

Antenatal Screening Standard Operating Procedure Combined and Quadruple Screening (Frimley Park Hospital)

Key Points

- Combined screening
- Quadruple screening
- First trimester screening
- High Chance result
- Oxford Screening laboratory

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Abbreviations

ANC	Antenatal Clinic
ARC	Antenatal Results and Choices
CRL	Crown rump length
CST	Combined Screening Test
DQASS	Down syndrome screening Quality Assurance Support Service
Epic	Electronic Patient Record (EPR)
FASP	Fetal Anomaly Screening Programme
FPH	Frimley Park Hospital
NOP	Notification of pregnancy
NSC	National Screening Committee
NT	Nuchal Translucency
SOP	Standard operating procedure
USS	Ultrasound Scan

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Purpose

All eligible pregnant women should be offered screening to assess the chance of their baby being born with Down, Edwards' or Patau's syndromes according to the National Screening Committee (NSC) fetal anomaly screening programme (FASP).

This SOP describes the patient and sample process for all patients who book prior to 20 weeks of pregnancy in line with the FASP requirements.

Introduction

In line with NSC standards, all women who book in pregnancy prior to 20 weeks should be offered screening.

The first trimester Combined Screening Test (CST) uses a combination of USS NT measurement and Biochemical markers in maternal blood and can be completed up to and including 14+1.

Combined screening can screen for:

- Down syndrome - Trisomy 21 (T21)
- Edward syndrome - Trisomy 18 (T18)
- Patau syndrome - Trisomy 13 (T13)

Most babies with Trisomy 18 or Trisomy 13 will be stillborn or die shortly after birth. Some babies may survive to adulthood, but this is rare.

The second trimester Quadruple screening test (QUAD) uses biochemical markers in a maternal blood sample only and can be offered from 14+2 -20+0 weeks.

Quadruple screening will only screen for:

- Down syndrome - Trisomy 21 (T21)

Scope

This SOP explains the patient, sample and result process for all women who consent to combined or quadruple screening at Frimley Park Hospital.

Responsibilities

Antenatal screening coordinator and screening midwives are responsible for maintaining guidelines and implementing FASP Standards and are responsible for reviewing all results and actioning high chance results.

Ultrasound screening lead / screening support sonographer: responsible for ensuring all Ultrasound staff meet FASP requirements. This must include the sonographer's personal FMF accreditation ID number. This ID number must be recorded on every screening request registered on the Astraia antenatal screening software.

This also enables monitoring of individual screener performance by the DQASS service, to ensure consistent and reliable performance of dating and NT measurements and allows any

practitioner whose performance is outside of acceptable limits to be offered additional training or practice development.

Phlebotomy department: responsible for taking correct sample, in the correct sequence, if taking multiple samples which includes a full blood count the CST/Quadruple sample must be taken first .This is to prevent the screening sample from becoming contaminated by a chemical in the FBC tube which would prevent it from being suitable for testing , labelling appropriately, reviewing the request form for completeness (sign and date the request form), and sending the samples to the pathology department at the end of each session (am/pm).

Biochemistry specials (send aways) department is responsible for cross checking samples with request form, spinning and packaging samples to be sent by Hospital Transport to the Oxford Screening Laboratory.

Site specific procedure (FPH)

Patient process:

Frimley Park Hospital community midwife

- Patient completes an online notification of pregnancy (NOP) form located on FHFT maternity website.
- Monday -Friday the NOP is received by clerical team at FPH and patient details are forwarded to relevant midwifery team identified from the patients registered GP surgery.
- Early booking 8-10 weeks is desirable.
- Community midwife arranges booking appointment and completes pregnancy booking on Epic. All screening tests are explained, and midwife ensures that the woman has sufficient information to allow her to make an informed decision whether to consent to screening or not. The woman should be encouraged to access the online digital 'Screening tests for you and your baby' information via the link shared on 'My Frimley Health App' or via the QR code. The link is shared with the women on receipt of NOP and after the midwifery booking appointment.
- Screening options and the woman's choice to enter into screening or decline screening is discussed at the booking appointment and confirmed by completing the questions on the Epic combined screening order and document on the antenatal screening flow sheet.
- Combined screening Test (CST) order to be made by community midwife; by completing all information, including consent, on Epic CST order.
- Epic order also placed for NT scan. The scan appointment will be made and sent to patient via My Frimley Health App. If an urgent scan is required, the community midwife can contact ultrasound department by phone once the Epic order is completed. If the patient is not active on the My Frimley Health App then appointment details will be sent via Text message.
- Phlebotomy can release the CST order label following completion of NT /dating scan when taking blood sample.

Ultrasound scan

- Patient attends for scan. Sonographer gains verbal consent to complete scan. If there is a language barrier and informed consent cannot be obtained interpreter should be used (face to face or telephone). Screening Midwives can support sonographers to ensure that informed consent is obtained for scan and appropriate screening blood test.

- 11^{+2} - 14^{+1} (CRL 45 mm-84 mm): Combined screening (CST) offered.
- 14^{+2} -20 weeks (CRL >84 / HC 101.0mm-172.0mm): Quadruple screening should be offered if the woman books late or presents for screening after 14^{+1} .
- If patient is $>14+1$ gestation but HC is less than 101.0mm patient to be referred to screening midwives and appointment to be scheduled on to the antenatal screening snapboard at approximately 16 weeks gestation.
- Twin pregnancies will be offered combined screening or quadruple screening as appropriate, but Sonographers will refer to screening team for enhanced counselling if required.
- If unable to measure NT on 2 x attempts, patient referred for quadruple screening.
- Women presenting with a second sac and non-viable fetus can we offered a modified combined screening test. The sonographer should refer all women to the screening team for enhanced counselling to ensure she understands the limitations of screening and if consents the screening Midwife will ensure documentation on the request form is clear for the Oxford screening lab to complete the modified combined screening test.
- Multiple pregnancy higher than twins can be offered NT only screening. (Patients must be informed that NT only screening falls out of the national FASP screening Programme).

Consent options for CST

- T21, T18 & T13 screening to be documented on the Astraia CST request form, by sonographer
- T21 screening only to be documented on the Astraia CST request form, by sonographer.
- T18 & T13 screening only to be documented on the Astraia CST request form, by sonographer
- All screening declined

N.B Quadruple test will only screen for T21

All screening declined

- Community midwife to document 'declined screening' on antenatal screening flowsheet. The Booking Midwife should still order a NT/ dating scan.
- Women will be verbally asked at the commencement of Nuchal scan if they consent to screening, to document 'decline screening' on Astraia scan report.
- The sonographer will contact the screening team if a woman requires further counselling at time of scan.
- NT Measurement for women who decline. Nuchal translucency will be reviewed as part of fetal wellbeing and if this appears to be within normal range the sonographer will select appropriate drop-down phrase from Astraia. If measurement appears significant and > 3.5 mm's this will be accurately measured and recorded on report. Women will be counselled by the sonographer and referred to the screening team.
- All unexpected US findings will be reported and patient referred to screening team for appropriate management.

Blood sample and request form

- **Frimley Site:** CST / Quad request form is generated by the Astraia scanning system and placed in the phlebotomy request tray in ANC and patient is asked to wait in the antenatal clinic waiting room to be called for their blood test. The phlebotomist will release the order from Epic and use the barcoded label to label the specimen. They will sign and date the Astraia CST / Quad request form.
- **Satellite scanning sites:** Patient is handed combined /quadruple Oxford request form by the sonographer and asked to attend the phlebotomy department in the appropriate

satellite site. Appointment for phlebotomy will have been made in advance of their scan by the screening team administrator. If no appointment available, the phlebotomy department will make a same day appointment for blood test to be taken. The screening team have a daily failsafe system to ensure all women who complete NT scans have had the combined screening blood test taken.

Anomalies identified at Scan: Fetal medicine referral pathway will be commenced.

- NT \geq 3.5mm screening team informed and patient counselled at time of scan or if scan completed at a satellite site the screening team will telephone the patient and invite them to attend the main hospital site or counsel over the phone. Individual care pathway agreed with the patient. Antenatal screening midwives contact telephone details given to patient.
- CST / Quad screening completed. FAST TRACK REQUESTED – by sending email to the Oxford screening laboratory.
- Patients with a failed twin pregnancy with the presence of a fetal pole for the demised twin can be offered modified combined screening. Women should be referred to the screening team for additional counselling ‘
- Multiple pregnancy higher than twins can be offered NT screening only.

Oxford Lab Screening request form is completed electronically from the Astraia scan system.

- Sonographer is responsible for ensuring all data fields are completed.
- For NT scans completed on main hospital site a member of the screening team can be asked to review the request form to ensure all key data fields are complete.
- Phlebotomist is asked to review request form and ensure all key data fields are complete, they will sign and date the request form once the sample has been taken.
- Biochemistry send away staff are asked to review request form and ensure all key data fields are complete.

Specimen Process

Phlebotomy

- **Frimley Park Site:** Combined and quadruple samples are taken to specimen reception at the end of the morning and afternoon session and placed in designated ‘combined screening’ sample box.
- **Satellite scan locations:** All combined / quadruple screening blood samples are collected by hospital transport and taken to specimen reception at FPH at the end of the morning and afternoon session.

Laboratory

- All screening samples received by specimen reception are booked onto lab IT System (Winpath).
- All samples are centrifuged and taken to biochemistry sendaways and stored in the fridge, ready for transportation.
- Request form photocopied and stored for one-week (in folder in sendaways) requests are scanned into DART lab system.
- Original request form and samples are packaged and labelled with box number, to help with tracking of samples that are sent and then received in the Oxford screening lab.

- All samples sent to Oxford are cross checked against request form and a final list of samples sent is emailed to screening team (generic email) with the Box number.
- Samples are sent daily via hospital transport collected at around 4pm from sendaways and delivered straight to main specimen reception at the John Radcliffe Hospital.

DATA entry and failsafe system

- The screening team track all incomplete bloods on their daily tracker report and will call / send an Epic letter or patient message to the women to invite her to attend to complete screening. As the gestation approaches 14+1 the team will make additional efforts to contact the women and encourage them to attend.

Frimley Park Site:

- Daily NT list & Quad test report is exported from Astraia every workday by the screening administrator and saved in CST Astraia daily test folder.
- This data is added to the combined screening database and additional columns are added to the excel report and labelled to collect additional information i.e Screening result, date of result, PAPP-A level.
- The combined screening database is used daily to track results received. Any patients identified that have not completed screening are reviewed to identify exclusion criteria or telephoned and invited in to complete screening.
- If unable to contact by phone, then an Epic patient message will be sent and community Midwife informed to support completion of screening.

NT Weekly tracking system

FHFT antenatal screening report is downloaded from Epic on a weekly basis. This captures all women booked for maternity care at FPH in the previous week. Report is saved to NT weekly folder, and further columns are added to capture:

- Confirmation that scan has been performed (nuchal)
- Declined or accepted CST / Quadruple screening test
- Outcome of pregnancy if pregnancy not viable.
- Whether rescan is required (e.g too early) and date of rescan

DNA Process

- Any women who DNA's a nuchal scan appointment is identified by the ANC admin team at the end of each clinic session and will inform the screening team by email.
- The Antenatal screening midwives will look on the woman's Epic record for any known reason for DNA of appointment e.g. Miscarriage, TOP.
- If no reason is identified, then screening midwives will contact woman by sending a patient message via Epic, to see if a further appointment is needed.
- If no response by the end of next working day the screening midwives will inform community midwife asking to follow up with woman and report back to screening team
- Screening Midwives will request ANC to rebook appointment.
- If patient is not using the My Frimley Health App, then patient is telephoned or community midwife informed to ensure she is aware of rebooked appointment.
- Screening admin will identify exclusion criteria for KPI FA3 from this weekly list.
- 16 weeks CMW checks that patient has completed screening pathway, documenting result in patient's booking screening bloods flowsheet.

Results process

- All combined and quadruple results are resulted on the Oxford Antenatal Screening laboratory portal – Lifecycle 7.
- Lifecycle 7 is accessed daily by the screening midwives and any held cases are reviewed and any missing information is added to allow Oxford laboratory to complete the screening.
- Details of **high chance results** are emailed to the generic screening email address (as well as the Lifecycle portal).
- Screening midwives must update Lifecycle to acknowledge receipt of high chance result, with the words FRIMLEY AWARE.
- Screening midwives will update the Lifecycle portal with the words FRIMLEY ACTIONED, once the patient has been informed of result.

Communication of results / Data Entry

- Combined / quadruple screening results accessed daily through the Lifecycle portal and downloaded.
- All results are added to each individual patients as an outside order – Oxford Combined Screening Report / Oxford Quadruple Screening Report.
- This is visible to the patient on their My FRIMLEY health app (and on Media Tab).
- All results entered onto combined screening database stored in electronic antenatal clinic files.
- Postal result letter is sent directly from Oxford Antenatal Screening Laboratory to patient.

High chance result

- Screening Midwife will communicate all high chance results to the woman.
- All women with high chance result should be offered a face-to-face appointment within 3 days of the result being available to the screening team.
- Phone patient on day of receipt or next working day with careful consideration given to contacting women on Friday afternoons or pre a bank holiday weekend.
- If no answer, leave a brief message asking patient to call back. Follow up with patient message sent via Epic.
- Continue to phone patient throughout the clinical day and if no response from either phone message or patient message within 2 working days contact community midwife. CMW asked to contact the patient either visiting them or via phone and ask patient to call antenatal screening midwives.
- Record all contact attempts and document all phone consultations on Epic using appropriate SMART TEXT phrases.
- Upload high chance result to Epic **AFTER** they have been informed of result and ensure all additional support information is shared.
- At 16weeks community midwife checks that women have received all her screening results in person. If no result received community midwife calls or emails the antenatal screening midwives so that result can be inputted on Epic.

Contact details

Screening Team email: fph-tr.antenatalscreening@nhs.net

Telephone 03006136989

References

Internal references

- [Antenatal and newborn screening](#)

External references

- Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome
<https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook/289099d7-ded0-43be-a901-600b78fb727e>
- Your choices after a higher chance screening result
<https://www.gov.uk/government/publications/downs-syndrome-edwards-syndrome-and-pataus-syndrome-options-after-a-higher-chance-screening-result/your-choices-after-a-higher-chance-screening-result>

Full version control record

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This guideline is for use in Frimley Health Trust hospitals only. Any use outside this location will not be supported by the Trust and will be at the risk of the individual using it.

Version History

Version	Date	Guideline Lead(s)	Status	Comment
3	December 2020	K Franks	Final	
3.1	May 2021	K Franks	Interim	Correction to Blood test (bullet point 3)
3.2	May 2022	K Franks	Draft	Changes to process
4.0	February 2025	K Franks	Final	Approved at Cross Site Obstetrics Clinical Governance meeting, 11 th February 2025

Related Documents

Document Type	Document Name
Guideline	Antenatal and newborn screening