RCOG Consent Advice No. 6
Peer review draft – August 2024

Amniocentesis for Prenatal Diagnosis

When to use this guidance

This is the second edition of this guidance, first published in May 2006 with the title *Amniocentesis*. This guidance is for healthcare professionals who care for women, non-binary and trans people requiring amniocentesis for prenatal diagnosis.

This guidance is for healthcare professionals to aid the provision of appropriate and balanced information about the potential benefits, risks and alternatives to those considering amniocentesis for prenatal diagnosis. Amniocentesis is predominantly offered for prenatal diagnosis, but it can also be undertaken for other indications that are outside the remit of this guidance.

This guidance is relevant for those who are aged 16 years and over with mental capacity, and those under 16 years of age who are Gillick competent*, to help make the decisions that are appropriate for them.

Within this document we use the terms woman and women's health. However, it is important to acknowledge that it is not only women for whom it is necessary to access women's health and reproductive services in order to maintain their gynaecological health and reproductive wellbeing. Gynaecological and obstetric services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex they were assigned at birth.

How to use this guidance

This guidance should be used by healthcare professionals to support meaningful discussions tailored to the individual's needs as part of the informed decision-making and consent process for those considering an **amniocentesis for prenatal diagnosis**, with reference to the General Medical Council's guidance on *Decision making and consent*[1] and *Intimate examinations and chaperones*,[2] and the following resources on procedures for prenatal diagnosis:

- Public Health England *Screening in pregnancy: CVS and amniocentesis information for parents* (www.gov.uk/government/publications/cvs-and-amniocentesis-diagnostic-tests-description-in-brief/nhs-fetal-anomaly-screening-programme-chorionic-villus-sampling-cvs-and-amniocentesis-information-for-parents).
- NHS website (www.nhs.uk/conditions/amniocentesis).
- Antenatal Results & Choices (www.arc-uk.org/tests-explained/amniocentesis).

How to provide information

* Gillick competence outlines whether a child (under 16) can consent to their own medical treatment without the need for parental knowledge or expressed permission. If the child has sufficient maturity and understanding to make informed decisions about their treatment, they would be considered Gillick competent.

For procedures such as amniocentesis, the information about the procedure should be provided when the possibility of prenatal diagnosis is first discussed with the woman to allow her enough time to consider the implications and to ask any questions.

Information should be made available in commonly used languages, and large print/Braille versions should be made available for those with impaired vision. Translators must be made available for those unable to read and/or understand the information. For non-English speaking users, consent should be obtained with the use of an interpreter. Healthcare professionals should not rely on family members or friends as interpreters.

Healthcare professionals are encouraged to consider using visual or other explanatory aids and to signpost to available resources[3] to support women in their understanding of the risks, taking account of their clinical and personal circumstances, compared with population level risk. **Discussions should take into consideration the importance a reasonable person in this position would be likely to attach to a risk. This should also include those risks that the clinician is already reasonably aware will be of importance to the person when deciding whether to have an amniocentesis for prenatal diagnosis.**

Recording informed consent

Using the information in the attached consent form, healthcare professionals should explain that the potential risks of amniocentesis, as stated, are summary estimates only, mainly based on available evidence from RCOG Green-top Guideline No. 8 *Amniocentesis and Chorionic Villus Sampling*.[4] It is acknowledged that there were some limitations with the quality of evidence, and not all the evidence was from a comparison of amniocentesis with not having this procedure in specific circumstances. Women should be informed by healthcare professionals that the risks include both relative effects (risks of an outcome in one group compared with another) and absolute effects (risks of a specific outcome in a group).

Women opting to have an amniocentesis should be informed that in the UK, it is carried out at or after 15^{+0} weeks of gestation. They should also be informed about the prerequisites, anticipated duration, precautions and recovery following the procedure. They should be informed that the procedure is carried out under continuous ultrasound guidance, using Local Safety Standards for Invasive Procedures (LocSSIPs).[5]

Local turnaround times for the results and how they will be communicated should also be stated.

Women having a twin or higher order multiple pregnancy who are considering amniocentesis should receive individualised counselling about the risks and benefits of the procedure for them, including the need for the procedure to be carried out in a tertiary fetal medicine clinic.

Women should be made aware that genetic, microbiological, viral and other studies can be performed on the amniotic sample, depending on the indication for the procedure. Genetic testing includes analysis of the chromosomes or individual genes, and other genomic studies. It is also helpful to explain that the yield of fetal cells from the amniotic fluid is crucial for rapid and reliable completion of the analysis.

Women should be informed that amniocentesis can provide information that may help them to make further choices around their pregnancy, may facilitate further care during their pregnancy and/or optimise care of the baby after birth.

Chorionic villus or placental sampling (CVS) can be offered as an alternative invasive test for prenatal **genetic** diagnosis. The placenta has a genetic make up with 99% of fetal origin; consequently, there is a 1% chance of finding anomalies which may not be present in the fetus. CVS can be carried out from 10^{+0} weeks of gestation and is suitable when earlier diagnosis is desired.[4]

Women should be informed that non-invasive prenatal tests on maternal blood samples can predict the likelihood of some genetic or chromosomal conditions for which reliable markers are identified, but confirmation of the diagnosis may still require an invasive test such as amniocentesis.[6] This can be offered as an alternative for prenatal diagnosis of some genetic disorders if approved by the national genomics laboratories.[7]

Women who are rhesus D negative serotype should be informed that they will be offered anti-D prophylaxis after their amniocentesis if there is a chance that their fetus may be rhesus D positive.

After provision and discussion of all available information, women should be offered time and opportunity to clarify any concerns they may have, before seeking their written consent.

References

1. General Medical Council. Decision making and consent [www.gmc-uk.org/professional-standards/professional-standards-for-doctors/decision-making-and-consent].
2. General Medical Council. Intimate examinations and chaperones [http://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/intimate-examinations-and-chaperones].
3. Antenatal Results and Choices [www.arc-uk.org].
4. Navaratnam K, Alfirevic Z; on behalf of the Royal College of Obstetricians and Gynaecologists. *Amniocentesis and chorionic villus sampling*. Green-top Guideline No. 8. *BJOG* 2022;129:e1–e15.
5. NHS England. *Patient Safety Alert – Supporting the introduction of the National Safety Standards for Invasive Procedures* [www.england.nhs.uk/2015/09/psa-natssips].
6. Royal College of Obstetricians and Gynaecologists. *Non-invasive Prenatal Testing for Chromosomal Abnormality using Maternal Plasma DNA*. Scientific Impact Paper No. 15. London: RCOG; 2014.
7. NHS England National Genomics Education Programme – GeNotes. Non-invasive prenatal diagnosis (NIPD) [www.genomicseducation.hee.nhs.uk/genotes/knowledge-hub/non-invasive-prenatal-diagnosis-nipd].

Consent form for amniocentesis for prenatal diagnosis

Patient identifier:

Name of proposed procedure: Amniocentesis for prenatal diagnosis

[insert brief description/outline of the procedure]

Anaesthetic:
Amniocentesis is usually performed without local or general anaesthesia.
This will be discussed further with you by the healthcare professional who will perform the amniocentesis.

Statement of healthcare professional (to be filled in by healthcare professional with appropriate knowledge of amniocentesis in pregnancy):

I have explained the above procedure to the woman, specifically, I have explained that:

- The procedure involves obtaining a sample of the amniotic fluid from around your baby for chromosomal, genetic or other tests as indicated.
- The sample will be obtained by passing a fine needle through your abdomen into the amniotic sac (pregnancy sac) inside your uterus (womb).
- The procedure will be carried out under ultrasound guidance using a sterile technique.
- The sample will be sent for testing which involves: **QF-PCR*** **/ Karyotyping / Chromosomal microarray / other ……**
  (circle all applicable)
- A blood sample from you and in some cases your partner will be taken and sent with the sample: **Yes / No** (delete as appropriate)

Below is a table showing the chance of experiencing certain complications when having an amniocentesis done by a fully trained healthcare professional. These numbers are estimates only and the chance of experiencing a complication will depend on the individual situation.

		Frequency/occurrence
Chance of procedure-related complications	**Miscarriage (if < 24^{+0} weeks pregnant)**	1 in 200 (0.5%) over the background risk which varies according to the individual situation
	Preterm labour (if > 24^{+0} weeks pregnant)	3–4 in 100
	Severe infection	Rare (1 in 1000–1 in 10 000)
	Blood stained sample	1 in 125 (0.8%) (higher in third trimester, 5–10 in 100)
	Maternal cell contamination	1–2 in 100
	Unable to give rapid result	2 in 100
	Failed cell culture	1–2 in 200 (0.5–1%) (higher in third trimester, up to 20 in 200 [10%])
	Injury to the baby	Rare
	Maternal organ injury	Rare
	Amniotic fluid leakage/bleeding	1–2 in 100

* QF-PCR, quantitative fluorescent-polymerase chain reaction

I have discussed the chance of complications that this individual considers are relevant to them, taking into account their personal circumstances, risk factors and plans for the future (specify details) ☐

I have discussed the alternatives (including not having the procedure, non-invasive prenatal testing; and chorionic villus sampling): ☐

I have discussed the procedures that may become necessary (tick as appropriate from following list if agreed by the woman):

- Repeat procedure if the sample is insufficient or no results from the sample ☐
- Additional more extensive genetic testing if necessary, e.g. ……☐

The following resources have been provided (specify details):

Public Health England *Screening in pregnancy: CVS and amniocentesis information for parents*
Antenatal Results & Choices: www.arc-uk.org/tests-explained/amniocentesis

I confirm that ……. has been offered the time and opportunity to ask further questions about the information provided.

Healthcare professional:

Signed ……Date……

Name (PRINT) ……

GMC/NMC number……

Job title ……

Contact details (if patient wishes to discuss options or ask further questions later)

……

Woman or service-user:

I do / do not agree* to the procedure, examination or treatment described, including the procedures, treatments or examinations which may become necessary.

I do / do not agree* for trainees/students to be present during the procedure.

I understand that I will be awake, and that no anaesthetic is used during the procedure Yes / No*
(*please delete as appropriate).

Signed .....Date.....

Name (PRINT) .....

Statement of interpreter (where appropriate)
I have interpreted the information above to the woman to the best of my ability and in a way in which I believe they can understand.

Signed ..... Date.....

Name (PRINT) ..... Contact details.....

Confirmation of consent (to be completed by a healthcare professional and the woman or service-user on the day of the procedure/treatment)

Healthcare professional:

Signed .....Date.....

Name (PRINT) .....

GMC/NMC number.....

Job title .....

Woman or service-user:
I confirm that I still want the procedure/treatment to go ahead.

Signed .....Date.....

Name (PRINT) .....

Or

I confirm I have withdrawn my consent for the procedure/treatment.

Signed .....Date.....

Name (PRINT) .....

This Consent Advice was produced on behalf of the Royal College of Obstetricians and Gynaecologists by the Patient Safety Committee.

The following individuals and organisations submitted comments at peer review:
[to be added post consultation].

The Patient Safety Committee lead reviewers were: Dr A Gorry FRCOG, London; and Dr EA Khan MRCOG, Milton Keynes.

The Chair of the Patient Safety Committee was: Dr SL Cunningham MRCOG, Stoke-on-Trent[1]; Dr CJ Calderwood FRCOG, Clydebank[2]; and the Vice Chair was: Dr J Elson FRCOG, Nottingham.

[1]until May 2024; [2]from June 2024

The final version is the responsibility of the Patient Safety Committee of the RCOG.

The review process will commence in XXXX, unless otherwise indicated.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces Consent Advice as an aid to good clinical practice. The ultimate implementation of a particular clinical procedure or treatment plan must be made by the doctor or other healthcare professional after obtaining a valid consent from the patient in light of the clinical data and the diagnostic and treatment options available. The responsibility for clinical care rests with the practitioner and their employing authority and should satisfy local clinical governance probity.