

## MATERNITY GUIDELINES

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### Dealing with Results of Screening and Diagnostic Tests

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#### 1. Statement

Giving results of investigations and diagnostic procedures to women should be dealt with sensitively, especially when there may be bad news. Midwives and medical staff need to be aware of this and to respond appropriately. Staff should ensure that they understand the results that they are conveying sufficiently so that they can explain and answer any questions that the woman might raise. They should also familiarise themselves with the woman's history and the reasons why the test was performed.

The following guidelines identify general issues relating to dealing with results and specific protocols to follow in relation to identified tests and procedures.

**The key message is that the results process must be included in the pre-test information.**

#### 2. General issues

- Before giving **ANY** results or information staff should ensure that a written copy of results is available.
- **DO NOT LEAVE MESSAGES** detailing the result on an answer phone or with a third party. Ask them to call the screening contact number.

- Always identify yourself to the woman.
- **PATIENT IDENTIFICATION** details (name, DOB, Hospital Number, address) should be checked before giving any information.
- If appropriate or necessary in exceptional cases, results and information can be relayed via a Community Midwife.
- Always ensure that the woman understands the information that you have given her.
- If the woman requires further information from medical staff, an appointment should be offered.

### 3. Combined Test Screening

**Biochemistry from 10 weeks & nuchal translucency scan from 11+2 weeks to 14+ 1. Biochemistry blood sample is sent to the Royal Devon & Exeter via Derriford Combined laboratories. A specific blood form is used and biochemistry sample is taken by Community Midwives.**

Providing the biochemistry sample is taken a few days before the scan date, when the woman attends for her scan the biochemistry levels are available on the computer software. Viewpoint is used to calculate the Down's, Edwards', and Patau's syndrome risk. When the crown rump length is inputted with the nuchal translucency the biochemistry is converted to MoMs (multiples of the mean). These values combined with the other variables including maternal age, weight, smoking status and ethnicity will then form the result, which is described as a higher or lower chance of having a baby with one of the three syndromes as above.

The result is mostly available to give face to face at the time of the scan but there will be occasions when this is not possible. In the event that the biochemistry is not available then the woman should be informed that a result will be generated within 3 working days providing they are already in progress or taken at the time of the scan. If the woman chooses to have them taken at the GP surgery at a later date, but within the appropriate timeframe a result will be available within 3 working days of the blood test.

The woman should be informed at the time of the test that she will be contacted by post and asked to place a copy of the result in her handheld notes if the result is low

risk but that if there is a high risk result she will be contacted by telephone. She will be offered telephone counselling or an appointment for face to face counselling to include the offer of a fetal medicine appointment for further discussion and possible diagnostic test.

All results not available at time of appointment are recorded in the incomplete risks database. This information is reviewed daily to ensure results are generated and patients are informed of the result as soon as possible. This is used to monitor and improve the service by identifying any gaps.

When giving a high-risk result it is necessary to explain that this does not mean that the woman is pregnant with an affected baby.

**When explaining individual results to women, screen negative and screen positive must not be used to explain higher risk and lower risk results.**

Supplementary information, including relevant informative/supportive websites or details of support organizations, should be offered to all women receiving a higher risk test result.

Women who go on to have a diagnostic test are recorded on the diagnostic tests spreadsheet.

Women who decline a diagnostic test are recorded on the fetal medicine spreadsheet under the heading "HR Decline". This allows for postnatal outcomes to be discussed.

#### **4. Quadruple Test**

**Biochemistry from 14 +2 weeks to 20 weeks dates confirmed by Ultrasound. Samples are sent to the Wolfson Institute in London via Derriford Combined laboratories. Specific Quadruple Test blood forms are used with biochemistry sample taken by staff working within the Women's Day Services Department.**

This test is available for women for whom the Nuchal Translucency measurement is unachievable, who book late or those who initially decline screening but later decide to opt in.

The woman must have a dating scan and the blood test be taken at that attendance if she is found to be more than 14 +2 weeks gestation.

The Wolfson is informed to expect the sample, confirm arrival of the sample.

Completed results are emailed to the antenatal and newborn screening generic email within 3 working days. The woman is informed that a low risk result will be posted to her to place in her handheld notes.

A high-risk Quadruple test result will be emailed to the screening generic email within 3 working days. The phone call to give the results will include counselling about a

diagnostic test, the offer of a face to face appointment to discuss the result and details of a Fetal Medicine appointment.

All Quadruple tests are recorded in the Quad Test database.

**Any woman who has a high risk screening test but declines a diagnostic test will be recorded onto the multidisciplinary (MDT) database & discussed at the regular multidisciplinary meetings.**

## 5. Amniocentesis/CVS Results

A diagnostic test is mostly performed for the identification of major chromosomal abnormalities e.g. Trisomy 21, Trisomy 18 and Trisomy 13 and gender chromosome disorders. Other indications for prenatal diagnosis include maternal age request, previous history of chromosomal or genetic disorders and abnormal findings on ultrasound scan USS.

Where there are abnormal findings on USS parental bloods will also be sent with consent.

All women having a diagnostic test will have pre-test information about how the results will be given. Most women request telephone contact as soon as possible.

All samples have a QF-PCR (Quantitative Fluorescent Polymerase chain reaction) requested, a rapid result that is available within 3-5 working days of receipt of the sample at the laboratory. For more detailed results an Array or Karyotype may be requested. This result is available approximately 10-14 days after the QF-PCR result.

Bristol Genetics Laboratory emails all results to the screening generic email, however they will contact the Screening Midwives by phone if they are sending an abnormal result.

The woman should be informed of the result within one working day of the result being received by the trust.

### **Giving QF- PCR result (Refer to general issues).**

- On receipt of the result, check if it is an amniocentesis or CVS result. **NB: blood chromosome results are reported on an identical form**
- Before phoning the woman, ensure that the results are complete i.e. that amniotic fluid has not been sent for further investigations. Partial information about results can be given following discussion with the doctor.
- Unless you have had contact with the woman, please check that notes are in file and that a miscarriage has not occurred
- **Record your actions on the back of the copy of the results, including date, time and your name. Also record information in the laboratory entry on Viewpoint including whether the woman knows the gender. On-going information about the pregnancy should be documented in the comments box on the Viewpoint system**

### **Confirmation result (Refer to general issues).**

- Ask the woman whether she wishes to know the sex/gender of the baby;  
**If yes** it is clearer to say 'boy or girl' rather than 'male or female'.  
Most of the results from karyotyping should be available within 14 working days.

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- **If telephone contact is not possible with the woman**, a suitable letter indicating the results should be sent by first class post where there is a normal result.
- **Record your actions on the back of the copy of the results, including date, time and your name. Also record information in the laboratory entry on Viewpoint including whether the woman knows the gender. On-going information about the pregnancy should be documented in the comments box on the Viewpoint system**

Following a confirmed diagnosis of an abnormality, appropriate information and support should be given to all women, no matter how they decide to proceed with the pregnancy.

If the chromosomes are normal and the woman has been given the sex of the baby on her request the copies of the results can be posted to her with her next scan appointment. If the woman does not wish to know the sex of the baby hard copies of the results, the QF-PCR and confirmation are both placed in an envelope within the woman's main hospital notes.

All diagnostic tests are recorded in the diagnostic test database. This includes condition confirmed, outcomes, turnaround times, NCARDS sent if appropriate and neonatal alerts sent.

Any woman continuing a pregnancy with an identified chromosome abnormality will be presented at the regular multidisciplinary meetings. The case will be recorded on the MDT database for discussion and care planning. Women who choose to end a pregnancy are also included on this list to for information and discussion.

### **Support for the women and her family**

The diagnosis of a fetal abnormality is a very distressing time for both the pregnant woman and her family. During this time the woman and her family are likely to require support not only from hospital staff but also from outside agencies. There are a wide variety of outside support groups related to specific conditions and the Screening team will be able to put the woman in contact with these groups dependent on the diagnosis.

There are also specific patient information for when an abnormality has been diagnosed in an unborn baby, both for women who choose termination and women who continue with their pregnancy provided by ARC (Antenatal Results and Choices).

The FASP website has specific patient information leaflets downloadable for patients and professionals <https://www.gov.uk/government/collections/fetal-anomalies-screening-conditions-diagnosis-treatment> **after confirmation of a suspected anomaly.**

A record of information leaflets given to parents and all discussions together with advice / support provided must be documented within the patient handheld pregnancy notes.

## 6. Record keeping

It is expected that every episode of care be recorded clearly, in chronological order and as contemporaneously as possible by all healthcare professionals as per Hospital Trust Policy. This is in keeping with standards set by professional colleges, i.e. NMC and RCOG. All entries must have the **date and time** together with **signature**. **The signature bank at the front of the pregnancy handheld notes must be completed.**

### **Monitoring Audit**

#### **Auditable standards:**

Evidence of documented discussion with parents  
 Evidence of patient information leaflet having been given to parents  
 Review if results undertaken appropriately  
 Evidence that women with positive results are managed and referred appropriately and within appropriate

Please refer to audit tool, location: 'Maternity on cl2-file11', Guidelines

#### **Reports to:**

Clinical Effectiveness Committee – responsible for action plan and implementation of recommendations from audit

Clinical Governance & Risk Management Committee

#### **Frequency of audit:**

Annual

#### **Responsible person:**

Antenatal screening midwife

### **Cross references**

UHP Policy documents for :

- Hepatitis B in Pregnancy
- 1<sup>st</sup> Trimester Screening for Down's, Edwards' and Patau's Syndromes (T21,T18,13) and Dating Scans
- Sickle Cell and Thalassaemia Screening (please rename Haemoglobinopathies)
- HIV in Pregnancy
- Screening for Infectious Diseases in Pregnancy
- Antenatal & Newborn Screening guidelines
- Guideline development within the maternity services
- When Fetal abnormality is detected

Clinical Records Keeping Policy – Derriford Hospital

**References**

**NHS public health functions agreement 2015-2016 Service** specification no.16

NHS Fetal Anomaly Screening Programme for Down's, Edwards' and Patau's Syndromes (T21,T18 &13)Fetal Anomaly Screening Programme Standards 2015-2016

Antenatal Results and Choices

<http://www.arc-uk.org>

CVS and Amniocentesis: information for parents

Amniocentesis and Chorionic Villus Sampling

Policy, Standards and Protocols Antenatal Screening Wales & FASP April 2008

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