Screening for Fetal Anomaly
In the 1st Trimester and 2nd Trimester Clinical Guideline

V1.0

December 2018
Summary. Pathway for 1st Trimester combined screening

1. Identify pregnant women and send ‘Screening tests for you and your baby’ in appropriate format

2. At booking appointment inform and offer screening choices. Input into maternity IT system and document.

- If screening declined
  - Fetal Medicine (FM) ward clerk to book and send dating scan appointment from 10 weeks

- If screening accepted and between 11+2-14+1 gestation
  - FM ward clerk to book and send appointment

  - If screening accepted and >14+1 gestation
    - FM ward clerk to book and send appointment for dating scan and 2nd trimester screening

  - If unable to measure NT or CRL >84mm
    - Inform and offer 2nd trimester screening

- No screening
  - T21 and T13/18
    - Offer 18+0 to 20+6 anomaly scan
  - T21
    - Lower chance result, letter to woman within 14 working days
  - T13/T18
    - Higher chance result, ANNSC informed, woman contacted and offered appointment within 3 working days
  - T21
    - Offer 18+0 to 20+6 anomaly scan

- Discussion with woman/couple and offer
  - CVS/Amnio
  - *NIPT
  - No further tests
CVS/amnio accepted

 unaffected

 *NIPT accepted

 Affected by T21, T18 or T13

 No further testing

 Unaffected

 Affected by T21, T18 or T13

 No result*

 Higher chance

 Lower chance

 Offer 18+0 to 20+6 anomaly scan

 Discuss options

 Continue with pregnancy

 Offer 18+0 to 20+6 anomaly scan

 Termination of pregnancy

 Offer follow up support

 Affected by T21, T18 or T13

 CVS/Amnio

 Unaffected

 Offer follow up support

 *NIPT is a non NHS funded test and not currently recommended by the national screening committee. **For 'no result' NIPT, offer repeat test or CVS/amnio. If 2nd 'no result' offer CVS/amnio and follow related pathways
Increased Nuchal translucency (NT) detected at either 1\textsuperscript{st} trimester screening or Dating scan

<table>
<thead>
<tr>
<th>NT between 3.5-5mm, with higher or lower chance 1\textsuperscript{st} trimester screening result</th>
<th>NT of 5mm or greater, with higher or lower chance 1\textsuperscript{st} trimester screening</th>
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</thead>
<tbody>
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<td>Offer CVS/amnio, with array and parental bloods</td>
<td>Inform of NIPT but advise it does not screen for all associated conditions so not recommended</td>
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<tr>
<td>Offer CVS/amnio with array and parental bloods</td>
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<td>Continuation of pregnancy</td>
<td>Continue pregnancy</td>
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<tr>
<td>Offer support and follow up</td>
<td>Fetal medicine scan at 20 weeks for NT between 3.5-5mm</td>
</tr>
<tr>
<td>Fetal medicine scan at 16 and 20 weeks if NT 5mm or greater</td>
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1. **Aim/Purpose of this Guideline**
   1.1. This guideline is for all health care professions involved in providing care for pregnant women. All health professions should ensure they are giving high quality information on screening, in a format to suit the individual woman’s needs. They should ensure that all eligible pregnant women are offered screening to assess the chance of their baby being born with Down’s syndrome (T21), Edwards’ syndrome (T18) and Pataus syndrome (T13) or a number of structural abnormalities that may affect the developing fetus.

2. **The Guidance**
   2.1. **The booking appointment**: All women should be encouraged to book with their midwife between 8-10 weeks of pregnancy. They should receive, pre booking, the leaflet ‘Screening tests for you and your baby’. The midwife should advise the woman to read the leaflet to help her prepare for the appointment. The woman should be informed that it is her decision whether to have any of the tests described in the booklet.

   2.1.1. At the booking appointment the midwife will explore the woman’s knowledge and views on the combined screening test and inform her that she has the option of:
   - Not to have screening
   - To have screening for all 3 conditions T21,T18/13
   - To have screening for T21 only
   - To have screening for T13/18 only
   - If gestation is over 14+1 weeks the second trimester quadruple test for T21 only should be offered. (T13/18 is screened for at the 18-20+6 anomaly scan)

   The woman’s decision should be recorded in the screening section of the maternity IT system (Euroking) and documented in the woman’s hand held notes. Either an LMP or an estimation of gestation must be entered in Euroking. The woman should be advised that she will receive an appointment through the post for either a dating scan, (if she has chosen not to have screening or her gestation is >14+1) or for a 1st trimester screening scan. The midwife should then print out the Antenatal booking section and send to the ward clerk, Fetal Medicine, Princess Alexandra Wing.

   2.2. **Generating appointment**: The Fetal Medicine ward clerk will receive the Euroking booking information, identify if 1st trimester screening is required, calculate gestation and generate an appropriate appointment. This will be sent by post to the woman.

   2.3. **No screening**: If the woman opts for ‘no screening’ she should be offered an appointment for a scan to date her pregnancy, confirm viability and fetal number. The woman should be informed that occasionally fetal anomalies are identified on scan such as acrania, major neural tube defects, gastroschisis or an enlarged nuchal translucency. This scan can take place from 10 weeks.
2.4. Screening for T21, T3/18/ (1st trimester combined test): This test can be offered between 11+4 weeks and 14+1 weeks, with the crown rump length (CRL) between 45mm and 84mm. However, the optimum time is around 12 weeks. The markers used for this test are:

2.4.1 Maternal age: The chance of having a baby affected with T13/18 or T21 increases with age.

2.4.2 Nuchal Translucency (NT): This is the measurement of a collection of fluid under the skin behind the neck of the fetus in the 1st trimester of pregnancy. An increased NT (3.5mm or greater) can be associated with autosomal trisomies and other fetal abnormalities such as cardiac defects. However, an increased NT can have a normal outcome.

2.4.3 Biochemical markers: The combined test uses two biochemical tests, free beta hCG and PAPP-A. These are 2 glycoproteins produced by the developing embryo and later by the placenta. An increased level of beta hCG and a decreased level of PAPP-A can be markers for T21 and decreased beta hCG and decreased PAPP-A can be markers for T13/18. Abnormal biochemical markers can also have a normal outcome.

2.4.4 Pregnancy associated plasma protein A (PAPP A) can also be a marker for fetal growth restriction (FGR). Any woman with a measurement below 0.4MoM, on 1st trimester screening, will be offered monthly growth scans from 26 weeks of pregnancy.

2.5. Other influencing factors:

2.5.1 Significant vaginal bleeding: Current evidence suggests that the biochemical marker levels are not significantly different in woman with significant vaginal bleeding and the screening should be offered in the normal way

2.5.2 Vanishing or demised twin: When ultrasound shows a second pregnancy sac with a non-viable fetus it could contribute to the biochemical markers for many weeks. It is therefore recommended that the screening is based on maternal age and NT only. However, the woman should be informed that the performance of the test will be slightly lower than the combined screening.

2.6. Performing the test: Appendix 3

The woman will attend the Fetal Medicine department

2.6.1: Performing the scan: Viability will be confirmed; the pregnancy will be dated and fetal number confirmed. The CRL and the NT will be measured and any obvious fetal anomalies excluded. The woman will be informed by the ultrasound midwife that if the screening gives a higher chance result, she will be contacted by phone in around 3 working days and if she has a lower chance result, she will receive a letter with 14 working days.

2.6.2: Taking the blood: The woman will then go into the phlebotomist and have blood taken for beta HCG and PAPP A. The sample will be labelled with the woman’s details and bar code labels generated, one bar code label is applied to the woman’s sample and a second bar code label applied to the working list against the woman’s name. The bar code is
then scanned into the woman’s Viewpoint details.

2.6.3: Transferring samples to the lab: Following a morning and an afternoon clinic the samples and the working list are taken by hand to the Clinical Chemistry lab reception window, where they are signed for and the person they are handed to identified on the receipt register. See Appendix 4

2.6.4 Second trimester Quadruple (QUAD) testing for T21 only. This test is offered to woman who book too late for 1st trimester screening or when an NT measurement cannot be obtained, despite 2 attempts. An ultrasound scan will be required to date the pregnancy and the fetal head circumference is the recommended measurement used for dating women presenting in the second trimester. This test uses 4 biochemical markers measured from 14+2 weeks to 20+0 weeks. (beta HCG, AFP, oestriol and inhibin A) The optimum time is around 16 weeks. Appendix 5

2.7. Twin pregnancies:
Woman with twin pregnancies are eligible for combined or QUAD screening dependent on gestational age. However, the test of choice is 1st trimester screening. Chronicity is more difficult to ascertain in the second trimester. Quad testing for Monochorionic twins is comparable to that of a singleton at 80%, however, dichorionic twins only has a 40-50% detection rate. A face to face discussion should be offered, with a member of the screening team, for women with a twin pregnancy requesting quad screening for T21. A woman with a dichorionic twin pregnancy can be offered NIPT, at cost price, as an alternative. However, data on the performance of the test for twins is limited and it is outside the NHS FASP programme.

2.8. Screening results:
The results for both 1st trimester combined screening and Quad testing will be produced as a chance result.
- 1 in 2-1 in 150 will be reported as a higher chance result
- 1in151 or less will be reported as a lower chance result

2.8.1 ‘Lower chance’ result:
The woman will be informed by the ultrasonographer undertaking the screening that if she has a lower chance result, she will receive a letter, by post, within 14 working days, informing her of the result. The woman should be advised that if she doesn’t receive the letter within this time to contact her named midwife. The woman will then be offered an appointment for a second trimester anomaly scan which will also arrive by post. Appendix 6

2.8.2 ‘Higher chance’ result:
The woman will be informed that if she has a higher chance result, she will be contacted by phone within 3 working days. The lab will contact the antenatal and newborn screening coordinator (ANNSC) by phone,
followed up by email, with the result. The ANNSC will contact the woman by phone and offer her and her partner an appointment to discuss the result within 3 working days. **Appendix 6**

During this discussion the ANNSC will discuss:

- How the risk was calculated
- The conditions of T13, T18 & T21, describing the large spectrum in development and prognosis
- The options available of invasive testing e.g. chorionic villi sampling (CVS), amniocentesis (amnio), non-invasive prenatal testing (*NIPT) or continue on a lower chance pathway
- The risks and limitations of the tests
- Results pathway
- That there is no urgency to make any decision.

2.9. **Diagnostic testing**

2.9.1 **Chorionic Villi sampling (CVS).** An invasive diagnostic test, with a 0.5% risk of miscarriage, where a sample of placental cells are taken and sent to the regional cytogenetics laboratory. This can usually be done between 11+2 – 14 weeks of pregnancy. A result for the 3 most common trisomies, (T13, T18, T21), can be expected in 3 working days, in most cases. The result is emailed to the secure screening generic email and telephoned to the woman on the day of receipt, by the screening coordinators. If it is a positive result the woman will be offered an appointment with the screening coordinator to discuss her options.

2.9.2 **Amniocentesis (amnio)** An invasive diagnostic test, with a 0.5% risk of miscarriage, where a sample of amniotic fluid is taken and sent to the regional cytogenetics laboratory. This can be done from 15 weeks onwards. A result for the 3 most common trisomies, (T13, T18, T21), can be expected in 3 working days, in most cases. The result is emailed to the secure screening generic email and telephoned to the woman on the day of receipt, by the screening coordinators. If it is a positive result the woman will be offered an appointment with the screening coordinator to discuss her options. If the CVS/Amnio is performed for a higher chance trisomy result but there is no anomaly on scan and the NT is less than 3.5mm, the lab will only perform a PCR test.

2.9.3 Twin pregnancies with a higher chance result chance result can opt for diagnostic testing. However, this may need to be carried out at a tertiary Fetal Medicine Centre.

2.9.4 **Increased Nuchal translucency (NT)** equal to or greater than 3.5mm. If the fetus has an increased NT, a CGH array will be requested, in addition to the PCR and parental bloods will be taken. This test uses laboratory methods to detect chromosome defects which are too small to be seen by routine culture. If a defect on array is found, parental bloods are tested to see if the detected anomaly has been inherited from either parent. Results for this test can take further 7-10 working days. A referral to the Genetics team may be required.
In addition, for NT between 3.5mm- 5mm, the 18-20+6 anomaly scan will be done in the Fetal Medicine department and for NT over 5mm an additional 16 week scan will be done in Fetal Medicine department.

2.10. Noninvasive pre-natal testing (*NIPT).
This is an additional screening test, which is non NHS funded and currently not recommended by the national screening committee. This can be offered to women with a higher chance result for T13, T18 or T21 on 1st or 2nd trimester quad screening. This test involves taking a blood sample from the woman to analyse the total cell free DNA (cfDNA). The test involves sequencing and counting the maternal and free fetal DNA, which can identify if there are additional 13, 18 or 21 chromosomes present. The result should be available within 5-7 working days and will be presented as a lower chance or a higher chance of having a baby affected by T13, T18 or T21. This test has a very low false positive rate and a high detection rate. However, it is a screening test and any positive results should be followed up with a diagnostic test before an offer is made to discontinue the pregnancy.

There are limitations to the test including the risk of ‘false positive’ and ‘false negative’ results and a ‘no result’. The test can be repeated a second time, but if a second ‘no result’ is received the woman should be offered a diagnostic test.

2.11. No further testing
If a woman opts not to have any further diagnostic or screening testing an appointment will be made for her to attend her routine 18-20+6 week anomaly scan.

2.12. Result giving and ongoing care following a diagnostic test
Diagnostic testing samples are sent special delivery by Royal mail, to the regional genetics’ laboratory. The laboratories will be contacted to be informed that samples are on the way. When a result is available it is emailed to the generic screening account and received by a member of the screening team. The screening team will have discussed with the woman by which method she wishes to receive her results and this method is followed. See Appendix 7

2.12.1 Abnormal result
If the diagnostic result confirms that baby has a chromosomal abnormality, the woman and her partner will need time to absorb the information. They should be offered a follow up face to face discussion, at a time that is right for them.

This discussion should include accurate balanced information about the condition that has been diagnosed, an offer of a Paediatric or Genetic specialist consultation, contact numbers for support groups for the condition and ‘Antenatal results and choices (ARC)’ leaflet. The discussion should include information about continuing the pregnancy.
and not continuing the pregnancy and the process by which this would be achieved. The woman should continue to be supported whilst she is making her decision.

2.12.2 If she chooses to continue her pregnancy, she will receive regular appointments in the Fetal Medicine department to monitor the progress of her baby. A letter will be sent to the Neonatal team and the Delivery suite team and a plan for birth will be developed. This plan must be available in the woman’s Euroking details. The ongoing progress of the baby will be discussed at the Fetalonatal multidisciplinary team meeting (FNMTD) as required. (see guideline for fetal abnormality).

2.12.3 If she chooses not to continue her pregnancy and is less than 14+3 weeks on the date of termination, she can be offered the choice of surgical or medical termination. If she is requesting surgical termination past the 14+2 gestation, she should be offered a referral to the British Pregnancy Advisory Service (BPAS).

2.12.4 If she is over 14+2 weeks, she will be offered medical termination in the Daisy suite. If she is over 22 weeks gestation feticide will be recommended and offered after 18 weeks gestation.

2.12.5 The woman will receive ongoing support from the bereavement team, following the procedure.

2.12.6 Normal result
The woman will be informed that the result shows that the baby does not have the condition that it was tested for. If the baby had an NT of below 3.5mm, she will enter back into routine care with her named midwife and have her 18-20+6-week anomaly scan in the main ultrasound department.

2.12.7 If she has received a normal PCR and array result but has an enlarged NT an appointment will be made for her in the Fetal Medicine department at either 16 and 20 weeks or just 20 weeks dependent on the measurement.

2.12.8 See 2.9.4. - If the woman has a PAPP-A result of below 0.4 MoMs a request will be submitted on Maxims for monthly growth scans from 26 weeks gestation.

2.13. 18+0-20+6 weeks anomaly ultrasound scan
As part of the booking and pre-booking process the community midwife will offer the mid trimester scan. The woman’s preference regarding this scan should be documented in the Euroking system as part of the booking process.

2.13.1 Booking the scan:
When the woman has attended for her 1st trimester screening or dating scan, the midwife conducting the scan will check the box ‘summary of
ultrasound findings’ if a 20-week scan is required the box will be marked ‘viable pregnancy’ this will automatically generate the scan appointment. It the box is left blank; a scan will not be generated. A comment should be left indicating why the scan is not required.

2.13.2 If the woman is late booking or moves from another area requiring a 20 week scan only, her community midwife must request the scan either by ordering on maxims, order com system or telephoning the main ultrasound department and requesting in person.

2.13.3 A telephone request must be made if the woman is already within the 18-20+6-time frame. If she is between 22-23 weeks it is recognized that it may not be possible to accommodate the woman within the 23 weeks’ time frame.

**Conditions screened for as a minimum:**
- Anencephaly
- Open spina bifida
- Cleft lip
- Diaphragmatic hernia
- Gastrochisis
- Exomphalos
- Serious Cardiac abnormalities
- Bilateral renal agenesis
- Lethal skeletal dysplasia
- Edwards syndrome (T18)
- Pataus syndrome (T13)

The purpose for screening for these conditions is to:
- Identify babies that may die shortly after birth
- Babies that may benefit from treatment before birth
- To facilitate planned delivery in an appropriate hospital/centre
- To optimize treatment after a baby is born
- To identify conditions which have a detection rate which exceeds 50%

2.13.4 The examination of placental position and amniotic fluid whilst not part of the screening protocol is good clinical practice and part of our local ultrasound anomaly examination.

2.13.5 An appointment should be offered to the woman within the 18-20+6 week time frame. Should the woman decline this time frame or the examination cannot be completed a single repeat scan must be offered and completed by 23+0 weeks.

2.13.6 There is no requirement to determine fetal gender within the national programme, so no further appointment should be offered to the
woman if the fetal sex is not identified due to poor visualization or difficult fetal position.

For information about the scan base menu. See Appendix 6

The National Standards require the service to provide assurance that screening is offered to everyone who is eligible and each individual accepting screening has a conclusive screening result. The screening team, on a monthly basis, identifies the cohort of women that have booked for care within an RCHT managed area. The women’s details are entered onto an antenatal tracker, along with details of whether they have accepted or declined 1st/2nd trimester screening and 20 week anomaly scan. The tracker is monitored daily to ensure women have a timely result for a test that was accepted or a decline status. This is used as a second level failsafe, the first level being the process described in 2.8 (screening results)

2.15. Data collection, audit and quality assurance
2.15.1 Data is collected, in the form of a monthly dashboard, on the total number of 1st & 2nd trimester screening tests completed, the number of tests with a chance above the cutoff point, number of women with an increased chance result who are offered an appointment within 3 working days, diagnostic testing turnaround time and results of the diagnostic testing. Outcome of pregnancy is also recorded.

2.15.2 Data is collected on the 20 week anomaly scan referral process. Total number of women referred to fetal medicine (FM) department with a suspected/confirmed abnormality and whether they were seen within 3 working days. Diagnostic results turnaround time and results of the diagnostic testing.

2.13.3 These dashboard should be reviewed at the 6 monthly antenatal and newborn screening board and included in the annual report that is presented at the ‘Women’s, Children’s and Sexual Health’ divisional board and received by Public Health England Quality Assurance(QA) team.

2.16. Key performance indicators (KPI’s)
On a quarterly basis data will be submitted to Public health England on a KPI submission template. The current KPI submissions for the FASP programme are:
-  **FA1**: completion of laboratory request forms. This submission
relates to minimizing delays in reporting results due to incomplete/inaccurate completion of 1st and 2nd trimester screening request forms. The **Acceptable** standard for lab forms being submitted with complete data is 97%, the **Achievable** standard is 100%.

- **FA2:** Ultrasound coverage. This submission is the proportion of pregnant women eligible for fetal anomaly screening for whom a conclusive result is available within the designated time frame. The **Acceptable** standard is equal to or greater than 90%, the **Achievable** standard is equal to or greater than 95%. This standard requires matched cohort data and the follow up of any missing cohort to ensure women are not missed.

- **FA3:** Coverage for Downs, Edwards and Pataus syndrome. Thresholds are not set for this KPI as FASP supports informed choice for women. This KPI ensures service providers to be assured that all eligible women are offered the opportunity for screening and where this opportunity is accepted that women complete the screening pathway

### 2.17. Screening safety incidents:

- Is any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme

- harm or a risk of harm because one or more persons eligible for screening are not offered screening. ref: managing safety incidents in the NHS screening programmes. PHE August 2017

2.17.1 Any health profession identifying a FASP screening incident should report it using the RCHT datix reporting system. The datix will be reviewed by the screening team and if a screening incident is identified the screening team will complete a ‘Screening Incident assessment Form’ (SIAF) which is submitted to the QA team PHE.

2.17.2 The datix incident will be investigated and managed as per ‘Incident and Serious Incident policy’ RCHT April 2018

2.17.3 The screening team will identify the investigating officer for the SIAF investigation.
3. **Compliance monitoring and effectiveness**

<table>
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<tr>
<th>Element to be monitored</th>
<th>2.15 Data collection, audit and quality assurance</th>
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<tbody>
<tr>
<td>Lead</td>
<td>Antenatal and newborn screening coordinators</td>
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<td>Tool</td>
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<td>Frequency</td>
<td>Audit of data will be annually</td>
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<td>Reporting arrangements</td>
<td>Any recommendations will be monitored by the antenatal screening operational group which meets biannual. The results and outcome of the recommendations will be reported at the Antenatal and Newborn Screening Board and included in the Annual report.</td>
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<td>Acting on recommendations and Lead(s)</td>
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<tr>
<td>Change in practice and lessons to be shared</td>
<td>A member of the screening team will be identified as the lead for implementing recommendations and sharing them with the relevant health care professional.</td>
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4. **Equality and Diversity**

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

4.2. **Equality Impact Assessment**

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
### Appendix 1. Governance Information

<table>
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<td>Date Valid From:</td>
<td>From PRG</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>10th January 2022</td>
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<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Jeanne Clarkson, Antenatal and Newborn screening coordinator. Obs and Gynae directorate</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253092</td>
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<tr>
<td>Brief summary of contents</td>
<td>This guideline is for all health care professions involved in providing care for pregnant women. All health professions should ensure they are giving high quality information on screening, in a format to suit the individual woman's needs. They should ensure that all eligible pregnant women are offered screening to assess the chance of their baby being born with Downs syndrome (T21), Edwards syndrome (T18) and Pataus syndrome (T13) or a number of structural abnormalities that may affect the developing fetus</td>
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<td>Medical Director</td>
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<tr>
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<td>December 2018</td>
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<td>Care Group Manager</td>
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Name and Post Title of additional signatories | Not Required
---|---
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings | Original Copy Signed
Name: Caroline Amukusana
Signature of Executive Director giving approval | Original Copy Signed
Publication Location (refer to Policy on Policies – Approvals and Ratification): | Internet & Intranet ✓ Intranet Only
Document Library Folder/Sub Folder | Midwifery and Obstetrics
Links to key external standards | FASP programme standards March 2018
Fetal anomaly screening: Ultrasound practitioners handbook Oct 2018
FASP lab handbook for Downs, Edwards and Pataus September 2018
Related Documents: | Screening tests for you and your baby: Gov.UK July 2017
Training Need Identified? | Bespoke training as part of induction for new staff

### Version Control Table

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<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<td>V1.0</td>
<td>New Document</td>
<td>Jeanne Clarkson, Antenatal and Newborn Screening Coordinator</td>
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This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

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### Appendix 2. Initial Equality Impact Assessment Form

*This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.*

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<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Fetal Anomaly Screening for 1\textsuperscript{st} Trimester and 2nd Trimester Clinical Guideline v1.0</th>
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<td>Directorate and service area:</td>
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<td>Jeanne Clarkson</td>
<td>01872 253092</td>
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1. **Policy Aim**
   - *Who is the strategy / policy / proposal / service function aimed at?*
   
   For all Maternity Staff who advise and care for women regarding Fetal Anomaly Screening in the 1\textsuperscript{st} and 2\textsuperscript{nd} Trimester pregnant women.

2. **Policy Objectives**
   - *To ensure that all women are given the advice and care they need regarding Fetal Anomaly Screening in the 1\textsuperscript{st} and 2\textsuperscript{nd} Trimester.*

3. **Policy – intended Outcomes**
   - *To ensure that all women receive the correct advice and care regarding Fetal Anomaly screening in the 1\textsuperscript{st} and 2\textsuperscript{nd} Trimester.*

4. *How will you measure the outcome?*
   - Compliance Monitoring Tool

5. **Who is intended to benefit from the policy?**
   - All pregnant women

6a Who did you consult with

<table>
<thead>
<tr>
<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**b). Please identify the groups who have been consulted about this procedure.**

- Maternity Guidelines Group
- Obs and Gynae Directorate
- Divisional Board
- Policy Review Group
7. The Impact
Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy could have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Race / Ethnic communities / groups</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td></td>
<td></td>
<td>x</td>
<td>All pregnant women</td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or

Guideline agreed.
8. Please indicate if a full equality analysis is recommended.  | Yes | No | x
---|---|---|---
9. If you are not recommending a Full Impact assessment please explain why.

Not required.

<table>
<thead>
<tr>
<th>Signature of policy developer / lead manager / director</th>
<th>Date of completion and submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeanne Clarkson</td>
<td>November 2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Names and signatures of members carrying out the Screening Assessment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Jeanne Clarkson</td>
<td></td>
</tr>
<tr>
<td>2. Human Rights, Equality &amp; Inclusion Lead</td>
<td></td>
</tr>
</tbody>
</table>

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust’s web site.

Signed ___ Sarah-Jane Pedler __________
Date __________January 2019_________
Appendix 3. Fetal Anomaly Screening Pathway for 1st Trimester Bloods Fetal Medicine Unit

- Woman attends Early Dating Scan appointment
  - Patient scanned for CRL & NT (if screening required)
  - During scan sonographer confirms any previous chromosomal abnormalities with woman and completes in appropriate Viewpoint boxes

- Sonographer will confirm consent and enter screening choice and NT measurement

- Woman sent to phlebotomist
  - Patient weight and height assessed and recorded in Viewpoint

- Phlebotomist confirms with woman her smoking, alcohol, ethnicity, diabetes, IVF and parity status and updates patient medication details as necessary and enters into Viewpoint

- Patient bled
  - PID label, barcode and VP number put on specimen and work list.
  - Matching barcode on paperwork is then sent with bloods to Exeter Via biochemistry lab RCHT
  - Duplicate list of bloods with barcodes sent to Exeter then kept in phlebotomy room for cross referencing purpose and letter printing

- Scan barcode on sample
  - Request export from Viewpoint by:
    - Click File, Export (or Ctrl E)
    - Press OK
    - Press F12 to save

- Bloods taken to the Clinical Chemistry laboratory reception at the end of the session
  - Do NOT use the air tube system
Appendix 4.
Daily process for submitting bloods for 1st trimester screening to Clinical Chemistry from Fetal medicine service

1st Trimester screening samples and paperwork bought to the Clinical Chemistry Laboratory by Fetal medicine staff.

Fetal Medicine staff hand the samples and paperwork to the staff member at the reception window and sign the sheet in the blue folder. Clinical Chemistry staff sign the sheet in the blue folder to say they have received the samples.

No samples should be accepted without appropriate documentation (ie Sample List).

The person who has signed for the samples at reception then takes them to the named Downs Biomedical Scientist (BMS) in the manual lab and signs the tick list. The BMS then signs it to say they have been received.

SAMPLES MUST BE DEALT WITH IMMEDIATELY AND HAVE A COMPLETE CHAIN OF CUSTODY

(Samples to be passed from one person to the next with a signature at each stage)

If samples arrive late, if there is no BMS in the manual lab or if there are any other concerns about the process:

Discuss with the Duty Biochemist (or any Biochemist)

(NEVER LEAVE SAMPLES AT ROOM TEMP UNSPUN)
Appendix 5. SOP for the communication process between community midwives, Princess Alexandra wing and the Biochemistry Lab, RCHT when taking a Quad test for Trisomy 21

Woman presents for 1st trimester screening but unable to screen due to fetal lie.

Quad testing for T21 offered, if accepted refer back to community midwife to take sample from 14+2 weeks

Community midwife takes sample and sends on courier system. Community Midwife sends email to rch-tr.biochem@nhs.net, stating patient name and hospital number, date of sample and which area sample is coming from

Email received by lab reception. Emails midwife back to confirm receipt of the email, and forwards email to duty Biochemist. Biochemist enters details of the expected sample into lab Quad spreadsheet on

Sample taken by phlebotomist at PAW. Enter sample details into blue Quad folder and email rch-tr.biochem@nhs.net, stating patient name and hospital number, date of sample and where sample is coming from. Transfer sample to lab and enter on the sample receipt list.

Biochemist will check the Quad spreadsheet daily(Mon-Friday) to ensure any expected Quads arrive, enter Quad number and details onto the spread sheet, send sample to Newcastle and then check daily (mon-Friday) for the result.

Woman presents for 1st trimester screening but unable to screen due to gestation

Quad test for T21 offered. If accepted sample taken at PAW.

Community midwife offers Quad test for T21, if accepted arrange urgent dating scan and sample taken at PAW

Woman presents at booked with a gestation between 14+2-20+0
Appendix 6.

Reporting Process for T13/18/21 Samples

Following analysis of samples, Exeter Lab, will phone and email screening coordinators/administrator [ext. 3092] to report higher chance results and fetal medicine administrator [ext. 2682] with lower chance results.

Higher Chance result

Screening Coordinators will contact women and offer an appointment within 3 working days to discuss screening result

Lower chance result

On receipt of confirmation of completed analysis for a sample batch, fetal medicine administrator and/or phlebotomist will print out lower chance letters. Higher chance results are removed from reference list by the fetal medicine administrator.

To print lower risk letters

In Viewpoint, check lower risk results corresponds to patient demographics and screening choices

Click early pregnancy then maternal serum biochemistry then risk for aneuploidies then press F4

If woman has requested all screening, this letter will be available to print; simply tick the box and create

If woman has requested T21 only or T13/18 only, press print preview and change printer to print appropriate letter

Press F12 to print and complete
Appendix 7.
Reporting Process for T13/18/21 Samples

Following analysis of samples, Exeter Lab, will phone and email screening coordinators/administrator [ext. 3092] to report higher chance results and fetal medicine administrator [ext. 2682] with lower chance results.

**Higher Chance result**
- Screening Coordinators will contact women and offer an appointment within 3 working days to discuss screening result.

**Lower chance result**
- On receipt of confirmation of completed analysis for a sample batch, fetal medicine administrator and/or phlebotomist will print out lower chance letters. Higher chance results are removed from reference list by the fetal medicine administrator.

To print lower risk letters
- In Viewpoint, check lower risk results corresponds to patient demographics and screening choices.

If woman has requested all screening, this letter will be available to print; simply tick the box and create.

Press F12 to print and complete.
### Appendix 8.

18<sup>+</sup>0 to 20<sup>+</sup>6 FASP ultrasound scan base menu

<table>
<thead>
<tr>
<th>Structure/Area</th>
<th>Detail</th>
<th>Fetal Measurements*</th>
<th>Images/measurements to capture/archive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and neck</td>
<td>Head shape</td>
<td>*Head circumference (HC)</td>
<td>Yes, to include HC, measurement, CSP, posterior horn and measurement of the ventricular atrium at the level of the glomus of the choroid plexus</td>
</tr>
<tr>
<td>- Skull</td>
<td>Cavum septum pellucidum (CSP)</td>
<td>Measurement not required</td>
<td></td>
</tr>
<tr>
<td>- Brain</td>
<td>Ventricular Atrium (VA)</td>
<td>*Atrium of the lateral Ventricle</td>
<td></td>
</tr>
<tr>
<td>- Neck</td>
<td>Cerebellum</td>
<td>*Transcerebellar diameter (TCD)</td>
<td>Yes, to include measurement of the TCD in the suboccipitobregmatic view</td>
</tr>
<tr>
<td>- Nuchal Fold (NF)</td>
<td>Measure if appears large</td>
<td>Distance between the outer border of the occipital bone and the outer skin edge</td>
<td>Yes, if measurement ≥ 6mm</td>
</tr>
<tr>
<td>Facial Features</td>
<td>Coronal view of lips &amp; nasal tip</td>
<td>Measurement not required</td>
<td>Yes</td>
</tr>
<tr>
<td>Lungs</td>
<td>Visceral situs/laterality of heart</td>
<td>Measurement not required</td>
<td>No</td>
</tr>
<tr>
<td>- Heart</td>
<td>a) Four chamber view (FCV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b) Aorta (Ao) arising from left ventricle</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>c) Pulmonary artery (PA) arising from right ventricle, or the 3 vessel view (3VV)</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>d) 3 vessel and trachea view (3VT)</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Structure/Area</td>
<td>Detail</td>
<td>Fetal Measurements*</td>
<td>Images/measurements to capture/archive</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------------------------------</td>
<td>---------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Abdominal content</td>
<td>Stomach &amp; position</td>
<td>Measurement not required</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>*Abdominal circumference (AC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Short intra-hepatic section of the umbilical vein (UV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Abdominal wall and cord insertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diaphragm</td>
<td>Measurement not required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kidneys</td>
<td>Measurement not required unless renal pelvis AP diameter &gt;7mm</td>
<td>Yes, if AP renal pelvis diameter measures &gt;7mm</td>
</tr>
<tr>
<td></td>
<td>Measure AP renal pelvis diameter if it appears large</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bladder</td>
<td>Measurement not required</td>
<td></td>
</tr>
<tr>
<td>Spine</td>
<td>Vertebrae</td>
<td>Measurement not required</td>
<td>Yes, image either sagittal or coronal plane</td>
</tr>
<tr>
<td></td>
<td>Skin covering</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cervical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thoracic</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lumbar</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sacral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limbs</td>
<td>Femur, tibia &amp; fibula (both legs)</td>
<td>*Femur length</td>
<td>Yes, image and measure a single femur only</td>
</tr>
<tr>
<td></td>
<td>Metatarsals (both feet)</td>
<td>Digit count not required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radius, ulna, humerus (both arms)</td>
<td>Measurement not required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metacarpals (both hands)</td>
<td>Digit count not required</td>
<td></td>
</tr>
<tr>
<td>Uterine cavity</td>
<td>Placenta</td>
<td>According to local policy/protocol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amniotic fluid</td>
<td>According to local policy/protocol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uterine content</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>