

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:

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

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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 Update¹.

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 comments² 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 Practice³ 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 Woman⁴.

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 us⁵.'

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

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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 them⁶.

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 2007³. 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 2003³.

***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 women's 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 standard 1.4) 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 NHS⁷.

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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> overall quality and management of the Trust's programme
Director of Public Health for a Primary Care Trust	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> co-ordinating and managing the screening programme at regional level
Strategic Health Team	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • Clinical Antenatal Screening Steering Group • Directorate Manager
Quality Service Managers, senior laboratory and ultrasound staff	<ul style="list-style-type: none"> • Medical Directors • Quality Programme Manager
Quality Programme Manager	<ul style="list-style-type: none"> • Clinical Antenatal Screening Steering Group • Chief Executive of the Trust
Clinical Antenatal Screening Steering Group	<ul style="list-style-type: none"> • The Trust's Governance Board • Chief Executive of the Trust
The Trust's Governance Board	<ul style="list-style-type: none"> • Chief Executive of the Trust • Medical Director for the Strategic Health Authority
Regional Antenatal Screening Co-ordinator	<ul style="list-style-type: none"> • 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 arrangements⁸ 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 settings⁹.

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 them¹¹ 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 English¹².

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 fold¹³.'

Standards:

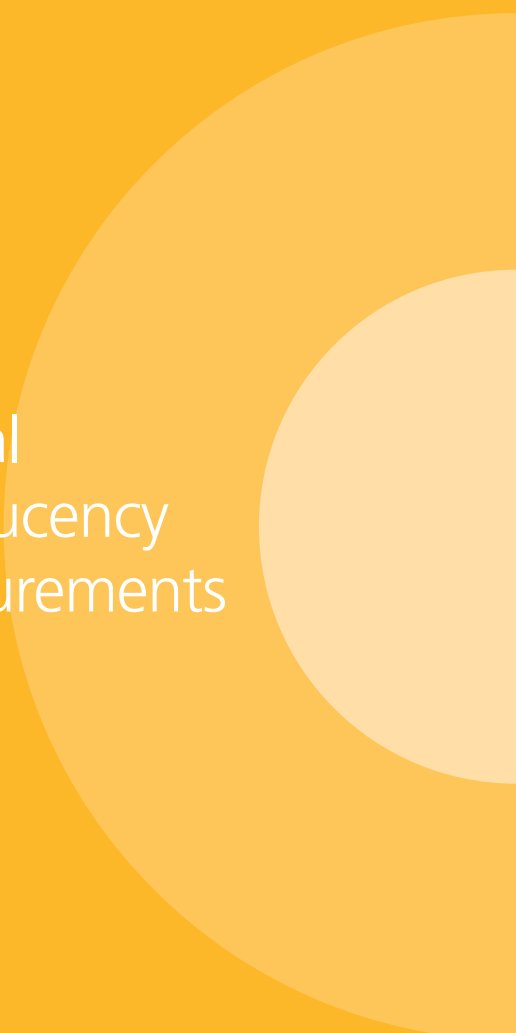
- 10.1 All pregnant women undergoing screening for Down's syndrome must have a dating scan:
- sometime after 8 weeks of gestation
 - before serum screening is done
 - between 11 to 13 weeks and 6 days gestation, if the nuchal translucency is to be measured
- 10.2 All ultrasound departments must have 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 available¹⁴.

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 software¹⁵. 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 used¹⁶ 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 software¹⁵. 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 guidelines¹⁷.**

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.

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6. Department of Health *Tackling Health Inequalities; A Programme for Action* 2003
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Supplementary Working Group
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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 original 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

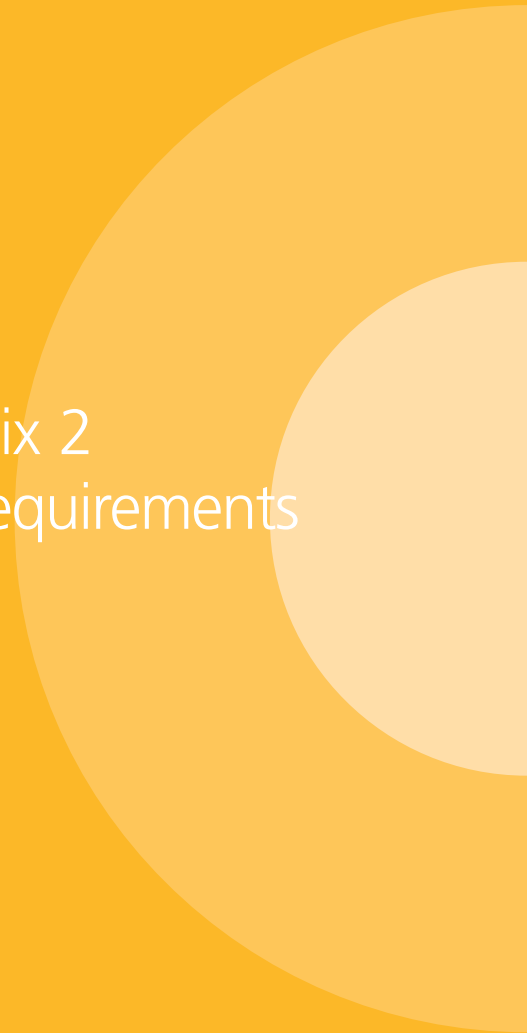
Association of Clinical Cytogeneticists
 British Fetal Maternal Medicine Society
 British Medical Ultrasound Society
 Genetics Department: Department of Health
 Society of Radiographers
 The Association for Clinical Biochemistry

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:

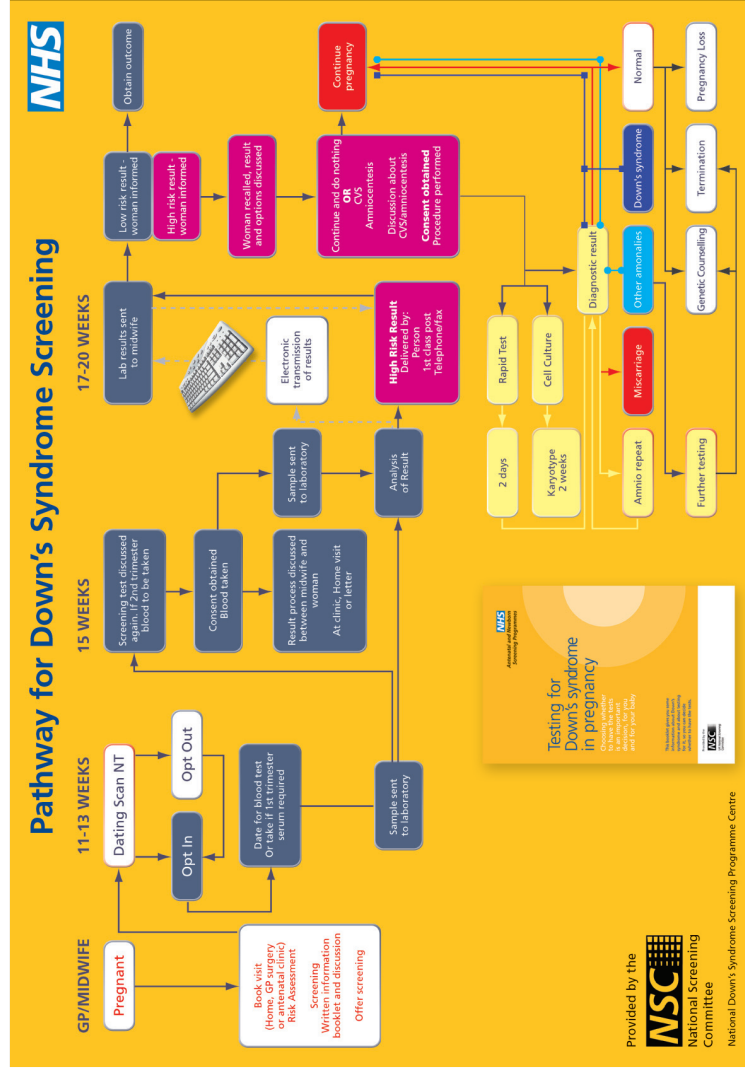
<http://www.screening.nhs.uk/downs/dqass.htm>

(Websites visited on 22/02/07)

Appendix 4 Pathway for Down's Syndrome Screening

Appendix 4

Pathway for Down's Syndrome Screening



Provided by the
NSC
 National Screening
 Committee
 National Down's Syndrome Screening Programme Centre

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.