1. Introduction and Who Guideline applies to

This guideline is intended for the use of all Medical, Midwifery, Nursing, Sonographers, General Practitioners and Laboratory staff involved in the care of pregnant women in both Primary and Secondary care settings.

It is to inform women about the chance of Down’s (trisomy 21) and Patau’s (trisomy 13) and Edwards’ (trisomy 18) syndrome in their current pregnancy as estimated by the screening tests and to ensure women understand the implications and consequences of opting into screening and the further assessment and management they may be offered.
NB: Down’s (trisomy 21), Patau’s (trisomy 13) and Edwards’ (trisomy 18) syndrome will collectively be known as Trisomies 21,13 and 18 throughout this guideline apart from where quad testing is carried out as this is to determine a chance of Downs Syndrome alone.

The way the programme is delivered cannot be defined rigidly because it has to be incorporated into the individual care of each pregnant woman. Therefore, everyone who is involved in antenatal care is responsible for delivery of the screening programme.

2. Guideline Standards and Procedures

This guideline is based upon recommendations from the Fetal Anomaly screening programme: programme handbook (2018) NICE Antenatal Care Guidelines (2019)

All eligible women who book for their maternity care with University Hospitals of Leicester (UHL) will be offered screening for Trisomies as recommended by the National Screening Committee. The gestation of the pregnancy at the time of screening will dictate the screening test available to the woman.

There is a designated lead for antenatal screening for the UHL Maternity Service (Midwifery Matron for Antenatal Services and Lead for Safeguarding). There is also an Antenatal and Newborn Screening Co-ordinator whose role it is to ensure appropriate processes are in place to offer women appropriate screening tests in pregnancy as per National Screening Committee Guidance. In addition the screening team also includes a Deputy Screening Coordinator, administration support and a failsafe officer.

Some centres now also offer non-invasive prenatal testing (NIPT) to women. If women are interested in NIPT then they should be signposted to one of the centres that can provide this service, including the private service at UHL.

First Trimester Combined Screening

The first trimester combined screening test uses two substances produced by the pregnancy which are circulated in the mother’s blood. These substances, free beta HCG and PAPP A are measured. In addition the nuchal translucency of the baby is measured by ultrasound. These results are mathematically combined to estimate, more accurately, the chance of Trisomy 21/13/18 for that pregnancy. Women will have the options for screening for these trisomies as follows:

1. Decline screening for all these trisomies
2. Accept screening for Trisomy 21 only
3. Accept screening for Trisomy 13/18 (as a single result for both)

The first trimester combined screening test calculation requires the mother’s age, weight, smoking status, ethnicity, specific IVF information (egg collection and implantation date & donor egg age if applicable), chorionicity in the case of twins and details of relevant medical conditions. This information is mandatory if a result is to be given to the woman. In addition accurate and detailed information from the dating scan and NT measurements are required.

For further guidance on the scan element of this screening test please refer to the UHL Ultrasound UHL Obstetric Guideline
The result of the screening is given as a probability (chance) figure, for example, 1 in 1,000 would indicate a LOW chance of Trisomy 21/13/18 and 1 in 10 would indicate a HIGH chance. A cut-off of greater than or equal to 1 in 150 is used to indicate that the pregnancy has a LOW or a HIGH chance of being affected by one of the Trisomies. In a twin pregnancy (monochorionic and dichorionic) there is a risk generated for each fetus for combined screening.

It is important to recognise that combined screening test is a screening test and will not detect all pregnancies affected by Trisomy 21/13/18. The detection rate for the Trisomies varies slightly; the combined screening test will detect approximately 85% of babies affected with Trisomy 21. This means that despite a low chance result the baby still may be affected with Trisomy 21. The detection rate for Trisomy 13/18 is slightly lower at 80%.

**Second Trimester Downs Syndrome Serum Screening**

The second trimester serum screening test (Quadruple test) is used to calculate the chance of having baby affected with Trisomy 21 only. It measures the levels of Alpha Fetoprotein (AFP), Human Chorionic Gonadotrophin (HCG) unconjugated Oestriol and Inhibin A in the mother’s blood. The Quadruple Test calculation also requires the mother’s age, weight, smoking status, ethnicity, specific IVF information (egg harvest collection and implantation date, and donor egg age if applicable), chorionicity in the case of twins, relevant medical conditions and accurate information from the dating scan in this pregnancy. This information is mandatory if a result is to be given to the woman.

The result of the serum screening is given as a probability (chance) figure, for example, 1 in 1,000 would indicate a LOW chance of Trisomy 21 and 1 in 10 would indicate a HIGH chance. A cut-off of greater than or equal to 1 in 150 is used to indicate that the pregnancy has a LOW or a HIGH chance of the fetus being affected by Trisomy 21.

In a twin pregnancy (both monochorionic and dichorionic) the result is generated for the ‘pregnancy’ not the individual fetus by the Quadruple test.

It is important to recognise that the Quadruple test is a screening test and will not detect all pregnancies affected by Trisomy 21, indeed this test has a detection rate of approximately 80%.

Therefore as for the first trimester screening test a low chance result does not mean that the baby is not affected with Trisomy 21.

**Recommendations:**

1. All eligible pregnant women booking with the University Hospitals of Leicester NHS Trust should be offered screening for Trisomy 21/13/18 (Down’s Patau’s and Edwards’ Syndrome)

2. Low chance results should be sent by the laboratory to the woman and the requestor and an appointment arranged to discuss this result with the woman.
3. High chance results should be emailed by the Trisomy screening laboratory to the Antenatal Services Midwives generic nhs.net email at the hospital where the woman is booked and a copy of the report is sent to the requestor.

4. ‘Equivocal results’ that require further action should be emailed to the Screening Coordinators generic nhs.net email address

5. Results found to not be unavailable should be followed up

6. The Antenatal Services Midwives should offer a full discussion with the woman about the implications of a high chance result and further testing is offered and initiated where accepted

7. NIPT results will be emailed to the Antenatal Services Midwives and communicated appropriately to the woman

8. Diagnostic test results should be obtained by the Antenatal Services Midwives and communicated appropriately to the woman

**Recommendation One: All eligible pregnant women should be offered screening**

All eligible pregnant women booking with University Hospitals of Leicester NHS Trust should be offered screening for Trisomy 21/13/18 (Down’s, Patau’s and Edwards’ syndrome).

- At the first contact with the Community Midwife (booking appointment) the woman should be given information about Trisomy screening so that she understands the tests that are available to her. There is also information from the NSC “Screening Test for you and Your Baby” available that women should be directed to via the leaflet or electronically about Trisomy Screening. This is to ensure she understands what the screening is and the implications of this screening test to enable her to make an informed choice.

- The offer, discussion and the woman’s decision should be documented in the Maternity health records.

- The woman’s choice about Trisomy screening must be documented on E3 at booking to allow the clinic co-ordinators to arrange the NT scan for the lady if she wants screening. There will be a print off of the relevant information at the booking hospital that will be given to the woman when she attends for her NT/dating scan.
• The community midwife should complete all of the white section of the Trisomy screening request form (see Appendix 7) accurately as missing or incorrect information could lead to false results or missed screening.

• All electronic handheld maternity records should be reviewed by the Antenatal Services Midwives (*). Therefore if a woman has booked late for screening urgent referral should be made by the Antenatal Services Midwives to the Clinic Coordinators to identify a scan slot that will ensure the woman receives her screening test within the required timeframe (see Appendix 3).

• A weekly Trisomy screening failsafe list is automatically generated from the maternity IT system and the woman’s Trisomy screening choices are logged. Women who request a screening test will be followed up by the failsafe officer 5 weeks after booking to ensure that screening is completed or declined. See Appendix 8 for the Standard Operating Procedure for the Down’s syndrome failsafe process.

• If the dating scan shows the woman to be eligible for nuchal translucency screening, it should be offered & completed at the time of the dating scan (see Appendix 1).
  o Women who are 14+2 to 20+0 week’s gestation (HC 85-172mm) at the dating scan should be referred to the Antenatal Services Midwives who should offer Quadruple testing for Trisomy 21 on the same day see (Appendix 1).
  o If the nuchal translucency cannot be measured after 2 attempts this should be explained to the woman and a plan made for Quadruple testing with the community midwife between 14+2 & 20+0 weeks. The information sheet (see Appendix 6) should be stapled to the front of the handheld notes as a reminder to the woman and the community midwife that quadruple testing still needs to be completed.
  o The Sonographer should complete the orange Gestational details on the Trisomy screening request form (see Appendix 7).

• If at the dating scan a twin pregnancy is diagnosed the woman is still eligible for 1st trimester combined screening for Down’s syndrome. If greater than 14+1 week’s gestation the woman should be offered quadruple testing after a clear explanation about the implications of the result due to the reduced detection rate for Down’s syndrome in twins.

• If there is a twin pregnancy with demise of one of the twins and only a yolk sac present the midwives should continue with first trimester combined screening test. If there is a measurable fetal pole for the demised twin/triplet, screening should be offered for Nuchal Translucency only following discussion with the Antenatal Services Midwives (see Appendix 4). It may also be possible to offer a Quad test for women who are not eligible for NT only screening but this should be discussed with the screening laboratory on an individualised basis.

• If the woman books for her Antenatal Care after 20 weeks gestation the Community Midwife should discuss the woman’s screening test result based on an age related chance of Trisomy 21 alone and refer the woman to the Antenatal Services Midwives should the woman wish to discuss her options in relation to prenatal diagnosis and referral to a Fetal Medicine Consultant if diagnostic testing is required.

• First trimester screening
  o Undertaken between 11+2-14+1 weeks gestation (CRL 45-84mm)
A follow up appointment should be made to discuss and document the result and also to initiate second trimester screening should a result not be available.

Process for the screening test appointment - see Appendix 1.

Where an NT measurement is found to be greater than or equal to 3.5mm at the dating scan, the screening test should be completed by taking the serum element of the trisomy screening test and sending the sample along with the scan details to the Lab. The woman should then be referred to a Fetal Medicine Consultant.

**Second trimester screening (Quadruple)**

- Undertaken between 14+2 & 20+0 weeks of pregnancy (HC 85-172mm)
- A follow up appointment should be made to discuss and document the result and also to initiate repeat screening should a result not be available.
- Process for the screening test appointment - see Appendix 2.

**NB:** An NHS number and full address including postcode is a mandatory requirement on the blood request form or that a low chance letter can be generated and sent to the woman.

The Community Midwife should remain the point of contact for the woman should she have any further queries or concerns.

On receipt of the screening sample at the Trisomy screening laboratory the information supplied on the form should be checked according to national guidance. Incomplete forms and requests for further information should be emailed by the Lab to the Antenatal Screening nhs.net email at UHL. The information is sought by the screening team and emailed back to the Lab by nhs.net email.

Interpreting services should be used where appropriate. Screening tests for you and your baby leaflet should be also downloadable in different languages from [www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief](http://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief)

**Recommendation Two: Low chance results**

**Low chance results**

- Women who have a low chance result should be sent a letter from the laboratory informing them of this within 2 weeks of the result being available

- Low chance results should be sent from the laboratory to the requestor. This is usually in an electronic format

- The midwife at the next antenatal appointment should ensure she has received this and document the result in the maternity health record. The midwife will also ensure that the woman understands that this is a screening result and therefore cannot completely exclude the possibility of her baby being affected with this condition.

- If the woman requires further or more detailed discussion about her low chance result she should be referred to the Antenatal Services Midwives or the Screening Coordinators
Recommendation Three: High chance results

High chance results are emailed by the Trisomy screening laboratory to the Antenatal Services Midwives generic nhs.net email and a copy sent to the requester

- The Antenatal Services Midwives should document the result on the Fetal Diagnostic Care Plan
- The result should be confirmed using iLAB or ICE.
- The gestational age at date of sample should be verified as correct
- Hospital notes should be obtained
- An appropriate appointment time for the woman to attend the hospital to discuss her result with the midwives and potential diagnostic test should be identified within 3 working days of the result being received.
- The woman should be informed of her result by telephone, no more than 24 hours prior to the planned appointment time and the appointment offered
- If the midwife is unable to contact the woman or the appointment is on a Monday the Community Office should be informed and the Community Midwife should inform the woman of her result and the appointment
- If the Community Midwife is unable to make contact with the woman she should post a note through the door asking that the woman contacts the Antenatal Service Midwives as soon as possible. (See Appendix 5)
- The Community Midwife should also let the Antenatal Services Midwives know that this has taken place.
- If the woman fails to contact the Antenatal Services Midwives within a week the above process should be repeated
- A contact number for further enquiries should be given

Recommendation Four: Equivocal results

``Equivocal results`` that require further action should be emailed to the Screening Coordinators generic nhs.net email address

- Equivocal results should be emailed to the Screening Coordinators generic nhs.net email
- An individualised management plan should be made by the Antenatal Services Midwives or Screening Coordinator in conjunction with the Consultant

Low Papp A (less than or equal to 0.41MOMs)

- Following a low Papp A result women will need to be informed that this result does not affect the results that they have been given for Trisomy screening.
- Women will need to be informed of the changes required for Fetal surveillance during pregnancy and scan pathway monitoring commenced.
- Arrange to commence Aspirin 150mg prior to 20 weeks gestation as per Aspirin guideline

Recommendation Five: Results not available follow up

Results found to not be available should be followed up

- If the health professional identifies that the result is not available at the follow up appointment they should contact the laboratory to check their records.
- If test has not been performed further testing should be initiated
- A follow up appointment should be made for the woman to receive her result within 2 weeks.

Recommendation Six: Antenatal Services Midwives discussion, Implications & further testing

The Antenatal Services Midwives should offer a full discussion with the woman about the implications of a high chance result and further testing is offered and initiated where accepted.

- The Antenatal Services Midwives should discuss the high chance result with the woman and her partner / family, ensuring she has an understanding of the screening test, including its implications and limitations.
- The midwife should inform the woman of her options, which may include continuing the pregnancy having accepted her screening result or proceeding on to diagnostic testing with its associated risk of miscarriage.
- It should be made clear at this point that if there are no abnormalities on scan the diagnostic test result will only be for T13/18/21 and the sex chromosomes (see recommendation 7 for details).
- The option of private NIPT should also be mentioned to the woman either through external providers or out of hours at UHL.
• UHL will follow the national guidance on the offer of NIPT as part of the high chance result pathway when this becomes available. This is currently planned to start from 1.7.2021 (see Appendix 10 for pathway and Appendix 11 for Crib sheet to aide discussion with the lady)

• The woman should be aware that she will be informed of any abnormal chromosome arrangement on diagnostic testing, regardless of consent choices at the time of screening. For example if the screening result is high chance for Trisomy 13/18 and the baby is affected with Trisomy 21 we will inform her of this result regardless of previous screening choices.

• Sufficient time should be given for decision making.

• If the woman wishes to proceed to a diagnostic test the midwives should ensure an appropriate appointment with a Fetal Medicine Consultant is in place and that the woman has a full understanding of the procedure, it’s risks and how the results will be communicated

• If the women wishes to proceed with NIPT this can be offered outside of working hours at UHL or once this is available on the NHS follow the process mapped out in the sample boxes provided by FASP.

• The midwives should then support the woman through the procedure and plan the process for communicating her results.

• All of the above should be documented fully in the Maternity Health Records

**Recommendation Seven: Results communication**

NIPT results will be emailed to the Antenatal Services Midwives and communicated appropriately to the woman

• Results will come by email from the Lab, high chance results will come in an individual email – more than once daily checking of fetal medicine shared emails is required.
  - Confirm receipt of results by responding to the email.
  - Clinical queries: Telephone – 02073077409 or email elaine.holgado@tdlpathology.com

• No result will be notified by an individual email and should be acknowledged by return email. The lab then should be informed when the repeat sample has been taken and sent (if repeated).

• The laboratory reception will notify the contacted on the request form if sample cannot be process e.g. insufficient blood, expired tube etc. No report will be generated if the sample is not tested.
Recommendation Eight: Diagnostic test results

Diagnostic test results should be obtained by the Antenatal Services Midwives and communicated appropriately to the woman

- Florescent In-situ hybridisation (FISH) test will be carried out for women who have an increased chance. This will give a result for Trisomy 21/13/18 and sex chromosome abnormalities only. The Antenatal Services Midwives should ensure that FISH results are available and reported to the woman within the expected timeframe. This will normally be between 24 hours and 48 hours but should always be within 3 working days.

- Where women have an increased chance and an NT measurement of >3.5mm and/or a fetus with suspected structural malformation will still have the FISH test and a micro-array. Micro-array results should be made available to the woman as soon as it is received. This will usually take between two to three weeks.

- Women who have had a normal FISH result early in pregnancy but the fetus is noted to have a structural problem at the anomaly scan can be offered a repeat invasive test for a full assessment of chromosomes & micro-array.

- The result, following rigorous checking of all demographic details to ensure that the result is correct should be communicated to the correct woman and documented in the Maternity Health Records.

- The midwife should attempt to contact the woman by telephone immediately that the result is available – this process should have been agreed with the woman at the time of the procedure.

- The midwife should document that she has given the woman her result or that she has been unsuccessful in making contact with her specifying the date and time. Further attempts should then be made until contact has been achieved.

- In the event of an abnormal result an appropriate appointment should already have been arranged for the woman to discuss her result and her options with the Antenatal Services Midwives and a Fetal Medicine Consultant.

3. Education and Training:

- Antenatal and newborn (ANNB) screening training is provided as part of induction training for midwives, obstetricians and midwifery care assistants.
- ANNB screening training is provided on annual mandatory training for midwives, MCA’s and children’s nurses.
4. Monitoring Compliance

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<th>Monitoring Lead</th>
<th>Frequency</th>
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<td>Monitoring of Trisomy screening standards</td>
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5. Related guidelines:

- Ultrasound UHL Obstetric guideline (B52/2011)
- Aspirin in Pregnancy UHL Obstetric guidelines (C36/2011)
- Fetal surveillance – Small for Gestational Age Fetus Obstetric guideline (C38/2017)
- Booking bloods and urine test UHL Obstetric guideline (C15/2011)

6. Supporting References:

2. Fetal anomaly screening programme standards 2015

7. Key Words

Trisomy screening, Down Syndrome, Patau Syndrome, Edward’s Syndrome.

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.
**Contact & review details**

**Original Author / Lead Officer:**
- Louise Payne, Senior Midwife for Community Services
- Lorraine Matthews, Midwife Quality and Safety
- Helen Ulyett, Antenatal and Newborn Screening Coordinator

**Reviewed by:**
- H Ulyett

**Approved by:**
- Guidelines Group and Maternity Service Governance Group

**Date Approved:** 16/06/2021

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**REVIEW RECORD**

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<th>Issue Number</th>
<th>Reviewed By</th>
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<td>June 2014</td>
<td>V2</td>
<td>H Ulyett, L Matthews and the Fetal Medicine Team</td>
<td>NIPE info inserted. Management of twins clarification, extra info on NT and completion of forms</td>
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<td>October 2015</td>
<td>V2</td>
<td>As above</td>
<td>Lab changed to Nottingham Quad testing to be performed by the Antenatal Services Midwives when scan shows woman is too late for first trimester</td>
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<td>February 2016</td>
<td>V3</td>
<td>As above</td>
<td>Addition of Quad testing for Twins if first trimester combined screening is not possible. Addition of screening for Edward’s and Patau’s syndrome to Down’s screening guideline</td>
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<td>October 2016</td>
<td>V4</td>
<td>As above</td>
<td>FISH only now for increased screening test result. Full culture for increased risk combined with NT of &gt;3.5mm and / or a fetus with suspected structural abnormality</td>
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<td>July 2018</td>
<td>V5</td>
<td>As above and L. Payne</td>
<td>Change of terminology from Down’s Edwards &amp; Patau’s screening to Trisomy 13/18 &amp; 21 screening Change of terminology from risk to chance throughout the document. Information for women about NIPT Change from full karyotype to micro-array for diagnostic testing</td>
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<td>January 2020</td>
<td>V6</td>
<td>As for V5</td>
<td>Updated use of emails instead of fax for missing information requests and high chance results from the Lab. Terminology changed to Trisomy screening Lab instead of the hospital of Laboratory provider in case it changes again Removal of NIPT from high chance pathway Changes to the Trisomy screening failsafe SOP.</td>
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<td>June 2021</td>
<td>V7</td>
<td>H. Ulyett, M.Bodley, L.Payne and Fetal medicine team</td>
<td>Addition of NIPT as part of the high chance results pathway on the NHS.</td>
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**DISTRIBUTION RECORD:**

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<td>Maternity</td>
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Appendix 1 – Process for the first trimester Trisomy 21/13/18 screening appointment.

1. Woman receives appointment and information letter for first trimester Trisomy Screening.

2. Woman attends for the screening test.

3. Sonographer confirms consent for Trisomy screening with woman prior to commencing scan (refer to Obstetric ultrasound guideline). NT scan performed & relevant section of Trisomy screening request form completed.

4. Woman weighed, yellow section of request form completed and blood test taken.

5. Addressograph label for the woman is added to the daily sample tracking list and sent to the screening team.

6. Woman informed of process for receiving her results.

7. Unable to measure NT or woman too late for combined screening – follow the map of care for first trimester screening in Appendix 3.

8. Woman decides to decline screening. This is documented on E3 and on the dating scan report.
Appendix 2 – Process for the second trimester Down’s syndrome screening appointment within the Community setting

Woman unable to have first trimester screening as the Nuchal Translucency could not be measured

Woman attends for results of first trimester screening and the test has not been performed

Midwife offers the second trimester Down’s syndrome serum screening test to the woman.

Consents to screening

Declines screening

Serum screening test performed at this appointment

Midwife documents the woman’s decision about screening in the Maternity Health Record and on E3

Midwife documents the date screening test was taken in the Maternity health record.

Midwife informs screening team on x 1)4860 that a quad test has been taken in order to track the sample to the lab

Appointment made for Woman to attend to discuss her results within 2 weeks
Appendix 3. Map of care for women attending for first trimester Trisomy screening through the Antenatal department.

Woman reports to clinic/scan reception desk for dating scan/Trisomy screening.

If the woman has attended for Trisomy screening - Confirm her details and give her the laminated information sheet to read prior to her scan.

Once in the scan room prior to the scan, Sonographer to confirm the woman’s consent for Trisomy screening, T21 only or T13/18 screening only.

Screening test declined – proceed to dating scan alone.

Consent obtained – proceed to dating scan & NT measurement.

Unable to measure NT.

Dating scan & NT measurement successful – Complete accurately Trisomy screening request form

Direct the woman to the MCA for weight and to check completion of the request form & addition to sample tracking list

Direct the woman to phlebotomy for blood test.

Once all elements of the appointment are completed direct the woman back to clinic/scan reception to hand in her information sheet and make her detailed scan appointment.

Unable to measure NT after 2 attempts or too late for first trimester screening

Encourage woman to mobilise for a while and try again.

Refer to antenatal Midwives/MCA’s. for Quadruple testing immediately after the scan.

Explain importance of seeing midwife between 14+2 – 20+0 weeks for Quadruple test and give information sheet

Too late for first trimester screening

Trust Ref No: C6/2001

Title: Down’s Patau’s and Edwards Syndrome Screening Guideline
V: 7
Approved by: Maternity Governance Committee : June 2021
Next Review: June 2024

NB: Paper copies of this document may not be most recent version. The definitive version is held on InSite in the Policies and Guidelines Library.
Appendix 4 - UHL process for Trisomy Screening following diagnosis of a “Demised Twin”.

If USS shows a second/third non-viable fetus with a measurable fetal pole but a surviving fetus.
If yolk sac only with surviving fetus continue with combined screening

Refer woman to Antenatal Services Midwives for consultation about the accuracy of Trisomy screening using NT only.
Complete trisomy request form and label - “For NT ONLY, No bloods needed”

If woman accepts NT only screening –
1. Complete trisomy screening request form inc. weight etc.
Send form to Trisomy screening lab and label **NT only**. Document screening in handheld notes and on scan report

Process for reporting results:
All trisomy screening results will be available electronically on ICE

Process for reporting the result to the woman:
This should follow the same pathway as for other Trisomy screening tests. (A low chance letter will be sent directly from the Trisomy screening laboratory to the lady) Remind the woman to see the Community Midwife within two weeks of test.

These women should not have **serum** screening for Trisomy 21 in either the first or second trimester.
Appendix 5 – Community letter

University Hospitals of Leicester NHS Trust

Date ..................................................

Dear ..................................................

I have tried to visit you at home today to give you some test results.

Could you please contact the Antenatal Midwives for further information as soon as possible?

If you are booked to have your baby at the LRI telephone 0116 2586106 (between 8.30am and 4pm)

If you are booked to have your baby at the LGH telephone 0116 2584829 (between 8.30am and 4pm)

Yours sincerely

Community Midwife
Appendix 6 – patient letter for incomplete screen

Testing for Down’s syndrome during pregnancy

Unfortunately, it has not been possible for you to have the combined test for Down’s syndrome today. You can have the quad (quadruple) blood test once you are 15 weeks pregnant, but this must be carried out before you are 20 weeks pregnant. You need to arrange for this blood test to be performed by your community midwife. Please contact them now to arrange this.

मसौद्यम ते आज आपल्यांना दिलेला निश्चित करणे की संपूर्ण वापरणे संगत नकार होय. जे अभ्यंग अंक 15 हजार रु. हा हे जप से अन्न सळण्य (वामन) संपूर्ण वापरणे करणे काहीच हे, त्याने ते आपल्यांना अंक 20 हजार रु. हा हे पाहतात ज्या जाणा चाहिए. या संपूर्ण वापरणे की निश्चित करणे आपण संपूर्ण वापरणे निर्णय करणे होय. इसीलिए वापरणे के लिए, कृपया उपर्युक्त संबंधी करो.

गर्भायनकास्था दरम्यान डाउन स्यंड्रोमची परीक्षण

जवळपास 15 हजार रु. हा हे जप से अन्न सळण्य (वामन) संपूर्ण वापरणे करणे होय. जे अभ्यंग अंक 20 हजार रु. हा हे पाहतात ज्या जाणा चाहिए. या संपूर्ण वापरणे की निश्चित करणे आपण संपूर्ण वापरणे निर्णय करणे होय. इसीलिए वापरणे के लिए, कृपया उपर्युक्त संबंधी करो.

Przeprowadzanie badań w kierunku zespołu Downa podczas ciąży


Baaadhitaanka Kaalacadda Down ee Xilliigaa Uurka

Nasib daro. may noogan suurtagal in aad hresko baadhitaanka dhan ee xaaladda Down. Waxaad iio durnaa baadhitaanka dhigga ee deneen (afar dhana) marka aad 15 todobaad uur leedhahay, baashi waa in la sameeyo ka hor inta oo uurkii gaar ah 29 todobaad. Waxaad u baahan tohah in aad ka samaysato ummulisada bixi kii xigaan ugu ugu samaysato.
Appendix 7 – Kettering Trisomy screening request form.
Appendix 8 - Standard Operating procedure to failsafe Trisomy Screening Programme.

**Standard Operating procedure to failsafe Trisomy Screening Programme.**

- Community Midwives document at booking on E3 the women’s choice of screening.
- Antenatal midwives review print out of the booking notes and select the timeframe for the screening scan.
- Clinic coordinators the scan appointment.
- When the woman attends the scan, the sonographer confirms her screening choice and documents this on the scan report. Where possible completes the NT measurement and records this on the scan report.
- If the screening cannot be completed because the NT could not be measured, the woman is told she needs to make an appointment with the community midwife for Quad testing between 15 and 20 weeks gestation. A printed information sheet is given to the woman explaining this in 6 different languages and is attached to the notes.
- If the woman is too late for 1st trimester screening, quad testing is offered and performed in the hospital.
- The women are told they will receive a written letter detailing the result within 2 weeks and are asked to ensure they have a follow up CMW appointment to discuss the results.
- Women who have had trisomy screening test within the hospital have their demographic details recorded on a list and this is forwarded daily to the screening team.
- A 'shipping manifest list', which contains all screening samples received by UHL laboratory, is emailed daily to the screening team (Mon-Friday). This manifest is then cross referenced with the patient demographic list and any samples not received by the laboratory are then identified and followed up to ensure a result is received by the woman.
- 5 weeks after the booking is entered onto E3, an automated weekly list of the bookings is matched with samples received in the UHL laboratory
and forwarded to the Screening Team. (The weekly list then contains women who to date have not had trisomy screening.)

- The screening team then follow up using this list all the women who accept screening to ensure they receive a conclusive result within the screening timeline.
Standard operating procedure for the daily checking of the Down’s shipping manifest

- Check for late bookers on FailSafe Officer’s calendar against shipping manifest and E3.

- Check sticker list against shipping manifest.

- Any not ticked on sticker sheet: Check E3 to see if bloods should have been taken & Check Lab for different names. If blood should have been taken, check list at blood room and check with woman if she had the bloods taken. If time allows, wait a day for bloods to arrive. If not arrived, arrange a retest.

- Any not ticked on shipping manifest, will most probably be a quad test. So check on E3 to see booking date and gestation. If it is a quad, find lady on cohort match and turn blue, and add the comment ‘Quad in progress’ in ‘chase quad from’ column.

- Check every incomplete cohort match for any scans that have been performed on the day that you’re checking, look on the shipping manifest to see if the bloods are in progress. If they are, change lady to blue and put in progress in ‘scan app’ section.

- If NT could not be measured, put this into ‘scan app’ section. Next to this in the ‘Chase quad test from’ section, write the date that the lady will be at 17 weeks gestation.

- Check cohort match for quads to chase (last column). Call the GP and/or midwife to see if they have any record of the lady declining their quad test. If they haven’t declined, request that the GP leaves a note on their system for the midwife to offer a quad test, or request directly from the midwife.

- Check that any quads that have been taken in the community are on the shipping manifest, mark the reason they couldn’t have combined screening in the ‘scan app’ column.

- Check for any miscarriages and put ‘miscarriage’ in the ‘scan app’ section, and turn blue.

- Make sure all ‘gestation at booking’ are filled in.
<table>
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<tr>
<th>Title of Standard Operating Procedure</th>
<th>Management of Trisomy screening failsafe for Women being cared for by Leicester area midwives</th>
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<tbody>
<tr>
<td>Author (include email and role)</td>
<td>Angie Godfrey (Screening Coordinator- <a href="mailto:angie.godfrey@nuh.nhs.uk">angie.godfrey@nuh.nhs.uk</a>)</td>
</tr>
<tr>
<td></td>
<td>Emma Haworth (Screening Coordinator- <a href="mailto:emma.haworth@nuh.nhs.uk">emma.haworth@nuh.nhs.uk</a>)</td>
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<tr>
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<td>Family Health - Obstetrics</td>
</tr>
<tr>
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<td>Bodil Hamilton –Cody</td>
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<tr>
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<td>Maternity Governance</td>
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<td>01.09.2020</td>
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<td>Audience</td>
<td>NUH and UHL Antenatal and Newborn screening Coordinators , Antenatal and newborn screening failsafe officer</td>
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<td></td>
<td>Leicester community matron</td>
</tr>
<tr>
<td></td>
<td>Leicester community midwives</td>
</tr>
</tbody>
</table>

This procedure is to be followed each time combined screening cannot be completed at NUH

**Responsibility of NUH Antenatal clinic maternity support worker / midwife to failsafe the NT list**

- Document on NT list reason for combined screening not performed
- Document on NT list any actions, e.g. contacted woman, appts made
- If unable to contact a Nottingham woman. Telephone community coordinator to follow up (07812268458)
- Document actions on MEDWAY
- Write any follow up actions in the ANC communication diary where appropriate
- Sign, date and document number of pages on NT list
- Scan in the NT list to the Antenatal scan folder.
- This will be checked daily by the Antenatal and Newborn Screening Failsafe Officer /Screening Coordinator who will then add all women who have not had combined screening to the Trisomy failsafe spread sheet.
- Keep NT lists for 1 month. The failsafe officer / ANNBSC will check on the 5th of each month all sheets have been received for the previous month and confirm with each ANC they can be disposed of
2. Responsibility of NUH Failsafe officer / Screening Coordinator for women cared for by Leicestershire community midwives

- Every Tuesday email via NUHNT.antenatal-empath@nhs.net, (NUHANNBscreening@nhs.net details of women to UHL ANNBSC who are 18 week gestation
- UHL to return outcome / action by the Friday of the same week (where a bank holiday occurs clear timescales to be agreed by email)
- Monitor Failsafe until outcome obtained e.g. decline or result obtained

**NUH Screening coordinators and Failsafe officer contact details**

Screening team generic email address NUHANNBscreening@nhs.net

Antenatal and newborn screening coordinator
  - City Campus – 0115 9691169 ext. 57408 mobile 07812268657
  - QMC Campus – 0115 9249924 ext.63986 mobile 07812268656

Failsafe officer – mobile 07812270085
Appendix 10 – High chance trisomy screening result pathway inc. NIPT on the NHS

START HERE
Combined or quadruple test

Lower chance result
No further tests offered

Higher chance result
Choose from:

No further tests
NIPT
CVS or amniocentesis

NIPT results
Lower chance result
No further tests offered

No result
Choose one further NIPT, diagnostic test or no further tests

Higher chance result
Choose from:

No further tests
CVS or amniocentesis

Appendix 11 – Discussion crib sheet

Crib sheet for discussion about a high chance Trisomy screening result including NIPT on the NHS.

Following a high chance Trisomy 13/18 or 21 combined or quad test result all women continue to have the choice to:

1. Do nothing
2. Have a diagnostic test with associated risk of miscarriage of 1:100 Results available with 1-3 days)

Once NIPT is available on the NHS also discuss option to:

3. Have NIPT (if eligible). Refer to the following for help with this discussion:
   a. NIPT is still a screening test but is more accurate than the combined or quad test.
   b. Results available in 1-2 weeks.
   c. A high chance NIPT result for T21 or T13/18 means that more than 90% of babies will have the condition and if this is the case we would offer them a diagnostic test to confirm the result.
   d. A low chance NIPT result means that it is unlikely that the baby has the condition but this is more likely if the result from combined/quad testing was really high (1:2-10).

This information is available to women electronically by scanning this QR code:

For women who want more information about the likelihood of a low chance result being incorrect and the baby is affected with the condition you can use the figures:

i. T21 – Any high chance Combined/Quad result – low chance NIPT = 1:1100 that baby is affected with Down’s Syndrome.

ii. T21 Combined/Quad result 1:2 – low chance NIPT = 1:100 that baby is affected with Down’s syndrome. Woman should be aware that this result is much lower than her result from combined/quad test.

iii. T21 – 50% of babies with T21 will show an abnormality at the anomaly scan where further discussion would take place about the low chance NIPT result and the offer of diagnostic testing should be considered.

iv. T13/18 -- Any high chance Combined/Quad result – low chance NIPT = 1:480 that baby is affected with Edward’s or Patau’s syndrome.

v. T13/18 Combined/Quad result 1:2 – low chance NIPT = 1:21 that baby is affected with Edward’s or Patau’s syndrome. Woman should be aware that this result is lower than her result from combined/quad test.

vi. T13/18 – 95% of babies with T13/18 will show an abnormality at the anomaly scan where further discussion would take place about the low chance NIPT result and the offer of diagnostic testing should be considered. This may be a reason for women with a low chance NIPT result for T13/18 from NIPT to wait for the anomaly scan prior to making a decision about a diagnostic test.