

NHS Fetal Anomaly Screening Programme: 18⁺⁰ to 20⁺⁶ Weeks Fetal Anomaly Scan National Standards and Guidance for England

NHS Fetal Anomaly Screening Programme

18⁺⁰ to 20⁺⁶ Weeks
Fetal Anomaly Scan
National Standards and
Guidance for England

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Royal College of
Obstetricians and
Gynaecologists

Setting standards to improve women's health



NHS Fetal Anomaly Screening Programme

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Foreword

Ultrasound has been used to detect fetal abnormalities in the UK since the early 1980s, and as ultrasound machines have improved, so have expectations about what might be diagnosed. Much of the evidence about the ability of ultrasound to diagnose specific conditions has come from small studies undertaken by ultrasound experts, but in more recent years population studies evaluating ultrasound as a screening tool, as opposed to a diagnostic tool, have been less encouraging.

The standards set out in this document will form the basis of the ultrasound screening service in England and will bring a sense of realism to what ultrasound screening can and, importantly, cannot achieve. A clear indication of how the service should be configured, the advice and information women should receive and the screening menu that should be used will, for the first time, produce explicitness for both sonographers and women alike. In addition it will enable robust auditing of the service.

These standards have been developed by a small group of professionals but subjected to widespread consultation by both professionals and users. It is felt that the standards reflect the view of all those involved and the NHS Fetal Anomaly Screening Programme is grateful for the very enthusiastic and encouraging contributions received.

This should be regarded as a 'living' document which will require modification over time but it does provide the basic structure needed to deliver the service.



Professor Martin Whittle

National Ultrasound Screening Standards Core Reference Group (Chair)



Introduction

Screening for fetal anomalies has been undertaken for many years in England although not part of a coordinated and uniform national programme. For the first time this has been addressed, and it gives me great pleasure to be able to introduce this document which denotes a significant step towards cementing a firm structure for high-quality ultrasound services.

In January 2009, the NHS Constitution for England set out a pledge that national screening programmes would be available for all and funded into the foreseeable future. This constitutes a commitment by the Government that services will be developed and that they will meet national standards.

To provide this for fetal anomaly ultrasound has resulted in a tremendous amount of hard work from the NHS Fetal Anomaly Screening Programme (NHS FASP) in an attempt to meet the needs, not only of pregnant women, but also of staff who will have to deliver to the standards and guidance set out in this document.

The contents are designed to provide not only standards and guidance within the 12 sections that relate to the care pathway that a pregnant woman will take, but also set out supplementary materials. These have been commissioned and designed by the NHS FASP to assist in supporting the service delivery to those standards.

One of the most difficult areas that we will all need to concentrate on is being able to audit and monitor against those standards to assess how effective the service is against the 11 conditions designated as the screening test. Improving patients' experiences and care is at the very core of what we wish to achieve, and knowing how effective the service is or is not is integral to that aim.

This document marks an important moment in ultrasound services and history, when we move towards a genuinely uniform national screening programme leading us into the next decade and beyond.



Pat Ward

Programme Director, NHS Fetal Anomaly Screening Programme



The practicalities of developing standards and guidance for England

Knowledge is of two kinds. We know a subject ourselves, or we know where we can find information upon it.

Samuel Johnson 1709–1784

Background

In 2004, the NHS Fetal Anomaly Screening Programme (NHS FASP) was given responsibility by the UK National Screening Committee for developing a national, quality assured, obstetric ultrasound screening programme for England. Under the directorship of Pat Ward, a number of high-level working projects were initiated in response to the findings of a national ultrasound survey undertaken in 2002. The survey highlighted 'some serious gaps and deficiencies' in how services were run despite recommendations set by the Royal College of Obstetricians and Gynaecologists (RCOG) in 2000. It was evident there was a need to improve quality and standardise all aspects of obstetric ultrasound given that the RCOG publication was a decade old, it was time to introduce a new set of auditable standards developed and led by the national programme which reflected the current landscape of obstetric practice.

In line with an agreed project plan, the National Ultrasound Screening Standards Core Reference Group (NUSCoRG), made up of seven senior experts working in the field of obstetric sonography was established in April 2008 to explore the variability of practice and policy within ultrasound services. Stakeholders were also encouraged to engage in the development as external input was fundamental to 'challenge' the integrity of draft proposals.

A fundamental building block in the success of these standards is the widespread ownership which was achieved through consultation. It was important to harness and value the experiences of everybody and the need to welcome enthusiasm and knowledge from the frontline. The group felt that the standards should not be an imposition from above or another 'bolt-on' for staff and organisations to implement. Without ownership and commitment the cultural shift required to embed the standards into hospital services would not take place. Instead the new document must permeate all that we do which means looking at the way we behave individually, in teams and as an organisation in order to improve the care we provide for the pregnant woman.

Over the past 18 months the standards publication has gone through a rigorous development over a period of 18 months. A national meeting took place in December 2008, followed in April by an on-line consultation and a further national meeting in June 2009. Each was positively received and well represented by a wide range of professionals



(including colleagues from Northern Ireland, Scotland and Wales) and it quickly became clear that there was genuine will by stakeholders to work in unison.

The 18⁺⁰ to 20⁺⁶ weeks fetal anomaly screening scan was the prime focus of discussions until April, with a meeting in June 2009 tailored specifically to agree whether screening for 'soft markers' should still be undertaken during the mid-pregnancy scan. A majority vote supported the discontinuation of reporting some of these findings.

Much has been achieved in bringing this document together, and it is the Programme Centre's wish that the standards are used to promote flexible and responsive services. Equally, evidence shows that improved practice does not usually mean increased costs and that there can be significant reductions in the cost of care when service is improved, redesigned or streamlined.

The practice of ultrasound is a clinical skill that must be governed by professional standards and although the standards are primarily aimed at ultrasound practitioners, those working in an obstetric directorate (midwives, obstetricians) and beyond (paediatricians, service managers, PCT commissioners and educationalists) will also find them useful and interesting as they contextualise the philosophy, application and environment of the ultrasound world.

The National Programme Centre commends these national standards to you and it is hoped that you will give them your support by ensuring their implementation. We know that they are eagerly awaited and we believe your contribution in leading this work will result in an improved ultrasound service for women and better outcomes for babies.



Donna Kirwan

National Projects Officer, NHS Fetal Anomaly Screening Programme

On behalf of the National Ultrasound Standards Core Reference Group



National Ultrasound Screening Standards Core Reference Group (NUSCoRG)

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Colin Davies	Consultant Radiologist, Cwm Taf Local Health Board, Wales
Trish Chudleigh	Advanced Practice Manager, Rosie Hospital, Cambridge University Hospitals
Jackie Williams	Programme Administrator, NHS Fetal Anomaly Screening Programme, Exeter



NUSCoRG Terms of Reference

Aims

The National Ultrasound Screening Standards Core Reference Group (NUSCoRG) is a subgroup of the NHS Fetal Anomaly Screening Programme (NHS FASP) Steering Group and this is part of the overarching Fetal, Maternal and Child Health (FMCH) Steering Group of the UK National Screening Committee (UK NSC).

On behalf of the NHS FASP Steering Group, the NUSCoRG will include members that will bring a broad perspective to the project so as to ensure that the final ultrasound standards are of high quality and reflective of the 18⁺⁰ to 20⁺⁶ fetal anomaly ultrasound scan offered to pregnant women within the wider English maternity health economy. Members will do this by fulfilling the role of both an expert advisor and critical friend.

More specifically, the NUSCoRG will, for example:

- reach informed decisions about what should be included in the publication and make recommendations where appropriate
- identify key sources of information that will support and enhance the development process
- identify key contacts that will be able to assist in meeting the objectives of the project
- provide the NHS FASP Projects Officer and Project Lead with advice and guidance on key aspects of the ultrasound standards such as:
 - the content and style of the publication
 - proposals to plan the scoping workshops
 - communication strategy both during and after the project.



Acknowledgements

This work is a synergistic product of many people and on behalf of the National Programme Centre I am grateful to all those people who have contributed to this work.

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I gratefully acknowledge all those who contributed to the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly standards on-line and national stakeholder events (see Acknowledgements (2)) for their valuable feedback to the draft document. Thank you also to the NHS FASP Communications Officer Fran Kennedy and the website officers of the British Maternal and Fetal Medicine Society (BMFMS), Society and College of Radiographers (SCoR) and the Association of Spina Bifida and Hydrocephalus (ASBAH) for their enthusiasm and support in advertising the on-line consultation events.

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Last but not least I would like to extend my thanks to all the members of the National Ultrasound Screening Standards Core Reference Group (NUSCoRG) - Martin, Peter, Tim, Rita, Colin, Alan and Trish - for their dedication, experience, judgement and professionalism in helping me develop this document, which is an up to date reflection of the modern concepts of obstetric sonography.



Policy statement

The UK National Screening Committee (NSC) policy on fetal anomaly screening in pregnancy

More Information

Around 700,000 women get pregnant in the UK every year. Over 95% of these pregnancies result in the birth of a healthy baby. However, in a few cases, there are problems affecting the baby's development. Fetal anomaly screening is a way of assessing whether the unborn baby (fetus) could develop or has developed an abnormality or other condition during pregnancy. The screening tests offered in pregnancy are either ultrasound scans or blood tests or a combination of both

Policy position

All Trusts must ensure that they provide a dating scan, and 18⁺⁰ to 20⁺⁶ weeks fetal anomaly ultrasound scan, in line with NICE and UK National Screening Committee recommendations.

Aims and objectives

NHS Fetal Anomaly Screening Programme

The main objectives of the NHS Fetal Anomaly Screening Programme are to:

1. Ensure access to a uniform screening programme which conforms to an agreed level of quality¹
2. Provide appropriate information for women so that they are able to make an informed choice
3. Offer choices to women about their screening options and pregnancy management
4. Identify serious fetal abnormalities, either incompatible with life or associated with morbidity, allowing women to make reproductive choices
5. Identify certain abnormalities that may benefit from antenatal intervention
6. Identify certain abnormalities that require early intervention following delivery.

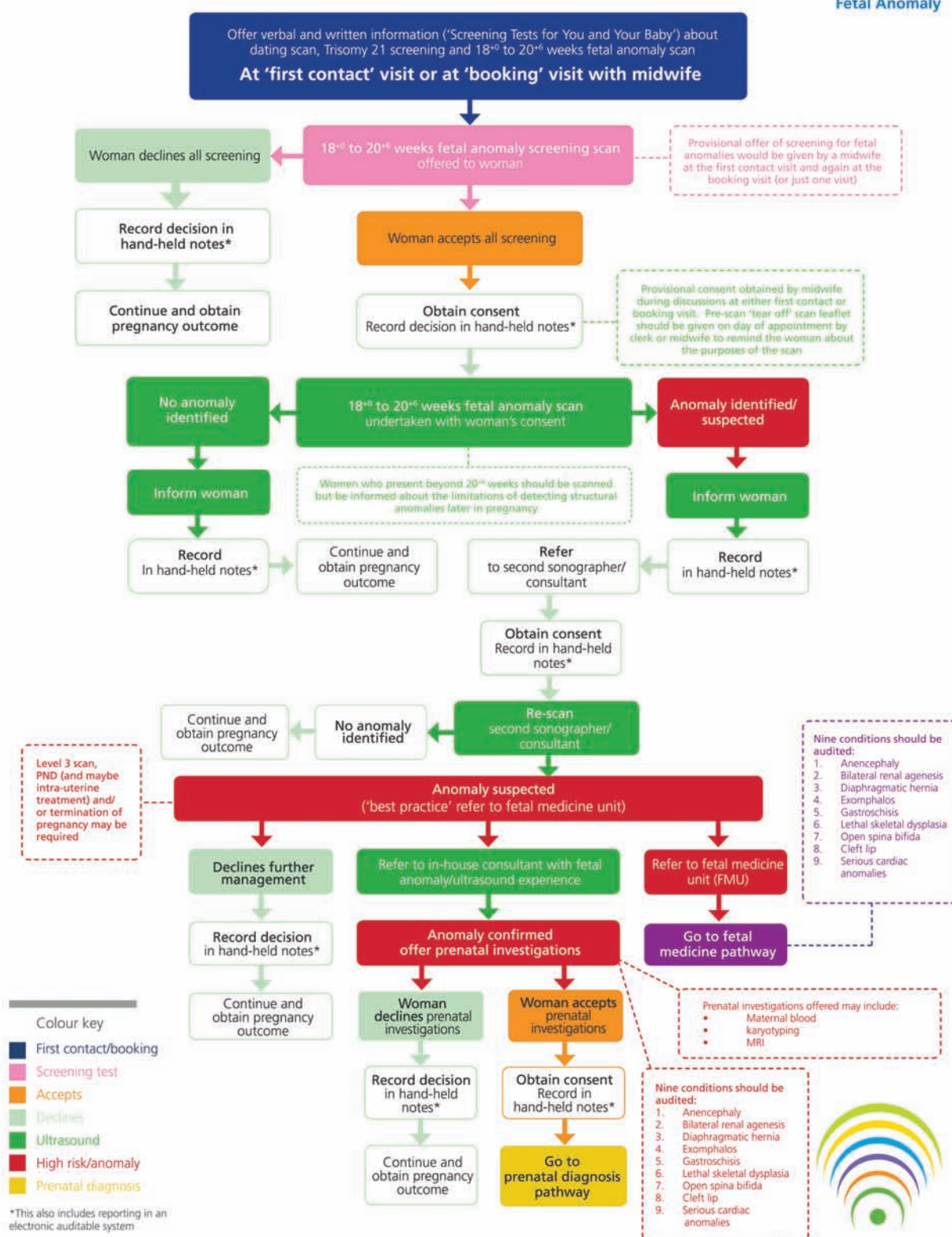
¹ At local level each Primary Care Trust (PCT) is accountable for the performance monitoring of all NHS screening programmes within its geographical footprint. Commissioners and providers of maternity care should ensure that obstetric ultrasound departments have access to high-quality trained staff, specialist equipment and electronic reporting and digital image storage.



Care pathway for fetal anomaly scan

Screening Programmes

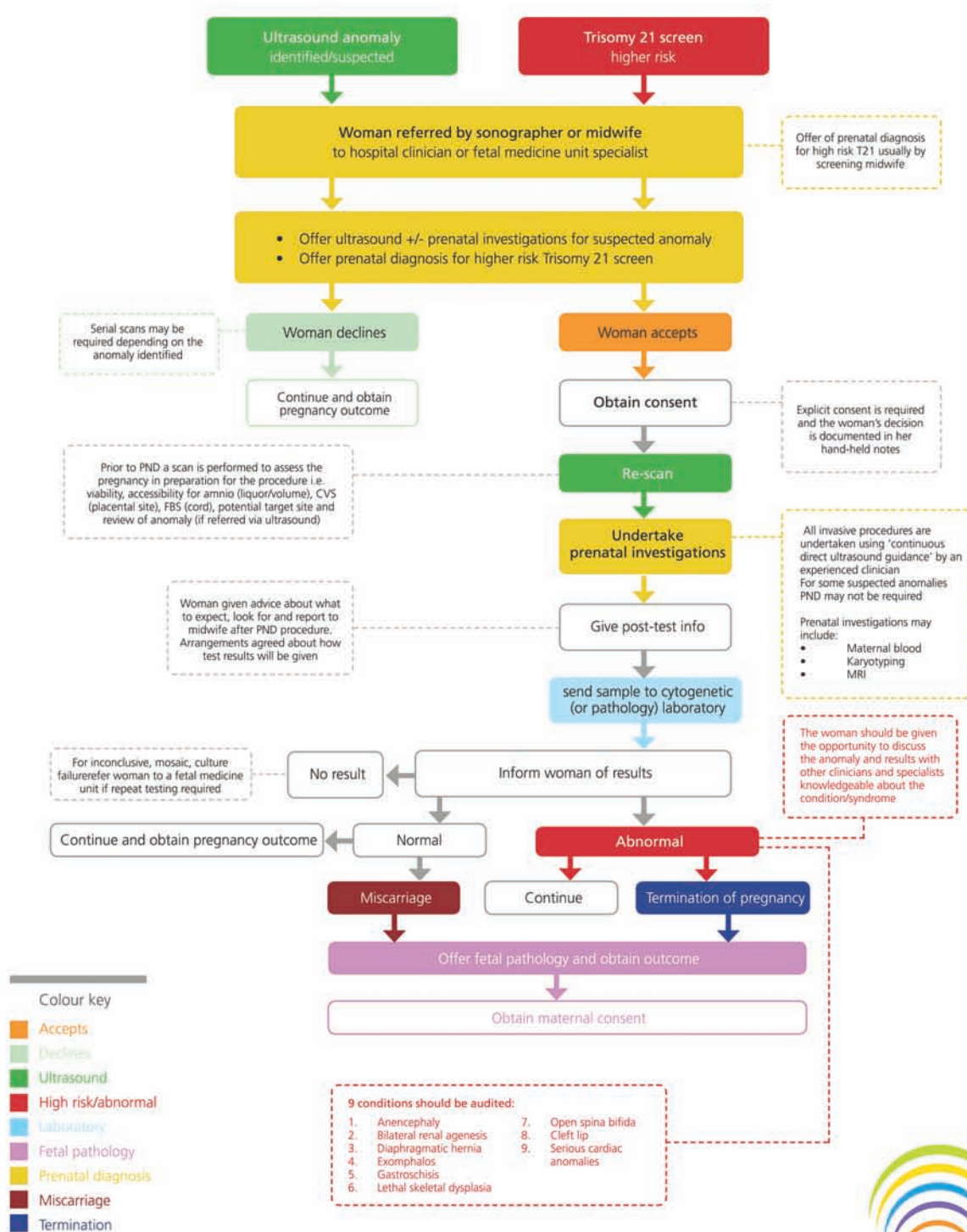
Fetal Anomaly



Care pathway for prenatal investigation

Screening Programmes

Fetal Anomaly



*This also includes reporting in an electronic auditable system



Having an 18⁺⁰ to 20⁺⁶ week mid-pregnancy scan?

Information leaflet (front)





Antenatal and Newborn Screening Programmes

Having an 18-21 week mid-pregnancy scan?

What is the scan for?

- This is a detailed examination that checks for possible physical problems with your baby.
- A scan is offered to all women, but not everyone will choose to have it. Remember, if you decide not to have the scan your choice will be respected.

- The probe sends sound waves through your tummy. The sound waves bounce back off the baby and are translated into an image on the screen.
- During the scan, many sonographers will have the screen in a position that gives them a good view. This helps them concentrate on checking your baby. You will get the chance to see your baby on the screen, either during the scan or when the sonographer has finished the check completely.
- The length of time the scan takes varies, but it is usually about 20 minutes.

Will I need to come back for another scan?

You may be offered a further scan on another day if the sonographer cannot complete all the checks, perhaps because:-

- Your baby is lying in a position which makes it difficult to see everything clearly.
- It is too early in your pregnancy for the scan to be completed.
- You are above-average weight. This makes looking at your baby more difficult because the images are often not as clear.

What will happen when I go in to the scan room?

- You will be introduced to your sonographer (the person who does the scan) when you are called into the scan room.
- If possible, please leave children in the waiting area, supervised by a friend or relative.
- Once in the scan room you will be asked to lie on your back to have the scan with only your tummy uncovered. The lights in the room will be dimmed to give a clear view of the screen.
- Gel is spread on your tummy so that a hand-held probe can be easily passed backwards and forwards over it.

What will happen if a problem is found, or suspected during the scan?

- The sonographer may ask for a second opinion, but the exact nature of the problem might not be clear at this stage.
- You may be offered further tests. You will be helped to choose whether you want to have them or not.



More information on ultrasound can be found in Screening tests for you and your baby (page 32) available from your midwife.



Having an 18⁺⁰ to 20⁺⁶ week mid-pregnancy scan?

Information leaflet (back)

After your scan...

☐ The ultrasound scan showed that your baby appears to be developing normally.

What this ultrasound scan result means

Your baby does appear to be developing normally. As you know, most babies are born healthy and with no physical problems. However, there is a small chance that your may still have a problem that is hard or impossible to see using ultrasound.

☐ The sonographer was not able to complete your scan and you are being offered another appointment.

What this ultrasound scan result means

The sonographer did not get a good view of your baby. This is because:

- ☐ your baby was lying in a position which made it more difficult to look at your baby
- ☐ it is too early in your pregnancy for the scan to be done
- ☐ you are above-average weight and this made looking at your baby more difficult because the images were not as clear

The sonographer will try and complete the scan at one more appointment, but this is not always possible.

More information

You can get more information about ultrasound scans from the "Screening tests for you and your baby" booklet (page 32), from your midwife or your hospital doctor (obstetrician). You can also get more information from the NHS Fetal Anomaly Screening website www.fetalanomaly.screening.nhs.uk



This information is provided by the NHS Fetal Anomaly Screening Programme expanding on text originally conceived by Antenatal Screening Wales.
Reorder information: DoH Publication Orderline 0300 123 1002, reference: ultrasound1
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Standards and Guidance



STANDARD 1

Access to the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly ultrasound scan

Rationale

Early access and engagement with maternity services enables a tailored plan of care to be established before the 12th week of pregnancy to meet the individual health and social care needs of the pregnant woman, as late booking is associated with poorer outcomes.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S1.1	All pregnant women should be offered the 18 ⁺⁰ to 20 ⁺⁶ weeks fetal anomaly scan by a midwife or clinician (at first contact visit and/or booking visit)	100%	100%
S1.2	All local maternity, radiology or ultrasound services should be 'inclusive', offering and providing a fetal anomaly scan with appropriate facilities for women who have learning and/or physical disability	100%	100%
S1.3	The 18 ⁺⁰ to 20 ⁺⁶ weeks fetal anomaly scan should be commissioned so that it is available in all hospital Trusts	100%	100%

Guidelines

- G1.4 The 18⁺⁰ to 20⁺⁶ fetal anomaly screening scan may be provided in a variety of local settings (e.g. poly/satellite clinics within the community) but must conform to the same regulations and standards as those based in an acute Trust setting²
- G1.5 If the anomaly scan is not undertaken for whatever reason (late booking or difficulty in accessing the service), another scan appointment should be arranged for the woman. However, the healthcare professional should inform her that the scan becomes significantly less effective the later it is performed.
- G1.6 Women who wish to have a fetal anomaly ultrasound scan, but who do not wish to be informed if abnormalities are found should be advised that all significant findings seen on the scan will be reported and that therefore they should consider not having ultrasound screening.
- G1.7 All obstetric ultrasound departments should be proactive and flexible in meeting the needs of each pregnant woman, particularly those who are vulnerable and 'hard to reach'.³

² Ultrasound services operating outside an acute Trust (i.e. poly/satellite clinics) must be commissioned appropriately in order to be fit for purpose. Sub-optimal care will result if there is not sufficient capacity (which includes senior staff that are readily available for providing a second opinion for suspected fetal anomaly), high-quality equipment and facilities and defined care pathways for quick referral to acute or tertiary services.

³ There should be provision of translation, interpreting and advocacy services, based on an assessment of the needs of the local population.



STANDARD 2

Governance arrangements

Rationale

The National Programme Centre supports Government policy aimed at improving quality and accountability in the NHS. It is essential that the screening process encompasses a multidisciplinary team approach which guides and promotes a robust service.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S2.1	All hospitals offering obstetric ultrasound should have a Trust Ultrasound Multidisciplinary Screening Group (TUMSG) to oversee the clinical management, governance and quality of the fetal anomaly screening service ⁴	95%	100%
S2.2	All Trusts must provide an annual Ultrasound Screening Service Report to key health professionals within and outside of the Trust screening programme	95%	100%

Guidelines

G2.3 Each TUMSG should set out a comprehensive strategic plan for improving quality in accordance with the Trust's overall service developments which:

- a. oversees the clinical management of the Trust's fetal anomaly screening service
- b. develops policies aimed at managing and reducing clinical risk
- c. ensures that multi-agency arrangements are in place to support women and their partners throughout the screening pathway
- d. contributes to the development and implementation of clinical policy and antenatal screening
- e. adheres to the NHS FASP national standards, policies and other national and professional standards
- f. adheres to the minimum audit criteria of the national programme.
- g. at least annually, reviews and modifies all care pathways to reflect the national programme's changing policies
- h. ensures that arrangements are in place to audit and monitor the screening programme
- i. ensures that the Trust programme is linked to an agreed quality assurance (QA) framework
- j. provides advice and support for staff on antenatal issues to ensure that they are working within a defined framework
- k. links and communicates with the local Primary Care Trust, Director of Public Health, PCT screening lead and PCT commissioner of services
- l. ensures that the relevant Trust directorates support an education and training programme for health professionals involved in ultrasound screening.

⁴ The group should include representatives from all services/departments that are included in the clinical care pathway, the local Primary Care Trust and lay representation. The TUMSG also has a specific role of ensuring that Trust staff comply with standards and reduce clinical risk.



Table 1 Trust Ultrasound Multidisciplinary Screening Group (TUMSG)⁵

Suggested health professional at secondary level	Suggested health professional at tertiary level
1 Sonographer 'lead' for fetal anomaly screening	
2 Lead ultrasound radiologist ^{5a}	
3 Superintendent sonographer	
4 Medical lead for antenatal ultra sound screening services	
5 Screening midwife/coordinator	
6 Antenatal clinical midwifery lead	
7 Community midwifery lead	
8 Obstetric lead for antenatal screening	
9 Clinical lead for cardiac imaging	
10	Fetal medicine specialist
11	Clinical geneticist
12	Genetic counsellor/genetic associate
13 Biochemist 'lead' for Down's syndrome screening	Biochemist 'lead' for Down's syndrome screening
14	Cytogenetics laboratory manager
15	Perinatal pathologist
16 Lay person	
17 General practitioner	
18 PCT screening lead	
19 PCT commissioner	
20 Clinical governance/clinical risk manager	
21	Paediatric lead for antenatal screening
22 Medical physics representative	
23 Service improvement manager ^{5b}	
24 Procurement manager ^{5b}	
25 Finance director or senior finance manager ^{5b}	

⁵ Most of the healthcare professionals listed in Table 1 would also be involved in other antenatal and newborn screening programmes, e.g. Down's syndrome screening, sickle cell and thalassaemia screening and the newborn blood spot screening programme. However, they would not be expected to sit on a local hospital TUMSG at secondary care level. Those listed in the second column are professionals working in tertiary level hospital Trusts that provide specialist services and accept referrals from neighbouring Trusts (e.g. clinical genetics, cytogenetic and molecular genetics and perinatal pathology services). Professionals working in these areas may be invited or choose to attend the local TUMSG meeting. Similarly, representation from the local PCT or community (e.g. lay person or GP) may also be invited to attend.

^{5a} In some areas, a radiologist will also be responsible for obstetric ultrasound if it is situated in the Trust radiology department.

^{5b} Not required for every meeting.



STANDARD 3

Leadership and service provision

Rationale

A dynamic multidisciplinary ultrasound team should be at the heart of every hospital Trust fetal anomaly screening programme, championing and steering the service for women attending during their pregnancy.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S3.1	All Trusts should have key professionals who work together, deputise for each other and work across programmes and directorates.	95%	100%
S3.2	The following professionals should be given the dedicated time necessary to undertake the role required to support the activities relevant to the screening programme:		
	● A lead screening sonographer (LeSSon) and deputy ⁶	80%	100%
	● An antenatal screening midwife/coordinator and deputy	90%	100%
	● An obstetrician(s) and/or radiologists(s) with fetal anomaly experience	90%	100%
	● An individual(s) with administrative/clerical skills	90%	100%
	● A healthcare assistant (HCA).	90%	100%

Guidelines

G3.3 Multidisciplinary, high-quality teamwork is essential. Health professionals should communicate with other health professionals in line with identified care pathways and policies for referral.

⁶ The lead screening sonographer is not the superintendent or manager of an obstetric ultrasound screening service but a distinct and separate role to oversee and coordinate the day-to-day running of the fetal anomaly screening service (e.g. inter-agency working, audit and monitoring, supporting education and training of staff, implementing standards, etc.). The role has similarities to the Trust antenatal screening midwife/coordinator role, which is responsible for leading and supporting all aspects of antenatal screening policy as set out by the UK NSC.



STANDARD 4

Clinical arrangements

Rationale

The NHS FASP supports the Care Quality Commission's (CQC) standard that women should not experience any unnecessary delay at any stage of the screening pathway.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S4.1	Each fetal anomaly scan appointment (duration) should be: ● 30 minutes (singleton pregnancy) ● 45 minutes (multiple pregnancy)	70% 70%	90% 90%
S4.2	All ultrasound scan appointments should include pre-scan counselling, the ultrasound examination, post-scan counselling and reporting.	90%	100%
S4.3	All Trusts must have clear policies and procedures for the communication of normal and abnormal scan results.	95%	100%
S4.4	There should be evidence of structured and accurate records of all obstetric ultrasound scans recorded in any combination of the following: ● Ultrasound clinical information system ● Data entry on an electronic auditable hospital information system ● On an ultrasound request/report form⁷ ● In the woman's maternity hand-held notes ● In the woman's hospital notes.	95%	100%
S4.5	All women should receive written information when a specific anomaly has been diagnosed.	95%	100%
S4.6	All pregnant women should be 'referred' for further examination or treatment if an anomaly is identified or suspected on scan to either an obstetric ultrasound specialist or fetal medicine unit. A report of the ultrasound examination should be communicated to the referring clinician within one working day. ⁸	95%	100%
S4.7	All women with a suspected or confirmed fetal anomaly should be seen by an obstetric ultrasound specialist within 3 working days of the referral being made ⁹	95%	100%
	Or Seen by a fetal medicine unit within 5 working days of the referral being made.	95%	100%

⁷ 'Declined' to be recorded in all formats for the purpose of audit.

⁸ The term 'referral' in this context means informing the obstetric ultrasound specialist or fetal medicine centre about the ultrasound findings.

⁹ The woman may need to be seen sooner than specified at the consultant's discretion. Some anomalies (e.g. fetal hydrops) will require rapid referral.



No.	Standard	Target Minimum (%)	Developmental Target (%)
S4.8	All women should be informed of an inconclusive or abnormal scan finding before they leave the ultrasound examination room.	100%	100%
S4.9	All hospital Trusts should have a suitable and quiet room available where the health professional can explain what has been seen on the ultrasound examination and where any further management (including the need for a further opinion), if necessary, can be discussed with the woman, her partner or another individual if she wishes. ^{10,11 & 12}	90%	100%
S4.10	When delay for referral is unavoidable then this should be explained to the woman by the health professional and recorded in all formats as per S4.4.	100%	100%
S4.11	All women diagnosed as having a fetal abnormality and receiving care from a number of specialists (or agencies) should receive the support and advocacy of a known midwife throughout pregnancy.	100%	100%
S4.12	All women should receive a written/printed report immediately following the scan procedure and, where necessary and wherever possible, information about the type of fetal anomaly identified. ¹³	100%	100%
S4.13	When a significant abnormality has been confirmed by ultrasound examination, all women should be given the time and support they need to decide upon the future of their pregnancy. ¹⁴	100%	100%
S4.14	All women should be able to discuss termination of pregnancy with an appropriate healthcare professional as soon as possible.	100%	100%
S4.15	Information about the termination procedure, including the possibility of feticide, should be explained to all women diagnosed with a fetal anomaly.	100%	100%
S4.16	All women pregnant with a fetal anomaly should be made aware of additional support from agencies such as Antenatal Results and Choices (ARC).	100%	100%
S4.17	Women who decide to continue their pregnancy will require access to a designated midwife to support her for the remainder of her pregnancy and carefully coordinated care.	100%	100%

¹⁰ Beyond one person the number of individuals allowed into the examination room should be in accordance with local Trust hospital policy.

¹¹ Ideally, the location of this room should be within the ultrasound department.

¹² Another individual could be a friend, relative, interpreter or advocate

¹³ The NHS FASP has produced a number of condition-specific information leaflets which can be given to patients who have received a diagnosis. See Appendix 8 'Complementary information'.

¹⁴ In addition to scan findings, ideally results should be obtained from other investigations, e.g. amniocentesis (karyotyping, if performed) prior to offering termination of pregnancy. However, there will be occasions when a fetal anomaly alone will warrant termination and a woman should not be made to wait for test results unless she wants to.



Guidelines

- G4.18 Where community-based obstetric ultrasound services are operational, they should be led by experienced sonographers who can access a second opinion, if necessary, in a timely manner.
- G4.19 When inconclusive or abnormal findings are identified on ultrasound examination, a second sonographer opinion may be required.
- G4.20 If the timelines for referring a woman in S4.7 cannot be met, the woman should be offered a referral elsewhere.
- G4.21 Options for management will need to be discussed with the woman when a fetal abnormality has been diagnosed on scan.
- G4.22 Women should not be hurried into a decision, but termination should be provided without undue delay once it is clear that a firm decision has been made.



STANDARD 5

Pre-scan preparation

Rationale

Overall, the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan should be a special and positive pregnancy experience if the woman is sufficiently prepared beforehand about the purposes, process and potential outcomes.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S5.1	All Trusts must provide pregnant women at 'first contact' with information about the 18 ⁺⁰ to 20 ⁺⁶ weeks fetal anomaly scan. ¹⁵⁺¹⁶	100%	100%
S5.2	The woman's choice to 'accept' or 'decline' the fetal anomaly scan must be clearly recorded in any combination of the following formats: ● Ultrasound clinical information storage system ● Data entry on an electronic auditable hospital information system ● Ultrasound request/report form ● In the woman's hand-held notes ● In the woman's hospital notes.¹⁷	95%	100%
S5.3	All women should be made aware about the purposes, limitations, benefits, risks and consequences of the 18 ⁺⁰ to 20 ⁺⁶ weeks fetal anomaly scan and the implications of normal findings and those that may follow when an abnormality is detected.	100%	100%
S5.4	All Trusts should provide information about the 18 ⁺⁰ to 20 ⁺⁶ weeks fetal anomaly scan in different formats as communication must be available in a form that is accessible to those pregnant women who have additional needs (i.e. physical, cognitive or sensory impairment). ¹⁸	100%	100%
S5.5	All maternity care providers should discuss the fetal anomaly scan as an 'option' rather than an inevitable aspect of routine antenatal care if the process of consent is to be meaningful. ¹⁹	100%	100%
S5.6	If the woman's first language is not English, a trained interpreter should be present. Arrangements for an interpreter should be made in advance, at the time of booking the fetal anomaly screening scan appointment. Interpretation should not be provided solely by a family member or friend.	100%	100%

Guidelines

G5.7 All maternity care providers should ensure that when a woman requests or declines screening her decision is acknowledged and respected and recorded to avoid repetition.

¹⁵ In some areas the first contact visit and the booking visit are just one appointment.

¹⁶ In line with the NICE Antenatal Care Guidelines (2008), all women should receive the UK NSC parent information booklets. Having a Mid-Pregnancy Ultrasound Scan and Screening Tests for You and Your Baby, as they explain the purposes and implications of the 18⁺⁰ to 20⁺⁶ fetal anomaly screening scan. For the purposes of informed consent, women should have information about the ultrasound scan at least 24 hours before the procedure.

¹⁷ Health professionals should record 'declined' on the ultrasound scan request form and all other formats.

¹⁸ The NHS FASP has produced a range of information leaflets available on their website.

¹⁹ Adapted from the NHS Fetal Anomaly Screening Programme document, 'Consent standards for screening fetal anomalies during pregnancy' (2007).



STANDARD 6

The 18⁺⁰ to 20⁺⁶ weeks fetal anomaly screening scan

Rationale

The 18⁺⁰ to 20⁺⁶ weeks 'ultrasound scan base menu' has been devised to provide consistency in the ultrasound procedure in terms of specifying techniques to be used to obtain fetal measurements and defining what anatomical structures should be assessed by professionals during the examination.

No.	Standard	Minimum (%)	Target Developmental (%)
S6.1	The fetal anatomy to be checked during the scan will be against the: ● Ultrasound scan base menu (see Appendix 1)²⁰ ● Fetal Cardiac Protocol (see Appendix 3).²¹	95% 50%	100% 75%
S6.2	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: ²² ● Ultrasound clinical information storage system ● Auditable electronic hospital information system ● Ultrasound request/report form ● In the woman's hand-held notes.	90%	95%
S6.3	All women should be offered a single further scan at 23 weeks of pregnancy to complete the screening examination if 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.	100%	100%
S6.4	Where an adequate assessment of the fetal anatomy remains compromised after the second scan, all women should be told that the screening is incomplete and this should be recorded in all formats.	100%	100%
S6.5	Where the first examination is sub-optimal and the sonographer is suspicious of a possible fetal abnormality, a second opinion should be sought as soon as possible. This should be recorded in all mentioned formats.	100%	100%

²⁰ This menu is the minimum assessment that should be undertaken.

²¹ This menu is the minimum assessment that should be undertaken.

²² The images required are:

1. head circumference demonstrating HC measurement and measurement of the atrium of the lateral ventricle
2. suboccipito-bregmatic 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



Guidelines

- G6.6 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) has been previously assigned in line with nationally approved charts and tables.²³
- G6.7 If the EDD has not been previously assigned the pregnancy should be dated by HC or FL.

²³ Loughna P, Chitty L, Evans T and Chudleigh T 'Fetal size and dating: charts recommended for clinical obstetric practice' *Ultrasound* 2008; 17(3): 160-166.



STANDARD 7

Image capture, storage and archiving

Rationale

Dramatic improvements in image technology have resulted in efficient ways of archiving and storing ultrasound images and reports for the purposes of providing information for women, evaluating practice through audit and monitoring and holding evidence for legal requirements.

No.	Standard	Minimum (%)	Target Developmental (%)
S7.1	Ultrasound images should be captured, stored and archived on an electronic reporting system.	85%	90%
S7.2	There should be a permanent electronic record of all imaging studies.	90%	100%
S7.3	All imaging studies should be accompanied by an electronic report available with the images.	90%	100%
S7.4	Every Trust obstetric ultrasound service should be able to upload ultrasound scan reports and images on an auditable electronic hospital reporting system in order to provide minimum audit data. ²⁴	90%	100%
S7.5	All required images should be captured, stored and archived for the purposes of a complete maternal record and to fulfil medico-legal requirements ²⁵ (see Appendix 2 and Appendix 4).	90%	100%

Guidelines

- G7.6 Maternity care providers and commissioners should make sure that sufficient clerical support, appropriate information technology (IT), equipment and software are available and that linkage is made with other data collection systems across other hospital Trust areas/departments.

²⁴ The system should be able to interface with the Trust's hospital information system, linked across all department/service areas (ideally including Congenital Anomaly Registers for the purposes of obtaining outcome data).

²⁵ Annex D1: Health Records Retention Schedule DH (2006). Reports are required for legal purposes, not necessarily scan images.

STANDARD 8

Evaluating the performance of the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan

Rationale

A high standard of collaborative reporting between the ultrasound, biochemistry, cytogenetic, paediatric and perinatal pathology services is an essential element of the fetal anomaly screening service.

No.	Standard	Minimum (%)	Target Developmental (%)
S8.1	All confirmed prenatal and postnatal fetal anomalies should be recorded in any combination of the following formats: ● Ultrasound clinical information storage system ● Data entry on an electronic auditable hospital information system ● On the ultrasound request form²⁶ ● In the woman's maternity hand-held notes ● In the woman's hospital notes ● Informing where appropriate the regional Congenital Anomaly Registers (CAR).²⁷	95%	100%
S8.2	All hospital Trusts on an annual basis should provide (as a minimum) the screen positive rate (SPR) and detection rates (DR) for the 11 conditions listed in Appendix 9. ²⁸	85%	90%
S8.3	All ultrasound scan findings proved to be normal should be kept on a database in line with the NHS Data Protection Act. ²⁹	95%	100%
S8.4	All hospital Trusts should follow a clear mechanism for managing clinical incidents relating to the fetal anomaly scan (this includes learning from the investigations, communication and, where necessary, implementing changes to existing systems, providing training and ensuring safe staffing levels).	100%	100%
S8.5	All clinical incidents should be communicated to the National Patient Safety Agency (NPSA) in line with their guidance.	95%	100%
S8.6	All hospital Trusts should have a comments and complaints procedure in place to enable pregnant women to express their views of their ultrasound experience.	95%	100%

²⁶ The Programme Centre advocates that health professionals write 'declined' on the ultrasound scan request form and in the maternity hand-held notes.

²⁷ Not all areas will have a Congenital Anomaly Register (CAR), but for those that do, it will be useful for collating fetal anomaly detection rates for the purpose of evaluating local and regional screening performance. Referral rates to tertiary centres - this gives two types of information: (a) about the ability of peripheral units to detect anomalies and (b) to determine whether hospital Trusts are referring an excessive number of cases which, when reviewed, are found to be 'normal'.

²⁸ This is the number of observed suspected or unexplained anomalies which are later confirmed as positive either by karyotyping or after delivery (therapeutic termination of pregnancy, stillbirth or miscarriage). Areas with Congenital Anomaly Registers (CAR) able to provide outcome data should be utilised.

²⁹ Department of Health 'Data Protection Act 1998' HSC 2000/009. DH, London, March 2000.



Guidelines

G8.7 A multidisciplinary approach should be adopted when auditing and monitoring the screening programme.³⁰



³⁰ Key professionals should collate and share data regularly in order to understand the performance of the ultrasound screening programme (i.e. ultrasound department, biochemistry and cytogenetic laboratory services).

STANDARD 9

Training and professional competence

Rationale

It is essential that healthcare professionals offering and providing fetal anomaly screening develop their knowledge and skills so that collectively as a team they can sustain and spread best practice, but more importantly be able to competently deliver difficult news to pregnant women after confirmation of an anomaly and be confident in dealing with their distress. The practice of ultrasound is a clinical skill that must be governed by professional standards equivalent to those issued by the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and Health Professions Council (HPC).

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S9.1	All ultrasound practitioners must hold minimum certification as specified by the NHS FASP in Appendix 6.	100%	100%
S9.2	All Trusts should provide multidisciplinary education and training programmes for health professionals involved in obstetric ultrasound and antenatal screening. ³¹	95%	100%
S9.3	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.	100%	100%
S9.4	All practitioners undertaking ultrasound screening should be funded by their hospital Trust to attend relevant continuous professional development (CPD) events.	90%	100%
S9.5	A performance development review (PDR) should be undertaken for each health professional involved in obstetric ultrasound once a year.	100%	100%

Guidelines

G9.6 All practitioners should ensure that their frequency of practice affords the maintenance of skill levels.

³¹ The programme should fulfil the requirements of the annual performance development review (PDR), ongoing continuous professional development (CPD) and induction programme to the ultrasound department.



STANDARD 10

Safety of ultrasound

Rationale

The safe use of ultrasound is of paramount importance and practitioners should be aware of, and adhere to, agreed national safety standards.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S10.1	All ultrasound practitioners should use a height-adjustable seat, height-adjustable couch, variable lighting and ergonomic reporting facilities when undertaking an obstetric ultrasound examination.	100%	100%
S10.2	Policies in relation to preventing and controlling the risks of healthcare-associated infections must be in place and include:		
	● Disinfection policy ● Uniform and work-wear policy.³²	100% 100%	100% 100%
S10.3	Each hospital Trust ultrasound department providing the 18 ⁺⁰ to 20 ⁺⁶ fetal anomaly scan should carry out a health and safety risk assessment at least once a year in line with their local Trust policy. ³³	100%	100%
S10.4	All hospital Trust ultrasound departments should ensure that electrical safety testing is performed at least once a year on all ultrasound equipment. In addition, regular maintenance and quality assurance testing to specified levels should also be carried out by qualified personnel in line with the manufacturer's instructions.	100%	100%
S10.5	Maintenance contracts which include emergency service cover must be agreed and in place.	100%	100%
S10.6	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) equipment and professional practice standards including the National Occupational Standards (NOS) as set out in the Skills for Health (SfH) framework ^{34 35 36}	95%	100%
S10.7	All health professionals should adhere to the British Medical Ultrasound Society (BMUS) recommended scanning time limits for obstetric scanning (see appendix 11) ³⁷	95%	100%

³² Guidance should be sought from the local hospital Trust policy

³³ Not all obstetric ultrasound services are based in standalone ultrasound departments; some are sited in fetal medicine or more usually in general radiology services.

³⁴ Royal College of Radiologists. Standards for Ultrasound Equipment. RCR, London, 2005.

³⁵ Society and College of Radiographers Industry Standards/or the Prevention of Work related Musculoskeletal Disorders in Sonography. RCR, London, 2003.

³⁶ National Occupational Standards and National Workforce Competences: As developed by Skills for Health, the Sector Skills Council for Health and collated by the NHS Fetal Anomaly Screening Programme, UK NSC, London, March 2009.

³⁷ British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment 2009 BMUS <http://www.bmus.org/policies-guides/BMUS-Safety-Guidelines-2009-revision-FINAL-Nov-2009.pdf>



Guidelines

- G10.8 The ALARA (as low as reasonably achievable) principle should always be applied when undertaking an ultrasound scan.³⁸
- G10.9 The room temperature of the ultrasound scan room should be maintained at a comfortable level, usually by air conditioning, and this should be adjusted according to the number of heat-generating units.
- G10.10 When designing ultrasound departments hospital Trusts should give due consideration to the floor area in relation to the potential use of the room (e.g. bed, walking, machine, cables), thereby allowing the woman and healthcare professional to move around safely.

³⁸ Society and College of Radiographers. *Industry Standards for the Prevention of Work related Musculoskeletal Disorders in Sonography*. RCR, London, 2003.



STANDARD 11

Purchasing ultrasound equipment

Rationale

Ultrasound equipment should be 'fit for purpose' and purchased in line with the NHS FASP and NHS Purchasing and Supply Agency (PASA) procurement list and any other national guidance.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S11.1	All ultrasound equipment should be assessed and evaluated in line with the recommendations set out by the RCR. ³⁹	100%	100%
S11.2	Each hospital Trust ultrasound department should purchase ultrasound equipment in line with recommendations from the NHS Supply Chain and equipment must conform to HEI 98 Regulations. ⁴⁰	100%	100%
S11.3	All hospital Trust ultrasound departments should have a robust policy to provide prompt and accurate ultrasound services for/within the whole healthcare economy.	90%	100%
S11.4	All hospital Trust ultrasound departments, prior to purchasing ultrasound equipment, should take into account the prospective location, available space and need for portability. ⁴¹	100%	100%
S11.5	A trial of equipment should be carried out in the ultrasound department to ensure that the product for purchase or lease is fit for purpose. Ultrasound machinery purchased 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 (i.e. 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.	100%	100%

³⁹ Board of the Faculty of Clinical Radiology, The Royal College of Radiologists. *Standards for Ultrasound Equipment*. RCR, London, February 2005.

⁴⁰ Health Equipment Information HE1 98. *Management of Medical Equipment Devices*. Medicines and Healthcare Products Regulatory Agency (MHRA), 1998.

⁴¹ Adapted with kind permission from Department of Health, *Ultrasound Clinical Governance*, October 2008.

Guidelines

G11.6 Each Trust should develop criteria for evaluation of bids for ultrasound equipment based on:

- a. clinical need
- b. estimated intensity of use
- c. need for equipment availability in an emergency
- d. the availability of skilled operators within the proposed clinical area
- e. availability of existing similar equipment which could be shared
- f. cost of maintenance
- g. an equipment replacement programme.⁴²

⁴² Adapted with kind permission from Department of Health, Ultrasound Clinical Governance, October 2008.
<http://www.18weeks.nhs.uk/Content.aspx?path=/achieve-and-sustain/Diagnostics/Imaging/#f53923>



STANDARD 12

Independent sector

Rationale

Obstetric ultrasound scanning cited within the Independent Health Care Sector should be registered with the Care Quality Commission (CQC) and adhere to the policies and standards set out by the NHS FASP.

No.	Standard	Target	
		Minimum (%)	Developmental (%)
S12.1	Independent sector services offering ultrasound screening must comply and participate with the standards, policies and quality assurance mechanisms set by the following bodies: ● Statutory Instruments (2001) No. 3968 Public Health England – ‘The Private and Voluntary Health (England) Regulations 2001’ ● Department of Health (2001) ‘Independent Health Care: National Minimum Standards - Regulations - Care Standards Act 2000’ ● UK National Screening Committee ● Society and College of Radiographers ● Royal College of Radiologists ● Royal College of Obstetricians and Gynaecologists ● Standing Joint Committee: Education Board of the RCOG and the RCR Council ● Care Quality Commission.	100%	100%
S12.2	All independent sector services must have in place antenatal screening policies and procedures as well as clinical care pathways for the purposes of referring women for NHS ultrasound and diagnostic services. All policies should be developed and agreed with the local acute Trust.	90%	100%
S12.3	A specific policy for the management of cases of fetal abnormalities must be in place.	100%	100%
S12.4	The woman, her GP and the midwife and consultant obstetrician under whom the woman has booked should all be made aware in writing of the ultrasound diagnosis and proposed plan of care.	100%	100%
S12.5	All independent sector services should be able to provide an annual fetal anomaly screening report to the CQC. ⁴³	90%	100%



⁴³ Independent private sector services do have to provide an annual report to either the local PCT or hospital Trust.

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British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment November 2009. BMUS <http://bmus.org>

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National consultations – contributors

Stakeholder organisations

Antenatal Results and Choices (ARC)

Association of Congenital Diaphragmatic Hernia Research, Advocacy and Support (CHERUBS)

Association for Spina Bifida and Hydrocephalus (ASBAH)

British Medical Ultrasound Society (BMUS)

British Maternal & Fetal Medicine Society (BMFMS)

Cleft Lip and Palate Association (CLAPA)

Department of Health (DH)

Fetal Medicine Foundation (FMF)

Royal College of Obstetricians and Gynaecologists (RCOG)

Society and College of Radiographers (SCoR)

Tiny Tickers (TT)



National Ultrasound Standards Workshop Event December 2008

Antenatal Screening Wales
Barts and the London NHS Trust
Basildon and Thurrock University Hospitals NHS Foundation Trust
Brighton and Sussex University Hospitals NHS Trust
Cambridge University Hospitals NHS Foundation Trust
Chelsea and Westminster Hospital NHS Foundation Trust
Gloucestershire Hospitals NHS Foundation Trust
City University London
Colchester Hospital University NHS Foundation Trust
Derby Hospitals NHS Foundation Trust
East Midlands Region - Leicestershire County and Rutland Primary Care Trust
East Sussex Hospitals NHS Trust
Frimley Park Hospital NHS Foundation Trust
Guy's and St. Thomas' NHS Foundation Trust
Heart of England NHS Foundation Trust
Heatherwood and Wexham Park Hospitals NHS Foundation Trust
The Hillingdon Hospital NHS Trust
Imperial College Healthcare NHS Trust
The Ipswich Hospital NHS Trust
Kingston Hospital NHS Trust
Liverpool Women's NHS Foundation Trust
London South Bank University
Luton and Dunstable NHS Foundation Trust
Maidstone and Tunbridge Wells NHS Trust
Newham University Hospital NHS Trust



National Ultrasound Standards Workshop Event December 2008

NHS National Services Scotland
The North West London Hospitals NHS Trust
Peterborough and Stamford Hospitals NHS Foundation Trust
Plymouth Hospitals NHS Trust
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Royal Devon and Exeter NHS Foundation Trust
Royal Free Hampstead NHS Trust
St. George's Healthcare NHS Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Sherwood Forest Hospitals NHS Foundation Trust
The Shrewsbury and Telford Hospital NHS Trust
Society and College of Radiographers, London
South London Healthcare NHS Trust
South West Region - South West Public Health Observatory
Southampton University Hospitals NHS Trust
Southend University Hospital NHS Foundation Trust
Surrey and Sussex Healthcare NHS Trust
The Leeds Teaching Hospitals NHS Trust
University Hospitals of Leicester NHS Trust
Teesside University, Middlesbrough
Warrington and Halton Hospitals NHS Foundation Trust
West Hertfordshire Hospitals NHS Trust
West Middlesex University Hospital NHS Trust
West Midlands Perinatal Institute, Birmingham



National Stakeholder Consultation April 2009

Association of Congenital Diaphragmatic Hernia Research,
Advocacy and Support (CHERUBS)

Barking, Havering and Redbridge University Hospitals NHS Trust

Barnet and Chase Farm Hospitals NHS Trust

Barnsley Hospital NHS Foundation Trust

Barts and the London NHS Trust

Basildon and Thurrock University Hospitals NHS Foundation Trust

Birmingham Women's NHS Foundation Trust

Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust

Burton Hospitals NHS Foundation Trust

Cambridge University Hospitals NHS Foundation Trust

City Hospitals Sunderland NHS Foundation Trust

City University London

Cleft Lip and Palate Association (CLAPA)

Colchester Hospital University NHS Foundation Trust

Department of Health, Social Services and Public Safety - Northern Ireland

Derby Hospitals NHS Foundation Trust

Down's Syndrome Screening Quality Assurance Support Service - Plymouth

East and North Hertfordshire NHS Trust

East Lancashire Hospitals NHS Trust

East Midlands Region - Leicestershire County and Rutland Primary Care Trust

The Hillingdon Hospital NHS Trust

Imperial College Healthcare NHS Trust

London Region - Westminster Primary Care Trust

Luton and Dunstable NHS Foundation Trust



National Stakeholder Consultation April 2009

The Mid Yorkshire Hospitals NHS Trust
NHS Birmingham East & North
Noble's Hospital, Isle of Man
The North West London Hospitals NHS Trust
Nottinghamshire County Teaching Primary Care Trust
Nottingham University Hospitals NHS Trust
The Princess Alexandra Hospital NHS Trust
Public Health - NHS Yorkshire and the Humber
Public Health Wales NHS Trust (previously Velindre NHS Trust)
Royal College of Obstetricians and Gynaecologists, London
Royal College of Radiologists, London
St. George's Healthcare NHS Trust
Salford Royal NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Sherwood Forest Hospitals NHS Foundation Trust
The Shrewsbury and Telford Hospital NHS Trust
Society and College of Radiographers, London
South Warwickshire General Hospitals NHS Trust
Southampton University Hospitals NHS Trust
Taunton & Somerset NHS Foundation Trust
University College London Hospitals NHS Foundation Trust
University Hospitals of Leicester NHS Trust
West Midlands Congenital Anomaly Register/West Midlands Regional Ultrasound Group
Worcestershire Acute Hospitals NHS Trust



Ultrasound Soft Marker Screening Consensus Event June 2009

Antenatal Screening Wales

Barts and the London NHS Trust

Buckinghamshire Hospitals NHS Trust

Calderdale and Huddersfield NHS Foundation Trust

Cambridge University Hospitals NHS Foundation Trust

Cardiff University, Cardiff, Wales

Central and South region - South Central SHA

Department of Health - 133-155 Wellington House, London

Department of Health, Social Services and Public Safety - Northern Ireland

Derby Hospitals NHS Foundation Trust

Guy's and St Thomas' NHS Foundation Trust

Hereford Hospitals NHS Trust

The Hillingdon Hospital NHS Trust

The Ipswich Hospital NHS Trust

Liverpool Women's NHS Foundation Trust

Luton and Dunstable NHS Foundation Trust

Mid Essex Hospital Services NHS Trust

The Newcastle upon Tyne Hospitals NHS Foundation Trust

NHS Fife, Scotland

NHS Grampian, Scotland

NHS National Services Scotland



Ultrasound Soft Marker Screening Consensus Event June 2009

Norfolk and Norwich University Hospitals NHS Foundation Trust

The North West London Hospitals NHS Trust

Northampton General Hospital NHS Trust

Nottingham University Hospitals NHS Trust

Peterborough and Stamford Hospitals NHS Foundation Trust

Plymouth Hospitals NHS Trust

Royal Free Hampstead NHS Trust

Society of Radiographers. London

South London Healthcare NHS Trust

South Tees Hospitals NHS Foundation Trust

Southampton University Hospitals NHS Trust

Surrey and Sussex Healthcare NHS Trust

The Leeds Teaching Hospitals NHS Trust

University College of London Institute of Child Health

University Hospitals Bristol NHS Foundation Trust

University Hospitals of Leicester NHS Trust

University of the West of England, Bristol

Yeovil District Hospital NHS Foundation Trust

York Hospitals NHS Foundation Trust

West Hertfordshire Hospitals NHS Trust

West Suffolk Hospital NHS Trust



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Abbreviations used in this document

AC	abdominal circumference
ALARA	as low as reasonably achievable
ANC	antenatal care
ARC	Antenatal Results and Choices
ASBAH	Association of Spina Bifida and Hydrocephalus
ATSM	Advanced Training Specialty Module in Fetal Medicine
AV	atrioventricular
BMFMS	British Maternal and Fetal Medicine Society
BMI	body mass index
BPD	biparietal diameter
CAR	Congenital Anomaly Register
CASE	Consortium for the Accreditation of Sonographic Education
CHD	congenital heart disease
CMU	Certificate in Medical Ultrasound
CPD	continuous professional development
CRL	crown rump length
CQC	Care Quality Commission
DH	Department of Health
DPH	Director of Public Health
DMU	Diploma in Medical Ultrasound
DQASS	Down's Syndrome Screening Quality Assurance Support Service
DR	detection rate
EDD	expected date of delivery
FASP	Fetal Anomaly Screening Programme
FL	femur length
GA	gestation age
GP	general practitioner
HEI	Health Effects Institute
HC	head circumference
HCA	healthcare assistant
HCG	human chorionic gonadotrophin
HPC	Health Professions Council
IT	information technology



LVOT	left ventricular outflow tract
LA	left atria
LV	left ventricle
LMP	last menstrual period
NHS PASA	NHS Purchasing and Supply Agency
NMC	Nursing and Midwifery Council
NOS	National Occupational Standards
NPSA	National Patient Safety Agency
NT	Nuchal translucency
NUSCoRG	National Ultrasound Screening Standards Core Reference Group
PA	pulmonary artery
PAPP-A	plasma-associated plasma protein A
PCT	Primary Care Trust
PGCert.MU	Post Graduate Certificate in Medical Ultrasound
PDR	performance development review
QA	quality assurance
RA	right atria
RCOG	Royal College of Obstetricians and Gynaecologists
RCR	Royal College of Radiologists
RIS	Radiology Information System
RV	right ventricle
RVOT	right ventricular outflow tract
SCoR	Society and College of Radiographers
SfH	Skills for Health
SPR	screen positive rate
SVC	superior vena cava
TCD	transcerebellar diameter
3VV	three-vessel view
TUMSG	Trust Ultrasound Multidisciplinary Screening Group
US	ultrasound
UKAS	United Kingdom Association of Sonographers
UK NSC	UK National Screening Committee



Glossary of terms

Advocate

An individual who acts independently on behalf of, and in the interests of, patients/users who may feel unable to represent themselves in their contacts with a healthcare or other facility.

ALARA principle

ALARA is an acronym formed from the phrase 'As Low as Reasonably Achievable'. The principle requires that ultrasound exposure be kept as low as reasonably achievable, economic and social factors being taken into account.

Antenatal care

Professional care provided to a woman and her partner to support them and their baby through the pathway of pregnancy and to help achieve the best possible health, psychological and social outcomes for the mother, baby and family.

Anomaly scan

A detailed scan offered to pregnant women by all hospital Trusts, and undertaken between 18 weeks ⁺⁰ days and 20 weeks ⁺⁶ days, for the purpose of assessing the fetal anatomy for malformations.

Booking visit

The visit/consultation at which the woman receives information about her pregnancy care and is registered for care with her midwife and/or hospital/unit for delivery.

Care pathway

Care pathways (also known as clinical pathways, integrated care pathways and various other terms) basically describe the route that a patient will take from their first contact with an NHS member of staff to the completion of their treatment

Care Quality Commission (CQC)

The body that regulates and inspects providers of health and adult social care in both the public and independent sectors in England. It replaced the Healthcare Commission (HCC), Mental Health Act Commission and the Commission for Social Care Inspection in April 2009.

Congenital Anomaly Register (CAR)

A centralised regional disease-specific register or database that provides continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies for the local population.

Counselling

For the purpose of this document, 'counselling' is defined broadly as supportive, listening, advice giving and information giving. It is facilitative, non-directive and/or relationship focused, with the content of sessions largely determined by the pregnant woman.

Cytogenetics

The study of the chromosomes. Clinical cytogenetics is the study of the relationship between chromosome aberrations and disease.

Detection rate (DR)

The proportion of fetuses affected by a condition which will be identified by a screening test or combination of screening tests.



Diagnostic test

A test that aims to give a definite answer about diagnosis. Screening tests are not usually diagnostic

Disability

A physical or mental impairment which has a substantial and long-term adverse effect on a person's ability to perform day to day activities.

Down's Syndrome Screening Quality Assurance Screening Service (DQASS)

DQASS was formed in April 2006 to improve screening services in England. It now also provides support to Scotland, Wales and has international links with screening programmes in the United States, Canada and Europe. All providers of prenatal screening in the UK are mandated to submit data on a biannual basis to DQASS, which maintains the national database of all prenatal screening tests carried out in the UK. DQASS works with screening service providers, with suppliers of devices and reagents and with the NSC to improve the safety and efficacy of prenatal screening.

Fetal echocardiography

This is used to screen the developing fetal heart and great vessels using ultrasound for major congenital heart disease during the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan.

Feticide

Feticide is a method of terminating a pregnancy to prevent the risk of the fetus being born alive. The RCOG recommends that the procedure, which involves injecting potassium chloride into the fetal heart under direct ultrasound guidance, is performed prior to induction of labour in termination of pregnancy for fetal anomaly when the gestation is more than 21 weeks and 6 days.

Fetal medicine unit (FMU)

A unit consisting of obstetricians trained in fetal medicine and specialist midwives who provide a referral service for the local population and a tertiary level service for women with a previous history of maternal or fetal conditions or who require fetal medicine intervention because of issues in their pregnancy.

First contact

The initial appointment where the woman with a confirmed pregnancy first meets the healthcare professional. This appointment includes referral into the maternity care pathway and is an opportunity for information giving to ensure the woman is able to make informed decisions about her pregnancy care, including all antenatal screening. It also provides an opportunity to raise awareness about health-related issues that are particularly relevant in early pregnancy.

Gestational age (GA)

The duration of an on-going or completed pregnancy, calculated either from the first day of the last menstrual period (LMP) or by ultrasound which is more accurate. Gestational age is usually measured in completed weeks and days. The expected date of delivery (EDD) is calculated as 40 weeks from the LMP.



Healthcare assistants

Assistants who work within hospital or community settings under the guidance of a qualified healthcare professional. The role can be very varied depending upon the area in which the person is employed.

HEI 98

The Health Effects Institute (HEI) is an organisation that oversees the safety standards of medical equipment. Directive no. 98 refers to the use of maternity ultrasound equipment for screening examination purposes.

Independent sector

The sector managed and owned by private companies. It has been established in the secondary care market and increasingly provides NHS services, either through free choice or through winning contracts to provide specific services via commissioning.

Karyotype

An individual's full chromosome complement.

Late booker

A woman who meets the healthcare professional with a confirmed pregnancy of more than 20 weeks gestation.

Lead screening sonographer (LeSSon)

A sonographer qualified in obstetric ultrasound and with additional knowledge, skills, experience and responsibility for overseeing and coordinating a fetal anomaly screening service at Trust level.

Midwife

A person who, having been regularly admitted to a midwifery educational programme that is duly recognised in the country in which it is located, has successfully completed the prescribed course of studies in midwifery and has acquired the requisite qualifications to be registered and/or legally licensed to practice midwifery. The educational programme may be an apprenticeship, a formal university programme or a combination. The midwife is recognised as a responsible and accountable professional who works in partnership with women to give the necessary support, care and advice during pregnancy, labour and the postpartum period, to conduct births on the midwife's own responsibility and to provide care for the infant.

Obstetrician

A qualified doctor who has successfully completed specialised training in the management of pregnancy, labour and postnatal care. He or she will also be trained in ultrasound to a varying degree.

Obstetric specialist

An obstetrician with an obstetric interest with a regional or subregional referral practice and involvement in subspecialist or special skills training.



Polyclinic or satellite clinic

A place where a wide range of healthcare services (including diagnostics) can be obtained without the need for an overnight stay. Polyclinics are sometimes co-located with a hospital or may be located in another locality entirely.

Prenatal diagnosis

A variety of invasive tests (biopsies) used in pregnancy to determine the chromosomal or genetic constitution of the fetus.

Screening midwife/coordinator

A qualified midwife with additional knowledge, skills, experience and responsibility for overseeing and coordinating an antenatal screening service at Trust level.

Screening

For the purpose of this document screening is a public health service which provides a systematic application of a test or inquiry (obstetric ultrasound), to identify those individuals (fetuses) at sufficient risk of a specific disorder (anomaly) which will benefit from further investigation (invasive test such as amniocentesis) or from direct preventative action (in utero treatment).

Screening programme

A whole system of activities needed to deliver high-quality screening.

Soft markers

Transient changes seen within the fetus which may indicate an added risk of a number of conditions, such as karyotypic abnormalities or conditions such as cystic fibrosis.

Sonographer

A healthcare professional qualified in ultrasound who carries out ultrasound examinations. An obstetric sonographer has the knowledge, skills, experience and responsibility for performing the ultrasound examinations for the antenatal screening service of the Trust.

Standard

A subjective judgement of a level of performance that could be achieved. Different levels of quality standard can be set.

Therapeutic termination of pregnancy

A planned medical abortion. The expulsion or extraction from the uterus of an affected fetus.

Ultrasound scan

A picture of part of the inside of the body using sound waves of a frequency above the audible range of the human ear. A small hand-held sensor, which is pressed carefully against the skin surface, both generates sound waves and detects any echoes reflected back from the surfaces and tissue boundaries of internal organs. The sensor can be moved over the skin to view the organ from different angles, the pictures being displayed on a screen and recorded for subsequent study.



Appendices



Appendix 1 – 18⁺⁰ to 20⁺⁶ weeks fetal anomaly ultrasound scan base menu

Ultrasound scanning in the second trimester of pregnancy to detect structural abnormalities has been undertaken in the UK since the 1980s. The development of ultrasound as a screening test has been largely technology driven, however the evidence base for its effectiveness is generally considered to be of poor quality.

The understanding of the purpose of the scan is variable – from the woman's perspective it is a chance to see the baby and confirm normality rather than a screening test to look for abnormalities. From the clinical perspective it is considered to be a useful tool to identify problems and to allow the clinician to develop management pathways which are likely to optimise outcome. This dichotomy appears to have led to confusion over the purpose, limitations and benefits of the use of ultrasound screening.

One of the problems of ultrasound as a screening test is that it is non-selective and neither the woman nor the ultrasonographers have a clear idea about what might be identified or its significance. In 2000 the RCOG attempted to define the purpose of the scan examination and the composition of the routine ultrasound scan.

The Department of Health has given a commitment to develop a national screening programme for fetal anomaly ultrasound which will set guidance and develop standards to produce a uniform, effective service for all pregnant women in England.

The base screening menu was developed over 4 years with evidence taken from a number of publications, including those referenced in the NICE 2008 guideline.⁴⁴ A review of the literature was commissioned to determine detection and screen positive rates (SPR), but it was clear that there was a lack of data on actual SPR for the majority of structural defects that were set out in the original RCOG report.

It is important that both women and health professionals appreciate that the scan is a screening test and because of that it has limitations. Inevitably some conditions will be missed or misidentified. Women should receive comprehensible information before the scan and if a woman chooses to decline the screening test then this must be respected.

⁴⁴ National Collaborating Centre for Women's and Children's Health. *Antenatal Care: Routine Care for the Healthy Pregnant Woman*, 2nd edn. RCOG Press, London, March 2008.



It has been attempted to make the purpose of the scan more focused by identifying the main structures to be assessed. These key structures lend themselves to identifying a number of conditions that should be screened for. These abnormalities and the expected detection rates for them form the basis of the NHS Fetal Anomaly Screening Programme. It is understood that other conditions may be detected using this ultrasound screening tool, but because there are insufficient data to confidently predict the standard which should be achieved, 11 conditions have been set out. These 11 conditions will be expected to be screened for and audited by ultrasound departments from 1st April 2010.

These conditions were chosen because they were considered important, being fatal, associated with morbidity or requiring immediate postnatal support. They had detection rates (DR) which exceeded 50%.

The conditions that should be screened for as a minimum from 2010 in the NHS for England are:

Conditions	Detection rate (%)
Anencephaly	98
Open spina bifida	90
Cleft lip	75
Diaphragmatic hernia	60
Gastroschisis	98
Exomphalos	80
Serious cardiac abnormalities	50
Bilateral renal agenesis	84
Lethal skeletal dysplasia	60
Edwards' syndrome (Trisomy 18)	95
Patau's syndrome (Trisomy 13)	95

The anatomy that should be assessed so that the above conditions can be detected are set out in the table above.

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 intertwined. This is particularly so in the management of multiple pregnancies or the result of other findings such as placental position on the scan or assessing the amount of amniotic fluid. 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 base menu, may give the impression that they should not be noted during the ultrasound scan. It is agreed good clinical practice and necessary in the case of multiple pregnancies in particular that the placenta and amniotic fluid are at least noted and commented upon.



18⁺⁰ to 20⁺⁶ weeks fetal anomaly ultrasound scan base menu

No.	Area	Structure	View
1	Head and neck	Skull Neck: Skin fold (NF) Brain: -Cavum septum pellucidum -Ventricular atrium -Cerebellum	Shape Subjective - measure NF if looks increased
2	Face	Lips	Coronal view
3	Chest	Heart: -Four-chamber view -Outflow tracts Lungs	Refer to Fetal Cardiac Protocol (Appendix 3)
4	Abdomen	Stomach: -Stomach and short intra-hepatic section of umbilical vein Abdominal wall Bowel Renal pelvis Bladder	Transverse, sagittal Transverse Transverse - measure AP if looks increased Sagittal and transverse
5	Spine	Vertebrae Skin covering	Sagittal and transverse Sagittal and transverse
6	Limbs (a) Limbs (b)	Femur Hands: -Metacarpals (right and left) Feet: -Metatarsals (right and left)	Length (one leg only) Visible (not counted) Visible (not counted)
7	Uterine cavity	Amniotic fluid Placenta	Subjective volume Visible and position noted

Images and measurements required:

- Head circumference demonstrating HC measurement and measurement of the atrium of the lateral ventricle
- Suboccipito-bregmatic demonstrating measurement of the transcerebellar diameter
- Coronal view of lips with nasal tip
- Abdominal circumference demonstrating AC measurement
- Femur length demonstrating FL measurement
- Sagittal view of spine including sacrum and skin covering

References:

Second-trimester ultrasound to detect fetuses with Down syndrome: a meta-analysis. Smith-Bindman R, Hosmer W, Feldstein VA, Deeks JJ, Goldberg JD JAMA 2001 Feb 28; 285(8):1044-55

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.

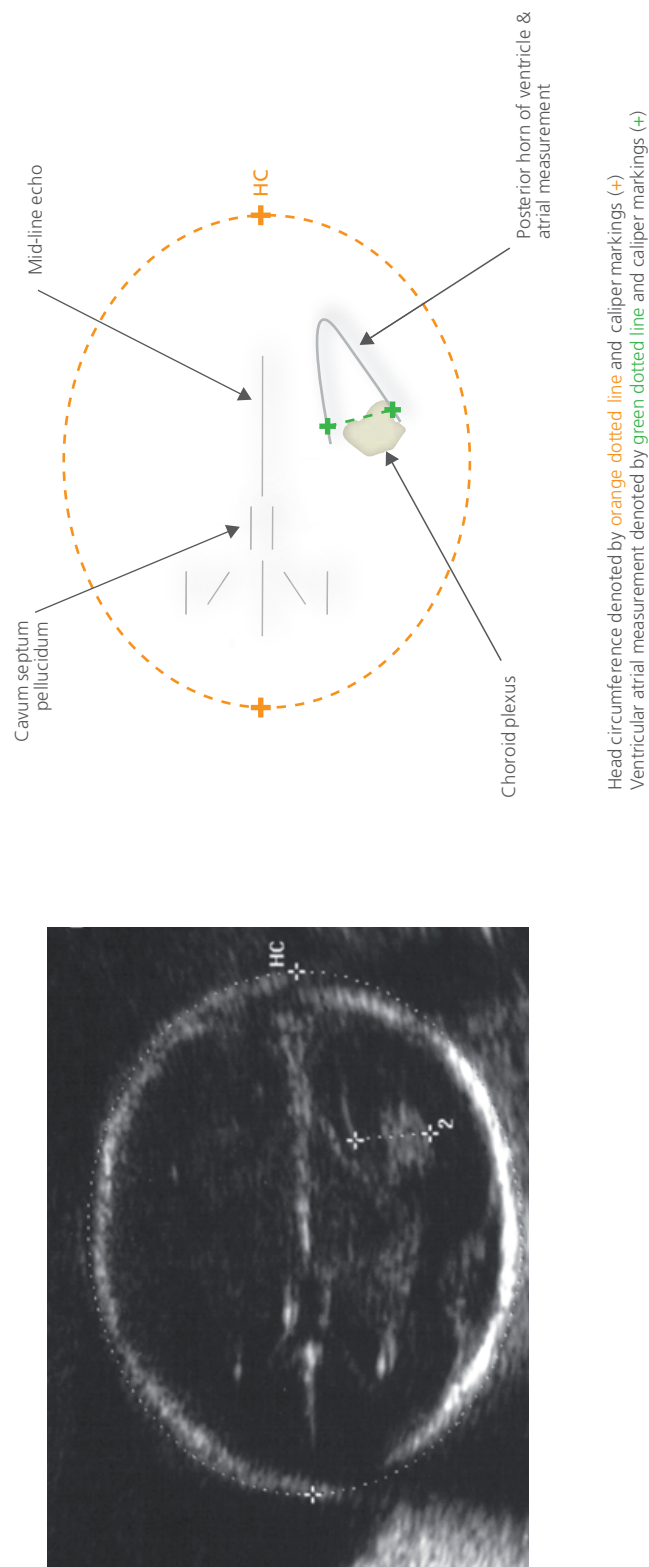
Ultrasound screening for fetal abnormalities. Report of the working party. Royal College of Obstetricians and Gynaecologists 2000.



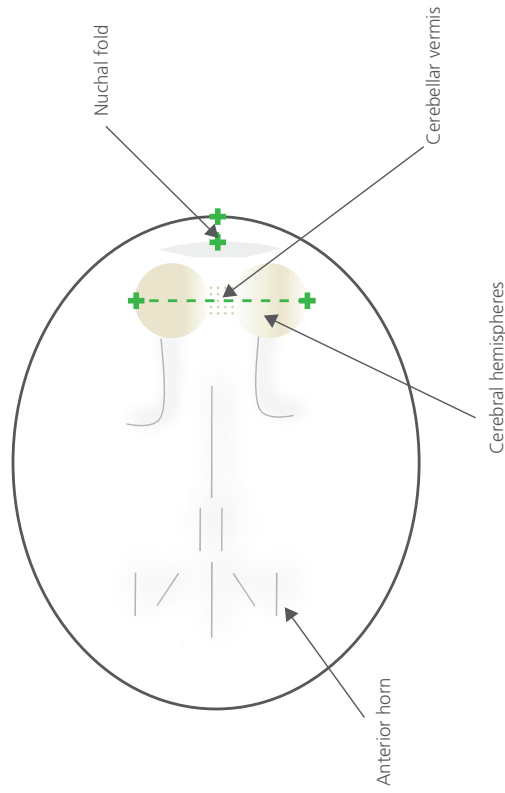
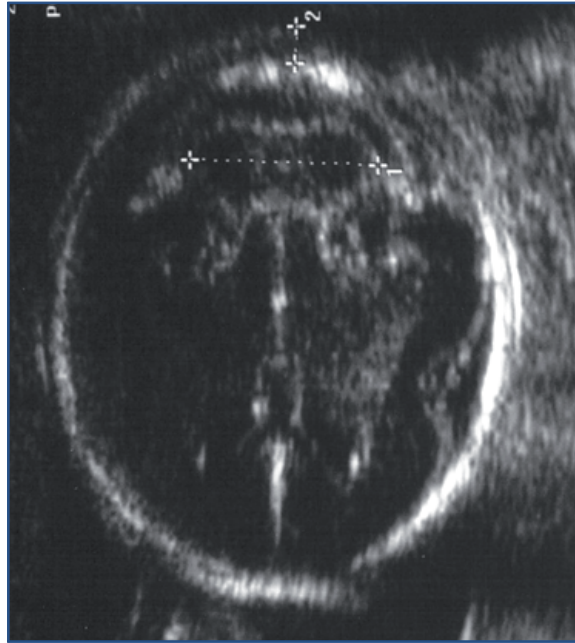
Appendix 2 -

Ultrasound images and schematic drawings

Head circumference and ventricular atrium



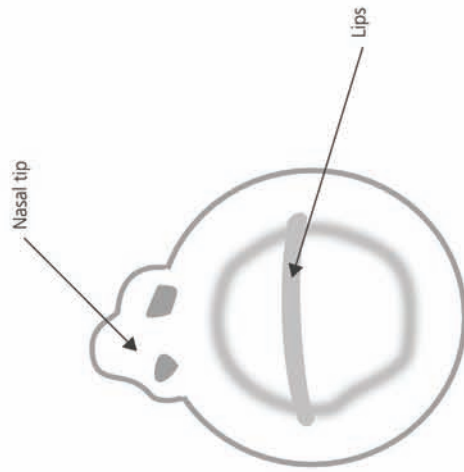
Transcerebellar diameter (TCD) and nuchal fold (NF)



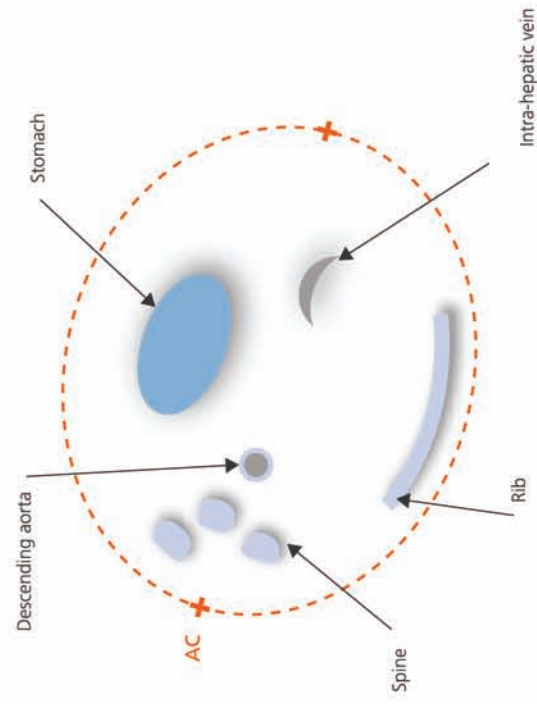
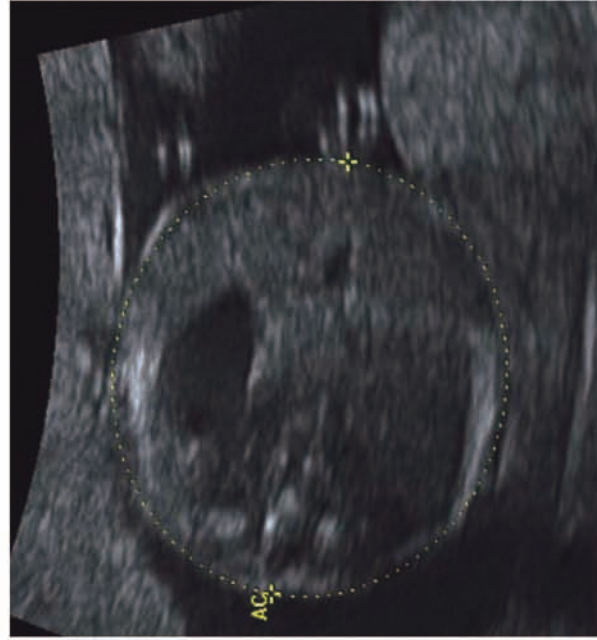
Transcerebellar diameter and nuchal fold diameter denoted by green dotted line and caliper marking (+)



Lips and nasal tip



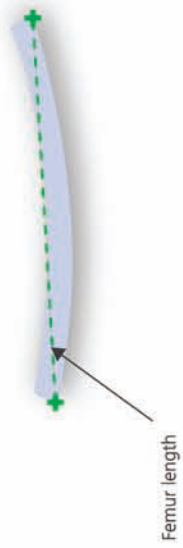
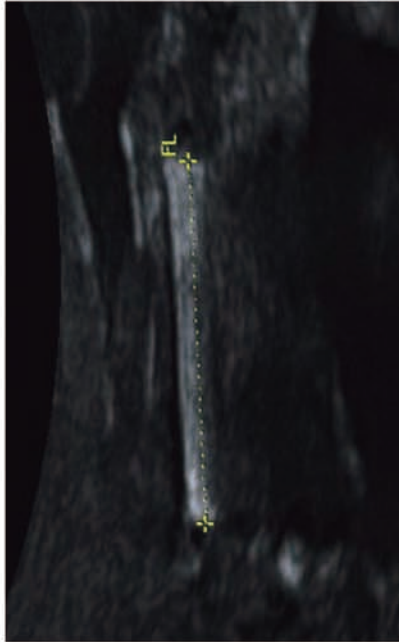
Abdominal circumference (AC)



Abdominal circumference denoted by orange dotted line and caliper markings (+)

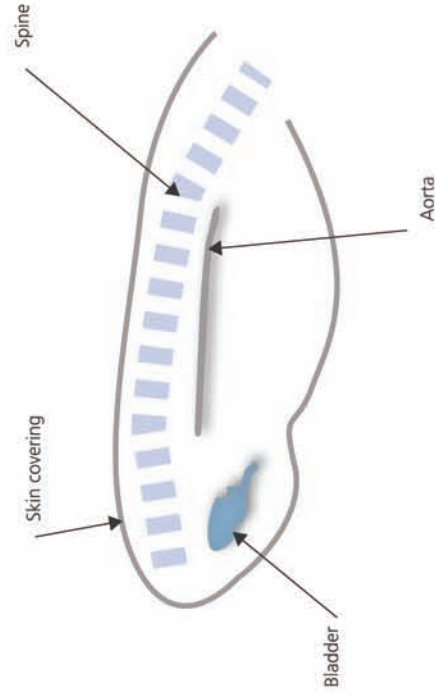


Femur length (FL)



Femur length denoted by green dotted line and caliper markings (+)

Longitudinal spine



Acknowledgements

The NHS FASP wish to thank all NHS professional staff, pregnant women and external charities who kindly provided the ultrasound fetal anatomy images demonstrated within this document.





Appendix 3 – Fetal Cardiac Protocol

Definition of major congenital heart disease (CHD)

CHD is a condition that will require immediate cardiac assessment and/or treatment within the first year of a child's life.

Fetal echocardiography screening

Fetal echocardiography involving the four-chamber view of the heart and the outflow tracts forms part of the 'ultrasound scan base menu'. As a minimum, four basic intracardiac views are required they are: laterality, the four-chamber view, the left ventricular outflow tract and the right ventricular outflow tract. A detailed description of all the structures that require assessment is outlined in detail below. The use of colour flow Doppler is not a requirement, but it should be encouraged as it may help provide additional information and improve detection of CHD. It is likely that the use of colour flow Doppler will be incorporated into the assessment of fetal echocardiography in 2013.

View	Size	Position	Structure	Function
Situs/Laterality Determine left and right side of the fetus from position in uterus		Stomach and heart on the left		
Four-Chamber Transverse section of the thorax including a complete rib and crux of the heart	* Normal cardiac size occupies 1/3 of area of the thorax (measurement not required) * X2 atria of equal size * X2 ventricles of equal size * X2 patent atrioventricular valves of equal size	* Mostly in the left chest * Apex points towards the left	* Left and right side of the heart are symmetrical * Moderator band at right ventricle apex * Crux - point at which lower part of atrial septum meet upper part ventricular septum and where both atrioventricular valves are inserted * Differential offsetting of valves, the tricuspid valve inserts more apically than the mitral valve * Ventricular septum intact from apex to crux * Foramen ovale flap in left atrium	* Rhythm - synchronous atrial and ventricular contractions * Two ventricles contract equally * Mitral and tricuspid valves open freely

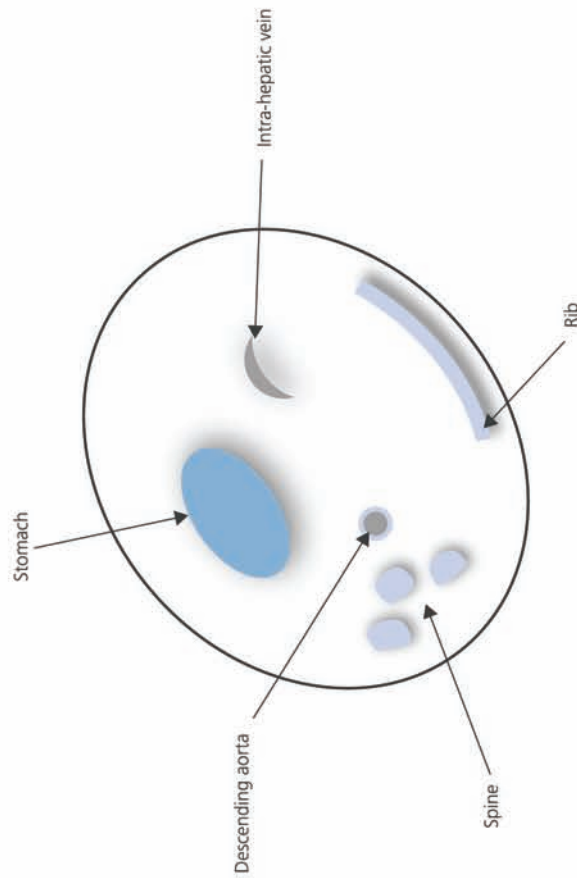
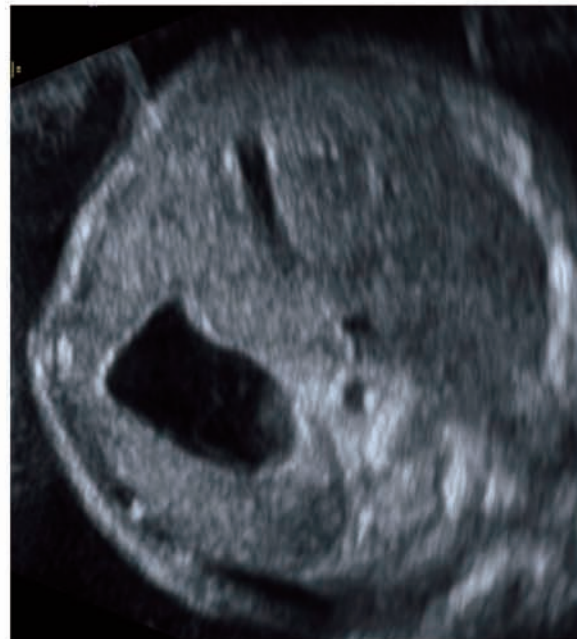
Appendix 3 – Fetal Cardiac Protocol

View	Size	Position	Structure	Function
Aorta/Left Ventricular Outflow Tract This view shows the outflow tract of the left ventricle		Aorta arises from the left ventricle & sweeps out towards the right shoulder	The anterior wall of the aorta is continuous with the ventricular septum	Aortic valve opens freely
*Pulmonary/Right Ventricular Outflow Tract This view shows the outflow tract of the right ventricle Or Three-Vessel View (3VV) This view shows the outflow tract of the right ventricle including the pulmonary artery, the aorta and the superior vena cava.	The diameter of the pulmonary artery is slightly greater than the diameter of the aorta which is slightly greater than the diameter of the superior vena cava	Main pulmonary artery arises from the right ventricle and is directed backwards towards the spine *The pulmonary artery lies to the left with the superior vena cava to the right and aorta in the middle *Pulmonary artery continues as the arterial duct	The main pulmonary artery bifurcates	Pulmonary valve opens freely

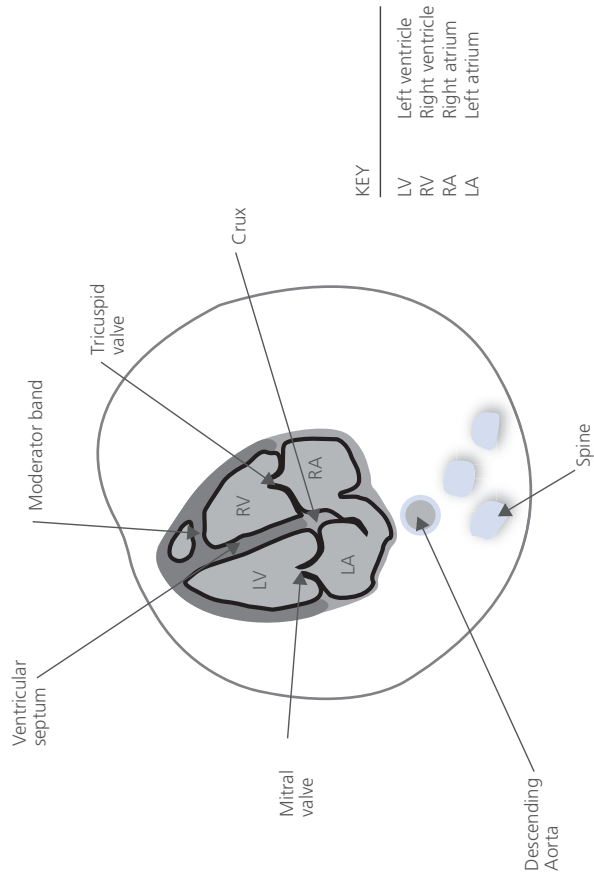


Appendix 4 – Cardiac images

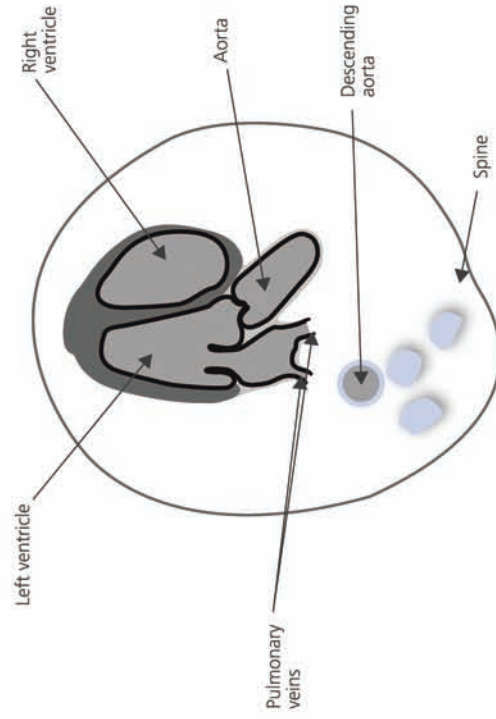
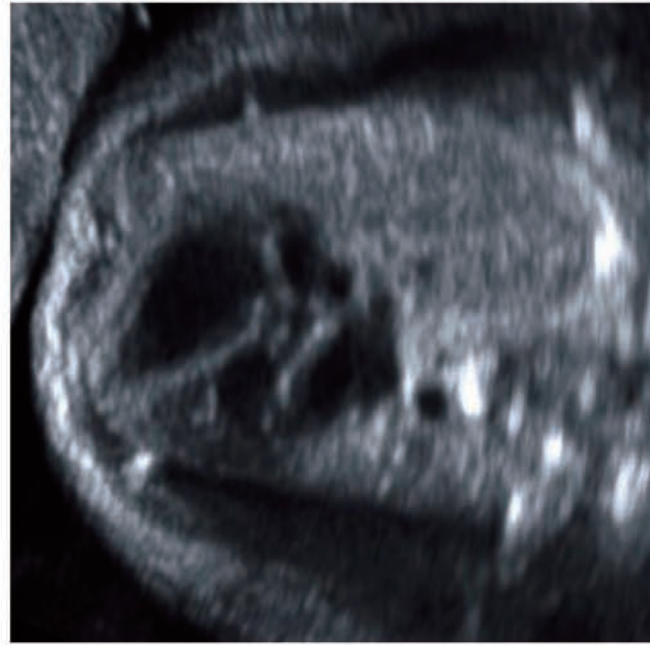
Situs/laterality



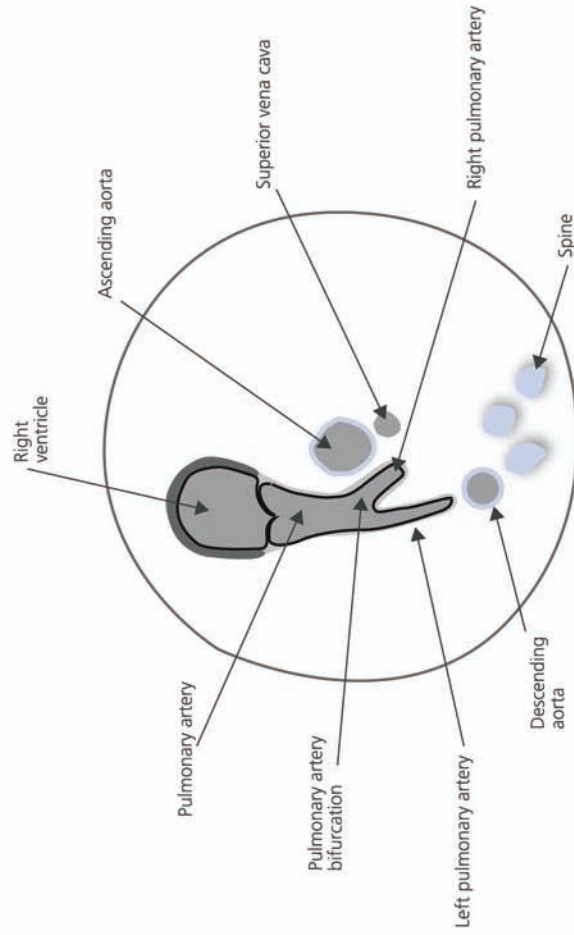
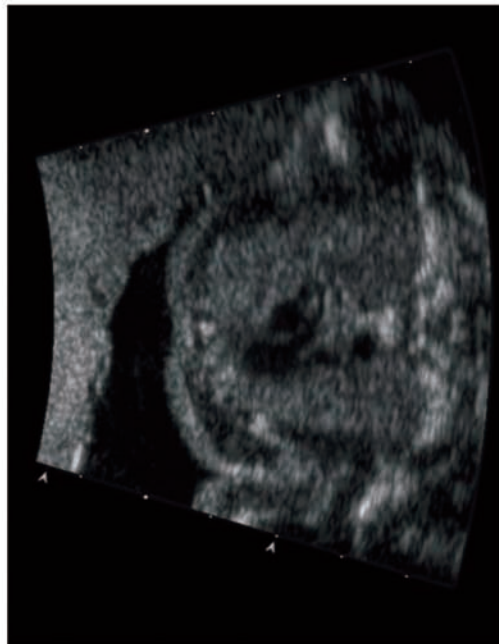
Four chamber heart view



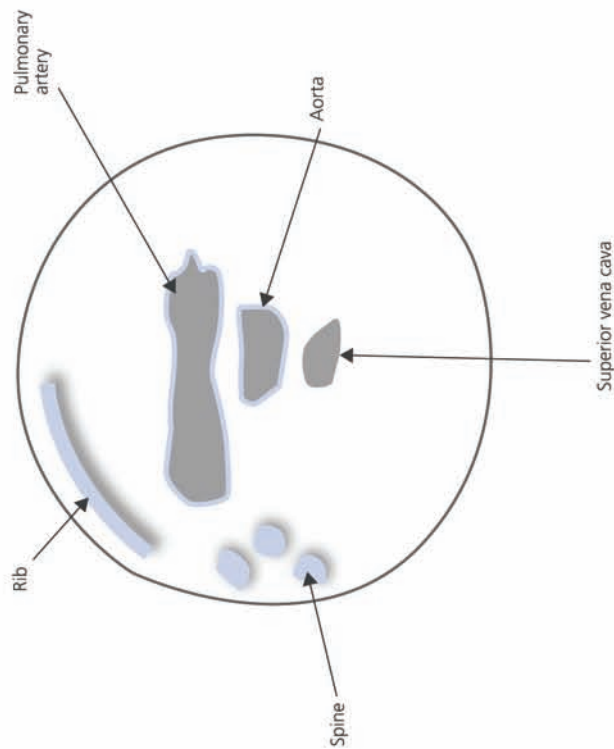
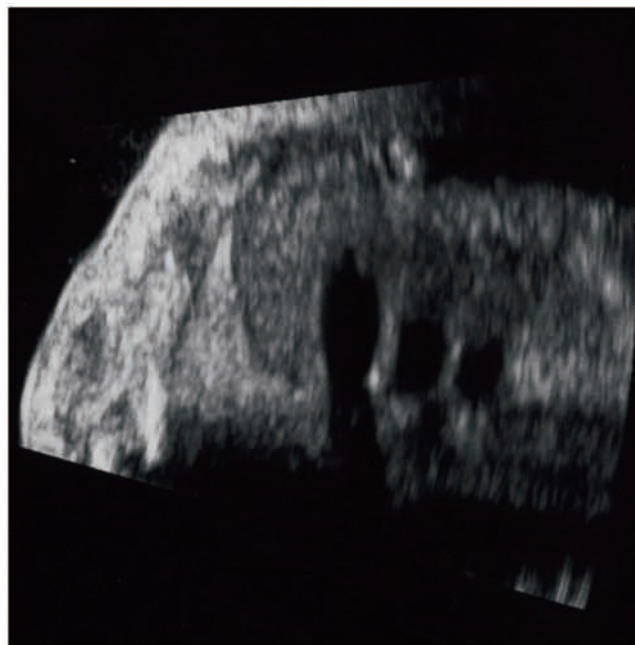
Aorta/left ventricular outflow tract



Pulmonary/right ventricular outflow tract



Three vessel view (3VV)



Acknowledgements

The NHS FASP wish to thank all NHS professional staff, pregnant women and external charities who kindly provided the ultrasound fetal anatomy images demonstrated within this document.

Appendix 5



Screening Programmes

Fetal Anomaly

Programme Statement	
Best Practice Guidance	Normal variant (previously known as 'soft markers')
Date:	01/07/09
To take effect from	01/04/2010
Distributed to	UK NSC; Regional Antenatal and Child Health Coordinators; SHA's - CE, RDPH; PCT's - DPH, Screening Leads, Commissioners; FASP Working Groups and Members; Hospital Trusts; RCOG; RCR; SCoR; RCM; RCN; Royal College of General Practitioners; RCP; BMUS; CASE; MIDIRS; BMFMS; FMF

Normal variant screening in pregnancy

Supersedes 'Ultrasound for Screening for Aneuploidy: Guidance for the professional' (RCOG 2000)

The introduction of a national Down's syndrome screening programme in early pregnancy has changed the way in which the 18⁺⁰ to 20⁺⁶ fetal anomaly scan findings should be interpreted. The Programme Centre has recommended that an established Down's syndrome screening test result should **not be recalculated at this time**.¹

There is now a universal offer of a nationally approved Down's syndrome screening test in all English hospitals.² The results are increasingly delivering higher detection rates for lower false positive rates. Therefore, women who are found to be 'low risk' through testing in either first or second trimesters, or who have declined screening for Down's syndrome **should not be referred for further assessment of chromosomal abnormality even** if normal variants such as the examples below (whether single or multiple) are seen at the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly screening scan. Indeed **we encourage that the term ultrasound "Down's soft marker" is no longer 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).

¹ UK NSC NHS FASP Programme Statement: *Recalculation of Down's syndrome screening risk following ultrasound examination at the mid-trimester ultrasound scan.*

² Women who have not had Downs screening (booked too late or are in a part of the UK in which this is not available) should have counselling based on maternal age and/or family history not on whether normal variants are found during scanning.



Appendix 6 – Training and professional competence

All healthcare professionals undertaking a fetal anomaly ultrasound scan for the purpose of screening and diagnosis of a related condition should hold, as a minimum, one of the following qualifications:

- **Certificate/Diploma** (as appropriate) in **Medical Ultrasound** (CMU/DMU) of the Society and College of Radiographers (SCoR) with evidence of appropriate continuous professional development (CPD).
- **Post Graduate Certificate in Medical Ultrasound** (PGCert.MU) approved and validated by a Higher Institute of Education and accredited by the Consortium for Sonographic Education (CASE) with evidence of appropriate CPD. 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**, RCOG **Immediate Ultrasound of Normal Fetal Anatomy Training Programme (Module 3)** and **Advanced Training Speciality Module (ATSM) in Fetal Medicine**. Evidence of appropriate CPD should also be provided.⁴⁶
- Sonographers who do not have a UK recognised ultrasound qualification, i.e. those trained overseas, should be registered under the **Voluntary Register of Sonographers**.⁴⁷
- Written evidence or certification for obstetricians or radiologists detailing previous obstetric ultrasound training and experience in this or another country.

⁴⁶ The NSC recognises that many senior experienced scanning professionals (obstetricians, radiologists and sonographers) may not have a formal qualification and would not wish to prevent these very important providers of the service to be excluded from practising. For these individuals NUSCoRG suggests that they should continue scanning under a 'grandfather clause' while applying the above qualification parameters to new practitioners to fetal anomaly scanning.

⁴⁷ The database is kept and controlled by the Society and College of Radiographers (SCoR) in association with the UK Association of Sonographers (UKAS).



Appendix 7 – Self-compliance tool

Equipment

1. Identify and list all ultrasound equipment in use in each department throughout the hospital.	☐
2. Identify what each machine is used for.	☐
3. Identify how many sessions per week the equipment is used for.	☐
4. Provide data on the numbers of examinations performed per machine per session.	☐
5. Provide the schedule of QA and electrical safety testing for each machine.	☐
6. Provide details of the maintenance contract for each machine.	☐
7. Provide details of the PACS connectivity of the equipment.	☐
8. Provide details of plans to achieve PACS connectivity where this is not already achieved.	☐
9. Provide details of measures for infection control	☐

Ultrasound users

1. Each Trust should hold a register of US practitioners.	☐
2. Each department should identify all users of US equipment and their professional grade, their qualifications in relation to US and the conferring body.	☐
3. Where there are no formal qualifications, describe the nature of training and the processes of assessment of competence.	☐
4. Describe the mechanisms whereby patients are given information about the examination. These should include, where available, patient information sheets.	☐
5. Where US is delegated to a non-medical member of staff, describe the governance arrangements of the process of delegation.	☐
6. Where the US is performed by a doctor (or sonographer) in training describe the arrangements for professional supervision.	☐
7. Describe the arrangements for obtaining informed consent from the patient.	☐
8. Where the US examination is performed by a trainee describe the process of informing the patient and eliciting consent.	☐
9. What arrangements are in place for CPD in US?	☐
10. What arrangements are in place for regular audit of US practice for each user?	☐
11. Describe the arrangements for ensuring that all staff are aware of US bio-effects and strategies to minimise these.	☐



Appendix 7 – Self-compliance tool

Documentation and communication of results

1.	Describe how records of imaging studies are currently stored and the availability of images for subsequent review for purposes of clinical management and audit.	☐
2.	Describe security arrangements for access to images and other patient data.	☐
3.	Describe how the results of imaging studies are recorded and communicated: a. within the notes b. within a departmental computer database c. within the radiology imaging system Radiology Information System (RIS) d. within another data storage system available to all other bona fide practitioners.	☐ ☐ ☐ ☐
4.	Describe how and when the results of imaging studies are communicated to the patient.	☐
5.	Describe the mechanisms for booking patients and outline the minimum standards for booking and report turnaround times.	☐
6.	For any instances where it becomes known that a scan has taken place and not been documented a clinical risk form should be completed and acted upon by the clinical risk department.	☐



Appendix 8 – Complementary information

Title of resource and availability

Description

Information to support parents and health professionals once a diagnosis of a congenital anomaly has been made.

Available:

www.fetalanomaly.screening.nhs.uk/fetalanomalyfolder

Various leaflets have been developed by the NHS Fetal Anomaly Screening Programme to help health professionals and parents understand more about the conditions that can be scanned for at the ultrasound stage. All of these leaflets have been put into a binder and two copies will be sent to every ultrasound department in England in early 2010 to coincide with the launch of the ultrasound standards.

The programme centre has also developed leaflets on CVS and amniocentesis:

Information for pregnant women about the amniocentesis tests

Information for pregnant women about chorionic villus sampling (CVS)

Chorionic villus sampling (CVS) and amniocentesis information sheet for health professionals

The 18⁺⁰ to 20⁺⁶ weeks fetal anomaly screening scan:

Your on-line resource available at:

www.fetalanomaly.screening.nhs.uk/fetalanomalyresource

To underpin the standards, the NHS FASP commissioned a project to develop a suite of innovative learning resources to support all staff involved in delivering the screening programme.

This project was managed by the Cambridge-based partnership of Jill Rogers Associates and Liberating Solutions, both independent consulting companies working within the healthcare and related sectors. These new learning materials are web based and include interactive material, video sequences and a user guide.

The resource has been developed to be used by individuals within teams or as part of group study sessions, and is capable of integration into generic and specialist related healthcare courses, like the PG certification in obstetric ultrasound.

The on-line materials map directly to the forthcoming NHS FASP ultrasound standards and support the NHS Knowledge and Skills Framework. The project team have held a series of meetings with a wide range of stakeholders and have consulted widely on the content of the resource.



Title of resource and availability

Description

Condensed Education Module for Trisomy 21 on-line resource available at:
www.fetalanomaly.screening.nhs.uk/CEMT21

The original Down's syndrome education and training pack (DETP) was produced by the NHS FASP and widely disseminated in 2005. Following the training needs analysis and assessment in 2008, the DETP has now been developed, based on user feedback, into the CEM T21.

CEM T21 is thoroughly updated and presented as a compact yet comprehensive and user-friendly educational resource, constituting approximately 60–90 minutes of web-based learning time. The resource allows you to study at your own speed and provides you with an assessment and evidence of learning for your CPD.

CEM T21 is a short, interactive education module which aims to support health professionals who care for women and their families along the screening pathway for Trisomy 21 (T21). The module responds to and reflects recent changes to national policy, specifically the recommendation and implementation of 'combined screening' for T21 across England.

The resource is targeted at front-line health professionals who offer and discuss the implications of screening with women and their families undertake any of the components of Trisomy 21 screening.

Gestational Wheels available from NHS FASP Programme Centre by calling 0845 527 7910 or emailing
enquiries@ansnsc.co.uk

As part of our commitment to improve the information related to ultrasound screening during pregnancy, the NHS FASP has developed several new resources for parents and healthcare professionals.

These resources are being offered to all NHS Trusts providing ultrasound scans and Down's syndrome screening services. They are nationally produced documents which have been developed by a team of expert reviewers. Their use is recommended to provide uniformity of pre-screening information and a consistent approach.

All have been designed to support parents and professionals in their understanding of the screening process.

Gestational wheels are available to order from the NHS FASP Centre and are meant to illustrate what screening is available to pregnant women and when this screening takes place. They can also be used to work out gestational age.

Tear-off pads – mid-pregnancy
They are available on the NHS FASP website at:
<http://fetalanomaly.screening.nhs.uk/educationalresources>.

The mid-pregnancy ultrasound scan tear-off pad and posters have been developed for women who are deciding whether to have the 18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan.

National Occupational Standards and National Workforce Competences for ultrasonographers
Available at:
<http://fetalanomaly.screening.nhs.uk/standardsandpolicies>

This document was commissioned by NHS FASP and developed by Skills for Health (Sector Skills Council). It is a reference document containing a detailed suite of competences with clear descriptions of good practice for those working in obstetric and gynaecological ultrasound. These standards complement the standards in this publication.



Appendix 9 - The 11 auditable conditions and detection rates

The NHS Fetal Anomaly Screening Programme has agreed that only 11 conditions may be detected by an ultrasound scan and these have limited detection rates, as derived from a number of major reference sources.

Conditions	Detection rate (%)
Anencephaly	98
Open spina bifida	90
Cleft lip	75
Diaphragmatic hernia	60
Gastroschisis	98
Exomphalos	80
Serious cardiac abnormalities	50
Bilateral renal agenesis	84
Lethal skeletal dysplasia	60
Edwards' syndrome (Trisomy 18)	95
Patau's syndrome (Trisomy 13)	95



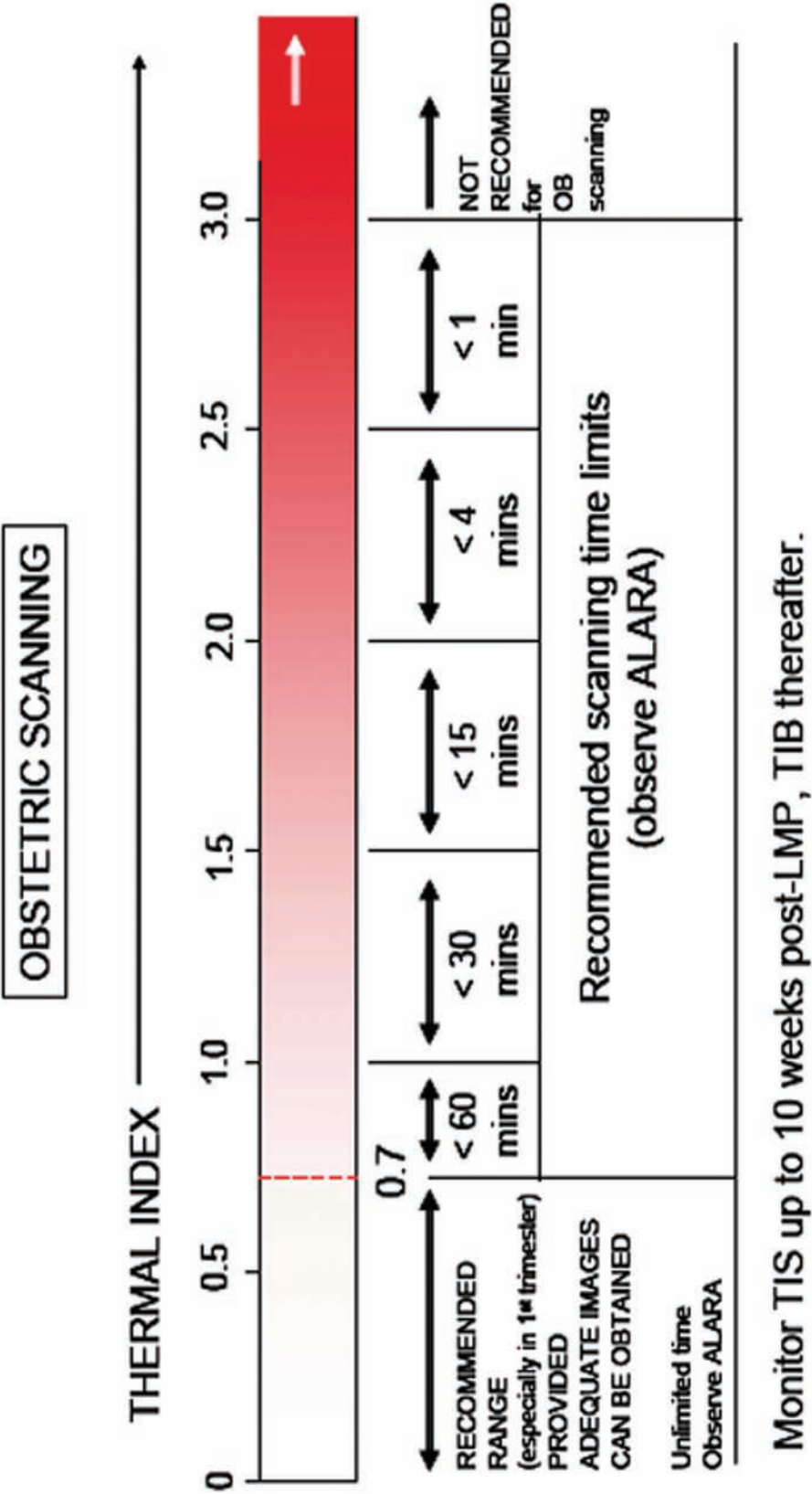
Appendix 10 – Websites

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.cdhsupport.org
Association of Spina Bifida and Hydrocephalus (ASBAH)	www.asbah.org
AXrEM Association 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 (BMFMS)	www.bmfms.org.uk
British Medical Ultrasound 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.nhs.uk/Claims/Schemes/CNST
Confidential Enquiry into Maternal and Child Health (CEMACH)	www.cemach.org.uk
Contact a Family	www.cafamily.org.uk
Department of Health	www.dh.gov.uk
Down's Syndrome Association	www.downs-syndrome.org.uk
Down's Syndrome Screening Quality Assurance Support Service (DQASS)	www.fetalanomaly.screening.nhs.uk/qualityassuranceprogramme
Genetic Interest Group	www.gig.org.uk
Health talk online	www.healthtalkonline.org
Health Professions Council	www.hpc-uk.org
MHRA – Medicines and Healthcare products Regulatory Agency	www.mhra.gov.uk
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
National Screening Committee	www.screening.nhs.uk
NHS Fetal Anomaly Screening Programme	www.fetalanomaly.screening.nhs.uk
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
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 Charity	www.tinytickers.org
United Kingdom Accreditation Service	www.ukas.com



Appendix 11:

Recommended maximum scanning times for obstetric examinations conducted with different displayed Thermal Indices (TI)



Reproduced and included in this document with kind permission from BMUS, Guidelines for the safe use of diagnostic ultrasound equipment. Prepared by the Safety Group of the British Medical Ultrasound Society. November 2009.

