Frimley Health
NHS Foundation Trust

Antenatal and Newborn Screening

Key Points

- Antenatal screening
- Fetal anomaly screening
- Infectious disease screening
- Sickle cell and thalassaemia screening
- Newborn screening.
- Newborn blood spot
- Newborn infant physical examination
- Newborn hearing

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Abbreviations

cffDNA	cell free fetal DNA cffDNA
CVS	Chorionic Villus Sampling
DQASS	Down syndrome screening quality assurance support service
FASP	Fetal Anomaly Screening program
FOQ	Family Origins Questionnaire
KPI	Key Performance Indicators
PCR	Polymerase Chain Reaction
PND	Prenatal Diagnosis
NBBS	Newborn Bloodspot Screening
NIPE	Newborn Infant Physical Examination
NIPT	Non Invasive Prenatal Testing
NSC	National Screening Committee
NT	Nuchal translucency
SIAF	Screening incident assessment form

Contents

Background and offer of screening

1. Purpose

The National Screening Committee (NSC) recommends that all pregnant women should be offered screening for Down syndrome, Edwards' syndrome and Patau syndrome; infectious diseases - HIV, Syphilis & Hepatitis B; Sickle cell and Thalassemia; and fetal anomalies detected by ultrasound scan.

All newborn babies should be offered the following screening tests: Newborn Infant Physical Examination, Newborn Hearing Screening and Newborn Bloodspot Screening.

All maternity screening programmes have a service specification and national standards associated with them. It is these which provide the foundation for this document and with continual adherence will enable consistent, high quality screening service to be delivered.

2. Scope

To outline the procedures and working practices for antenatal screening, ensuring that the following aims are achieved:

1. To offer gestation appropriate screening and diagnosis to all women booked for maternity care at Frimley Health NHS Foundation Trust.
2. To provide adequate high-quality information on the screening process to support each woman and her partner to make an informed decision on whether to accept or decline the offer of screening.
3. In the event of an increased chance result from screening to provide subsequent advice and treatment in a safe, sensitive and timely manner
4. To ensure good communication between different departments across all stages of the screening pathway.

3. Roles and Responsibilities

3.1 Trust Antenatal and Newborn Screening Board

The Trust Antenatal and Newborn Screening Board will:

- Ensure that National Screening Committee policies are implemented locally.
- Monitor compliance with all National Screening standards.
- Ensure audits against standards are completed.
- Report via Obstetric Clinical Governance to the Trust Board.
- Review screening incidents and Key Performance Indicators (KPI reporting).

3.2 Antenatal and newborn screening teams

The screening teams will:

- Ensure national policies, protocols and guidelines for antenatal and newborn screening are in place.
- Ensure that failsafe systems are in place in line with National Screening Standards.
- Ensure that training on antenatal and newborn screening is available for all

appropriate staff.

- Ensure quarterly screening KPIs are reported in a timely manner.
- Produce an annual report.
- Ensure that all screening incidents are reported in line with local and the NSC incident reporting guidance.

3.3 Matrons

The matron for community services and the matrons for hospital service will ensure that:

- all midwifery staff have access to training on antenatal and newborn screening.
- all national policies, protocols and guidelines are implemented into practice.
- remedial actions are taken when KPIs fall below the expected standards.
- screening related incidents are investigated and managed appropriately.

3.4 Individual staff members

Staff have professional responsibility to ensure that:

- Knowledge and skills on antenatal and newborn screening are regularly updated.
- They provide all women with information to enable informed choice on screening.
- Their individual practice is in line with national policies and protocols, and local guidelines.

4. Definitions

Down syndrome	the commonest cause of learning disability in children. Can be associated with other problems such as cardiac anomalies and hypothyroidism. Caused by having an extra copy of chromosome 21, also known as Trisomy 21.
Edwards' syndrome	a largely lethal chromosome disorder caused by having an extra copy of chromosome 18. Also called Trisomy 18.
Patau syndrome	a rare and lethal chromosome disorder caused by having an extra copy of chromosome 13. Also called Trisomy 13.
Nuchal translucency	the fluid filled space at the back of the fetal neck visible on ultrasound scan. An increased NT measurement can be associated with chromosome disorders and cardiac anomalies in the fetus.
Serum / biochemical screening	using the levels of certain biochemical markers in the mother's blood to determine a risk of Down, Edwards' & Patau syndromes in the fetus.
DQASS	the Down syndrome screening quality assurance support service. All laboratories and ultrasound departments involved in Down syndrome screening have to submit data to DQASS at least every 6 months.
NIPT	Non Invasive Prenatal Testing is a maternal blood test which measures the cell free fetal DNA (cffDNA) giving a screening risk for T21/T18/T13.

PCR	(Polymerase Chain Reaction) : a method of providing a quick chromosome analysis for Trisomy 13, 18 and 21 using fluorescent probes specific to the affected chromosomes. Usually gives a result in 24-48 hours.
Prenatal Diagnosis (PND)	amniocentesis and CVS to determine specific problems in the fetus.
Amniocentesis	the method of obtaining a sample of amniotic fluid for cytogenetic analysis of the fetus.
Chorionic Villus Sampling (CVS)	the method of obtaining a small placental biopsy for cytogenetic analysis of the fetus.
Cytogenetics	the laboratory process whereby a diagnosis of chromosomal normality or abnormality can be made.
Family Origins Questionnaire (FOQ)	should be completed at booking by the Community Midwife discussing booking bloods. This is the screening tool which provides essential information to the Laboratory for sickle cell and thalassemia screening.

5. Booking

Pregnancy notification

Women should complete the online pregnancy notification form to advise the trust of her pregnancy, link available on the maternity website.

When the woman notifies the Trust she is pregnant the clerical team will register the patient on EPIC or review and update an existing health record. The information is then forwarded electronically to the appropriate community team. A booking appointment with a Frimley Health midwife should be made for 8-10 weeks gestation or as soon as possible if we are notified of a pregnancy at a later gestation, careful attention should be made to ensure opportunity for screening is maximized. Mothers should be supported to download digital format of " Screening tests for you and your baby". A copy of the information booklet is available if required. The digital information is available in 12 languages.

https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby

5.1 Infectious Disease Screening

https://www.gov.uk/topic/population-screening-programmes/infectious-diseases-in-pregnancy

Blood tests are offered for HIV, Syphilis and Hepatitis B.

If a woman declines screening for any infectious disease, she must be referred to the screening team for counselling. Community midwife is responsible for informing the screening team and recording decline on the EPIC order. The screening team will follow up all declines.

5.2 Sickle Cell and Thalassemia Screening *(Haemoglobinopathy)*

https://www.gov.uk/topic/population-screening-programmes/sickle-cell-thalassaemia

Blood tests are offered for sickle cell and thalassaemia presence determination. The completion of the family origin questionnaire is essential as the test will not be done without it.

5.3 Combined/Quadruple screening

https://www.gov.uk/guidance/fetal-anomaly-screening-programme-overview

Down syndrome, Edwards' syndrome and Patau syndrome screening is offered, dependent upon gestation.

Declined screening should also be noted and recorded according to the site specific Combined and Quadruple screening Standard operating procedure.

- *Combined Screening Test*
  This involves a nuchal translucency scan and a blood test preferably on the same day and should be done between 11^{+2} and 14^{+1} weeks. (CRL measurement on scan 45mm-84mm)

  Women who are too late for this should be offered a dating scan and quadruple test.

- *Quadruple Test (Down syndrome screening only)*
  It is not possible to give a chance result for Edwards' and Patau syndromes using this test. The quadruple test may be performed between 14+2- and 20-weeks gestation, but the pregnancy must be dated by ultrasound (head circumference of 101-170mm).

5.4 Multiple pregnancies

The test of choice for twin pregnancies is first trimester combined screening. Every opportunity must be made to maximise the offer of first trimester combined screening.

Quadruple screening is available for women.

- Who present for the first time in the second trimester?
- Where the nuchal translucency could not be measured in the first trimester.

Careful counselling is required for women as the quadruple test is less sensitive than first trimester combined screening and any subsequent decisions about invasive diagnostic testing and selective reduction will have to be made later in the pregnancy.

Demised Twin pregnancy

- When ultrasound shows there is an empty second pregnancy sac combined screening can be offered
- Currently when ultrasound shows that there is a second sac containing a non-viable fetus (sometimes called 'vanished' twin) combined screening cannot be offered. NT screening only can be considered but 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. FASP are currently reviewing guidance on screening in vanished Twins with an update expected April 2024. Frimley Health will comply with the new FASP guidance once screening laboratory software aligns.

5.5 **Non Invasive prenatal testing (NIPT)**

NIPT is available on the NHS to women with an increased chance result on combined or quadruple screening. Frimley Health also supports NIPT for women with a previous history of an affected baby with confirmed T21 , T18 & T13.with specialist counselling supported by the Screening team. NHSE are expected to supported this nationally from April 2024 and trust guidance will be adapted to follow their recommendations.

Women with a low chance screening result can request a private NIPT. The screening team will support and can arrange a private NIPT only after the woman has completed the NHS screening pathway and received specialist counselling.

5.5.1 *Nuchal Translucency Scan*

On completion of the NT measurement, the woman will be able to view a copy of her scan report on her 'My Frimley Health App'. Following scan the women should attend the phlebotomy service for the blood test to complete the combined screening
All scans are entered onto the maternity ultrasound system and images stored according to the national standards.

5.5.2 *Increased NT measurement ≥3.5mm)*

All women with a fetal NT measurement of ≥ 3.5mm will have bloods for the combined test fast tracked by direct request to the laboratory. This is to enable a risk calculation to be performed urgently. All women with an increased NT measurement will be seen in fetal medicine and all appropriate ongoing investigations considered, not just based on the combined screening result indicating a high or low chance. All women will require a fetal cardiac scan at around 16 weeks' gestation. This referral will be made by the screening team to the tertiary center.

In cases where the sonographer cannot obtain a NT measurement despite multiple attempts including rebooking the appointment if pregnancy gestation allows or if the gestation is too far advanced, the woman will be offered a quadruple test.

5.5.3 *Combined screening/nuchal scans at satellite clinics* – see local standard operating procedure.

5.5.4 *Anomaly scan*

https://www.gov.uk/guidance/fetal-anomaly-screening-programme-overview
The anomaly scan is performed from 18 weeks to 20+6 weeks gestation. It is part of the Fetal Anomaly Screening program (FASP). Suspected anomalies will be managed according to the national guidelines and local protocols and women's choice.

5.6 Late bookers/transfer

All appropriate gestation specific screening should be offered unless documented evidence is available that confirms screening has already been done. Ultrasound scan reports should be written in English , if not consideration should be given to repeat the scan if the women presents within the screening window.

5.7 Miscarriage

It is the responsibility of the community midwife to inform all women in their case load of their normal antenatal screening results, when they are made aware of a miscarriage. All results will be released and be able to be viewed on the 'My Frimley Health app' If women choose not to have access to the app then the community midwife should inform the patient of their results .
Positive antenatal screening results will be actioned by the screening team and relevant multidisciplinary referral appointments arranged.

6. Newborn screening

6.1 *Newborn Infant Physical Examination - NIPE*
https://www.gov.uk/topic/population-screening-programmes/newborn-infant-physical-examination

The newborn infant physical examination is offered and should be completed within 72 hours of birth. Examination is recorded on the NIPE S4Nsystem and a copy of the report is managed according to the local protocol. Referrals as a result of the completed examination are the responsibility of the examining clinician and must be completed on the same day as the examination. KPI's are reported quarterly by the national team. Local mitigation reports are completed and sent back to the national team prior to KPI submission. Completing the mitigation reports ensures local oversight of where quality improvements can be made.

6.2 *Newborn hearing screening*
https://www.gov.uk/topic/population-screening-programmes/newborn-hearing

This screening test is offered prior to discharge from hospital but can take place in the community should the mother wish to be discharged home prior to it being practicable to take place.

The Hearing screening service and governance is managed by Kingston Hospital NHS Foundation Trust with support from the local screening team to monitor staffing and clinic availability.

The national system SMART4Hearing is used to manage the process and for reporting purposes.

National standards, guidelines and protocols are in place and adhered to.
KPI NH1 and NH2 are reported quarterly by the hearing screening manager and shared at our local screening board .

6.3 *Newborn Bloodspot Screening (NBBS)*
https://www.gov.uk/topic/population-screening-programmes/newborn-blood-spot

The Northgate failsafe system is used in conjunction with local laboratory reporting methods, to manage newborn bloodspot screening. This ensures that all babies will be offered and complete the screening. Declined tests must have a sample card completed and submitted to the screening laboratory. Local protocols prevail for the management of transportation, repeat notification and requesting, unavoidable repeat management & training. KPI reporting takes place quarterly and is collaboration between the Trust and the laboratory to enable accurate data collection and reporting.

7. Schedule for antenatal screening tests, results and communication

TEST	GESTATION	RESPONSIBILITY	RESULTS	INCLUSION
ALL SCREENING TESTS		**ALL MIDWIVES / OBSTETRIC DOCTORS**	All professionals should take every opportunity to ensure appropriate screening tests have been offered and completed. Community midwife will ensure that all screening bloods have been released to the patient's app and the booking bloods flow sheet has been completed on EPIC at the 16-week appointment. Any outstanding results need to be repeated and a RL completed	
COMBINED SCREENING	**11+2-14+1**	**SCREENING TEAM**	**LOW** chance - women notified of result within 7-10 days. WPH , 12 week scan report will update with Combined screening result on EPIC following calculation of screening result . FPH. Oxford screening report will be uploaded to EPIC record by the screening team and Oxford screening laboratory will post a paper copy out to the women. **HIGH chance** – screening midwife will contact woman and offer an appointment to discuss results and options available. If unable to contact the woman, they will inform the community midwife who will be asked to visit the woman. Screening midwife will discuss further options which will include, no further testing, NIPT and /or prenatal diagnosis. Screening midwife will disseminate results as per local protocol. Community midwife to check that woman has received result and document on EPIC booking bloods flow sheet at 16 week visit.	
QUADRUPLE TEST Down screening only. Dating USS and Blood			**LOW** chance– All Quadruple testing for both sites is completed at Oxford screening laboratory and women are notified by letter (within 7-10 days) all results are uploaded to the EPIC record by the screening team and released to their 'My Frimley App' **HIGH** chance – screening midwife will contact woman and offer an appointment to discuss results and options available. If unable to contact the woman, they will inform the community midwife who will be asked to visit the woman. High chance results will not be released on the App until the woman has been informed. Screening midwife will discuss further options which will include no further testing , NIPT and /or prenatal diagnosis. Screening midwife will disseminate results as per local protocol. Community midwife to check that woman has received result and complete booking blood flow sheet on EPIC record at 16week visit.	

DATING SCAN AND ANOMALY SCAN	**8-20 WEEKS**		Verbal results given to woman at time of scan by the sonographer and validated so can be viewed on 'My Frimley App' Any suspected abnormalities sonographer will refer to screening team for additional support /information and they will ensure local fetal medicine scan within 3 working days and/or tertiary referral within 5 working days as per national guidance.	
NIPT	**FOLLOWING COMPLETION OF COMBINED/QUADRUPLE SCREENING**	**SCREENING MIDWIVES**	**LOWER chance** - women notified by telephone. Results are downloaded from NIPT portal and uploaded to the EPIC media tab. A patient message is sent with result attached for women to view. **HIGHER chance** – screening midwife will contact woman and offer an appointment to discuss results and further testing. If unable to contact the woman, they will inform the community midwife who will be asked to visit the woman. Prenatal diagnosis will be arranged if required. Screening midwife uploads result to media tab and attach to a patient message for the women to view Community midwife to check that woman has received result and document on EPIC record	
PRENATAL DIAGNOSIS (AMNIOCENTESIS OR CVS)			Rapid results of QF PCR/Array (normal and abnormal) are emailed via NHS.net to screening midwife and then telephoned to woman on a previously agreed number. Screening midwife will arrange appointment with fetal medicine consultant for women to discuss abnormal results and further pregnancy management.	If relevant genetic or family history, women should be referred to the screening team directly for further discussion.
INFECTIOUS DISEASE SCREENING	**AT BOOKING APPOINTMENT**	**COMMUNITY MIDWIFE**	**ALL results are checked within 10 days by the community midwife responsible for the case .The screening blood results will be released to the My Frimley App and the booking blood flow sheet must be completed on EPIC record**	
			HIV POSITIVE **SYPHILIS POSITIVE** **HEPATITIS B POSITIVE**	**See infectious disease screening guideline**

SICKLE CELL AND THALASSAEMIA: **FAMILY ORIGIN QUESTIONAIRE (FOQ) MANDATORY**	**AT BOOKING APPOINTMENT (< 10 WEEKS)**	**COMMUNITY MIDWIFE**	**Haemoglobinopathy carrier or disease results** All women who are carriers of abnormal haemoglobin types, or affected by any sickle cell disorder, are notified to the screening team from the Haematology Lab as per local protocol. Counselling by appropriately trained screening midwives regarding biological father testing and prenatal diagnosis will be arranged. Results recorded by screening midwife in accordance with local protocol. Frimley Park Hospital is classified as low prevalence. All women will have thalassaemia screening and completion of the FOQ will aid clinical interpretation and alos determines if sickle cell screening is completed. Wexham Park Hospital is classified as high prevalence, all conditions are tested for and FOQ aids clinical interpretation. National classifications as per NSC Sickle Cell and Thalassemia screening programme	

8. Late booking/unbooked women

At the first contact with the healthcare professional the woman should be counselled, and **all** outstanding tests performed as appropriate. When completing the EPIC order for infectious disease screening, mark as URGENT>24 weeks booking/in labour. The virology laboratory will then prioritise these samples and produce results on an urgent basis.

For women arriving in labour, this must be discussed with the on-call laboratory staff and arrangements made for results to be sent urgently to delivery suite.

9. Missing/lost/mislabeled samples

The screening team download a tracking failsafe report every 2 weeks, 2 weeks in arrears monitoring any incomplete screening bloods and escalate to the midwifery team responsible for her care. Failsafe tracking for completion of combined, quadruple and anomaly screening is also in place, actioned by the screening team and including managing the DNA process.

In the case of samples which are missed, lost or mislabeled the woman will be contacted by her community midwife in the first instance and arrangements made to repeat the blood tests. In the event of a woman missing the window for a screening test, the community midwife should refer her to one of the screening team. Any additional measures that are available as an alternative will be outlined and a plan made for that individual woman. This will vary depending on the screening test that has been missed.

10. Screening Incident management

Any adverse incident will be reported via the internal reporting system for investigation, management and learning.

Serious incidents will also be reported in the same way but will also be reported as specified in ‘Managing Safety Incidents in NHS screening programmes’; and a SIAF (screening incident assessment form) should be commenced.

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

11. Useful telephone numbers

- Wexham Park Hospital Screening Team 03006153301
- Wexham Park Hospital Antenatal Clinic 03006154500
- John Radcliffe Screening laboratory 01865 220488
- Frimley Park Hospital Screening Team 03006136989
- Frimley Park Hospital Antenatal Clinic 03006134154

12. Training

All midwives are expected to attend an annual session on antenatal and newborn screening as part of their mandatory training or complete the NSC e learning module. https://www.e-lfh.org.uk/

Attendance will be monitored according to the local protocol.

13. Auditable standards

- All pregnant women booking at Wexham Park will be offered screening for Sickle cell and Thalassaemia at booking. Women booking at Frimley Park will follow the low prevalence protocol. All women identified as carriers of significant haemoglobin types will be counselled regarding biological father testing by a trained counsellor and arrangements made for the testing. All high-risk couples to be offered prenatal diagnosis as per Sickle Cell and Thalassaemia Screening protocol. The date of test taken, result, woman informed, and action taken will be documented as per local protocol. 50% of women to be tested by 10 weeks of pregnancy (NSC Key Performance Indicator ST2).
- All pregnant women will be offered at booking an infectious disease screening that includes HIV, Syphilis, and Hepatitis B. All women with positive results for HIV, Syphilis and Hepatitis B will be contacted, advised about the results and offered an appointment within 5 days of the result being given to the maternity services. All women with negative results for HIV, Syphilis and Hepatitis B will be informed of results at the next antenatal appointment.
- All pregnant women will be offered a dating ultrasound scan between 10 weeks 0 days and 13 weeks 6 days to determine gestational age and to detect multiple pregnancies. The combined screen may also take place at this time. The ultrasound scan report will reviewed under the imaging tab on the EPIC patient record.
- All pregnant women booking at less than 20 weeks gestation will be offered screening for Down syndrome via the Combined or the Quadruple tests. All women will receive the result via the ‘MyFrimley HealthRecord’ app within 2 weeks of the date of the test. All women with high chance results will be offered an appointment within 3 working days of the result being available to the maternity services.
- All pregnant women will be offered an ultrasound screening for fetal anomalies between 18 weeks 0 days and 20 weeks 6 days (NICE). If a rescan is required, this must be offered before 23 weeks. The ultrasound scan report will be viewed under the imaging tab on the patients EPIC record.
- Data for the key performance indicators will be collected and submitted to the UK National Screening Committee quarterly.
- All women that book after 12 week+6 days will be offered all routine screening tests appropriate for their gestational age. Infectious disease screening and sickle cell and thalassaemia screening should be offered at any point that a woman presents to the maternity service.

14. Communication

If there are communication issues (e.g., English as a second language, learning difficulties, blindness/partial sightedness, deafness) staff will take appropriate measures to ensure the patient (and her partner, if appropriate) understand the actions and rationale behind them. Trust interpreter guidance should be considered.

15. References

1. Fetal anomaly screening programme

   https://www.gov.uk/guidance/fetal-anomaly-screening-programme-overview

2. Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome

   https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook/screening-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome--3#screening-in-twin-pregnancies

3. Infectious Diseases in Pregnancy Screening Programme Standards, 2016, UK National Screening Committee.

   https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards

4. NHS Sickle Cell and Thalassaemia Screening Programme.

   https://www.gov.uk/guidance/sickle-cell-and-thalassaemia-screening-programme-overview

5. Key Performance Indicators for Screening

   https://www.gov.uk/government/publications/nhs-population-screening-reporting-data-definitions/population-screening-kpis-purpose-and-data-submission-guidance

6. NICE antenatal care NG 201.

   Overview | Antenatal care | Guidance | NICE

7. Antenatal Screening

   https://www.gov.uk/topic/population-screening-programmes

8. Managing safety incidents in NHS screening programmes

   https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

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 Control Sheet

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1.0	March 2017	Katharine Franks, Susan Tunnacliffe	Final	Cross site review
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	Feb 2018	Updated by Katharine Franks	Interim	Change of screening service provider (s 6.2)
3.0	Dec 2020	Updated by Katharine Franks	Final	Cross site version, approved at OGCGC
3.1	Sept 2022	Katharine Franks	Final	Review after Epic EPR go-live.
4.0	March 2024	Katharine Franks	Final	Approved at Cross Site Obstetrics Clinical Governance meeting, 27 March 2024

Related Documents

None