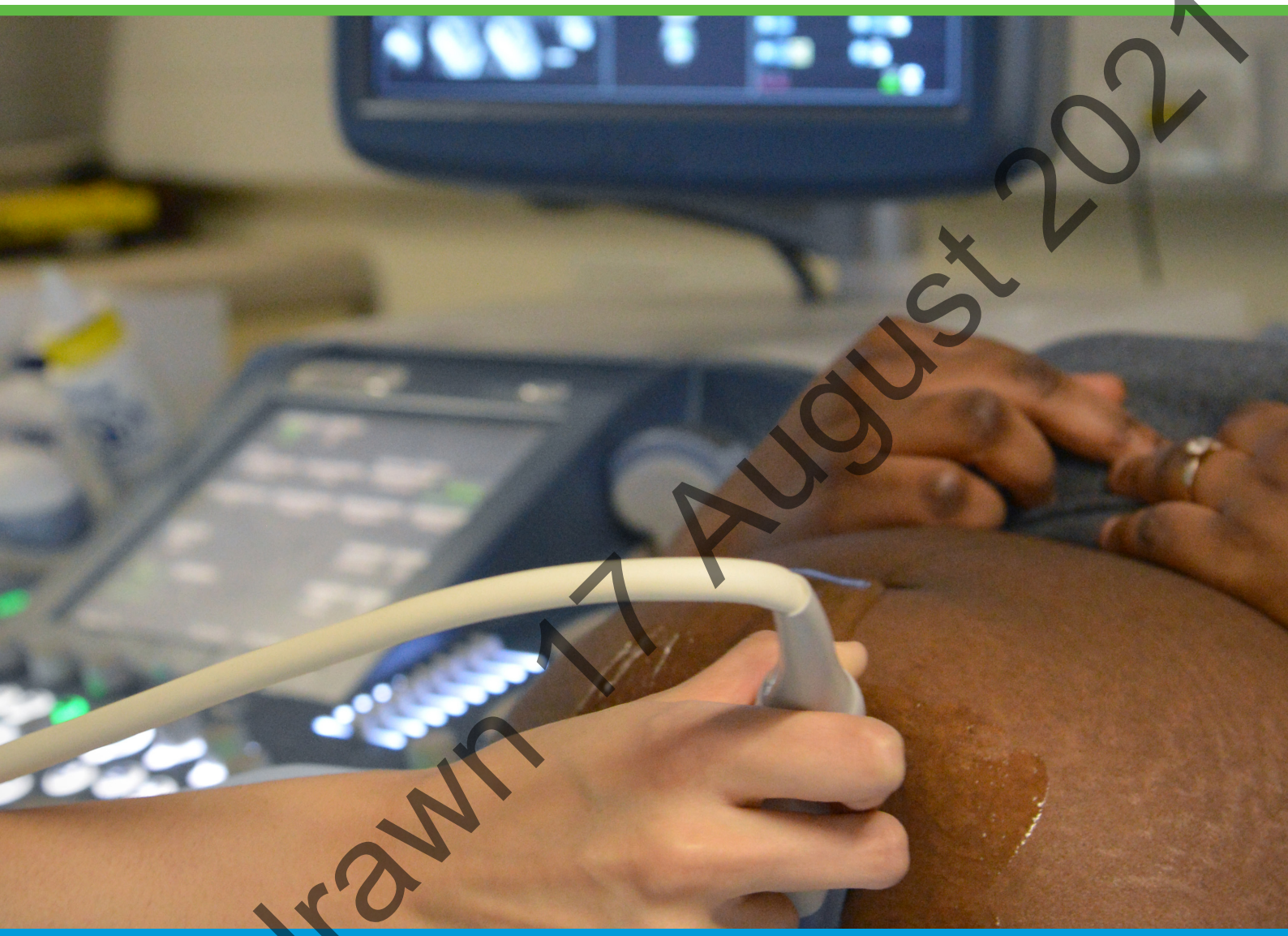
NHS

Screening Programmes

Fetal Anomaly



Fetal Anomaly Screening Programme

Handbook for ultrasound practitioners

April 2015

About the NHS Screening Programmes

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

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

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Contents

1 Introduction

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

1.1 Conventions

Throughout the document the following are used interchangeably:

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

1.2 Related documents

a. Handbook for laboratories

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

fetalanomaly.screening.nhs.uk/publications

b. Ultrasound Practitioner's Handbook

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

fetalanomaly.screening.nhs.uk/publications

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

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

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

fetalanomaly.screening.nhs.uk/specification

d. Standards

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

fetalanomaly.screening.nhs.uk

2 The Fetal Anomaly Screening Programme (FASP)

2.1 General principles of screening

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

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

www.screening.nhs.uk

2.2 Background

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

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

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

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

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

2.3 The policy

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

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

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

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

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

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

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

3 Screening tests

3.1 First trimester combined test

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

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

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

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

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

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

3.2 Second trimester quadruple test

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

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

3.3 National standards

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

Table 1. National standards

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

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

4 Markers used in screening tests

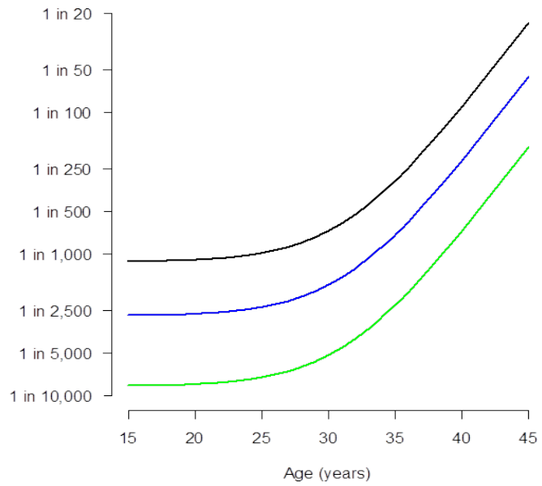
4.1 Maternal age

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

Table 2

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

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



4.2 Biochemical markers

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

fetalanomaly.screening.nhs.uk/publications

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

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

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

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

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

4.3 Ultrasound markers

Nuchal translucency (NT)

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

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

Crown rump length (CRL)

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

Head circumference (HC)

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

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

fetalanomaly.screening.nhs.uk/combinedscreeningresources

5 Screening risk

5.1 Risk cut-off

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

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

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

5.2 Risk calculation software

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

fetalanomaly.screening.nhs.uk/dqass

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

6 Role of the Screening Support Sonographer

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

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

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

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

6.1 Functions

The main functions of the SSS are:

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

7 Criteria for measuring NT and CRL

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

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

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

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

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

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

8 Departmental review of images

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

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

8.1 Rationale

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

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

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

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

fetalanomaly.screening.nhs.uk/leafletsforprofessionals

8.2 Local quality assurance

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

8.3 Supplementary audit activities

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

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

8.4 The scoring process for departmental review of images

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

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

- sample score sheets can be found in Appendix 1

Table 5 - Scoring images

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

Suggested management following image review

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

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

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

Table 6 - Image guidance tool for NT

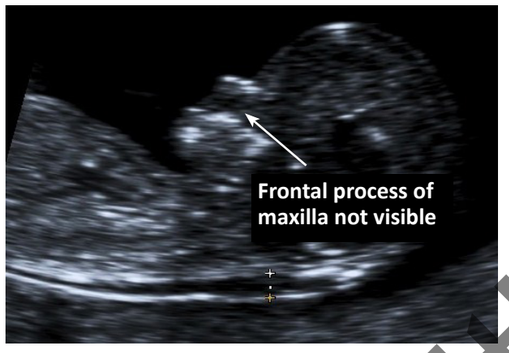
Sections	Twelve Components to assess the NT image appearance
Midline section	1. Horizontal sagittal section of the fetus extending from crown to include at least the upper aspect of the heart* 2. Head in line with the body with the nuchal translucency visible along the length of the neck 3. Echogenic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

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

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

Absence of frontal process of maxilla

Component 6 = ✓



Presence of frontal process of maxilla

Component 6 = X

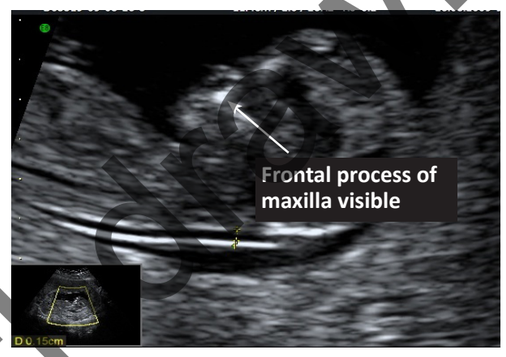
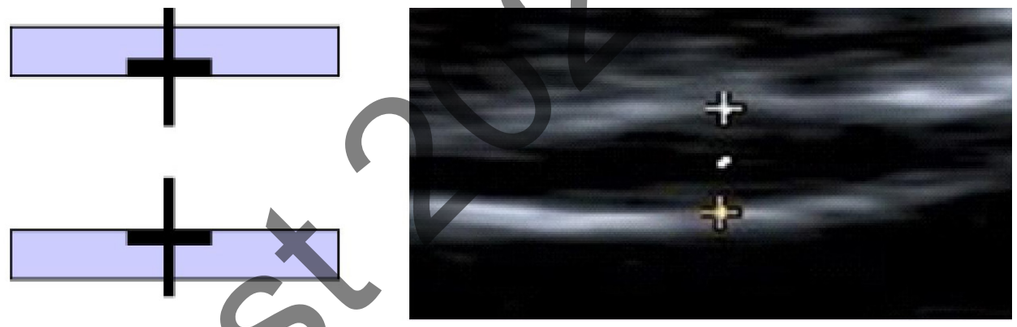


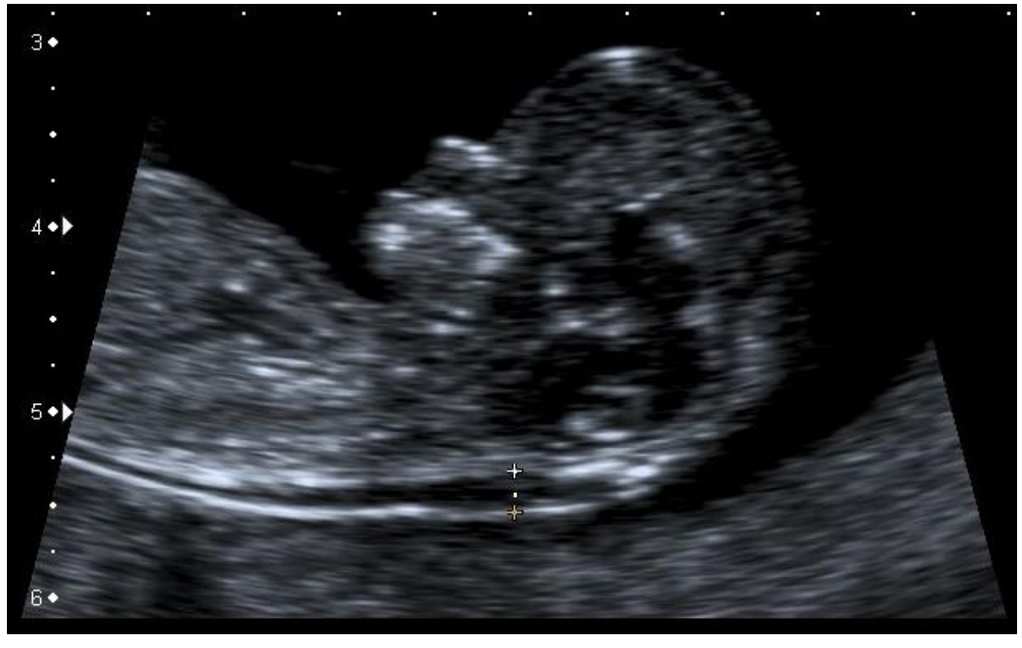
Diagram 2 Where to place callipers for the NT measurement



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

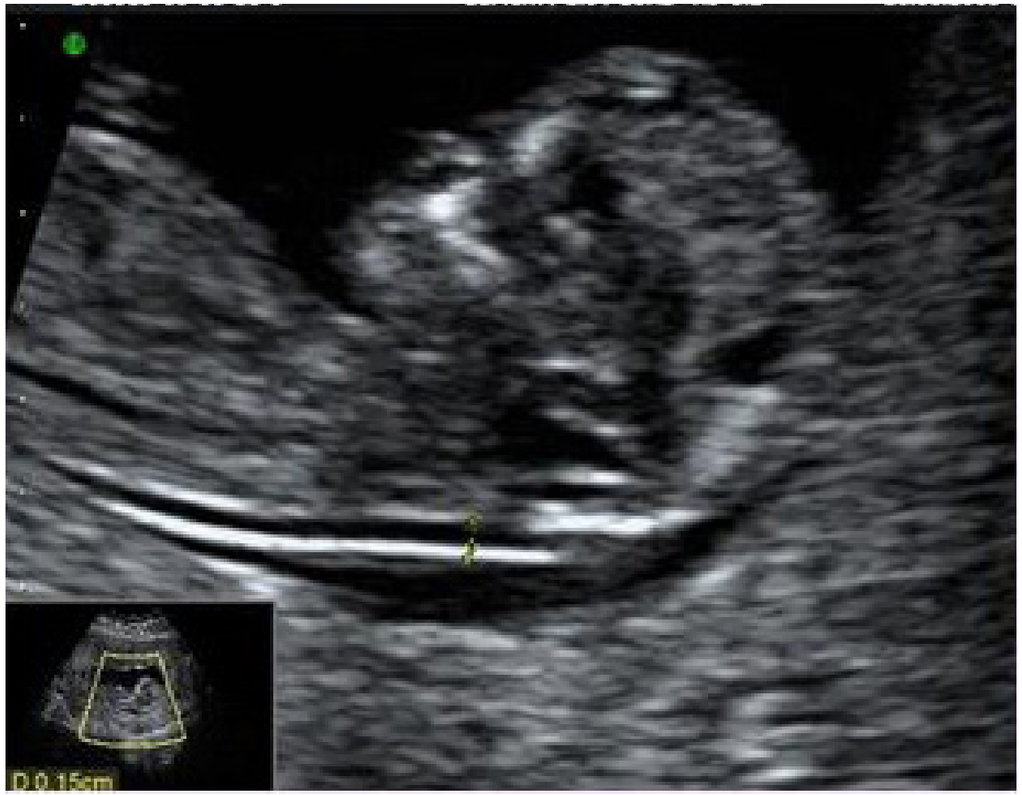
Diagram 3 Examples of scoring NT images

Image 1 Good



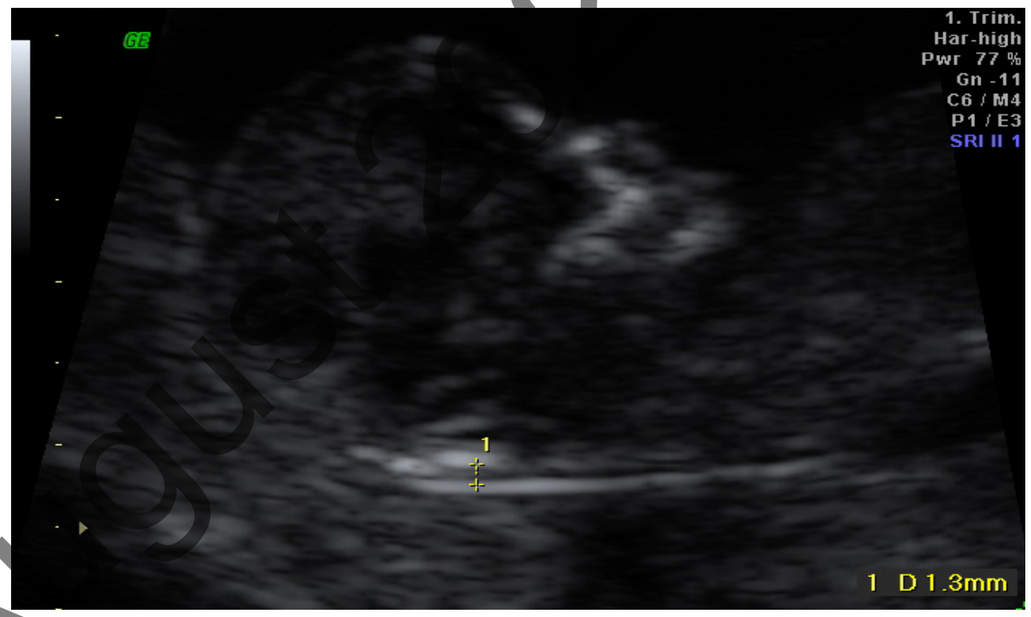
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present												Good

Image 2 Acceptable



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

Image 3 Poor



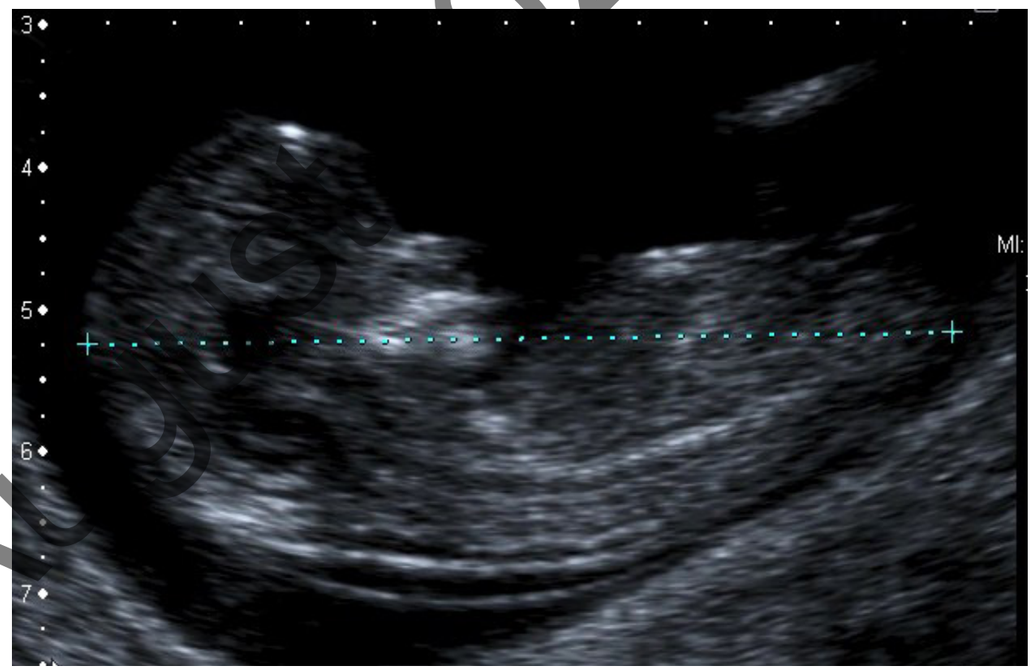
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	x	X	✓	x	✓	x	X	
7/12 components present **6)** Frontal process of the maxilla is present **7)** No pocket of fluid under the chin **9)** Nasal tip below anterior chest wall **11)** Callipers are not correctly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

Table 7 - Image guidance tool for the CRL

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

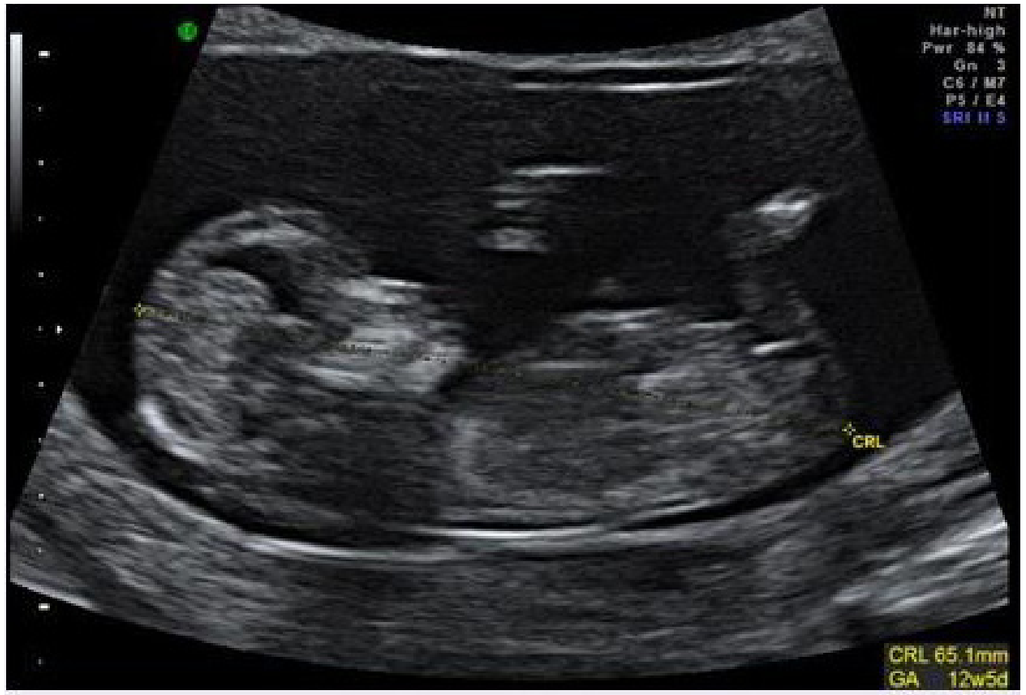
Diagram 4 Examples of scoring CRL images

Image 4 Good



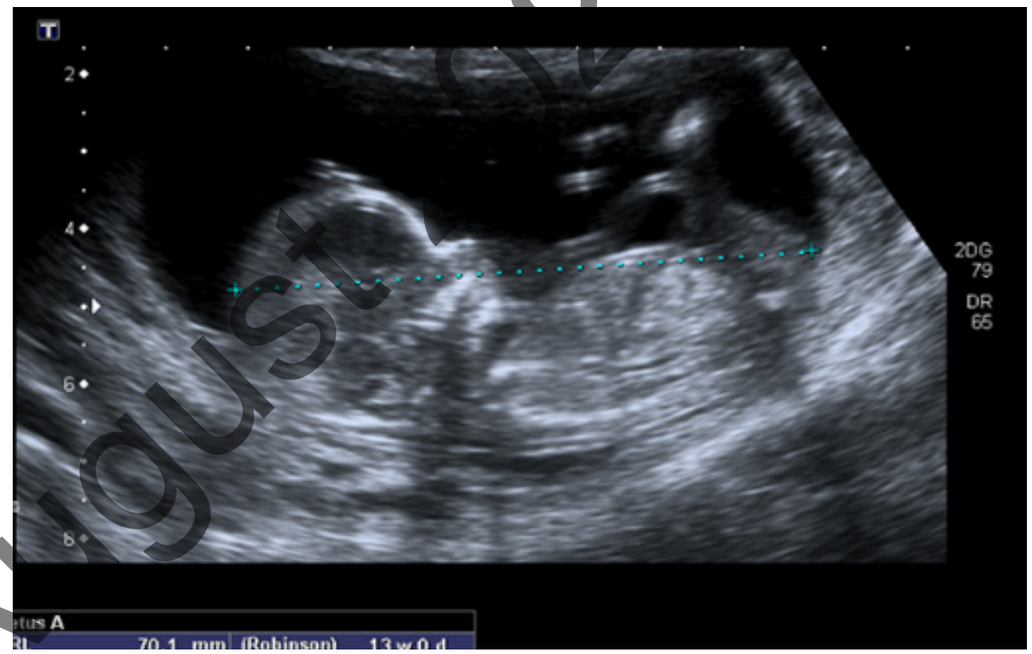
Midline section						Position			Mag	Callipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present												Good

Image 5 Acceptable



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

Image 6 Poor



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

9 DQASS

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

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

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

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

9.1 Aims of DQASS

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

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

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

9.2 Information DQASS needs from laboratories

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

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

fetalanomaly.screening.nhs.uk/publications

9.2.1 Ultrasound Scan

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

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

9.3 DQASS reports

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

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

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

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

9.4 Contacting DQASS

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

Information required when contacting DQASS via email

Inform of a new staff member

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

Request a trainee DQASS identity code

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

Sending 25 paired measurements for assessment

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

9.5 Completing blood test forms

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

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

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

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

fetalanomaly.screening.nhs.uk/sssresources

Table 8 - DQASS reports

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

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

9.6 Flag status

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

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

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

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

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

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

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

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

Table 9 - Flag category and bias

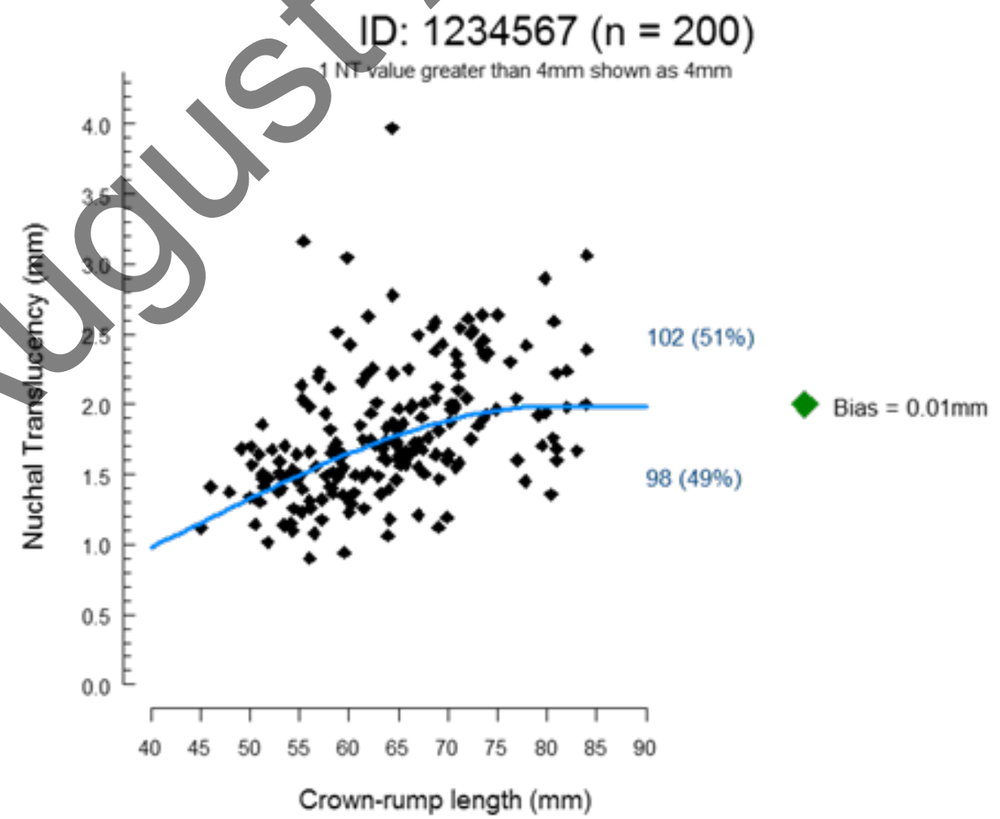
Flag type	Bias
Green flag	Assigned when bias is **less than or equal to 0.10mm**
Amber Flag	Assigned when bias is **between 0.11mm and 0.40mm**
Red Flag	Assigned when bias is **greater than 0.40mm**
Red Flag with 4 [4]	Assigned if fewer than 25 paired CRL/NT measurements over 4 cycles
No Flag	Assigned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

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

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

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

Diagram 5 Green bias

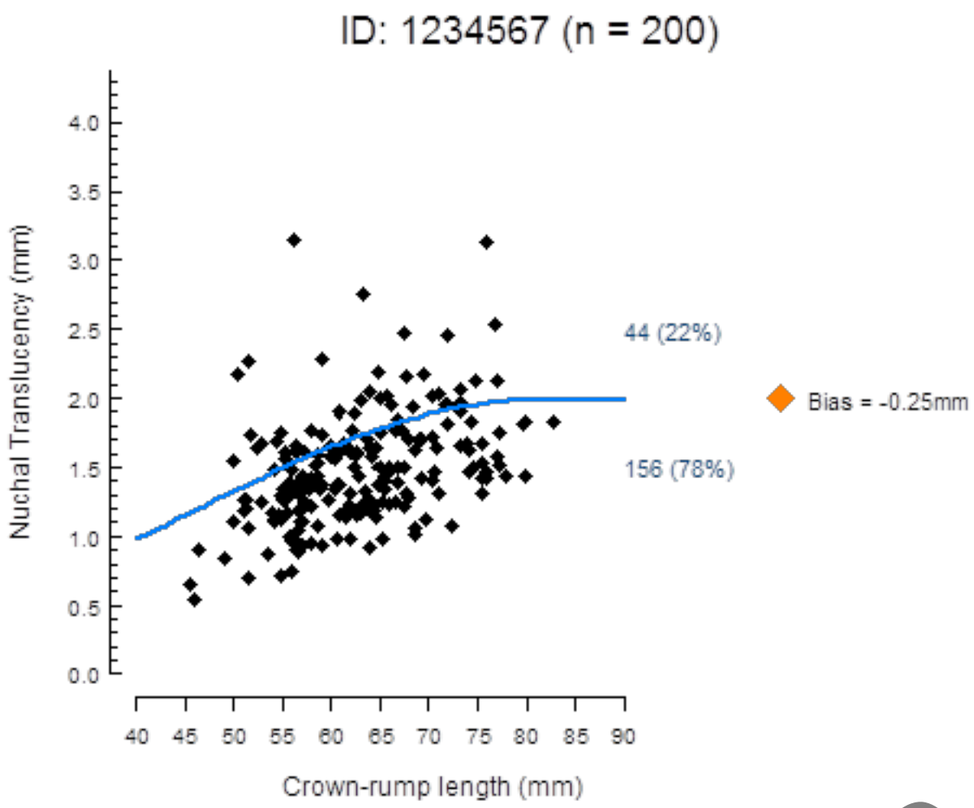


This report indicates a bias of 0.01mm relative to the FMF reference curve and satisfies the criteria for a green flag.

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

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

Diagram 6 Amber bias

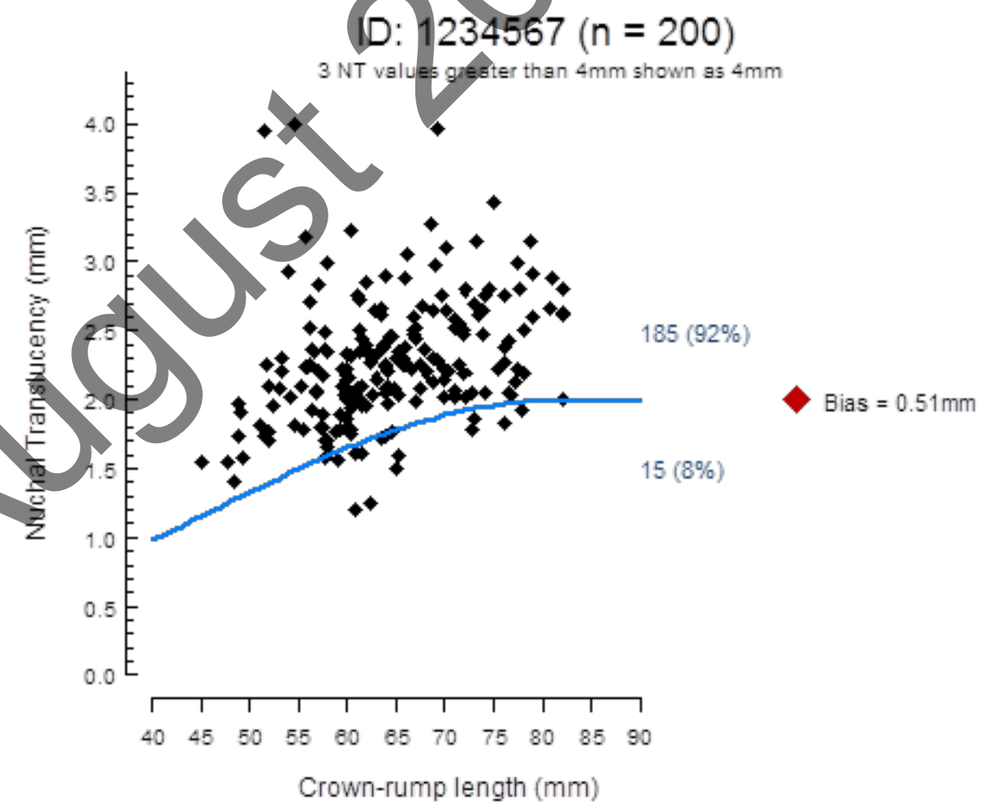


This report indicates a negative bias of 0.25mm relative to the FMF reference curve and satisfies the criteria for an amber flag.

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

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

Diagram 7 Red Flag



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

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

Bias can directly impact on the risk calculation women receive.

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

9.7 Managing red flags

A red flag is issued in two cases

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

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

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

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

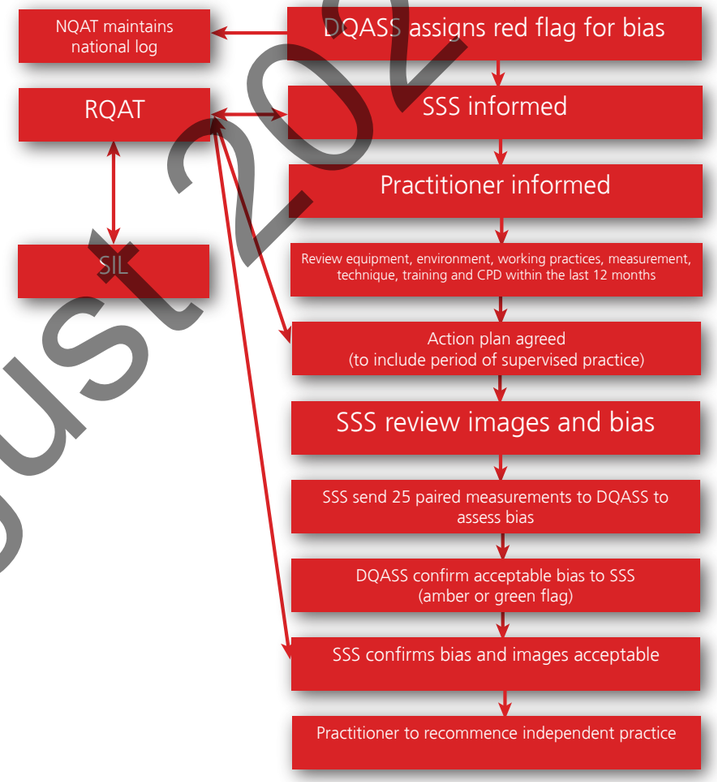
Guidance for managing a red flag for bias

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

Diagram 8 Flowchart for management of a red flag for bias

Glossary

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



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

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

9.8 Throughput (number of scans undertaken per cycle)

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

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

9.9 Guidance for managing red flag for throughput

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

9.10 Scenarios

DQASS report received.

Table 10

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

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

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

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

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

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

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

10 Education and Training

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

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

FASP recommends that any practitioner undertaking a fetal anomaly ultrasound scan on pregnant women, for the purpose of screening and diagnosis of a related condition should hold, as a minimum, one of the following:

- Certificate/Diploma (as appropriate) in Medical Ultrasound (CMU/DMU) of the College of Radiographers (CoR) with evidence of appropriate continuous professional development (CPD)
- Post Graduate Certificate in Medical Ultrasound (PgCert) approved and validated by a Higher Institute of Education and accredited by the Consortium for Sonographic Education (CASE) or equivalent. The qualification should be relevant to obstetric ultrasound practice
- Royal College of Obstetricians and Gynaecologists (RCOG)/Royal College of Radiologists (RCR) Diploma in Obstetric Ultrasound or the Advanced Training Skills Module (ATSM)

10.1 NHS model of training in NT and CRL measurements

There are two components:

1. theory component
2. practical component

10.2 Theory component

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

The theoretical modules include:

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

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

10.3 Practical component

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

Table 11 - Practical training requirement

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

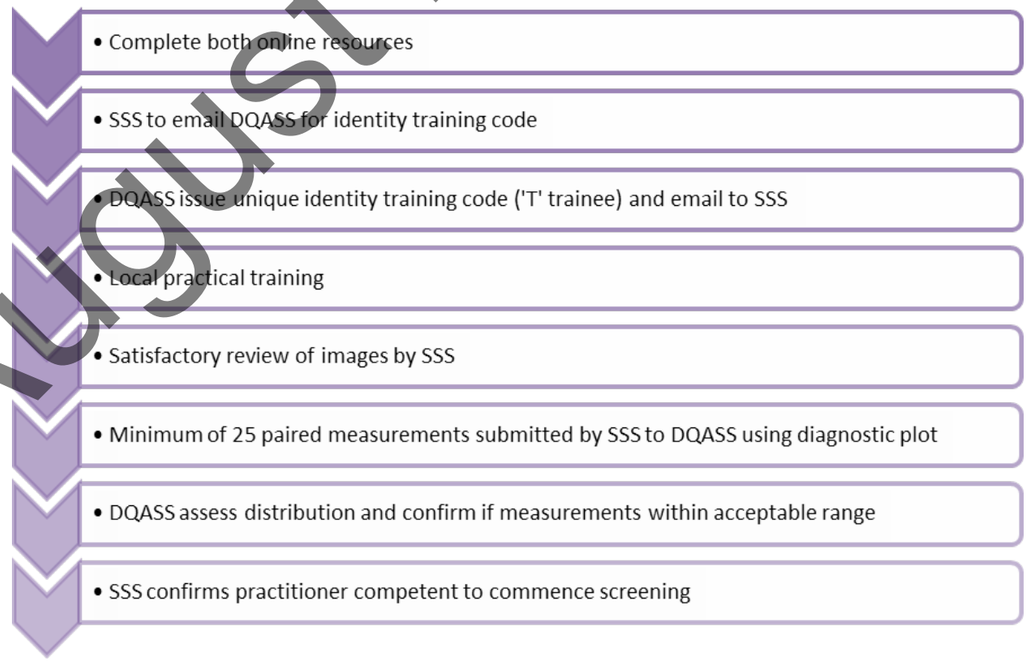
* A diagnostic plot self-assessment tool is provided for practitioners to enter their 25 paired measurements. This must be used when the SSS sends the data to DQASS and can be found at **fetalanomaly.screening.nhs.uk/SSSresources**

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

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

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

Diagram 9 Progression of training for practitioners new to NT measurement



Guidance for experienced practitioners from overseas

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

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

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

Recommendations

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

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

Table 12 - Summary of training requirements

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

Screening Matters

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

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

11 Quality Improvement and Assurance

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

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

11.1 Quality Improvement

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

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

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

11.2 Quality Assurance (QA)

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

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

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

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

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

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

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

11.3 Key performance indicators (KPIs)

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

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

11.4 Screening safety incidents

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

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

More information about managing screening safety incidents is available at:

www.screening.nhs.uk/incidents

cpd.screening.nhs.uk/incident-resource

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

www.screening.nhs.uk/si-learning

12 Information for the public

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

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

Acknowledgments

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

Glossary

Amniocentesis

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

Amniotic fluid

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

Anomaly

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

Biochemical markers

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

Chorionic Villus Sampling (CVS)

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

Combined test

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

Crown rump length (CRL)

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

Detection rate

The proportion of affected individuals with a positive screening result.

Diagnostic test

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

Down's Syndrome (trisomy 21)

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

Edwards' Syndrome (trisomy 18)

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

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

Fetal anomaly

Structural abnormalities with how the fetus has developed.

Fetal anomaly ultrasound scan

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

Gestational age

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

Invasive diagnostic procedure

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

Marker

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

Nuchal scan (Nuchal transluscency scan NT)

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

Patau's Syndrome (trisomy 13)

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

Prenatal

Relating to the period before birth

Quadruple test

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

Quality assurance (QA)

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

Risk

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

Risk cut-off

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

Screen positive rate (SPR)

The number of women who receive a higher risk result.

Screening

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

Screening pathway

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

Screening programme

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

Screening safety incident

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

Screening test

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

Syndrome

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

Throughput

Number of samples undertaken per cycle

Trisomy

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

Ultrasound scan

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

Tables, Diagrams and Images

References

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Abbreviations

AFP	Alpha fetoprotein
BPD	Biparietal Diameter
CEMT21	Condensed Education Modules for Trisomy 21
CPD	Continuous professional development
CRL	Crown Rump Length
DQASS	Down's syndrome screening Quality Assurance Support Service
DR	Detection rate
FASP	Fetal Anomaly Screening Programme
FMF	Fetal Medicine Foundation
FPR	False Positive Rate
HC	Head Circumference
hCG	Human chorionic gonadotrophin
KPI	Key Performance Indicator
MoM	Median multiple of the median
NT	Nuchal Translucency measurement
OFD	Occipital-frontal diameter
PAPP-A	Pregnancy associated plasma protein – A
PHE	Public Health England
QA	Quality Assurance
RQAT	Regional Quality Assurance Team
SIL	Screening and Immunisation Lead
SIT	Screening and Immunisation Team
SPR	Screen Positive Rate
SSS	Screening Support Sonographer
STFYAYB	Screening Tests for You and Your Baby
T	Trisomy
uE3	Unconjugated oestriol
UK NSC	United Kingdom National Screening Committee

Appendices

Appendix 1. Score sheets

NT score sheet

Sonographer ID

NT score sheet for Image Review																							
Date of review																							
Assessor																							
Patient ID																							
Horizontal mid sagittal section	1																						
Head in line with body, visible skin line	2																						
Echogenic tip of the nose	3																						
Rectangular shape of the palate	4																						
Translucent diencephalon	5																						
Frontal process of maxilla not visible	6																						
Pocket of fluid under chin visible	7																						
Palate angle 30 - 60°	8																						
Nasal tip level or above chest wall	9																						
Fills over 60% of the screen	10																						
Callipers on upper and lower skin line	11																						
Measure widest part of NT	12																						
Outcome																							
Comments																							

CRL score sheet

CRL score sheet for Image Review	
Sonographer ID	
Date of review	
Assessor	
Patient ID	
1 Mid sagittal section, head in line with body	
2 Echogenic tip of the nose	
3 Rectangular shape of the palate	
4 Translucent diencephalon	
5 CRL axis between 0° and 30° to horizontal	
6 Clearly defined crown and rump	
7 Pocket of fluid under chin visible	
8 Palate angle 30 - 60°	
9 Nasal tip level or above abdominal wall	
10 Fills over 60% of the screen	
11 Callipers on outer borders of crown and rump	
12 Longest measurement of fetus	
Outcome	
Comments	

Appendix 2. Red flag action plan (bias)

Suggested action plan for practitioners assigned a red flag for bias

Practitioner DQASS identity code	
Audit cycle number	
Name of SSS	
Name of local organisation/NHS trust	
Date	

FASP recommends that an individual training plan be negotiated between SSS and practitioner

Action	Date Completed	Comments
Practitioner informed by SSS		
Supervised screening commenced		
Manager and local screening board informed		
Review equipment, environment, working practices, technique and training needs		
SSS to review previous paired images with practitioner		
SSS to liaise with Regional QA team		
Confirm action plan in place with Regional QA team within 2 weeks of DQASS report being received. (Regional QA team to inform SIL team).		
Review online training resources		
Supervised training sessions with SSS		
SSS to review new images to confirm acceptable		
SSS to send 25 paired measurements to DQASS		
DQASS confirm new measurements within acceptable range		
SSS confirms practitioner may resume independent practice		
Review of outcome within 12 weeks and update sent by SSS to regional QA team		

Appendix 3. Red flag action plan (throughput)

Suggested action plan for practitioners assigned a red flag for throughput.

Practitioner ID number	
Audit cycle number	
Name of SSS	
Name of local organisation/NHS trust	
Date	

FASP recommends that an individual training plan be negotiated between SSS and practitioner.

Action	Date Completed	Comments
Practitioner informed by SSS		
Unsupervised screening ceases		
Manager and local ANNBSP board informed		
Review working practices		
SSS to liaise with Regional QA team		
Confirm action plan in place with Regional QA team within 2 weeks of DQASS report being received. (Regional QA team to inform SIL team)		
DQASS reassess bias and throughput as acceptable		
SSS confirms practitioner may resume independent practice		
Review of outcome within 12 weeks and update sent by SSS to regional QA		

Appendix 4. Training logbook for new practitioners

Name of ultrasound practitioner	
DQASS identity code	
Name of SSS	
Name of organisation/NHS trust	

ITEM	Date completed	Comments
Condensed education module for T21 (CEMT21) **Essential**		
NT training resource **Essential**		
Training number requested from DQASS		
Log-book of supervised scans completed		
Log book of 25 independent scans completed		
Images reviewed and scored as good or acceptable with SSS		
25 paired measurements submitted to DQASS		
SSS confirms competent to scan independently		
Signed declaration		
The above named ultrasound practitioner has successfully completed all the training requirements and is therefore competent to undertake the ultrasound aspect of the NHS T21 combined screening programme.		
Signature of SSS		
Date.		

Appendix 5. Return to practice logbook

DQASS identity code	
Name of SSS	
Name of organisation/NHS trust	

ITEM	Date completed	Comments
Condensed education module for T21 (CEMT21) **Essential**		
NT training resource **Essential**		
Supported practice if required		
Satisfactory image review with SSS completed		
25 paired measurements submitted to DQASS		
SSS confirms may continue screening		

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