Mid Essex Hospital Services NHS Trust

INTERPRETING AND ACTING ON CHORIONIC VILLUS SAMPLE (CVS) AND AMNIOCENTESIS RESULTS	CLINICAL GUIDELINE Register No: 08046 Status: Public

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Contributes to CQC Regulation	9,12

Consulted With	Individual/Body	Date
Anita Rao/ Alison Cuthbertson	Clinical Director for Women's and Children's Division	February 2018
Vidya Thakur	Consultant for Obstetrics and Gynaecology	
Dr Hassan	Consultant Paediatrician	
Alison Cuthbertson	Associate Director of Midwifery/Nursing	
Paula Hollis	Lead Midwife Acute Inpatient Services	
Chris Berner	Lead Midwife Clinical Governance	
Ros Bullen-Bell	Lead Midwife Community Services	
Sarah Iskander	Antenatal Clinic Midwife	
Sarah Moon	Specialist Midwife Guidelines and Audit	
Deborah Lepley/Ian Wilkes	Warner Library	
Professionally Approved By		
Anita Rao	Lead Consultant for Obstetrics and Gynaecology	February 2018

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Author/Contact for Information	Emma Neate, Antenatal Newborn Screening Co-ordinator
Policy to be followed by (target staff)	**Midwives, Obstetricians, Radiology**
Distribution Method	Intranet and Website; Notified on Staff Focus
Related Trust Policies (to be read in conjunction with)	04071 Standard Infection Prevention Precautions 04072 Hand Hygiene 04272 Maternity Care 08058 Antenatal Screening for Downs Syndrome, Edwards and Pataus 08045 Guideline for Amniocentesis for Antenatal Diagnosis 06036 Guideline for Maternity Record Keeping including Documentation in Handheld Records 06031 Receiving and Acting on Test Results in Maternity by both Hospital and Community

Document Review History:

Review No:	Reviewed by:	Issue Date:
1.0	Kathleen Bird	September 2004
2.0	Kathleen Bird	June 2008
3.0	Nicola Leslie	February 2012
3.1	Sarah Moon – clarification to 5.0, 6.0	February 2013
4.0	Nicola Leslie	March 2015
4.1	Nicola Leslie – Clarification to point 1.2, 4.0 and 16.0	5th July 2016
5.0	Emma Neate – Full review	23rd April 2018

INDEX

1.0 Purpose

1.1 The aim of this guideline is to interpret and act on amniocentesis and chorionic villus sample (CVS) results.

1.2 Counselling and pre-natal diagnosis should be provided as part of the health service, whatever the frequency.
(Refer to the guideline entitled 'Antenatal Screening for Downs, Edwards and Pataus Syndrome'; register number 08058)

2.0 Background

2.1 The national screening programme makes sure that it meets set quality standards and guidance. They recommended that valid up to date information is given to cover the following:

- The purpose of the test and the conditions being screened for
- The test procedure
- When and how the results are available
- The interpretation of the results
- Options following a positive result
- Options following a positive diagnosis
- The consequences for life
- How further information can be obtained

3.0 Equality and Diversity

3.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

4.0 Aetiology

4.1 The results are looking for genetic conditions of three copies of chromosomes 21, 18 and 13 and 'x' linked anaploidy:

- The incidence of Downs Syndrome is 1 per 1,000 births.
- The incidence of Edwards Syndrome is 3 per 10,000 births
- The incidence of Pataus Syndrome is 2 per 10,000 births

5.0 CVS Results

5.1 CVS is undertaken at a tertiary unit, either at the University College London, Kings College Hospital, London or The Rosie Maternity Unit at Addenbrooke's.

5.2 Results are provided by the tertiary unit where the CVS took place. Polymerase chain reaction (PCR) are available within 2-3 working days and full karyotype results are available within 2-3 working weeks.

5.3 Normal results are reported direct to the woman by the fetal medicine unit who undertook the procedure.

5.4 Abnormal results are either reported direct to the antenatal Screening team or the woman; this depends on the fetal medicine unit. The woman will be contacted by the Screening team within 2 working days of receiving the prenatal diagnostic results.

6.0 Amniocentesis Results

(Refer to the guideline entitled 'Guideline for Amniocentesis for Antenatal Diagnosis'; register number 08045)

6.1 Amniocentesis can be undertaken at Broomfield Antenatal Clinic or at a fetal medicine unit.

6.2 Normal and screen positive results are provided by the cytogenetics laboratory and emailed to the Screening team Office. PCR results are available within 2-3 working days and full karyotype results, if requested are available within 2-3 working weeks.

6.3 The woman will be contacted by the Screening team within 2 working days of receiving the amniocentesis results.

7.0 Normal Results

7.1 All results should be read and signed by two midwives or doctors.

7.2 Normal results are telephoned to the woman's contact telephone number, home, mobile, (work as a last option) or partners telephone, (if documented permission is given, as discussed at previous consultation).

7.3 Inform the patient of the normality of Trisomy 13, Trisomy 18, Trisomy 21 and 'x-linked' anaploidy.

7.4 Reassure the woman.

7.5 Date and sign conversation on the results to comply with the record keeping.

7.6 Update screening database with results.

8.0 Abnormal Results

8.1 All results should be read and signed by two midwives or doctors.

8.2 Inform the patient's obstetric consultant, general practitioner (GP) and community midwife of the outcome and a plan of care discussed and formulated. The Antenatal Screening Team will inform the patient.

8.3 To minimise the anxiety of receiving an abnormal result. Ring the patient on her preferred contact telephone number. An immediate appointment should be offered to the woman and her partner to discuss the results.

8.4 At the appointment ensure that the following is discussed and undertaken:

- Confirm the details of the results with the couple

- Written information if available is given on the syndrome/abnormality
- Antenatal Results and Choice (ARC) booklet
- Mifipristone/ misoprostol leaflet if appropriate
- Contact names and telephone numbers as recorded in the health care records

9.0 Continuing with the Pregnancy

9.1 Make a plan of care for this pregnancy, with support from the multidisciplinary team (MDT). Offer an antenatal clinic (ANC) appointment with consultant. Inform the G.P and community midwife.

10.0 Termination of Pregnancy

10.1 If the patient decides to terminate this pregnancy (TOP) offer a date and time to come in to clinic and meet a consultant/obstetric registrar with the screening coordinator in an appropriate environment.

10.2 The patient and her partner will be counselled for either a surgical or medical termination, consultant choice. (Refer to appendix A for chart to illustrate gestational period for medical or surgical abortions)

10.3 Procedures will be discussed at the time of booking the TOP.

10.4 For a gestation greater than 21weeks a feticide should be discussed with the fetal medicine unit on an individual basis.

10.5 White certificate 'A Abortion Act 1967' must be signed by two doctors, to comply with section 1(1) of the act, prior to TOP of all live babies. Consent form must be signed and HSA4 form commenced.

10.6 The Abortion Act Certificate will be completed at tertiary units when feticide is performed.

10.7 Inform Bereavement Midwife of termination

11.00 Surgical Termination of Pregnancy

11.1 Arrange with Gynae waiting lists (ext 3093/3554) a date and time for a surgical TOP.

11.2 White certificate 'A Abortion Act 1967' must be signed by two doctors, to comply with section 1(1) of the act, prior to TOP of all live babies. Commence 'Checklist One Fetal Loss under 24 weeks'. 'Consent form One' should be completed at this appointment

11.3 Ensure notes are up to date and sent to Surgical Day Stay Unit (TADS), Level 3.

11.4 If booked onto a morning list - eat until 02:00; drink until 06:00; admission to TADS 07:30
If booked onto an afternoon list – eat until 07:30; drink until 11:30; admission to TADS 12.00

12.0 Medical Termination of Pregnancy

12.1 Follow clinical guidelines for the use of Mifipristone and Misoprostol in the Induction of Mid-trimester Abortion.

12.2 ‘Consent form 3’ should be completed by the Obstetric Consultant/Registrar

12.3 Inform GP and Community Midwife of outcome by telephone.

12.4 Inform Labour Ward and/or Gosfield Ward of the woman’s admission as appropriate.

13.0 Infection Prevention

13.1 All staff should follow Trust guidelines on infection prevention by ensuring that they effectively ‘decontaminate their hands’ before and after each procedure.

14.0 Staffing and Training

14.1 All midwifery and obstetric staff must attend yearly mandatory training, which includes skills and drills training, involving an antenatal screening update.

14.2 All midwifery and obstetric staff are to ensure that their knowledge and skills are up-to-date in order to complete their portfolio for appraisal.

15.0 Audit and Monitoring

15.1 Audit of compliance with this guideline will be considered on an annual audit basis in accordance with the Clinical Audit Strategy and Policy (register number 08076), the Corporate Clinical Audit and Quality Improvement Project Plan and the Maternity annual audit work plan; to encompass national and local audit and clinical governance identifying key harm themes. The Women’s and Children’s Clinical Audit Group will identify a lead for the audit.

15.2 As a minimum the following specific requirements will be monitored:

- Designated lead for antenatal screening in the maternity service
- Antenatal screening tests, which follow the UK National Screening Committee guidance
- System for ensuring that appropriate tests are undertaken within appropriate timescales
- System for ensuring that appropriate tests are undertaken when patients book late
- Process for the review of the results
- Process for reporting all results to patients
- Process for reporting results to other relevant healthcare professionals
- Process for ensuring that patients with screen positive test results are referred and managed within appropriate timescales
- Maternity service’s expectations for staff training, as identified in the training needs analysis
- Process for audit, multidisciplinary review of results and subsequent monitoring of action plans

15.3 A review of a suitable sample will be audited from the health care records of patients who have delivered to evidence the process for ensuring that patients with screen positive test

results are referred and managed within appropriate timescales. A minimum compliance 75% is required for each requirement. Where concerns are identified more frequent audit will be undertaken.

15.4 The findings of the audit will be reported to and approved by the Multi-disciplinary Risk Management Group (MRMG) and an action plan with named leads and timescales will be developed to address any identified deficiencies. Performance against the action plan will be monitored by this group at subsequent meetings.

15.5 The audit report will be reported to the monthly Directorate Governance Meeting (DGM) and significant concerns relating to compliance will be entered on the local Risk Assurance Framework.

15.6 Key findings and learning points from the audit will be submitted to the Clinical Governance Group within the integrated learning report.

15.7 Key findings and learning points will be disseminated to relevant staff.

16.0 Guideline Management

16.1 As an integral part of the knowledge, skills framework, staff are appraised annually to ensure competency in computer skills and the ability to access the current approved guidelines via the Trust's intranet site.

16.2 Quarterly memos are sent to line managers to disseminate to their staff the most recently approved guidelines available via the intranet and clinical guideline folders, located in each designated clinical area.

16.3 Guideline monitors have been nominated to each clinical area to ensure a system whereby obsolete guidelines are archived and newly approved guidelines are now downloaded from the intranet and filed appropriately in the guideline folders. 'Spot checks' are performed on all clinical guidelines quarterly.

16.4 Quarterly Clinical Practices group meetings are held to discuss 'guidelines'. During this meeting the practice development midwife can highlight any areas for further training; possibly involving 'workshops' or to be included in future 'skills and drills' mandatory training sessions.

17.0 Communication

17.1 A quarterly 'maternity newsletter' is issued and available to all staff including an update on the latest 'guidelines' information such as a list of newly approved guidelines for staff to acknowledge and familiarise themselves with and practice accordingly.

17.2 Approved guidelines are published monthly in the Trust's Focus Magazine that is sent via email to all staff.

17.3 Approved guidelines will be disseminated to appropriate staff quarterly via email.

17.4 Regular memos are posted on the guideline notice boards in each clinical area to notify staff of the latest revised guidelines and how to access guidelines via the intranet or clinical guideline folders.

18.0 References

UK National Screening Committee. (2011) NHS Fetal Anomaly Screening Programme: Consent Standards and Guidance.

Public Health England (2018) Our approach to fetal anomaly screening standards. [online] Available at: https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards/fetal-anomaly-screening-standards-valid-for-data-collected-from-1-april-2018#resources-to-support-providers-and-commissioners

Royal College of Obstetricians and Gynaecologists (2010) Termination for Fetal Abnormality in England, Scotland and Wales. London: RCOG
Available at:
https://www.rcog.org.uk/globalassets/documents/guidelines/terminationpregnancyreport18may2010.pdf

NHS Fetal Anomaly Screening Programme (2012) Trisomy 13 (also called Patau's syndrome or T13): information for parents.

Available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/674609/Trisomy_13_-_Parents_-_FASP76_2.pdf

NHS Fetal Anomaly Screening Programme (2012) Trisomy 18 (also called Edwards' syndrome or T18): information for parents.

Available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/674610/Trisomy_18_-_Parents_-_FASP76_2.pdf

Appendix A

Chart to illustrate Gestational Period for Medical or Surgical Abortions

Consultant	Surgical	Medical
	Weeks + Days	Weeks + Days
Mrs Thakur	12	12+1
Mr Partington	15+6	16
Miss Sharma	13	13+1
Mr Spencer	13	13+1
Miss Rao	12	12+1
Miss Joshi	12	12+1
Mr Fiadjoe	Transfer to consultant on call	Transfer to consultant on call
Mr Gangooly	Transfer to consultant on call	Transfer to consultant on call