FREEDOM OF INFORMATION ACT

I am responding to your request for information under the Freedom of Information Act. The answers to your specific questions are as follows:

1  Do you have a care pathway for expectant women who receive a screen positive result for Down syndrome? If so, please provide a copy/link.

   Yes, please see attached.

2  When a pregnant woman receives a screen positive result for Down syndrome is she referred for counselling? If so, to whom and when?

   East Sussex Healthcare NHS Trust has no specific referral pathway for a counselling appointment at this stage, however, the woman is offered further information and support from the screening midwives. This includes further information regarding the syndrome for which the screen positive result relates to, for example, the NHS website; The Downs Syndrome Association; local support groups; SOFTUK (Information relating to Edwards and Patau’s Syndrome). This information however is sometimes declined by women. Women are also informed of the charity Antenatal Results and Choices as a source of further information and support if required.

3  What training do the staff providing counselling have appertaining to a) providing counselling & b) knowledge of Down syndrome?

   The Trust does not have any mandatory training sessions for staff offering this support, either locally or nationally. However on entering the screening team, the role of individual team member is reviewed and where appropriate the staff member is referred for external training. For example: at the Tell it Right, Start it Right study days run by the Downs Syndrome Association; Antenatal Result and Choices Training days (Communication skills and delivering difficult news, Supporting parents’ decisions, When a prenatal diagnosis is made: Providing best care), and
specific training sessions relating to combined / quad screening at the laboratory that process our screening samples. In addition to this, staff have access to e-learning for health for completion of modules relating to all screening programs. Several members of the screening team also attended the Public Health England NIPT training days (x2) which included a vast amount of resources and training in relation to the three trisomies including hearing from parents.

If I can be of any further assistance, please do not hesitate to contact me.

Should you be dissatisfied with the Trust’s response to your request, please write to Lynette Wells, Director of Corporate Affairs, East Sussex Healthcare NHS Trust (lynette.wells2@nhs.net) quoting the above reference.

Yours sincerely

Linda Thornhill (Mrs)
Corporate Governance Manager
esh-tr.foi@nhs.net
Clinical Guidelines for First Trimester Ultrasound and Screening for Down’s, Edwards’ and Patau’s syndromes

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<td>Ratified by:</td>
<td>Women and Children’s Division</td>
</tr>
<tr>
<td>Date ratified:</td>
<td>January 2018</td>
</tr>
<tr>
<td>Name of author and title:</td>
<td>Specialist Midwife Antenatal and Newborn Screening</td>
</tr>
<tr>
<td>Date Written:</td>
<td>December 2017</td>
</tr>
<tr>
<td>Name of responsible committee/individual:</td>
<td>Chair of the Guideline Implementation Group for Maternity Services</td>
</tr>
<tr>
<td>Date issued:</td>
<td>April 2018</td>
</tr>
<tr>
<td>Issue number:</td>
<td>2018290</td>
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<tr>
<td>Review date:</td>
<td>January 2021</td>
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<td>Target audience:</td>
<td>All Staff</td>
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<td>National Screening committee key performance indicators.</td>
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<td>Clinical Guidelines for Obstetric Ultrasound in the Third Trimester</td>
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<td>Care of Women with Suspected or Identified Fetal Abnormality</td>
</tr>
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<td></td>
<td>Communication of Test Results in Maternity</td>
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<td>Clinical Guideline for the care of women with a Multiple Pregnancy</td>
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</tbody>
</table>

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## Version Control Table

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<th>Author</th>
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<td>V1 2011265 (8.23 Guidelines for First Trimester Ultrasound and Screening)</td>
<td>October 2011</td>
<td>Prabha Sinha,</td>
<td>New Guideline</td>
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<tr>
<td>V1.0 2015178</td>
<td>September 2015</td>
<td>Dexter Pascall, Nicky Roberts and Specialist Midwife</td>
<td>Review</td>
<td>Updated information regarding new guidance from the National screening committee</td>
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<td>V2 2018290</td>
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<td>Dexter Pascall, Nicky Roberts and Specialist Midwife</td>
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## Consultation Table

This document has been developed in consultation with the groups and/or individuals in this table:

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<tr>
<th>Name of Individual or group</th>
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<tr>
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<td>May 2011</td>
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<td>Obstetrics and Gynaecology</td>
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<tr>
<td>Women and Children’s Governance and accountability meeting</td>
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<td>March 2018</td>
</tr>
</tbody>
</table>
This information may be made available in alternative languages and formats, such as large print, upon request. Please contact the document author to discuss.

Table of Contents

1. Introduction ..................................................................................................................  4
2. Rationale ......................................................................................................................  4
3. Scope............................................................................................................................  4
4. Definitions ....................................................................................................................  4
5. Responsibilities and Accountabilities........................................................................ 5
   5.1. Midwives and Obstetricians .................................................................................  5
   5.2. Management .........................................................................................................  5
6. Process.........................................................................................................................  5
   6.1. Routine USS is offered at approx 12 weeks Gestation: ......................................  5
   6.2. Fetal anatomical check ......................................................................................  6
   6.3. Risk Assessment for Down’s, Edwards’ and Patau’s syndrome screening ....  6
   6.4. Serum screening – Quadruple Test .....................................................................  8
   6.5. Interpreter ..........................................................................................................  9
   6.6. Women booking too late for the Quadruple test ..............................................  9
   6.7. Women at low risk of Down’s, Edwards’ and Patau’s syndrome requesting an invasive test ............................................................  9
   6.8. Referral for invasive testing .............................................................................. 10
   6.9. Pre-test information ......................................................................................... 10
   6.10. Amniocentesis ............................................................................................... 11
   6.11. Result handling ............................................................................................ 11
       6.11.1. QF-PCR for the Major Trisomies ................................................................. 11
       6.11.2. Full karyotype ............................................................................................ 12
   6.12. Chorionic Villus Sampling (CVS) ................................................................. 12
   6.13. Pre-test Information .................................................................................... 12
   6.15. Screening in the Second Trimester Anomaly scan ........................................... 13
7. Evidence Base/References ....................................................................................... 13
8. Monitoring Arrangements ......................................................................................... 15
9. Equality and Human Rights Statement .................................................................... 16
Appendix A – Measurements for Pregnancy Dating at Different Gestations ........... 17
Appendix B – NT Measurements ............................................................................. 18
Appendix C – NT Screening ..................................................................................... 19
Appendix D – Ultrasound Payments ......................................................................... 20
Appendix E – EHRA Form ....................................................................................... 21
1. Introduction

All eligible women in their pregnancy are offered a first trimester ultrasound scan and screening for Down's, Edwards' and Patau's syndromes. Timings of when these are offered are in the guideline. The ultrasound scan service and screening for Down's, Edwards' and Patau's syndrome which is offered reflects evidence based recommendations following National Institute for Health and Clinical Excellence (2008) Antenatal Care: Routine care for the healthy pregnant woman and '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 and NHS England Public Health Commissioning, April 2017.

2. Rationale

The first trimester ultrasound scan and Down’s, Edwards’ and Patau’s syndrome screening aims to:

- Offer all eligible women a first trimester ultrasound scan and screening for Down’s, Edwards’ and Patau's syndromes
- Provides a service which meets national recommendations
- Provides appropriate, accessible information in a range of formats for women to enable them to make an informed choice about their screening options and management
- Provides a pathway including the management of care and options available to the woman if abnormalities are detected and the way in which results are communicated

3. Scope

To provide Guidance for professional staff within the obstetric department; midwives, sonographers and medical staff in Obstetrics and Gynaecology

These guidelines consider that staff ensure the patient has an understanding of the screening offered, even if English is not their first language. Assessment of their mental capacity may be indicated.

4. Definitions

**Dichorionic**- In relation to multiple pregnancy – two chorion’s are present

**EDD** - Expected date of delivery

**EPAU** - Early pregnancy assessment unit

**IVF** - In vitro fertilisation

**LMP** - Last Menstrual period

**MCDA - Monochorionic Diamniotic**

Within multiple pregnancies, one chorion, and two amnions – these are the membranes that surround the baby/babies while in the uterus

**Monochorionic**- In relation to multiple pregnancy – one chorion is present
USS - Ultra Sound Scan

5. Responsibilities and Accountabilities

5.1. Midwives and Obstetricians

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

5.2. Management

- To ensure the guideline is reviewed as required in line with the Trust and National guidelines
- To ensure the guideline is accessible to all relevant staff
- To monitor the audit process

6. Process

6.1. Routine USS is offered at approx 12 weeks Gestation:

Purpose of USS at this time:

- Assessment of viability
- An accurate assessment of gestational age
- The early detection of multiple pregnancies
- Assessment of chorionicity and amnionicity (i.e. presence of Lambda or ‘T’ sign:)
- Lambda sign indicates a dichorionic pregnancy
- ‘T’ sign indicates a monochorionic pregnancy
- Limited fetal anatomy assessment
- Risk assessment for Down’s, Edwards’ and Patau’s syndrome: combined test.

Assessment of viability

Delayed miscarriage

Women with findings of a delayed miscarriage or other early pregnancy problems should be referred to the early pregnancy unit (EPAU).

An accurate assessment of gestational age

All pregnancies will now be dated using ultrasound parameters only (not LMP) LMP will only be used in pregnancies where the woman declines ultrasound scanning.

All pregnancies: The Crown–rump length (CRL) measurement should be used to determine gestational age between 10 and 13 weeks and 6 days to determine gestational age, if however the measurement is above 84mm the gestational age should be estimated using Head Circumference

IVF: For IVF pregnancy, please use the EDD given by the IVF unit based on date of egg collection. If an egg donor is used, please use the donor DOB or age for the Down’s, Edwards’ and Patau’s syndrome risk calculation

Twins dating: To date twin pregnancies the largest CRL will be used to calculate the EDD
Please see Appendix A for ‘MEASUREMENTS FOR PREGNANCY DATING AT DIFFERENT GESTATIONS’ table.

Early detection of multiple pregnancies and assessment of chorionicity and amnionicity (ie presence of Lambda or ‘T’ sign):

The lambda or T signs should be used to assess chorionicity in cases of multiple pregnancy. Twins should be called A and B and their location, and particularly sac location, should be clearly documented. Refer to consultants undertaking the high risk ultrasound scan lists on the two acute sites if there is any doubt regarding chorionicity as soon as possible.

Monochorionic twin (see under MCDA twins) pregnancies should be referred to the consultants undertaking the high risk ultrasound scan lists on the two acute sites for the rest of pregnancy. Referral should be made as soon as the diagnosis is made (if unsure then review at 15-16 weeks). The amniotic fluid, bladder size, and free floating membrane should be assessed and documented (look also at CRL and NT discrepancy). They will make individualized plans usually offering 2-3 weekly scans. From 28/40 gestation scans may be undertaken in the obstetric ultrasound department as part of routine scanning clinics. For further information see 2.17 Multiple Pregnancy

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 test of NT, PAPP-A and free beta HCG can be used to calculate the risk. If ultrasound shows that there is a second sac containing a dead fetus (sometimes called ‘vanished’ twin), it is possible that there could be a contribution to the maternal biochemical markers for many weeks. Royal College of Obstetricians and Gynaecologists recommend that in this event the screening laboratory services undertake the risk calculation based on the maternal age and nuchal translucency only (i.e. without biochemistry) which complies with NHS screening programmes

6.2. Fetal anatomical check

The cranial vault should be clearly visualized to exclude anencephaly. The following fetal anatomy should be reviewed and assessed as normal for the gestation:- skull/brain, abdominal wall, and four limbs,. It should be made clear to the woman that normal appearances at this scan are reassuring but will be reviewed fully at the 20 week scan according to National Screening Committee standards.

6.3. Risk Assessment for Down’s, Edwards’ and Patau’s syndrome screening

Combined test: which is the recommended screening test in the first trimester:

See Appendix B

This involves combining the following 3 markers:

- Measurement of nuchal translucency from ultrasound scan
- PAPP-A (Pregnancy associated plasma protein-A) substance in the maternal blood used as biochemical marker
- Free β-hCG (Free β-human chorionic gonadotrophin) substance in the maternal blood used as a biochemical marker
During the first contact or pre-booking visit with the midwife, verbal and written information about the first trimester scan and screening for Down’s, Edwards’ and Patau’s syndromes is given to the woman.

First trimester combined screening for Down’s, Edwards’ and Patau’s syndrome, is offered to all eligible women booking at ESHT when the fetal crown-rump length is between 45 and 84mm (approximately 11+2 and 14+1 weeks’ gestation). Women booking too late for the combined test are offered the quadruple test (maternal serum screening) in the second trimester. This can be offered from 14+1 to 20+0 weeks.

The CRL should be measured according to the approved national guidelines see Appendix A. The measured image of the CRL should be recorded. If the CRL is less than 45mm a repeat NT screening appointment should be offered in the ultrasound department. If the NT cannot be measured at the first attempt, a second appointment is offered in the ultrasound department. If the NT cannot be measured after the second attempt the woman can be referred to the consultants undertaking the specialist scan service provided there is sufficient capacity. If there is no availability then the woman is offered the quadruple test.

Nuchal translucency (NT) screening should only be performed and reported by sonographers who are accredited by DQASS. Non-accredited sonographers must be supervised by an accredited sonographer who is responsible for producing and countersigning all reports.

If the NT measurement is 3.5mm and greater the woman is offered bloods for first trimester screening and referred to the Specialist Midwives for Screening for a discussion of the implications of this result and referral to the consultants undertaking the specialist scan lists.

If the CRL is <=7mm and/or a missed miscarriage is suspected, please refer to Early Pregnancy Unit.

Women with a multiple pregnancy can be offered screening. The serum marker levels are always raised and adjustments are made to take account of this by the screening laboratory.

For DCDA twin pregnancies Down’s, Edwards’ and Patau’s syndrome screening is based on a NT fetus based risk assessment (where only the NTs are measured). In this case the screening request form is completed with ‘NT based risk assessment only’ included and emailed to the screening laboratory email nhs.net email account by the sonographer. For MCDA or MCMA twin pregnancies the combined test can be offered.

An appointment can also be offered to discuss screening for multiple pregnancies further with the consultant / specialist midwife for screening if requested.

The Down’s, Edwards’ and Patau’s syndrome screening programme is overseen by the Specialist Midwife for Screening. The practitioner booking the screening test for the woman is responsible for explaining it to her, via an interpreter if required, and must ensure that the woman has enough information to make an informed decision on whether or not to accept the offer of screening and proceed with the test. The woman’s choice to decline or accept screening is documented in the pregnancy record. The woman must also sign the consent form accordingly.

Information explaining the combined test is available from the Woman’s Pregnancy Health record, the NHS Screening Programme booklet (2017) ‘Screening tests for you and your baby’, and the Wolfson Institute of Preventive Medicine at (www.wolfson.qmul.ac.uk/epm/screening), which is provided to women at or prior to the booking appointment by the community midwifery team. Local information is available on
the trust intranet. The examination should only be performed after the parents have given written consent to have screening for Down’s, Edwards’ and Patau’s syndromes. Patient details including full name and date of birth should be checked before starting the examination.

Nuchal translucency (NT) screening should only be performed and reported by sonographers who are accredited by DQASS. Non-accredited sonographers must be supervised by an accredited sonographer who is responsible for producing and countersigning all reports.

After the woman has had her first trimester scan, maternal blood for the combined test is taken in the phlebotomy department where 5ml of blood is taken in an Ocre (gold top) tube. This must be taken first if more than one blood sample is being taken to avoid EDTA contamination in the other vacutainers

The blood is sent to an external laboratory by the pathology department with the completed request form including the following essential information that will correctly identify the woman and provide the most accurate risk assessment:

- Correct maternal demographics
- Gestational age determined by ultrasound and expected date of delivery
- Sonographers code
- Smoking status (if yes or formerly, how many and date stopped)
- Maternal weight on day sample was taken
- Family origin or ethnicity
- Diabetic (yes/no)
- Single or multiple pregnancy and note of fertility treatment (e.g; donor egg or IVF and donor’s date of birth)

### 6.4. Serum screening – Quadruple Test

The quadruple test is offered to all women where the CRL is greater than 84mm (usually around 14 weeks+2 days gestation and who have not had combined screening performed but request screening for Down’s syndrome. The test involves taking a maternal blood sample from 14+2 – 20 weeks +0 days.

The HC or FL should be measured according to the approved national guidelines see Appendix A. It is the responsibility of the practitioner offering the test to make sure that the nature and purpose of the test has been explained to the woman. The quadruple test form should be fully completed and given to the woman together with the ‘The Quadruple Test’ leaflet.

The quadruple test can only be carried out accurately when the dates of the pregnancy are known. Therefore, all women having the quad test must first have an ultrasound scan performed. The bloods are taken as for combined bloods

The sample is analysed by the screening laboratory and a chance that is higher or lower is determined using a cut-off of 1:150 for both first and second trimester screening.

The quadruple test can also be offered to women with a twin pregnancy and the guidance should be followed according to the leaflet ‘Twin Pregnancies: second trimester screening for Down’s syndrome (T21) Information for health professionals.

Lower chance (screen negative) results

The screening team receive results electronically from the screening laboratory via the generic screening results nhs.net mail-box: esh-tr.ScreeningResults@nhs.net. This is accessed every weekday. Women with lower chance results will be sent a letter informing them of the result. They are requested to place this result in their pregnancy record. The result is sent within two weeks of the test being taken. The results are then entered manually on the combined screening results excel spreadsheet in the screening folder on the ESHT shared drive. It is also sent to the community midwife to ensure the result is placed into the woman’s pregnancy record. No further action is indicated.

Higher chance (screen positive) results

The screening team receive higher chance results electronically from the screening laboratory via the generic screening results nhs.net mail-box: esh-tr.ScreeningResults@nhs.net. This is accessed every weekday and the screening team confirm receipt of the higher chance result with the external laboratory by email and/or telephone. All women with higher chance results (screen positive) will be telephoned within 3 working days of the sample being received and offered an appointment to discuss the result with the specialist midwife for screening and/or the consultant after liaising with the community midwife. All options will be discussed including:

- To have no further testing
- Offered diagnostic testing (refer to 6.8 onwards). This option should be offered within three working days of receiving the screening test results.

All women having serum screening are advised to contact their community midwife or the specialist midwife for screening if they have not had their result within 14 days of being tested.

6.5. Interpreter

Any woman who does not speak fluent English should be accompanied by an interpreter. Children less than 16 years of age are not acceptable as interpreters. A telephone interpreter should be used for providing information about screening but a face to face interpreter should be arranged if the woman receives a higher chance screening result. Interpreting services can be arranged by completing and submitting the trust intranet interpreting services referral form electronically.

Report: Use First Trimester screening Report, A copy of the ultrasound report should be fixed in the woman’s pregnancy record. If she has no notes the women should be instructed to take the report to her midwife or GP.

6.6. Women booking too late for the Quadruple test

If a woman books too late for screening by the quadruple test she is not eligible for screening. An urgent ultrasound scan in the ultrasound department should be arranged.

6.7. Women at lower chance of Down’s, Edwards’ and Patau’s syndrome requesting an invasive test

The trust policy is to offer all eligible women screening for Down’s, Edwards’ and Patau’s syndrome, regardless of their age. The screening test used is as described above and no further testing is indicated if the result is lower chance. The woman can be offered a further
appointment with the Specialist Midwives for screening and/or consultant if she wishes to have a further discussion about her result or requests invasive testing. All screening tests take into account maternal age when calculating the chance to that pregnancy so age **should not** be seen as a separate issue.

Please refer to the combined test pathway in Clinical Guideline for Routine Care for Healthy Pregnant Women for the management of women with a high-chance result.

The Specialist Midwives for screening and or consultant will provide information to the woman and her partner about Down’s, Edwards’ and Patau’s syndromes, the implications of the screening result, the screening pathway for lower chance results i.e. that she is not eligible for invasive testing within the pathway and the risks of invasive testing.

### 6.8. Referral for invasive testing

Specialist tertiary centres used in ESHT are Guy’s and St Thomas’s Hospital or King’s College Hospital where quantitative fluorescence polymerase chain reaction (QF-PCR), full karyotyping or CGH array is offered for pre-natal diagnosis. Sample collection for the test is performed by chorionic villus sampling (CVS) between 12 and 15 weeks +6 days or amniocentesis following 16 weeks gestation. Multiple pregnancies are conducted in accordance with the NICE clinical guideline 129. Multiple pregnancy: The management of twin and triplet pregnancies in the antenatal period. September 2011

It is essential that the **blood group** of women having invasive tests is known prior to the test because of the risk of isoimmunisation. The professional requesting the appointment should ensure the result is emailed with the referral form to avoid repeat blood test and delay in administration of Anti D. It is also essential that the antenatal serology is known prior to the test and recorded on the referral. If a woman is **HIV and or Hepatitis B positive** there is a risk of transmission to the fetus during an invasive procedure. This should be discussed in the first instance with her consultant and a plan made to minimise the risk of transmission. This may require anti-retroviral therapy prior to testing so should be done as soon as the woman requests an invasive test to minimise delay.

It is the responsibility of the Specialist midwife and or consultant for screening to check whether a woman who has been referred for an invasive procedure has been tested for HIV and to email the result. The tertiary specialist centre should be informed if the woman is HIV and or Hepatitis B positive to allow counselling about the risks to the fetus.

Any woman not speaking fluent English should have a professional interpreter booked for her appointment and this request should be indicated as a requirement on the referral form.

The tertiary specialist centre is also informed about any safeguarding concerns about the patient.

### 6.9. Pre-test information

Specialist Midwives for Screening provide pre-test information to ensure the woman is aware of the purpose, benefits, limitations, implications of undergoing an invasive test, how the results are communicated, what the results will tell them and the options that are available to them on the basis of these results, including:

- There is a 1% risk of miscarriage which may occur up to 6 weeks after the procedure although the majority will be within 2 weeks
• Miscarriage may be heralded by persistent pain, bleeding, amniotic fluid leakage or infection and the woman should be advised to report signs of these to her local acute unit where she has booked her maternity care.

• Where an invasive test is proposed at 22 weeks or beyond specific mention should be made of the possibility of a live birth resulting in a neonatal death or a live but impaired infant.

• Invasive testing is performed using continuous direct ultrasound guidance by an experienced clinician

The information booklet about CVS and amniocentesis is provided: NHS Fetal Anomaly Screening Programme, Chorionic villus sampling (CVS) and amniocentesis: information for parents Public Health England 2017 (PHE publications gateway number: 2016570). Directions to the specialist tertiary centre are also provided. Women are also offered an appointment to see the consultant prior to referral.

6.10. Amniocentesis

Amniocentesis is performed from 16 weeks onwards (greater risk of miscarriage if performed earlier).

6.11. Result handling

Results are telephoned by the fetal medicine midwives in the specialist tertiary centre directly to the woman unless she requests otherwise and then an individualised plan is made.

6.11.1. QF-PCR for the Major Trisomies

QF-PCR is attempted in all cases to test for trisomies 21, 18 and 13 with results taking about three to five working days. It is now the standard single test offered for diagnostic testing subsequent to a high-risk screening result (see below). Occasionally this test will not be possible (e.g. if sample is heavily bloodstained) and in such cases the laboratory will inform us that a rapid result will not be available and in that situation cellular culture will be set up and karyotyping attempted. PCR identifies number of copies of chromosomes 21, 18 and 13 and can confirm a normal number for these chromosomes (2 copies of each) and therefore exclude the major trisomies (Trisomy 21, 18 and 13). It is considered to be a suitable standalone test in cases, which primarily are at risk for a major trisomy. These include:

1) Chance equal to or greater than 1:150 for Down’s, Edwards’ and Patau’s syndromes on 1st trimester screening test
2) Chance equal to or greater than 1:150 for Down’s, Edwards’ and Patau’s syndrome on a 2nd trimester screening test
3) Increased nuchal translucency where the measurement is equal to or greater than than 3.5mm
   4) Incidental chromosomal testing in conjunction with a primary molecular indication
   5) Or, as part of a testing for cases of fetal abnormality

If the result is normal she will be phoned and informed. She will receive the result via the community midwife and by post from the tertiary centre and continue with the pregnancy. The outcome will be entered onto the excel referral spreadsheet to close the screening episode
If the result is **abnormal**, the Fetal medicine Midwives in the specialist tertiary centres telephone the specialist midwives for screening or the consultant to make an individual plan to action the result with the appropriate follow up. The woman will be provided with all the information about the result and given the opportunity to discuss the results with health professionals who are knowledgeable about Down’s, Edwards’ and Patau’s syndromes. This will include the offer of a termination to end the pregnancy. If the woman continues the pregnancy the outcome is obtained. If she ends the pregnancy the termination is undertaken in line with the Abortion Act 1967.

6.11.2. **Full karyotype**

The full karyotype result will only be performed by the cytogenetic laboratory if:

- Nuchal translucency is equal to or greater than 3.5mm
- Fetal abnormalities detected
- Intrauterine growth restriction detected
- Considered if the screening result is equal to or below 1 in 50 depending on the clinical findings

This result is available 2-3 weeks after the test and a copy is sent to the specialist screening midwives.

6.12. **Chorionic Villus Sampling (CVS)**

Chorionic villus sampling (CVS) is performed from 12 weeks to 15+6 weeks as obtaining an adequate sample may be more difficult at later gestations.

Women considering CVS to exclude Down’s, Edwards’ and Patau’s syndromes should be given the appropriate information prior to the procedure, as stated above.

Women having CVS for genetic diagnosis should be referred to the genetics department prior to the procedure. Results of prenatal genetic diagnosis where the woman has seen a genetic counsellor are usually given by them unless specifically arranged otherwise.

The result from the CVS will be communicated in the same way as for amniocentesis.

6.13. **Pre-test Information**

CVS is almost always performed by the transabdominal (TA) route. The transcervical (TC) route is rarely performed due to a higher rate of miscarriage.

The discussion should also include:

There is a 1 in 1000 risk of the PCR and full karyotype results being different if both tests are performed.

This can arise when there is placental mosaicism. In this situation the karyotype of the fetus cannot be predicted with certainty although more information may be obtained by amniocentesis. It is particularly important to remind women with an **apparently structurally normal fetus and an abnormal PCR result** that there is a 1 in 1000 chance the PCR result may be inconclusive, and so the laboratory will await the culture and full karyotype and **so the woman would be advised to await this result**. If the full karyotype shows a different result to the PCR this may indicate that the abnormality is confined to the placenta but may not be present in the fetus. Subsequent amniocentesis may be offered in this situation.
6.14. Fail-safe process

To ensure that all eligible women who request Down’s, Edwards’ and Patau’s syndrome screening receive a result the following fail-safe process is in place:

- Weekly down-loads of all those women booking at ESHT for their pregnancy care are received electronically by the screening team. All women who book in this trust are recorded on the maternity IT system at their booking appointment with their community midwife. This list is then checked against their dating and/or first trimester scans where the decision of whether or not screening is requested, is recorded. The screening clerk then checks if a result is available for all those women who requested screening. These lists are held on the ESHT shared screening drive.

- The screening clerk generates a list of all those women where there is no screening result. A letter is sent to the woman and copied to the community midwife and GP. The letter states that no result has been received and offers the woman the opportunity to have Down’s, Edwards’ and Patau’s syndrome screening with details of how to arrange the test. The letter also states that if the woman has not contacted the screening midwives or community midwife within 2 weeks of the letter being sent then it will be assumed that she has declined screening and records are documented accordingly.

6.15. Screening in the Second Trimester Anomaly scan (Please refer to the Clinical Guidance for Second Trimester Obstetric Ultrasound)

All women will be offered a second trimester ultrasound scan. The purpose of this scan is to identify structural abnormalities, check fetal viability, and assess placental site and liquor. Documentation of any fibroids/ovarian cysts noted. This should ideally be performed at 20 weeks; however 18-23 weeks is acceptable. The following measurements will be taken: HC, AC and FL.

Assessment of the following is required: Skull, brain, face, thorax, heart and outflow tracks, diaphragm, stomach, abdomen, kidneys, bladder, cord insertion and detail, legs and feet, arms and hands, and spine.

Fetal sexing is not part of the scan but if parents wish to know the gender of their baby and the sonographer can visualize the genitalia it should be explained that this is a professional opinion only.

If the scan and information required cannot be completed during a repeat scan by 23 weeks gestation then please refer to consultants undertaking the specialised scan lists.

7. Evidence Base/References


Screening programmes Fetal Anomaly. Programme Statement. Considerations relating to the biochemical component of the combined screening test for Down’s syndrome in the first trimester January 2010

Replace with https://www.gov.uk/topic/population-screening-programmes/fetal-anomaly

NICE clinical guideline 129: Multiple pregnancy: The management of twin and triplet pregnancies in the antenatal period Issued: September 2011
### 8. Monitoring Arrangements

#### Document Monitoring Table

<table>
<thead>
<tr>
<th>Element to be Monitored</th>
<th>Lead</th>
<th>Tool for Monitoring</th>
<th>Frequency</th>
<th>Responsible Individual/Group/Committee for review of results/report</th>
<th>Responsible individual/group/committee for acting on recommendations/action plan</th>
<th>Responsible individual/group/committee for ensuring action plan/lessons learnt are Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual screening audit alongside KPI.</td>
<td>Specialist Midwife for Antenatal and neonatal screening</td>
<td>Data document provided by UK national screening committee</td>
<td>Annually</td>
<td>This is completed by the Specialist Midwife for Antenatal and neonatal screening and presented to obstetrics and gynaecology audit meeting, National screening committee</td>
<td>Clinical Unit lead and Head of Midwifery, Ultrasound Lead, Specialist Midwife for Antenatal and neonatal screening</td>
<td>Clinical Unit lead and Head of Midwifery, Ultrasound Lead, Specialist Midwife for Antenatal and neonatal screening, through mandatory training etc</td>
</tr>
</tbody>
</table>
9. Equality and Human Rights Statement

An Equality and Human Rights Analysis Form has been completed for this document. Please see Appendix E.
# Appendix A – Measurements for Pregnancy Dating at Different Gestations

## MEASUREMENTS FOR PREGNANCY DATING AT DIFFERENT GESTATIONS

<table>
<thead>
<tr>
<th></th>
<th>Ideal Measurement to obtain EDD</th>
<th>Other measurement to obtain EDD</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;9 weeks</td>
<td>CRL</td>
<td>Do not enter LMP</td>
<td>Indicate on report approximate gestation (free text) e.g. 5-6 weeks 6-7 weeks and then report that ‘formal EDD will be given at the booking 12 week scan’.</td>
</tr>
<tr>
<td>9-14 weeks</td>
<td>CRL</td>
<td>Do not enter LMP</td>
<td>No further action</td>
</tr>
<tr>
<td>14-25 weeks</td>
<td>Use LMP if known and correlates with measurements (i.e. within 3rd and 97th centiles) otherwise date by HC</td>
<td>HC, if fetal position difficult use FL</td>
<td>No further action</td>
</tr>
<tr>
<td>&gt;25 weeks</td>
<td>As for 14-25 weeks but note on report due to late gestation dating is less accurate</td>
<td>HC, if not possible use FL</td>
<td>All patients scanned after 25 weeks that are re-dated or no LMP will require a growth scan 4 weeks later to confirm Ultrasound EDD</td>
</tr>
</tbody>
</table>

**N.B.**
- For IVF pregnancies use egg collection date to calculate EDD
- For multiple pregnancies use the above protocol and use the largest CRL to calculate EDD

References:
BMUS (2008)
NICE (2008)
Appendix B – NT Measurements

1 NT measurement:

1.1 An optimal measurement of the NT should be obtained from three different images. Ideally the three NT measurements should differ by no more than 0.2mm. The largest of the values should be used. The three images should be recorded and stored. If the optimal measurement cannot be obtained either transabdominally or transvaginally a repeat NT appointment should be offered. If no appointment is available with the sonographer the consultants undertaking the high risk ultrasound scan lists on the two acute sites should be contacted. The woman should then follow appendix in Care of Women with Suspected or Identified Fetal Abnormality.

2 Measurement of Nuchal Translucency

2.1 The fetal crown-rump length should be between 45 and 84mm. A good sagittal section of the fetus must be obtained, with the fetus horizontal on the screen. The correct view is a clearly visualized fetal profile. The fetus should be in a neutral position, with the head in line with the spine, not hyper-extended or flexed. Ideally only the fetal head and upper thorax should be included. The magnification should be as large as possible and ALWAYS such that each slight movement of the callipers produces only a 0.1mm change in the measurement. The widest part of translucency must always be measured.

2.2 Measurements should be taken with the inner border of the horizontal line of the callipers placed ON the line that defines the nuchal translucency thickness – the crossbar of the calliper should be such that it is hardly visible as it merges with the white line of the border, not in the nuchal fluid.

2.3 In magnifying the image (pre or post freeze zoom) it is important to turn the gain down. This avoids the mistake of placing the calliper on the fuzzy edge of the line which causes an underestimate of the nuchal measurement. Do not use tissue harmonic imaging for measurement of nuchal translucency because this thickens the lines and underestimates the measurement. Care must be taken to distinguish between fetal skin and amnion.

3 NT ≥3.5mm: Women with an NT measurement of 3.5mm or greater will activate Guideline 8.17 Care of Women with Suspected or Identified Fetal Abnormality, and her care should follow the relevant pathway.

3.1 Women with known twin pregnancies can be offered the combined test. Women with ‘vanished twin syndrome’ cannot be offered the combined test but can be offered a risk assessment based on the nuchal translucency measurement.
Appendix C – NT Screening

<table>
<thead>
<tr>
<th>Nuchal Translucency</th>
<th>Chromosomal Defects</th>
<th>Normal Karyotype Fetal death</th>
<th>Major fetal anomalies</th>
<th>Alive and well</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 95&lt;sup&gt;th&lt;/sup&gt; centile</td>
<td>0.2%</td>
<td>1.3%</td>
<td>1.6%</td>
<td>97%</td>
</tr>
<tr>
<td>95&lt;sup&gt;th&lt;/sup&gt;-99&lt;sup&gt;th&lt;/sup&gt; centile</td>
<td>3.7%</td>
<td>1.3%</td>
<td>2.5%</td>
<td>93%</td>
</tr>
<tr>
<td>3.5 - 4.4 mm</td>
<td>21.2%</td>
<td>2.7%</td>
<td>10.0%</td>
<td>70%</td>
</tr>
<tr>
<td>4.5 – 5.4 mm</td>
<td>33.3%</td>
<td>3.4%</td>
<td>18.5%</td>
<td>50%</td>
</tr>
<tr>
<td>5.5 – 6.4 mm</td>
<td>50.5%</td>
<td>10.1%</td>
<td>24.2%</td>
<td>30%</td>
</tr>
<tr>
<td>≥ 6.5 mm</td>
<td>64.5%</td>
<td>19%</td>
<td>46.2%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Table 1: View point fields to be completed during NT examination

<table>
<thead>
<tr>
<th>Primary Field</th>
<th>Secondary Field</th>
<th>Option to be selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt details</td>
<td>Name; Other name; Date of Birth; Address</td>
<td></td>
</tr>
<tr>
<td>Indication</td>
<td>Department; Type of Scan</td>
<td>First Trimester Screening</td>
</tr>
<tr>
<td>First trimester (for NT or delayed miscarriage)</td>
<td>Department; Operator; Supervised by; U/S system; Scanned; View; Gest Age Findings – use drop down menu on viewpoint or free text</td>
<td>Fetal heart activity CRL; NT; Skull/brain Abdominal wall Four limbs</td>
</tr>
<tr>
<td>Growth (when &gt;14)</td>
<td>Department; Operator; Supervised by; U/S system; Scanned; View; Gest Age Early anatomical check Findings: Use drop down menu or free text as appropriate. Offer screening for Down’s syndrome in second trimester if too late for first trimester screening. Offer anomaly scan at 20 weeks.</td>
<td>HC; AC; FL Fetal heart activity Fill in early anatomical check as above Appropriate report</td>
</tr>
</tbody>
</table>

Conclusions

Table 2: Information to be included in discussion and the report template can be used following NT screening

<table>
<thead>
<tr>
<th>Maternal age risk of Tri 21</th>
<th>Adjusted risk of Tri 21</th>
<th>To be included in discussion</th>
<th>View point report template</th>
<th>Anomaly scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>NT ≥ 3.5mm</td>
<td>Risk of major fetal anomalies increased by 10%</td>
<td>Refer to Guideline 8.17 Care of Women with Suspected or Identified Fetal Abnormality</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix D – Ultrasound Payments

Ultra sound Payments

This Appendix advice is Relevant to:

All sonographers undertaking ultrasound scans at 12 and 21 weeks gestation, O & G Divisional Management team.

Process to Follow:

The agreed price for 3 photographs is £5. These will only be offered at the 12 and 21 week scans.

No scan photographs will be provided free of charge.

No change will be given by the receptionist.

Information relating to the cost of the scan pictures and how to pay, including the fact that change cannot be given, will be distributed in the early pregnancy information by community midwives and will included in the hand held maternity records.

Posters in the department will advertise all the above information.

The receptionist at the clinic will take the £5 from any woman wishing to purchase her scan pictures and issue a raffle ticket as proof for the sonographers to issue the pictures.

The remaining raffle ticket will stay in the cash box as proof of how many pictures have been purchased.

If a woman has no money on day of scan, the pictures can be put in an envelope and they can return for the pictures at a later date.

The cash box will be secured under the desk in the clinic.

The cash must be taken to the cashiers every lunchtime, to ensure minimal amount left in department over night.
**Title of document:** Clinical Guidelines for First Trimester Ultrasound and Down’s syndrome Screening

**Who will be affected by this work?** E.g. staff, patients, service users, partner organisations etc. Staff

**Please include a brief summary of intended outcome:**
All eligible women in their pregnancy are offered a first trimester ultrasound scan and screening for Down’s syndrome. Timings of when these are offered are in the guideline. The ultrasound scan service and screening for Down’s syndrome that is offered reflects evidence based recommendations following National Institute for Health and Clinical Excellence (2008) Antenatal Care: Routine care for the healthy pregnant woman and the UK National Screening Committee guidance for Down’s syndrome screening, Model of Best Practice 2011-2014.

<table>
<thead>
<tr>
<th>Does the work affect one group less or more favourably than another on the basis of: (Ensure you comment on any affected characteristic and link to main policy with page/paragraph number)</th>
<th>Yes/No</th>
<th>Comments, Evidence &amp; Link to main content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Disability (including carers)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Religion &amp; Belief</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>yes</td>
<td>Only pregnant women can have a screening USS performed</td>
</tr>
<tr>
<td>Sexual Orientation (LGBT)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pregnancy &amp; Maternity</td>
<td>yes</td>
<td>All pregnant women are offered all screening available in pregnancy</td>
</tr>
<tr>
<td>Marriage &amp; Civil Partnership</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Gender Reassignment</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Other Identified Groups</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

| Is there any evidence that some groups are affected differently and what is/are the evidence source(s)? | No | (Ensure you comment and link to main policy with page/paragraph number) |

| What are the impacts and alternatives of implementing / not implementing the work / policy? | The guideline follows National Screening Committee guidance on offering pregnant women for screening, if this was not followed there would be a higher incidence of undiagnosed high risk pregnancies which does not give parents informed choice about wishing to continue with the pregnancy or not. |

<p>| Please evidence how this work / policy seeks to “eliminate unlawful | All women are offered the same screening information and testing if they |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.</strong> Please evidence how this work / policy seeks to “advance equality of opportunity between people sharing a protected characteristic and those who do not” as per the Equality Act 2010?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>6.</strong> Please evidence how this work / policy will “Foster good relations between people sharing a protected characteristic and those who do not” as per the Equality Act 2010?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>7.</strong> Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and staff are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)</td>
<td>All women are offered the same testing at the beginning of the pregnancy -</td>
</tr>
<tr>
<td><strong>8.</strong> Please evidence how have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available?</td>
<td>(Ensure you comment and link to main policy with page/paragraph number)</td>
</tr>
<tr>
<td><strong>9.</strong> Have you have identified any negative impacts or inequalities on any protected characteristic and others? (Please attach evidence and plan of action ensure this negative impact / inequality is being monitored and addressed).</td>
<td>No</td>
</tr>
</tbody>
</table>