Patient information and consent to amniocentesis

Key messages for patients

- Please read this information carefully, you and your health professional will sign it to document your consent.

- This test is not offered as a matter of routine. It is used to detect Down’s/Edwards’/Patau’s syndrome and specific known genetic disorders. There is no evidence that the procedure itself harms the baby as the test is carried out under ultrasound guidance, but the test is most safely performed after 15 weeks of pregnancy.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Painkillers may be required after your hospital stay – ensure you have appropriate supplies at home.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Change of appointment. Please call us if you need to cancel your appointment for any reason (including illness) so your slot can be used by others. You can call the Fetal Medicine Unit direct on 01223 216185 (or please call the hospital contact centre on 01223 245151 extension2185).

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

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About amniocentesis

Who should consider amniocentesis?
The final decision about having any test in pregnancy is yours, but the following women may want to consider amniocentesis:

- Women with a high-risk result from a nuchal translucency scan for Down’s/Edwards’/Patau’s or quadruple test designed to find out the risk of having a baby with Down’s syndrome.
- Women who have a potential problem found on the ultrasound scan, which may suggest a chromosomal abnormality.
- Women who have had a pregnancy or a child affected by a genetic condition that can be tested for by an amniocentesis.
- Couples who have had a baby with Down’s/Edwards’/Patau’s syndrome or those who have had a family history of genetic disorders, including some rare inherited diseases that can be tested for by amniocentesis.
- Women who have missed the screening tests for Down’s syndrome, or request invasive testing for their own reasons.

The chance of having a baby with Down’s syndrome by age is as follows:

- 25 1 in 1500
- 30 1 in 910
- 35 1 in 380
- 38 1 in 190
- 40 1 in 110
- 45 1 in 30

Benefits of the procedure
It is the only way to know whether baby’s chromosomes are normal or not.

Who will perform my procedure?
We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

What are the problems associated with amniocentesis?
Amniocentesis has now been available for a number of years and in Britain over 15,000 women have the test performed every year. We therefore know a lot about its safety and accuracy. We know that the test can sometimes cause a miscarriage and approximately 1 in every 100 women, who have the test, will miscarry as a result of the procedure. There is no evidence that the procedure itself harms your baby as the test is carried out under ultrasound guidance.

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Is the amniocentesis test reliable?

No test is absolutely perfect, but the chromosome test for Down’s/Edwards’/Patau’s syndrome is very reliable.

It fails to give a clear result in less then 1 in 1000 cases. If you are having the amniocentesis for other genetic disorders, you should discuss the accuracy of the test with your genetic doctor or counsellor.

Will the test reveal anything other than Down’s/Edwards’/Patau’s syndrome?

Although you may be having an amniocentesis to detect Down’s/Edwards’/Patau’s syndrome, the test may occasionally detect problems with the other chromosomes.

If the results show anything abnormal you will be told what the abnormality is and how this will affect your baby.

How is amniocentesis performed?

The test involves taking a small amount of the amniotic fluid (water) that surrounds the baby in the womb. This fluid contains cells from the baby that are tested in the laboratory.

Before the test is performed, an ultrasound scan is carried out to check your dates and the position of both the baby and the placenta (afterbirth). You will not need a full bladder for this scan.

The skin over the abdomen is cleaned and a fine needle is then passed into the womb. A sample of the fluid that surrounds the baby is removed and sent to the laboratory. The position of both the baby and the needle are monitored throughout the procedure by ultrasound.

Is amniocentesis painful?

Most women say afterwards that the test is uncomfortable rather than painful and feels similar to period pain. Generally, women say that the thought of it is worse than the actual test.

What happens after the amniocentesis test?

You will probably be at the hospital for about half an hour, but the test itself just takes a few minutes.

If your blood group is Rhesus negative, you will be given an injection following the procedure to prevent the formation of antibodies in your blood, which may otherwise affect future pregnancies.
We encourage you to bring a companion with you for support during and after the test. It is a good idea to take things easy for a couple of days, although this will not affect your risk of miscarriage.

The “period pain” feeling may persist for 24 to 48 hours. This is not unusual and should settle after rest and Paracetamol, which is safe to take in pregnancy. If you have excessive pain, are leaking any fluid, bleeding or develop a high temperature, please contact your local labour ward for advice.

When do you get the results?

The laboratory test involves the extraction of DNA from amniotic fluid cells. The DNA is tested using a rapid method called a QF-PCR (Quantitative Fluorescent Polymerase Chain Reaction) test. These tests will assess 3 of the possible 23 pairs of chromosomes in the baby. The chromosomes that will be assessed will be chromosome 21, 18 and 13, as too many of these chromosomes in an individual are the most common cause of fetal abnormality in the population namely trisomy 21 (Down’s syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau’s syndrome).

These tests do not detect other chromosomal rearrangements (a structural change in a chromosome) or abnormalities of the sex chromosomes. If clinically indicated, sex chromosome tests and microarray may be undertaken (the microarray test can detect changes that cause extra or missing copies of genes, and a separate information leaflet and consent form are required).

The QF-PCR test usually takes about three working days. In certain situations a further test will check all chromosomes of the baby and this result will take about two weeks. If the chromosomes are normal, we will send you a written report by post.

If you are having an invasive test because of ultrasound anomaly, genetic conditions or history then the rapid QF-PCR and microarray will be performed. The rapid test result will be available within three working days and the microarray result will be available at 10-14 working days.

If you are having an invasive test due to an increased risk from Down’s screening then only the rapid QF-PCR test would be performed. If you wish to have the microarray test or a full karyotype then an additional charge would be made to cover the laboratory expenses involved in this.

As the full karyotype is not performed, it is anticipated a small number of babies will be affected by clinically important chromosomal abnormalities which will not be detected by QF-PCR.
What if the results are abnormal?
If a chromosome problem is detected, you will usually be contacted by either the Fetal Medicine Unit or your own referring hospital. You will usually be contacted by telephone and given an opportunity to discuss the findings. You will be told what the abnormality is and how this could affect your baby. You will have the chance to discuss the results fully before making any decisions.

You will be contacted by either:
- a) a genetics counsellor by prior arrangement,
- b) the Fetal Medicine Unit at the Rosie Hospital, or
- c) your own referring hospital.

Alternative procedures that are available
We will discuss with you whether an alternative procedure such as CVS (chorionic villus sampling) would be appropriate.

HIV infection
We would encourage women who are HIV positive to discuss invasive testing with their specialist midwife or doctor to obtain further information. This is because there is a small risk that the HIV virus can be passed on to the developing baby during the procedure.

Outcome of pregnancy
Outcome information is very important to us as this enables us to audit and improve our service. Following your appointment with us, you may be given an outcome form and an addressed envelope, which we would be very grateful if you would complete and return to us.

Information and contacts
Please telephone the fetal medicine unit at the Rosie on 01223 216185 if you have any questions about amniocentesis. We can arrange for a fetal medicine midwife to talk to you if you wish. We recognise that everyone will have their own particular questions and concerns. The midwife or doctor will usually be able to answer any questions you may have before you have your test.
Information about important questions on the consent form

1 Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue

As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
We are a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language or audio, please contact Interpreting services on telephone: 01223 256998, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.

Document history

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It is the only way to know whether the baby’s chromosomes are normal or not.

The test can sometimes cause a miscarriage in approximately 1 in every 100 women.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
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d) any extra procedures that might become necessary during the procedure such as:

☐ Blood transfusion  ☐ Other procedure (please state)

2 The following information leaflet has been provided:

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Version, reference and date: CF238 version 7, December 2019
or  ☐ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:

☐ General and/or regional anaesthesia  ☐ Local anaesthesia  ☐ Sedation  ☐ None

Signed (Health professional): __________________________ Date: P.P./M.M./Y.Y.Y.Y.

Name (PRINT): __________________________ Time (24hr): H.H.:M.M.

Designation: __________________________ Contact/bleep no: __________________________

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.

☐ Yes  ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

☐ Yes  ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

☐ Yes  ☐ No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training.

☐ Yes  ☐ No

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File: in the procedures and consents section of the casenotes

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4 Use of Tissue
   a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.

   b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): Date: __/__/__
Name of patient (PRINT): ____________________________

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.

Signed: Date: __/__/__
Relationship to patient: ____________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): Date: __/__/__
Name of witness (PRINT): ____________________________
Address: ____________________________

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**D  Confirmation of consent**

Confirmation of consent (where the treatment/procedure has been discussed in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): .................................................. Date: ........................................

Name (PRINT): ................................................................. Job title: ........................................

Please initial to confirm all sections have been completed:

**E  Interpreter’s statement** (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): .................................................. Date: ........................................

Name (PRINT): .................................................................

Or, please note the language line reference ID number:

**F  Withdrawal of patient consent**

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): .................................................. Date: ........................................

Signed (Health professional): .................................................. Date: ........................................

Name (PRINT): ................................................................. Job title: ........................................