Amniocentesis and Chorionic Villus Sampling

University Hospitals of Leicester NHS
NHS Trust

Maternity

1. Introduction and Scope

This guideline is intended for the use of obstetric and midwifery staff involved in the care of pregnant women undergoing amniocentesis or chorionic villus sampling (CVS).

It is estimated that around 5% of the pregnant population (approximately 30,000 women per annum in the UK) are offered a choice of invasive prenatal diagnostic tests. The type of test offered is dependent on several factors including gestational age, indication and placental position.

Amniocentesis is the most common invasive antenatal diagnostic procedure undertaken in the United Kingdom (UK). Most amniocenteses are performed to obtain amniotic fluid for karyotyping. It is a procedure to remove amniotic fluid from the uterus.

CVS involves aspiration or biopsy of placental villi and can be done via trans abdominal or trans cervical methods. In UHL this is done by a trans abdominal approach.

2. Recommendations

1. Women undergoing amniocentesis or CVS should be fully counselled prior to the procedure of the risks involved and informed consent documented.

2. Amniocentesis and CVS should be performed at the appropriate gestation.

3. A safe technique should be used to perform amniocentesis and CVS.

4. Operators performing amniocentesis and CVS should be trained to the local competencies expected, those expected by the Royal College of Obstetricians (RCOG) or an international equivalent.

5. Clinical considerations for performing amniocentesis or CVS for multiple pregnancy / in the third trimester / IUD / BBI.

1. Women undergoing amniocentesis or CVS should be fully counselled prior to the procedure and informed consent documented.

Women should be advised of the risks of undergoing amniocentesis or CVS.

Women should be informed of the following:

- Written information about the procedure should be given prior to the consent being undertaken. It is good clinical practice to obtain formal written consent for amniocentesis or chorionic villus sampling and an interpreter should attend, as required.
- **Consent should contain, as a minimum, the following:**
- Verification of the procedure
- Estimated risks of procedure related pregnancy loss
- Accuracy and limitations of the particular laboratory test(s) being performed, with information noted on culture failure rates (1:500) and reporting times (up to 48 hours for FISH and 2-3 weeks for a microarray or targeted karyotype, if required. If blood-stained amniotic fluid sample, warn patient that FISH may not be possible.
- Any additional tests performed on the sample individualised to the patient.
- For molecular genetic study indications, eg single gene disorders, confirm whether patient wants concomitant karyotyping. The laboratory in Leicester will perform FISH only unless full karyotype requested and clinical indication (e.g. fetal anomalies) mentioned on the request form.
- That the risk of miscarriage with both procedures is around 1%
- Risk of maternal infection
- Invasive procedures performed after 24 weeks can cause preterm birth with associated complications of fetal prematurity.

2. Amniocentesis and CVS should be performed at the appropriate gestation.

- Amniocentesis should be performed after 15 weeks of gestation. Early amniocentesis is associated with increased rates of miscarriage and talipes. CVS is usually performed between 11 (11+0) and 13 (13+6) weeks of gestation and should not be performed below 10 weeks gestation due to a higher incidence of limb reduction defects.
- In certain circumstances clinicians may decide that CVS is a more appropriate invasive procedure than amniocentesis at later gestations, due to placental localisation.
- Late amniocentesis (>34 weeks) may be offered in certain circumstances where fetal FISH testing or Micro-array would be useful for planning delivery and postnatal management of baby. Antenatal corticosteroid administration should be considered as per local guideline.

3. A safe technique should be used to perform amniocentesis and CVS.

Asepsis

Both amniocentesis and CVS should be performed under aseptic techniques. The patient's abdomen should be cleaned with clear Chlorhexadine Gluconate 0.5% or equivalent. The Ultrasound probe should be cleaned using alcohol wipes, with sterile aqueous gel used as the ultrasound medium. All practitioners and assistants should wear sterile gloves. Check equipment and trolley are set up appropriately.

Chorionic villous sampling:

- Check first trimester screening results including infection screen.
- Trans abdominal approach preferred. Trans cervical rarely used where access problematic (i.e. low posterior placenta, retroverted uterus).
- Check the amnio / cvs needle is compatible with the syringe available.
- Choose entry site and track to target on ultrasound.
- Infiltrate up to 20 ml 1% lignocaine into superficial maternal tissues.
- Use 18-20 gauge needle, aseptic technique, with needle tip under continuous ultrasound guidance at all times.
- Check fetal heart rate post-procedure, demonstrate to parents.
- Check samples in correctly labelled bottles, and show to parents.
- Document procedure in the health record

Amniocentesis:

- Check first trimester screening results including infection screen
- Local anaesthesia not required.
- Check the amnio / cvs needle is compatible with the syringe available.
- Choose entry site and track to target on ultrasound.
- Maximum 20 gauge needle should be used under aseptic technique, with needle tip under continuous ultrasound guidance at all times.
- Aspirate the fluid – normally 20 mls or less.
- Check fetal heart rate post-procedure and demonstrate to parents.
- Check samples in correctly labelled bottles, and show to parents
- Document procedure in the health record

Post procedure care

Following the procedure the patient should be informed of

- Method of communication of results – complete the Fetal Diagnostic form (see Appendix 1).
- Indications for seeking medical advice following the test
- The need for anti-D post procedure if the woman is RhD negative

- Correspondence to GP (viewpoint proforma)
- Follow-up plan for ongoing management if results are normal
- Follow up plan for ongoing management if the results are abnormal.

4. Operators performing amniocentesis and CVS should be trained to the local competencies expected, those expected by the Royal College of Obstetricians (RCOG) or an international equivalent.

- Operators carrying out unsupervised amniocentesis and CVS should be trained to the competencies expected of subspecialty training in maternal and fetal medicine, the RCOG Fetal Medicine Advanced Training Skills Module (ATSM) or other international equivalent.
- Clinical skills models, assessment of interaction with patients and supervised procedures should be an integral part of training.
- Units and operators should carry out continuous audit of frequencies of multiple insertions, failures, bloody taps and post procedure losses.
- Further opinion should be sought from a more experienced operator if difficulties are anticipated or encountered.
- Expert opinion suggests that an operator's competence should be reviewed where loss rates appear high and audit should certainly occur where they exceed 4/100 consecutive amniocenteses or 8/100 CVS.

5. Clinical considerations should be made when performing amniocentesis or CVS for multiple pregnancy / in the third trimester / IUD / BBI

Multiple pregnancy

It is recommended that, in the case of multiple pregnancies, a CVS or amniocentesis is performed by a specialist who has the expertise in performing complex procedures and in planning a selective termination of pregnancy if required.

Intrauterine fetal demise

The success of culture for fetal cytogenetic investigation in cases of IUFD is higher when performed antenatally when compared to postnatal skin biopsy or placental tissue culture. This should be offered to all women as an option provided in appropriate clinical circumstances. Good communication between referring teams and the fetal medicine teams should be maintained to allow prompt and sensitive care to be provided to these women.

Rhesus, HIV and Hepatitis B status

It is important to know the woman's HIV, Rhesus and hepatitis B status before undertaking either amniocentesis or CVS.

The woman's **Rhesus** status should be stated on the referral form. It is vitally important that women who are Rhesus D negative are offered and given, where consent obtained, an appropriate amount of anti-D immunoglobulin according to their gestation to reduce the risk of Rhesus iso-immunisation (refer to Anti-D immunoglobulin UHL Obstetric guideline). The anti-D immunoglobulin should be given after the procedure in line with national guidance (Royal College of Obstetricians and Gynaecologists 2010).

Knowledge of the woman's **HIV** status and **hepatitis B** status (Refer to relevant UHL Obstetric guideline) are important to minimise the risk of transmission of the virus to the unborn fetus and to ensure that appropriate precautions are taken by hospital and laboratory staff. If women have declined screening for bloodborne viruses, the potential risks of infection to the fetus if positive should be discussed and that discussion documented (Royal College of Obstetricians and Gynaecologists 2010).

In known cases of blood borne infection it is mandatory to label specimens as high risk and alert laboratory staff.

In cases where mothers are HIV positive, liaise with the HIV specialist team for individualised management, with clear documentation in the mother's maternity notes.

3. Training and Education:

Performing Amniocentesis and CVS is part of fetal medicine training and should only be carried out by those trained or currently training under supervision.

4. Auditable standards:

- Women should be counselled prior to the procedure and advised of a 1% miscarriage rate
- Amniocentesis and CVS should be performed at appropriate gestation
    - Amniocentesis should be performed after 15 weeks of gestation.
    - CVS should be performed between 11 (11+0) and 13 (13+6) weeks of gestation.
- Aseptic technique should be used
- Operator should either be certified, covered by the grandfather clause or be supervised by an appropriately trained clinician
- Where difficulties were anticipated or encountered an opinion should be obtained from a more experienced operator
- Rhesus status of the mother should be known

- A Fetal Diagnostic Form was completed (can only be audited if in notes)

Continuous Audit: (via E3)

● Rate of pregnancy loss at any gestation after a procedure.
● Rate of pregnancy loss less than 24+0 weeks after a procedure.
● Rate of pregnancy loss within 14 days of procedure.
● Local cytogenetic laboratory culture failure rates for amniocentesis and CVS.
● Proportion of procedures requiring more than one needle insertion.
● Proportion of procedures with failure to obtain an adequate sample.
● Complication rates ('bloody' tap, amniotic fluid leakage).
● Maintenance of a register of invasive diagnostic procedures to facilitate audit. Audit should be performed annually and the results made accessible to patients.
● Rate of anti–D prophylaxis for women who are RhD-negative undergoing amniocentesis or CVS.

5. Supporting References:

"Amniocentesis and Chorionic Villus Sampling" Green-top guideline (2010). RCOG

"Amniocentesis and Chorionic Villus Sampling" – a guide for health professionals" Green-top guideline. Fetal anomaly screening programme (2011)

Related documents:

Anti-D immunoglobulin UHL Obstetric guideline

Hepatitis B and Syphilis screening in Pregnancy UHL Obstetric guideline

HIV screening in Pregnancy and the Intrapartum/postnatal management of women who are HIV positive UHL Obstetric guideline

6. Keywords: Amniocentesis CVS Micro array FISH Karyotype

Appendix 1.

UHL Safer Surgery Checklist:

Womens Services—Amniocentesis/CVS/Feticide

Patient Sticker: **Identity confirmed:** ☐ **Written consent obtained:** ☐	**Consultant:** _____ **Date of Test:** _____
Contact Details: Home: _____ Work: _____ Mobile: _____ Husband / Partners name: _____	**Procedure:** Amnio / CVS / Other If other please specify: _____ Blood group: _____ Kleihaeur taken: ☐ Yes ☐ No Anti D given: ☐ Yes ☐ No
Procedure details:	**Amniocentesis:** Samples taken labelled correctly and checked with parents: ☐ Yes ☐ No **Feticide:** Green syringe used for Potassium Chloride / Lidocaine: ☐ Cardiac bloods taken: ☐ Yes ☐ No Samples taken labelled correctly and checked with parents: ☐ Yes ☐ No
Operator:	**Assistant:**
Results and comments: FISH: _____ Date received: _____	Patient informed by: _____ Date: _____
Comments from lab report if complicated	Follow up plan (e.g. next appointment)

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
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July 2016	V1	L Matthews	No change to practice but inclusion of documentation requirements and verification of test to patient as per NHS England "National Safety Standards for Invasive Procedures
October 2018	V2	L. Matthews M. Bodley H. Ulyett	Importance of checking the connection between needles and syringes. Update of the amnio/CVS checklist to align with NatSSIPs guidelines. Update of Karyotype and Micro-array testing

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