RCOG Consent Advice No. 6b
Peer review draft – January 2025

Chorionic Villus Sampling

1. When to use this guidance

This is the first edition of this guidance. This guidance is for healthcare professionals who care for women, non-binary and trans people who are offered chorionic villus sampling (CVS).

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 CVS.

This guidance is relevant for those 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. Obstetric and gynaecological 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.

2. How to use this guidance

This guidance should be used by healthcare professionals to support meaningful discussions tailored to the individual's needs. It is designed to aid informed decision-making and consent process for those considering CVS. This guidance should be used 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/chorionic-villus-sampling-cvs).
- Antenatal Results & Choices (www.arc-uk.org/tests-explained/chorionic-villus-sampling-cvs).

3. How to provide information

Information about CVS 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. Healthcare professionals must make all reasonable efforts to make translators available to those unable to read and/or understand the

* 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.

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 understanding their personalised risks, taking into account their clinical and personal circumstances, compared with population level risk. **Discussions should take into consideration what matters to the individual considering invasive tests for prenatal diagnosis in pregnancy. This should also include those risks that the clinician is already reasonably aware will be of importance to the woman when deciding whether to have CVS. Information from local audits, including that of Local Safety Standards for Invasive Procedures (LocSSIPs), should also be shared when discussing the risks of the procedure.**

It should be explained that genetic testing of the cells from the placental tissue includes analysis of the chromosomes or individual genes, and other genomic studies, and that prenatal diagnostic tests provide information that may help women to make further choices around their pregnancy. These tests may also facilitate further care during the pregnancy and/or optimise care of the baby after birth. Women should be offered genetic counselling appropriate to the condition(s) being tested for, prior to obtaining consent for the procedure.

4. Documentation of informed consent

Using the information in the attached consent form, healthcare professionals should explain that the potential risks of CVS, 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 having CVS with not having this procedure in specific circumstances. Women should be informed by healthcare professionals that the risks include both relative effects (occurrence of an outcome in one group compared with another, e.g. miscarriage in the intervention group versus control group with matched characteristics) and absolute effects (risks of a specific outcome in a group, e.g. risk of bloodstained sample in CVS after 14^{+0} weeks).

4.1 Details of the procedure

Women should be informed that CVS involves taking a tissue sample from the placenta, which can be carried out through the abdomen (transabdominal) or through the cervix (transcervical), although the former is more commonly performed in the UK. Women opting to have CVS should be informed that it can be offered from 10^{+0} weeks of gestation, but to reduce the risk of technical challenges, it should be performed from 11^{+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 LocSSIPs.[5]

Local turnaround times for the results and how they will be communicated should also be stated. It is also helpful to explain that the yield of chorionic villi is crucial for rapid and reliable completion of the analysis.

4.2 Tests on the placental sample

Women should be informed that the placental sample will be processed, tested and that any of the remaining genetic material extracted will be stored in the genetics laboratory to be available for any further testing, should the need arise. It should also be explained that samples will be disposed of

according to the recommended laboratory protocols, compliant with the Human Tissue Act 2004.[6] They should also be informed that a maternal blood sample might be required along with the placental sample, and a blood sample from the biological father might also be requested later to help with the interpretation of the results.

As CVS involves taking a tissue sample from the placenta, women should be made aware that there is a chance of finding anomalies limited to the placental tissue only that are not present in the fetus, known as confined placental mosaicism. This occurs in in up to 2% of samples, and to establish this further tests may be advised. Women should be informed that they might be advised to wait for more specific testing of cultured cells from the the sample to confirm any anomalies, or if the sample is insufficient to yield results on rapid testing (in up to 6% of cases). In rare instances another procedure (amniocentesis) might also be advised.

4.3 Alternatives

The following alternatives and their potential risks and benefits compared with CVS should be discussed with the woman.

- No further testing.
- Cell-free fetal DNA (cffDNA) prenatal testing, which includes:
  - Non-invasive prenatal testing (NIPT) of cffDNA from maternal blood samples can predict the likelihood of some genetic or chromosomal conditions for which reliable markers are identified (e.g Trisomies 21, 18 or 13), but confirmation of the diagnosis may still require an invasive test.[7] A low chance result does not completely rule out the possibility of the condition in the fetus.
  - Non-invasive prenatal diagnostic testing (NIPD) of cffDNA from maternal blood samples can be offered as an alternative for prenatal diagnosis of some genetic disorders if approved by the national genomics laboratories.[8]
- Amniocentesis can be offered as an alternative to CVS for prenatal diagnosis, but this would be carried out only at or after 15^{+0} weeks of gestation.
- Postnatal testing:
  - Testing of cord blood or neonatal sampling can be offered with the understanding that specific antenatal information cannot be made available and the choice to end the pregnancy or optimise care during the pregnancy or perinatal period is excluded.

All of the above, except amniocentesis, avoid the additional risks of an invasive procedure during pregnancy.

4.4 Specific circumstances

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

4.5 Post procedure care

Women who are rhesus D negative serotype should be informed that they will be offered an anti-D injection after CVS in case their fetus is rhesus D positive. This prophylactic tratment prevents the baby developing haemolytic disease of the fetus and newborn (HFDN).

The above discussions should be supplemented by providing patient information which is accessible to individual needs; women should also be given contact details for the team who organise appointments, provide test results and who to contact for advice if they experience symptoms suggestive of complications following their procedure.

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. B.R.A.I.N. can be a helpful tool to share with the person considering whether or not to have any procedure, in order to make sure informed consent is authentically obtained, that is:

- **B**enefits – What are the benefits of making this decision?
- **R**isks – What are the risks associated with this decision?
- **A**lternatives – Are there any alternatives?
- **I**ntuition – How do I feel? What does my 'gut' tell me?
- **N**othing – What if I decide to do nothing/wait and see? What happens next?

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* [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 Physicians, Royal College of Pathologists and British Society for Genetic Medicine. Consent and confidentiality in genomic medicine: Guidance on the use of genetic and genomic information in the clinic. 3rd edition. Report of the Joint Committee on Genomics in Medicine. London: RCP, RCPath and BSGM; 2019.
7. 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.
8. 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 chorionic villus sampling

Patient identifier:

Name of proposed procedure: Chorionic villus sampling (CVS)

Anaesthesia:

Transabdominal CVS is usually performed with the use of local anaesthesia to numb the entry area into your abdomen.

This will be discussed further with you by the healthcare professional who will perform the CVS.

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

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

- The procedure involves obtaining a small tissue sample from the placenta and testing the cells for chromosomal, genetic or other analyses as indicated.
- The sample will be obtained by passing a thin needle through your abdomen, into your uterus (womb) and your placenta.
- The procedure will be carried out under continuous ultrasound guidance using an aseptic technique.
- The procedure will involve the use of local anaesthetic.
- The sample will be sent for testing which involves: **QF-PCR*** **/ Karyotyping / Chromosomal microarray / other (for which detailed consent may be required)**
  ……
  (circle all applicable)
- A blood sample from you, and in some cases the other biological parent, may be taken and sent with the placental sample or afterwards: **Yes / No** (delete as appropriate)

Below is a table showing the chance of experiencing certain complications when having a CVS performed by an appropriately 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 of gestation)**	1 in 200 over the background risk, which varies according to the gestation and the individual circumstances of your pregnancy
	Confined placental mosaicism (genetic anomaly found to be present only in the placenta)	1–2 in 100
	Severe infection	Rare (1 in 1000–1 in 10 000)
	Maternal cell contamination	1–2 in 100
	Unable to give rapid result	2 in 100

* QF-PCR, quantitative fluorescent-polymerase chain reaction

	Failed cell culture	1–2 in 200 (higher in third trimester, up to 20 in 200)
	Second or repeat procedure advised	6 in 100
	Injury to the baby	Rare
	Maternal organ injury	Rare

I have discussed the chance of complications taking into account their personal circumstances, and plans for the future (specify details) ☐

I have discussed the alternatives (including not having the procedure, cell-free fetal DNA [cffDNA] prenatal testing from maternal blood, testing after birth and amniocentesis): ☐

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

- 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/chorionic-villus-sampling-cvs

I confirm that ..... has been offered time and opportunity to seek clarification on 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)

.....

Patient:

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 local anaesthetic is used during the procedure Yes / No*

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

Name (PRINT) .....

(*please delete as appropriate).

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient 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 patient on the day of the procedure/treatment)

Healthcare professional:

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

Name (PRINT) .....

GMC/NMC number.....

Job title .....

Patient:

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:
[Guidance Editorial Manager to add post consultation].

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

The Chair of the Patient Safety Committee was: Dr CJ Calderwood FRCOG, Clydebank; and the Vice Chair was: Dr J Elson FRCOG, Nottingham.

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.