Patient information and consent to live donor liver transplantation (using part of a liver from a living donor)

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

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

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- 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.

- Laxatives and painkillers may be required after your hospital stay; please 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.

- Please call the live donor liver co-ordinator via the hospital switchboard: **01223 245151** if you have any questions or concerns about this procedure or your appointment.

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. All information we hold about you is stored according to the Data Protection Act 1998.
About to live donor liver transplantation (using part of a liver from a living donor)

This is a complex and major procedure to remove your diseased liver and replace it with a new healthy liver lobe donated by a living donor through a different operation. This procedure is generally recommended for patients who suffer from non-reversible, end stage liver disease. The transplant procedure typically takes eight hours or more to perform. However, if we encounter any difficulties, the operation might take substantially longer.

Intended benefits

- Liver transplantation is considered to be a life-saving procedure.
- Most people who have had a liver transplant consider they have more energy and a better quality of life after the operation. They find that most of the symptoms of liver failure, such as jaundice, itching, fluid in the tummy, swelling of legs etc, will gradually disappear.
- After a liver transplant, you can expect a 60 to 70% chance of being alive at the end of a 10 year period

Who will perform my procedure?

The liver transplant operation will be carried out by an appropriately experienced surgical team within the liver transplant unit.

Before your procedure

You have been prepared for this procedure by a team of Hepatologists, with input from Surgeons, Anaesthetists, Psychiatrists, Dentists, Co-ordinators Paramedical staff and Nursing personnel. Your name will have been added to the Cambridge liver transplant waiting list. You and the donor would have undergone extensive investigations to make sure that the proposed living donor liver transplantation is possible from a surgical point of view. You will be given a date for this procedure and will be admitted to the transplant ward the day before the operation.

Most patients attend a pre-admission clinic, when you will meet the surgeon performing your operation. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

Live donor liver transplantation, CF400, Version 3, November 2016
• When you arrive, a doctor will see you in the transplant ward, go through your medical history again, examine you and take some blood for final laboratory tests.
• On the day of the operation you will be taken to the operating theatre as soon as the surgeons carrying out the donor operation are happy with the appearance of the liver in the donor.
• Very occasionally, the donor liver having been inspected will be found to be unsuitable for you, just prior to your planned operation. Your operation will then be cancelled. If this should happen, it will not affect your place or priority on the waiting list for another liver.
• Following a liver transplant operation, you are likely to need to stay in hospital for at least 10 to 14 days. You might however, need to stay longer, depending on your clinical condition and your doctor’s opinion.

Hair removal before an operation
For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team need to see or reach your skin and if this is necessary they will use an electric hair clipper with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

During surgery, you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. The blood transfusion can involve giving you other blood components such as plasma and platelets which are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend for you to have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. Your doctor can explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment. There is a patient information leaflet for blood transfusion available for you to read.

During the live donor liver transplantation (using part of a liver from a living donor)
• We will give you a general anaesthetic, which means you will not be conscious during the operation.
• We will place several lines (tubes) into some blood vessels in your arms and neck. These give you medication, fluids and/or blood, and help us take blood for tests and monitor your condition. In addition, a tube might be passed into your stomach through the nose to empty your stomach.
• We also place a urinary catheter into your bladder during and after the operation to drain the urine.
A team of surgeons will first prepare the new liver and then carry out the liver transplant procedure in you.

The surgeon will make a long curved incision (cut) in the upper part of your abdomen (tummy) and remove the diseased liver. The new liver will then be connected up to the blood vessels and bile duct.

Typically, this takes eight hours or more. However, if we encounter any difficulties, the operation might take substantially longer.

**After the live donor liver transplantation (using part of a liver from a living donor)**

- After the liver transplant procedure has been carried out you will be taken to an intensive care bed. You might be woken up the same day from the anaesthetic or depending on your condition, the team might decide to keep you anaesthetised and ventilated (placed on a breathing machine) for a day or two in intensive care.
- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.
- You will be attached to several tubes and monitors for a number of days.

**If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.**

**Eating and drinking.** After this procedure, you will be allowed to eat and drink a couple of days after the operation.

**Getting about immediately after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy help.

**Leaving hospital.** Generally most people who have had this operation will be able to leave hospital after 10 to 14 days. You might however, need to stay longer, depending on your clinical condition and your doctor’s opinion. However, the actual time that you stay in hospital will depend on your general health, how quickly you are recovering from the procedure and your doctor's opinion.

**Resuming normal activities including work.** When you leave hospital, you should be able to carry out light daily activities at home. However, it might be a few months before you can return to normal active work. Your doctor will advise you on how quickly you can resume normal and more vigorous activity.
Special measures after the procedure: As soon as you are able, you will be encouraged to be mobile and carry out deep breathing exercises. This both reduces the chance of getting a blood clot in the leg and also helps you to avoid chest infections. We will give you further information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (eg infection).

Check-ups and results: In the period after the operation, you will be seen very frequently in the transplant clinic to check your progress and to make sure your new liver is functioning well.

Significant, unavoidable or frequently occurring risks of this procedure

- Liver transplant is a complex and major procedure and there is up to 10% risk of death in the first year following the transplant. There is a very small but real risk of death during the operation itself.
- Following the operation, there is a small risk (of 2%) that the new liver might not function or a risk (of 4%) that the blood vessels taking blood into the liver might get blocked. This will lead to failure of the liver and we will need to urgently re-transplant the liver within 48 hours, without which survival is not possible.
- In the event of bleeding or a bile leak, a further operation may be needed to sort out the problem.
- Bile duct narrowing and bile leaks may occur in up to 25% (1 in 4) of patients undergoing this procedure. This would require further procedures and occasionally a new liver transplant.
- Occasionally the transplanted lobe may not be sufficiently big enough to work adequately in you (‘small for size syndrome’) and this may result in prolonged hospital stay. It may also result in jaundice and fluid retention until the lobe grows in size and starts to function normally.
- After the operation, there is a 25% risk of acute rejection of the new liver. If this happens, we need to give you some extra treatment with more powerful medications.
- In the longer term, you might develop chronic rejection of the new liver. If this happens you might need to have a further transplant procedure.
- The primary liver condition (that caused your original liver failure) can recur in the new liver.
- Most people who have had a liver transplant need to undergo further admissions into hospital in the subsequent months and years. These are necessary so that we can check you, using blood tests, scans, endoscopies and/or liver biopsies.
- As with any other operation, complications can occur, such as wound infections, fluid leaks from drains and wound sites etc. These complications can often be managed with medication, rather than any further surgical procedures and every effort will be made to prevent this.
- We take every effort to screen liver donors for infections and tumours; however, we cannot guarantee that an infection or tumour will not be transmitted from the donor to you, the recipient. The risks are, however, extremely low and similar to that of blood transfusion.
You will need to take a number of medications on a long-term basis to prevent rejection of the new liver. This is called Immunosuppression.

**Immunosuppression**

In order to protect the new ‘foreign’ liver from rejection by your immune system, you will need to take some powerful immunosuppressive medications. Although these should protect your new liver, they also reduce your immunity for example; they make you more susceptible to some infections.

**Side effects of immunosuppressive medication**

The potential side effects of these medicines include infections, kidney problems, diabetes, stomach upset and wound problems. There is also a higher risk of cancer in patients taking these medications.

To reduce any side effects, the medical team will try adjusting the dose of medications you take, based on your specific condition.

It is very important that you follow our instructions on when and how to take your medication. If you do not follow the dosage schedule strictly (ie if you miss taking tablets), you run a significant risk of losing your liver without the prospect of a new one.

**Please remember that the Transplant Unit has recommended the liver transplant procedure to you because the team feels that the benefits will greatly outweigh the risks for you.**

**Alternative procedures that are available**

Liver transplantation is the only successful form of treatment for non-reversible, end stage liver failure. However, symptoms such as jaundice, itching, fluid overload can occasionally be managed non-operatively, for a limited period of time, with medication.

An alternative to this surgery is a decision not to have surgery. We will discuss with you the implications of deciding not to have surgery.

**Information and support**

If you have any anxieties or questions, please feel free to ask any member of staff. Further information can be obtained from the transplant co-ordinators who can be reached through the Addenbrooke’s Switchboard or 01223 216672. Further information can also be found on the Addenbrooke’s website: [www.addenbrookes.org.uk](http://www.addenbrookes.org.uk) or [www.cambridgetransplant.org.uk](http://www.cambridgetransplant.org.uk)
Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness. Sometimes different types of anaesthesia are used together.

Before your operation

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

Pre-medication

You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.

Moving to the operating room or theatre

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.
**General anaesthesia**

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

**Regional anaesthesia**

Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

**Local anaesthesia**

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted. Some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

**Sedation**

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain and the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.
What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (1 in 10 people) and common side effects (1 in 100 people)
Feeling sick and vomiting after surgery
Sore throat
Dizziness, blurred vision
Headache
Bladder problems
Damage to lips or tongue (usually minor)
Itching
Aches, pains and backache
Pain during injection of drugs
Bruising and soreness
Confusion or memory loss

Uncommon side effects and complications (1 in 1000 people)
Chest infection
Muscle pains
Slow breathing (depressed respiration)
Damage to teeth
An existing medical condition getting worse
Awareness (becoming conscious during your operation)

Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications
Damage to the eyes
Heart attack or stroke
Serious allergy to drugs
Nerve damage
Death
Equipment failure
Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: www.rcoa.ac.uk
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 biomedical 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.
Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now 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, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.info@addenbrookes.nhs.uk.
Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history
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Live donor liver transplantation

More energy and a better quality of life, symptoms of liver failure gradually disappear and after a liver transplant, you can expect a 60 to 70% chance of being alive at the end of a 10 year period.

10% risk of death in the first year following the transplant, very small but real risk of death during the operation itself, small risk (2%) that the new liver might not function, a 4% risk that the blood vessels taking blood into the liver might get blocked, bleeding, bile leak and bile duct narrowing. Transplanted lobe mat not be big enough to work in you resulting in jaundice and fluid retention until the lobe grows in size and starts to function normally. 25% risk of acute rejection of new liver.

Wound infections, fluid leaks from drains and wound sites. Infection and/or tumour can be transmitted from donor to recipient.

The intended benefits of the procedure (please state)

More energy and a better quality of life, symptoms of liver failure gradually disappear and after a liver transplant, you can expect a 60 to 70% chance of being alive at the end of a 10 year period.

The possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient.

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:
 Consent Form

Live donor liver transplantation

2 The following information leaflet has been provided:
Live donor liver transplantation

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: D.D./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
check 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
Consent Form

Live donor liver transplantation

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.

☐ Yes ☐ No

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.

☐ Yes ☐ No

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: D.D./M.M./Y.Y.Y.Y.
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: D.D./M.M./Y.Y.Y.Y.
Relationship to patient:

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

Signed (Witness): ................................................................. Date: D.D./M.M./Y.Y.Y.Y.
Name of witness (PRINT): .................................................................
Address: .................................................................

Patient safety – at the heart of all we do

Addenbrooke’s Hospital | Rosie Hospital

Live donor liver transplantation, V3, November 2016
Consent Form

Live donor liver transplantation

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: ..........................................................

For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: ______ / ______ / ______
Use hospital identification label