



Setting standards to improve women's health

AMNIOCENTESIS

This paper provides advice for clinicians in obtaining consent of women undergoing amniocentesis. It follows the structure of the Department of Health/Welsh Assembly Government Consent Form 3 and should be used in conjunction with RCOG Clinical Governance Advice No. 6: Obtaining Valid Consent. Its aim is to ensure that all patients choosing this particular procedure are given consistent and adequate information for valid consent. It is recognised that specific issues will assume different levels of significance from one patient to another, sometimes dependent on the particular clinical circumstances. However, clinicians should be prepared to discuss any or all of the following with the patient and to document in the record that the discussion has taken place.

1. Name of procedure

Amniocentesis.

2. The proposed procedure

The procedure will involve obtaining a sample of amniotic fluid from the pregnancy sac using a needle inserted through the woman's abdomen. Explain the procedure as it is described in the patient information.

3. Intended benefits

The procedure intends to provide the woman with information regarding the karyotype (chromosomal make-up) of her fetus(es). Less commonly, it is carried out with the intention of obtaining biochemical, metabolic or genetic information.

4. Serious or frequently occurring risks

It is recommended that clinicians make every effort to separate serious from frequently occurring risks. Women who are obese must be aware that the procedure may be technically difficult and that this could lead to an increased rate of complications.

4.1 *Serious risks*

include:

- failure to obtain a sample of amniotic fluid. An experienced operator is likely to obtain success at the first attempt in 94% of procedures.
- An experienced operator is likely to obtain blood stained samples in approximately 0.8% of procedures assuming the use of continuous ultrasound guidance.
- miscarriage. A rate of 1% over the norm is usually quoted during counselling. A rate lower than 1% should be quoted only if it is supported by robust local data.
- fetal injury. This is rare and has been described only in case reports. This complication may be minimised by the now standard use of continuous ultrasound guidance.

- maternal bowel injury. This is also rare and, again, the risk is minimised by the use of continuous ultrasound guidance at the time of needle insertion.
- amniotic fluid leakage – temporary or prolonged and with the added risk of preterm delivery
- chorioamnionitis. Severe sepsis, including maternal death, has been reported but the risk of severe sepsis is likely to be less than 1/1000 procedures. Standards for control of infection should conform to those for any invasive diagnostic radiological procedure.
- failure of cell culture in the laboratory.

4.2 Frequent risks

include:

- mild discomfort at needle insertion site. This is estimated to be equivalent to the experience of venepuncture.

5. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment

The procedure will be carried out or supervised by an operator who is deemed to be experienced by national standards. It is carried out after 15 weeks of gestation, as confirmed by ultrasound. Usually it involves the passage of a 20- or 22-gauge needle through the abdomen under direct ultrasound guidance into the amniotic sac followed by aspiration of 10–15 ml amniotic fluid. Any local variation should be explained prior to the procedure. The risk of miscarriage should have been explained prior to performing the procedure. The consequences of not performing the procedure should have been made clear in the pretest counselling. Rhesus prophylaxis with anti-D immunoglobulin must be offered following the procedure to all women who are rhesus negative, in line with national recommendations.

6. Information

A record should be made of the information given to the woman prior to the procedure, which should include the method of communicating results, the reporting time and the indications for seeking medical advice after the test. There should also be information about storage and eventual disposal of the sample.

7. Anaesthesia

The woman should be made aware if any form of local anaesthesia is to be used.

Reference

Royal College of Obstetricians and Gynaecologists. *Amniocentesis and Chorionic Villus Sampling*. London: RCOG; 2005.

This advice was produced on behalf of the Royal College of Obstetricians and Gynaecologists by:

Dr AD Cameron FRCOG, Glasgow

and peer reviewed by Professor Z Alfirevic FRCOG, Miss MC Davies FRCOG, Mr DT Liu FRCOG, Mr MD Read FRCOG, Professor CH Rodeck FRCOG, Mr DR Stewart FRCOG, Mr SA Walkinshaw FRCOG, Mrs P Ward, National Screening Committee, Professor MJ Whittle FRCOG, Consumers' Forum. The Professional Standards Committee lead peer reviewer was Mr G Thomas FRCOG.

The template was developed by the RCOG Consent Subgroup and the final version is the responsibility of the Professional Standards Committee.

Valid until May 2011
unless otherwise indicated