University Hospitals Sussex
NHS Foundation Trust

First Trimester US Screening: Dating Scan, Combined Test & Declined Combined Test Ultrasound

OVERVIEW

The purpose of this protocol is to enable sonographers to safely complete the first trimester scan with or without screening, incorporating national and local guidance.

This protocol applies to sonographers carrying out first trimester scanning.

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1.0 INTRODUCTION

The purpose of this protocol is to enable sonographers to safely complete the first trimester scan with or without screening, incorporating national and local guidance.

12-week combined test & declined combined test ultrasound scans must only be performed by a sonographer/ fetal medicine specialist / ultrasound practitioner with a minimum of a post graduate certificate or academic equivalent. The sonographer must also have undertaken and passed the 'Fetal Medicine Foundation' theoretical and practical course, followed by annual renewal of FMF licence. This is the individual operator's responsibility.

2.0 DEFINITIONS AND ABBREVIATIONS USED IN THIS DOCUMENT

ANST - Antenatal Screening Team	**FASP -** Fetal anomaly Screening Programme
CT - Combined Test	**NT -** Nuchal Translucency
QUAD - Quadruple test: maternal age, AFP, hCG uE3 and inibin-A: optimum time for testing = 16 weeks.	**DQASS -** The Downs syndrome screening quality assurance support service
SSS - Screening Support Sonographers	**MIS -** Maternity Information System e.g. BadgerNet
CRL - Crown Rump Length	**EPAC -** Early Pregnancy Assessment Clinic
RPOC - retained products of conception	**FH -** fetal heart
HC - Head circumference	**TAS -** Trans abdominal scan
TVS - Trans vaginal scan	**UKAS -** United Kingdom Accreditation Service
CRIS - Computerised Radiology Information System	**MIS -** Maternity information System e.g. Badgernet

3.0 DUTIES AND RESPONSIBILITIES

All staff working in the Trust	• To access, read, understand and follow this protocol. • To use their professional judgement in application of this protocol.
Managers	• To ensure the protocol is reviewed three yearly and aligns with national standards. • To ensure the protocol is accessible to all relevant staff.

4.0 INFORMATION FOR PREGNANT WOMEN AND BIRTHING PEOPLE PRIOR TO SCAN

- All pregnant women and birthing people must be counselled by a midwife prior to the first trimester ultrasound examination, to enable pregnant women and birthing people to make an informed choice regarding screening. The pregnant woman or birthing person is not required to decide straight away but must have decided by the time of the scan appointment. A dating/NT/CT scan is requested at point of receipt of referral by admin team. They should indicate where possible if an interpreter is required or if there are mobility considerations.
- Midwives, obstetricians or admin requesting an ultrasound scan make this via ICE and must ensure there is sufficient clinical information to justify the scan.
- All pregnant women and birthing people are asked to attend with a moderately full bladder.
- All appointments are allocated 25 mins as per UKAS national guidance - Updated by BMUS 2018.
- Patient information leaflets are available on the MIS

5.0 FASP: SCREENING PROGRAMME

Screening is offered to assess the risk of the baby being born with Downs syndrome (Trisomy 21), Patau's Syndrome (Trisomy 13) and Edwards Syndrome (Trisomy 18).

The test of choice for both singleton and multiple pregnancies is first trimester combined screening. Pregnant women and birthing people can choose:

- Not to have screening
- To have screening for T21 only
- To have screening for T18 & T13 only
- To have screening for T21, T18 & T13.

5.1 Trust notes

- The pregnant woman and birthing person must be properly identified according to the trust policy with name, date of birth and address prior to the ultrasound examination.
- Verbal consent should be obtained by the operator prior to the ultrasound examination.
- If a pregnant woman or birthing person declines first or second trimester screening, and other abnormalities are found (such as for example: a cystic hygroma, NT > 3.5mm, megacystis or anencephaly) the pregnant woman or birthing person must be aware that results will be communicated to them and same day referral to the ANST will be made.
- If the CRL is >84mm the combined test cannot be done. A Quadruple test can be performed by completing an HC measurement. The HC measurement must be calculated using Viewpoint, not done as a manual calculation, as these do not always match.
- A Quadruple test can only be done if HC is >101mm and less than 172.0mm inclusive. If the HC is less than 101mm on the day, record the HC and refer to a midwife who will book the pregnant woman or birthing person in for bloods in a few days. The Quadruple test can be offered from 14+2 to 20+0 inclusive (FASP July 2022).

- If the pregnant woman or birthing person consents to screening at booking appointment then declines at time of scan, the sonographer should document on scan report and notify ANST to confirm patient choice and document declined on MIS. An NT measurement can be completed in case the pregnant woman or birthing person changes their mind to prevent rescan if screening is subsequently accepted after counselling with ANST.
- If the pregnant woman or birthing person changes their mind and requests screening after a declined test, a Quadruple Test will be offered if a second scan for NT cannot be offered due to availability.
- If the pregnant woman or birthing person consents to screening but changes their mind AFTER the ultrasound scan and before bloods are taken, this should be documented, and the screening midwife should be notified.
- If the pregnant woman or birthing person declines screening, they should still be sent to the ANC to have their height and weight checked – this allows for the entry of EDD and number of babies, as well as BMI, to be accurately recorded on the MIS.
- All examinations must be properly attended, post-processed and auto reported on CRIS on the day of the investigation.
- All images must be properly stored on PACS in the correct pregnant woman or birthing person's file.
- A Viewpoint report must be completed. Please see appendix 2 for a guide on completing Viewpoint reports.

5.2 Images to be recorded.

- CRL must be between 45-84 mm (must be a minimum of 3 images)
- NT measurement (must be a minimum of 3 images)

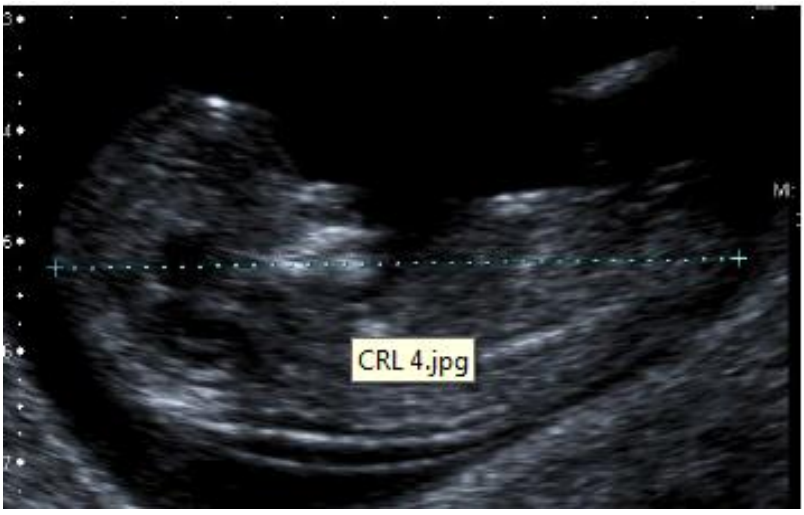
The following fetal structures should be examined:

- Skull/ brain
- Fetal Hands
- Fetal Feet
- Stomach
- Bladder if visible.
- Abdominal wall/ Cord Insertion
- Location of the placenta(s)
- Longitudinal view demonstrating cervix & uterus to identify the pregnancy is correctly sited.
- Assess maternal or birthing person adnexa.
- Document quality of view; where poor, include possible reason for poor view

5.3 FASP recommended assessment for the CRL for pregnancy dating and combined screening.

Criteria for CRL	Detail to be Demonstrated
CRL range in mm	• 45.0- 84.0 mm.
Midline Section	• Sagittal section of the fetus with the head in line with the full length of the body. • Echogenic tip of the nose visible. • Rectangular shape of the palate. • Translucent diencephalon. • CRL axis should be between 0 and 30 degrees to the horizontal. • Clearly defined crown and rump.
Position	• Pocket of fluid, at least equivalent in the size to the width of the palate, should be visible between the chin and chest. • Fetal palate angle should be 30 to 60 degrees, relative to the horizontal. • Nasal tip should be at the level of above the level of the abdominal wall.
Image Magnification	• The magnification of the fetus is made as large as possible before the image is frozen. The entire CRL section should be magnified to 60 – 98% of the screen.
Calliper Placement	• Correct calliper placement on the outer borders of crown & rump. • Longest length of the fetus should be recorded.
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.

Below is a FASP good example of a CRL, incorporating all of the above points:



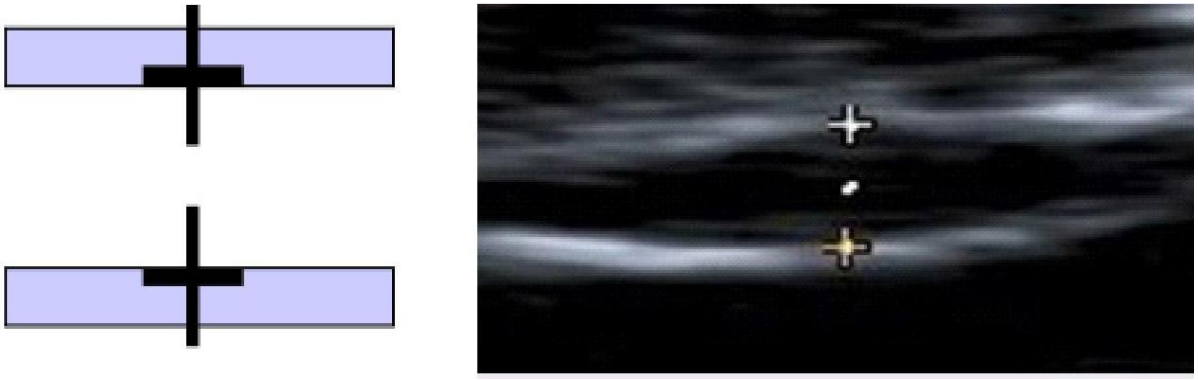
5.4 FASP: Recommended criteria for measurement of NT for combined screening

Criteria for NT	Twelve Components to assess the NT image appearance
Midline section	• Horizontal sagittal section of the fetus extending from crown to include at least the upper aspect of the heart. • Head in line with the body with the nuchal translucency 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 (see Diagram 1)
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 300 and 600. • Nasal tip should be level with, or above, the anterior chest wall.
Magnification	• The image should be magnified to 60 – 98% of the screen.
Calliper placement	• Callipers should be placed on the upper and lower skin line (see Diagram 2) • Widest part of the NT should be measured

Diagram 1: FASP good example of a NT measurement - incorporating all of the above points:

5.5 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.



*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.

5.6 Measuring the CRL & NT to one decimal point.

To ensure consistent, standardised and safe practice, sonographers must measure and report both the CRL & NT to one decimal place as recommended by NHS FASP. It is recommended for all ultrasound equipment to display measurements to one decimal place.

5.7 Unable to obtain NT.

If unable to obtain NT measurement due to fetal lie or high BMI etc, attempt to rebook the pregnant woman or birthing person. If on the second attempt the NT still cannot be obtained, measure the CRL and HC. Document and refer the pregnant woman and birthing person to the ANST re a QUAD test.

TVS may be offered as alternative to TAS if possible, within time constraints.

5.8 Increased Nuchal Translucency (NT)

If the NT is equal to or more than 3.5 mm with a CRL between 45-84 mm, a fetal abnormality must be considered.

An increased NT is associated with an increased chance of these autosomal trisomy's 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. Inform the pregnant woman and birthing person and document this on the report then refer the pregnant woman or birthing person to the ANST.

5.9 Multiple Pregnancy

Unexpected DCDA twins found at the CT scan do not need to be referred to ANST. MCDA, MCMA or triplet pregnancies are to be referred to the ANST as it can complicate screening. Take CRL and NT for both foetuses. Midwives in ANC should be alerted to all multiple pregnancies to ensure scan and appointment times can be adjusted accordingly.

Chorionicity should be determined as early as possible as pregnant woman or birthing person management differs. Comment and document the presence of the lambda or T-sign membrane. An image must be recorded of the membrane insertion on which the diagnosis of chorionicity is based. If you are unable to determine the chorionicity at the earliest scan, seek the second opinion of a senior sonographer or rebook another appointment in 2 weeks' time.

- *Dichorionic, Diamniotic:* there will be two gestation sacs, a thick dividing membrane, lambda sign two yolk sacs and two placentas.
- *Monochorionic, Diamniotic:* there will be one gestation sac, a thin dividing membrane, T sign two yolk sacs and a single shared placenta.
- *Monochorionic, Monoamniotic:* there will be one gestation sac, no dividing membrane, one yolk sac and a single shared placenta (likely to be intertwined cords).

The test of choice for twin pregnancies is the combined test. Every effort must be made to offer and complete this test. The larger of the 2 CRL measurements should be used in the chance result calculation. Measure the NT for each of the fetuses. Identification of Twin 1/A should be made as the fetus closest to the maternal cervix.

For screening using the combined test, where a dichorionic twin pregnancy is identified the chance result will be reported for each fetus. In a monochorionic twin pregnancy both foetuses are either affected or unaffected, so the chance result will be the same.

5.9.1 Quadruple Screening in Twin Pregnancies

For the small number of pregnant women and birthing people who have a twin pregnancy and miss the opportunity of having first trimester screening they can be offered the choice of a second trimester quadruple test for Down's syndrome only. This means the decision-making process is more difficult for pregnant women and birthing people as this test is less sensitive than first trimester screening and any subsequent decisions about invasive diagnostic testing and selective reduction will have to be made later in the pregnancy.

The quadruple test is offered to pregnant women and birthing people with a twin pregnancy to screen for T21 only when one or both of the:

- NT measurements cannot be obtained.
- CRL measurements are greater than 84.0mm. The larger of the 2 HC measurements should be used in the chance result calculation.

5.9.2 Demised Twin Syndrome

The definition of a vanished twin is when one fetus in a twin pregnancy is non-viable. It may be partially or completely reabsorbed.

An ultrasound scan for the combined or quadruple test may show either:

- An empty second pregnancy sac.
- A second pregnancy sac containing a non-viable fetus.

5.9.2.1 Empty second pregnancy sac and the combined test

When there is an empty second pregnancy sac, the CT can be used to calculate the chance result.

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

5.9.2.2 Second pregnancy sac containing a non-viable fetus and the combined test.

When there is a second pregnancy sac containing a non-viable fetus, the CT cannot be used to calculate the chance result - it is possible there could be a contribution to the maternal bio-chemical markers for many weeks.

It is recommended that in this event services undertake the chance calculation based on the maternal age and NT only (i.e. without the biochemistry) this will be done by the Laboratory.

Please refer to the NICE guidance on screening for Down's Edwards and Patau's syndrome in higher multiple pregnancies (triplets & more): these are referred to Tertiary care.

5.10 Fertility treatment pregnancies

In IVF pregnancies or other fertility treatments (i.e. ICSI) the pregnancy must not be redated by the CRL. The IVF details must be obtained from the pregnant woman or birthing person and inputted onto Viewpoint to establish the pregnant women and birthing people EDD.

In the scenario where the pregnant woman or birthing person does not know this information - redate the pregnancy by the CRL and state this on the report. Refer to the ANST.

If the date of birth or age of the donor at the time of egg collection is unknown, every effort must be made to find this information for the chance result calculation. This includes IVF treatment received outside England. If this information cannot be determined, laboratories can use the upper age limit of egg donation in England which is under 36 years (that is; 35 years and 364 days). When this approach is used, it must be clearly written on the chance result report. We recommend using this cut-off due to limited information on egg donation outside England. In these cases, the healthcare professional should discuss the limitations of this approach and the impact on the chance result.

6.11 Abnormalities

If abnormalities are present, the sonographer is required to inform the pregnant woman or birthing person of their findings, document on the report and refer to ANST. Please refer to the EPAC Protocol if there is no evidence of pregnancy, no sac contents, no FH or RPOC. If the quiet room is needed, check its vacant its code is: c248x: (SRH).

6.12 Non-obstetric abnormalities

If a uterine anomaly is suspected such as didelphic, unicornuate, bicornuate or septate - report that these cannot be easily characterised with 2D ultrasound.

Abnormalities of the uterine shape: i.e. bicornuate and didelphus/subseptate – document on the report. When assessing the maternal adnexa a simple ovarian cyst measuring 3-5 cm should be documented on viewpoint. No follow up required. If there is a simple cysts greater than 5cm/ or complex cyst please refer to the antenatal clinic midwives. Document position and size and position of any fibroids.

MONITORING THE EFFECTIVENESS OF THIS PROTOCOL

- Every 3 months the SSS will conduct an audit of paired CRL & NT measurements for every sonographer. Scores are either 'Good', 'Acceptable' or 'Poor'. Audit results are sent back to each individual via the superintendent sonographer and copied to the superintendent sonographer.
- Every 6 months DQASS provides a report to our department and laboratory documenting activity and performance. Sonographers receive a graph to demonstrate their plot spread of NT measurements via the SSS. Red flags are managed according to the Trust protocol.

PROTOCOL VERSION CONTROL LOG

Change Log – First Trimester US Screening

Version	Date	Author(s)	Reason for change
1.0	Feb 2015	Rebecca Coombes	New guideline.
2.0	Jan 2020	Rebecca Coombes	Review completed.
2.1	May 2020	Rebecca Coombes	FASP reference added.
3.0	May 2022	Rebecca Coombes	Appendices on filming in scan rooms and other people in scan rooms added. Name changed to 'Dating Scan, Combined Test & Declined Combined Test USS Protocol'.
4.0	Feb 2024	Rebecca Coombes, Amanda Sutton	Updated this to reflect FASP changes (up to 23/11/23).

Due Regard Assessment Tool

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**		
	Age	*No*	
	· Disability	*No*	
	· Gender (Sex)	*No*	
	· Gender Identity	*No*	
	· Marriage and civil partnership	*No*	
	· Pregnancy and maternity	*No*	
	· Race (ethnicity, nationality, colour)	*No*	
	· Religion or Belief	*No*	
	· Sexual orientation, including lesbian, gay and bisexual people	*No*	
2.	**Is there any evidence that some groups are affected differently and what is/are the evidence source(s)?**	*No*	
3.	**If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?**	*NA*	
4.	**Is the impact of the document likely to be negative?**	*No*	
5.	**If so, can the impact be avoided?**	*NA*	
6.	**What alternative is there to achieving the intent of the document without the impact?**	*NA*	
7.	**Can we reduce the impact by taking different action and, if not, what, if any, are the reasons why the protocol should continue in its current form?**	*NA*	
8.	**Has the document been assessed to ensure service users, staff and other stakeholders are treated in line with Human Rights FREDA principles (fairness, respect, equality, dignity and autonomy)?**	*Yes*	

If you have identified a potential discriminatory impact of this protocol, please refer it R. Coombes, & A. Sutton, together with any suggestions as to the action required to avoid/reduce this impact. For advice in respect of answering the above questions, please contact uhsussex.equality@nhs.net 01273 664685).

TEMPLATE DISSEMINATION, IMPLEMENTATION AND ACCESS PLAN

	Dissemination Plan	Comments
1.	Identify:	
	Which members of staff or staff groups will be affected by this protocol?	Sonographers and midwives.
	How will you confirm that they have received the protocol and understood its implications?	Dissemination through the usual Communication channels and highlighted at Safety Huddles.
	How have you linked the dissemination of the protocol with induction training, continuous professional development and clinical supervision as appropriate?	All new members of staff shown where to access Clinical documents that are relevant to their area of practice.
2.	How and where will staff access the document (at operational level)?	Accessed by staff via SharePoint

		Yes/No	Comments
3.	Have you made any plans to remove old versions of the protocol or related documents from circulation?	Yes	Previous versions will be archived.
4.	Have you ensured staff are aware the document is logged on the organisation's register?	Yes	Dissemination plan includes notifying staff via email, safety noticeboards, departmental newsletter and social media. Summary sent to sonographers.

ADDITIONAL GUIDANCE AND INFORMATION

Lees, C.C., Stampalija, T., Baschat, A.A., da Silva Costa, F., Ferrazzi, E., Figueras, F., Hecher, K., Kingdom, J., Poon, L.C., Salomon, L.J. and Unterscheider, J. (2020), ISUOG Practice Guidelines: diagnosis and management of small-for-gestational-age fetus and fetal growth restriction. Ultrasound Obstet Gynecol, 56: 298-312. https://doi.org/10.1002/uog.22134

Kennedy, L.M., Tong, S., Robinson, A.J. *et al.* Reduced growth velocity from the mid-trimester is associated with placental insufficiency in fetuses born at a normal birthweight. *BMC Med* **18**, 395 (2020). https://doi.org/10.1186/s12916-020-01869-3

Professional guidance for fetal growth scans performed after 23 weeks of gestation
British Medical Ultrasound Society 3rd Trimester Special Interest Group. January 2022 BMUS 2022.

New Zealand Maternal Fetal Medicine Network. Guideline for the Management of Suspected Small for Gestational Age Singleton Pregnancies and Infants after 34 Weeks' Gestation. NZMFM:2014.

Clinical protocol [CDL 4588] governance and approval

Owner	Tim Taylor
Author/further information	R. Coombes, Superintendent Sonographer A. Sutton, Sonographer
Protocol version	v4.0
Related policies	N/A
Related documents	Antenatal Care and Patient Information
Standards	Saving Babies Lives version 3 (2023) Antenatal Care. NICE guideline [NG201] (2021) Guidelines for Professional Ultrasound Practice Society and College of Radiographers and British Medical Ultrasound Society Revision 5 (2023) Fetal anomaly screening programme handbook - GOV.UK (www.gov.uk)
Superseded documents	N/A
Review due	February 2027
Reference number	CG2003

Approval

JOGG	**Date approved:**	21st February 2024
Women & Children's Clinical Effectiveness Meeting	**Date approved:**	21st March 2024

Consultation

Add relevant Trust-wide governance group (see table below)	**Date approved:**	N/A
Add other specialist teams or groups as appropriate	**Date approved:**	N/A

Ratification

Clinical Document Approval Group	**Date approved:**	19th April 2024

Consultation

Please select any appropriate consultation groups/ committees:

Trust Wide Governance Group	**Tick as required:**
Medicines Governance Committee (MGC - replaces 'Medicines Optimisation Committee' and 'Drug and Therapeutics Committee')	
Antimicrobial Stewardship Group	
Resuscitation Committee	
Resuscitation Operational Management Group (ROMG)	
Trust Transfusion Committee	
Trust Infection Prevention Committee (Chief Nursing Officer)	
Thrombosis Committee	
Health Records Committee	
BSUH Trauma Committee	
Major Trauma Committee	
Sussex Trauma Network	
Children's Safeguarding Strategy Committee	
Radiation Safety Committee	
Medical Devices & Equipment Committee	
Patient Blood Management Committee	
Patient Safety Committee	
BSUH Diabetes In-Patient Care Committee	
Carer and Patient Information Group (CPIG)	
Women's Safety and Quality Committee	
Food Improvement Group	
NIV Steering Group	
NMAHP Board	
Deteriorating Patient Group	
Other (please specify)	