

Antenatal Screening Standard Operating Procedure

Combined and Quadruple Screening

Wexham Park Hospital

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Abbreviations

CMW	Community Midwife
CRL	Crown rump length
CST	Combined screening test
DQASS	Down syndrome screening Quality Assurance Support Service
EDD	Estimated date of delivery
FASP	Fetal Anomaly Screening Programme
NSC	National screening committee
NT	Nuchal Translucency
USS	Ultrasound Scan

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1. PURPOSE

All eligible pregnant women should be offered screening to assess the chance of their baby being born with Downs, Edward or Patau syndromes, according to the NSC Fetal Anomaly Screening Programme (FASP).

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

2. INTRODUCTION

In line with National Screening Committee (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 screen for **T21** (Down syndrome - Trisomy 21), **T18** (Edward syndrome - Trisomy 18) & **T13** (Patau syndrome - Trisomy 13), and can be completed up to and including 14+1. 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 Quadruple screening test uses Biochemical markers in a maternal blood sample only, and can be offered from 14+2 -20+0 weeks, and will only screen for T21.

3. SCOPE

This Standard operating procedure details the patient, sample and result process for all women who consent to Combined or Quadruple screening at Wexham Park Hospital.

4. RESPONSIBILITIES

Antenatal screening coordinator / and screening team: 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, the CST/Quad sample must be taken first), labelling appropriately, reviewing the request form for completeness, and sending the samples to the pathology department at the end of each session (am/pm).

Biochemistry screening laboratory are responsible for cross checking samples with EPIC request and analyzing samples as per laboratory SOP.

Clinical Leads: consultant grade or equivalent clinical leads will take overall responsibility for ensuring a safe, reliable and adequately resourced screening pathway that confirms to SQAS and UKAS National standards. The two clinical leads will take responsibility for the clinical, and the laboratory parts of the FASP screening service.

5. SITE SPECIFIC PROCEDURE (WEXHAM)

5.1 Patient process

Wexham community midwife

- Midwife notified of new booking via online notification form located on the maternity website. Pregnancy notification is received by clerical team 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 EPIC booking. 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 have a copy of 'Screening tests for you and your baby' booklet or given information and supported to download the digital version on to their personal phone or electronic device.
- Screening options and the woman's choice of screening or declined is discussed at the booking appointment and confirmed by completing the questions on the EPIC order.
- Combined screening Test (CST), quadruple screening or declining screening. Blood order completed on EPIC; consent questions completed as part of EPIC 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.
- Phlebotomy can release the blood order form following completion of NT /dating scan.

Ultrasound

- Patient attends for scan.
- 11⁺² -14⁺¹ (CRL 45 mm-84 mm) combined screening offered.
- 14⁺²-20 weeks (CRL >84 mm) quadruple screening offered if books late or presents for screening after 14⁺¹
- Twin pregnancies will be offered combined screening or quadruple screening as appropriate, but USS 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 cannot complete combined screening but can be offered quadruple screening or NT only calculation can be offered. Multiple pregnancy higher than twins can be offered NT screening only. (Patients must be informed that NT only screening falls out of the national FASP screening Programme)

5.2 Consent options:

- T21 & T18/T13 - consent is clearly stated on EPIC order and documented during the community booking appointment.
- T21 only - consent is clearly stated on EPIC order and documented during the community booking.
- T18/T13 only - consent is clearly stated on EPIC order and documented during the community booking.

N.B. QUADRUPLE TEST can only screen for T21.

All screening declined.

Community midwife requests 'declined screening' on EPIC order and documents in EPIC. The Booking Midwife should still order a NT/ dating scan. The Screening team will be contacted by the scan department if a woman wishes to revisit her decision when she attends for her scan. In the event where combined screening has been accepted at booking and the woman changes her mind at the time of scan, a dating scan will be completed.

All women will be sent communication via my Frimley Health App confirming their decision to decline screening. This will be as an EPIC patient letter. To the My Frimley app. The Community Midwife is responsible for documenting the final decision in the screening bloods flow sheet on EPIC at the 16week appointment.

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 counseled 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.

5.3 Blood test

- **Wexham site:** following completion of scan women wait in antenatal clinic and take a number for the phlebotomy service. EPIC blood order is released by the phlebotomist and sample sent to the laboratory with the EPIC request form. Phlebotomy service available Mon-Fri 09:00-17:00.
- **Satellite sites include St Marks, Heatherwood and King Edward VII hospitals:** Women complete the scan and attend the phlebotomy department who will release the blood order and send sample to the Wexham laboratory on hospital transport. These sites have limited phlebotomy availability when phlebotomy service is not available women will be asked to attend Wexham Park maternity phlebotomy service as above and will be instructed that they must attend before 14+1 weeks to

complete combined screening. Women are asked to contact screening team before travelling to the main site.

N.B. EPIC combined screening /quadruple screening blood order must be placed in advance of attending phlebotomy. Women will need to contact the screening team to book an appointment to attend Wexham site for bloods if an order is required.

- The screening team track all incomplete bloods on their daily tracker report and will 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.
- **Anomalies identified at Scan:** Fetal medicine referral pathway commenced.
- NT ≥ 3.5 mm screening team informed by sonographer 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. Individual care pathway agreed with the patient. Contact telephone numbers given.
- Combined screening completed. FAST TRACK REQUESTED.
- Women presenting with a second sac and non-viable fetus cannot complete combined screening but can be offered quadruple screening or NT only calculation can be offered. Multiple pregnancy higher than twins can be offered NT screening only.
- Women should be referred to the screening team for additional counselling prior to calculating a chance result, based on maternal age and NT only, as this falls out of the remit of the national fetal anomaly screening Programme.

5.4 Specimen process

5.4.1 Phlebotomy

- **Wexham Park site:** All samples are sent to pathology specimen reception where the sample integrity and identity is checked, and the request is then registered on the pathology IT system with a unique specimen number. The samples are stabilized by centrifugation, and then transferred to the Biochemistry laboratory.
- **Satellite sites (St Marks, King Edward VII, Heatherwood):** Samples collected 1 x day by hospital transport and delivered to pathology specimen reception at Wexham Park.
- All samples are centrifuged and stored at in the fridge (4 degrees centigrade) until analysis.
- The relevant pregnancy episode is selected on the Astraia antenatal screening software, which has already been entered by the USS staff at the scan appointment. The relevant patient data is then added to this Astraia record by qualified laboratory BMS staff, manually from the EPIC order, according to laboratory SOP.
- After analysis, the PAPP-A and fbHCG Biochemical results are imported directly from the analyser into the Astraia record via an electronic interface. This transfer is checked, and the patient data checked again from the original EPIC request at this stage by qualified laboratory BMS staff.
- Samples requiring Quadruple testing are identified by laboratory BMS staff and

sent to Oxford daily via courier. Daily list compiled by the lab and list shared with the screening team. Screening team access Oxford lifecycle system for quadruple results

There is continuous daily dialogue between the screening team and key laboratory staff.

5.5 Combined screening calculation /failsafe

- Daily NT list is exported from Astraia every workday by the screening administrator and saved in screening team folder /Down's spreadsheets/daily list.
- Screening Team copy the report and save on to a daily running list. A new tab is opened each day and renamed with the date.
- Additional columns are added to the excel report and labelled to collect additional information:

Papp A.level, Anomaly Scan date , Date risk calculation for T21and T18/13. Result Validated. Comments and Patient Message.

- Screening administrator will work through the daily list, check on Astraia that all required fields have been populated by the laboratory, and will then select the calculate button to complete the chance calculation.
- Screening administrator will validate all low chance results by selecting the validate button on the individual Astraia record. This will update the 12 week scan report on the women's EPIC record with the combined screening calculation and the result is now available on the My Frimley Health App for the women to view.
- High chance results will be validated by the screening Midwife once the women have been contacted and counselled regarding further options.
- Screening administrator will transcribe the calculated result from Astraia onto the daily running list and complete the required columns. Any queries will be highlighted by coloring the row amber.
- Screening administrator will indicate a high chance calculation by highlighting the row RED.
- Screening Midwife will review each tab on the daily running list each day and work through all Amber and Red rows and update comments as required.
- High chance result screening midwife will document on daily running list when actioned and validate result once the women has been informed.
- EPIC patient record will be updated and additional NHS screening information will be shared with the woman to support ongoing decision making.
- If no blood sample is received in the lab for combined screening this is identified on the daily running list. EPIC letter/message is sent to the woman asking her to contact the team to arrange to attend for a blood test (see Appendix 1 (WPH, HW, STM) and Appendix 2 (FPH, ACH, Fleet, Farnham). Row filled amber on daily running list with 14+1 gestation documented in comments section.
- CMW informed via email if no blood received by 14+1 so a quadruple screening can be offered at 16-week appointment.
- When all amber and red rows are actioned the screening midwife is responsible for copying the daily running list onto the completed file which is stored in the same folder and deletes it from the daily running list. This ensures continuous daily oversight of all outstanding queries and an audit trail of actions completed.

- High chance weekly failsafe query is run from Astraia and cross checked with the combined screening high chance spreadsheet.
- US will note if quadruple test is recommended on the Astraia recommendations. An Astraia query report is run weekly which populates the Quadruple spreadsheet, results are documented on spreadsheet as received from life cycle. Oxford notify us of high chance results and team action appropriately.
- If patient does not have quadruple sample taken after scan screening team will contact the patient weekly until 19 + weeks either via an EPIC patient message or telephone call to invite them in to complete screening.
- 16 weeks CMW checks that patient has completed screening pathway and documents on the EPIC screening bloods flow sheet. If screening incomplete Quadruple screening can be offered up to 20+0 weeks gestation.
- A weekly report is downloaded from EPIC cross checking all maternity bookings with 12week scan appointment 2 weeks in arrears. If any midwifery booking is identified without a 12-week scan appointment this will be investigated by the screening team to ensure the appropriate exclusion criteria are identified or appointment arranged.
- This weekly list will identify the exclusion criteria for KPI FA3.

5.6 FASP Screening spreadsheets maintained by screening team

- High Chance COMBINED result
- QUADRUPLE Samples sent
- HIGH chance QUAD results received
- NIPT sent

5.7 KPIs

Combined screening FA4 KPI

- Key data fields are mandatory on EPIC order.
- Key data fields are rechecked at time of combined screening calculation

Quadruple Screening FA4 KPI

- Key data fields are mandatory on EPIC order
- Key data fields are rechecked by Oxford Laboratory

5.8 DNA process

- US clerical team email community midwife who ordered the scan and copy in generic community team. Details and actions kept on spreadsheet maintained by radiology administrator. If no response and scan not reordered within 1 week then further email is sent and the screening team are copied in to actively investigate.
- Screening team will review patient history to identify if exclusion criteria met, i.e., miscarriage
- Community team are responsible for reordering scan if required or documenting exclusion criteria.
- USS clerical will rearrange scan appointment if required.

5.9 Results process

- All combined biochemistry is imported on to the ultrasound system ASTRAIA through the interface with the laboratory analyser.
- Quadruple screening result is sent directly to the patient from the Oxford screening laboratory. The result is downloaded from Oxford lifecycle system and uploaded to the patient's EPIC media tab.

5.10 Communication of results

- Combined screening results are calculated daily by the screening team.
- Low chance screening result is validated and updates the scan report on the patients EPIC imaging tab and is then available to be viewed by the patient on the My Frimley Health App.
- Low chance quadruple result. Patient informed directly by Oxford. Letter sent to patient's home address.
- Screening team download the result from Oxford lifecycle system and upload to the EPIC patient record under the media tab. Screening spreadsheet populated by screening administrator.

High chance combined screening results

- Screening Midwife will communicate all high chance results to the woman.
- Calculation and biochemistry will be reviewed by screening midwife.
- Patient contacted by phone and explained further screening options as per FASP guidelines. All women are offered a face-to-face consultation and an EPIC patient message is sent with links to all relevant national screening information '**Your choices after a higher-chance screening result**' NHS patient information.
- Result added to combined high chance spreadsheet.
- Screening Midwife is responsible for validating the high chance result after the women has been informed

Low chance combined screening results

- Screening administrator will work through daily list, check on Astraia that all required fields are populated from laboratory and push calculate button.
- Screening administrator will validate all low chance results which updates the 12 week scan report on the woman's EPIC record with the combined screening calculation and the result is now available on the My Frimley Health App for the women to view.

Quadruple results

- Low risk quadruple results are sent to patient directly from the Oxford Laboratory.
- Screening team download all quadruple result from the Oxford lifecycle system and upload to the EPIC media tab on a women's record.

High Chance Quadruple Result

- Oxford laboratory contact screening team by phone and email the result to generic NHS.net email

- Screening Midwives are responsible for contacting the women and informing her of high chance result including the appropriate counselling and additional testing available in line with FASP recommendations.

High chance results

- All women with high chance result should be offered a face-to-face appointment within 3 days of the result being made available to the screening team.
- Screening Midwife will phone patient on day of calculation.
- If no answer, a brief message will be left and/or an EPIC patient message asking the patient to contact the screening team.
- Phone/messaging will continue throughout the clinical day and if no response within 48 hours CMW will be asked to visit patient and request her to phone the screening team.
- All contact attempts will be documented on EPIC.
- Once patient has been contacted and verbal explanation given a high chance result can be validated and will update on the patient's EPIC record.
- A 'Smart text' patient message summarising the discussion will be sent which ensures additional links are shared with national information.
- At 16 weeks community midwife checks that women have received all screening results and ensures the screening bloods flow sheet is completed.

6 FORMS/TEMPLATES TO BE USED

Forms and templates are available from the antenatal screening team.
Contact email: fph-tr.antenatalandnewborn@nhs.net
Telephone 03006153301.

7 REFERENCES

Internal reference

[Antenatal and newborn screening guideline](#)

External reference

[Fetal anomaly screening programme: standards - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards)

APPENDIX 1: FHFT SCREENING. WPH COMBINED SCREENING NOT COMPLETED - MISSING BLOODS

For use at Wexham Park / Heatherwood / St Marks

Dear Ms

You recently had your ultrasound scan as part of the antenatal screening programme to assess the chance for selected chromosomal disorders Down's syndrome, Patau's syndrome & Edwards' syndrome (T21/T18/T13).

I am writing to advise you that to date we are unable to locate a record of the blood results to enable the chance calculation to take place. A short delay may occasionally occur if your blood was taken at one of our satellite clinics (St Marks, King Edward or Heatherwood).

However, to ensure that the screening you selected is complete, may I request that you contact us to either confirm the blood test has been done or to arrange an appointment for your bloods to be taken? **The telephone number is 03006153301.**

If your pregnancy by scan dates is below 14 weeks and 1 day the combined test can still be carried out. If your pregnancy is more advanced then a Quadruple test can be done from 14 weeks and 2 days, however it is more accurate when performed from 15 weeks and up to 20 weeks at the latest. Quadruple screening can only screen for Down's syndrome (T21)

Please may I reassure you that we have found nothing of concern at this stage.

Yours sincerely

Screening team

Antenatal & Neonatal Screening Co-ordinator

APPENDIX 2: FHFT SCREENING. FPH COMBINED SCREENING NOT COMPLETED - MISSING BLOODS

For use at Frimley Park / Aldershot Centre for Health / Fleet / Farnham

Dear

You recently had your ultrasound scan as part of the antenatal screening programme to assess the chance for selected chromosomal disorders Down's syndrome, Patau's syndrome & Edwards' syndrome (T21/T18/T13).

I am writing to advise you that to date we are unable to locate a record of the blood sample to enable the chance calculation to take place. A short delay may occasionally occur if your blood was taken at one of our satellite clinics (Aldershot, Fleet or Farnham).

However, to ensure that the screening you selected is complete, may I request that you contact us to either confirm the blood test has been done or to arrange an appointment for your bloods to be taken? **The telephone number is 03006136989.**

If your pregnancy by scan dates is below 14 weeks and 1 day the combined test can still be carried out. If your pregnancy is more advanced then a Quadruple test can be done from 14 weeks and 2 days, however it is more accurate when performed from 15 weeks and up to 20 weeks at the latest. Quadruple screening can only screen for Down's syndrome (T21).

Please may I reassure you that we have found nothing of concern at this stage.

Yours sincerely

Screening team

Antenatal & Neonatal Screening Co-ordinator

APPENDIX 3: SCREENING NOT COMPLETE – LETTER TO CMW

Dear Community Midwife,

Please be aware that this lady has NOT been screened for Down's Syndrome, Edward Syndrome or Patau's syndrome.

She attended the ultrasound department for a Nuchal Translucency scan but did not have her blood taken; without the biochemical component of the Combined Test her adjusted risk cannot be calculated.

We have sent an EPIC letter/message explaining that it is now too late for her to have a Combined Test and offered her a Quadruple Test (2nd trimester serum screen). This may be performed at any time up until 20 + 0 weeks gestation, it is ordered on EPIC and the blood sent to pathology in the usual way. You may use the CRL from the NT scan on the order request. Please note quadruple screening can only screen for Down syndrome.

Please discuss at the next antenatal appointment and complete the screening, if patient declines, please document clearly in the EPIC patient record.

Any further concerns or queries the patient may have please ask her to contact us directly.

Many Thanks
Catherine McPadden
Antenatal & Neonatal Screening Co-ordinator
Direct Line: 03006153301 (Wexham Extn: 153301)

FULL VERSION CONTROL RECORD

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This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Caution is advised when using guidelines after the review date. 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
1.0	March 2017	K Franks	Final	
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3.1	May 2021	K Franks	Interim	Correction to Blood tests - NT bullet point (page 5)
3.2	Sept 2022	K Franks	Draft	Update post Epic EPR go-live
4.0	October 2023	K Franks	Final	Updated to reflect EPIC pathway changes, Ratified at Obstetric Clinical Governance Committee 21.11.23

Related Documents

None