Private Non Invasive Prenatal Testing (NIPT) UHL Obstetric Guideline

University Hospitals of Leicester NHS
NHS Trust

Trust ref: C31/2018

1. Introduction and Who Guideline applies to

This guideline is intended for the use of midwives and obstetricians within Antenatal Services to determine the pathway for pregnant women and people who wish to have private non-invasive pre-natal screening using free fetal DNA harvested from the maternal blood stream.

Background:

Both in singleton and multiple pregnancies the accepted standard of care is to offer screening for fetal anomalies with either first or second trimester screening for fetal trisomy and for structural abnormality at approximately 20 weeks gestation.

Where pregnant women or pregnant people are identified as having an increased chance of carrying a fetus with a trisomy or sex chromosome abnormality, they are counselled about the chance and if appropriate, offered a diagnostic test, either an amniocentesis or a chorionic villus sampling. Both of these tests increase the chance of a pregnancy ending in miscarriage.

Over the past few years extensive research has been carried out to try to improve the detection rate of fetal trisomies using a non-invasive method which does not increase the risk of intra-uterine infection and miscarriage of the pregnancy but still provides a high level of reassurance. The research identified that it was possible to extract cell free fetal DNA (cfDNA) from the maternal blood stream. This screening test (and several different tests are available) has been shown to have a high detection rate for fetal trisomy with a very low false positive rate. This screening test could result in a significant reduction in the need for invasive diagnostic procedures resulting in a reduction in the number of miscarriages associated with the screening programme.

Currently UHL provides NIPT on the NHS for patients with a high chance screening result for trisomies 21, 18 and 13 and those who had a previous baby with one of the three trisomies. Please refer to the Down's, Edward's and Pataus' screening guidelines for further details.

NIPT is not a diagnostic test and where a high chance result is reported a diagnostic test should be offered to confirm the result

2. Antenatal screening options:

- All pregnant women and pregnant people should be offered NHS screening tests through their normal hospital provider
- All pregnant women and pregnant people should be offered NHS screening as per the UHL "Downs, Patau's and Edward's Syndrome Screening guideline.
- If requested pregnant women and pregnant people should also be given information about the private NIPT screening test.

- If the pregnant woman or pregnant person chooses to have private NIPT instead of the NHS screening tests on offer, it must be documented that they are declining the NHS screening tests.

- It is a good practice to include a copy of the results in the patient hospital and handheld notes.

2.1 Referral to non-invasive pre-natal screening service

- All pregnant women and pregnant people who are referred or self-refer to the non-invasive pre-natal screening service must have had an ultrasound scan to confirm viability of the pregnancy and gestation.

- Pregnant women and pregnant people must have been scanned by an NHS provider or a private medical practitioner prior to making the appointment. This will ensure the validity of the dating scan. A valid written report of the scan findings must be available.

- NIPT can be performed after 11 weeks gestation and up to delivery. Appointments can be arranged once a dating scan has been carried out but will not be until after the pregnancy has reached 11 weeks.

2.2 Payment

- Ensure the pregnant woman or pregnant person understands that they are opting in to a private fee paying service. They will be required to pay for their test prior to having their blood taken.

- Currently, UHL are able to accept cash and card payments. Ideally the on-line payment method is preferred.

- The pregnant woman or pregnant person must be informed that there are other tests and other providers available.

2.3 Test limitations and results

Ensure that the pregnant woman or pregnant person understands that the test that they are being booked for is a screening test and not a diagnostic test.

The accuracy of the test is higher than the accuracy than for the second trimester screening currently offered on the NHS.

- If the test result indicates that the pregnancy is at high chance for a fetal trisomy the pregnant woman or pregnant person should be offered a diagnostic test to confirm the diagnosis. This test would normally be an amniocentesis or placental biopsy.

- If a diagnostic test is accepted, this should be carried out and a result received before a termination can be offered. (There may be some rare exclusions where there is a fetal abnormality identified by ultrasound).

- Pregnant women and pregnant people should be aware that NIPT can be offered for twins but it has a lower success rate. If a screening result is positive, the pregnant woman or pregnant person should be informed that the test will not identify which fetus is affected. It will be advisable to sample the two sacs.

2.4 Timing of the test

- Make an appointment at a time that a clinic is available as soon as appropriate after 11 weeks' gestation.
- Ideally the appointment should be outside of normal NHS working hours.
- Ensure the correct patient contact details are provided (email address and telephone number), correct demographic details as well as pregnancy details.
- Ask the pregnant woman or pregnant person to bring their handheld notes with them and any documentary evidence they have regarding their scan.
- If they have a mobile phone, offer to confirm the appointment by text.
- Complete the booking proforma and file it in the folder. Ensure the pregnant woman or pregnant person knows where the appointment will take place.

2.5 On Arrival

When the pregnant woman or pregnant person arrives for their appointment, check that they have their handheld record and that there is evidence of the viability scan having been performed.

- Review the scan report and confirm this is a singleton pregnancy
- Confirm the gestation of the pregnancy from the EDD prior to proceeding with the counselling for NIPT

2.6 Pre-test counselling and documentation

- The pregnant woman or pregnant person should be counselled so they fully understand the test they are about to undergo.
- They should be asked to sign a consent form and pay for the test prior to taking the required blood sample.
- Ensure the NIPT proforma is completed so that there is evidence that the pregnant woman or pregnant person has been fully informed regarding this test.
- Ensure that the contact details are correct. Please record a contact telephone number and an email address.

2.7 Sampling procedure

A blood sample should be taken using the current UHL guidance for venepuncture

Immediately after it has been obtained it should be labelled in the presence of the pregnant woman

or pregnant person.
The blood sample should be packaged with the request form and prepared for posting / pick up.

2.8 Reporting of results

- The pregnant woman or pregnant person should be made aware of how they will be informed of the test results.
- Please make clear how many working days we expect the result to take and make sure that this does not include weekends.
- Ensure the pregnant woman or pregnant person understands that they will receive the results of their test by telephone and also written confirmation.
- Pregnant women and pregnant people should be informed that results will be provided by a phone call irrespective of high or low chance results.
- If the result is a high chance result, the pregnant woman or pregnant person will be invited in to the hospital to discuss the result on the next available fetal medicine scan list, at the hospital where they are booked.
- This appointment should be within 3 working days of notification of the result.
- Should the pregnant woman or pregnant person want to end the pregnancy, an invasive diagnostic test will be advised prior to a termination of pregnancy.
- Pregnant women or pregnant people who decide to continue the pregnancy and decline any invasive testing should be informed that confirmation of test results will be offered following discussion after the baby is born.
- Fetal Medicine consultant will need to plan patient care pathway. A Paediatric alert should be produced.
- Low chance results are communicated to the pregnant woman or pregnant person as above. Please ensure the pregnant woman or pregnant person has a routine follow up appointment with their booking hospital if required.

2.9 Advertising

- All advertising of NIPT must comply with the code of conduct for advertising in broadcast and non-broadcast media. This is monitored by the Committee of Advertising Practice (CAP)
- The code states that the advertisements must not be misleading, harmful or offensive.

2.10 Fetal structural malformation

- Pregnant women and pregnant people with a confirmed diagnosis of fetal malformation should have formal counselling by a fetal medicine Consultant before referral for NIPT and it should be documented on the consent form.
- Pregnant women and pregnant people should be made aware that anomalies in the number of only 3 different chromosomes pairs are screened for with standard NIPT.
- Pregnant women and pregnant people should be made aware that around 15% of chromosomal problems will not be identified with NIPT.
- Pregnant women and pregnant people should be made aware that 4-7% of cases of structural malformation could be associated with genetic problems that will not be screened for by NIPT.
- Pregnant women and pregnant people with a low-chance screening result on NIPT who are found to have structural malformations on anomaly scan, should be counselled by a

fetal medicine consultant. They should be offered amniocentesis/chorionic villous sampling as a diagnostic test for fetal chromosomal anomalies.

2.11 Multiple pregnancy

- Pregnant women and pregnant people with an apparently normal multiple pregnancy should be counselled by a fetal medicine consultant or an experienced midwife.
- Pregnant women and pregnant people should be informed that the test will not identify which fetus is affected.
- Cases with intra-uterine fetal death of one of the babies could affect the results. NIPT should only be considered after at least 2-3 weeks of fetal demise. Pregnant women and pregnant people should be made aware that results may still be affected.

3. Education and Training

Fetal Medicine Team Lead, Ward Manager for Antenatal Services, Antenatal and Newborn Screening Lead Midwife and Community Team Lead have attended specific training sessions. Cascade training is provided to the Antenatal Core Midwives and Community Midwives.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
All NIPT tests must be entered into the relevant data base on the day of the test.		Consultant lead		
Number of tests that are received by the laboratory in a timely manner.		Consultant lead		
Time taken from taking the NIPT blood test to giving the patient the result		Consultant lead		`
Number of patients where a re-draw of blood is required		Consultant lead		
Number of tests that are reported as high risk subsequently confirmed as a trisomy		Consultant lead		
Number of tests where the NIPT was reported as low chance that have an identified trisomy anomaly (13, 18 and 21 only) after delivery		Consultant lead		

5. Supporting References

None

6. Key Words

Prenatal screening, fetal DNA, Private screening, Trisomies 21 18 13

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	H Ulyett - Antenatal screening coordinator	**Job Title: Chief Nurse**
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
Sept 2020	V2	M Bodley	Minimal changes. Recommendation 3, online payments preferred.
Sept 2024	V3	Helen Ulyett	Updated with NIPT for high chance results