Patient information and consent to a pancreas transplantation alone

Key messages for patients

- When you are called to come in for a transplant, follow the instructions given by the transplant coordinator; they will usually ask you not to eat or drink anything following the call. Do not give yourself any long acting insulin.

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

- 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.

- Simple painkillers such as paracetamol and ibuprofen may be required after surgery. Simple bowel medication such as senna and lactulose may be required after surgery. It is suggested that you discuss with your pharmacist and have a seven day supply of these medications at home to take as you need according to the instructions.

- When a suitable pancreas is available, you will be contacted by phone. This may be at any time of the day or night: please keep your mobile phones charged and with you. At this time, you will be asked to report to Ward G5 without delay. This is because the pancreas cannot survive outside the human body for more than a few hours.

- Transplantation is not without risk. Some of these risks are outlined in this document. By putting you on the transplant waiting list your doctors and you have decided that the risks to your life from having a transplant are fewer than the benefit you will get from a successful pancreas transplant. Nevertheless if there are some risks that you would rather avoid you can indicate them when you sign the consent form.

- Please call the transplant co-ordinators on 01223 216536 if you have any questions or concerns; out of hours phone 01223 245151.

Please read this information carefully. You and your health professional will sign it to document your consent. 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. If you do change your mind and no longer wish to have a transplant, it is important that you inform your transplant co-ordinator.
immediately, so that you can be removed from the transplant waiting list.

We will only carry out the procedure on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to you. 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. We also send your information to NHS Blood and Transplant, the national administrators for organ transplantation.

About pancreas transplantation
A pancreas transplant operation has been recommended for you because either you have already had a kidney transplant and would now like a pancreas to treat your diabetes, or because you have life-threatening hypoglycaemic episodes (Hypos). The pancreas transplant will provide the insulin that your own pancreas no longer provides. Pancreas transplantation is a major operation involving a team of transplant surgeons working for four to six hours. If successful, it will control your blood sugars without the need for any insulin injections or special diets.

Intended benefits
Pancreas transplantation offers you the possibility of coming off insulin. By controlling your diabetes some of the complications of diabetes that you experience may slow, stop or even reverse. In the long term it might increase your chances of living longer. We expect 85 out of 100 of our pancreas transplants to work at least one year after the transplant operation. The average “life” of a pancreas when transplanted alone is five years, although half will last longer than this. When it fails you will need to return to using insulin to control your diabetes.

Who will perform my procedure?
The pancreas transplant operation will be carried out by an appropriately experienced and trained surgical team led by one of the consultant transplant surgeons.

Before your procedure
If you have already had a kidney transplant your nephrologist (kidney specialist) and the Transplant Surgeon will have discussed your condition with you and with other surgeons and personnel related to the Transplant Programme. If you have not had a kidney transplant your diabetic specialist will have recommended a pancreas transplant for you and discussed it with you and the transplant personnel. They will have decided to add your name to the Cambridge Transplant Waiting List for a pancreas transplant. When an appropriately matched pancreas is available, you will be contacted by phone.
When you arrive on ward G5, a doctor will see you and go through your medical history again, examine you, and take some blood for urgent tests. You will then wait for the pancreas to reach Addenbrooke’s, before you are prepared and taken to the theatre for the transplant operation.

The transplant procedure involves the use of general anaesthesia and often also an epidural anaesthetic. See below for further details about this type of anaesthesia.

**During the procedure**

We will place several fine tubes (cannulas/lines) into some blood vessels in your arms and neck. These give you fluids and/or blood, and help us take blood for tests and monitor your condition. In addition, a tube will be passed into your stomach through your nose to decompress (deflate) your stomach. We also place a urinary catheter into your bladder during the operation to drain the urine, and this will stay in place for about five days. You may also be fed through a tube (a feeding jejunostomy) placed through the skin directly into the bowel at the time of your transplant operation. Lastly you will have two tubes (drains) draining inflammatory fluid away from the operation site – these will be removed a few days later.

A team of surgeons will first prepare the donor pancreas and then carry out the transplant procedure in you. The surgeon will make a long vertical incision (cut) in your abdomen. The donor pancreas will then be connected up to the blood vessels that take blood to and from your legs, and also connect the pancreas to the bowel so that the digestive juices it makes can drain away. Typically, this takes four to six hours; if we encounter any difficulties or if you have had previous abdominal surgery, the operation might take substantially longer.

Occasionally we cannot completely close your abdomen after performing the pancreas transplant. In this case we may have to use a piece of plastic mesh or use some plastic surgery to close the abdomen.

In exceptional circumstances we may encounter a problem during the transplant operation that makes it unsafe to continue, either because of technical difficulties during your operation, or new and unexpected findings either with you or with the donor pancreas. If that happens your operation will be stopped and you will be woken up and returned to the ward.

**It is common for us to remove your appendix**, if you still have it, during the course of the procedure. If you have gallstones we will usually remove your gall bladder at the same time to stop you having problems after the transplant operation.

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.

**After the procedure**

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward.

You will be taken either to the intensive care unit on level three, or to the high-dependency unit on ward F5. Usually you are woken up from the anaesthetic on the same day. Occasionally, depending on your condition, the team might decide to keep you anaesthetised and on a breathing machine (ventilated) for a day or two in intensive care.

**Eating and drinking.** Generally, you will be allowed to eat and drink on the third or fourth day after the operation. You will also be fed through a tube called a jejunostomy which passes through the skin into the bowel. It is inserted at the time of your operation.

**Getting about immediately after the procedure.** We will encourage you to move around and carry out deep breathing exercises as soon as you are able to do so. This both reduces the chance of getting a blood clot in the leg and also helps you to avoid chest infections. If you have any mobility problems, we can arrange nursing or physiotherapy help.

**Leaving hospital.** Following a pancreas transplant, you are likely to need to stay in hospital for 10 to 21 days. You might however, need to stay longer. The actual time that you stay in hospital will depend on your general health, how quickly you recover 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.
Special measures after the procedure: 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 medicines to make you more comfortable.

We will give you more detailed 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 (for example, infection).

Check-ups and results: In the period after the operation, you will be seen in the transplant outpatient clinic very regularly (twice a week to start with) to check your progress and to make sure your pancreas transplant is functioning well.

Significant, unavoidable or frequently occurring risks of this procedure
Pancreas transplantation is a complex procedure. **There is a 2 in 100 chance of death** in the first year after the transplant. Your doctors will tell you if they think your risk of death is higher than 2 in 100.

**There is a small risk (5 in 100, 5%) that the blood vessels of the transplanted pancreas will become blocked following the transplant.** This will lead to failure of the pancreas and we may need to remove it in a further operation. A further 5% of patients will have a clot which does not result in loss of the pancreas, but for which they need to take medicines to thin the blood to help the clots dissolve.

To help you to understand what this means visually we have printed a cartoon below which shows 100 people. We have shaded 95 of these, and left five unshaded, illustrating a risk of 5 in 100 (the risk of a clot); it also means that there is a 95 in 100 chance that this will not happen.
There is a reasonable chance (30 to 40 in 100) that you will require at least one further operation following the transplant. This might be to treat any of a number of possible complications, including bleeding, leaking from the join with the bowel, or to take a tissue sample (a biopsy) from the pancreas.

After the operation, there is an overall 25 in 100 risk of acute rejection of the pancreas transplants. If this happens, we will need to give you some more powerful treatment which will usually reverse the situation, although rarely (1 or 2 in 100 cases) the transplant may be lost from acute rejection.

Chronic rejection. In the longer term, you might develop chronic rejection of the transplanted pancreas. This is much more difficult to treat and usually results in failure of the transplant. If this happens you will need to start back on insulin.

If you have previously had a kidney transplant it is likely that having a pancreas transplant will impair the function of your kidney by up to 10%; that is equivalent to losing around two years of function from the kidney with the result that you will return to dialysis sooner.

Recurrent autoimmune diabetes. Most diabetic patients who undergo a pancreas transplant have type 1 diabetes, that is, their own insulin producing cells were destroyed when they were a child or young adult and they have been on insulin ever since. This destructive process, called autoimmune diabetes, can reoccur in the transplant pancreas in 2 or 3 in 100 cases. If this does occur, you will need to return to taking insulin.

Admissions. Most people who have had a pancreas transplant need to undergo further admissions into hospital in the subsequent months and years. These are necessary so
that we can check you by using blood tests, scans, and biopsies.

**Complications.** As with any other operation, complications can occur, such as wound infections, blood clot in the legs or on the lungs, fluid leakage from drains and wound sites. These complications can often be managed with medication, rather than any further surgical procedures. There is also a small risk of a heart attack (myocardial infarction) as a consequence of the operation; to reduce the chances of this you will have had several tests on the heart to check it is strong enough to get through the operation. There is also a small risk (less than 2 in 100) of nerve damage following the operation, which may affect an arm or leg, or occasionally may result in paralysis.

**Drugs**

In order to protect the pancreas transplant from attack (rejection) by your immune system, you need to take immunosuppressant medications. It is common for drugs like these to be used in combinations or for conditions for which they were not originally licensed. This is common practice in transplant units such as ours, and such use has been acknowledged by the National Institute of Health and Care Excellence. Any new drugs that we use will have been approved by Addenbrooke's Hospital Joint Drugs and Therapeutic Committee, or, in the case of clinical trials, by the Research Ethics Committee.

**Problems with immunosuppression**

The powerful immunosuppressive medications which you need to take to protect your pancreas transplant can also reduce your immunity and make you more susceptible to some infections, particularly viral infections. In the first six months we will give you some antiviral drugs to minimise the risks of harmful viral infections. After six months the amount of immunosuppression you need is less, so the risks of infection are less.

The potential side effects of the immunosuppressive medicines include, kidney problems, stomach upset and wound problems. The immunosuppressive medication also increases your chances of developing cancer. Some cancers are much more common in transplant patients. Around 2 in 100 patients may develop a cancer of the lymph glands (lymphoma), which would require treatment and which can be fatal. Skin cancer is also very common, particularly if you have spent your life working outdoors. To reduce your chance of skin cancer you will be advised to wear a sun block cream whenever you are out in the sun, and cover up where possible.

To reduce any side effects, the medical team will regularly monitor the medications you take and adjust them when required, 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 (i.e. if you miss taking tablets), you run a significant risk of losing your pancreas from rejection without the prospect of a further transplant.**
Please remember that the Transplant Unit has recommended the pancreas transplant procedure to you because the team feels that the benefits will greatly outweigh the risks for you.

The Donor Organs

It is important that you appreciate that transplantation involves taking a risk. When deciding to have a transplant you need to balance the risks of transplantation against the risks of continuing on insulin. Your doctors have recommended that you join the transplant waiting list because they believe that the risks of a transplant are less than the risks of not having one. The following section is about the donor pancreas and highlights some of the risks of transplantation.

Although the organs you get are new to you, you will not be getting a new pancreas. The pancreas will have come from someone who has died and wanted to donate it to help someone like you after their death. It is uncommon for a young patient to be an organ donor, or for the donor to die of an accident; most organ donors have died of a medical condition such as a stroke or heart attack. The average age of an organ donor in the UK is increasing, and in 2012 was 54 years old, with some donors aged up to 80 years old.

Because pancreases from older donors have poorer long term results we try to give you organs from donors who are 60 years or younger. Half of all organ donors are smokers; we do not think this affects the function of the pancreas.

Some donors have medical problems that we do not know about at the time of death and which might be transmitted to you. We make every effort to check carefully all organ donors for the presence of life threatening infections, but some donors may have viral infections that we either do not know about or which we believe represent a low risk to you as a recipient (for example cytomegalovirus, which we can readily treat after the transplant). The risks of you catching life threatening infection are small (less than 1 in 100).

Some donors are known to have taken intravenous drugs or had other behaviour that increases their chance of having a hepatitis virus or HIV AIDS. We check all donors for these viruses but there is a small chance (say 1 or 2 in 100), that an infection in a high risk donor such as these may be missed and therefore transmitted to the recipient. If one were transmitted inadvertently you would need to take anti-viral drugs for the rest of your life in addition to immunosuppression.

Approximately 1 in 2000 donors has a cancer that we do not know about, and which can be passed on with the pancreas transplant. This is often a fatal complication. Unfortunately we cannot predict which donors may have a hidden cancer or when this might occur.
Around 2 in 100 donors have died from a cancer in the brain. Such cancers only rarely spread outside the brain so it is common for transplant doctors to transplant organs from such donors. Nevertheless there is a small chance (less than 2 in 100) that, if your pancreas donor had such a cancer, it might be passed on to you. There is a 98 in 100 chance that this will not happen.

Some donors may have had a cancer treated in the past and are thought to be cured of it. We make every effort to get all the details of these cancers and the treatment before deciding that the organs are safe to use. No cancers have been transmitted from such donors in the UK, but there is a small risk that this might happen.

If you do not wish to take these risks let your doctor know and indicate your wish on the consent form so that and you will not be called in for a transplant from such a donor.

Brain death and circulatory death donors. Some organ donors are confirmed to be dead by testing the brain function while they are on a ventilator, and while their heart is still beating; these are brain dead donors. Others have irreversible damage to their brain but are not brain dead; nevertheless the brain damage is such that they will not recover so they have their treatment, including ventilation, stopped and as a result their heart stops; these are called circulatory death donors. Almost half of all dead donors in the UK (42% in 2012) were circulatory death donors.

After a transplant, most pancreases begin to work straight away, but occasionally a patient may need to continue insulin for a day or two before it recovers function completely. The long term results of circulatory death and brain death donor organs are similar. If you do not wish to have organs from a donor following a circulatory death let your doctor know and indicate your wish on the consent form so that and you will not be called in. However because such donors account for 1 in 4 of our pancreas transplants you will have to wait longer for a transplant.

We will only use a pancreas that we think will work and will give long, life-supporting function, and which we think has an acceptable risk when balanced against how sick you are. In allocating an organ to you for a transplant we believe it will give you the best chance of long life, while reducing your chance of dying on the waiting list or becoming too unfit for a transplant.

Alternative procedures that are available
You can live without a pancreas transplant by continuing with insulin. Islet transplantation, where the insulin producing cells are separated from the pancreas, is currently being developed in specialised centres around the world, but is not widely available and the results have not been proven to be as good as pancreas transplantation.
Information and support

If you have any anxieties or questions, please feel free to ask any member of the staff. Further information can be obtained from the pancreas transplant coordinators on 01223 216536 or from the Addenbrooke’s website www.cuh.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. For a pancreas transplant, patients usually have an epidural anaesthetic and a general anaesthetic combined.

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

Before starting your anaesthesia the medical team will perform a check of your name, personal details and confirm the operation you are expecting.

You will 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, 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 and 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 (epidural) anaesthesia may be performed for your operation together 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.

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

We are committed to treating all patients with privacy and dignity in a safe, clean and comfortable environment. This means, with a few exceptions, we will care for you in same sex bays in wards with separate sanitary facilities for men and women.

In some areas, due to the nature of the equipment or specialist care involved, we may not be able to care for you in same sex bays. In these cases staff will always do their best to respect your privacy and dignity, eg with the use of curtains or, where possible, moving you next to a patient of the same sex. If you have any concerns, please speak to the ward sister or charge nurse.

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.

In agreeing to join the waiting list for a pancreas transplant you have agreed to stop smoking. If you are found to have been smoking when admitted for a transplant you will be sent home and removed from the waiting list.

Help with this leaflet

If you would like this information in large print, another language or in audio format, please ask the department to contact Patient Information on 01223 216032 or patient.information@addenbrookes.nhs.uk

Document history
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To remove the need for insulin by transplanting a pancreas.

Controlling your diabetes should slow, stop or even reverse some of the complications of diabetes. It may also increase your chances of living longer.

We expect eight or nine out of ten of our pancreas transplants to work at least one year after the transplant operation; we expect five out of ten to be still working after five years.

A 2 in 100 chance of dying in the first year following the transplant operation.

A 5 in 100 risk that the blood vessels of the pancreas transplant will become blocked following transplantation leading to failure of the pancreas which will then need to be removed.

There is a chance (30 to 40 in 100) that you will require at least one further operation following the transplant.

A 25 in 100 risk of acute rejection of the pancreas transplant requiring admission for treatment.

Chronic rejection of the pancreas. If this happens you might need to have a further transplant procedure and/or you might need to start back on insulin.

Around 2 in 100 patients will get recurrent autoimmune diabetes and need to return to insulin.

Wound infections, blood clot in the legs or on the lungs, fluid leak from drains and wound sites.

We take every effort to screen pancreas donors for infections and cancers, but we cannot guarantee that an infection or cancer will not be transmitted from the donor to you the recipient. The chances of this happening are small.

Most patients will need further admissions to hospital in the months or years after transplantation.

Having a pancreas transplant after a previous kidney transplant will reduce the function and life of the kidney transplant.

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:
Consent Form

Solitary pancreas transplantation

\(d)\) any extra procedures that might become necessary during the procedure such as:

\(\checkmark\) Blood transfusion \(\square\) Other procedure (please state)

The following information leaflet has been provided:

Pancreas transplantation alone

Version, reference and date: CF169 version 6 October 2018

or \(\square\) I have offered the patient information about the procedure but this has been declined.

This procedure will involve:

\(\checkmark\) General and/or regional anaesthesia \(\square\) Local anaesthesia \(\square\) Sedation \(\square\) 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 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.

\(\square\) Yes \(\square\) 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.

\(\square\) Yes \(\square\) No

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

\(\square\) Yes \(\square\) No

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

\(\square\) Yes \(\square\) No

Patient safety – at the heart of all we do
Patient Information

Solitary pancreas 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.

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.

5 Donor specific choices
We assume that you are willing to accept a pancreas from any donor that we consider appropriate for you considering your health at the time unless you indicate donor types below that you do not wish to consider. A full explanation is given in the information sheet. If you indicate you do not wish a particular type of donor you should remember that you reduce your chance of receiving a pancreas.

a). I do not wish to receive organs from a donor after circulatory death and understand that 1 in 4 pancreas donors are circulatory death donors. Pancreases from such donors have similar long term outcomes, but may be slower to start to work immediately after transplantation.

b). I do not wish to receive organs from a donor who has died from a brain cancer, although I realise that there is only a small (less than 2 in 100) chance of the cancer being transmitted to me. 2 in 100 organ donors have died from a brain cancer.

c). I do not wish to receive organs from a donor known to use intravenous drugs or whose behaviour puts them at risk of viral infections even though their viral tests suggests I would have less than 2 in 100 chance of becoming infected and needing to take antiviral drugs as a result. Around 2 in 100 donors exhibited such high risk behaviour.

d) I do not wish to receive organs from a donor who has a history of cancer, although I realise that there is only a small (less than 1 in 100) chance of that cancer being transmitted to me.
Consent Form

Solitary pancreas transplantation

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:

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:

Patient safety – at the heart of all we do

Addenbrooke’s Hospital | Rosie Hospital

CF169 Solitary pancreas transplantation v6 October 2018

File: in the procedures and consents section of the casenotes

page 4 of 5
Consent Form

Solitary pancreas transplantation

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: ...D./...M./...Y.Y.Y.Y.Y.

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: ...D./...M./...Y.Y.Y.Y.Y.

Signed (Health professional): .................................................. Date: ...D./...M./...Y.Y.Y.Y.Y.

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