

Trust Guideline for Antenatal Screening for Trisomy 21, Trisomy 18 and Trisomy 13

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V 7.0	15/06/2021	Richard Smith and Alison Evans	Confirmation of pathway for vanishing twin and pathway for raised AFP
V 8.0	19/10/2022	Richard Smith and Alison Evans	The guideline has been updated to reflect the new CT/QT request pathway (1. Combined Screening Test and Quadruple Screening Test Screening Request Pathway) attached. Furthermore, added a minor revision to the already approved Appendix 1 A025 - Antenatal Screening for Down, Edwards and Patau syndromes pathway (also attached) to ensure all related pathways are consistent.
V 9.0	19/04/2023	Charlotte Aldous	Changes in CT process for

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			vanishing twin, Appendix 3 reformatted, Inclusion of Needlephobia pathway
V 9.1	19/02/2024	Charlotte Aldous	Inclusion re R445 pathway

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet

Consultation

During the development of this guideline, advice has been sought from obstetricians with fetal medicine subspecialty, sonographers and the laboratory lead for screening for Down, Edward and Patau syndrome. This version has been endorsed by the Clinical Guidelines Assessment Panel.

The following were consulted during the development of this document:

R Smith	Consultant Obstetrician, Fetal Medicine Specialist, Chair of Antenatal Screening Steering Group
V Maxey	Consultant Obstetrician, Chair of Guidelines Committee
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Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline/non-clinical guideline applicable to the Norfolk and Norwich Hospital please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

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Quick reference

This guideline is to be used when offering women antenatal screening for Down, Edwards and Patau syndromes

- All pregnant women to be offered screening for Down, Edwards and Patau syndromes.
- Women have different options for screening
 - Combined test – can choose to be screened for all 3 major trisomies, Down syndrome only or Edwards/Patau syndrome only.
 - Quadruple test – screens for Down syndrome only, cannot screen for Edwards or Patau syndrome as not enough research evidence linked to quadruple screening. Edwards and Patau syndrome screening in the 2nd trimester is the fetal anomaly scan at 18+0 – 20+6 weeks.
- The combined test can be performed when the baby's crown rump length (CRL) is between 45.0mm and 84.0mm. This is between 11+2 and 14+1 weeks. The nuchal translucency (NT) measurement is needed to calculate the chance result. The blood sample can be taken from 10 weeks.
- If the NT cannot be measured, or the CRL measurement is greater than 84.0mm, the woman is offered the quadruple test. If accepted, this test can be performed when the baby's head circumference (HC) is between 101.0mm and 172.0mm. This is between 14+2 and 20+0 weeks. The blood sample can be taken from 14+2 weeks
- Women found to be higher chance for any of the syndromes to be offered the options of non-invasive prenatal testing (NIPT) and prenatal diagnosis Non-Invasive Prenatal Testing (NIPT) for Down, Edwards and Patau Syndromes Trust Docs ID [18818](#)
- **Women who have had a confirmed previous full trisomy 21, full trisomy 13 or full trisomy 18 are eligible for the R445 pathway (R445- NIPT for those with a previously confirmed full T21, T13 or T18)**
- NICU alert system to identify babies at higher chance where prenatal diagnosis and NIPT are declined

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1. Introduction

1.1. Rationale

The UK National Screening Committee (UKNSC) has stated that the 1st trimester Combined test is the preferred method of screening as it supports screening being completed in one stage without the need for more than one attendance. It will also give a risk before 14+2 weeks of pregnancy allowing earlier decision-making for parents. It meets the NSC outcome of a detection rate (DR) for Down syndrome of greater than 75% of affected pregnancies with a screen positive rate (SPR) of less than 3%⁽¹⁾. The recent revision of the NICE clinical guideline on “Antenatal care: routine care for the healthy pregnant woman” also advises that the 1st trimester Combined test is used⁽²⁾.

Where it is not possible to offer the Combined test, the UKNSC recommend the Quadruple test is the preferred second trimester screening test for Down syndrome but Edwards and Patau syndrome should be screened for as part of the 18+0 – 20+6 weeks fetal anomaly scan. The Quadruple test can be performed between 14+2 and 20 +0 weeks (note the optimum time is after 15+0 weeks, so those booking an appointment specifically for the Quadruple test should be seen on or after 15+0.) A cut-off of 1 in 150 is used for all syndromes on both tests to detect higher and low chance. (3)

Screening should only be performed after documented verbal consent (i.e.. completion of the serum screening request form, M43). If the woman declines the test, this should be recorded in the hand held notes and on E3 (the maternity IT system).

1.2. Objective

The objective of the guideline is to ensure all women are offered Antenatal Screening for Down, Edwards and Patau syndrome and are able to give informed consent. Where a result is shown to be higher chance, appropriate information should be given to allow decision-making about prenatal diagnosis.

1.3. Scope

The purpose of document is to provide direction on the management and act of performing trisomy screening. The scope of the document covers patients who are eligible for trisomy screening at the Norfolk and Norwich Hospital and staff involved in this pathway. This guideline should be reviewed by all medical staff and implemented to prevent incidents occurring.

1.4. Broad Recommendations

- To offer all eligible women screening for Down, Edwards and Patau syndrome.
- To offer women with higher chance results options for prenatal diagnosis in a timely manner.
- To utilise the NICU alert system where prenatal diagnosis is declined in a higher chance result.

1.5. Glossary

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The following terms and abbreviations have been used within this document:

Term	Definition
AFP	Alpha-fetoprotein
ANS	Antenatal and Newborn Screening
CT	Combined Test
DQASS	Down syndrome Quality Assurance Support Service
E3	Euroking
NIPT	Non Invasive Prenatal Test
NT	Nuchal Translucency
PAPP-A	Pregnancy Associated Plasma Protein-A
QT	Quadruple Test
STFYAYB	Screening tests for you and your baby”

2. Responsibilities

All staff to fully comply with this guideline to ensure timely review and management of results.

3. Processes to be followed

3.1. Management

Ideally women should have access to screening information prior to making a decision about a test. The NHSE “Screening tests for you and your baby” (Screening tests for you and your baby (STFYAYB) - GOV.UK (www.gov.uk). information is available to women via the link on the NNUH electronic self-referral form, this gives access to all screening information in different languages and formats to allow accessibility for all. Where it has not been possible for a woman to access this due to language or vulnerability issues, signposting to the link or a hard copy can be given at the time of the face-to-face booking appointment with the community midwife.

3.2. Declined Trisomy Screening

Some women may decline trisomy screening. It is imperative to discuss the rationale for offering trisomy screening with the woman fully to ensure an informed decline is confirmed. This must be recorded on the E3 Booking workflow and the patient informed how to arrange trisomy screening if they wish to opt into this pathway. Patients must be fully apprised of the cut-off timeframes for trisomy screening (11+2-14+1 for Combined Screening and 14+2-20+0 for Quadruple testing) and it is good practice to document this conversation at the end of the E3 Booking workflow.

For those that decline blood test screening due to a needlephobia, the needlephobia pathway should be initiated (See Appendix 1).

3.3. Midwife Responsibilities in Trisomy Screening Pathway

All antenatal screening tests should be discussed at the booking appointment with the midwife, including screening for Down, Edwards and Patau syndromes. If the patient provisionally opts for the Combined Test, this should be indicated on the antenatal booking workflow on the maternity IT system and on the maternal serum screening request on the ICE requesting system. The Combined Test/ Quadruple Test (CT/QT) ICE electronic request will explicitly specify the choice of trisomy

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screening the patient wishes to proceed with. Incorrect or missing data on the ICE request form may lead to delay or incorrect results.

Although antenatal clinic staff will endeavour to assist patients attending appointment without a completed ICE request form or without a full understanding of the test, the responsibility of consenting the patient for trisomy screening ultimately lies with the health professional conducting the booking appointment. All CT request forms will be printed off ICE by the Antenatal Screening Team daily and taken to Antenatal Clinic ready for the patients planned ultrasound appointment.
(See Appendix 2 and 3).

For women who have had a previous pregnancy or child confirmed to have a **full** trisomy 21, 18 or 13 instead of being offered a CT, they will be offered The R445 pathway. The R445 pathway offers non-invasive prenatal testing (NIPT) to pregnant women because this cohort of women are known to have an increased chance of recurrence of primary trisomy in any future pregnancy (*a priori* chance of around 1% **or** the chance related to maternal age, whichever is the greatest). Therefore, R445 offers these women the opportunity to proceed directly to the more sensitive screening test and at an earlier stage of pregnancy (See Appendix 4 for R445 pathway and Appendix 5 for R445 Inclusion Criteria). Women who are eligible for the R445 will be identified at booking by the community midwife (Appendix 6). The community midwife will contact the Antenatal and Newborn Screening team via email to notify them of a service user who is eligible. Subsequently the ANNBS team will contact the patient to offer the R445 once eligibility is confirmed. All eligible patients will be stored in a centralised location within the S-Drive on the trust computer database. See Trust Guideline for Non-Invasive Pre-natal Diagnosis for more information (Trust ID No: 18818).

3.4. Antenatal Clinic Reception Staff Responsibilities in Trisomy Screening Pathway

The dating (NT) scan appointment is made by the receptionist from information received within the automated referral sent following completion of the E3 booking workflow. It should be booked between 11+2 and 14+1 weeks of pregnancy inclusive (crown rump length 45 to 84 mm inclusive). This will require timely booking appointments (ideally by 8 weeks) to take place at least three weeks prior to optimum window for scanning. On arrival at the appointment, the antenatal clinic receptionist will check the woman wishes to proceed with trisomy screening and provide the patient with her CT ICE request form following confirming the patient's identity. If the patient has changed her address the request form should be re-printed by the ANC Midwife to ensure results are posted to the correct address. All CT ICE requests will be kept securely in a specified folder, safely stored by the ANC receptionist.

If the woman is unsure whether she wishes to proceed with trisomy screening, even if there is a completed request form, an Antenatal Clinic midwife will be asked to counsel the woman to ensure informed consent.

(See Appendix 2).

3.5. Sonographer Responsibilities in Trisomy Screening Pathway

Before the scan, the sonographer will confirm with the woman whether she wishes to opt for screening, including women who have declined at booking, in which case the nuchal translucency (NT) will be measured at the same time as the dating scan.

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Women who decline screening should be asked whether they wish to be informed of any obvious abnormality including an NT measurement of 3.5mm or more. (Those who decline will be offered a dating scan without NT measurement). The sonographer will check and complete the part of the request form relating to bleeding in pregnancy and attach an extra copy of the report to the request form for either combined or quadruple testing.

If the NT is $\geq 3.5\text{mm}$, the patient should be referred to Fetal Medicine for review, but the Combined test should still be completed. Those who declined screening but where the NT is incidentally found to be $\geq 3.5\text{mm}$ should still be referred to Fetal Medicine because of the increased risk of other abnormalities.

If the NT is not obtainable but the gestation is correct, the patient will be offered a re-scan, including a transvaginal scan, later that day. If the NT is still not obtainable the patient will be advised, they can have a quadruple test with the community midwife 14+2 – 20+0 and this will be documented on the scan report. The sonographer will leave a copy of the report for the Antenatal and newborn screening team who will ensure the community midwife is informed via Medicom re need for quadruple test.

If the gestation is too early, the patient should be re-booked for the appropriate gestation.

If the gestation is too late (i.e. $\geq 14+2$ weeks, head circumference must be $> 101\text{mm}$), then the Quadruple test can be offered between 14+2 and 20+0 weeks. For convenience, this can still be done on the same day as the scan, remembering that the optimum time for the Quadruple test is after 15 weeks.

Where a patient can only be offered the Quadruple test due to gestation or unobtainable NT, she should be informed that the test cannot screen for Edwards or Patau syndromes but that screening for these are part of the Fetal Anomaly Scan at 18+0 – 20+6 weeks gestation.

After 20+0, no screening is available, other than the fetal anomaly scan.

If the patient communicates that she has had a previous pregnancy/child confirmed with a full trisomy 21, 13 or 18, the woman should be immediately referred to the ANNBS team so R445 can be offered (Appendix 7). **R445 cannot be offered after CT or QT has taken place.**

3.6. After scan:

The sonographer will inform the woman to wait in the waiting area and will place the request form in the Antenatal Clinic Phlebotomist's tray. The woman will be given her hand-held notes following her scan unless she is attending a face-to-face Antenatal clinic appointment.

(See Appendix 2 and 3).

At the ANC review with the consultant or junior doctor, if the patient communicates that she has had a previous pregnancy/child confirmed with a full trisomy 21, 13 or 18, the woman should be immediately referred to the ANNBS team so R445 can be

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offered (See Appendix 7). **R445 cannot be offered after CT or QT has taken place.**

3.7. Phlebotomist Responsibilities in Trisomy Screening Pathway

The phlebotomy staff will weigh the patient and take 5ml of clotted blood (yellow top bottle). Samples will be sent by the pod system and need to be spun down the same day. If samples are sent after 5pm (by antenatal clinic staff), the pathology reception need to be notified on extension 5419. The phlebotomist is required to weigh and record weight on the ICE CT/QT form.

Please see Appendix 1 for the Combined Screening Test and Quadruple Screening Test Screening Request Pathway detailing each professional's responsibility in the requesting process for trisomy screening.

(See Appendix 2).

If a patient is eligible for an R445, this will be taken by the ANNBS midwife to ensure full counselling has been offered. If blood is unobtainable, the ANNBS midwife will complete the counselling and then take the patient for venepuncture with the phlebotomy team.

3.8. Results

The results will be issued by the biochemistry department. The Combined test will provide a result for Down syndrome and a joint result for Edwards and Patau syndromes. The Quadruple test will give a result for Down syndrome only. Low chance patients will be notified by letter directly from the laboratory. The letter will state that the patient should file the result (i.e. the letter) in her hand-held notes. Higher chance results will be saved in a shared folder on the "S" drive and the Antenatal and Newborn Screening (ANS) team emailed via the generic antenatal.newbornscreening@nnuh.nhs.uk address, to inform them there is a result to action. The ANS midwives will contact the patient directly and discuss options within 3 working days of the result being reported, in line with UK NSC standards.

R445 results will be communicated via the telephone with the service-user as soon as possible when the result becomes available. If a repeat sample is required, this will be arranged. If two 'no results' are issued, the service-user will no longer be eligible for NHSE serum screening and will await FAS at 20 weeks. Results will be saved on the service-users maternity records, a copy sent in the post and in the ANNBS shared S-Drive.

3.9. Low PAPP-A and AFP

Trisomy screening can sometimes identify significant coincidental findings such as low Pregnancy Associated Plasma Protein-A (PAPP-A) from a Combined test and raised Alpha-fetoprotein (AFP) from a quadruple test.

Low PAPP-A (< 0.415 MoM) is a risk factor for placental issues in a pregnancy. See Trust guideline for the assessment of fetal growth and referral and management of large for gestational age fetuses. No 8882 for full pathway. The screening team will contact the woman, discuss the result and arrange an initial growth scan around 28 weeks gestation.

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A raised AFP can be an indicator of a neural tube or abdominal wall defect. If 2.5 MoM or above (5.0 MoM for twins), the screening team will contact the woman and offer an early detailed ultrasound scan in the Fetal Medicine Dept.

Women on the R445 pathway are not eligible for combined / quad screening, therefore a PAPP-A result will not be available. Therefore, women on the R445 pathway should be monitored for fetal growth restriction along the same local pathways in place for women who have declined combined screening or booked too late for combined screening (who also do not have a PAPP-A level measured).

3.10. Multiple pregnancies

Combined screening is the recommended screening test for twin pregnancies. It is essential that women with a twin pregnancy are fully counselled re Down, Edwards and Patau syndrome screening prior to accepting the test, i.e. discuss issues of one twin only being higher chance, increased complication risks of prenatal diagnosis and options such as selective feticide.

These women should be seen in the Specialist Twin Antenatal Clinic for discussion, this may require the woman being given a further appointment on another day. The NT will be measured for each twin and this, together with the blood sample will give a result. It is important to be sure of chorionicity as there will be either individual twin results for a dichorionic pregnancy or one result for a monochorionic pregnancy. If it is an IVF pregnancy, details of this, i.e., age of donor eggs/frozen embryos etc. must be on the request form.

If the NTs are unobtainable or the gestation too late for the Combined test, the Quadruple test can be offered in twin pregnancies but will only give one overall result of the pregnancy being affected – it cannot give individual twin results if dichorionic.

For higher multiple pregnancies, i.e., triplets etc. it is not possible to offer Combined or Quadruple tests. In these cases, the woman can only be offered a NT measurement for each fetus. The laboratory will then calculate a result for each fetus using NT and maternal age alone.

Due to the limitations of screening for multiple pregnancies, if a NT is unobtainable the patient should be recalled the same day to try to achieve a measurement and if still unobtained, must be offered another appointment on another day, where gestation allows.

Women pregnant who meet the eligibility criteria for R445 with a singleton or twin pregnancy are eligible for the R445, as long as there is no evidence of a vanished twin.

3.11. Vanishing twin

Where there is a surviving fetus but evidence of initial multiple pregnancy, this can influence what screening should be offered.

Down syndrome Quality Assurance Support Service (DQASS) state that where there is

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evidence of a vanished twin/second sac with or without a fetal pole, the Combined test can still be offered using **age and NT alone (no venous blood sample required)**.

DQASS detection rates show that the quadruple test performance rate is lower than the alternative of the Combined test when using NT and age alone for vanishing twins (NT and age alone 80% detection rate, QT 77% detection rate - DQASS vanishing twin data Oct 2019) . Therefore, where there is evidence of a vanished twin/second sac with or without a fetal pole and when an NT is obtainable, **Combined Screening using NT and age alone is the test of choice at NNUH**, if an NT is unobtainable, the woman can be offered a quadruple test with her community midwife. The woman should be informed at the time of the scan, the findings of vanishing twin, and be advised of her trisomy screening options by someone qualified to discuss this scenario – i.e., sonographer, Screening midwife, senior doctor in Antenatal Clinic.

Women who with a vanished twin, are not eligible for the R445 pathway.

4. Screening Safety Incidents

Due to the nature and characteristics of screening tests, safety incidents within screening programmes require special attention and management. (Ref. no. 5) Where an incident occurs along any of the antenatal and newborn screening pathways the ANSC should be informed and the NHSE document “Managing Safety Incidents in NHS Screening Programmes: updated Jan 2018” referred to.

5. Training & Competencies

Sonographers undertaking the measurement of NT must be fully accredited to perform this measurement.

6. References

1. Fetal anomaly screening programme: Down’s syndrome, Edwards’ syndrome and Patau’s syndrome screening Handbook for Laboratories. August 2018
2. Fetal Anomaly Screening Programme Standards 2015-16: UKNSC
3. NHSE Managing Safety Incidents in NHS Screening Programmes: August 2017 (updated Jan 2018) [Managing safety incidents in NHS screening programmes - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/674441/managing-safety-incidents-in-nhs-screening-programmes-august-2017-updated-jan-2018.pdf)
4. Non-Invasive Prenatal Testing (NIPT) for Down, Edwards and Patau Syndromes [Trustdocs Id 18818](#)

7. Audit of the process

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Proportion of eligible women who accepted	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly

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trisomy screening who have a result (combined test) (NHSE KPI FA3)				
Inadequate CT/QT samples for trisomy screening received by laboratory (NHSE KPI FA4)	Quarterly review and submission to NHSE	Antenatal and Newborn Screening Team	Antenatal and Newborn Steering Group Meeting	Quarterly
DQASS 6 monthly audit of Laboratory and sonographer performance	Bi-annual review	NNUH Biochemistry Laboratory/Sonography Team	NNUH Biochemistry Laboratory/Sonography Team	Bi-annually

The audit results are to be discussed at relevant governance meeting such as Clinical Governance, the Antenatal and Newborn Steering Group Meeting and externally at the NHSE Antenatal and Newborn Screening Board Meetings. These groups will review the results and recommendations for further action. Then sent to the relevant committee or Sub-Board who will ensure that the actions and recommendations are suitable and sufficient.

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Appendix 1: Needlephobia in pregnancy

Below action to be taken when service user discloses needlephobia.

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Appendix 2 Combined Screening Test and Quadruple Screening Test Screening Request Pathway.

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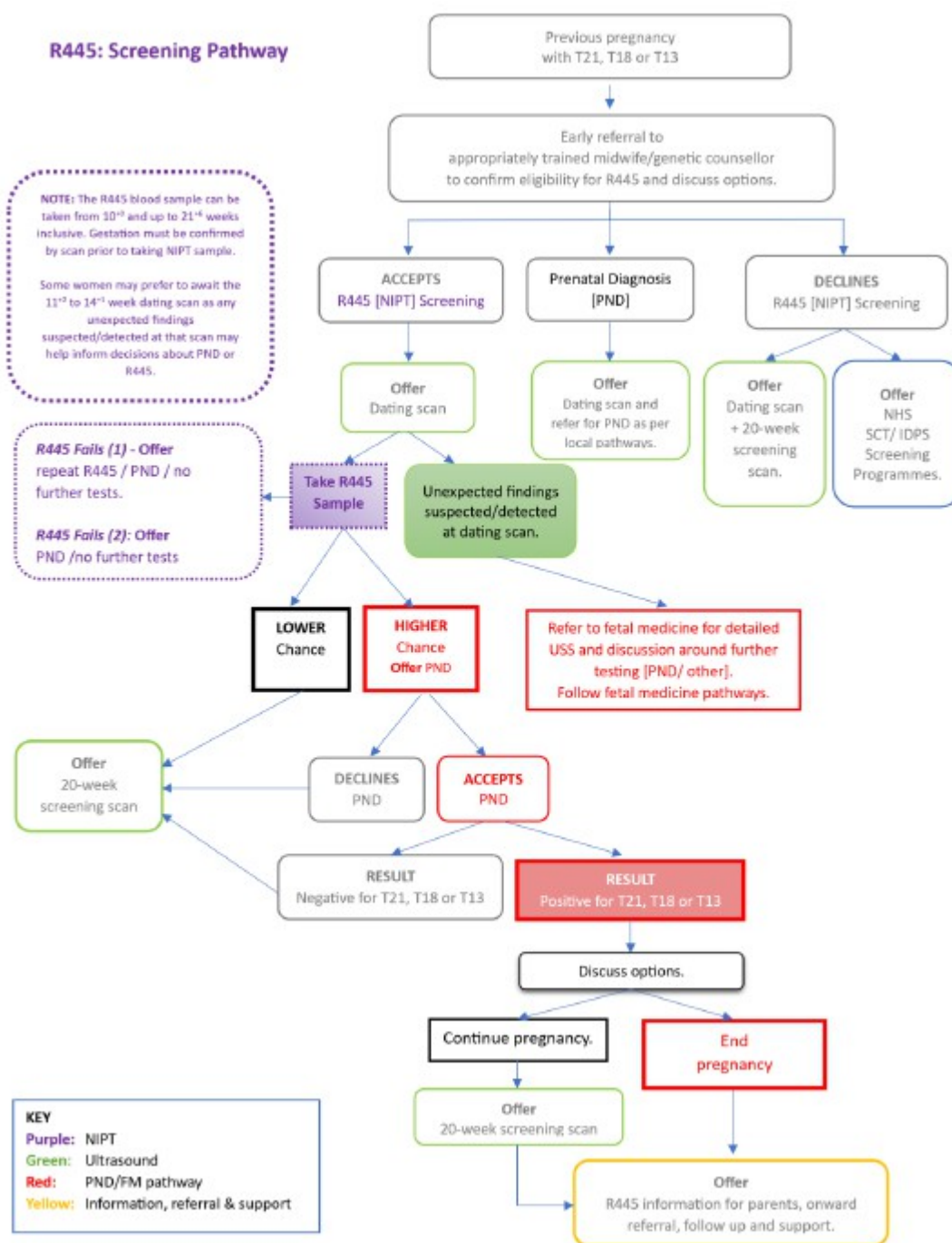
Appendix 3 – Antenatal screening for Down, Edwards and Patau syndromes pathway

Antenatal Screening for Down, Edwards and Patau syndromes

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Appendix 4- R445 Screening Pathway



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Appendix 5- R445 Inclusion Criteria

R445 Common aneuploidy testing - NIPT

Testing Criteria

Any previous pregnancy with reported full trisomy of chromosomes 13, 18 or 21, meeting the following criteria:

Inclusion:

- From 10 weeks (gestational age confirmed by dating scan) and up to 21 weeks and 6 days (21+6) of pregnancy.
- Two attempts at NIPT per pregnancy can be offered.

Exclusion:

- Maternal cancer (unless in remission)
- Blood transfusion in the last 4 months (whole blood or plasma)
- Bone marrow or organ transplant recipient
- Vanished twin pregnancy (an empty second pregnancy sac or a second pregnancy sac containing non-viable fetus)
- Maternal T21
- Maternal balanced translocation or mosaicism of T21, T18 or T13
- Immunotherapy in the current pregnancy, excluding IVIg treatment.
- Stem cell therapy
- Previous pregnancy was not a full trisomy (reciprocal translocation or partial trisomy)
- Women who have used a donor egg for current pregnancy.

Overlapping indications

- R401 Common aneuploidy testing – prenatal should be used where amniocentesis or Chorionic villus sampling (CVS) taken.

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Appendix 6- SOP for R445: Community Midwife Referral

Appendix 7-SOP for R445: Sonographer/Doctor Referral

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8. Equality Impact Assessment (EIA)

Type of function or policy	Existing			
Division	Women and Children's	Department	Maternity and Gynaecology	
Name of person completing form	Charlotte Aldous	Date	19/4/2023	
Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	None	N/A	No
Pregnancy & Maternity	None	None	N/A	No
Disability	None	None	N/A	No
Religion and beliefs	None	None	N/A	No
Sex	None	None	N/A	No

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Gender reassignment	None	None	N/A	No
Sexual Orientation	None	None	N/A	No
Age	None	None	N/A	No
Marriage & Civil Partnership	None	None	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?		N/A		
<ul style="list-style-type: none">• A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty• Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service• The policy or function/service is assessed to be of high significance				
IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED				
The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.				