.1 Quality Improvement 41
11.2 Quality Assurance (QA) 41
11.3 Key performance indicators (KPIs) 42
11.4 Screening safety incidents 42

12 Information for the public 43

Acknowledgments 43

Glossary 44

Tables, Diagrams and Images 47

References 48

Abbreviations 49

Appendices 50

1 Introduction

The purpose of this handbook is to bring together in one publication the Fetal Anomaly Screening Programme's (FASP) guidelines and recommendations that relate to the screening pathway and are not covered in detail in the other handbooks.

1.1 Conventions

Throughout the document the following are used interchangeably:

- Down's syndrome is referred to as T21
- Edwards' syndrome as T18
- Patau's syndrome as T13

1.2 Related documents

a. Handbook for laboratories

This sets out the requirements for laboratory staff involved in the pathways for first trimester screening for Down's, Edwards' and Patau's syndromes and second trimester biochemical screening for Down's syndrome.

fetalanomaly.screening.nhs.uk/publications

b. Ultrasound Practitioner's Handbook

This sets out the requirements for ultrasound practitioners involved in the pathway for first trimester screening for Down's, Edwards' and Patau's syndromes.

fetalanomaly.screening.nhs.uk/publications

c. Department of Health / NHS England Service – Specification for Screening for Down's, Edwards' and Patau's syndromes (No. 16) and Specification for 18^{+0} to 20^{+0} fetal anomaly scan (No.17)

These outline the service and quality indicators expected by NHS England for the population for whom it is responsible and which meets the policies, recommendations and standards of the UK National Screening Committee (UK NSC). It is relevant for both commissioners and providers of the screening service to enable an understanding of the care pathway pregnant women should expect and how that service should be delivered.

Both documents should be read in full to gain a better understanding of the expected roles and responsibilities for the various healthcare professionals involved in providing the screening pathway. These are updated annually and new versions posted to the website.

fetalanomaly.screening.nhs.uk/specification

d. Standards

These define a set of standards relating to screening for Down's, Edwards' and Patau's syndromes and the 18^{+0} to 20^{+6} week fetal anomaly scan.

fetalanomaly.screening.nhs.uk

2 The Fetal Anomaly Screening Programme (FASP)

2.1 General principles of screening

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition.

Further information regarding the general principles of screening can be found at:

www.screening.nhs.uk

2.2 Background

NHS FASP, based in Public Health England, is an expert team that ensures national consistency and provides expertise. They support and manage on-going roll out, technical and professional development of the programme and ensure quality and safety standards are maintained and continuously improved.

The screening programme has evolved from its establishment in 2001 when the majority of screening was performed using maternal biochemistry in the second trimester. The recommended method of screening is now first trimester screening, combining maternal age, biochemistry and ultrasound measurement of fetal nuchal translucency to provide a pregnant woman with the risk of having a baby with Down's, or Edwards'/Patau's syndromes.

The offer of a fetal anomaly scan is recommended and where accepted should be undertaken between 18^{+0} to 20^{+6} weeks of pregnancy. The fetal anomaly scan base menu sets out the fetal anatomy to be examined. The fetal anomaly scan screens for 11 conditions. For further information see section 5.6 of this handbook.

FASP has established standardisation of the following to enable commissioners and quality assurance teams to assess the quality of the service provided. These include:

- national standards, guidance and risk cut-off for Down's, Edwards' and Patau's syndromes screening programme in the light of emerging evidence
- a statistical service to ensure that laboratories have access to the best advice in maintaining their population medians
- specifications for risk calculation software to make sure that all laboratories calculate risks in a uniform way
- use of a base menu and fetal cardiac protocol to enable consistency in the structures examined as part of the 18^{+0} to 20^{+6} week fetal anomaly scan

2.3 The policy

FASP offers screening to all eligible pregnant women in England to assess the risk of the baby being born with Down's, or Edwards'/Patau's syndromes or a number of fetal anomalies (structural abnormalities of the developing fetus).

FASP aims to ensure there is equal access to uniform and quality-assured screening across England and women are provided with high quality information so they can make an informed choice about their screening and pregnancy options. Education and training resources are available for staff covering all stages of the process, from informing women of test availability, through to understanding and supporting their decisions.

The screening policy is to offer screening to assess the risk of the baby being born with Down's or Edwards'/Patau's syndromes. The test

of choice for both singleton and twin pregnancies is first trimester combined screening. Women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only

The first scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for Down's, Edwards'/Patau's syndromes, with a second scan for fetal anomalies between 18^{+0} to 20^{+6} weeks. The timing of the scans allows for further diagnostic tests if required and ensures women have time to consider decisions about continuing their pregnancy.

The second scan is designed to identify abnormalities which indicate the baby may die shortly after birth, conditions that may benefit from treatment before birth, to plan delivery in an appropriate hospital/centre and/or to optimise treatment after the baby is born. Some women may choose not to be screened at all, or only for some conditions and it is important that this choice is respected.

3 Screening tests

3.1 First trimester combined test

The combined test uses maternal age, the nuchal translucency measurement (NT) and two biochemical tests, free beta hCG and PAPP-A, together with the gestational age calculated from the crown rump length (CRL) measurement, to calculate the risk of the pregnancy being affected by T21 or T18/T13. The optimal time to perform the combined test is between 11^{+2} weeks to 14^{+1} weeks of gestation, which corresponds to a CRL of 45.0 mm to 84.0 mm. If the ultrasound measurement shows that the CRL is less than 45.0 mm, the woman should be recalled for a further scan to measure the NT. If the CRL is greater than 84.0 mm, the second trimester quadruple test should be offered.

The first trimester combined test allows earlier decision making for parents. In practice, two models are available for performing the combined test:

A maternal blood specimen may be taken (from 10 weeks onwards) prior to the ultrasound scan. The biochemistry results can then be made available at the time of the NT scan and the combined test result can be calculated at the time of the appointment. Although the result may be calculated by the sonographer, it is recommended that the laboratory take primary responsibility for the risk calculation software and audit all results.

A maternal blood specimen may be taken at the time of the ultrasound scan and the combined test result made available within a few days of the biochemistry results being authorised by the laboratory.

In cases where screening is accepted but it is not possible to obtain the NT measurement at the first appointment, at least one other attempt should be offered, this may be on the same day or at a later date. If it is not possible to obtain an accurate NT measurement despite 'twice on the couch' then further attempts do not have to be offered and the woman should be referred in to the second trimester screening pathway.

FASP recommends that the Down's and/or Edwards'/Patau's screening risk generated from first trimester combined screening must not to be recalculated up or down following the initial screening test or at the 18^{+0} to 20^{+6} fetal anomaly ultrasound scan due to the presence or absence of a single ultrasound marker of less predictive power than increased nuchal fold (Smith-Bindman et al, 2001).

3.2 Second trimester quadruple test

The quadruple test uses maternal age and four biochemical markers measured from 14^{+2} weeks until 20^{+0} weeks - AFP, hCG (total, intact or free beta subunit), uE3 and Inhibin-A. Although this combination of markers has a lower detection and standardised screen positive rate than the combined test, it is the nationally recommended screening strategy for the second trimester. The optimum time for testing in the second trimester is around 16 weeks of gestation.

There will always be a need for a screening test in the second trimester for those women who book too late for first trimester testing or when an NT measurement cannot be obtained in the first trimester. An ultrasound scan will be required to date the pregnancy and a fetal head circumference is the recommended measurement used for women presenting in the second trimester. Further information regarding the practicalities of a solution to combining dating and screening requirements at the early pregnancy scan are explored in more detail in the following article by Chudleigh et al (2011), a practical solution to combining dating and screening for Down's syndrome.

3.3 National standards

The national standards seen in Table 1 state the threshold for the national programme and will be reported on each year by DQASS.

Table 1. National standards

Screening strategy	Thresholds	
	Acceptable	Achievable
T21	Standardised DR 85%	
	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
T18/T13	Standardised DR 80%	
	Standardised SPR 0.1-0.2%	Standardised SPR 0.13-0.17%
T21/T18/T13	Standardised SPR 1.8-2.5%	Standardised SPR 1.9-2.4%
Quadruple (T21)	Standardised DR 80%	
	Standardised SPR 2.5-3.5%	Standardised SPR 2.7-3.3%

*The DR and SPR for the quadruple test relate to singleton pregnancies only

4 Markers used in screening tests

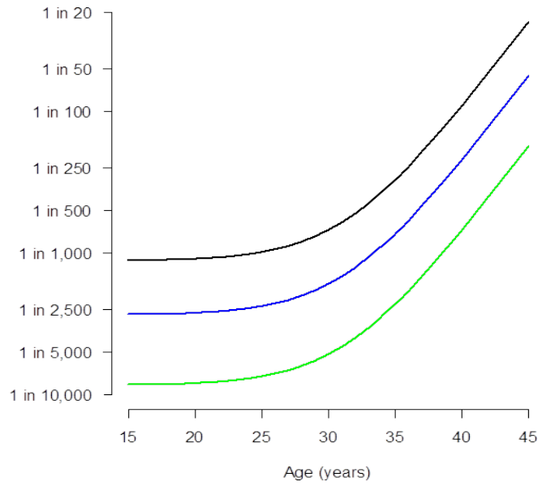
4.1 Maternal age

All women have a chance of having a baby with Down's or Edwards'/Patau's syndrome and this chance increases with age. Table 2 below shows that the older a mother, the more chance she has of having a baby with one of these conditions.

Table 2

Maternal age	Chances of having a pregnancy affected by Down's syndrome	Probability
20 years	1 in 1500	0.07%
30 years	1 in 900	0.1%
40 years	1 in 100	1%

Figure 1: Graph to illustrate the likelihood of a pregnancy affected by Down's, Edwards' or Patau's syndromes according to maternal age showing T21 (black line), T18 (blue line), T13 (green line). Risks are at the time of the 12 weeks scan.



4.2 Biochemical markers

Information about biochemical markers can be found in the Handbook for Laboratories at:

fetalanomaly.screening.nhs.uk/publications

Effect of vaginal bleeding on biochemical markers used in screening for Down's, Edwards' and Patau's syndromes

There are concerns that a history of significant maternal vaginal bleeding might change the levels of biochemical markers used in the combined test. FASP recommends women are offered the combined test in the normal way (calculating the risk based on maternal age, NT, free beta hCG and PAPP-A levels), as current evidence suggests that the biochemical marker levels are not significantly different in women with this history.

Effect of 'vanished twin' on biochemical markers used in screening for Down's, Edwards' and Patau's syndromes

When ultrasound shows there is an empty second pregnancy sac, the biochemical markers appear no different to those in a singleton pregnancy and the combined test of NT, PAPP-A and free beta hCG can be used to calculate the risk.

When ultrasound shows that there is a second sac containing a non-viable fetus (sometimes called 'vanished' twin), it is possible there could be a contribution to the maternal biochemical markers for many weeks. It is recommended that in this event services undertake the risk calculation based on the maternal age and nuchal translucency only (ie without biochemistry).

4.3 Ultrasound markers

Nuchal translucency (NT)

Nuchal translucency is the ultrasound appearance of a collection of fluid under the skin behind the neck of the fetus in the first trimester of pregnancy. The thickness of the nuchal translucency is measured by the sonographer and used in calculating the chance of the pregnancy being affected by Down's and/or Edwards'/Patau's syndromes. An increased NT measurement is associated with an increased chance of these autosomal trisomies as well as other fetal anomalies such as cardiac defects but as with all screening tests, a pregnancy with an increased NT may also have a normal outcome.

Where screening in the first trimester using the combined screening strategy is accepted, the biochemical component of the test must be completed. Therefore, where an NT measurement of ≥3.5 mm is recorded, a blood sample must be taken but referral should not be delayed to await the biochemistry marker levels and results should be forwarded to the clinician as soon as they are available to support discussion of further investigative options with the woman.

Crown rump length (CRL)

The gestational age of the fetus is calculated from the ultrasound measurement between the top of the head (crown) to the bottom of the buttocks (rump) known as the crown rump length (CRL). The gestational age in days can be calculated by the use of tables or an equation from the CRL measurement. Whilst it is acknowledged that the description of the first trimester screening test is primarily described within a gestational age timeframe (10^{+0} weeks to 14^{+1} weeks), entry into the screening programme within the laboratory should be based on CRL measurements of 45.0mm to 84.0mm rather than gestational age of weeks and days. Because the concentration of the biochemistry markers is dependent on the gestational age of the fetus, it is important that the CRL is measured accurately.

Head circumference (HC)

If the CRL is greater than 84.0mm, it is recommended that the gestational age of the fetus is calculated using the fetal head circumference (HC). Ultrasound measurements of the biparietal diameter (BPD using 'outer to outer' calliper placement) and the occipital-frontal diameter (OFD using 'outer to outer' calliper placement) are used to calculate the head circumference which can then be used to date the pregnancy. Loughna et al (2009).

Information about NHS training for competency in the measurement of nuchal translucency (NT) and crown-rump length (CRL) and the recommend measurements charts can be found at:

fetalanomaly.screening.nhs.uk/combinedscreeningresources

5 Screening risk

5.1 Risk cut-off

FASP defines the national cut off and this is currently set at 1 in150 at term for both first and second trimester screening tests. A woman with a risk of 1 in 150, or greater (1 in 2 – 1 in 150), of having a pregnancy affected by Down's or Edwards'/ Patau's in the first trimester or Down's syndrome only in the second trimester is considered to be in the 'higher risk' group. Women in this group are offered diagnostic test such as chorionic villus sampling or amniocentesis to directly investigate the fetal chromosomes. Women having screening using the combined test, dependant of their screening choice, up to two risks will be reported:

- a risk for T21 and a risk for T18/T13
- a risk for T21 only or T18/T13 only

The cut-off is based on a risk at term rather than a risk at the time of the screening test. The main reason for this is that the original studies on the likelihood of having a Down's syndrome affected pregnancy is based on the birth prevalence of the condition before screening was implemented. There is a significant fetal loss rate between the time of screening and delivery but the loss rate is not exactly known. A risk at the time of screening would need to make assumptions about the fetal loss rate during the various stages of pregnancy. This will be kept under review.

5.2 Risk calculation software

The software used to calculate the Down's, and Edwards'/Patau's syndromes risk from the biochemical and ultrasound markers is complex and best provided and supported by commercial suppliers. The screening programme developed a specification for the risk calculation software to be supplied to the English laboratories and which is available at:

fetalanomaly.screening.nhs.uk/dqass

This specifies in detail all the aspects that need to be incorporated into the software package to provide consistent risk results across the country. Some variables that need to be entered into the software are defined by the local user to take account of the reagents used for screening and the characteristics of the local population they are screening. These would normally be decided by the laboratory in collaboration with Down's syndrome screening Quality Assurance Support Service (DQASS) – the statistical support service provided by Public Health England (PHE).

6 Role of the Screening Support Sonographer

To achieve the national standards and to ensure a high quality test it is imperative that the ultrasound measurements are accurate. To assist the service in achieving these key aims, this handbook sets out the following:

- role of the Screening Support Sonographer (SSS)
- departmental review of images
- Down's syndrome screening Quality Assurance Support Service (DQASS)
- education and training process
- quality assurance process

The Screening Support Sonographer (SSS) role is pivotal in ensuring local providers offer a safe and effective service and in meeting the national targets set out in the service specification http://fetalanomaly.screening.nhs.uk/specification

Providers must have a nominated SSS or a designated person to carry out the functions. Each department should have a SSS and a deputy SSS. Throughout the handbook where the SSS is discussed this term also refers to the deputy SSS or designated individual.

6.1 Functions

The main functions of the SSS are:

- internal quality assurance – regular departmental review of images is an essential aspect of the role and will provide ongoing support to ensure improvements in practice can be achieved and maintained
- DQASS – liaise with the Down's syndrome Screening Quality Assurance Support Service (DQASS) to facilitate a high quality local screening programme. DQASS also provides a statistical service in relation to screening for Edwards' and Patau's syndromes, however, the name will remain unchanged
- action plans – devise and implement supportive action plans where required. Monitor progress and resolution of these action plans
- communication – liaise with ultrasound practitioners, the Trust's antenatal and newborn screening board, the screening laboratory, screening and immunisation lead and teams (SILs) and regional quality assurance team (RQAT)
- record keeping – maintains departmental records of training, support and both internal and external quality assurance
- training and support – involvement in the practical training and support of colleagues in relation to the measurement of NT and CRL

7 Criteria for measuring NT and CRL

Table 3 - Recommended criteria for measurement of NT for combined screening

NT	Detail to be demonstrated
Midline section	• Horizontal sagittal* section of the fetus extending from crown to upper aspect of the heart which may be supine or prone** • Head in line with the body with the NT visible along the length of the neck • Echogenic tip of the nose • Rectangular shape of the palate • Translucent diencephalon • Frontal process of the maxilla should not be visible
Position	• Pocket of fluid, at least equivalent in size to the width of the palate, should be visible between the fetal chin and chest • Angle of the palate relative to the horizontal should be between 30° and 60° • Nasal tip should be level with, or above, the anterior chest wall
Magnification	• The section should fill over 60% of the screen
Calliper placement	• Callipers should be placed on the upper and lower edges of the NT • Widest part of the NT should be measured
Image archiving	• The NT should be measured at least twice and the maximum measurement that meets the criteria should be recorded • The image demonstrating the measured NT which has been reported should be archived

* In all criteria the term sagittal describes a midline longitudinal section

** FASP does not recommend screening for nasal bone absence or hypoplasia, thus allowing measurement of the NT with the fetus in the prone position

Table 4 - Recommended criteria for measurement of CRL for pregnancy dating and combined screening (Loughna P et al (2009))

CRL	Detail to be demonstrated
Midline section	• Sagittal section of the fetus with the head in line with the full length of the body • Echogenic tip of the nose • Rectangular shape of the palate • Translucent diencephalon • CRL axis should be between 0° and 30° to the horizontal • Clearly defined crown and rump
Position	• Pocket of fluid, at least equivalent in size to the width of the palate, should be visible between the fetal chin and chest • Fetal palate angle should be 30° to 60° relative to the horizontal • Nasal tip should be level or above the anterior abdominal wall
Magnification	• Entire CRL section should fill over 60% of the screen
Calliper placement	• Correct calliper placement on outer borders of crown and rump • Longest length of the fetus should be measured
Image archiving	• The CRL should be measured at least twice and the maximum measurement that meets the criteria should be recorded • The image demonstrating the measured CRL which has been reported should be archived

8 Departmental review of images

The role of the screening support sonographer (SSS) is to:

- perform quarterly departmental review of images
- record results as per local organisational policy
- feedback results of review to individual practitioners
- develop action plan for improvement if required
- prepare audit information for RQAT when required

8.1 Rationale

Departmental review of images is equally as important as the DQASS statistical analysis of an individual's NT and CRL measurements.

Departmental review of images is not designed to be a performance management tool but provides local quality assurance.

The review process aims to encourage best practice and to assist and support ultrasound practitioners in making continuous improvements in their NT and CRL measurement technique and maintain best practice once achieved.

Taking part in three-monthly image review with the SSS and consulting the document entitled 'A guide to getting the most from the ultrasound equipment when measuring Nuchal Translucency' is strongly recommended.

fetalanomaly.screening.nhs.uk/leafletsforprofessionals

8.2 Local quality assurance

- each practitioner must have three randomly selected paired images (NT and CRL) reviewed every three months
- each image should be subjectively scored using the FASP image guidance tool
- each practitioner should receive timely feedback from the SSS
- evidence may be sought by the RQAT that, as a minimum, all components of the departmental image review is audited

8.3 Supplementary audit activities

These are designed to support and encourage best practice (not mandatory and not audited).

- group review of a selection of images
- anonymised scored images shared within team
- each practitioner measures selected NT/CRL images previously stored on the ultrasound machine. Results are then compared and shared
- companion scanning – good for image optimisation, communication skills and time management
- sharing the overall departmental review with individual practitioners should also be considered

8.4 The scoring process for departmental review of images

The 12 components that make a good NT or CRL image are shown in tables 4 and 5 below.

- each image is rated as either 'good', 'acceptable' or 'poor' depending on the score obtained as shown in Table 3
- for an image to be considered good or acceptable at least 9 out of the 12 components must be present (75%). In categories of more than one component, there should be no more than 2 components in each section absent
- examples of scored NT images are shown in Diagram 3 and of scored CRL images in Diagram 4

- sample score sheets can be found in Appendix 1

Table 5 - Scoring images

Number of components present	Overall Score
All 12 present	GOOD
9 – 11 present (no more than 2 absent in a section)	ACCEPTABLE
9 - 11 present (3 or more absent in a section) **or** **8 or fewer present**	POOR

Suggested management following image review

- when all images score either 'good' or 'acceptable' this demonstrates evidence of good clinical practice
- when any one image scores 'poor' it is recommended that a further three paired images are reviewed

If a practitioner continues to score 'poor' when these images are reviewed, it is recommended that the ultrasound practitioner has an individualised training plan to support improvements to their imaging and measurement techniques.

Table 4 details the NT and CRL image components that should be analysed and scored using the following image guidance tool.

Table 6 - Image guidance tool for NT

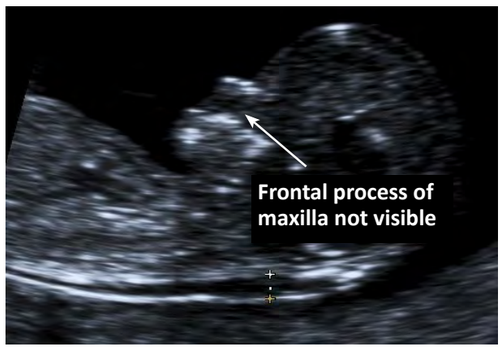
Sections	Twelve Components to assess the NT image appearance
Midline section	1. Horizontal sagittal section of the fetus extending from crown to include at least the upper aspect of the heart* 2. Head in line with the body with the nuchal translucency visible along the length of the neck 3. Echogenic tip of the nose 4. Rectangular shape of the palate 5. Translucent diencephalon 6. Frontal process of the maxilla should not be visible (see Diagram 1)
Position	7. Pocket of fluid, at least equivalent in size to the width of the palate, should be visible between the fetal chin and chest 8. Angle of the palate relative to the horizontal should be between 30^0 and 60^0 9. Nasal tip should be level with, or above, the anterior chest wall.
Magnification	10. The section should fill over 60% of the screen
Calliper placement	11. Callipers should be placed on the upper and lower skin line (see Diagram 2) 12. Widest part of the NT should be measured

*Note the NT and CRL image guidance tool developed with the assumption that the fetus is supine. The image components can still be applied when the fetus is prone, although it may not be possible to score component 3 (echogenic tip of nose). Therefore when the fetus is prone an image score of 'good' may not be achievable.

Diagram 1 Images to show absence and presence of frontal process of maxilla

Absence of frontal process of maxilla

Component 6 = ✓



Presence of frontal process of maxilla

Component 6 = X

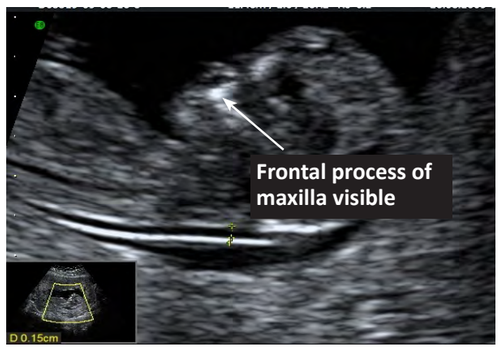
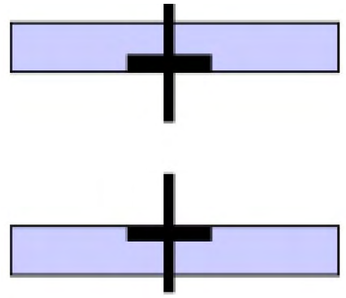
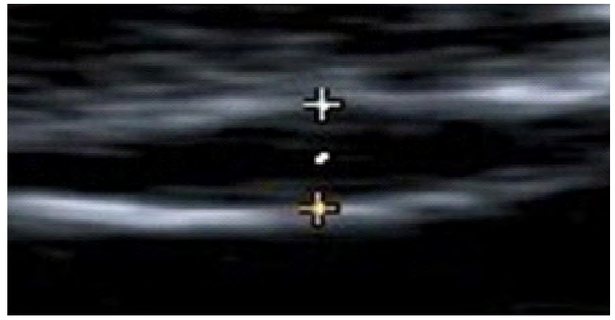


Diagram 2 Where to place callipers for the NT measurement

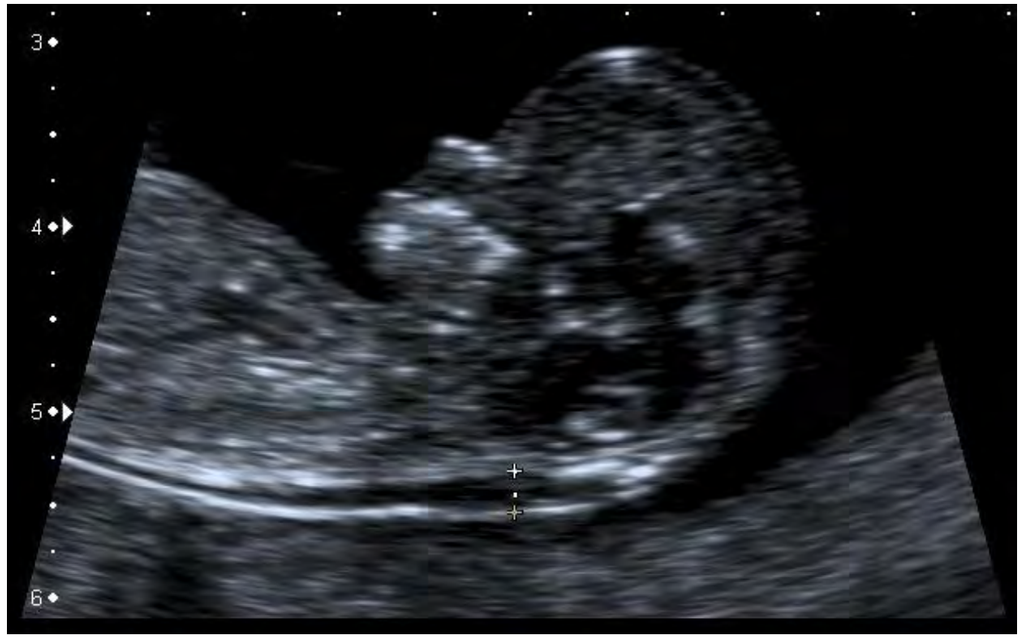




Measurement should be taken with the inner border of the horizontal of the callipers placed ON the line that defines the NT thickness. The crossbar of the calliper should be such that it is hardly visible as it emerges with the white line of the border. It should not be visible in the nuchal fluid.

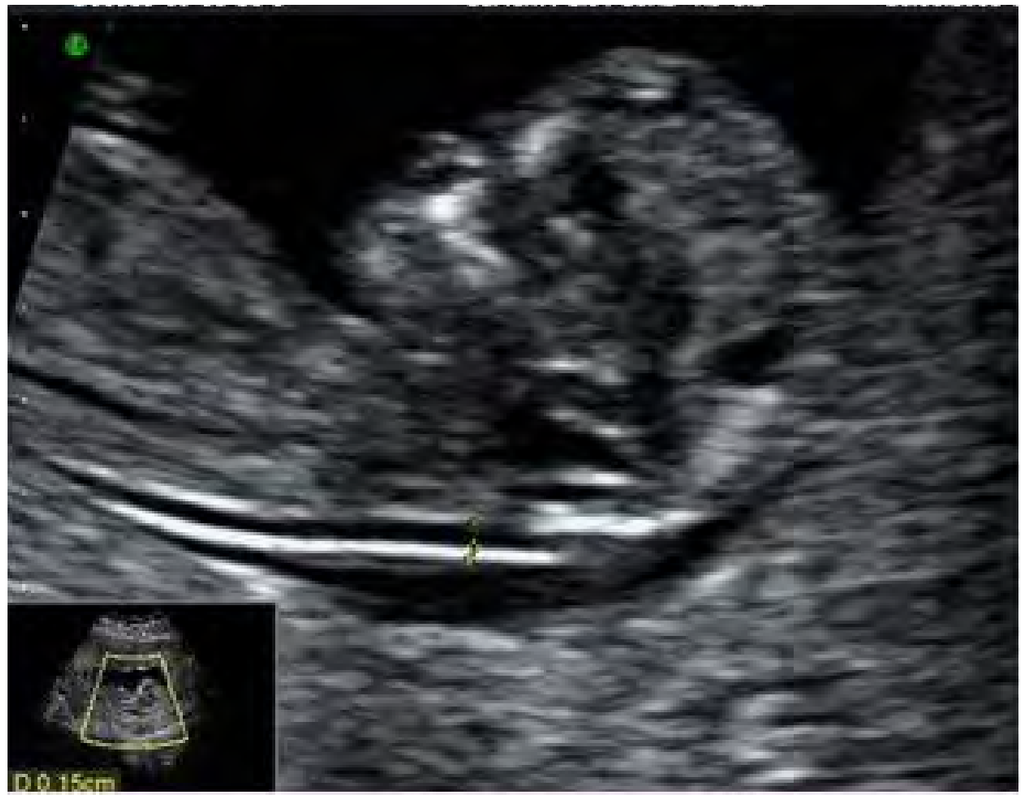
Diagram 3 Examples of scoring NT images

Image 1 Good



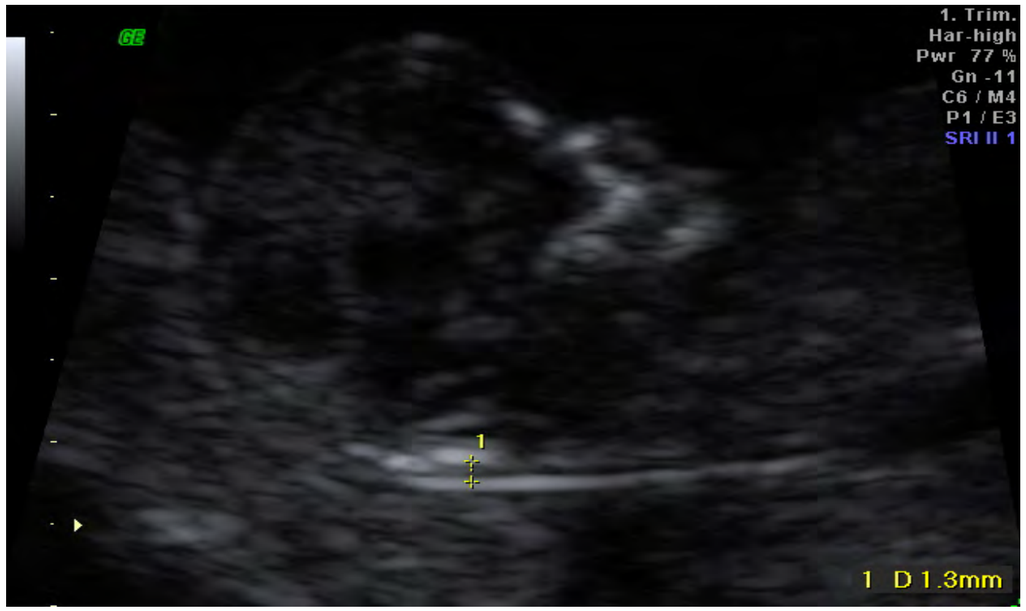
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present												Good

Image 2 Acceptable



Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	x	✓	✓	✓	✓	✓	✓	
11/12 components present **6)** Frontal process of the maxilla is present												Accept-able

Image 3 Poor



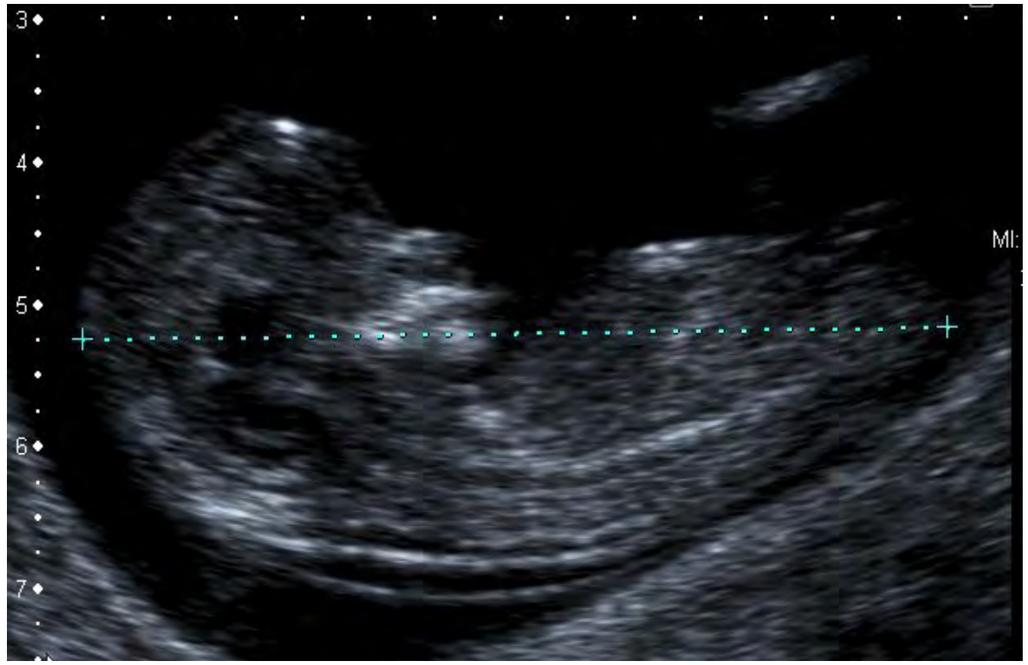
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	x	X	✓	x	✓	x	X	
7/12 components present **6)** Frontal process of the maxilla is present **7)** No pocket of fluid under the chin **9)** Nasal tip below anterior chest wall **11)** Callipers are not correctly placed on the skin lines **12)** Widest part of the NT not measured												Poor

Table 7 - Image guidance tool for the CRL

Sections	Twelve Components to assess the CRL image appearance
Midline section	1. Sagittal section of the fetus with the head in line with the full length of the body 2. Echogenic tip of the nose 3. Rectangular shape of the palate 4. Translucent diencephalon 5. CRL axis should be between 0° and 30° to the horizontal 6. Clearly defined crown and rump
Position	7. Pocket of fluid, at least equivalent in size to the width of the palate, should be visible between the fetal chin and chest 8. Fetal palate angle should be 30° to 60° relative to the horizontal 9. Nasal tip should be level or above the anterior abdominal wall
Magnification	10. Entire CRL section should fill over 60% of the screen
Calliper placement	11. Correct calliper placement on outer borders of crown and rump 12. Longest measurement of the fetus taken

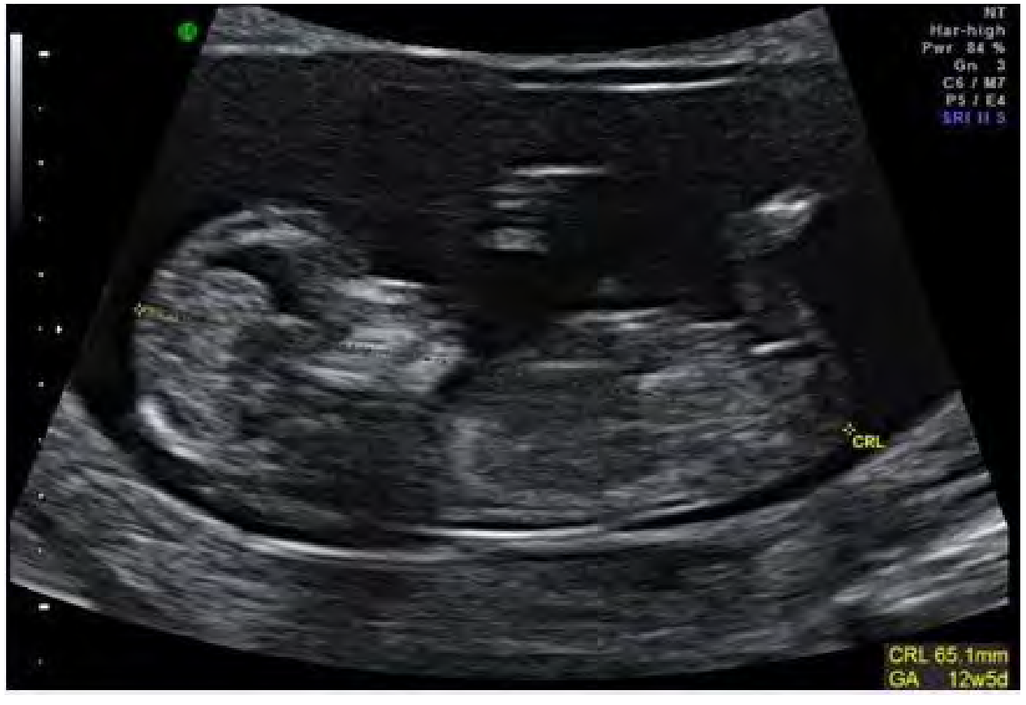
Diagram 4 Examples of scoring CRL images

Image 4 Good



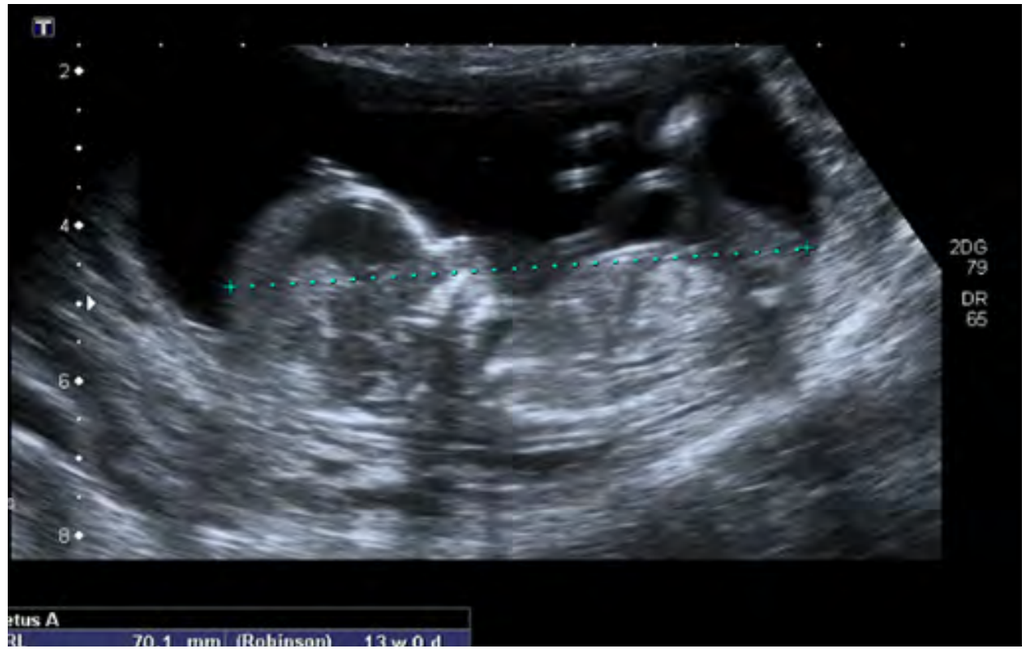
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present												Good

Image 5 Acceptable



Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	x	✓	✓	✓	✓	✓	✓	✓	✓	
11/12 components present **4)** Diencephalon absent												Accept-able

Image 6 Poor



Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
x	✓	✓	✓	✓	x	✓	✓	✓	✓	x	x	
8/12 components present **1)** the full length of the body is not present **6)** the rump is not clearly defined **11)** callipers are not correctly placed on the rump **12)** the longest measurement has not been taken												Poor

9 DQASS

The role of the screening support sonographer (SSS) is to:

- inform DQASS and screening laboratory of new staff members
- inform DQASS and screening laboratory when a member of staff leaves the Trust
- ascertain from sonographers if they work at other sites and inform DQASS
- monitor throughput for each practitioner
- liaise with laboratory before submission to ensure all practitioner DQASS identity codes are correct and all information is up to date
- receive 6 monthly DQASS report and check for accuracy
- feedback to DQASS any omissions or errors so an updated report can be issued
- feedback DQASS reports to individual sonographers
- develop any red flag action plans with practitioner concerned
- document and organise any support/training required
- liaise with RQAT and SILs regarding red flags
- maintain departmental log of any practitioners who have combined cycle reports for throughput (for internal information only)
- inform agency sonographers that they are responsible and not DQASS for providing their agency with their DQASS report if it is required

DQASS is a service commissioned by Public health England to support the NHS Fetal Anomaly Screening Programme.

All screening laboratories are required to be part of this service and submit their data according to the schedule provided by DQASS.

9.1 Aims of DQASS

The main aim of DQASS is to monitor and support the quality and effectiveness of prenatal screening in England. DQASS provides feedback and support to laboratories, sonographers and to the FASP programme.

The analyses provided by DQASS are used to improve the performance of the screening through feedback on all aspects of the test to laboratories, ultrasound departments and commercial suppliers.

DQASS works on a rolling audit of screening test data on a six monthly cycle. The statistical analysis monitors the screening process at various levels; from the overall standardised screen positive rate at the top level to specific adjustments for ethnicity, smoking and other factors applied to individual biomarkers. Through meta-analyses DQASS provides information on effects of factors such a smoking that can be used to improve screening performance.

9.2 Information DQASS needs from laboratories

A designated person in each laboratory should provide data for a 6-month period in Excel format with anonymised individual patient data contained in separate rows. Each column should correspond to a specific data field. The first row should contain the variable label. For the combined test, each row should correspond to a fetus. For the quadruple test each row should correspond to a pregnancy.

The ultrasound information required is listed below. Detailed information on the demographic and biochemical information can be found in the Laboratory handbook at:

fetalanomaly.screening.nhs.uk/publications

9.2.1 Ultrasound Scan

- scan date
- CRL mm (One decimal place)

- HC mm (One decimal place)
- NT mm (One decimal place)
- DQASS Identity code of sonographer and USS department

The laboratory should liaise with the screening support sonographer (SSS) to ensure that the DQASS ID codes for the sonographers are up to date and that the codes can be matched to an ultrasound department to enable feedback to be given.

9.3 DQASS reports

DQASS undertakes a range of statistical analysis on the data provided and produces reports summarising activity and performance.

Laboratories receive detailed information on serum analyte performance and a summary ultrasound report of the departments they support.

Ultrasound practitioners receive information on their paired NT and CRL distributions in relation to the FMF reference curve and a summary laboratory report will be sent to the SSS.

More information is available at **fetalanomaly.screening.nhs.uk/dqass**

9.4 Contacting DQASS

- Only the SSS should contact DQASS
- Individual practitioners should not contact DQASS directly
- Contact via email using **DQASS@plymouth.ac.uk**
- DQASS should not be contacted to ask what date or time reports will be sent

Information required when contacting DQASS via email

Inform of a new staff member

- practitioner's name
- hospital Unit
- date practitioner started working at the hospital unit
- is this the practitioner's primary place of work? If 'No' where is this sonographer primarily based?
- previous place of work
- provide their unique DQASS identity code matched to an ultrasound department

Request a trainee DQASS identity code

- practitioner's name
- hospital Unit
- state that they require a trainee DQASS identity code

Sending 25 paired measurements for assessment

- practitioner's Name
- practitioner's DQASS identity code matched to an ultrasound department
- hospital Unit
- diagnostic plot

9.5 Completing blood test forms

Ultrasound practitioners are responsible for ensuring the following information is included on the blood test form.

- unique DQASS identity code matched to an ultrasound department
- hospital name
- CRL/HC
- NT measurement
- gestational age
- date of ultrasound scan
- number of fetuses and chorionicity

FASP recommends that practitioners check their NT and CRL distributions at least once within the six-monthly DQASS QA cycle by performing a 'self-assessment'. This acts as either reassurance or a very helpful early warning sign by increasing awareness of their own performance and allowing them to take corrective action, if necessary, to improve their measurement technique.

Some software IT systems, allow practitioners to check their own distributions. For local organisations that do not have these IT systems, the simple Excel spreadsheet devised by DQASS and entitled NT diagnostic plot should be used to check individual distributions.

fetalanomaly.screening.nhs.uk/sssresources

Table 8 - DQASS reports

Report	Recipient	Information included
Individual practitioner report	Practitioner via SSS FASP (only red flags) National QA team (only red flags)	Practitioner's DQASS identity code matched to an ultrasound department Number of measurements Flag status Bias relative to FMF reference curve
Ultrasound Department summary report	SSS Laboratory FASP National QA team Regional QA team SILs via RQAT	Screening laboratory and time period covered by report For each practitioner - DQASS identity code, number of scans, median NT, median CRL, median bias and flag status. 95% confidence intervals for estimated bias for each practitioner Previous cycle flag status
Laboratory summary report	Laboratory SSS NHS trust chief executives - all trusts using the laboratory FASP National QA Team RQAT SILs via Regional QA team	Number of pregnancies covered in the data set and the number with a risk given DQASS modelled screening performance (DR, FPR, SPR)* Data collected, ultrasound measurements and algorithm parameters used First trimester marker performance with reference to the NT comparison to the FMF reference curve NT MoM diagnostics Biochemistry estimated median values DQASS identity code compliance Recommendations and actions

* Detection rate = DR False positive rate = FPR Screen positive rate = SPR

9.6 Flag status

Flags are assigned to a dataset of NT and CRL measurements. These flags indicate the bias of the dataset which is the extent of the measurement deviation from the Fetal Medicine Foundation (FMF) reference curve. The evidence used to develop the flag status derived from the impact on screening performance, (Kagan et al 2009).

It is important to note that it is the data set that is flagged NOT the individual practitioner.

Bias can usually be improved by developing a thorough understanding of the factors that affect it. Factors include:

1. machine factors (level of sophistication, recent upgrades, servicing, local quality control (QC) arrangements)
2. ambient light levels within the examination room exceeding Lux level 15

3. department workload and the time allocated to perform the scan
4. departments where slave monitors are not available
5. ultrasound practitioner's eyesight
6. ultrasound practitioners sharing the same DQASS identity codes
7. very low numbers (less than 25) of NT measurements performed in a six-month period
8. practitioner under or over measuring the CRL
9. practitioner under or over measuring the NT to maintain a bias to the FMF reference curve
10. practitioner's improvements in measurement technique
11. high-risk caseloads
12. demographic factors (e.g. high prevalence of women with raised BMI)
13. automated measurements

The flag system is designed to help the SSS to identify where to focus training efforts. It is important that all factors affecting the acquisition of high quality images are considered when agreeing an action plan to support ultrasound practitioners.

Examples of distribution plots with flags assigned and how to interpret them can be found in this section.

FASP reviewed the bias deviation relative to the FMF reference curve ranges against the programmes quality agenda and assigned the following categories:

Table 9 - Flag category and bias

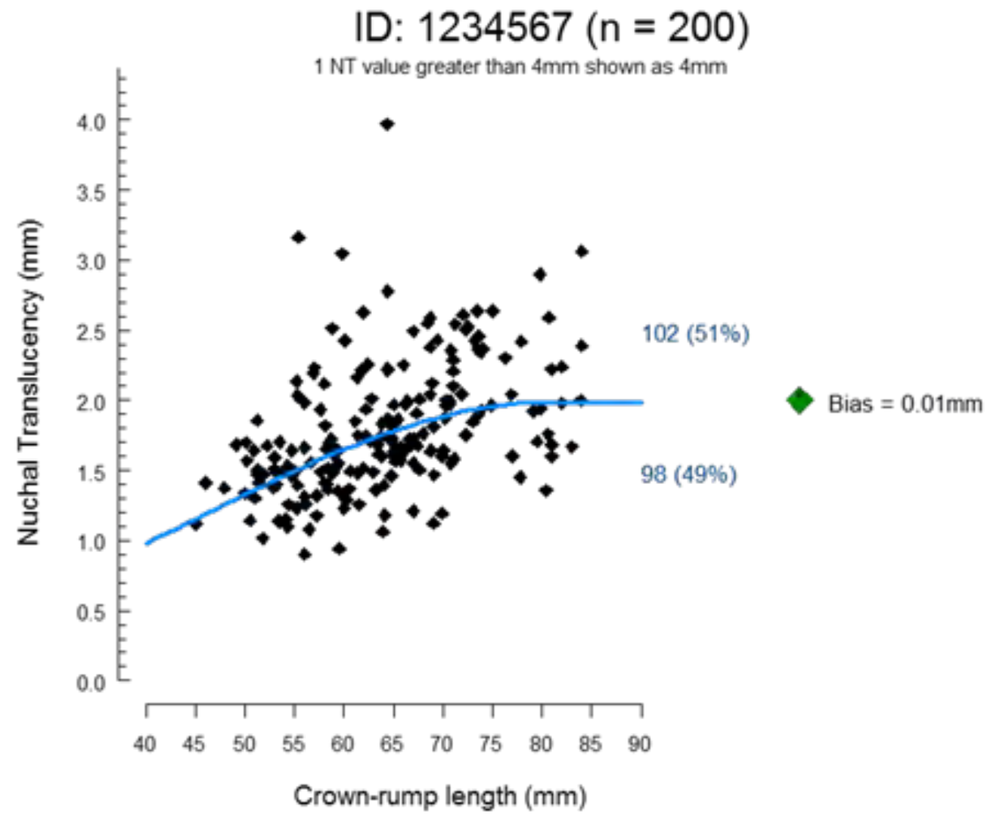
Flag type	Bias
Green flag	Assigned when bias is **less than or equal to 0.10mm**
Amber Flag	Assigned when bias is **between 0.11mm and 0.40mm**
Red Flag	Assigned when bias is **greater than 0.40mm**
Red Flag with 4	Assigned if fewer than 25 paired CRL/NT measurements over 4 cycles
No Flag	Assigned if a trainee sonographer has fewer than 25 paired NT/CRL measurements

- each individual report demonstrates the NT and CRL measurements relative to the FMF reference curve
- bias describes the number of measurements above and below the FMF reference curve
- the bias is either negative in terms of under-measurement (below the FMF reference curve) or positive which refers to over-measurement (above the FMF reference curve)
- the evidence used to develop the flag status was derived from the impact on screening performance. For positive biases greater than 0.40mm, the standardised screen positive rate (SPR) exceeds 5% and increases the number of pregnancies exposed to the potential risks and anxieties associated with a screen positive result which may lead to invasive diagnostic procedures

- for negative biases with magnitudes of 0.40mm or greater, there is a loss of 5% or more in the detection rate (DR)

An example of 'green flag' distribution plot (continue screening)

Diagram 5 Green bias

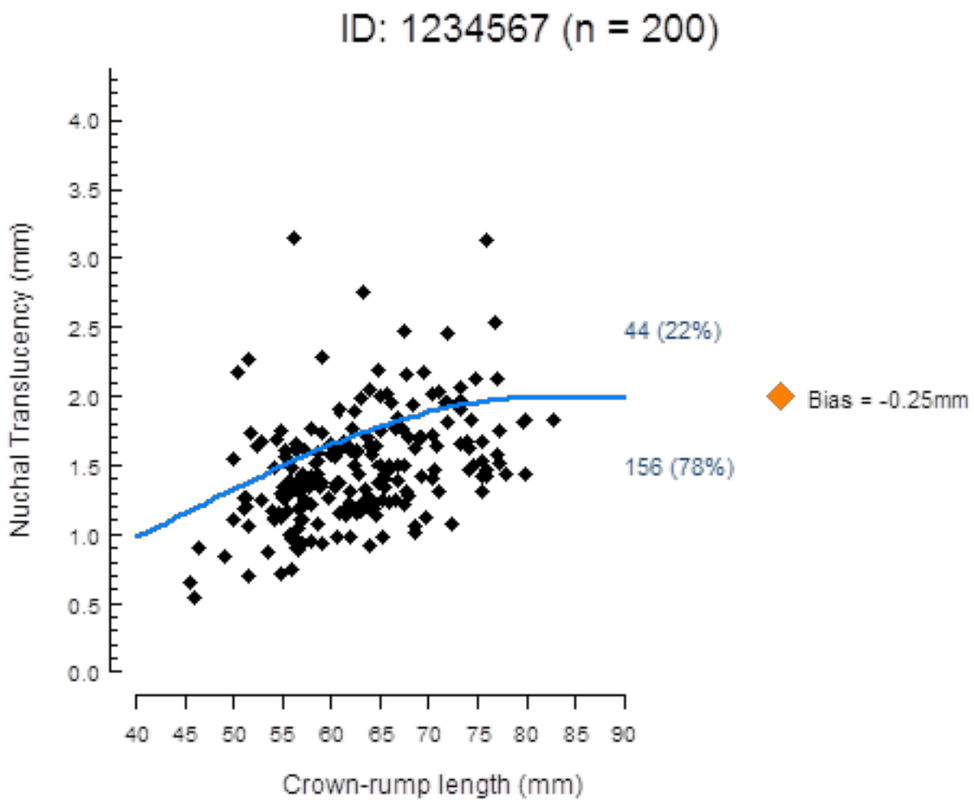


This report indicates a bias of 0.01mm relative to the FMF reference curve and satisfies the criteria for a green flag.

This means there are an almost equal number of measurements above the curve (102 - 51%) as below (98 – 49%).

An example of ‘amber flag’ distribution plot (continue screening)

Diagram 6 Amber bias

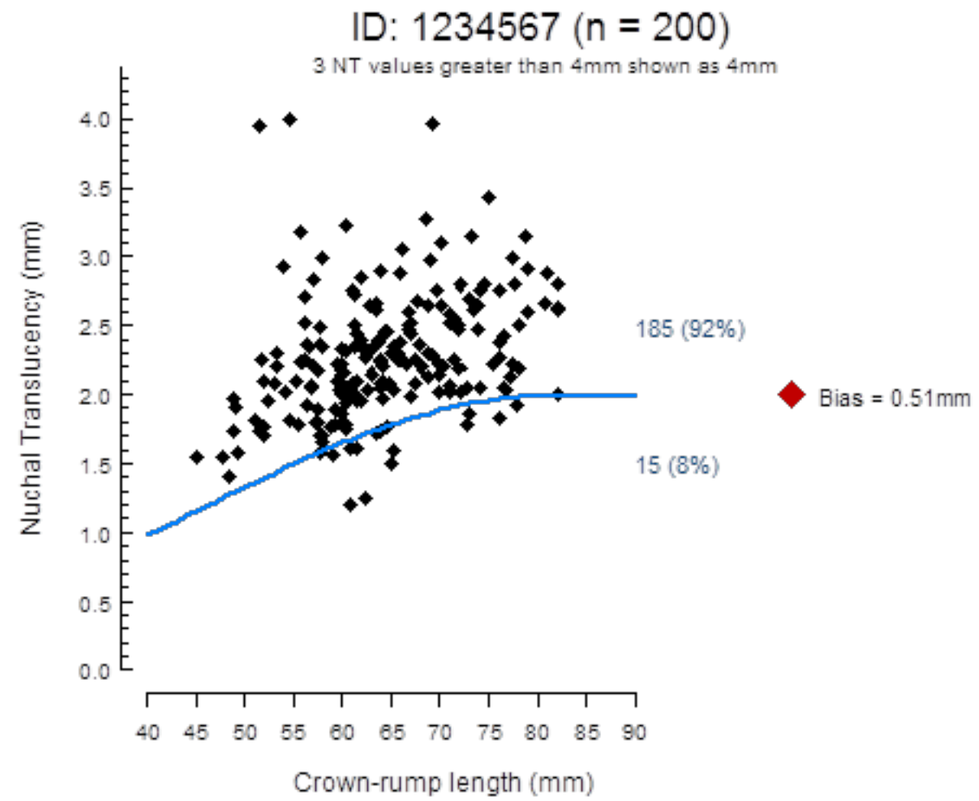


This report indicates a negative bias of 0.25mm relative to the FMF reference curve and satisfies the criteria for an amber flag.

This means there are more measurements below the curve (156 – 78%) than there are above (44 – 22%).

Example of ‘red flag’ distribution plot (assess the need for supervised practice)

Diagram 7 Red Flag



This report indicates a positive bias of 0.5mm relative to the FMF reference curve; therefore the data set is assigned a red flag.

This means 92% (185) measurements plotted above the curve, with only 8% (15) plotted below.

Bias can directly impact on the risk calculation women receive.

This dataset indicates that there will be an increase in detection rate (91%), however, the standardised SPR is unacceptable and potentially could lead to approximately a 5% increase in invasive procedures performed on unaffected pregnancies.

9.7 Managing red flags

A red flag is issued in two cases

1. bias – if individual bias is greater than 0.40mm
2. throughput – if fewer than 25 paired NT/CRL measurements are submitted over four cycles

Both will potentially impact on detection and screen positive rates, therefore the SSS must inform the practitioner promptly and devise an urgent supportive action plan.

The national quality assurance team maintains a national database of all DQASS identity codes assigned a red flag including training and intervention outcomes.

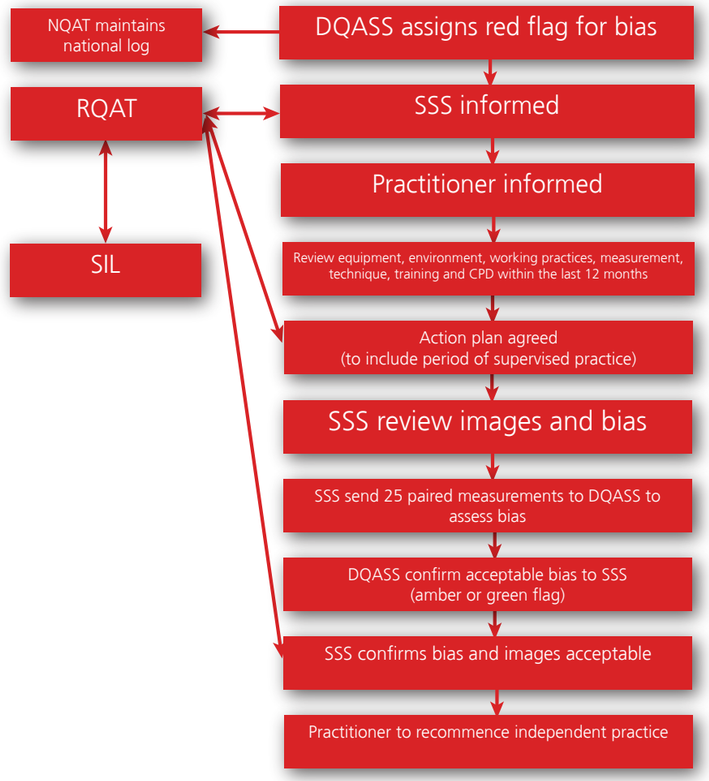
The local organisation is responsible for ensuring the competency of their employees and should review the individual circumstances and training requirements.

Guidance for managing a red flag for bias

- SSS to inform the ultrasound practitioner and manager
- review equipment, environment, working practices, measurement technique, training and CPD within the last 12 months
- FASP recommends that any practitioner with a dataset assigned a red flag where it is established that additional practice support is required should not screen unsupervised until bias distributions are within the acceptable range following reassessment by DQASS and SSS
- SSS to devise a supportive action plan using the documentation provided in Appendix 2. The training plan should be completed within 12 weeks from commencement and it is recommended that this should include a period of supervised practice
- SSS to send a copy of the training plan to the RQAT, who in turn forward to SIL
- local review of images for new paired measurements against the FASP criteria
- SSS to review new bias distribution and if within acceptable range send to DQASS for analysis
- documentation of support, actions and progress to be maintained
- SSS to keep the RQAT and SIL informed of actions, progress and resolution. This may be done through the quarterly programme board

Diagram 8 Flowchart for management of a red flag for bias

Glossary	
SSS	Screening support sonographer
DQASS	Down's Syndrome Screening Quality Assurance Support Service
FASP	Fetal anomaly screening programme
NQAT	National quality assurance team
RQAT	Regional quality assurance team
SIL	Screening and immunisation lead



The SSS can consider including a range of educational and operational interventions when devising a supportive action plan. Some examples include:

- complete the online resources
- practical sessions with the SSS
- reminder of how the bias can impact on the risk calculation
- a session reviewing previous and current images using the image guidance tool
- 'buddying' alongside a colleague to gain confidence
- a review of the working environment, process and equipment

9.8 Throughput (number of scans undertaken per cycle)

- practitioners must make an individual effort to ensure they meet the NHS minimum requirement of 25 paired NT and CRL measurements within each cycle. This is to ensure individuals remain competent and achieve NT measurement distributions within the acceptable range
- if an ultrasound practitioner does not meet the minimum number of measurements in a cycle, then the number of scans required from up to three previous cycles will be amalgamated with the current cycle to reach the minimum 25 required
- a departmental log of reasons why the cycles were combined should be maintained by SSS
- the bias will be calculated and any appropriate action plans should be applied
- if the amalgamated throughput is still less than 25 after combining four cycles then a red flag with a 4 will be issued

- the Trust should consider whether a practitioner with a red flag for throughput should continue participation in the NHS screening programme

9.9 Guidance for managing red flag for throughput

- SSS to inform the ultrasound practitioner and manager/clinical director
- discussion as to whether it needs to be put on the Trust's risk register must take place
- if necessary the SSS may escalate to the superintendent sonographer or head of midwifery
- SSS to devise a supportive action plan using the documentation provided in Appendix 3
- SSS to liaise with the RQAT and SIL for advice and support
- SSS to send action plan to the RQAT who in turn will send it to the SIL
- SSS to keep the RQAT and SIL informed of actions, progress and resolution
- documentation of support, actions and progress to be maintained
- discuss at both the local screening board and the quarterly programme board

9.10 Scenarios

DQASS report received.

Table 10

DQASS identity code	Number of paired measurements	Bias	Flag
9898989	25	0.08	Green
7676767	25	-0.46	Red
5454545	16	-	Red[4]

Practitioner 9898989 has been on long term sick and has only 8 paired NT/CRL measurements in current cycle.

- DQASS combines those with 17 measurements from previous cycle to get 25
- the bias is assessed and a green flag issued
- practitioner continues to practice as bias acceptable

Practitioner 7676767 has just returned from maternity leave and only has 4 paired NT/CRL measurements in current cycle.

- DQASS combines those from 2 previous cycles to get 25 measurements
- the bias is assessed and a red flag for bias is issued
- SSS to devise red flag action plan for bias

Practitioner 5454545 performs very low number of obstetric scans and only has 2 paired NT/CRL measurements in current cycle.

- DQASS combines all measurements with the 3 previous cycles but the practitioner still has fewer than 25 measurements
- bias cannot be assessed and a red flag with a 4 is issued for throughput
- SSS to devise red flag action plan for throughput

10 Education and Training

The role of the screening support sonographer (SSS) is to:

- inform DQASS of a new practitioner's details to obtain DQASS identity training code matched to an ultrasound department
- ensure online training is completed and record dates
- review images before sending paired measurements to DQASS
- send 25 paired measurements to DQASS
- ensure ongoing review by all practitioners of online theory training resources and record dates

FASP recommends that any practitioner 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) or equivalent. 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 or the Advanced Training Skills Module (ATSM)

10.1 NHS model of training in NT and CRL measurements

There are two components:

1. theory component
2. practical component

10.2 Theory component

- there are two online resources that contain current recommendations and guidance on screening
- both resources must be undertaken prior to starting practical training
- registration is required to access these modules and a certificate of completion is provided
- the SSS has access to audit staff completion of the resources. The certificate of completion does not indicate competency to perform the required measurements but indicates appropriate theory training is complete

The theoretical modules include:

- Condensed Education Modules for Trisomy 21 (CEMT21). An education module which aims to support health professionals who care for women and their families along the screening pathway. (60–90 minutes). To be completed every 24 months
- NT training resource. This resource supports practitioners undertaking the ultrasound component of the combined screening test (60–90 minutes). To be completed every 12 months

It is recommended that these resources are reviewed as part of continuous professional development to ensure all ultrasound practitioners remain informed of any guidance changes. A reminder will be sent one month in advance to each registered practitioner when it is time to review the modules.

10.3 Practical component

This training is overseen by the SSS and it is important that some of the practical training sessions are with the SSS. The minimum practical training requirements are set out in Table 11.

Table 11 - Practical training requirement

Number of scans/images/measurements	Action
1-5 scans	Observation
10-20 scans	Supervised by the SSS
3-5 images	Independently performed and reviewed with SSS as acceptable or good
25 paired measurements	SSS to send diagnostic plot to DQASS *

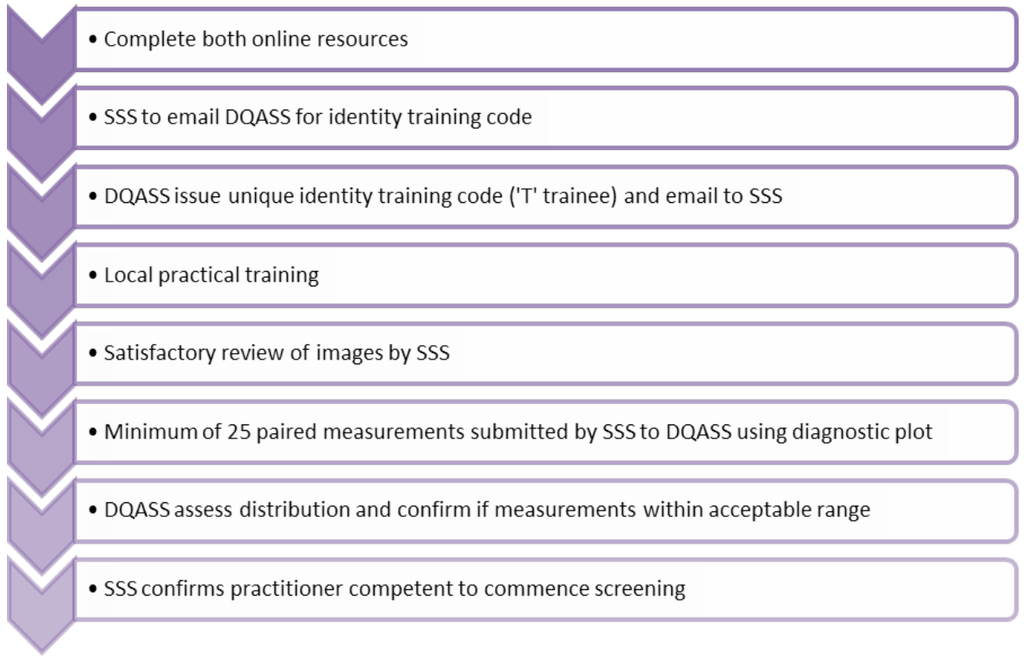
* A diagnostic plot self-assessment tool is provided for practitioners to enter their 25 paired measurements. This must be used when the SSS sends the data to DQASS and can be found at **fetalanomaly.screening.nhs.uk/SSSresources**

- to commence practical training a unique identity code from DQASS is required
- ultrasound practitioners in some departments require a Fetal Medicine Foundation (FMF) code to access risk assessment software locally. Where this is the case, DQASS will use the FMF identity code for the practitioner but it is important to note that this only applies to FMF codes issued in England. Ultrasound practitioners with a FMF identity code from outside England will require a DQASS training code. The SSS's plays a pivotal role in communicating with DQASS in these circumstances
- DQASS issues the unique DQASS identity code matched to an ultrasound department to the SSS with the suffix "T" to indicate a practitioner in training
- it is recommended that the training process should take no longer than six months and the training code "T" will remain valid for those six months. If training is not completed within six months then the reasons should be documented by the SSS and DQASS contacted to advise if an extension is required
- trainees should use their own DQASS identity code on the biochemistry form if their measurements are used
- it is not necessary for the supervising practitioner to use their DQASS identity code, unless they have re-measured the NT and/or CRL
- it is recommended that the qualified practitioner supervising the scan should also document their name on the ultrasound report along with the trainee
- ultrasound students who achieve a satisfactory bias must continue to use the training code "T" and have supervised practice until they have gained their obstetric ultrasound qualification
- a good practice point is for the trainee to visit their screening laboratory during their training period
- a sample training logbook is available in Appendix 4

Assessment of competence to commence independent scanning lies with the organisation in which the ultrasound practitioner is working.

Competency to undertake NT scans cannot and should not be assessed by review of the DQASS distribution plots alone.

Diagram 9 Progression of training for practitioners new to NT measurement



Guidance for experienced practitioners from overseas

All practitioners from overseas will require a unique DQASS identity code linked to an ultrasound department. They should then follow the guidance for new staff.

Guidance for new staff and experienced practitioners with a break in clinical practice

Practitioners will vary in experience, academic knowledge and previous level of training; it is therefore acknowledged that the level of support required may also vary.

Recommendations

- if new staff member, SSS to email DQASS and screening laboratory with details
- practical support should be decided on an individual basis with the SSS
- SSS to document any decisions on training and support that may be required
- both online theoretical resources are reviewed
- SSS review images as satisfactory
- 25 paired measurements sent to DQASS for assessment
- SSS confirm practitioner is approved to continue screening

- a sample return to practice logbook is available in Appendix 4

Table 12 - Summary of training requirements

Staff member	Training Requirement
Experienced practitioner returning to practice or new staff member	• Online NHS NT resource • Online CEM T21 course • Period of supported practice is required • Images reviewed with SSS • SSS to send 25 paired measurements to DQASS • SSS confirm may continue screening
Trainee	• DQASS provide identity training code linked to a department • Online NHS NT resource • Online CEM T21 course • Visit screening laboratory • Supported practical training • Images reviewed with SSS • SSS to send 25 paired measurements to DQASS • SSS confirm may continue screening • If student – continued supervised practice until qualified

Screening Matters

Screening Matters is the newsletter of the UK NSC. It is aimed at everyone involved in screening - policy makers, commissioners, providers and wider public health professionals. It covers evidence and policy development, training and education, quality assurance and IT and information, as well as providing updates on all the antenatal, newborn and young persons and adult screening programmes in England. It is published three times a year - in February, June and October.

You can register to receive screening matters at **www.screening.nhs.uk/screeningmatters**

11 Quality Improvement and Assurance

The role of the screening support sonographer (SSS) is to:

- liaise with local antenatal and newborn screening board and attend meetings
- provide evidence of departmental review of images audits
- provide other evidence requested by the QA team
- work closely with screening laboratory

11.1 Quality Improvement

Each local programme must have clear arrangements for managing quality and have a systematic approach to quality improvement.

Participation in regional quality assurance activity is in addition to routine departmental quality improvement (such as failsafe checks, departmental audit, learning and development) and regular, informal contact with QA teams. It is not intended to preclude local initiatives or more detailed internal scrutiny of professional performance.

A local programme, which has effective departmental QA processes in operation, will be well placed to respond with minimum effort to scheduled QA assessments.

11.2 Quality Assurance (QA)

Each NHS screening programme has a defined set of standards that providers have to meet to ensure that local programmes are safe and effective. Quality assurance (QA) is the process of checking that these standards are met and encouraging continuous improvement and includes:

- advice on the development of national quality standards
- monitoring of how services meet (or fail to meet) standards
- providing expert screening advice for incident management
- facilitating quality review of services, including peer advice
- support on a day-to-day basis, those involved in commissioning or providing screening services.

QA covers the entire screening pathway; from identifying who is eligible to be invited to screening, through to referral and treatment where required/appropriate.

The aim of QA in NHS antenatal and newborn screening programmes is the maintenance of minimum standards and the continuous improvement in the performance of all aspects of screening to ensure that all women and their babies have access to high quality screening wherever they live. QA is essential in order to minimise harm and maximise benefits of screening.

Formal QA visits to a local screening programme provide the forum for a peer review of the whole multidisciplinary screening pathway, and an assessment of the effectiveness of team working within the local screening programme and associated referral sites.

- regional teams advise providers and commissioners about reducing risks in local screening programmes
- they assess the robustness of local arrangements through audit, as part of peer review and in the investigation of any incidents as they occur
- they act as a conduit for information and dialogue at national, regional and local levels, additionally sharing good practice
- participation in a formal process of QA is the responsibility of each local screening programme
- the performance of the local programmes is monitored in a variety of ways such as review of statistics, regional meetings or informal

visits to local programmes, all of which offer a valuable insight into the activity of a local programme

11.3 Key performance indicators (KPIs)

Key performance indicators (KPIs) for the NHS screening programmes were introduced to provide a way of measuring how well the screening programmes are doing in important areas. They contribute to the quality assurances of screening programmes but are not, in themselves, sufficient to quality assure or performance manage screening services. They help local screening services to identify potential problems so they can be put right and have led to changes in practice and implementation of measures to prevent errors occurring in the screening pathway.

More information on KPIs can be found at **www.screening.nhs.uk/kpi**

11.4 Screening safety incidents

A screening safety incident is any unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening; or to staff working in the screening programme.

A screening safety incident can affect populations as well as individuals. It is an actual or possible failure in the screening pathway and at the interface between screening and the next stage of care. Although the level of risk to an individual in an incident may be low, because of the large numbers of people offered screening, this may equate to a high corporate risk. It is important to ensure that there is a proportionate response based on an accurate investigation and assessment of the risk of harm. Due to the public interest in screening, the likelihood of adverse media coverage with resulting public concern is high even if no harm occurs.

More information about managing screening safety incidents is available at:

www.screening.nhs.uk/incidents

cpd.screening.nhs.uk/incident-resource

Lessons to be learnt from screening incidents can be found at:

www.screening.nhs.uk/si-learning

12 Information for the public

Screening Tests for You and Your Baby (STFYAYB) is the recommended information booklet covering both antenatal and newborn screening. Each screening programme is described in a standard format. This makes it easier for the public to compare the various tests and, crucially, to understand that some decisions are more complex than others.

A copy of STFYAYB can be accessed at **www.screening.nhs.uk/annbpublications**

Acknowledgments

The Fetal Anomaly Screening Programme expresses thanks to members of the Laboratory & Ultrasound Group who contributed to the production of this handbook.

Glossary

Amniocentesis

An invasive procedure undertaken from about 15 completed weeks (15^{+0}) onwards to obtain a sample of amniotic fluid (liquor) surrounding the fetus. Using an aseptic technique whilst under continuous ultrasound guidance, a sterile needle is passed through the mother's abdomen, uterus and amniotic sac. A sample of amniotic fluid is aspirated with a syringe and sent for analysis to test for a range of chromosomal and inherited disorders. Out of 100 women who have this test from 15 weeks it is likely that one will miscarry as a direct consequence of the procedure.

Amniotic fluid

Also known as 'liquor', this is the fluid surrounding the fetus during pregnancy. It contains substances and cells from the fetus, which can be removed by amniocentesis and examined.

Anomaly

An aberration or change often used related to a gene or physical structure that may or may not result in a disease or condition.

Biochemical markers

Analytes (commonly referred to as markers) measured by the laboratory that are used to calculate the likelihood of a pregnancy being affected by a condition or syndrome.

Chorionic Villus Sampling (CVS)

An abdominal or cervical procedure performed under continuous ultrasound guidance after 10 completed weeks in pregnancy to obtain a sample of placental tissue for chromosomal or genetic analysis. The range of chromosomal and genetic conditions that can be detected is similar to those for amniocentesis. For every 100 women who have this test one will miscarry.

Combined test

Between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy, a combination of the nuchal scan measurement and a blood sample from the mother which measures the concentration of pregnancy associated plasma protein-A (PAPP-A), and free beta human chorionic gonadotrophin (Free beta hCG). Together with the mother's age and the gestation of the pregnancy, these are used to estimate the chances that the fetus is affected with Down's syndrome.

Crown rump length (CRL)

Ultrasound measurement between the top of the head (crown) to the bottom of the buttocks (rump)

Detection rate

The proportion of affected individuals with a positive screening result.

Diagnostic test

Refers to the process involved in obtaining a definite diagnosis. For example the diagnostic test on an amniocentesis sample (invasive procedure) is the full karyotype or QF-PCR.

Down's Syndrome (trisomy 21)

A disorder caused by the presence of an extra copy (three instead of two) of chromosome 21. It affects all population groups and is distinguished by a number of features occurring together including low muscle tone, a face that appears flatter with eyes slanting upward, small ears and an unusually wide neck and a deep crease across the palm of the hand. Some may have heart problems or visual problems or may develop Alzheimer's disease. Although people with Down's syndrome have learning difficulties, these vary in severity.

Edwards' Syndrome (trisomy 18)

A syndrome caused by the presence of an extra copy (three instead of two) of chromosome 18. The combination of features present in babies affected with trisomy 18 can lead to many different problems including growth deficiency, feeding and breathing difficulties, developmental delays, learning difficulties, undescended testes in males, kidney malformations, heart defects. They may also have malformations in the bones. Survival of infants with trisomy 18 depends on how severely they are affected. Most do not survive the first year of life.

Fetal anomaly

Structural abnormalities with how the fetus has developed.

Fetal anomaly ultrasound scan

A screening test offered to pregnant women to monitor the growth and development of the fetus before birth by producing a real-time visual image. Scans before 16 weeks are useful for dating and assessing the viability of the pregnancy (and are able to detect some major malformations). Detailed scanning at 18 weeks, 0 days to 20 weeks, 6 days should show up most malformations as well as some minor ones.

Gestational age

The duration of an ongoing or completed pregnancy, measured from the first day of the last menstrual period (usually about two weeks longer than that measured from conception). Gestational age is usually measured in weeks and days.

Invasive diagnostic procedure

A method used to obtain a sample used to aid diagnosis , for example, amniocentesis or chorionic villus sampling.

Marker

An identifiable physical location on a chromosome whose inheritance can be monitored. Markers can be expressed regions of DNA (genes) or some segment of DNA with no known coding function but whose pattern of inheritance can be determined.

Nuchal scan (Nuchal transluscency scan NT)

Between 11 weeks and 2 days and 14 weeks and 1 day of pregnancy the thickness of fluid in the tissue space within the nape of the fetal neck, the nuchal translucency can be measured. An increased amount of fluid may indicate that the fetus has Down's syndrome, structural or genetic anomaly. By combining the mother's age and the gestation of the pregnancy with information from the scan an individual statistical chance of an anomaly can be given for that particular pregnancy. If the chance is one in 150 or higher a diagnostic test, such as CVS, will be offered.

Patau's Syndrome (trisomy 13)

A disorder caused by the presence of an extra copy (three instead of two) of chromosome 13. The disorder is characterised by low birth weight, cleft lip or palate, defects of the heart, eye structure, spine, scalp and abdomen, abnormal genitalia, low set ears, abnormal palm pattern, extra digits and overlapping of fingers over thumb. Between 80 per cent and 90 per cent of babies do not survive infancy and those that do survive have learning disabilities.

Prenatal

Relating to the period before birth

Quadruple test

Second trimester test to calculate the risk of Down's syndrome, usually based on the measurement of AFP, uE3, free b-hCG (or total hCG), and inhibin-A together with the woman's age.

Quality assurance (QA)

A system for monitoring and maintaining high standards in every aspect of a screening programme.

Risk

Risk is usually taken to mean the chance of an event happening. It can be be expressed in a number of ways, see diagrams in the UK NSC Resource Cards for Midwives Nos 3 and 5.

Risk cut-off

Determines those women who are in the 'higher risk' group and considered 'screen positive'.

Screen positive rate (SPR)

The number of women who receive a higher risk result.

Screening

Testing people who do not have or have not recognised the signs or symptoms of the condition being tested for, either with the aim of reducing risk of an adverse outcome, or with the aim of giving information about risk.

Screening pathway

The whole system of activities needed to deliver high quality screening. It ranges from identifying and informing those to be offered screening through to the treatment and follow up of those found to have abnormality, and support for those who develop disease despite screening

Screening programme

The whole system of activities needed to deliver high quality screening. It ranges from identifying and informing those to be offered screening through to the treatment and follow up of those found to have abnormality, and support for those who develop disease despite screening

Screening safety incident

An unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening; or to staff working in the screening programme.

Screening test

A test or inquiry used on people who do not have or have not recognised the signs or symptoms of the condition being tested for. It divides people into low and higher risk groups.

Syndrome

Combination of symptoms and signs grouped together to form a disorder.

Throughput

Number of samples undertaken per cycle

Trisomy

Three copies of a particular chromosome rather than the usual pair.

Ultrasound scan

A ultrasound scan is a safe and painless test that uses sound waves to make images. It is like radar.

Tables, Diagrams and Images

Table 1	National standards for screening tests	Page 9
Table 2	Maternal age and chance/probability of having a pregnancy affected by Down's syndrome	Page 10
Table 3	Recommended criteria for measurement of NT for the purposes of combined screening	Page 14
Table 4	Recommended criteria for measurement of CRL for purposes of pregnancy dating and combined screening	Page 15
Table 5	Scoring images for departmental review of images	Page 17
Table 6	Image guidance tool for NT	Page 18
Table 7	Image guidance tool for the CRL	Page 22
Table 8	DQASS reports	Page 29
Table 9	Flag category and bias	Page 30
Table 10	Scenarios	Page 36
Table 11	Practical training requirement	Page 38
Table 12	Summary of training requirements	Page 40

Diagram 1	Images to show absence and presence of frontal process of maxilla	Page 18
Diagram 2	Where to place callipers for the NT measurement	Page 19
Diagram 3	Examples of scoring NT images	Page 19
Diagram 4	Examples of scoring CRL images	Page 23
Diagram 5	Example of 'green flag' distribution plot	Page 31
Diagram 6	Example of 'amber flag' distribution plot	Page 32
Diagram 7	Example of 'red flag' distribution plot	Page 33
Diagram 8	Flowchart for management of a red flag for bias	Page 35
Diagram 9	Progression of training for practitioners new to NT measurement	Page 39

Image 1	Images to show absence and presence of frontal process of maxilla – Good	Page 19
Image 2	Images to show absence and presence of frontal process of maxilla – Acceptable	Page 20
Image 3	Images to show absence and presence of frontal process of maxilla – Poor	Page 21
Image 4	Examples of scoring CRL images – Good	Page 23
Image 5	Examples of scoring CRL images – Acceptable	Page 24
Image 6	Examples of scoring CRL images – Poor	Page 25

References

- Smith-Bindman R,Hosmer W, Feldstein VA, Deeks JJ, Goldberg JD. Second-trimester ultrasound to detect fetuses with Down syndrome: a meta-analysis. JAMA 2001; 285:1044-55.
- Chudleigh T, Loughna P and Evans T (2011) A practical solution to combining dating and screening for Down's syndrome Ultrasound 2011; 19: 154–157
- Loughna P, Chitty L, Evans T, Chudleigh T (2009) Fetal size and dating: charts recommended for clinical obstetric practice, Ultrasound 17: 161-167
- (Kagan et al (2009) Effect of deviation of nuchal translucency measurements on the performance of screening for Trisomy 21 Ultrasound in Obstetrics & gynaecology 33:657-664

Abbreviations

AFP	Alpha fetoprotein
BPD	Biparietal Diameter
CEMT21	Condensed Education Modules for Trisomy 21
CPD	Continuous professional development
CRL	Crown Rump Length
DQASS	Down's syndrome screening Quality Assurance Support Service
DR	Detection rate
FASP	Fetal Anomaly Screening Programme
FMF	Fetal Medicine Foundation
FPR	False Positive Rate
HC	Head Circumference
hCG	Human chorionic gonadotrophin
KPI	Key Performance Indicator
MoM	Median multiple of the median
NT	Nuchal Translucency measurement
OFD	Occipital-frontal diameter
PAPP-A	Pregnancy associated plasma protein – A
PHE	Public Health England
QA	Quality Assurance
RQAT	Regional Quality Assurance Team
SIL	Screening and Immunisation Lead
SIT	Screening and Immunisation Team
SPR	Screen Positive Rate
SSS	Screening Support Sonographer
STFYAYB	Screening Tests for You and Your Baby
T	Trisomy
uE3	Unconjugated oestriol
UK NSC	United Kingdom National Screening Committee

Appendices

Appendix 1 Score sheets for NT and CRL

Appendix 2 Red Flag Action Plan for Bias

Appendix 3 Red Flag Action Plan for Throughput

Appendix 4 Documentation of evidence: Training logbook for New Practitioners

Appendix 5 Documentation of evidence: Return to practice logbook

Appendix 1. Score sheets

NT score sheet

NT score sheet for Image Review																			
Date of review																			
Assessor																			
Patient ID																			
Horizontal mid sagittal section	1																		
Head in line with body, visible skin line	2																		
Echogenic tip of the nose	3																		
Rectangular shape of the palate	4																		
Translucent diencephalon	5																		
Frontal process of maxilla not visible	6																		
Pocket of fluid under chin visible	7																		
Palate angle 30 - 60°	8																		
Nasal tip level or above chest wall	9																		
Fills over 60% of the screen	10																		
Callipers on upper and lower skin line	11																		
Measure widest part of NT	12																		
Outcome																			
Comments																			
Sonographer ID																			

CRL score sheet

CRL score sheet for Image Review																		
Sonographer ID																		
	Date of review																	
	Assessor																	
	Patient ID																	
	Mid sagittal section, head in line with body	1																
	Echogenic tip of the nose	2																
	Rectangular shape of the palate	3																
	Translucent diencephalon	4																
	CRL axis between 0° and 30° to horizontal	5																
	Clearly defined crown and rump	6																
	Pocket of fluid under chin visible	7																
	Palate angle 30 - 60°	8																
	Nasal tip level or above abdominal wall	9																
	Fills over 60% of the screen	10																
	Callipers on outer borders of crown and rump	11																
	Longest measurement of fetus	12																
	Outcome																	
	Comments																	

Appendix 2. Red flag action plan (bias)

Suggested action plan for practitioners assigned a red flag for bias

Practitioner DQASS identity code	
Audit cycle number	
Name of SSS	
Name of local organisation/NHS trust	
Date	

FASP recommends that an individual training plan be negotiated between SSS and practitioner

Action	Date Completed	Comments
Practitioner informed by SSS		
Supervised screening commenced		
Manager and local screening board informed		
Review equipment, environment, working practices, technique and training needs		
SSS to review previous paired images with practitioner		
SSS to liaise with Regional QA team		
Confirm action plan in place with Regional QA team within 2 weeks of DQASS report being received. (Regional QA team to inform SIL team).		
Review online training resources		
Supervised training sessions with SSS		
SSS to review new images to confirm acceptable		
SSS to send 25 paired measurements to DQASS		
DQASS confirm new measurements within acceptable range		
SSS confirms practitioner may resume independent practice		
Review of outcome within 12 weeks and update sent by SSS to regional QA team		

Appendix 3. Red flag action plan (throughput)

Suggested action plan for practitioners assigned a red flag for throughput.

Practitioner ID number	
Audit cycle number	
Name of SSS	
Name of local organisation/NHS trust	
Date	

FASP recommends that an individual training plan be negotiated between SSS and practitioner.

Action	Date Completed	Comments
Practitioner informed by SSS		
Unsupervised screening ceases		
Manager and local ANNBSP board informed		
Review working practices		
SSS to liaise with Regional QA team		
Confirm action plan in place with Regional QA team within 2 weeks of DQASS report being received. (Regional QA team to inform SIL team)		
DQASS reassess bias and throughput as acceptable		
SSS confirms practitioner may resume independent practice		
Review of outcome within 12 weeks and update sent by SSS to regional QA		

Appendix 4. Training logbook for new practitioners

Name of ultrasound practitioner	
DQASS identity code	
Name of SSS	
Name of organisation/NHS trust	

ITEM	Date completed	Comments
Condensed education module for T21 (CEMT21) **Essential**		
NT training resource **Essential**		
Training number requested from DQASS		
Log-book of supervised scans completed		
Log book of 25 independent scans completed		
Images reviewed and scored as good or acceptable with SSS		
25 paired measurements submitted to DQASS		
SSS confirms competent to scan independently		

Signed declaration

The above named ultrasound practitioner has successfully completed all the training requirements and is therefore competent to undertake the ultrasound aspect of the NHS T21 combined screening programme.

Signature of SSS .....

Date. .....

Appendix 5. Return to practice logbook

DQASS identity code	
Name of SSS	
Name of organisation/NHS trust	

ITEM	Date completed	Comments
Condensed education module for T21 (CEMT21) **Essential**		
NT training resource **Essential**		
Supported practice if required		
Satisfactory image review with SSS completed		
25 paired measurements submitted to DQASS		
SSS confirms may continue screening		

NHS Screening Programmes
Floor 2, Zone B
Skipton House
80 London Road
London SE1 6LH

Tel: 020 368 20890
Email: PHE.screeninghelpdesk@nhs.net
Web: fetalanomaly.screening.nhs.uk
Twitter: @PHE_Screening

Informing your midwife

□ First trimester bloods

Unfortunately we were not able to take blood from you today to complete the first trimester screening test. Please arrange to see your midwife **as soon as possible** so she can take blood and we will complete the test.

□ Second trimester bloods

Unfortunately we were not able to perform the screening test to calculate the chance of your baby having Down's syndrome today because:

□ *Your pregnancy is further on than we thought.*

□ *We have not been able to measure the neck region (nuchal translucency) of your baby.*

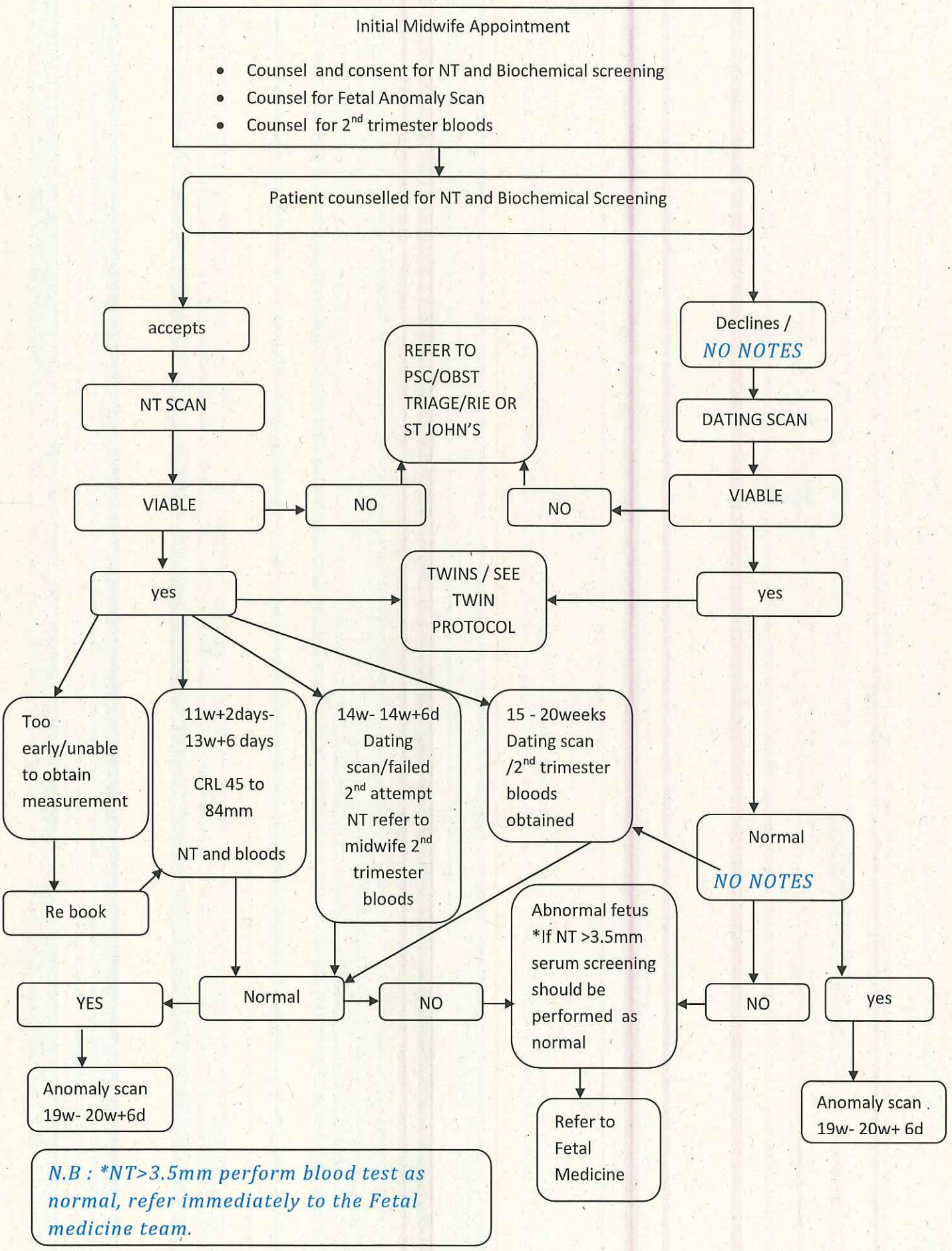
□ *There is no evidence of your consent to perform the test on TRAK or in your maternity notes (or you did not bring your notes with you)*

However you are still able to find out the chance of your baby having Down's syndrome by seeing your midwife for a blood test between 14 weeks 2 days and 20 weeks.
Please contact your midwife promptly to arrange an appointment for this screening test.

Thank you!

GYNAE AND OBSTETRIC ULTRASOUND PROTOCOLS

Combined Ultrasound & Biochemical Screening Pathway



First trimester screening

Singleton & Twin

Second Trimester - Downs only

HC: 101mm-172mm 14 weeks 2 day – 20 weeks 0 days.

- Form. Single pregnancy: white form with blue writing. Twin pregnancy: white form with pink writing.
- Twin pregnancy/one demise. Use white form with **blue** writing in the comments section: twin pregnancy with one demise - for non viable twin put: Fetal pole seen – CRL = or no fetal pole seen at booking

Second Trimester

CRL >84mm and HC<101mm

Ask patient to contact her midwife at the appropriate time

First Trimester

CRL: 45mm-84mm 11 weeks 2 days – 14 weeks 1 day.

If Twin pregnancy circle section on green form with type of chorionicity

Second trimester bloods

14 weeks 2 day – 20 weeks 0 days

Twin issues

One on-going fetus (CRL: 45mm – 84mm) and one second sac seen at booking +/- yolk sac but no fetal pole (regardless if a second fetal pole seen on earlier scans)

Mark on green form twin pregnancy with one demise – no fetal pole seen at booking

One on-going fetus (CRL: 45mm-84mm) and one demise (any CRL)

Mark on green form twin pregnancy with one demise – fetal pole seen at booking

NT and first trimester bloods

11 weeks 2 days – 14 weeks 1 day

Multiple pregnancy >twins

NT or bloods not required. If NT looks thickened measure and refer to Fetal Medicine Team

First Trimester Ultrasound Protocol

First trimester examinations are routinely performed between 11+2 -14+1 wks gestation

Preparation

- Full Bladder

Areas to be examined

- Uterus
- Ovaries (when possible)
- Adnexa
- Gestation sac/s
- Fetus/s
    - Heart pulsation
    - Structure, dependant upon gestation: Limbs, abdominal wall, cranium, stomach, bladder, heart
    - Measurements – see below
- Chorionicity in cases of multiple pregnancy

Measurements (see appendix 1)

- CRL: 6 – 14+1 weeks
- HC: 14+1 – 25 weeks
- NT : CRL of 45 – 84mm

Report to include:

- Single or multiple pregnancy
- Confirmation of heart pulsation
- Measurements
- Estimated gestation
- Nuchal translucency
- Any fetal abnormality noted (dependent on gestation)
- Chorionicity in cases of multiple pregnancy
- Uterine/ovarian/adnexal abnormality

Repeat US needs to be organised if satisfactory dating or NT measurement cannot be achieved at the first visit. This should be within the recognised time frame for NT measurement.

Images for documentation

- All measurements
- Any abnormality
- Twin pregnancy – presence/absence of lambda sign

NOTES

1. DATE DISCREPANCY – patients found to be less than 11+2 weeks, arrange US at appropriate gestation.
2. CORPUS LUTEAL CYSTS 5 cms or less in diameter are considered normal. Report if >5 cms and suggest rechecking at 19-22 week US.
3. ASYMPTOMATIC HAEMATOMA do not require reporting or ultrasound follow up

Appendix 1

Measurement techniques:

CRL

From 'Charts recommended for clinical obstetric practice', February 2007, produced by the British Medical Ultrasound Society

- Perform TA or TV if necessary
- Obtain midline sagittal section of the whole embryo or fetus, ideally horizontally orientated on the screen
- Measure maximum extended/unflexed length in which the end points of the crown and rump are clearly defined.
- Take the best of 3 measurements as the CRL

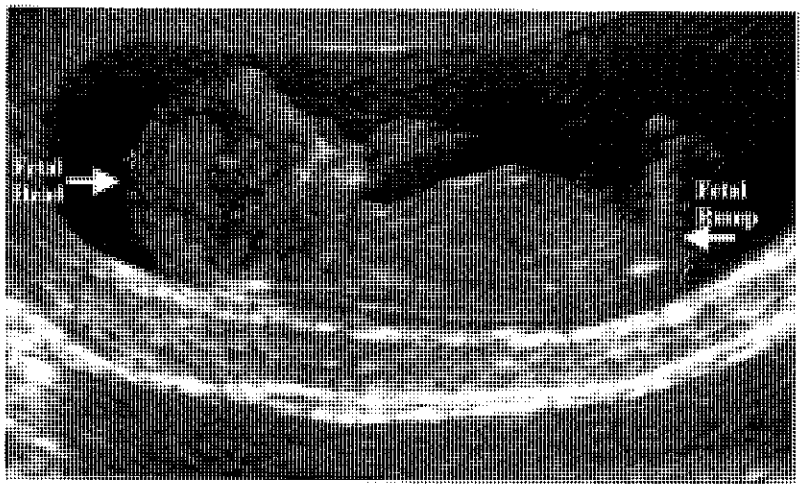


Figure 1b:Measurement of CRL at 13 weeks

HC

From 'Charts recommended for clinical obstetric practice', February 2007, produced by the British Medical Ultrasound Society

- Obtain a cross-sectional view of the fetal head at the level of the ventricles
- The following landmarks should be identified
    - Rugby football shape
    - Centrally positioned, continuous midline echo broken at one third its length by the cavum septum pellucidum
    - Anterior walls of the lateral ventricles centrally placed around the midline
    - The choroid plexus should be visible within the posterior horn of the ventricle in the distal hemisphere
- The measurement should be taken from an image with the midline echo lying as close as possible to the horizontal plane
- Providing a good image is obtained a single measurement is adequate

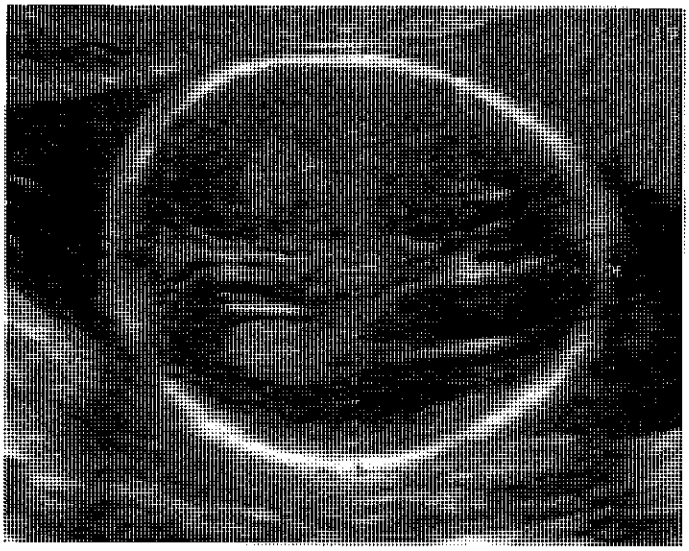
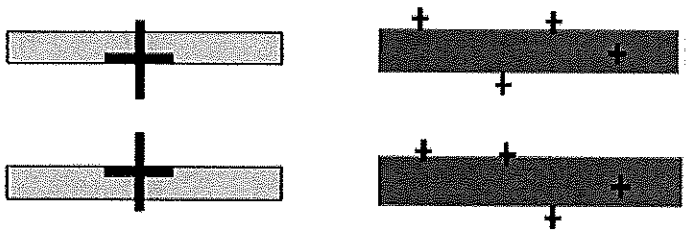


Figure 2. Estimation of fetal HC from measurements of OFD ('outer to outer') and BPD ('outer to outer'))

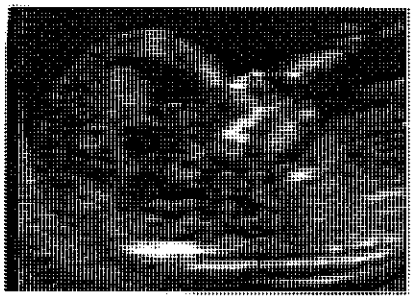
NT

From www.fetalmedicine.com/nuchal.htm

- The fetal CRL should be between 45-84mm
- A good sagittal section of the fetus must be obtained, with the fetus horizontal on the screen. The correct view is a clearly visualised profile.
- The fetus should be in a neutral position, with the head in line with the spine, not hyper-extended or flexed
- Ideally only the fetal head and upper thorax should be included. The magnification should be as large as possible and always such that a slight movement of the callipers produces only a 0.1mm change in the measurement
- The widest part of the NT should be measured.
- Measurements should be taken with the inner border of the horizontal line of the callipers placed on the line that defines the NT – the crossbar of the calliper should be such that it is hardly visible as it merges with the white line of the border, not in the nuchal fluid.



- When magnifying the image keep the gain down so that the edge of the line does not become 'fuzzy'.
- Take care to distinguish between fetal skin and amnion
- More than one measurement must be taken and the **maximum** one that meets all the above criteria should be recorded



Crown Rump Length (CRL) and Head Circumference (HC) dating tables.

- The Nuchal Translucency (NT) measurement should be made when the Crown Rump Length (CRL) is between 45mm and 84mm.
- Using the current BMUS 2009 dating formula, the gestational age range for NT measurement is from 11 weeks + 2 days to 14 weeks + 1 day.
- From 14 weeks + 2 days to 20 weeks + 0 days, the quadruple test should be offered.
- Where both dating and Down's syndrome screening are requested, and the CRL is between 45.0 and 84.0mm the pregnancy should be dated by CRL and combined screening performed.
- Where both dating and Down's syndrome screening are requested and the CRL is ≥ 84.1mm, the pregnancy should be dated by HC.
- If the HC is ≥101.0mm and the gestational age is ≥14 weeks + 2 days, date by HC. The CRL should be ignored as it is ›84.0mm. Quadruple screening should be offered.
- If the HC is ‹101 mm and the CRL is ›84mm, date by HC. If the gestational age as calculated from the HC is ≤ 14 weeks + 1 day, the woman should be informed that the NT risk cannot be calculated from a CRL ›84mm, even though the gestational age of her pregnancy as estimated by the HC, lies within the gestational age window for combined screening. Combined screening is not an option but quadruple screening can be offered from 14 weeks + 2 days gestation.

Crown Rump Length (CRL) dating table
GA (days) = 8.052√ (CRL X 1.037) + 23.73

CRL (mm)	GA (wks + days) 50th centile	5th centile	95th centile
43	11+0	10+3	11+5
44	11+1	10+3	11+6
45	11+2	10+4	11+6
46	11+2	10+5	12+0
47	11+3	10+5	12+1
48	11+4	10+6	12+1
49	11+4	10+6	12+2
50	11+5	11+0	12+2
51	11+5	11+1	12+3
52	11+6	11+1	12+4
53	11+6	11+2	12+4
54	12+0	11+2	12+5
55	12+1	11+3	12+5

56	12+1	11+3	12+6
57	12+2	11+4	12+6
58	12+2	11+4	13+0
59	12+3	11+5	13+0
60	12+3	11+6	13+1
61	12+4	11+6	13+1
62	12+4	12+0	13+2
63	12+5	12+0	13+3
64	12+5	12+1	13+3
65	12+6	12+1	13+4
66	12+6	12+2	13+4
67	13+0	12+2	13+5
68	13+0	12+3	13+5
69	13+1	12+3	13+6
70	13+1	12+4	13+6
71	13+2	12+4	14+0
72	13+2	12+5	14+0
73	13+3	12+5	14+0
74	13+3	12+6	14+1
75	13+4	12+6	14+1
76	13+4	13+0	14+2
77	13+5	13+0	14+2
78	13+5	13+0	14+3
79	13+6	13+1	14+3
80	13+6	13+1	14+4
81	14+0	13+1	14+4
82	14+0	13+2	14+5
83	14+0	13+3	14+5
84	14+1	13+4	14+6

Head Circumference (HC) dating table *

Log_e (GA weeks) = 0.010611 X HC – 0.000030321 X HC^2 + 0.43498 X 10^{-7} X HC^3 + 1.848

HC (mm)	Gestation (wks+days)
80	12+3
81	12+4
82	12+5
83	12+5
84	12+6
85	12+6
86	13+0
87	13+0
88	13+1
89	13+2
90	13+2
91	13+3
92	13+3
93	13+4

HC (mm)	Gestation (wks+days)
115	15+3
116	15+3
117	15+4
118	15+4
119	15+5
120	15+6
121	15+6
122	16+0
123	16+0
124	16+1
125	16+1
126	16+2
127	16+3
128	16+3

HC (mm)	Gestation (wks+days)
150	18+2
151	18+2
152	18+3
153	18+3
154	18+4
155	18+5
156	18+5
157	18+6
158	18+6
159	19+0
160	19+0
161	19+1
162	19+2
163	19+2

94	13+5
95	13+5
96	13+6
97	13+6
98	14+0
99	14+0
100	14+1
101	14+2
102	14+2
103	14+3
104	14+3
105	14+4
106	14+4
107	14+5
108	14+6
109	14+6
110	15+0
111	15+0
112	15+1
113	15+2
114	15+2

129	16+4
130	16+4
131	16+5
132	16+5
133	16+6
134	17+0
135	17+0
136	17+1
137	17+1
138	17+2
139	17+2
140	17+3
141	17+4
142	17+4
143	17+5
144	17+5
145	17+6
146	17+6
147	18+0
148	18+1
149	18+1

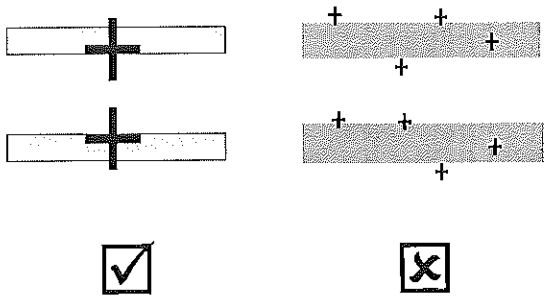
164	19+3
165	19+3
166	19+4
167	19+4
168	19+5
169	19+6
170	19+6
171	20+0
172	20+0
173	20+1
174	20+1
175	20+2
176	20+3
177	20+3
178	20+4
179	20+4
180	20+5
181	20+5
182	20+6
183	20+6

*Loughna P, Chitty L, Evans T, Chudleigh T (2009). Fetal size and dating: charts recommended for clinical obstetric practice. Ultrasound, 17: 161-167

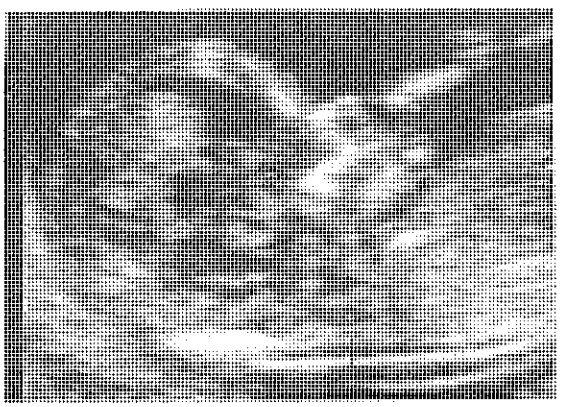
Fetal Medicine Foundation

Guidelines for the measurement of nuchal translucency

- The fetal crown-rump length should be between **45 and 84mm**.
- A good **sagittal section** of the fetus must be obtained, with the fetus horizontal on the screen. The correct view is a clearly visualised fetal profile.
- The fetus should be in a **neutral position,** with the head in line with the spine, not hyper-extended or flexed.
- Ideally only the fetal head and upper thorax should be included. The **magnification** should be as large as possible and ALWAYS such that each slight movement of the callipers produces only a 0.1mm change in the measurement.
- The **widest part of translucency** must always be measured.
- Measurements should be taken with the inner border of the horizontal line of the **callipers placed ON the line that defines the nuchal translucency thickness** - the crossbar of the calliper should be such that it is hardly visible as it merges with the white line of the border, not in the nuchal fluid.



- In magnifying the image (pre or post freeze zoom) it is important to turn the gain down. This avoids the mistake of placing the calliper on the fuzzy edge of the line which causes an underestimate of the nuchal measurement. Do not use tissue harmonic imaging for measurement of nuchal translucency because this thickens the lines and underestimates the measurement.
- Care must be taken to **distinguish between fetal skin and amnion.**
- During the scan more than one measurement must be taken and the maximum one that meets all the above criteria should be recorded in the database. It is good practice to retain at least one image for your patient records.



July 2003

Informing your midwife

□ First trimester bloods

Unfortunately we were not able to take blood from you today to complete the first trimester screening test. Please arrange to see your midwife **as soon as possible** so she can take blood and we will complete the test.

□ Second trimester bloods

Unfortunately we were not able to perform the screening test to calculate the chance of your baby having Down's syndrome today because:

□ *Your pregnancy is further on than we thought.*

□ *We have not been able to measure the neck region (nuchal translucency) of your baby.*

□ *There is no evidence of your consent to perform the test on TRAK or in your maternity notes (or you did not bring your notes with you)*

However you are still able to find out the chance of your baby having Down's syndrome by seeing your midwife for a blood test between 14 weeks 2 days and 20 weeks.
Please contact your midwife promptly to arrange an appointment for this screening test.

Thank you!

18-20^{6} Week Fetal Anomaly Ultrasound Protocol

The Procedure: structures and views

Head and neck
- Skull shape
- Measure HC, lateral ventricular atrium (normal ≤ 10mm) and cerebellum
- Cavum septum pellucidum
- Subjectively assess nuchal fold and measure if it appears enlarged i.e. >6 mm

Face
- Lips (coronal view)

Chest
- 4 chamber and outflow tract views of heart
- Cardiac situs
- Lungs

Abdomen
- Measure AC
- Stomach
- Abdominal wall
- Bowel (echogenicity normal less than that of bone)
- Kidneys & measure AP renal pelvis if enlarged subjectively i.e. >7 mm
- Bladder

Spine
- Vertebra and skin covering (sagittal and transverse views required)

Limbs
- Femur: measure length of one
- 12 long bones
- Feet: metatarsals, right and left visible but not counted
- Hands: metacarpals, right and left visible but not counted

Uterine cavity
- Subjective assessment of amniotic fluid volume
- Placenta: assess site in relation to internal cervical os. *(See separate protocol, Appendix 1)*

Minimum images to be stored electronically

- HC demonstrating measurement and measurement of lateral ventricular atrium
- Suboccipito-bregmatic demonstrating transcerebellar diameter
- Coronal view of lips with nasal tip
- AC measurement
- FL measurement
- Sagittal view of spine with sacrum and skin covering
- Placental site including relation to cervix

Normal variants (previously called minor markers)

Women who are found to be low risk through testing in either the 1st or 2nd trimesters or have declined screening for Down's syndrome, should not be referred for further assessment of chromosomal abnormality if normal variants such as those below (whether single or multiple) are seen at the 18-20[6] scan.:

- Choroid plexus cyst
- Left ventricular echogenic focus ('golf ball')
- 2 vessel cord.

However please report and refer for further assessment the findings of:

- Renal pyelectasis > 7 mm *(see appendix 2)*
- Lateral ventriculomegaly >10 mm
- Bowel of echogenicity greater than that of bone
- Nuchal fold > 6 mm

Check list

Name		**Chi**	
Date of scan		**Room/sonographer**	
Gestational age		Stomach	
		AC	I,M
Placenta	I	Abdo wall	
Liquor volume		Bowel	
HC	I,M	Right kidney	
Ventricle	I,M	Left kidney	
Cerebellum	I,M	Bladder	
Cavum septum pellucidum		Spine sagittal incl sacrum and skin covering	I
Nuchal fold		Spine transverse	
Nose/ lips coronal	I	Femur length	I,M
4 chamber heart		Arms	
Outflow tracts		Legs	
Lungs		Hands (metacarpals, not counting)	
Diaphragm		Feet (metatarsals, not counting)	

Key:
[I] Take an image of structure
[M] Measure structure. Only measure other structures, e.g. renal pelvis, nuchal fold if appear increased

DRAFT

Your guide to screening tests during pregnancy

healthier scotland
SCOTTISH GOVERNMENT

NHS
Health Scotland

Published by NHS Health Scotland

Edinburgh Office
Woodburn House
Canaan Lane
Edinburgh EH10 4SG

Glasgow Office
Elphinstone House
65 West Regent Street
Glasgow G2 2AF

ISBN: 978-1-84485-475-2

NHS Health Scotland is a WHO Collaborating Centre for Health Promotion and Public Health Development.

Contents

Screening and diagnostic tests 5

Screening for sickle cell and thalassaemia disorders in early pregnancy 8

Routine blood tests offered during pregnancy 16

The screening test for Down's syndrome 20

Mid-pregnancy fetal anomaly ultrasound scan 28

Having a scan 30

More information 38

This booklet is about the screening tests you will be offered during your pregnancy.

Some of the tests need to take place early in pregnancy, so you should start to read this booklet as soon as possible.

This will help you to better understand the tests, and prepare you for any conversations or questions you may have for your midwife or doctor.

It is important that you read the information in this booklet carefully, and remember to keep it handy for any hospital visits or when you meet with your midwife or doctor.

The following pages explain what conditions can be tested for and what the tests involve, so that you can decide whether you want to have them. The health professional taking care of you will always explain the tests in detail and ask for your permission. You can decide at any point that you do not want to be tested or you can choose to have only some of the tests offered to you.

It is important that you realise the reasons for screening, and understand the possible outcomes if you choose not to have the tests.

The health professional taking care of you will be able to provide further information if you are offered any other tests not covered in this booklet.

Throughout this booklet, the term 'health professional taking care of you', is used. This is because there can be different specialists responsible for different screening tests.

Screening and diagnostic tests

There are two types of test:

- **Screening tests**, which are offered to everyone, and are intended to show whether there is a chance your baby may have a condition.
- **Diagnostic tests**, which are further tests that may be carried out depending on the results of the screening test, to confirm what, if any, problem there may be.

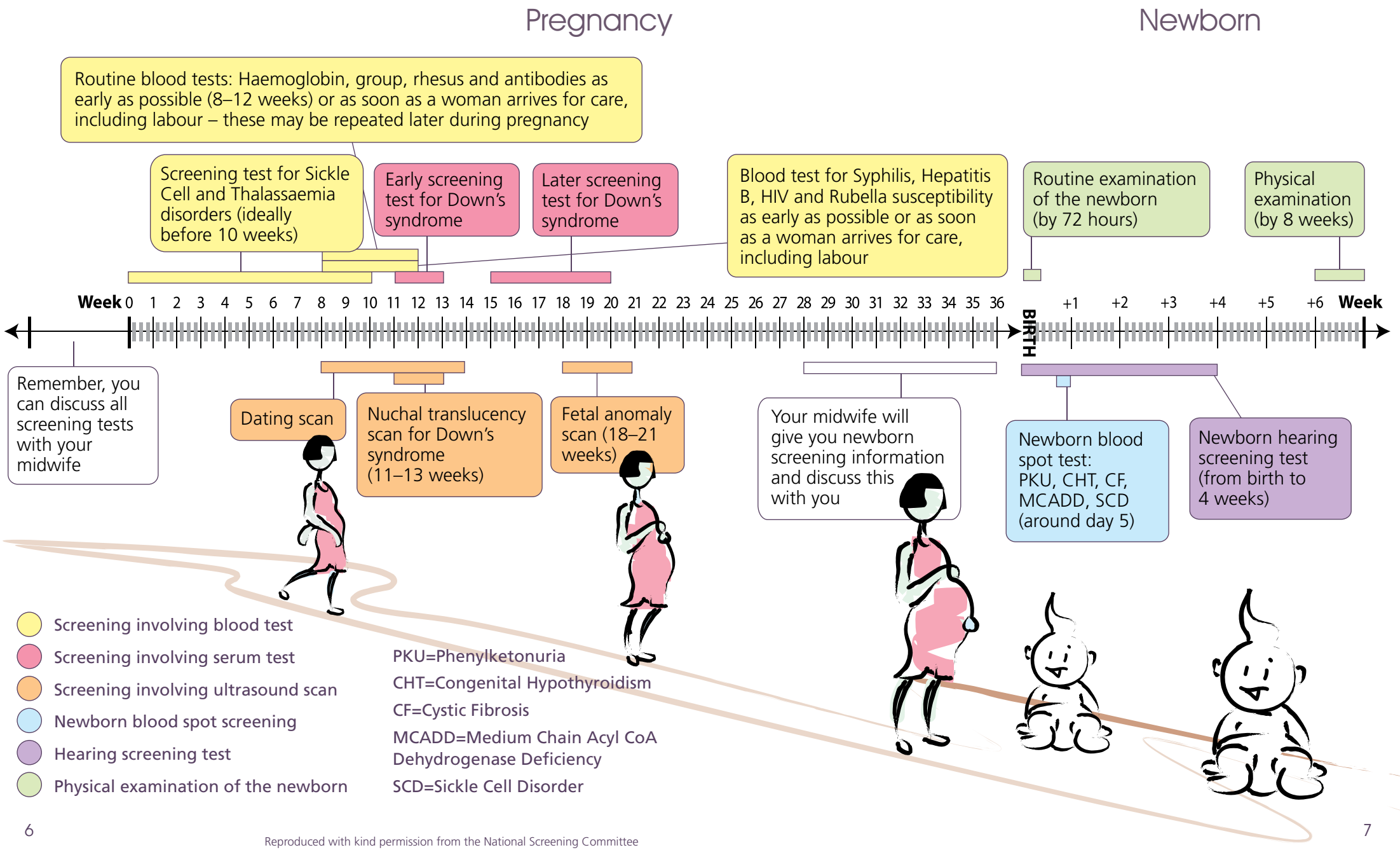
While screening offers a good way to assess how likely it is that your baby has a condition or health problem, it may not detect all problems.

If you do not want to be screened for any (or all) of the conditions, please talk this through with your midwife or doctor. The pregnancy screening programme will keep a record of your results. Only authorised staff and appropriate healthcare professionals have access to this information. All NHS staff are bound by a strict code of confidentiality. Towards the end of your pregnancy, your midwife will talk to you about screening tests for newborn babies and you will receive another booklet 'Your guide to newborn screening tests' that explains these in detail. For more information on screening tests during pregnancy, please talk to the health professional who is taking care of you, and they will be happy to help.

The organisations listed at the back of this booklet can also provide further information and support.

Pregnancy and newborn screening timeline

The health professional taking care of you will explain all tests offered to you



Screening for sickle cell and thalassaemia disorders in early pregnancy

In the first weeks of your pregnancy you will be offered screening tests for sickle cell and thalassaemia disorders.

Screening for sickle cell is by the Family Origin Questionnaire. You will be offered a questionnaire about your family origins and those of the baby's father too (see page 11 for more information). This helps determine whether you have a higher chance of passing on sickle cell. If there is, you will be offered a blood test.

The Family Origin Questionnaire is also used to screen for thalassaemia along with the results from one of your booking blood tests (the full blood count). If there is a high chance you are a carrier you will be offered a diagnostic blood test.

What are sickle cell and thalassaemia disorders?

These disorders affect the part of the blood that carries oxygen around the body, called haemoglobin. People who have these conditions will need specialist care throughout their lives.

Sickle cell disorder

People with certain types of sickle cell disorder:

- can experience attacks of very severe pain
- may have serious, life-threatening infections
- are usually anaemic (which means that their blood has difficulty carrying oxygen)
- will need medicines and injections when they are children, and throughout the rest of their lives, to stop them from getting infections.

Thalassaemia

People with certain types of thalassaemia:

- are very anaemic
- need blood transfusions every four to six weeks
- need injections and medicines throughout their lives.

There are also other, less common, haemoglobin disorders. Many of these are not as serious.

How are these disorders passed on?

Sickle cell and thalassaemia disorders are passed on from parents to their children. People are only usually affected if they inherit two or more of the affected (unusual) haemoglobin genes – one from their mother and one from their father. People who inherit just one unusual gene are known as 'carriers' (some people call this 'having a trait').

It's important to understand that carriers are healthy and do not have the disorder. However, if a carrier has a baby with someone else who is also a carrier, or who has one of the disorders, there is a chance that their baby could have the disorder.

Who can be a carrier?

Anyone can be a carrier. But you are more likely to carry the genes if your parents or grandparents come from countries with malaria, or where malaria was common in the past. This means you're more likely to be a carrier if your parents or grandparents come from Poland, the Mediterranean, Africa, the Caribbean, the Middle East, India, Pakistan, South America, or South and South-East Asia.

Don't worry if you don't know. You will be given a questionnaire (called the Family Origin Questionnaire) to help find out where your family, and the father's family, comes from.

Assisted conception using donor eggs or sperm can affect the screening result. It is important that you give the staff as much information as you can, in order for you to be given the most accurate screening results possible.

What tests are involved?

The **Family Origin Questionnaire** is used to screen for both sickle cell and thalassaemia disorders.

If it shows you have a higher chance of carrying sickle cell you will be offered a diagnostic blood test. Usually the test can be made on blood already taken as part of your antenatal care.

The Family Origin Questionnaire and the full blood count (one of your routine booking blood tests – see page 16) are used to screen for thalassaemia. If either show you have a higher chance of carrying thalassaemia you will be offered a diagnostic blood test. Again the test can be made on blood already taken as part of your antenatal care.

Ideally, the best time to have these tests is before you are 10 weeks pregnant.

Why should I be tested?

The test gives important information about your baby's health:

- If it shows that you're a carrier, your baby's father will be invited for a test. If he is also a carrier, your baby has a chance of having the disorder.
- Finding this out early in your pregnancy gives you the chance to talk to the health professional taking care of you, and to find out more about what this means for you and your baby and the care that is available.

How the test can benefit you and your family

- If the test shows that you're a carrier, there's a chance other family members are too. You may want to encourage them to ask for a test, especially if they are planning to have a baby themselves.
- Although sickle cell carriers are healthy, they can experience some rare problems in situations when their bodies might not get enough oxygen (for example, when having an anaesthetic). Knowing that you are a carrier can help you manage these situations.
- People who are thalassaemia carriers do not experience these problems.

Are there any risks I should be aware of?

The screening is a very simple blood test, with almost no risk to you or your baby.

How will I get my results?

The person taking the blood test will discuss this with you at the time.

What will the results tell me?

The most likely result is that you aren't a carrier. Your pregnancy should continue as normal.

If the result shows that you are a carrier for sickle cell, thalassaemia or another blood disorder, the health professional taking care of you will talk to you about what this could mean for you, your baby and your family.

The baby's father will be offered a test to find out whether he's a carrier. In very rare cases, the test may show that one of you has a blood disorder without even knowing it. If this happens, a health professional (for example, a nurse, doctor or midwife) will talk this through with you, and give you more information.

The test is between 95 % and 99 % accurate, which means it is very reliable. However, in a very small number of cases the result may be unclear. If this happens, you will usually be offered another test.

Why should my baby's father have a test?

Babies can only inherit these disorders if both parents are carriers. So if you're a carrier, it is important to find out if your baby's father is also a carrier.

He will be offered a test, but if he's not available or does not want to have the test, you may be offered another option – this may be a test to find out whether your baby has a sickle cell or thalassaemia disorder (see overleaf).

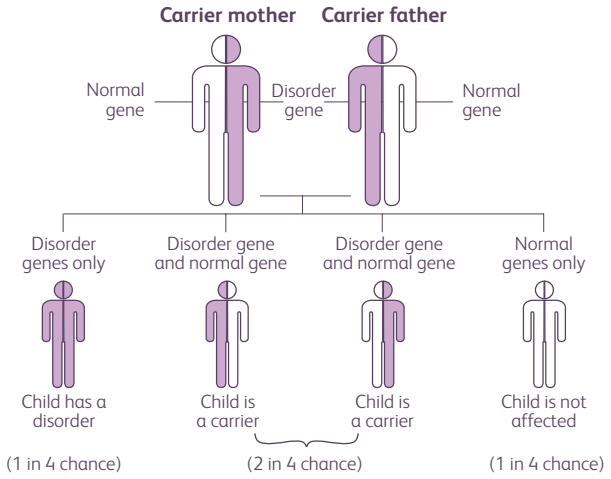
What if my baby's father is also a carrier?

If you and the baby's father both carry the gene for sickle cell, thalassaemia or another blood disorder, for each baby you have there is:

- a 25% (one-in-four) chance that your baby will not be affected
- a 50% (two-in-four) chance that your baby will be a carrier
- a 25% (one-in-four) chance that your baby will have a disorder.

Some forms of thalassaemia are more complex.

The health professional taking care of you will talk to you about what this means for you, your family and your baby. If you wish, you can choose to have a diagnostic test on the fetus when you are pregnant. This is called a 'diagnostic test', and it is explained on page 26. Leaflets are available that explain these tests in more detail.



Adapted with kind permission from the National Screening Committee (NSC)

What happens if I decide to have my baby tested?

This diagnostic test will show whether your baby has a disorder. A health professional will explain the different types of test, and help you to decide whether you want it. If you do want the test, it's important to have it as early as possible in your pregnancy.

If results show that your baby has a blood disorder, the health professional taking care of you will help you to understand what this may mean for you, your baby and your family. They will talk with you about the care that is available, and whether you wish to continue with your pregnancy.

Testing for new babies

As well as the tests described here, all newborn babies are offered a newborn 'blood spot' screening test, usually when they are five-to-seven days old. The test is done by taking some blood from your baby's heel, and looks for a number of health problems including sickle cell. It will show whether your baby is not affected, is a carrier, or has a disorder. You will be given more information about the tests for newborn babies later in your pregnancy.

Any questions?

It is understandable that this information can be a lot to take in. If you have any questions about the test at all, please discuss them with your doctor, midwife, obstetrician or specialist counsellor. They will be able to give you advice, and may also have information about other organisations who can offer support.

Routine blood tests offered during pregnancy

You will be offered a number of other routine blood tests, that together form an important part of your care during pregnancy. These tests are to help protect your health and the health of your baby.

All the tests can usually be done using one blood sample, usually taken from your arm at one of your first visits with your midwife.

It is your decision whether to accept these tests or not, and it won't affect the quality of your care. However, having the tests could help you make decisions about the care of your baby, both before and after birth. All results are confidential and only health professionals closely involved in your care will be able to see them. No one will be told about your results without your consent.

What will my blood be tested for?

Full blood count

This measures the level of iron in your blood. If it's low, it means you could be anaemic. You may simply be offered iron tablets, or other appropriate treatments which will help your health and the health of your baby. If any other problems are found, then further tests can be carried out if required.

Blood group

This shows which main blood group you belong to, either A, B, O or AB. The test will also show if you belong to the Rhesus positive or Rhesus negative group, and whether there are any blood group antibodies in your blood. Some of these antibodies can occasionally affect the baby, and if this is the case it will be discussed with you. More often, it is important to know whether these are present in the event that you require a blood transfusion, so that the correct type of blood for your particular antibody is made available.

What if I'm Rhesus positive?

You will not need any treatment.

What if I'm Rhesus negative?

You will be offered an injection of 'anti-D'. This helps prevent serious illness during your current pregnancy, as well as protecting any future babies you may have. This is quite a common blood group – around one in six women are Rhesus negative.

Infections

You may be offered a blood test for infections that can affect you and your baby, such as Rubella, Hepatitis B, Syphillis and HIV.

Rubella (German measles)

Rubella infection in the first 20 weeks of pregnancy can be harmful to your baby. It can in some cases, for example, lead to deafness.

The good news is that most women are now protected from Rubella because they were immunised in childhood. If you are immune, you and your baby are both protected if you come into contact with the illness during pregnancy.

The test will show whether you are immune. If it shows you're not, or you have low levels of immunity, you will be given advice and offered immunisation **after you have had your baby**.

Please remember, Rubella is usually a mild illness, and it is easily confused with other rashes in children and adults. If you do come into contact with someone with a rash or develop a rash yourself, you should contact your doctor or midwife as soon as possible.

Hepatitis B

Hepatitis B infection can be passed on from mother to baby during birth. It is a virus that affects the liver, and can be carried in the blood for many years before causing any signs of illness.

Without a test, you may not know that you're infected. If the test shows that you are infected with Hepatitis B, specialist help will be provided.

Immunisation at birth can usually prevent infection in babies born to infected mothers. Without immunisation, many babies born to mothers who are Hepatitis B carriers become infected. These babies are at risk of developing serious liver disease as they grow older.

Syphilis

This infection, passed on through having sex, is uncommon these days. It is tested for because if it's not treated it can damage the health of you and your baby. If syphilis is found, it can be quickly and simply treated with antibiotics.

Human Immunodeficiency Virus (HIV)

The Human Immunodeficiency Virus (HIV) is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).

Infected women can pass HIV to their babies during pregnancy, childbirth and also through breastfeeding.

HIV damages the immune system, and destroys the body's defences against infection and disease. It can take years for HIV to do enough damage for someone to become ill. Many women with HIV will not know that they are infected unless they have a test.

If the test shows that you are HIV positive, you will be offered guidance and treatment by specialists. This will include medication that will greatly reduce the chance of infection passing to your baby. You will also receive advice about the best type of delivery and methods of feeding your baby.

If the screening tests for syphilis or HIV suggest that you might have either of these conditions then you will be offered a second test to confirm the results. This is because sometimes the tests can report an incorrect result (called a false positive).

Results of routine blood tests

You will usually be able to get the results at your next clinic visit.

Occasionally technical problems can occur and you may be asked to have another sample taken.

If any health problems are found, you will be contacted as soon as possible and given advice and care. Some tests are routinely repeated later in pregnancy.

Having a blood test does not affect current or future life insurance policies. However, if a health problem is found, this could affect your insurance. You might wish to check any policies you have for further details.

The organisations listed at the back of this booklet can also provide further information and support.

The screening test for Down's syndrome

A small number of babies are born with Down's syndrome. You may choose to have a test during pregnancy which can help to detect this condition.

What is Down's syndrome?

Most people have 23 pairs of chromosomes. These chromosomes carry the genes that determine how we develop.

People with Down's syndrome (sometimes called 'trisomy 21') have an extra copy of chromosome 21 – they have three instead of two. It is a chromosomal accident and is not caused by anything parents do before or during pregnancy.

It is sometimes inherited, but this is very rare. Older mothers are more likely to have a baby with Down's syndrome, but it can occur in women of any age.

Down's syndrome occurs:

- once in every 1,500 births to women aged 20 years or younger
- once in every 900 births to women aged 30 years
- once in every 100 births to women aged 40 years.

Children with Down's syndrome, like all people, vary a lot in appearance, personality and ability. They will have varying levels of learning difficulties and will need special help with their education. Many people with Down's syndrome enjoy a healthy life, but there are a number of health problems associated with Down's syndrome, such as heart defects, thyroid problems and reduced hearing and eyesight. Many of the problems can be treated, and frequent health checks can minimise some of these problems.

However some problems can be severe or require surgical repair and result in repeated, sometimes prolonged, periods of hospitalisation.

Should I have the screening test?

Your midwife will discuss the test with you, and you should think about it very carefully. It's a personal decision for you to make, and you should take time to think about it and to talk it through with the health professional taking care of you, your partner or people close to you.

All pregnant women, no matter what age, can have the test.

How is the test done?

There are two stages to testing for Down's syndrome.

The first stage is a screening test. This is offered to everyone. You can choose whether to have this test or not. Depending on the results of the screening test, some women (about 1 in 20) will be offered a second follow-up test. Again, you can choose whether or not to have this follow-up test.

The follow-up test is a diagnostic test, and it will show whether your baby has a health problem. However, having this diagnostic test increases your chance of a miscarriage. This is why it is not offered to all women. You can choose whether or not to have one, or both parts of the testing process.

If the screening test shows the chance of the baby having Down's syndrome is low, you will not be offered a diagnostic test. Most screening test results (about 95 %) fall into this category. This is known as having a 'low-chance' result.

It's important to understand that a low-chance result does not mean that there is no chance at all that your baby has Down's syndrome, just that it is unlikely. There is still a small possibility, because some babies with Down's syndrome aren't detected by screening tests. Overall, about a quarter of babies (one in four) with Down's syndrome will not be detected by screening.

If the screening test shows that your baby has a 'high-chance' result of having Down's syndrome, you will be offered a diagnostic test.

Can any other types of abnormality be detected by screening?

Occasionally, some other abnormalities may be detected by the screening test. Some of these can be serious, while others will have only a minor, or no effect, on the baby. If the tests show that there may be a problem, you will be given information on the options available and support to help you make your decisions.

What type of screening test for Down's syndrome will I be offered?

There are different ways of screening for Down's syndrome. These tests will involve either blood samples taken from you, or blood samples taken from you combined with a special ultrasound scan, depending on how far along you are in your pregnancy.

Blood tests

Blood tests measure substances that have passed between you and your baby. A sample of your blood is usually taken between 10 and 18 weeks.

Several factors can affect the screening result, including if you smoke and if it is an assisted conception (especially if it is a donor egg or frozen embryo). It is important that you give the staff this information in order for you to be given the most accurate screening result possible.

A computer programme then uses the results of your blood test, along with your age, weight, stage of pregnancy and any other relevant factors to work out the chance of the baby having Down's syndrome.

Ultrasound scan

A 'nuchal translucency scan' (NT) is a special ultrasound scan usually done at 11-to-13 weeks. The amount of fluid lying under the skin at the back of the baby's neck is measured. A computer programme uses this measurement, along with your blood test result to work out the chance of Down's syndrome for your baby. This is sometimes known as the 'combined' test.

Because the ultrasound test is based on the measurement of an individual baby, it can be used separately without the blood test if you are having a multiple pregnancy, for example, if you are having twins or triplets, to give the chance for each baby.

What if the results show a high-chance result?

If the screening results show a 'high-chance', this means that there is higher chance that your baby is affected, and you will be offered diagnostic tests to confirm whether your baby has Down's syndrome. The health professional will talk this through with you and answer any questions you have. The follow-up tests, which you have the option to choose or refuse, will be fully explained.

Diagnostic tests for Down's syndrome

If you are offered a diagnostic test for Down's syndrome, it will be either an 'amniocentesis' or Chorionic Villus Sampling (CVS) test. These are explained below.

While many women find the procedures uncomfortable, they shouldn't be painful. For a day or two afterwards, you will be advised to take things easy. If possible, you should avoid lifting, bending or stretching. You may have some discomfort in your lower abdomen for a day or two after the procedure. This is normal, and you can take paracetamol to relieve the discomfort.

Amniocentesis

Amniocentesis can be done after 15 weeks of pregnancy. It usually takes about 10 minutes. You will have an ultrasound scan to check the position of your baby in the womb. A fine needle will then be inserted through your abdomen, into the womb. The needle will be used to take a sample of fluid surrounding the baby (called 'amniotic fluid'). This fluid contains cells from the baby which will be examined later at the laboratory and the baby's chromosomes counted. For around one in every 100 samples the results are not clear. If this happens, you may be offered further tests.

Chorionic Villus Sampling (CVS)

CVS can be done from 11 weeks of pregnancy. It's usually only offered in a specialist centre. An ultrasound scan is used to guide a fine needle through your abdomen. A small sample of tissue is taken from the placenta. This is analysed in the laboratory, and the baby's chromosomes are counted. As with amniocentesis, very occasionally (about two in every 100 samples) CVS does not produce a clear result.

How safe are these diagnostic tests?

They are not completely safe, and this is why they are not offered to everybody. For every 100 women who have amniocentesis, one will miscarry. And for every 100 women who have CVS, one or two will miscarry. If you would like to know more about the miscarriage rates after CVS or amniocentesis in your hospital, please ask the health professional taking care of you.

What happens if the diagnostic test does find a problem?

In most cases, follow-up testing finds a healthy baby. If the testing finds a chromosome variation, the health professional will talk to you about it and the options that you have. Then you'll be able to choose what you feel is best for you. Some people may decide to continue with the pregnancy, while others will feel that termination is right for them.

There will be no pressure to influence you in your decision – the hospital staff will provide you with help and support whatever you decide.

The organisations listed at the back of this booklet can also provide further information and support.

DRAFT

Mid-pregnancy fetal anomaly ultrasound scan

Why am I offered a mid-pregnancy scan?

All pregnant women are offered a mid-pregnancy scan. It usually takes place between 18 and 21 weeks. The main purpose is to look for anything that might affect the health of your baby.

What kind of scan will I be offered?

You will be offered a scan that produces a two-dimensional black and white image. The three-dimensional (3D) and colour scan images you sometimes see on television and in magazines are not made by ordinary scan machines, and are not used in the NHS screening programme.

What can a scan tell me about my baby?

During the scan, the health professional will take a very careful look at your baby.

Most people find that their baby is healthy and developing well. Sometimes, however, a problem is found. In most cases, any problems are minor and the health professional taking care of you will be able to explain them to you. Rarely, some serious problems are detected.

Scans have their limitations, too. Your health professional may tell you that there might be a problem, but will not be able to say for certain. In a small number of cases, babies are born with health problems that were not picked up by the scan.

Always remember that for most people, the scan is a happy experience. Unfortunately this is not true for everybody, which is why you should read this information carefully, and then make a decision about whether you want a scan or not. Your choice will always be respected.

Whatever you decide, it will not affect the quality of care you receive.

Is the mid-pregnancy scan safe?

Ultrasound scans are considered completely safe for mother and baby.

Does everybody have a scan?

All pregnant women are offered the scan, but you don't have to have it if you don't want to. Before you make up your mind there are a few things you need to know, so please read the next section carefully.

Having a scan

Can I bring family or friends with me when I have the scan?

Hospitals have different policies about this, and it's a good idea to check beforehand. Most hospitals welcome partners in the room. Young children may not be allowed because they can be a distraction.

What will happen when I go into the scan room?

Most scans are carried out by trained heath professionals called 'sonographers'.

In order for the sonographer to take good quality images of your baby, the room will be dimly lit. Scanning requires a lot of concentration, especially if your baby is very active.

First, you'll be asked to lie on a couch. Then you'll be asked to raise your top up to your chest, and lower your skirt or trousers to your hips. Tissue paper will be tucked around your clothing to protect it from the ultrasound gel, which will then be applied to your abdomen.

The sonographer then passes a hand-held device across your abdomen, which sends and picks up ultrasound waves. These ultrasonic waves allow the computer to build an image of your baby. The scan doesn't hurt at all, but the gel might be a little cold at first.

Occasionally the sonographer may need to apply slight pressure to your abdomen if some parts of your baby are difficult to see.

How long will my scan take?

A scan can take anything from 10-40 minutes. The images created on the screen are usually recognisable, for example you may see the head, heart and limbs. However, the sonographer may be prevented from getting clear pictures depending on the position of your baby, or if they are moving around a lot.

If you are overweight, this can reduce the quality of the scan image. If it's difficult to get a good image, scanning may take longer, or have to be repeated at another time.

The vast majority of scans show that the baby is healthy, and no problems are found. This is because most babies are healthy.

Will the sonographer tell me the sex of my baby?

This depends on the policy of your hospital. It is the policy of some hospitals not to look for the sex of the baby unless clinically indicated. In others, you can be given the information – if the sonographer can get a clear picture of the baby. In some cases it is impossible to tell because of the position of the baby. This information is not completely reliable and can turn out to be wrong.

Can I have a picture of my baby?

You will need to check if your hospital provides this service. If they do, there may be a charge.

Will I need another scan?

If the baby appears to be healthy, you probably won't need another scan during this pregnancy. If the sonographer is not able to see everything clearly, the scan may need to be repeated on a different day. This happens quite often.

Can the scan detect all problems?

No. Sometimes the sonographer is not able to get a clear view – this can be due to the position or age of your baby, the amount of fluid ('waters') surrounding your baby, your own bodyweight, or any scar tissue left by an abdominal operation, such as a previous Caesarean section.

Also, some health problems only develop after 18-21 weeks (when you are offered the scan), and some can never be seen on a scan because they have no effect on the appearance of the baby. This means that in a small number of cases, babies are born with health problems that were not picked up by the scan.

What kind of problems can be seen?

Major health problems affecting the development of the baby, such as Spina Bifida, are usually easily diagnosed on the scan. In these cases, the sonographer and doctors can be absolutely certain of the findings.

Scans are not as reliable at detecting problems such as some heart defects, and they are not expected to be able to pick up every heart condition before birth.

Sometimes minor irregular features of the baby's body are picked up. Usually these mean nothing at all, but sometimes a pattern can be seen which might suggest an underlying problem.

What will happen if a problem is found or suspected?

If a problem is found or suspected, the sonographer may ask for a second opinion from another sonographer or doctor. You will be told what the concerns are, but the exact nature or extent of the problem might not be clear at this stage.

You might be offered another test, such as an amniocentesis (see page 26), to find out for certain if there is a problem. If you're offered further tests, the health professional taking care of you will give you more information. You can then choose whether you want to have the test or not.

You might be referred to a specialist doctor for fetal medicine. They will be the best person to talk to about any health problems your baby might have. This could be in another hospital. You will usually be given an appointment within a few days.

In most cases, further tests don't find any health problems. However, they can cause great worry for parents, and for some people this worry can continue throughout the rest of their pregnancy. You may want to ask questions and talk about these concerns with your own midwife, doctor or consultant. Other sources of information and support are listed at the back of this booklet.

If a definite health problem is found, what happens next?

If a problem is found, it will depend on what the condition is and how serious it is, as to what happens next. Some problems may turn out not to be serious, and others will get better on their own. You may be offered further scans throughout the pregnancy to monitor these problems.

If the health problem is serious, you'll be talked through your options, which may include having a termination. If you need to make any decision, you will be given time, support and information by your midwife and the hospital team.

Contact details of organisations and support groups you might find helpful are given at the back of this booklet.

Can anything be done before the birth?

Finding out about a health problem before birth can help parents to prepare themselves.

Sometimes it can help them to plan treatment after the baby is born. For example, if your baby is known to have a problem that will need an operation soon after birth, such as the repair of a hernia in your baby's tummy, arrangements can be made to deliver your baby in a hospital where this can be done within the first few hours after birth.

Can the baby have an operation before birth?

Unfortunately, very few problems can be treated in this way.

I would prefer not to know if my baby has an abnormality

If you would prefer not to know, you need to think carefully about whether you should have a scan at all. You may find it useful to talk to your midwife before deciding.

More information

Thank you for taking the time to read this booklet.

The information can be a lot to take in. Please talk to the health professional taking care of you if you have any questions or concerns.

You may also find the following contacts useful:

Antenatal Results and Choices (ARC)
Provides non-directive support and information to expectant and bereaved parents throughout and after the antenatal screening and testing process.

Tel: 0207 631 0285
www.arc-uk.org

Contact a Family Scotland
Provides information, advice and support to parents and carers of children with any special need or disability.

Tel: 0808 808 3556
(voice and text).
www.cafamily.org.uk

Down's Syndrome Scotland
Works to help people with Down's syndrome reach their full potential by providing information and support to them, their families, carers and professionals.

Tel: 0131 313 4225
www.dsscotland.org.uk

Family Planning Association Scotland

Tel: 0141 576 5088
www.fpa.org.uk

Positively Women
Offers a range of peer support, advice, information and advocacy services for HIV positive women.

Tel: 020 7713 0222
www.positivelywomen.org.uk

Scottish Spina Bifida Association
Offers a multi-faceted family support service to those affected by spina bifida, hydrocephalus and allied conditions, across Scotland.

Tel: 01236 794500
www.ssba.org.uk

Sickle Cell Society
Offers information, counselling and care for people with sickle cell disorders and their families.

Tel: 020 8961 7795
www.sicklecellsociety.org

SOFT UK
Supports families affected by Patau's Syndrome (Trisomy 13), Edward's syndrome (Trisomy 18), partial Trisomy, mosaicism, rings, translocation, deletion, and related disorders.

Tel: 0121 351 3122
www.soft.org.uk

UK Thalassaemia Society

Tel: 020 8882 0011
www.ukts.org

Waverley Care
Provides care and support to people living with HIV and Hepatitis C and their partners, families and carers.

Tel: 0131 661 0982
www.waverleycare.org

Notes

Notes

Notes

中文 **CHINESE**

想得到更多关于该信息的不同语言或者格式的版本,请浏览以下网址
http://www.healthscotland.com/publications

如果你不能浏览互联网或者需要别人帮助你浏览互联网,请联系你本地的NHS(全民健康服务),免费**NHS**帮助热线是**0800 22 44 88**(文本电话 18001 0800 22 44 88).

POLSKI **POLISH**

Więcej informacji w innych językach i formatach znajdą Państwo na stronie internetowej http://www.healthscotland.com/publications

Jeżeli nie mają Państwo dostępu do Internetu lub potrzebują pomocy w znalezieniu informacji prosimy kontaktować się z lokalną siedzibą Narodowego Funduszu Zdrowia (NHS Board) lub telefonować pod bezpłatna **infolinię NHS** pod numer **0800 22 44 88** (numer telefonu testowego 18001 0800 22 44 88).

URDU اردو

درج ذیل پتے پر دیگر زبانوں اور شکلوں میں مزید معلومات دستیاب ہیں
http://www.healthscotland.com/publications

اگر آپ کے پاس انٹرنیٹ کی سہولت نہیں ہے یا اس کام میں مدد کی ضرورت ہے تو، اپنے مقامی NHS Board (این ایچ ایس بورڈ) سے رابطہ کریں یا **NHS Helpline** (این ایچ ایس ہیلپ لائن) کو **0800 22 44 88**(ٹیکسٹ فون18001 0800 22 44 88) پر مفت فون کریں۔

DRAFT

Useful contact numbers

NHS 24 08454 24 24 24

GP

Health visitor/public health nurse

Nearest accident and emergency department

Local hospital

Other

This booklet has been designed to be kept with your Scottish Woman-Held Maternity Record, so that you can keep all your information together in one place.

www.pnsd.scot.nhs.uk
www.healthscotland.com

2884 12/2009