University Hospitals Sussex
NHS Foundation Trust

Fetal Anomaly Screening Programme

Maternity Protocol: MP002

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Contents

Key Principles

A protocol is a set of measurable, objective standards to determine a course of action. Professional judgment may be used in the application of a protocol.

Scope

This protocol applies to:

- All pregnant women and people

Responsibilities

Midwives & Obstetricians

- To access, read, understand and follow this guidance
- To use their professional judgment in application of this protocol

Management Team

- To ensure the protocol is reviewed as required in line with Trust and National recommendations
- To ensure the protocol is accessible to all relevant staff
- To ensure the protocol is available to service users on request

1 Introduction

The NHS National Screening Committee (NSC) published recommendations for Fetal Anomaly Screening Programme (FASP) May 2009. Further guidance can be found in Service Specification No.16: NHS Fetal Anomaly Screening Programme – Screening for Down's, Edwards' and Patau's Syndromes [Trisomy 21,18 and 13] [Public Health England [PHE] 2018a], Service Specification No.17: Fetal Anomaly Screening Programme – 18+0 – 20+6 week fetal anomaly scan [PHE 2018b] and national programme standards [PHE 2019a].

Screening for triplet and higher order multiple pregnancies does not come under the remit of the NSC, therefore refer to NICE guidance on AN care for Multiple pregnancy - The management of twin and triplet pregnancies in the antenatal period [NICE 2011]

The leads for the Antenatal Screening programme can be found in Appendix A

2 Section A: Screening for Down's, Edwards' and Patau's syndrome

2.1 Screening for Down's, Edwards' and Patau's syndrome

The UK NSC recommends that all pregnant women and people are offered screening to assess the chance of the baby being born with Down's [T21], Edwards' [T18] and Patau's [T13] syndromes [PHE 2018a].

2.2 Aims and Objectives

2.2.1 The aims and objectives of the screening programme are:

2.2.2 To offer all eligible women and people a screening test to assess the chance of the baby being born with Down's, Edwards' or Patau's syndromes

2.2.3 To provide appropriate accessible information for women and people so that they are able to exercise informed choice about their screening options and pregnancy management

2.2.4 To facilitate choice in appropriate diagnostic testing and pregnancy management

2.3 Screening tests offered at UHSussex East

Table 2.2 [PHE 2018a]

Screening Test	Time at which test can be undertaken
Combined screening test [nuchal translucency scan and maternal or parental blood test for two biochemical markers] T21 & T18/13	Only to be performed where CRL [crown rump length] is between 45mm and 84 mm inclusive. This correlates to a gestational age of 11+2 to 14+ 1 weeks.
Quadruple screening test [maternal or parental blood test of 4 biochemical markers]T21 only	Where CRL is greater than 84mm the pregnancy is dated by HC. Screening can be performed between 14+2 weeks and up to a maximum gestation of 20+0 weeks inclusive]

2.4 The eligible population and offer of screening

2.4.1 Women and people should be booked for antenatal care as early as possible, and preferably before 10 weeks; this means that all screening options are available to them allows time for further diagnostic testing if required and ensures they have time to consider decisions about continuing their pregnancy.

2.4.2 All women and people in the eligible population should be offered the appropriate screening test by the midwife at booking according to the criteria below.

2.4.3 The midwife must emphasise that all screening tests are optional.

2.4.4 Women and people have choice over which conditions they are screened for. These options are explained further in section 2.6

2.4.5 For Down's syndrome the eligible population for screening is all pregnant women and people under 20+0 weeks gestation as confirmed by ultrasound scan. See table 2.2

2.4.6 For Edwards' and Patau's syndrome screening, the eligible population are pregnant women and people less than or equal to 14+1 weeks gestation by ultrasound scan. See table 2.2.

2.4 Eligible populations and offer of screening [National Institute for Health and Care Excellence [NICE] 2011, PHE 2018b, PHE 2018c]

Screening for Down's syndrome	**Singleton pregnancy**	**Twin pregnancy**	**Triplet or higher order multiple**

CRL: 45-84mm inclusive [correlates to GA of 11+2 – 14+1 Weeks]	Offer combined screening. Options: • T21 and combined chance for T18/13 • T21 alone • T18/13 alone	Offer combined screening. Options: • T21 and combined chance for T18/13 • T21 alone • T18/13 alone	Offer screening by NT and maternal or parental agealone Options: • T21 and combined chancefor T18/13 • T21 alone • T18/13 alone
14+2 – 20+0 Weeks Were CRL greater that 84mm or more with an HC between 101-172mm	Offer quadruple test. Screens for T21 and/or T18 only.	Offer quadruple test Screens for T21 and/or T18 only.	No screening available although mid-trimester anomaly scan screens for T18/13
20+1 – 22+6 Weeks [where CRL is over 84mm and pregnancy dated on HC]	No screening available although mid-trimester anomaly scan screens for T18/13	No screening available although mid-trimester anomaly scan screens for T18/13	No screening available although mid-trimester anomaly scan screens for T18/13

2.5 Pre-Test information and the offer of screening

2.5.1 All women and people should be given verbal and written information about screening for T21, T18 and T13 at the first contact or booking visit by the midwife. The trust uses the Public Health England [PHE 2019b] national patient information leaflet 'Screening tests for you and your baby'. This includes the section 'Screening tests during your pregnancy: Down's syndrome, Edwards' syndrome and Patau's syndrome'. The leaflet may be posted to the woman or person prior to the first appointment. The midwife must document in the digital notes that the leaflet hasbeen given/directed to the leaflet online.

2.5.2 Copies of 'Screening tests for you and your baby' are available in some other languages, easy-read versions for people with learning difficulties, and mp3 audio files for those with sight loss and can be downloaded via the PHE website: Screening tests for you and your baby (STFYAYB) - GOV.UK (www.gov.uk). If the leaflet is not available in the language required from the national website, it is possible to ask for the leaflet to be translated via the trusts Equality, Diversity and Inclusion Team.

2.5.3 Interpreting services [including sign language] should be used for communicating with parents who are not fluent in English at all stages of the screening pathway.

2.5.4 Women and people booking before 14 completed weeks of pregnancy should also be given the UHSussex East information leaflet 'Information about Combined Screening in pregnancy' by the midwife at booking. This is also available on the intranet and at the Trust's website for pregnant women and people : https://www.bsuh.nhs.uk/maternity/

2.5.5 Women and people booking after 14 weeks of pregnancy or found tobe more than 14 weeks and 1 day at the time of dating scan are too late for the combined screening test [see **section 2.4**]. These women and people [singleton and twin pregnancy only] should be offered the quadruple test and directed to the information in the leaflet 'Screening tests for you and your baby' [PHE 2019b]

2.5.6 Any woman or person can be referred direct to the Antenatal Screening Co-ordinator or Screening Support Midwives [referred to as screening midwives throughout remainder of document] for further information and discussion about screening and diagnostic tests [contacts *Appendix A*].

2.5.7 The midwife at booking should clearly document any discussions that have taken place in the digital notes and the woman or person's decision to accept [consent to screen] or decline screening.

2.5.8 A woman or person should only have one screening test. A woman or person cannot have both the combined and quadruple tests

2.5.9 It is the responsibility of the midwife who discusses antenatal screening at pre- booking or booking to ensure that the estimated date of delivery is correctly calculated and screening tests arranged at the appropriate gestation where requested. If there are any doubts about gestation a dating scan should be performed as soon as possible to accurately date the pregnancy before arranging the screening tests.

2.5.10 Some women and people will opt to have non-invasive pre-natal testing [NIPT] which is currently only available in the private sector. NIPT is a screening test and so will not detect all babies with Down's, Edwards' or Patau's syndromes. Therefore, where women and people have had NIPT, they MUST still be offered either the combined or quadruple screening test [according to gestation] as part of their NHS care. This applies even when the NIPT result was low chance. The rationale for this is thatcombined and quadruple screening tests may detect some babies with these conditions that NIPT may miss and vice versa.

2.6 Offering women and people choice over which conditions they are screenedfor [PHE 2018c, PHE 2018d]

2.6.1 With first trimester combined screening women and people can choose to have screening for:

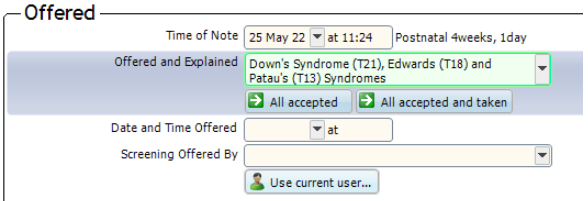
- All three conditions [T21 and T18/T13]
- T21 alone
- T18/T13

- None of the conditions

2.6.2 Where screening for trisomy 18 and trisomy 13 is accepted, the chance is givenas a single combined chance for the two conditions

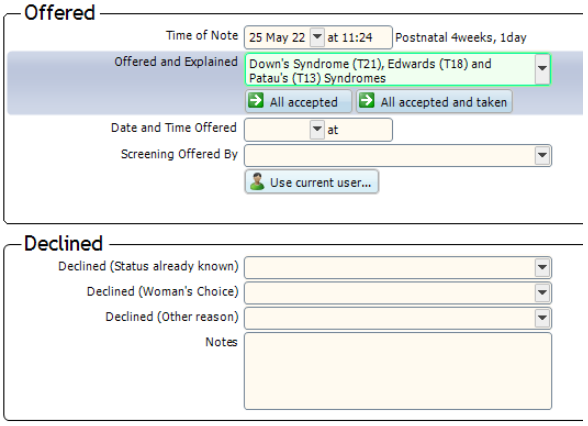
Screening consent	Accept	Decline
Combined screening		
Quadruple test		

2.6.3 The community midwife should document that combined screening for all three trisomies have been offered in the digital notes under 'Blood Tests, Results and Actions'(see form below)



2.6.4

2.6.5 Where a woman or person declines combined screening following the offer this should be documented by the community midwife (see form below)



2.6.6

2.6.7

2.6.8 The choice of screening options should also be recorded on the combined screening form. This may be recorded by the midwife at booking, the sonographer at scan or by the Antenatal Screening Support Worker [ASSW] who takes the blood. The ASSW must only document the woman or person's choice on the combined screening request form if it has already been documented in the digital notes by a midwife previously [as per 2.6.3].

2.6.9 With the second trimester quadruple test, women and people canchoose to have screening for:

- T21 alone
- No conditions

2.6.10 The woman or person's choice is documented at the time the blood test is taken on the quadruple test form as well as in the digital notes.

2.6.11 Women and people should be made aware that regardless of which conditions they accept or decline screening for [on either the combined or quadruple test], if they later opt for invasive testing the result will always test for T13, T18 AND T21.

3 Combined Screening

3.1 Arranging a combined screening test

3.1.1 If English is not the woman or person's first language, it is the midwives responsibility at booking to inform the ultrasound appointments team at the time of arranging the scan of the need for an interpreter and the language required. The ultrasound appointments team will arrange for an interpreter to be present for the scan.

3.2 NT Scan: Role of sonographer in the combined screening process

3.2.1 The scan is performed according to trust ultrasound policy [for further information please refer to US005 Ultrasound 1st Trimester Scan.

3.2.2 The sonographer will confirm with the woman or person prior to undertaking the NT scan, that they have consented to combine screening.

3.2.3 The sonographer allocates a unique barcoded number at the time of NT scan and scans this barcode into Viewpoint [software programme]. This number, known as the 'RXH number', is unique to the pregnant woman or person and the clinical episode. The sonographer then produces two sticky labels containing this barcoded number: one of which is affixed to the combined screening request form, the second is inserted into the specimen bag so that it may be affixed to the sample bottle at time of blood test. This system alerts the laboratory to expect a sample for this woman or person for this clinical episode. When the laboratory does not receive a sample within 3 working days of date of scan, the laboratory will contact the screening midwife to action follow up. This acts as a failsafe to ensure that the lab receives a blood sample for all women and people who have entered the screening programme having had a NT scan.

3.2.4 The sonographer imports a copy of the scan report from Viewpoint to the digital notes and gives a copy to the woman or person.

3.2.5 Following the NT scan, the sonographer completes the combined screening request form by ensuring there are three correct patient identifiers on the form and entering details relating to the ultrasound scan.

3.2.6 The sonographer gives the woman or person their combined screening request form and advises them to attend for the bloodtest and weight in the antenatal clinic immediately after.

3.3 Blood Test and Weight: The role of the Antenatal Screening Support Worker [ASSW]

3.3.1 The] **Antenatal Screening Support Worker [ASSW]** will normally see the woman or person in ANC immediately after the scan to complete the screening test. This role may also be undertaken by a midwife. At this appointment they will:

3.3.2 Check all the details on the combined screening request form with the woman or person to ensure it is correct and complete any missing information.

3.3.3 Weigh the woman or person, recording the weight on the combined screening request form in kilograms. Heavy clothing/footwear should be removed prior to weighing.

3.3.4 Take a blood sample in a gold topped [clotted] bottle [according to trust venepuncture policy] completing all patient identifiers on the sample bottle. Sticky bloodhound patient labels may be used but details must be checked with the woman or person first.

3.3.5 Where women and people require other bloods taking at the same time as the combined screening, then the combined screening sample must be takenfirst. This is because EDTA additives from pink and purple bottles can affect the markers in the blood if there is contamination of the combined sample bottle.

3.3.6 Affix the label containing the unique barcode of the 'RXH number' to the sample bottle as provided by the ultrasound department [see section 3.4.1].

3.3.7 Send the sample with request form direct to the laboratory at whichever site the woman or person was screened at, noting that samples should be processed by lab staff within 6 hours of the sample being taken.

3.3.8 Document in the digital notes that combined screening has been accepted and blood has been taken with informed consent using the 'Blood Tests, Results and Actions' form opened by the community midwife.

3.3.9 Ensure the woman or person is aware of the results process and knows how to contact the screening midwives if they wish to discuss the test or results in more detail [see contacts in Appendix A].

3.3.10 If the woman or person has any questions at this appointment that the ASSW cannot answer, then they should be referred direct to the screening midwives.

3.3.11 The ASSW will keep a daily record of all blood samples taken for combined screening and cross check this with the list of women and people expectedfor scan. If any women and people attended for scan but failed to attend for blood

test then the ASSW will alert both the lab and the screening midwives to action follow up.

4 Combined Screening: Results process

4.1 Blood samples are processed in UHSussex East pathology laboratory at the RSCH site. Samples taken at PRH are sent to the PRH laboratory where they are forwarded to the RSCH lab. The samples are processed and results generated Monday through toFriday.

4.2 The biochemists are responsible for calculating the chance.

4.3 Results should usually be available within 3 working days of the blood sample being received by the laboratory.

4.4 Results are categorised as being high chance or low chance using the cut-off of 1 in 150which is defined according to PHE guidance [2018a]

High chance = 1 in 2 to 1 in 150 [inclusive]
Low chance = greater than 1 in 150

4.5 The Laboratory Screening Co-ordinator [LSC] will process the results according to whether they are high or low chance.

4.6 It is the community midwife's responsibility to confirm that the woman or person has received their result [either high or low chance] and ensure it has been documentedin the digital notes at the next antenatal check [usually 16 weeks] [BSUH NHS Trust 2018].

5 Low chance results

5.1 The Laboratory Screening Co-ordinator sends a copy of the low chance result to the woman or person with a covering letter within 2 weeks [10 working days] of the test [PHE 2018a].

6 High chance results

6.1 The Laboratory Screening Co-ordinator contacts the screening midwives by email to inform them of a high chance result. In all cases the screening midwife confirms with theLaboratory Screening Co-ordinators by email that the result has been received and isbeing actioned [PHE 2018a].

6.2 The screening midwife contacts the woman or person by phone to inform them of the result, discuss options and arrange follow up care. The first attempt to contact the woman orperson will usually be within 1 working day of receiving the result.

6.3 Discussions with the woman or person can take place over the phone or in person according to their preferences. All women and people with a high chance result are offered a hospital appointment with a screening midwife or consultant to discuss the test result in more detail, within 3 working days of the result being issued [PHE 2018a, PHE 2019a].

6.4 Documentation of all discussions should be made by the screening midwife or doctor in the digital notes.

6.5 All women and people with a high chance result should be offered information about the support group ARC [Antenatal Results and Choices] [see contacts in Appendix B]

6.5.1 All women and people with a high chance result should be offered invasive [diagnostic] testing. The woman must be informed that these testscarry a chance of miscarriage [PHE 2018a].

6.5.2 All women and people with a high chance result should also be offeredthe Non Invasive Prenatal Test (NIPT) in line with PHE 3 year pilot commencing 1/6/21. This is not available on the NHS for low chance combined Screening and Quadruple test results. See Algorithm 7.0

6.6 All women and people with a high chance result should be informed that further testing is optional – they do not have to have any further testing and if they decline diagnostic testing then we will not be able to diagnose Down's syndrome until after birth. However, while the 20 week mid-trimester anomaly scan is not a screening testfor Down's syndrome, it is a screening test for Edwards' and Patau's syndrome and may detect features of either condition [PHE 2018b].

6.7 If a woman or person requests NIPT screening, then the Antenatal Screening Midwives must discuss the test with them and explain that it is not diagnostic. The blood test can be taken at both hospital sites by the screening Team and logged onto the NIPT screening IT portal linked to St Georges, where the samplewill be processed and the result reported. The woman or person must be advised that if a low chance NIPT is reported they are not able to have diagnostic testing on the NHS. If a high chance NIPT is reported the woman or person will be advised they can have a diagnostic test to confirm the result either locally or tertiary depending on test requested and availability. See Algorithm 6.9

6.8 If a woman or person requests invasive testing, then this should be arranged by the screening midwife or doctor for the next available appointment [with regard to the gestationallimits of the chosen test i.e. CVS or amniocentesis: see Algorithm 10.1]. Where there is no availability locally, then women and people may be referred to the tertiary centre in London. [Note multiple pregnancies will always be referred to Kings College Hospital, London

6.9 When the increased risk is for Trisomy 13 (Patau's syndrome) or Trisomy 18 (Edwards' syndrome) the option of detailed fetal anomaly scans as an alternative to CVS or amniocentesis should be discussed with the woman or person.

6.10 When a woman or person declines invasive testing after a high risk result, the

midwife or doctor should document details of the discussions that have taken place as follows:

6.10.1 Where women and people are seen for a face-to-face discussion, details of that discussion will be documented in the digital notes [clearly stating the woman or person's decision to decline a diagnostic test].

6.10.2 Where women and people opt for telephone discussions, a copy of the result with a covering letter should be sent to them by the screening midwife. The covering letter should summarise the discussions that have taken place and the woman or person's decision to decline a diagnostic test. Copies of this letter should be sent to their GP and scanned and uploaded to the digital notes.

6.10.3 Women and people who decline further testing should be made aware that they can change their mind in the future and should be given the screening midwives' phone number in case they wish to discuss and/or arrange testing later.

6.10.4 The antenatal screening midwives will cross check all high chance results with the laboratory screening co-ordinator on a weekly basis to ensure all high chance results have been received and actioned. A record of this cross check is recorded on the database maintained by the screening midwives as a recordof all high chance results and outcomes.

7 Quadruple Test

Eligibility [PHE 2018a, PHE 2018c]

7.1 The quadruple test can be performed between 14+2 and 20+0 weeks inclusive. When gestational age is 14+ CRL greater than 84mm (with an HC between 101-172mm

7.2 The quadruple test is only available to women and people with singleton and twin pregnancies who request screening for Down's syndrome but are over 14+1 weeks [by HC] and so too late for the combined test. This might be because of late booking, late diagnosis of pregnancy or the pregnancy being more advanced than anticipated.

7.2.1 Women and people requesting screening who are too late for combined screening at the time of the dating scan should be referred to the screening team immediately to be counselled about the quadruple test, and to complete the process. Where women and people choose to take time to consider their options or if there is no one to take the blood, then the woman or person must be given an appointment to return to the ANC at a later date.

7.3 The quadruple test is not available to women and people with triplets or more[NICE 2011].

7.4 The quadruple test is a screening test for Down's syndrome. It is not a screening test for Patau's or Edwards' syndrome.

7.5 Whilst the quadruple test may detect women and people at increased chance of having a baby with neural tube defect [NTD], it should not be recommended specifically for this purpose. The recommended screening test for NTD is the mid-trimester anomalyscan [PHE 2018b].

7.6 Pre-test information [see also section 2.5]

7.6.1 Women and people considering the quadruple test should be referred to the PHE [2019b] leaflet: 'Screening tests for you and your baby' as well as the information on the trust website [BSUH NHS Trust No date], available at: https://www.bsuh.nhs.uk/maternity/your-pregnancy/screening-tests-pregnancy/.

7.6.2 Women and people with twin pregnancies must be referred for further discussion with the screening midwife team prior to screening in order to explain the discrepancy in detection rates between monchorionicand dichorionic twins [PHE 2018c].

7.7 Taking the quadruple test

7.7.1 Where women and people have accepted the offer of a quadruple test, the midwife should complete all sections of the quadruple test requestform. The form may also be completed by an ASSW where the woman or person has already consented to screening after counselling by a midwife.

7.7.2 The woman or person must have a dating scan to confirm the exact gestation prior to the blood test and details of the scan must be recorded on the request form.

7.7.3 All quadruple tests are to be taken within the hospital antenatal clinic or Maternity Assessment Unit [MAU] at either PRH or RSCH. The test may betaken by a member of the screening team, ANC or MAU staff.

7.7.4 A gold topped [clotted] blood sample is taken by the midwife or ASSW, according to UHSussex East venepuncture policy. They should document that bloodhas been taken with consent in the digital notes using the 'Blood Tests, Results and Actions' form opened by the community midwife.

7.7.5 At the time the sample is taken, the woman or person should be weighed and the weight recorded on the form in kilograms. Heavy clothes/foot wear should be removed prior to the weight.

7.7.6 Samples are sent with the completed request form to UHSussex East pathology where they are then forwarded to the Clinical Biochemistry

Department at Oxford University Hospital NHS Foundation Trust (Oxford Labs) for processing.

7.7.7 A record of all women and people having the quad test is maintainedby the screening team on a shared database. The results are later entered onto this database to ensure all women and people having a quadruple test receive a result.

7.7.8 ASSWs will email the lead at UHSussex East laboratory to inform them that a quadruple test has been taken. They thenknow a sample is being sent.

7.8 Quadruple test results process

A record of all women and people having the quad test is maintained by the screening team on a shared database. The results are later entered onto this database to ensure all women and people having a quadruple test receive a result. The database is checked every week during the Wednesday failsafe check andany missing results are then discussed with the laboratory.

7.8.1 Results are categorised as being high chance or low chance for Down's syndromeusing a cut-off of 1 in 150 which is defined according to PHE guidance [2018c].

7.8.2 Staff at Oxford Labs process the results according to whetherresults are low or high chance.

7.8.3 It is the community midwife's responsibility to confirm that the woman or person has received the result at the next visit following sample taking and that the result along with any follow up care is documented in the digital notes.

7.8.4 Women and people should be informed to expect a result within 2 weeks of having the test taken. If they have not received a result by 2 weeks, they should be advised to call the screening midwives to follow up the results.

7.9 Low chance results

7.9.1 Low chance results are uploaded to the LifeCycle portal by the Oxford Labs. This can then be accessed by the UHSussex East screening midwives and laboratory screening co-ordinator.

7.9.2 The UHSussex East laboratory screening co-ordinator sends a copy of the result with a covering letter to the woman or person within 2 weeks of the test.

7.10 High chance result [for Down's syndrome]

7.10.1 High chance results are also uploaded to the LifeCycle portal by the Oxford Labs. This can then be accessed by the UHSussex East screening midwives and laboratory screening co-ordinator.

7.10.1 7.10.2 The antenatal screening midwives are responsible for checking the LifeCycle portal daily and acknowledging the receipt of a high chance result within the portal. If the high chance result is not acknowledged within 2 working days then the Oxford Labs will email the generic antenatal screening email address to alert the screening midwives that a high chance result is awaiting acknowledgement and actioning.

7.10.2 The screening midwife contacts the woman or person by phone to inform them of the result, discuss options and arrange follow up care. The first attempt to contact the woman or person will usually be within 1 working day of receiving the result.

7.10.3 Discussions with the woman or person can take place over the phone or in person according to the woman or person's preferences. All women and people with a high chance result are offered a hospital appointmentwith a screening midwife or consultant to discuss the test result in more detail, within 3 working days of the result being issued.

7.10.4 Documentation of all discussions and women and people's choices regarding further testing should be made by the screening midwife or doctor in the digital notes.

7.10.5 All women and people with a high chance result should be offered invasive [diagnostic] testing by amniocentesis. The woman or person must be informed that these tests carry a risk of miscarriage. All women and people with a high chance on the Quadruple test should also be offered theNon Invasive Prenatal Test (NIPT) in line with PHE 3 year pilot commencing 1/6/21. This can be taken up to 21+6 weeks gestation. See Algorithm 6.9 for pathway.

7.10.6 All women and people with a high chance result should be informed that further testing is optional – they do not have to have any further testing and fthey decline diagnostic testing then we will not be able to diagnose Down's syndrome until after birth.

7.10.7 If a woman or person requests invasive testing, then this should be arranged by the screening midwife or doctor for the next available appointment as per section 7.

7.10.8 All women and people with a high chance result should be informed ofthe support group ARC [Antenatal Results and Choices] see in Appendix B.

7.10.9 Where women and people decline invasive testing after a high chance result, the midwife or doctor should document details of the discussions that have taken place as follows:

- Where women and people are seen for a face-to-face discussion, details of that discussion will be documented in the digital notes [clearly stating the woman or person's decision to declinea diagnostic test] and a copy of the result scanned and uploaded to the digital notes.
- Where women and people opt for telephone discussions, a copy of the result with a covering letter should be sent to the woman or person by the screening midwife. The covering letter should summarise the discussions that have taken place and the woman or person's decision to decline a diagnostic test. Copies of these documents should be scanned and uploaded to the digital notes.

7.10.10 Women and people who decline further testing should be made aware that they can change their mind in the future and should begiven contact numbers for the screening midwives in case they do so.

8 Screening: Special Cases

8.1 Multiple pregnancies [NICE 2011, PHE 2018c]

8.1.1 All women and people with multiple pregnancies should be offered screening according to the number of fetuses and chorionicity as detailed in this section

8.1.2 Pre-test counselling in a twin or triplet pregnancy should include the following additional information [NICE 2011]:

- The greater likelihood of Down's syndrome in a twin and triplet pregnancy
- The different options for screening

- The false positive rate is higher than for a singleton
- The likelihood of being offered invasive testing is higher than for a singleton
- The greater likelihood of complications for invasive testing
- The physical risks and psychological implications in the short and long term relating to selective fetal reduction

8.1.3 At the initial scan where multiple pregnancy is diagnosed the ultra-sonographer should assess viability, gestational age and chorionicity.This should be documented on the USS report and imported from Viewpoint to the digital notes.

8.1.4 All triplets and higher order multiples should be referred to a consultant obstetrician at the next available appointment for early discussion about the plan of care and options available.

8.1.5 Major congenital malformations will be assessed at the fetal anomaly scan undertaken as per section 8 below.

8.1.6 The woman or person should be referred, by the sonographer, midwife or GP to the screening midwives or senior grade obstetrician if they wish to discuss any aspect of screening further.

8.2 Twin pregnancies [NICE 2011, PHE 2018c]

8.2.1 Women and people booking prior to 14+1 weeks, with a viable twin pregnancy, should be offered combined screening by the midwife at booking.

8.2.2 In monochorionic twin pregnancies, the chance of Down's syndrome, Edwards'and Patau's syndromes at combined screening will be calculated per pregnancy.

8.2.3 In dichorionic twin pregnancies, the chance of Down's syndrome, Edward's andPatau's syndromes at combined screening will be calculated for each fetus.

8.2.4 After 14+1 weeks and up to and including 20+0 weeks, women and people with twin pregnancies should be referred to the screening midwifeteam to discuss the quadruple test as per section 5.

8.3 Triplets and higher order multiples [NICE 2011, PHE 2018c]

8.3.1 Women and people booking prior to 14+1 week with a triplet or higher order multiple pregnancy should be offered screening for Down's syndrome

by the health professional at booking. Screening for Edwards' andPatau's syndromes is not possible in a triplet or higher order multiple pregnancy.

8.3.2 Neither the combined screening test nor quadruple test can be used to assessthe chance of Down's syndrome in a triplet or higher order multiple pregnancy. Therefore chance is assessed using maternal or parental age and NT alone where CRLs in all fetuses fall between 45 and 84mm [see Algorithm 10.4: Calculating chance assessment by NT alone]. The sonographer should measure the NT on all fetuses according to local ultrasound policy [BSUH 2017].

8.3.3 In monochorionic triplet pregnancies the chance of Down's syndrome will becalculated per pregnancy.

8.3.4 In dichorionic and trichorionic triplet pregnancies, the chance of Down'ssyndrome will be calculated for each fetus.

8.4 Referral to Kings College Hospital, Fetal Medicine Unit should be offered if:

- chance assessment for Down's syndrome is high in one or more of thefoetuses
- the NT measurement is 3.5mm in one or more of the foetuses
- the sonographer is unable to record a NT for one or more of the foetuses

8.5 Vanishing twin pregnancies [PHE 2018c]

8.5.1 Combined screening

8.5.1.1 When ultrasound shows that there is an empty second pregnancy sac, the biochemical markers appear no different to those in a singleton pregnancy and the combined screening test can be used to calculate the chance.

8.5.1.2 When the ultrasound shows that there is a second sac containing a non-viable fetus [sometimes called a 'vanished' twin], it is possible that this could contribute to the maternal or parental biochemical markers for many weeks. In such cases the chance calculation should be based on maternal or parental age and NT alone [see Algorithm 10.4: Calculating chance assessment by NT alone].

8.6 Quadruple screening

8.6.1 When ultrasound shows there is an empty second pregnancy sac or there is a second sac containing a non-viable fetus (sometimes called a 'vanished' twin), the biochemical markers appear no different to those in a singleton pregnancy and the Quadruple test can be used.

8.7 Calculating chance assessment by NT alone

8.7.1 Chance is calculated by NT alone in the following circumstances only: triplet orhigher order multiple pregnancy OR vanishing twin pregnancy. It is the sonographer's responsibility to inform the woman or person that chance assessment can only be made by NT alone and give the reason why. If the woman or person has further questions they can be referred to the screening midwives.

8.7.2 The sonographer should document why the chance is to be calculated by NTalone on the scan report and import the scan report from Viewpoint to the digital notes.

8.7.3 The chance assessment for Down's syndrome screening must be undertaken bythe laboratory, even if based on ultrasound findings alone [PHE 2018c]. In such cases the sonographer informs the woman or person that combined screening is not possible and that the chance will be calculated on NT alone.

8.7.4 Immediately after the scan, the sonographer must refer the woman or person to a member of the screening team [either midwife or ASSW] as the request form must still be completed in full.

8.7.5 The midwife or ASSW sends the completed combined screening request form to the laboratory screening co-ordinators by internal post [or hand delivers] and informs the laboratory screening co-ordinators, screening midwives and biochemists by email that a calculation is required on NT alone and that the request form has been sent to them.

8.7.6 The laboratory staff – either lab screening co-ordinator or biochemist, informs the screening midwives by email when the results are ready for reporting.

8.7.7 **Low chance results:** The screening midwife sends a copy of the result with acovering letter to the woman or person.

8.7.8 **High chance results:** The screening midwives inform the woman or person asfor combined screening [section 4.3].

8.8 Increased nuchal translucency [NT]: Greater than or equal to 3.5mm

8.8.1 A NT measurement of 3.5mm or above is a significant pregnancy scan finding [where CRL is between 45 -84mm inclusive]. It is associated with an increased chance of fetal cardiac and syndromic problems as well as chromosomal aberrations [PHE 2018c].

8.8.2 Women and people found to have an NT measurement of 3.5mm ormore should be referred by the sonographer to the screening midwives or fetal medicine consultant [as per Algorithm 10.4] for further discussion and offered further tests [as detailed in section 6.6.3] even if screening for Down's, Edwards' and Patau's syndrome has been declined [PHE 2018c].

8.8.3 Discussion of scan findings may take place over the phone or face-to-face according to woman or person's preference. When discussion of findings do not take place immediately after scan then women and people should be offered an appointment for further discussion within 3 working days.

8.8.4 These women and people should be offered the following tests:

8.8.4.1 Combined screening
To complete the testing process. An increased NT measurement does not automatically mean that the chance assessment for Down'ssyndrome will be increased. The combined screening result can therefore help women and people decide both whether to haea diagnostic test and decide which diagnostic test is right for them.

8.8.4.2 Invasive [diagnostic testing] for chromosome anomaly regardless of the chance for Down's syndrome.
Women and people do not have to wait for the result of the combined screening test before having invasive testing although in most cases this should be available by the time of theinvasive test. In these cases the laboratory will perform both PCRfor common trisomies AND either a CGH array or full karyotype [the laboratory will decide which test to perform based on the results of the PCR]. Women and people should be advisedof the limitations of diagnostic tests and informed that such testsare designed to test for chromosome abnormalities and so will not detect genetic disorders [unless specifically requested in women and people who are known to be at chance of havinga baby with a specific genetic disorder].

8.9 Fetal cardiac scan.
Refer women and people to the Fetal Cardiac Unit, Evelina Children'sHospital, St Thomas Hospital, London [see contacts in appendix B]. The earliest gestation at which this can be performed is 14 weeks.

8.10 Fetal anomaly scan
As per routine policy at 20 - 20+6 weeks gestation

8.11 The chance of fetal cardiac defect in relation to the size of the NT may be discussed with the woman or person as given in table below Major cardiac defects in chromosomally normal fetuses [Souka et al 2004].

Major cardiac defects in chromosomally normal fetuses
Souka et al 2004

Nuchal translucency (mm)	Major cardiac defects
below 95th centile	0.16%
2.5 – 3.4	1%
3.5 – 4.4	3%
4.5 – 5.4	7%
5.5 – 6.4	20%
6.5 or more	30%

8.11.1 If an anomaly is detected at any stage, referral should be made according to the policy: Antenatal detection of fetal anomaly. See Algorithm 10.8.

8.11.2 If all the test results are normal, then the woman or person should be advised that the most likely outcome is a normal baby, however, no test can exclude all anomalies and the chance of there being a syndromic problem is slightly above the background chance.

8.11.3 All women and people with an increased NT measurement should be advised of the support group ARC [see contacts in appendix B] and be given the contact number for the antenatal screening midwives.

8.11.4 The midwife or doctor should document information given at every stage along with acceptance or decline of tests and subsequent results in the digital notes.

8.12 Nuchal measurement 3.0mm to 3.4 mm inclusive

8.12.1 Where the NT is between 3.0mm and 3.4mm inclusive, and the chance of T21,T18 and T13 is assessed as high, then women and people should be informed that if they opt for invasive testing the laboratory will conduct a full CGH array as well as rapid PCR test for common trisomies.

8.13 Pre-Natal Invasive Testing

8.13.1 An amniocentesis is available at UHSussex East at the RSCH site for singleton pregnancies. However women and people should be referred toLondon when there is no local availability.

8.13.2 All women and people with multiple pregnancies who request an invasive test should be referred by the screening midwife or consultant to the Harris Birth right Unit at Kings College Hospital as these cases require theexpertise of a tertiary level fetal medicine unit [PHE 2018a].

8.14 Pre-test information

8.14.1 All women and people considering invasive testing should be offereda copy of the UHSussex East leaflet ‘CVS and Amniocentesis’ prior to the test. This is available in hard copy or on the trust’s website https://www.bsuh.nhs.uk/maternity/leaflets/

8.14.2 All women and people considering invasive testing should have a discussion about the purpose, benefits, limitations and implications of invasive testing with a screening midwife or senior grade obstetrician beforethe appointment for the test is made. Pre-test discussion should include the following:

- Risk of miscarriage associated with both CVS and amniocentesis
- Gestation at which tests can be performed
- What exactly is being tested for and what information these results will provide about their unborn baby, emphasising that no test can rule out all chromosome and genetic disorders
- Pre and post-test care including results process, signs of miscarriage and who to contact if any concerns after the test
- Options if anomaly diagnosed which may include continuing the pregnancy, continuing and putting the baby up for adoption, and termination

8.14.3 Discussion may take place face-to-face or over the phone. The discussion and decision to accept or decline the test should be documented in the digital notes.

8.14.4 Where the blood group of the woman or person is not known, this should be taken prior to the appointment for invasive testing so that women and people who are rhesus negative can be offered anti-d post procedure.

8.15 HIV and hepatitis B testing pre procedure

8.15.1 HIV and hepatitis B testing should be arranged prior to the test and results should be available at the appointment.

8.15.2 Women and people who are HIV / Hep B positive should discuss therisk of vertical transmission with a fetal medicine consultant/GUM consultant prior to making a decision about proceeding with the test.

8.15.3 If women and people have declined screening for blood borne viruses, the doctor should discuss the potential risks of infection to the fetus if positive and that discussion documented in the digital notes (RCOG 2010].

8.16 Arranging an appointment

8.16.1 CVS and amniocentesis are available at RSCH and appointments are arrangedvia the screening midwives.

8.17 Gestation limits [RCOG 2010]

8.17.1 Amniocentesis should be performed after 15^{+6} weeks of gestation.

8.17.2 CVS should not be performed before 11^{+0} weeks of gestation.

8.18 At the CVS/amniocentesis procedure

8.18.1 It is the responsibility of the consultant performing the test to ensure the woman or person has given their informed consent and that this is documented in the digital notes.

8.18.2 The sample must be labelled with the women and people details andthese checked with the woman or person prior to sending the sample.

8.18.3 The consultant should ensure the sample request form is completed in full and is sent with the sample to the Genetics Laboratories at Guy's and St Thomas' NHS Foundation Trust via courier.

8.18.4 The consultant should document that the procedure has taken place in the digital notes to include indication, number of uterine insertions, bloody taps or any complications.

8.18.5 It is the consultant's responsibility to ensure rhesus negative women and people have been offered anti-d to prevent rhesus isoimmunisation, and where accepted, administered as per protocol [Crossreference with anti d policy] prior to leaving the unit.

8.18.6 Agreement should be reached between the consultant and the woman or person about how the test results will be given [see section 7.8].

8.18.7 The midwife or consultant seeing the woman or person post procedure should ensurethey have their correct telephone number for results documented in the digital notes.

8.18.8 The woman or person should be given the contact number for the screening midwivesin case of any concerns post procedure and to follow up results if necessary.

8.18.9 The woman or person should also be advised who to contact in case of any complications post procedure [normally Maternity Assessment Unit [MAU: RSCH] or Day Assessment Unit DAU: PRH].Symptoms to report include:

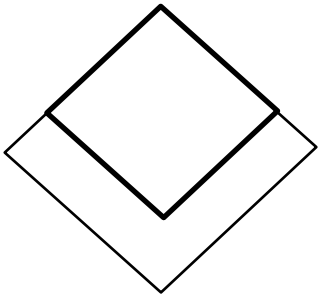
- Feeling generally unwell (shivery, nauseous, abdominal discomfort)
- Pyrexia
- Persistent bleeding from the vagina
- Persistent lower abdominal/back pain
- Clear watery type loss (not urine) from the vagina
- Offensive smelling discharge from the vagina.

8.19 Sample transport

8.19.1 All samples are sent by courier to Guys Hospital cytogenetic centre [contacts for both Courier Company and lab in contents].

8.19.2 The consultant taking the sample is responsible for informing administration staff that a sample has been taken and requires couriering.

8.19.3 Samples should be packaged according to UN P650 Packaging Instruction for Diagnostic Samples Sample bottles should be wrapped in absorbent material and inserted into a secondary watertight plastic container. Outer packaging must include the secondary packaging and request form and addressed correctly. The outer packaging should be clearly marked URGENT DIAGNOSTIC SPECIMEN FRAGILE HANDLE WITH CARE along with the following symbol:



UN 3373

8.19.4 Where samples are not sent immediately after the procedure, they should be stored in a refrigerator overnight and sent at the first opportunity the following day. Samples cannot be left in the refrigerator over the weekend as the sample will have deteriorated during this time and so unusable.

8.20 Results process

8.20.1 PCR results for trisomy 13, 18 and 21, and where indicated X and Y, will usually be available in 3 working days. Women and people should be informed that it is not always possible to obtain a rapid PCR result and in which case they will need to wait further testing.

8.20.2 The cytogenetic laboratory will decide whether further testing by CGH array or full karyotype is indicated, according to clinical history. Women and people should be advised that results for either test may take up to between 2 and 3 weeks.

8.20.3 Tests for specific gene disorders may take longer and requires liaison with staff at the cytogenetic laboratory so that the woman or person can be advised of thelikely timeframe for results.

8.20.4 Women and people have the option as to how they receive their results. They can opt for a phone call or can come into the hospital and receive the results in person. The woman or person's preferred option should be documented on the request form and in the digital notes. Guy's cytogenetic laboratory will email the results to the antenatal screening shared NHS net email account.These results are password protected.

8.20.5 Women and people are informed of their results by either a screening midwife or senior grade obstetrician. Results [whether normal or abnormal] should never be given out to women and people by non- registered professionals or anyone who does not fully understand the resultand its implications or the indication for invasive testing.

8.21 Normal results

8.21.1 Where results are given over the phone, the woman or person should be given the option of a follow up appointment to discuss the result in more detail with aspecialist screening midwife or senior grade obstetrician.

8.21.2 It is the responsibility of the professional who informed the woman or person of theresult to document that the result has been given in the digital notes.

8.21.3 In all cases a confirmatory letter is sent to the woman or person by the obstetrician who performed the test within 1 week of the result being received by the hospital.

8.22 Anomaly results

8.22.1 Discussions can take place over the phone or face-to-face at the hospital according to the woman or person's preference.

8.22.2 In all cases the woman or person is offered an appointment to come up to hospital to discuss the results in more detail and arrange appropriate follow-on care.

8.22.3 See section 10 for care to be offered after diagnosis of fetal anomaly

Section B

Fetal Anomaly Ultrasound Programme

1 Fetal Anomaly Ultrasound Programme

Aims and Objectives The main aim of the NHS screening programme for Fetal Anomaly Ultrasound is to offer all pregnant women and people in England a minimum of two ultrasound scans.

1.1 The first is an early ultrasound scan, undertaken after 8 weeks gestation and used mainly for confirming viability, dating the pregnancy and assessing early fetal development. In most cases, where women and people consent to screeningfor Down's, Edwards' and Patau's syndromes, this will be undertaken at around 12 weeks of pregnancy as part of the combined screening test. Refer to dating of pregnancy protocol for further clarification of dating pregnancy – for further information please see US005 1st Trimester ultrasound Scan

1.2 The second ultrasound scan is carried out during mid-pregnancy between 18^{+0} to 20^{+6} weeks of the pregnancy to screen for a range of structural anomalies. This scan is known as the anomaly scan which is the term used throughout this document. At UHSussex East women and people should be referred for the anomaly scanideally between 20^{+0} and 20^{+6} weeks. For further information please see US004 Ultrasound

Anomaly Scan

1.3 The objectives of the 18+0 to 20+6 weeks anomaly scan are to [PHE 2018b]:

1.3.1 Ensure access to a uniform screening programme which conforms to an agreed level of quality.

- Offer screening to eligible women and people in England to identify anomalies that are life limiting
- Identify anomalies which may benefit from antenatal treatment
- Identify anomalies which require early intervention following delivery
- To facilitate choice in appropriate diagnostic testing and pregnancy management, including continuation of the pregnancy or termination

1.4 Pre-test information [PHE 2018b]

1.4.1 The eligible population includes all women and people booking priorto 23+0. All women and people in the eligible population are offeredan anomaly scan. This is ideally performed between 20^{+0} and 20^{+6} weeks [see section further for late bookers].

1.4.2 It is the midwife's responsibility to discuss and offer the scan at the pre-booking or booking appointment, emphasising that this is a screening test and is optional. Algorithm 10.1 details the issues that should be considered during pre-test discussion.

1.4.3 All women and people should be given written information, ideally prior to being offered screening. The trust uses the PHE [2019b] national patient information leaflet 'Screening tests for you and your baby'. This includes the section'11 physical conditions (20-week scan). This leaflet is available via the digital notes patient portal. .

1.4.4 Copies of 'Screening tests for you and your baby' are available in some other languages, easy-read versions for people with learning difficulties, and mp3 audio files for those with sight loss and can be downloaded via the PHE website:Screening tests for you and your baby (STFYAYB) - GOV.UK (www.gov.uk) . If the leaflet is not available in the language required from the national website, it is possible to ask for the leaflet to be translated via the trusts Equality, Diversity and Inclusion Team.

1.4.5 Discussion should take place with a translator for those women and people not fluent in English.

1.5 Women and people booking after 20^{+6} weeks, who haven't had an anomaly scan elsewhere, should be referred for a scan by the midwife at booking at the next available appointment. Women and people booking late should be aware that depending on gestational age, not all fetal structures will be clearly seen and a full anomaly scan may not be possible. The sonographer will advise the woman or person at the time of scan

1.6 Any woman or person can be referred direct to the antenatal screening midwives for further information and discussion about screening and diagnostic tests.

1.7 The midwife at booking must document in the digital notes that screening has been offered and the acceptance of [consent to screen] or decline of the test.

2 Arranging the anomaly scan

2.1 In most cases the ultrasound department will give the appointment for the anomaly scan to the woman or person when they attend for their dating scan. Otherwise, the USS booking team will send a letter to the woman or person with the appointment details. Alternatively the midwife or doctor can call the ultrasound booking line direct to arrange the scan.

2.2 If English is not the woman or person's first language, it is the midwives responsibility at booking to inform the ultrasound appointments team at the time of arranging the scan, of the need for an interpreter and the language required. The ultrasound appointments team will arrange for an interpreter to be present for the scan.

2.3 Rescans

2.3.1 The woman or person should be offered a single further scan at 23 weeks of pregnancy to complete the screening examination if the image quality of the first examination is compromised. Common reasons for poor image quality include:

- Increased maternal or parental BMI
- Suboptimal fetal lie
- Uterine fibroids
- Abdominal scarring

2.3.2 If after the second scan the assessment of fetal anatomy remains incomplete, the woman or person is told by the sonographer that screening is incomplete and this should be recorded on the scan and the scan imported from Viewpoint to the digital notes by the sonographer [PHE 2018b]. No further scans for the purpose of routine assessment of fetal anomaly are indicated.

2.4 Results process

2.4.1 Where no anomaly is identified: it is the responsibility of the sonographer to inform the woman or person of the results after the scan and import the scan from Viewpoint to the digital notes [see ultrasound policy]. The sonographer should emphasise that ultrasound scan cannot exclude all anomalies.

2.4.2 Where anomaly is suspected or identified, the sonographer should inform

the woman or person of the scan findings and import the scan from Viewpoint to the digital notes. It is the responsibility of the sonographer to arrange referral for further opinion and care according to Algorithm 10.8 'Antenatal detection of fetal anomalies'.

3 Referral process following suspected fetal anomaly on ultrasound scan

3.1 Role of sonographer

3.1.1 Fetal anomaly may be suspected on scan at any gestation. The referral process is the same regardless of gestation.

3.1.2 If the sonographer suspects an anomaly on scan, a second opinion should be sought. This may be with another sonographer or fetal medicine consultant.

3.1.3 The sonographer will inform the woman or person of the scan findings before they leave the ultrasound department and advise the woman or person of the follow up that has been arranged.

3.1.4 All women and people with suspected fetal anomaly should be given the following contact numbers by the sonographer at the time the anomalyis diagnosed:

- The mobile number for the screening midwife team
- The helpline number for the support group Antenatal Results andChoices [ARC] [details in contacts list in Appendix B].

3.1.5 The sonographer who has performed the scan where fetal anomaly is suspected should refer direct to the screening midwives. Ideally the referral is made in person or by phone. Messages can be left on the screening mobile answerphone. In all cases the sonographer should also email details to the antenatal screening midwives and sonographer audit leads for audit purposes.

3.1.6 It is the responsibility of the referring sonographer to ensure that the referral has been received and actioned by the screening midwife / obstetrician.

3.1.7 If no screening midwife is available and the sonographer feels an immediate review is required, then the sonographer should refer to Maternity Assessment Unit [MAU] / DAU or labour ward. The midwives can then refer the case to the on-call obstetric team.

3.1.8 The type of follow-up offered will depend upon the type of anomaly suspected: see Algorithm 10.8

3.2 Follow-up of referral of suspected fetal anomaly

3.2.1 Once referral has been received, the screening midwife will liaise with the

fetal medicine team/ consultant obstetrician to arrange appropriate follow up. The screening midwife will inform the woman or person of options for follow up and arrange appointments according to the woman or person's choice. Options for follow up depend upon the type of anomaly suspected: see Algorithm 10.8

3.2.2 Where women and people decline further management, the decisionshould be recorded in the digital notes and continue with routine antenatal care. In such cases the woman or person should be given contact details in case they change their mind in the future and requests follow up at a later stage. Additionally the screening midwife will inform the GP, community midwife, obstetric consultant and neonatal team that an anomaly has been suspected on ultrasound scan but that the woman has declined follow-up. A copy of this letter will be scanned and uploaded to the digital notes to alert teams prior to birth that an anomaly was suspected but follow-up declined and hence has not been confirmed.

3.2.3 Where women and people accept further management but further screening does not identify an anomaly, then this is recorded in the woman or person's digital notes and they continue with routine antenatal care

3.2.4 Where women and people accept further management and an anomaly is confirmed then refer to section 10.

3.3 Referral to a tertiary centre

3.3.1 Referral to a tertiary centre may be recommended at any stage of pregnancy. The centre to which a woman or person is referred will vary according to the reason for referral and occasionally the woman or person's preference.

3.3.2 Regardless of which centre a woman or person is referred to, the referral process isthe same. The professional making the referral will:

- Call the tertiary centre to discuss the case, ensure referral is appropriate and make the appointment.
- Complete a referral form according to tertiary centre guidance. Copies of screening results, blood results and scan reports should be attached if relevant the referral and any additional documents should be emailed to the appropriate address. A copy of the referral should be scanned and uploaded to the digital notes.
- Discuss the reasons for referral with the woman or person along withinformation about what to expect including any additional procedures that may be offered.
- Give the appointment to the woman or person, or inform them if the tertiary centres are going to call them direct with an appointment.Directions to the centre should also be given.

- Ensure the woman or person knows who to contact at UHSussex East after they have been seen at the tertiary centre to arrange localfollow up. All women and people should be given the telephone number of the screening midwives for further adviceand information as necessary.
- Document the reason for referral, discussion with the woman or person, andfollow up arrangements in the digital notes.

3.4 Care following confirmation of anomaly by ultrasound scan or prenatal diagnosis

3.4.1 Anomaly may be confirmed by ultrasound alone, either in-house or at a tertiary referral centre. In some cases confirmation can only be made following additional tests such as amniocentesis or CVS.

3.4.2 The professional giving the diagnosis of anomaly, whether confirmed by scan or prenatal testing, should ensure the woman or person is aware of the exact diagnosis and its implications, recognising that in some instances referral tospecialists may be indicated for a fuller explanation [section 10.1.3].

3.4.3 Referral to specialist services should be offered according to the anomaly detected and the woman or person's preference. Such services may include genetic counselling, neonatal services, paediatric services, nurse specialists [e.g. cystic fibrosis or cleft - nurse specialists], physiotherapy and specialist health visitor for children with disability. The offer of, acceptance or decline of referrals should be clearly documented in the digital notes.

3.4.4 Discussion may include the following according to the anomaly diagnosed:

- Treatment or surgical options [where available]
- Likely prognosis
- Short and long term support for the child and family
- Effect on pregnancy or birth management
- Continuing the pregnancy, continuing and adoption or termination.

3.5 Women and people should be advised of appropriate support groups relevantto the condition diagnosed.

3.6 All women and people should be informed of the support group AntenatalResults and Choices [ARC]. They provide support when an anomaly is diagnosed prenatally, for parents with an on-going pregnancy or for those who choose termination, via helpline, website and written information leaflets.

3.7 Written information should be offered pertaining to the condition where available. Leaflets on a selected number of conditions are available from the FASP screening programme website.
The diagnosis, details of all discussions and outcomes of discussion must be documented in the digital notes.

4 Continuing a pregnancy after a diagnosis of anomaly

4.1 Where the woman or person opts to continue the pregnancy, on-going care is co-ordinated by the screening midwives and/or fetal medicine consultant. This will include verbal andwritten referral and plans of care with the neonatal and specialist teams as required.All communication and referrals should be clearly documented in the digital notes.

4.2 Where women and people continue their pregnancies and there is a possibility that neonatal treatment may be necessary, they should be either offered an appointment with a neonatologist and, if neonatal surgery may be required, a paediatric surgeon to discuss postnatal care. Such cases are ideally referred to the Joint Paediatric Antenatal Clinic [known as the Joint Clinic]. All cases must be discussed with either the fetal medicine consultant or the screening midwife prior to booking an appointment in the Joint Clinic.

4.3 The Joint Clinic is held once every month in the antenatal clinic in Sussex House. Copies of all correspondence should be filed in the hospital notes and sent to the GP, TMBU and Consultant Paediatrician at the Royal Alexandra Children's' Hospital.The screening midwives will liaise with the community midwife and health visitor where necessary.

4.4 Where women and people are unable to attend an appointment in the JointClinic or require urgent review with the neonatal or paediatric teams, then ad hoc appointments can be made with the consultants direct.

4.5 The Joint Clinic is for women and people who have decided to continue their pregnancy. It is not appropriate to refer women and people who remain undecided about continuing and are looking for further information about the anomaly in their baby prior to making a decision. These women and people often require more time than is available at Joint Clinic and so require ad hoc appointments arranged on an individual basis.

4.6 The antenatal and birth management plan should be discussed with the woman or person by the professional making the plan and clearly documented in the digital notes. In addition, a set of notes will be issued antenatally forthe baby by the neonatal team and will include a neonatal management plan

4.7 When the woman or person is admitted to delivery suite the midwife in charge of the woman or person's care should refer to the obstetric registrar who should familiarise themselves with the birth plan and inform the neonatal team and obstetric consultant. If appropriate,the neonatal staff should inform the on-call neonatal surgeon and should ensure thatthe appropriate staff and equipment are present at the birth.

4.8 Postnatally it is important that any problems with the baby are communicated from the neonatal unit to the staff working on the post natal ward caring for the mother or birthing parent and baby.

4.9 The neonatal/ paediatric teams are responsible for ensuring that postnatal follow up is arranged for the baby and communicated to the parents.

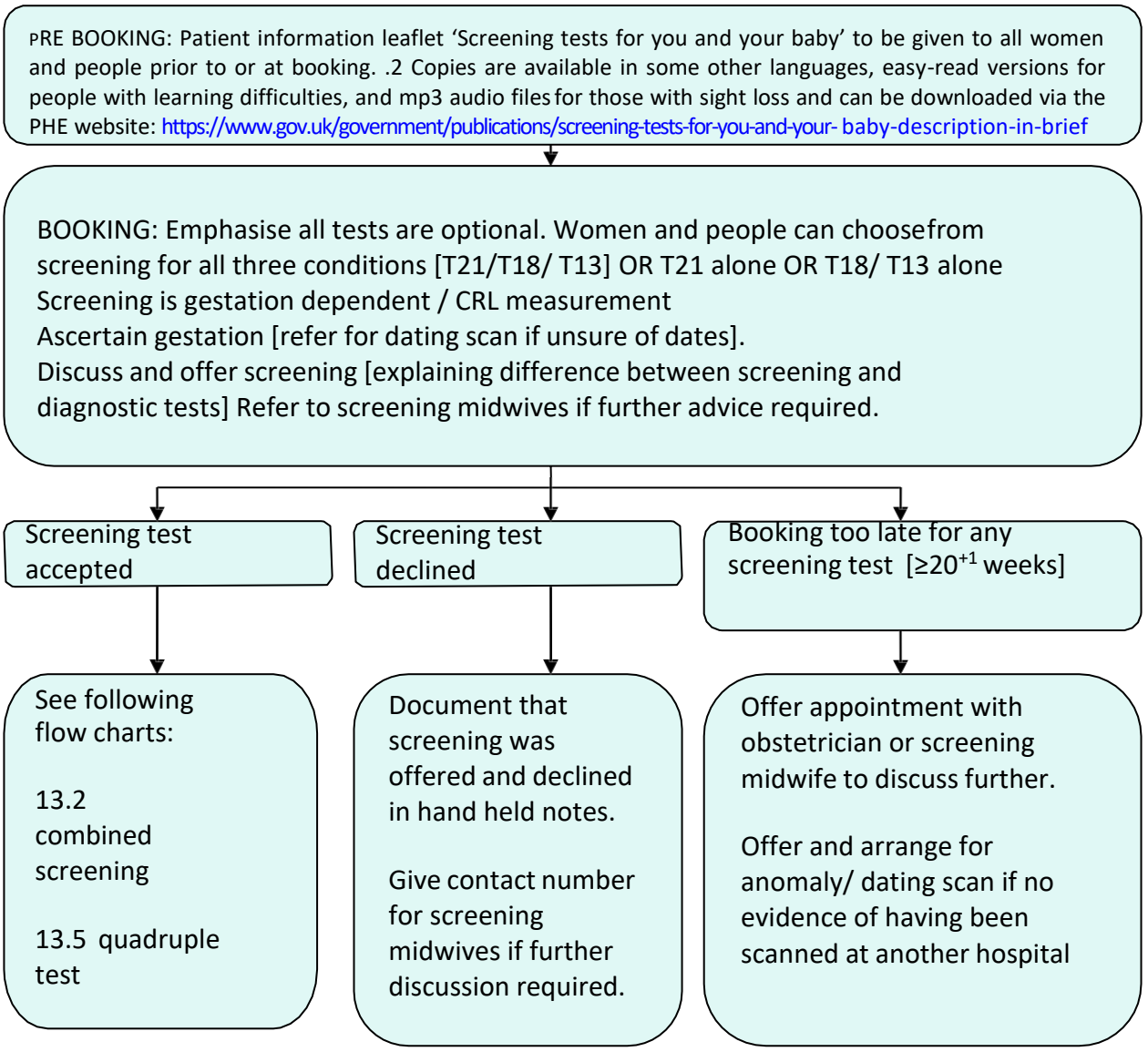
5 Opting for termination following a diagnosis of an anomaly

5.1 Where the woman or person opts for termination, this may take place within UHSussex East or be referred to MSI Reproductive Choices according to gestation and method of termination chosen. For further information see protocol GP010 Termination of Pregnancy Under 14 Weeks and MP073 Pregnancy Loss >14 Weeks. See Algorith 6.8 Termination of Pregnancy for Fetal Anomaly and Life Limiting Conditions

6 Algorithms

The following algorithms deal with the different elements of the FASP in accordance with PHE guidance

6.1 First trimester screening for Down's syndrome: Information process



MP002

6.2 First trimester combined screening

- Woman or person has opted for combined screening - Document discussion and decision over which conditions they request screeningfor in digital notes.
- Nuchal scan can only be performed when CRL is between 45 – 84mm inclusive [equivalent to 11+2 and 14+1 weeks gestation]

Attends for scan: CRL 45-84mm inclusive: NT measured.

Viable singleton pregnancy, NT < 3.5mm No obvious anomaly

Refer to ANC for completion of combined screening test:
-weight
-blood test
-check all details completed on form

Viable multiple pregnancy

Sonographer measures NT on all fetuses and gives the woman or person the PHE leaflet
'Screening for Down's syndrome in multiple pregnancy'.
TWINS: Refers to ANC to complete combined screening
TRIPLETS OR MORE: Combined screening not possible. Chance calculation from NT alone.Sonographer sends request form to lab andemails Laboratory Screening Co-ordinator to advise that a chance calculation is required from NT alone. Also:

- Refer to screening midwife / obstetrician
- Follow multiple pregnancy referral protocol

'Vanished twin' – two sacs seen but only one fetus viable

Second sac empty

Refer to ANC for completion of combined screening test [weight and blood]

Second sac contains fetus with no FH

Combined screen not possible. Chanceto be calculated from NT alone. Sonographer informs lab.

Viable pregnancy: NT ≥3.5mm or other abnormality

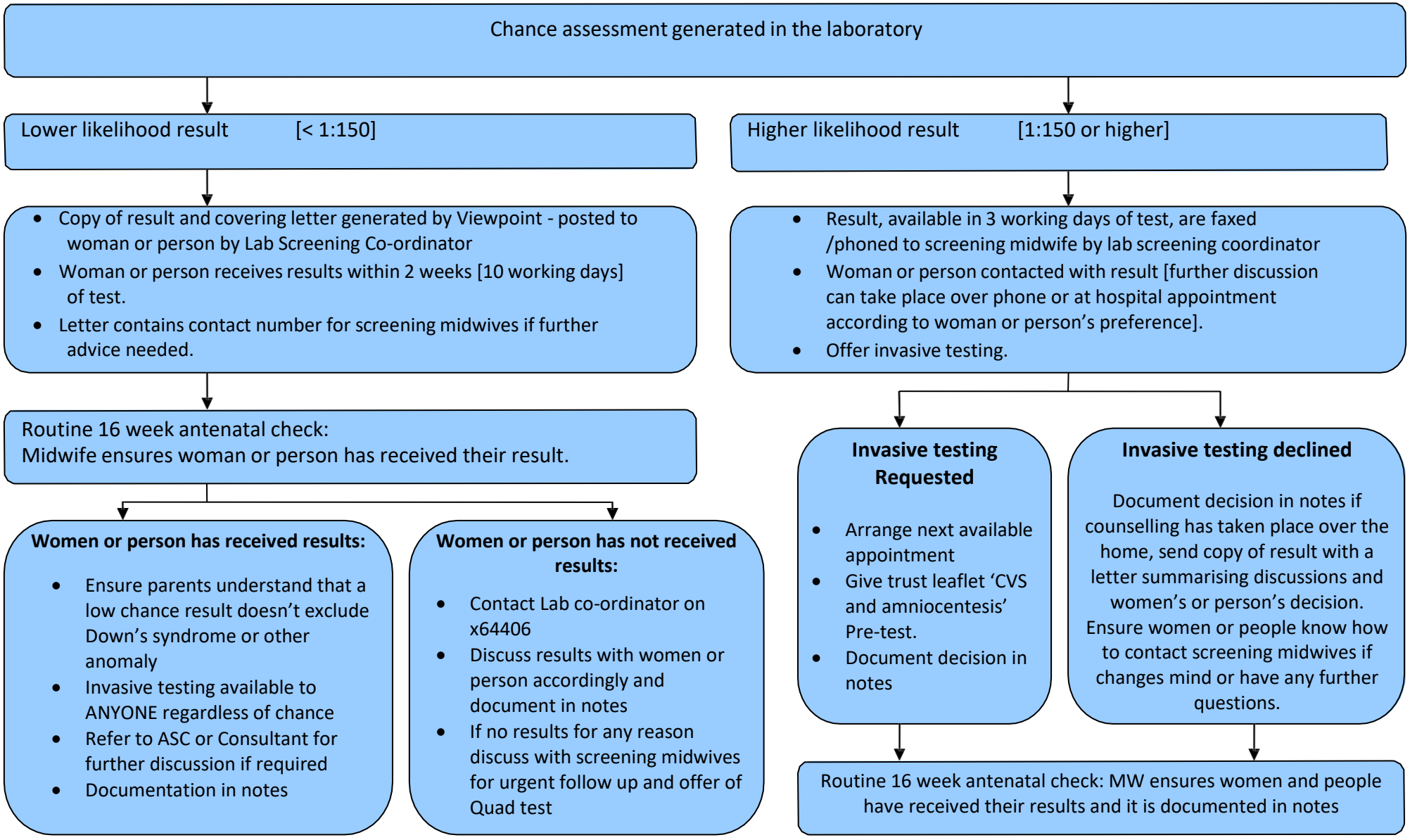
Refer to ASC for discussion.

1. NT 3.5mm or above: increased chance of cardiac/ other defect [PHE 2018c]. Refer to chart 1:4
2. Other abnormality detected.

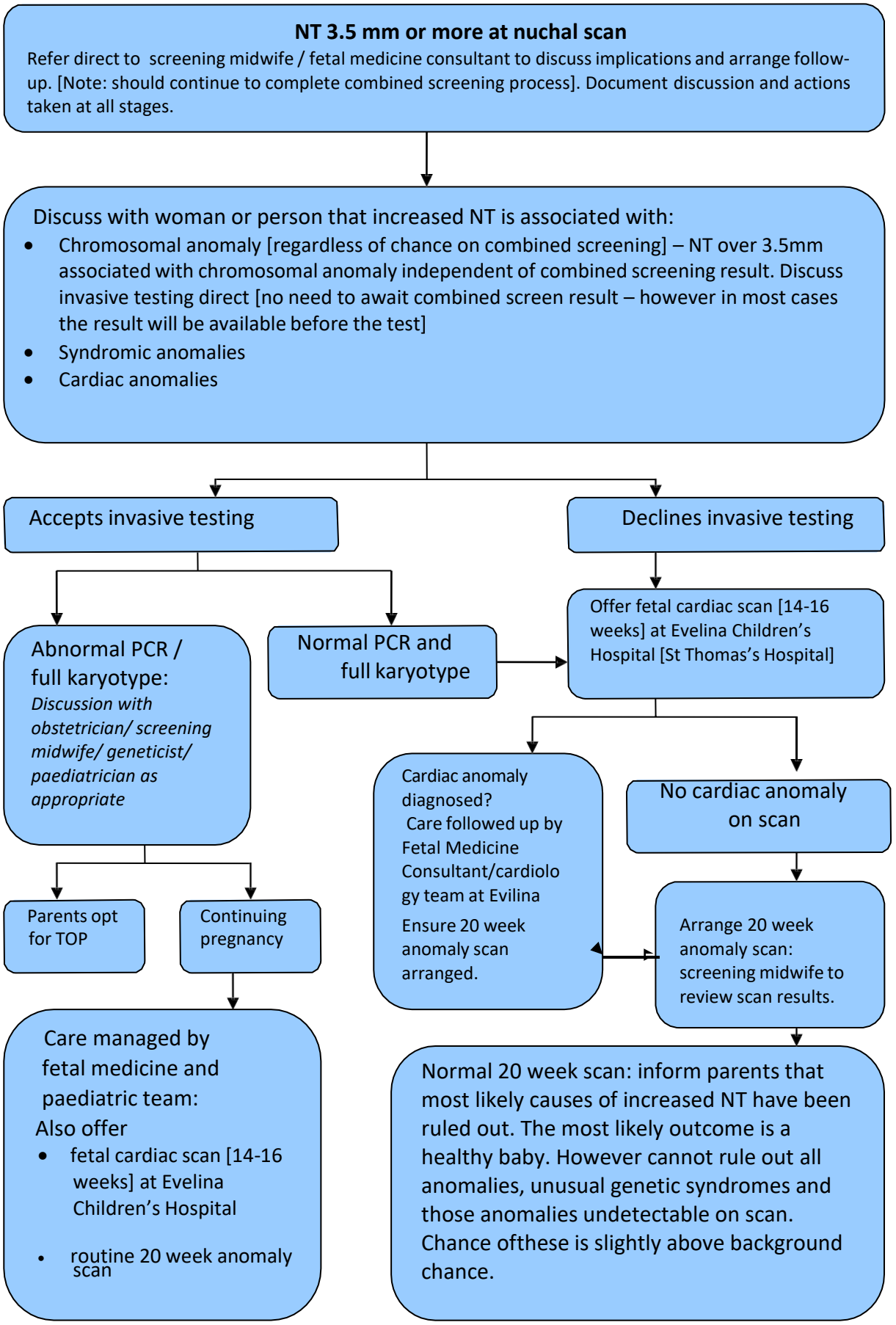
Non-viable pregnancy

Refer to chart 1:8 Refer to Gynae team / Early Pregnancy Unit.

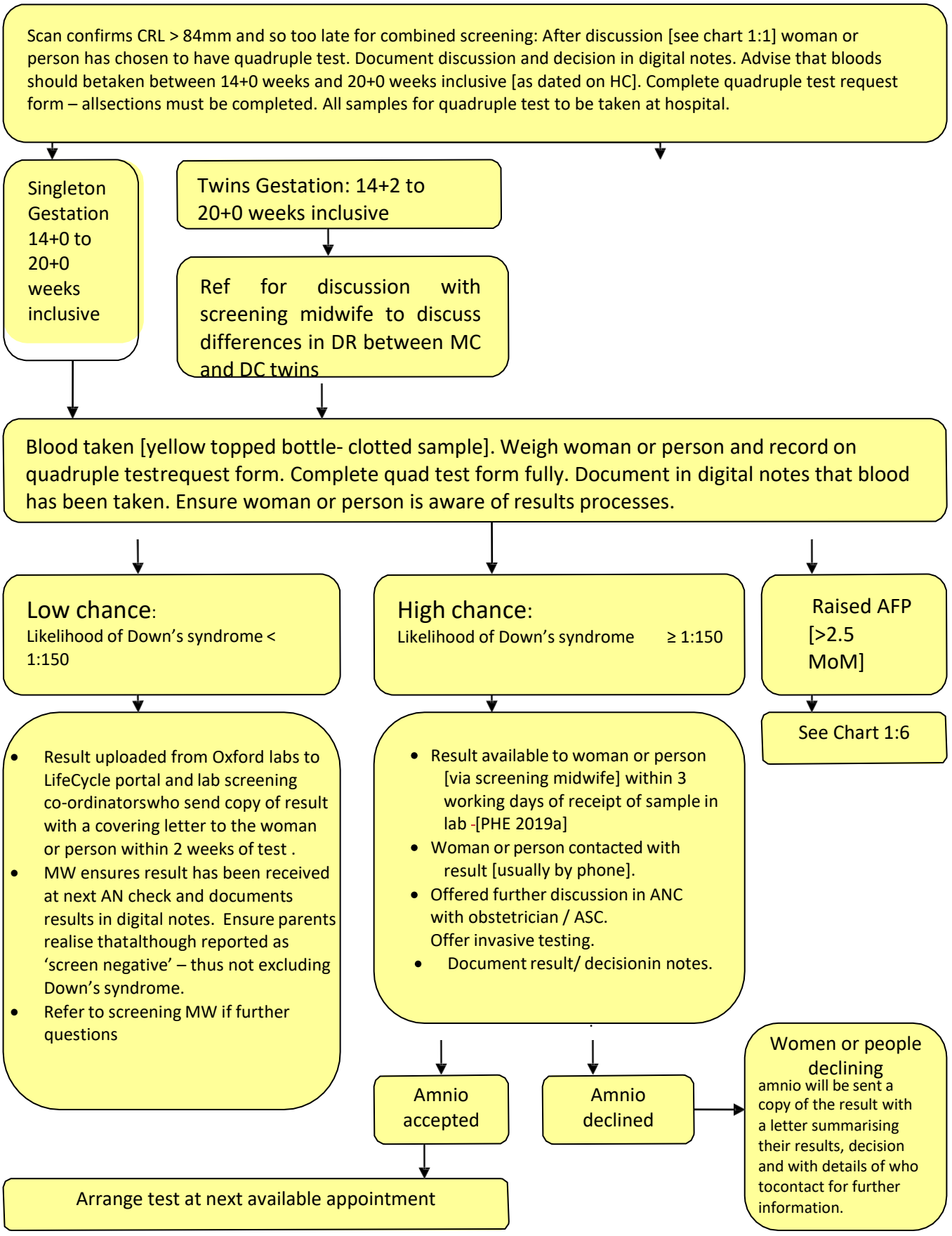
6.3 Combined screening results process



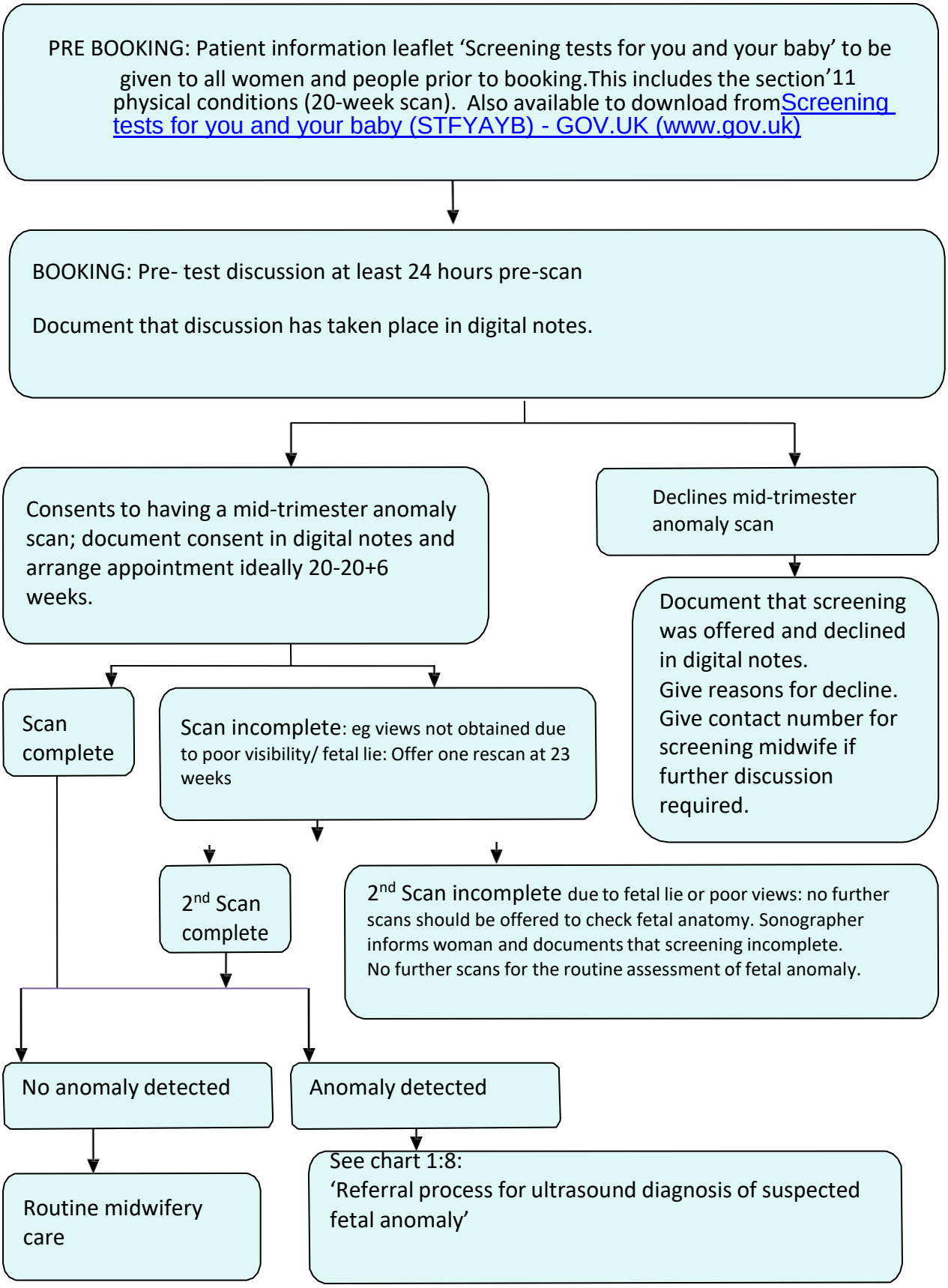
6.4 Increased NT - 3.5mm or above
[Based onPHE 2018c]



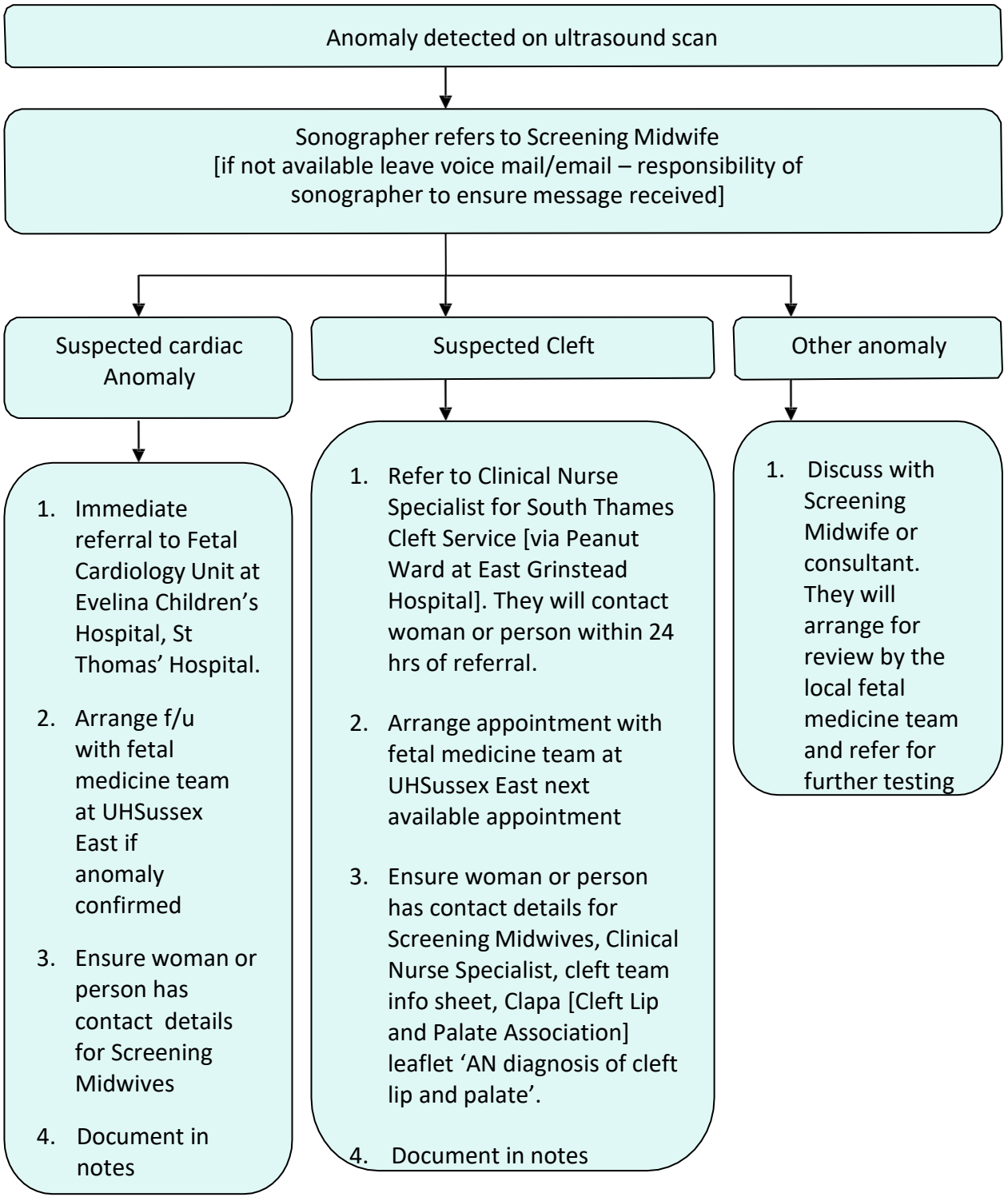
6.5 Second trimester serum screening: Quadruple test [singleton and twins only]



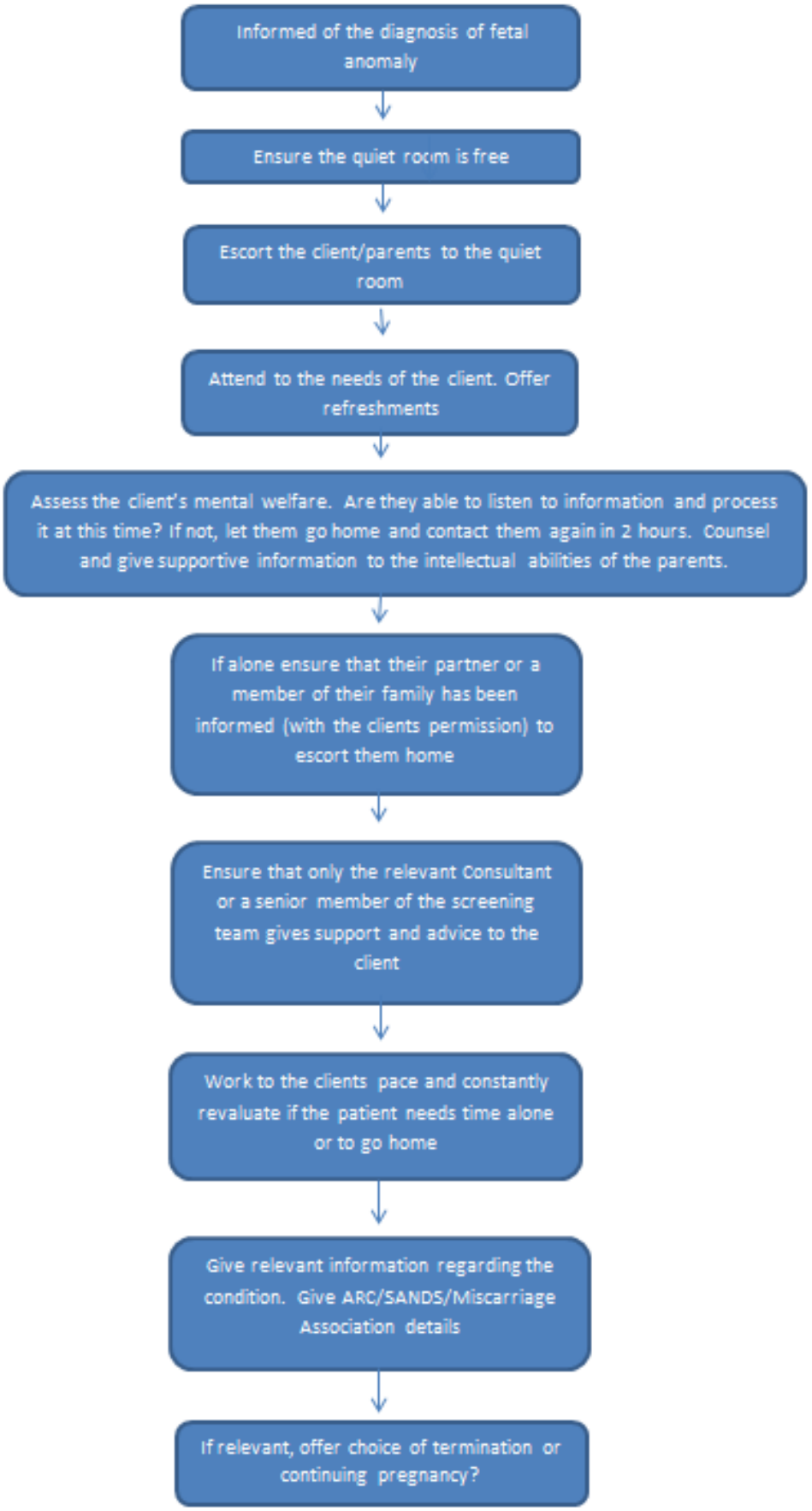
6.6 Mid-Trimester Fetal Anomaly Scan

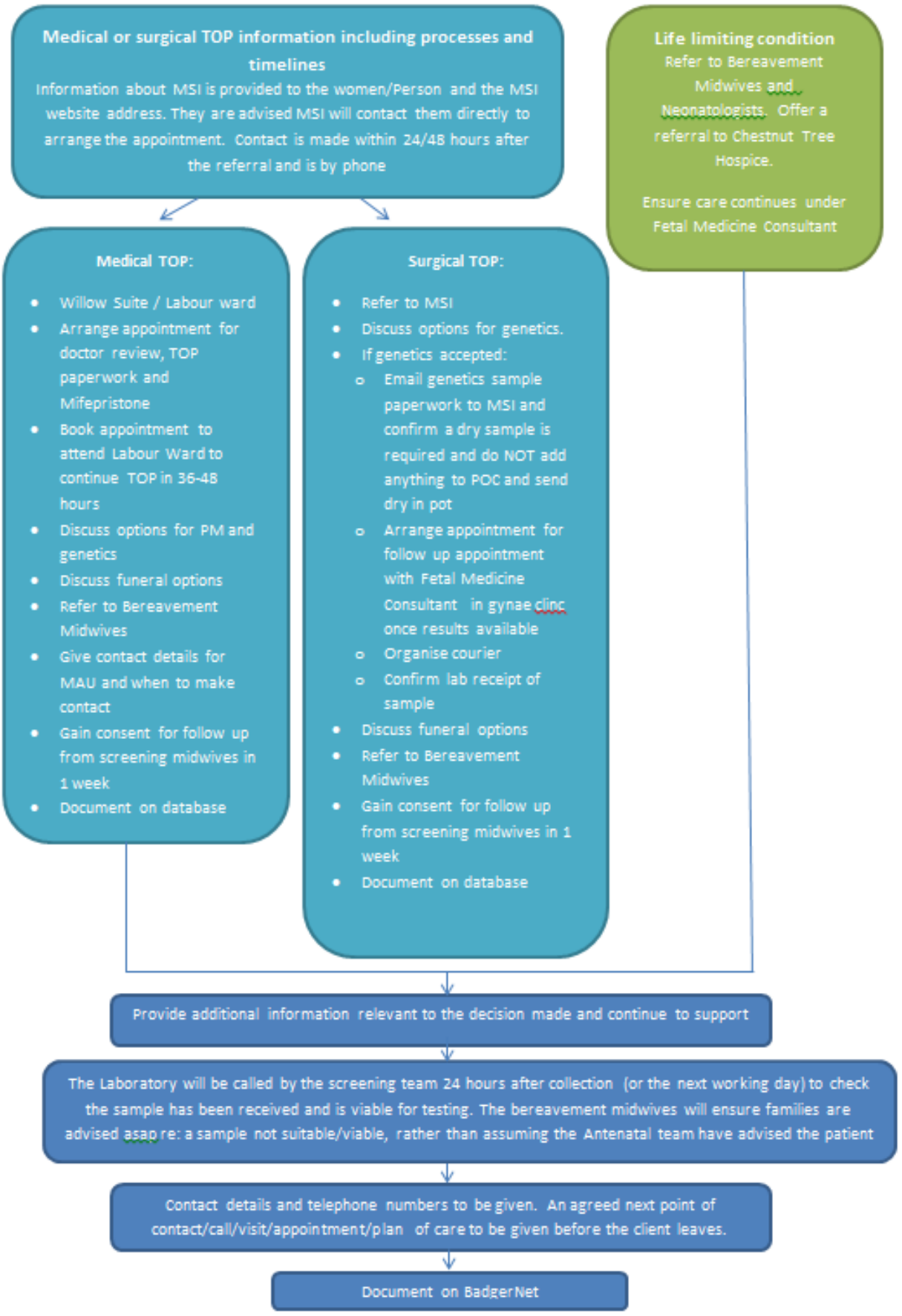


6.7 Referral processes for ultrasound diagnosis of suspected fetal anomaly



Algorithm 6.8 Termination of Pregnancy for Fetal Anomaly and Life Limiting Conditions

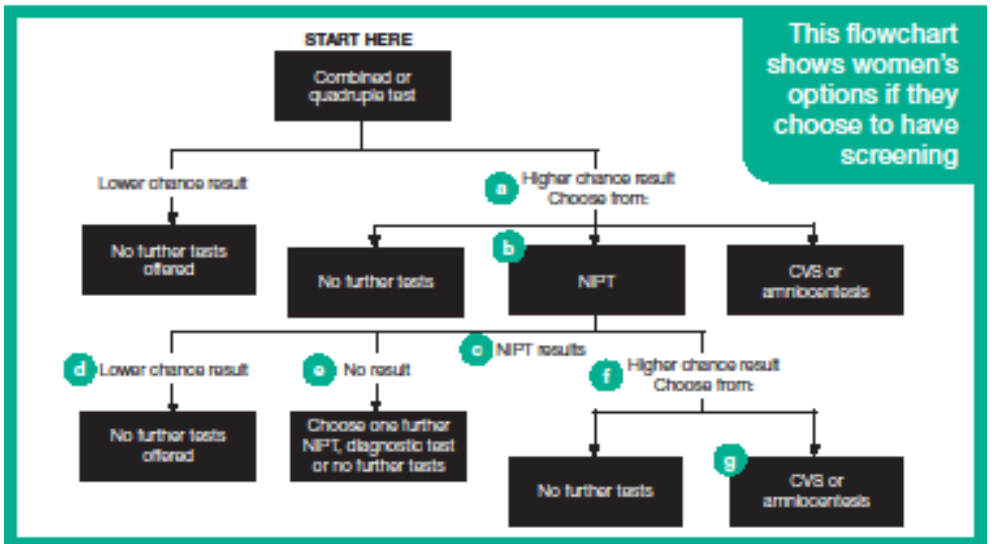



Medical or surgical TOP information including processes and timelines
Information about MSI is provided to the women/Person and the MSI website address. They are advised MSI will contact them directly to arrange the appointment. Contact is made within 24/48 hours after the referral and is by phone
Life limiting condition
Refer to Bereavement Midwives and Neonatologists. Offer a referral to Chestnut Tree Hospice.
Ensure care continues under Fetal Medicine Consultant
Medical TOP:
Willow Suite / Labour ward
Arrange appointment for doctor review, TOP paperwork and Mifepristone
Book appointment to attend Labour Ward to continue TOP in 36-48 hours
Discuss options for PM and genetics
Discuss funeral options
Refer to Bereavement Midwives
Give contact details for MAU and when to make contact
Gain consent for follow up from screening midwives in 1 week
Document on database
Surgical TOP:
Refer to MSI
Discuss options for genetics.
If genetics accepted:
Email genetics sample paperwork to MSI and confirm a dry sample is required and do NOT add anything to POC and send dry in pot
Arrange appointment for follow up appointment with Fetal Medicine Consultant in gynae clinc once results available
Organise courier
Confirm lab receipt of sample
Discuss funeral options
Refer to Bereavement Midwives
Gain consent for follow up from screening midwives in 1 week
Document on database
Provide additional information relevant to the decision made and continue to support
The Laboratory will be called by the screening team 24 hours after collection (or the next working day) to check the sample has been received and is viable for testing. The bereavement midwives will ensure families are advised asap re: a sample not suitable/viable, rather than assuming the Antenatal team have advised the patient
Contact details and telephone numbers to be given. An agreed next point of contact/call/visit/appointment/plan of care to be given before the client leaves.
Document on BadgerNet

Algorithm 6.9

Non-invasive prenatal testing (NIPT)

for Down's syndrome, Edwards' syndrome and Patau's syndrome



This flowchart shows women's options if they choose to have screening

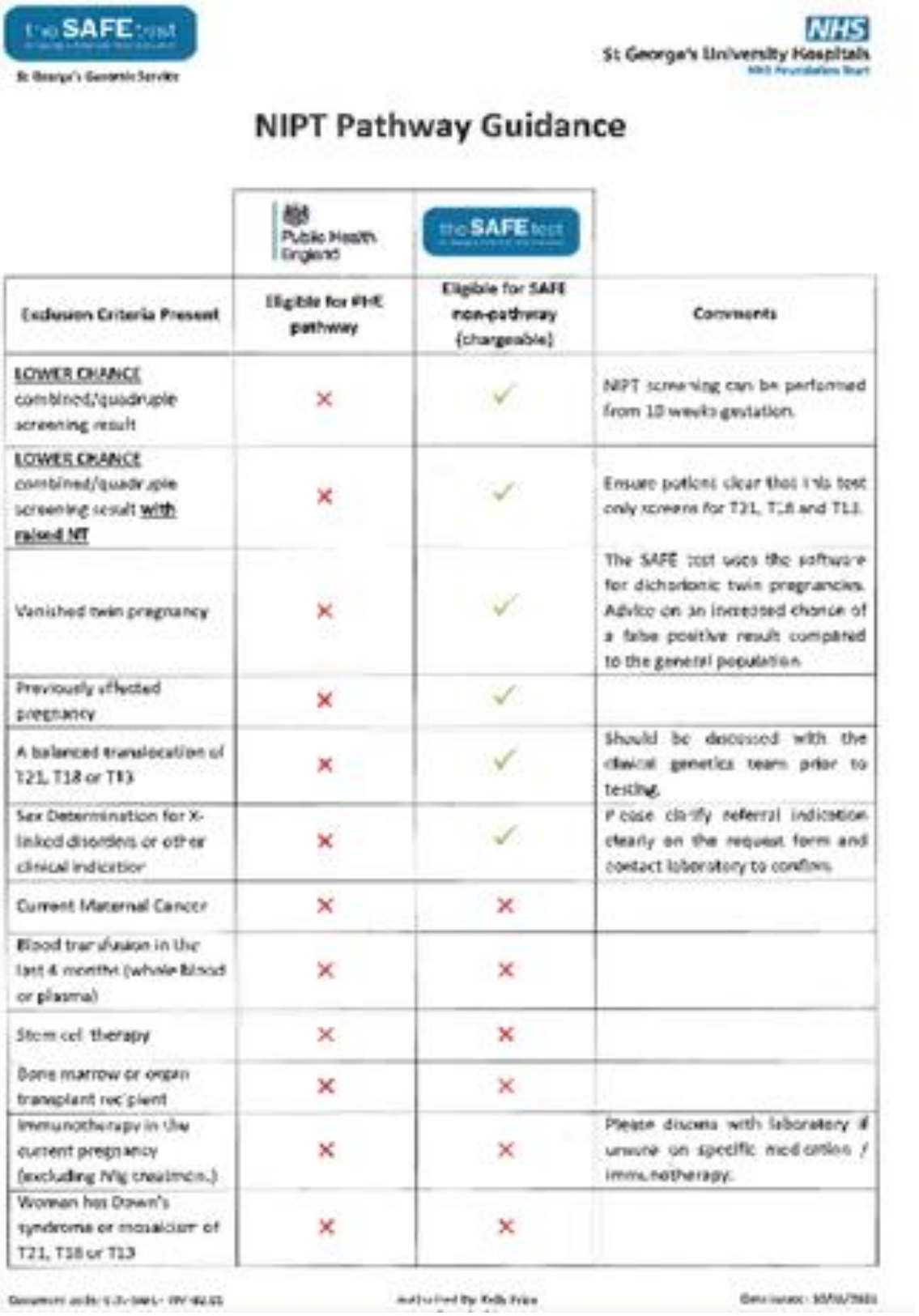
Whatever results women get from any of these screening or diagnostic tests, they should be offered care and support in the decision that is right for them.

As part of the NHS screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome, NIPT:

- can be offered to women who have received a higher chance result from combined or quadruple screening
- can be offered to women with single and twin pregnancies
- might be less accurate in twin pregnancies
- can be offered until 21^{+6} weeks of pregnancy
- does not screen for other conditions or fetal sex
- is not suitable for everyone

Find out more in the e-learning module at
https://portal.e-lfh.org.uk/Component/Details/671159

Algorithm 7.0



St George's University Hospitals NHS

NIPT Pathway Guidance

Exclusion Criteria Present	Eligible for PHE pathway	Eligible for SAFE non-pathway (chargeable)	Comments
LOWER CHANCE combined/quadruple screening result	✗	✓	NIPT screening can be performed from 10 weeks gestation.
LOWER CHANCE combined/quadruple screening result with raised NT	✗	✓	Ensure patient clear that this test only screens for T21, T18 and T13.
Vanished twin pregnancy	✗	✓	The SAFE test uses the software for dichorionic twin pregnancies. Advise on an increased chance of a false positive result compared to the general population.
Previously affected pregnancy	✗	✓	
A balanced translocation of T21, T18 or T13	✗	✓	Should be discussed with the clinical genetics team prior to testing.
Sex Determination for X-linked disorders or other clinical indication	✗	✓	If case clarify referral indication clearly on the request form and contact laboratory to confirm.
Current Maternal Cancer	✗	✗	
Blood transfusion in the last 4 months (whole blood or plasma)	✗	✗	
Stem cell therapy	✗	✗	
Bone marrow or organ transplant recipient	✗	✗	
Immunotherapy in the current pregnancy (excluding Mg sulphate.)	✗	✗	Please discuss with laboratory if unsure on specific medication / immunotherapy.
Woman has Down's syndrome or mosaicism of T21, T18 or T13	✗	✗	

7 Auditable Standards

Based on national programme standards [PHE 2019a] and Key Performance Indicators. The data is reported annually in the annual report unless otherwise indicated.

7.1 First trimester combined screening/ second trimester quadruple test:

7.1.1 Coverage – number of women and people in the eligible populationwho accept screening

7.1.2 Coverage - number of women and people in the eligible populationwho are tested [by combined screen and by the quadruple test]

7.1.3 Coverage – number of women and people in the eligible populationwho decline screening

7.1.4 Completion of laboratory request forms – number of incomplete laboratory request forms [combined screening to be reported by Brighton Pathology, Quadruple test to be reported by the Wolfson Institute] [KPI DATA COLECTED QUARTERLY]

7.1.5 Test turnaround time – number of samples reported within three working days of sample receipt

7.1.6 Test performance – number of women and people who receive ahigher chance result [Collected via DQASS – Downs Syndrome Screening Quality Assurance Support Service] – screen positive rate.

7.1.7 Test performance – the number of women and people who receivea lower chance result

7.1.8 Time to intervention – number of women and people with higher chance result offered an appointment within three working days

7.1.9 Intervention – the number of women and people with a high chance result who are offered invasive testing and who subsequently accept or decline

7.1.10 Diagnosis: the number of chromosomal abnormalities diagnosed as a result of post screening diagnostic testing

7.1.11 Detection rate for Down’s syndrome

7.1.12 Detection rate for Edwards’ and Patau’s syndrome

7.1.13 Outcomes for pregnancies diagnosed with chromosomal abnormality

7.2 Invasive testing

7.2.1 Number of CVS/amniocentesis per operator

7.2.2 Indications for invasive testing

7.2.3 Conditions diagnosed by invasive tests

7.2.4 Pregnancy loss rate per operator

7.3 Mid-Trimester Ultrasound Scan

7.3.1 Coverage – identify the number of women and people who accepted screening and were tested.

7.3.2 Number of abnormalities diagnosed - as defined by the National Standards [PHE 2019b]

7.3.3 Time to intervention- Local referral: number of women and people with suspected abnormality seen within 3 working day

7.3.4 Time to intervention- Tertiary referral: number of women and people with suspected abnormality seen within 5 working days

7.3.5 Specific cardiac abnormality reporting: Report the number of babies with confirmed Transposition of Great Arteries [TGA], Atrioventricular SeptalDefect [AVSD], Tetraology of Fallot [TOF] and Hypoplastic Left Heart Syndrome [HLHS].

7.4 Summary of Failsafes

7.4.1 All women and people accepting combined screening have had a result. Every Wednesday, a member of the screening midwife team performs a failsafe check to ensure that all women and people who had a NT recorded on Viewpoint in the preceding week, have had a chance calculated. This ensures that every woman or person who accepted an NT measurement at the time of scan has had a screening result whether this was calculated by NT alone OR NT and blood test. The findings of this failsafe are documented on the combined screening database. Missing results are actioned.

7.4.2 All high chance combined screening results have been actioned. Every Wednesday, a member of the screening team checks all high risk results on Viewpoint from the preceding week to ensure these have been actioned. In addition the screening team performs a cross-check of all highchance results with the laboratory screening co-ordinator. The findings of these two failsafe checks are documented on the combined screening database

7.4.3 All women and people accepting quadruple screening have had a result. The screening team record the names of all women and people who have had a quad test on a database. This database is accessible to members of the screening team and the laboratory screeningco-ordinator. The screening midwives check the database every Wednesday to ensure all results have been received for women and people who had screening the preceding week and that high chance results were actioned.

8 Staff training and education

8.1 Specific cardiac abnormality reporting: Report the number of babies with confirmed Transposition of Great Arteries [TGA], Atrioventricular Septal Defect [AVSD], Tetraology of Fallot [TOF] and Hypoplastic Left Heart Syndrome [HLHS].

8.2 All midwives / screening MCAs new to the trust should:

- Complete the UK NSC e-learning screening module.
- All band 5 midwives must complete the UK NSC e-learning screening module as part of their competencies before they can apply for a band 6.

8.3 All midwives must attend a yearly update on the fetal anomaly screening programme as part of their mandatory education update sessions

9 Governance

9.1 All midwives must attend a yearly update on the Fetal Anomaly Screening Programme as part of their mandatory education update sessions

9.2 All incidents related to fetal anomaly screening are reported via the trusts internal reporting system known as DATIX.

9.3 All incidents related to fetal anomaly screening should also be reported to the Antenatal screening co-ordinator who will complete a SIAF [Screening incident assessment form] in order to notify the Regional QA the Screening and immunisations lead.

9.4 For further information relating to management of incidents please refer to the protocol : MD085 Maternity & Gynaecology Risk Management Strategy.

10 References

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Brighton and Sussex University Hospitals [BSUH] NHS Trust [2017] US005 Ultrasound 1st Trimester Scan. May 2017.

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National Institute for Health and Care Excellence (NICE) [2011] Multiple pregnancy: antenatal care for twin and triplet pregnancies. Clinical guideline number 129. Available at: https://www.nice.org.uk/guidance/cg137

Public Health England [2018a] NHS public health functions agreement 2018-19. Service specification no.16: NHS Fetal Anomaly Screening Programme-Screening for Down's Syndrome, Edwards' Syndrome and Patau's Syndrome (Trisomy 21, 18 & 13). Available at: https://www.england.nhs.uk/wp-content/uploads/2017/04/Gateway-ref-07837-180913-Service-specification-No.-16-NHS-FASP-Trisomy-screening-2018-19.pdf

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Public Health England [2018d] NHS Fetal Anomaly Screening Programme Handbook. Valid from August 2018. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/749742/NHS_fetal_anomaly_screening_programme_handbook_FINAL1.2_18.10.18.pdf

Public Health England [2019a] Fetal anomaly screening standards valid for data collected from 1 April 2018. PHE publications gateway number: GW-369. Available at: https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards/standards-valid-from-1-april-2018

Public Health England [2019b] 'Screening tests for you and your baby' leaflet. PHE publications gateway number: GW-389. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/800673/Screening_tests_for_you_and_your_baby.pdf

RCOG [2010] Green-top Guideline No. 8 Amniocentesis and Chorionic Villus Sampling June 2010

Souka et al [2004] Increased nuchal translucency with normal karyotype. Am J Obstet Gynecol. Sited in Chapter 3 – Increased nuchal translucency with normal karyotype in The 11-13+6 weeks scan. Edited by Nicolaides K, Fetal Medicine Foundation, London p 71-94

Appendix A – UHSussex East Contacts

UHSussex East designated programme leads for maternityservices Midwifery: Karen Gregory – Antenatal screening co-ordinator
Obstetrics: Win KhineConsultant obstetrician

Leads for ultrasound and laboratory
Ultrasound: Julie Allen and Sharon Cook – Superintendent sonographers
Laboratory: Nik Hawes and Tamsyn Cromwell - Biochemists

Antenatal Screening Co-ordinator at UHSussex East [cross site]
Karen Gregory
karen.gregory12@nhs.net Mobile: 07876 357 423
Office: 01273 696955 ex62755

Antenatal Screening Support Midwives [UHSussex East]
RSCH and PRH
Melanie Sander: melanie.sander1@nhs.net
Rosie Darling: rosemary.darling@nhs.net

Mobile:07876 357423
RSCH office: 01273 696955 ex67477
PRH office: 01444 441881 ex 65404

Trust shared antenatal screening NHS net email account:
bsu-tr.antenatalscreening@nhs.net

Fetal Medicine Consultants at UHSussex East
Sec: 01273 696955 ex64031

Laboratory Service Leads
Nil Hawes , Tasmyn Cromwell Tel: 01273 696955 ex64234

Laboratory Screening Co-ordinator
Karen Hilton Tel: 01273 696955 ex64406

Ultrasound Department:

Service Managers
Emma Cockburn/Julie Allen ex67450

RSCH: Lois Southon Scan Department 01273 696955 ex67450
Appointments
ex64575
EPAC ex64402

PRH: ANC ultrasound department 01444 441881
ex68042

EPAC [Horsted Keynes Ward] ex65685

Appendix B - External Contacts

MSReproductive Choices
Brighton Treatment Centre
175 Preston Road
Brighton
BN1 6AG

Cytogenetics [used by PRH and RSCH]
Cytogenetics Laboratory, Genetics Centre, Guys Hospital, 5th Floor Tower Wing, Great Maze Pond, London, SE1 9RT
Tel: 020 7188 1709
Fax: 020 7188 1697

Fetal Cardiac Referrals
Fetal Cardiology Unit, 1st Floor, Evelina Children's Hospital, St Thomas' Hospital, Lambeth Palace Road, London, SE1 7EH
Tel: 020 7188 2308/ 020 7188 9201 Fax: 020 7188 2307

Genetic Counselling:
Where you refer to depends on the woman or person's address/post code. If in doubt either genetics department will advise.

RSCH: generally refer to Guys and St Thomas's
Genetics Counseling Department, Genetics Centre, Guys Hospital, 5th Floor Tower Wing, Great Maze Pond, London, SE1 9RT
Tel: 0207 188 1364

PRH: generally refer to St Georges
Genetics Counselling Department
Tel 0208 725 0957
Fax 0208 725 3444

Quadruple Test Laboratory
Antenatal Screening Co-ordinator: Rhiannon Marr

Clinical Biochemistry Department
Level 4
John Radcliffe Hospital
Headley Way
Headington
Oxford
OX3 9DU

Tertiary Fetal Anomaly Referrals [includes multiple pregnancy invasive testing]
Harris Birthright Research Centre, Suite 9, 3rd floor, Golden Jubilee Wing, Kings College Hospital, Denmark Hill, London, SE5 9RS
Tel: 0203 299 3040 FAX: 0203 299 3898

Appendix C - Abbreviations

ASC	Antenatal Screening Co-ordinator
AFP	Alpha-fetoprotein
AN	Antenatal
ANC	Antenatal Clinic
ARC	Antenatal Results and Choices
ASSW	Antenatal Screening Support Worker
CVS	Chorionic Villus Sampling
DNA	Did not attend
GP	General
Practitioner HCA	Health Care
Assistant MW	Midwife
NT	Nuchal Translucency
PCR	Polymerase Chain Reaction [rapid chromosome
test] PRH	Princess Royal Hospital
RACH	Royal Alexandra Children's Hospital
RSCH	Royal Sussex County Hospital
SCD	sickle cell disorders
TOP	Termination of pregnancy
USS	Ultrasound scan
NIPT	Non Invasive Prenatal Testing

Appendix D - Best Practice: Areas for discussion prior to mid-trimester anomaly scan

Pre-test discussion should ideally explore the following areas:

- The scan is optional [this is an 'opt-in' screening test]
- The nature, purpose, benefits, risks, consequences and timescales of ultrasound
- Purpose of scan [to check fetal development and so may detect structural anomalies and soft markers for chromosomal abnormalities, position of the placenta]
- Ultrasound scans will not detect all abnormalities ['a normal scan does not guarantee a normal baby']. Likewise, some anomalies may be detected but these may not cause a serious problem in the baby
- Some anomalies may lead to the offer of prenatal diagnosis. In some cases, where structural, lethal or inherited abnormality is diagnosed, there may be the choice to continue or end the pregnancy
- Referral process if an abnormality is detected. Occasionally referral for a second opinion may be recommended, to a specialist fetal medicine centre