Sgrinio Cyn Geni Cymru
Antenatal Screening Wales

NHS WALES GIG CYMRU

Amniocentesis and Chorionic Villus Sampling

Policy, Standards and Protocols

NHS Fetal Anomaly Screening Programme

NHS
Antenatal and Newborn Screening Programmes

Amniocentesis and Chorionic Villus Sampling

Policy, Standards and Protocols

Public consultation on these standards and protocols was held from August 2007 to November 2007.

Antenatal Screening Wales and the NHS Fetal Anomaly Screening Programme are extremely grateful to those who took the time to respond to the consultation. All consultation responses have been reviewed and a number of important changes have been incorporated in this document.

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Preface

Amniocentesis is the most common invasive antenatal diagnostic procedure undertaken in the United Kingdom (UK). The potential for maternal anxiety and difficulty with making a decision regarding accepting or declining amniocentesis or chorionic villus sampling (CVS) procedure was a principal consideration during the development of this document.

Amniocentesis is a procedure to remove about 15 millilitres of amniotic fluid from the uterus. The fetal cells in the amniotic fluid can be tested in the laboratory to examine the chromosomes. This procedure is usually performed after 15 completed weeks of pregnancy.

CVS is a procedure where a small amount of tissue from the placenta is removed. The cells in this tissue are tested in the laboratory to examine the chromosomes. The CVS can be performed from 10 weeks but is usually only performed from 11 weeks of pregnancy.

The procedure should be performed by specially trained health professionals. Women may therefore be required to attend a different maternity hospital to the one where they are booked for maternity care.

Contents

1.0 Introduction

All aspects of amniocentesis and CVS procedures, except the laboratory processes (QF-PCR and/or karyotype), have been considered during the development of this guidance. The document considers counselling, information for women, the procedure, clinical standards, record keeping, sample labelling and results handling.

The recommended audit arrangements for amniocentesis and CVS procedures are currently being considered and will be the subject of a separate consultation.

This document has been developed through collaboration between Antenatal Screening Wales and the National Screening Committee (NSC) Fetal Anomaly Screening Programme (see appendix 1 for details of group membership) and was subject to consultation in the autumn of 2007.

Standards are defined as:

> "... means of describing the level of quality that health care organisations are expected to meet or to aspire to. The performance of the organisations can be assessed against this level of quality".[1]

These standards and protocols should be used in conjunction with the Royal College of Obstetricians and Gynaecologists guidelines for amniocentesis and CVS (RCOG, 2005).[2]

This document also builds on the following well established principles.

Confidentiality

All health professionals have a duty to maintain confidentiality in their practice as emphasised in their professional codes of practice. Hospital and laboratory services must adhere to the Data Protection Act.

Record Keeping

There should be auditable documented evidence of all information provision, consent and care.

Published national data from recognised professional sources should be used when giving verbal or written information to women regarding miscarriage and other associated risks of amniocentesis and CVS.[3] It is expected that service providers will collect and audit their own data on miscarriage outcomes following amniocentesis and CVS procedures.[4]

1 Department of Health (2003) Standards for Better health, page 5. Available from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4086666.pdf [Accessed on 08/04/08]

2 Royal College of Obstetricians and Gynaecologists (2005) Amniocentesis and Chorionic Villus Sampling, Guideline No.8, Available from: http://www.rcog.org.uk/resources/Public/pdf/aminiocentesis_chorionicjan2005.pdf [Accessed on 08/04/08]

3 For example: Information published by: Royal College of Obstetricians, National Institute for Health and Clinical Excellence, National Screening Committee, British HIV Association, British Medical Ultrasound Society etc.

4 Local audit should be performed as outlined in the Royal College of Obstetricians and Gynaecologists (2003) Clinical Governance Advice No. 5, Understanding Audit. Available from: http://www.rcog.org.uk/resources/Public/pdf/understanding_audit.pdf [Accessed on 08/04/08]

2.0 Amniocentesis and CVS Policy, Standards and Protocols

2.1 Amniocentesis and CVS Policy

Policy: All women who are offered and accept amniocentesis or CVS should receive information and care which meet these agreed national minimum standards and protocols.

Rationale: Amniocentesis and CVS should only be performed with the woman's explicit and informed consent. The woman will require adequate and timely information about the procedure, which includes the risks of the procedure, the reliability of the tests and the results handling process.

Amniocentesis and CVS diagnostic procedures may precipitate a miscarriage. The risks of miscarriage and other untoward events can be reduced if care meets these agreed standards.

2.2 Amniocentesis and CVS Standards and Protocols

Minimum **Standards** and *Protocols* for Amniocentesis and CVS Diagnostic Testing

Patient Information	**Standard 1** The woman must be given verbal and written pre-test information. A record of the information provided must be made in the maternity records.	
	Protocol 1	The purpose, benefits, limitations and implications of an amniocentesis or CVS must be explained and discussed with the woman by an appropriately trained health professional. A record of the information provided must be made in the maternity notes.
	Protocol 2	Written information (and adequate time to read the information) should be given to the woman before she is asked to consent to an amniocentesis or CVS.
	Protocol 3	The woman must be provided with a verbal explanation in a way she is able to understand about; • the procedure • the risks of the procedure • the genetic information that will be available • the results handling process • pregnancy choices following the results • her right to accept or decline the procedure.

Protocol 4	The reason for offering the woman the test should be explained, for example; • a history of an inherited disorder • a previous pregnancy or a child with a chromosome disorder • a raised chance of Down's syndrome following Down's syndrome screening • suspected anomaly following an ultrasound scan.
Protocol 5	If karyotyping is offered, the woman should be informed that subtle chromosomal changes and single gene defects will not normally be detected. The implications of this should be explained, i.e. not all inherited conditions will be identified.
Protocol 6	The woman should be informed of the usual reporting times for karyotyping and/ or PCR before the procedure.

Consent

Standard 2

The woman's informed verbal and written consent is required for this test. The record of her consent must be documented and retained in the maternity notes.

Protocol 7	A copy of the completed consent form should be made available to the woman.

Timing

Standard 3

Amniocentesis should not usually be performed before 15 completed weeks of gestation (15+0).

CVS should not be performed before 10 completed weeks of gestation (10+0).

Procedure

Standard 4
Amniocentesis and CVS should be performed under direct ultrasound control with continuous echogenic needle tip visualisation.[5]

Standard 5
When performing an amniocentesis procedure, the amniocentesis outer needle diameter should not be wider than 20-gauge (0.9 mm).

Standard 6
During the amniocentesis, operators should only use a transplacental approach if a clear pool of amniotic fluid can only be reached by passage through the placenta.

Protocol 8 CVS Procedure
The CVS needle/ cannula gauge and method of aspiration should be documented.

Protocol 9 A new needle should be used with each attempt (See Protocol 17 re: number of attempts).

Standard 7
Fetal viability should be confirmed and documented before and after the amniocentesis or CVS procedure.

Protocol 10 Local protocols should determine whether ultrasound scanning during the procedure should be performed by the person inserting the needle or by another practitioner.

Protocol 11 Amniocentesis and CVS can be performed in women who are hepatitis B or C carriers, but with due regard to the RCOG guidance.[6]

5 RCOG (2005) Amniocentesis and Chorionic Villus Sampling, Guideline No.8, page 3
6 RCOG (2005) Amniocentesis and Chorionic Villus Sampling, Guideline No.8, page 8

Protocol 12 The procedure can be performed in women who are HIV positive **but additional care and treatment may be required as outlined in the existing BHIVA Guidelines.**[7]

Protocol 13 The woman's privacy must be respected and the discussion and procedure performed in a room where privacy is assured.

Control of Infection

Standard 8

Amniocentesis and CVS should be performed using an aseptic technique (see appendix 2).

Protocol 14 There should be a process for probe decontamination and for ultrasound gel microbiological surveillance.

Protocol 15 Operators should adhere to local infection control policies and these policies should include:

- enclosing the probe in a sterile bag during an amniocentesis or CVS procedure.[8]
- using a separate sterile gel sachet for each patient.

Operator Competence

Standard 9

Amniocentesis and CVS procedures should only be performed by an operator following adequate training.

Protocol 16 The person performing ultrasound as part of the amniocentesis or CVS procedure should be trained to the competencies of the RCOG guidelines.

Protocol 17 When difficulties with amniocentesis are anticipated, further opinion should be sought from a more experienced operator.

A more experienced operator should be consulted if two attempts at uterine insertion have failed to produce an adequate sample for analysis.

Standard 10

Amniocentesis and CVS in multiple pregnancies should be performed only by a specialist who (should it be required) has the expertise to perform selective termination. Expertise in ultrasound scanning is essential to adequately 'map' the uterine contents, i.e. to ensure that separate samples are taken for each fetus.[9]

Rhesus Status

Standard 11

The woman's rhesus status should be obtained and available to the operator before the procedure is performed.[10, 11]

Protocol 18 All women who are rhesus negative should be offered anti D following an amniocentesis or CVS procedure.

Confirmation of Sample Identification

Standard 12

The maternity services should follow the locally agreed protocol for labelling the sample.

Protocol 19 The maternity services should develop a clear system for confirmation of the sample identity. This process should usually include confirming with the woman that the name and date of birth on the sample is correct.

7 Refer to British HIV Association and Children's HIV Association Guidelines for the Management of HIV Infection in Pregnant Women. Available from: http://www.bhiva.org [Accessed on 08/04/08]

8 In the absence of research evidence the RCOG recommend the use of sterile probe covers as a good practice point, i.e. "Recommended best practice based on the clinical experience of the guideline development group."

9 RCOG (2005) Amniocentesis and Chorionic Villus Sampling, Guideline No.8, page 7

10 RCOG (2005) Amniocentesis and Chorionic Villus Sampling, Guideline No.8, page 8

11 In exceptional circumstances, where the woman's rhesus status is not known before or at the time of the procedure, the rhesus status should be obtained as soon after the procedure as possible.

Request Cards

Standard 13
The laboratory request form should be fully completed.

Protocol 20 All clinical and demographic information fields should be completed clearly on the laboratory request form.

Transport

Standard 14
Maternity services should adhere to the current instructions on the safe transport of samples (see appendix 3).

Standard 15
To reduce the risk of samples being lost or delayed, the genetic laboratory should be informed by the requesting services about amniocentesis and CVS samples sent to them.

Record Keeping

Standard 16
A record of the procedure should be made and retained in the notes.

Protocol 21 A record of the needle gauge used, the number of uterine insertions and number of 'bloody taps' should be documented in the woman's maternity notes.

Protocol 22 The clinical indication for the procedure being offered should be documented.

Results Handling

Standard 17
The woman should be informed of the result within one working day of the result being received by the service provider.

Standard 18

All women must be informed of the amniocentesis or CVS result by an appropriately trained person.

Protocol 23 All maternity services should have a written pathway for communication of results. The process for the communication of results should be discussed and agreed with the woman before the procedure.

Protocol 24 When an amniocentesis or CVS is performed at a tertiary centre, that centre should provide written results to the referring clinician.

Pregnancy Outcome Forms

Standard 19

To facilitate audit, pregnancy outcome forms should be completed and returned to the genetic laboratory, or other locally agreed collating centre, at the end of the pregnancy.

Protocol 25 The service provider should develop a written pathway for the completion and return of pregnancy outcome forms to the centre collecting the data, usually the genetic laboratory.

Audit

Standard 20

Each department performing amniocentesis and CVS procedures should maintain a register of amniocentesis and CVS diagnostic procedures performed and outcome of pregnancy.

Protocol 26 Patient evaluation of service provision is an integral aspect of overall service audit and should be included as part of the audit and performance management framework.

Appendices

Appendix 1 Group Membership

Name	Designation
Judith Bibby	Fetal Medicine Midwife
Karen Brunsdon	Antenatal & Screening Services Coordinator
Jenny Butters	Screening Midwife
Christine Conner	Fetal Medicine Consultant
Colin Davies	Consultant Radiologist
Andrew Dawson (Chair)	Consultant Obstetrician
Andrea Edwards	Genetic Counsellor
Hayley Heard	Regional Coordinator for Antenatal Screening Wales
Rosemary Johnson	All Wales Programme Coordinator for Antenatal Screening Wales
Mary Longworth	Regional Coordinator for Antenatal Screening Wales
Andrea Matthews	Community Health Council Representative
Marsham Mosheli	Consultant Obstetrician
Christopher Overton	Consultant Obstetrician
Annie Procter	Director of All Wales Medical Genetic Services
Janet Purton	Infection Control Nurses Association (ICNA) Representative
Selwyn Roberts	Head of Cytogenetics Laboratory For Wales
Amanda Taylor	Screening Midwife
William Taylor	Consultant Obstetrician
Pat Ward	Programme Director for Down's Syndrome & Fetal Anomaly Screening (England)
Llywela Wilson	Regional Coordinator for Antenatal Screening Wales

Appendix 2 Control of Infection

Step	Action	Rationale / evidence
1	**Preparation of the Environment**	
	The room should be a designated treatment room fit for the purpose. There must be a clinical hand washing sink in the room.	In preparation for an aseptic procedure the environment must be organised appropriately.
	All surfaces and fabrics in the room must be suitable for decontamination/cleaning/ washing.	Equipment can become contaminated with organisms while in use from both patients and staff and dust accumulates on surfaces.
	Ideally only clean activities should occur in this room (i.e. no urine testing); however, should the area be used for other purposes it must be cleaned after use.	
	There must be a cleaning schedule to ensure that all of the area is cleaned daily following use. This should include equipment, sinks, work surfaces, floors etc.	Cleaning is a process which physically removes organic matter and infectious agents.
	Prior to the procedure all surfaces should be cleaned with warm water and detergent/ detergent wipes.	Cleaning is an essential prerequisite to ensure the effective disinfection or sterilisation. Detergent and warm water provides a simple cleaning solution (detergent wipes are effective and easy to use).
	The couch should be covered with disposable paper roll which is disposed of after each patient and the surface wiped as above. If linen is used this should be changed after each patient.	
	All medical equipment, including the scanner, must be cleaned before and after use using the manufacturer's recommendation regarding suitable	

Step	Action	Rationale / evidence
	cleaning agents (see section 5 for ultrasound probe decontamination). To allow for easy cleaning the area should be kept clutter free with no storage of inappropriate equipment. The procedure trolley should be cleaned daily and just prior to the procedure the top/working surface should be wiped with an alcohol wipe. There should be a sharps bin in the room for disposal of used needles – ideally this should be on the bottom of the procedure trolley.	
2	**Patient preparation** After settling the patient on the couch, she should be asked to adjust her clothing so that the abdomen is exposed. The clothing should not touch the site/area of skin on the abdomen that is to be disinfected.	The abdominal area needs to be visible and accessible to enable the procedure to occur. Since the procedure is invasive and sterile equipment is used to prevent infection, the clothing should not be in contact with this area/site in order to maintain the disinfection at the site.
3	**Preparation of sterile field and procedure pack** Operator (and/ or assistant) should: • put on a protective apron • wash their hands ensuring all surfaces of the hands are washed thoroughly using the correct technique • check that all disposable items are in sealed packs (undamaged and not expired) • open the packs taking care not to touch the contents	Aprons should always be worn to protect the wearer as there is risk of contamination of the operators clothing with blood and body fluids. Aprons must be single use and disposable. An aseptic technique is

Step	Action	Rationale / evidence
	• open any additional sterile items onto the sterile field, e.g. cannula, syringe, needle, sterile gloves, sterile probe cover, sterile gel sachet, taking care not to touch the sterile items themselves. Note: single use items must not be reused.	required because severe sepsis, including maternal death has been reported following amniocentesis and CVS antenatal procedures. The risk of severe sepsis is less than one in 1,000 procedures.
4.	**Skin preparation** The operator should apply alcohol rub to their hands and rub into all skin surfaces before applying sterile gloves using the correct donning technique. The patient's skin should be prepared using recommended antiseptic and swabs, e.g. alcoholic chlorhexidine. The antiseptic should thoroughly clean the skin site and the area allowed to dry before proceeding. Used swabs should be placed in the waste bag on the trolley. The sterile drape (as supplied in the pack) should be applied to the abdomen.	Wearing gloves prevents cross infection and reduces the amount of inoculums in the event of needlestick injury. Skin cleaning reduces the risk of endogenous infection by reducing the number of skin flora.
5	**Use of the ultrasound probe and gel** The ultrasound probe should be decontaminated prior to use and after use on each patient following the manufacturer's instructions, e.g. clean with detergent wipe, dry with disposable towel, wipe over surface with alcohol or other disinfectant wipe and allow to dry. A sterile probe cover should be applied to the device.	Infection can be caused by inadvertent puncture of the bowel, skin contaminants or organisms present on the ultrasound probe or gel. Cleaning is a process which physically removes organic matter and infectious agents. Cleaning is an

Step	Action	Rationale / evidence
	The gel should be applied to the device and abdominal site. Only single use gel sachets should be used as there is a risk of contamination from multi-use bottles.	essential pre-requisite to ensure the effective disinfection or sterilisation. Detergent and warm water provides a simple cleaning solution (detergent wipes are effective and easy to use). Disinfection reduces the number of viable infectious agents.
6.	**Insertion of the needle**	
	When the fetus/uterus/placenta is visualised, the needle should be inserted into the pool of amniotic fluid via the abdomen. When attaching the needle to the syringe care should be taken to avoid touching the ends of the sterile connections or the shaft of the needle. A sample of the fluid should be drawn into the syringe. The needle/syringe should be withdrawn from the abdomen.	An aseptic technique must be used when introducing an invasive device or when carrying out any activity that breaches the body's natural defensive system. Asepsis suggests a procedure designed to prevent any introduction of micro-organisms to the site and is achieved by non-touch technique.
7.	**Transfer of the amniotic fluid specimen**	
	The assistant should wash their hands and then use the alcohol hand rub. The assistant should remove the top of the specimen bottle/s. The operator should carefully transfer the aspirated amniotic fluid into the specimen bottle. All documentation should be completed on the specimen container and the accompanying forms.	A non-touch technique must be employed during transfer of the fluid into the specimen bottle/s.

Step	Action	Rationale / evidence
	A 'high risk' sticker should be applied if appropriate.	
8.	**Post-procedure care** The site should be observed for oozing, and an absorbent dressing applied if this occurs. A semi-permeable film dressing should be applied to the puncture site and should be left in place for 48 hours. The midwife or operator should advise the patient regarding post procedure care and provide written information. The patient should be allowed to recover before leaving the examination room.	Semi-permeable/ occlusive dressings are thin and unobtrusive and provide a viral and bacterial barrier. This should be left intact for 48 hours to prevent entry of micro-organisms. During this time the wound should have healed/sealed.

Appendix 3
Guidance on the Packaging and Transport of Diagnostic Samples for Laboratories

Diagnostic samples are classified by the United Nations (UN) as Dangerous Goods (Division 6.2 and assigned to UN3373) and must be packaged for transport in a way that meets the requirements of UN packaging instruction P650 as outlined below. Such packaging may be specially purchased for this purpose or constructed from suitable components.[12]

UN P650 Packaging Instruction for Diagnostic Samples

Packaging should be strong enough to withstand the shocks and loadings normally encountered during transport, including manual and mechanical handling, and should be constructed and closed so as to prevent any loss of contents in the event of leakage or breakage. The packaging consists of:

1. Primary receptacle, watertight and sealed, containing the specimen (e.g. universal container or blood tube), not exceeding 50 ml or 50 g, individually wrapped with enough absorbent material to absorb all fluid in the event of leakage or breakage.

2. Secondary packaging, durable, watertight and leak-proof container, to enclose and protect primary receptacle(s). Multiple individually wrapped primary receptacles may be placed in one secondary packaging. Sufficient additional absorbent material must be used to cushion multiple primary receptacles and absorb the entire contents of the primary receptacles in the event of leakage or breakage.

3. Outer packaging to protect the secondary packaging and contents from outside influences, such as physical damage and water while in transit.

   In addition, the following instructions must be followed:-

   - A laboratory request form must be completed indicating which tests are being requested, providing relevant clinical details and full patient details (use a patient identification label if available).

12 For further information refer to ACDP (2005). Biological agents: managing the risks in laboratories and healthcare premises, Appendix 1.2: http://www.hse.gov.uk/biosafety/ biologagents.pdf [Accessed on 08/04/08]

- The sample tube/universal container should be placed in a leak-proof plastic bag.
- The plastic bag should be sealed.
- There should be enough absorbent material, e.g. cotton wool or paper tissues, wrapped around the plastic bag and tube/universal container to absorb all fluid in the case of breakage.
- The sample container should be placed in suitable secondary packaging, e.g. robust, leak-proof, screw-cap plastic container with a waterproof gasket/seal.
- The laboratory request form and any additional paperwork should be placed within the container, but not within the plastic bag containing the specimen tube/universal container.
- High risk of infection samples should be identified using 'Danger of Infection' labels on the sample and request form.
- The secondary packaging should be placed in suitable outer packaging, e.g. large padded bag, close-fitting rigid cardboard box, or cardboard box with polystyrene foam insert.

The name and address of the laboratory should be clearly shown on the outside of the outer packaging:

- The outer packaging should be clearly labelled:

URGENT DIAGNOSTIC SPECIMEN
FRAGILE HANDLE WITH CARE

- The outer packaging should be clearly marked:

Samples for genetic investigations should not be frozen or exposed to excessive heat. If samples need to be stored, they should be kept in a cool place or in a refrigerator (+4°C).

Genetic investigations require living cells. It is therefore important that the laboratory receives the sample as soon as possible after it is taken. Although first class post is usually satisfactory for blood samples, special arrangements, e.g. by courier, hospital transport, ambulance service or taxi should be made for antenatal samples.

Please ensure that samples are taken and dispatched to arrive well before any Public Holidays when the laboratory may not be open.

On-site packaging and transport of samples

On-site packaging and transport of samples needs to be performed safely and is covered by the Health and Safety Commission guidance – *Safe working and the prevention of infection in clinical laboratories*.[13] This stipulates that individual specimens should be placed in sealable plastic transport bags. These should then be placed in suitable transport carriers for on-site transport. Transport carriers should be metal or plastic deep sided trays or boxes, which can be easily disinfected and cleaned.

13 Health and Safety Executive (2003) Safe working and the prevention of infection in clinical laboratories and similar facilities. HSE Books.

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