Patient information and consent to a combined kidney and pancreas transplantation

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 bring with you any medications you use (including patches, creams, inhalers, herbal remedies, and CPAP machines) and any information that you have been given relevant to your care in hospital, such as X-rays or test results.

- When a suitable kidney and pancreas are 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 kidney and 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 have decided that the risks to your life from having a transplant are fewer than the chances of you dying if you did not have a 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 scan the consent form into your medical notes.

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.

Combined kidney and pancreas transplantation requires a general anaesthetic. You will have the opportunity to discuss this with the anaesthetist.

We will 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 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.

**About a combined kidney and pancreas transplant**

A kidney transplant operation has been recommended for you because either your own kidneys have already failed and you are on dialysis already, or your kidneys are failing and you will need to start dialysis soon. As a patient with diabetes the kidney transplant can be combined with a pancreas transplant from the same donor and performed as part of the same transplant operation to provide the insulin that your own pancreas no longer provides.

This is a major operation involving a team of transplant surgeons working for six to eight hours. If successful, it will restore your kidney function and you will not need dialysis. Your blood sugars will also be controlled for you without the need for any insulin injections or special diets.

**Intended benefits**

Kidney transplantation offers you the possibility to either come off dialysis or to avoid starting it. Most people who have had a kidney transplant consider they have a better quality of life and also gain relief from (or avoid) several of the complications associated with dialysis.

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 than if you had a kidney transplant alone.

We expect 85 out of 100 of our kidney and pancreas transplants to work at least one year after the transplant operation; we expect 60 out of 100 to be still working after 10 years.

**Who will perform my procedure?**

The kidney and 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**

Your nephrologist (kidney specialist) and transplant surgeon will have discussed your condition with you and with other surgeons and personnel related to the National Transplant Programme. They will have decided to add your name to the Cambridge Transplant Waiting List for a combined kidney and pancreas transplantation.

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 kidney and pancreas to reach Addenbrooke’s, before you are prepared and taken to the theatre for the transplant operation.
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.

Smoking
We do not knowingly offer a pancreas transplant to anyone who is still smoking, and only agree to put patients on the waiting list if they have assured us they have stopped smoking. This is because the pancreas is more likely to be lost to thrombosis (clotting, see below) and also because the benefits of a pancreas transplant are in reducing the complications of diabetes, particularly those affecting the blood vessels; smoking causes its own damage to the blood vessels so the benefit of having a pancreas is lost. If you are found to have been smoking when you are admitted for a transplant the procedure will be cancelled and you will be asked to return home. We may test patients when they arrive on the ward to check whether they have smoked in the days before admission.

During the procedure
This procedure involves the use of general anaesthesia; see below for further details about this type of anaesthesia.

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 or three tubes 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 kidney and pancreas and then carry out the transplant procedure in you. The surgeon will make a long vertical incision (cut) in your abdomen, and possibly a second incision on one side of your lower abdomen. The donor kidney and pancreas will then be connected up to the blood vessels that take blood to and from your legs. We also connect the tube that takes urine from your kidney (the ureter) to your bladder so you can pass urine as normal, and connect the pancreas to the bowel so that the digestive juices it makes can drain away. Typically, this takes six to eight 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 and kidney transplants. In this case we may have to use a piece of plastic mesh or use some plastic surgery to close your 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 new pancreas or
kidney. 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** 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.

**We leave a small plastic tube called a stent across the join** between the urine tube from the kidney (the ureter) and the bladder. This will be removed a few weeks after the transplant under local anaesthetic.

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. You may be given oxygen via a facemask, fluids into your drip and appropriate pain relief until you are comfortable enough to return to your ward.

You will be taken either to the John Farman 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 and left there for three months.

**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.
Leaving hospital. Following a combined kidney and 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 kidney and pancreas transplants are functioning well.
Significant, unavoidable or frequently occurring risks of this procedure

A combined kidney and pancreas transplantation is a complex procedure. **There is a small risk (5 in 100, 5%) that the blood vessels of the transplanted kidney or pancreas will become blocked by a blood clot following this procedure.** This will lead to failure of the kidney and/or pancreas and we will need to remove the kidney and/or pancreas transplants in a further operation. A further 5% of patients will have a blood 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 losing the pancreas because of a clot); it also means that there is a 95 in 100 chance that this will not happen.

There is a **2 in 100 chance of death** (98 in 100 chance of being alive) in the first year following the transplant operation; this is represented by the two black figures in the cartoon. Your doctors will tell you if they think your risk of death is higher than 2 in 100, as might be the case if you have heart problems.

**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 bladder or 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 kidney or 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 transplants may be lost from acute rejection.

**Chronic rejection.** In the longer term, you might develop chronic rejection of the transplanted kidney or pancreas. This is much more difficult to treat and usually results in failure of the transplants. If this happens you might need to have a further transplant procedure and/or you might need to go back on dialysis (for example, while you wait for another kidney) and/or start back on insulin.

**Recurrent autoimmune diabetes.** Most diabetic patients who undergo a kidney and 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 kidney and 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 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. When we transplant the pancreas and kidney we have to clamp the blood vessels to the legs for a short while to allow us to sew the organs in safely. Occasionally (less than 1 in 100) this can result in damage to the artery which may affect the blood flow to the legs. This may result in calf pain when you walk, or ulceration on the lower leg, or, very rarely, it may result in a patient losing part of the leg.

**Nerve damage**
There is a small risk (less than 2 in 100) of nerve damage following the operation, which may affect an arm or the legs, or which may result in permanent paralysis of the legs (paraplegia, which occurs in 1 in 100 transplants); this latter is usually related to disease in the blood vessels affecting the blood supply to the spinal cord, which may result in the spinal cord being starved of blood if the blood pressure falls during or soon after the operation. In addition, some male patients complain of impotence after the operation, which may also be due to nerve damage.
We cannot predict who these complications will affect.

You will need to take a number of medications on a long-term basis to prevent rejection of the kidney and pancreas. This is called immunosuppression. If you stop the immunosuppression medicines you may lose the transplants.
The Donor Organs

It is important that you appreciate that transplantation involves taking a risk, but you should remember that 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 kidney and 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 kidney and pancreas. The organs have come from someone who has died and wanted to donate them 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 2016 was 54 years old, with some donors aged up to 80 years old. Because pancreases from older donors have poorer long term results we will only consider organs from donors who are 60 years or younger. Half of all organ donors are smokers.

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 our 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 kidney and pancreas transplant. This is often a fatal complication, or we may need to remove the transplanted organs to control it. 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 kidney and 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 2016/7) were circulatory death donors.

After a transplant, kidneys do not work straight away, but take a few days or weeks to recover function. This is more common (50 in 100) with circulatory death donors than brain death donors (25 in 100). 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 (25 in 100, 25%) of our kidney and pancreas transplants you will have to wait longer for a transplant.

**The risks of waiting.** In choosing not to have a particular sort of donor you should be aware that there are complications associated with waiting on the list for a long time. For example, of all the patients placed on the waiting list for a combined kidney and pancreas transplant in the UK between April 2013 and March 2014, 74% had received a transplant within two years, while 5% had died on the waiting list and 6% had been removed from the waiting list because they were no longer fit enough to have a transplant; 15% of patients were still waiting. The average waiting time for a kidney and pancreas transplant is a year.

We will only use a kidney and 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.

**Drugs**

In order to protect the kidney and 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 Drug 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 transplant organs 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, diabetes, 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 (Factor 50) 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 kidney and/or pancreas from rejection without the prospect of a further transplant.

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

Alternative procedures that are available

It is possible to live without a kidney transplant; depending on the condition of your kidneys, you will need to continue with (or start) either haemodialysis or peritoneal dialysis to perform some of the functions of healthy kidneys. You can live without a pancreas transplant by continuing with insulin. You can also choose to have a kidney transplant without a pancreas transplant. However, patients who undergo a combined kidney and pancreas transplant are more like to live longer and have a better quality of life.

Islet transplantation, where the insulin producing cells are separated from the pancreas, is currently being developed in specialized 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 transplant co-ordinators who can be reached through the Addenbrooke’s contact centre 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 combined kidney and 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 may 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 may be performed together with a general anaesthetic. Regional anaesthesia may be used to provide pain relief after your surgery for several days. Your anaesthetist will discuss the procedure, benefits and risks with you.

**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.

When the effects of the anaesthesia wear off you may need pain relieving medicines. If the team decide to keep you anaesthetised and on the breathing machine (ventilator), you will be looked after in the intensive care unit.

**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
Equipment failure
Death.
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.

In agreeing to join the waiting list for a kidney and 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.**

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.

Help with this leaflet

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.information@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

Authors          Prof Chris Watson
Pharmacist      Claire Bullen
Department      Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk
Contact number  01223 245151
Publish/Review date February 2018/February 2021
File name       Combined_kidney_pancreas_transplant.doc
Version number/Ref 9/CF170/1867
Consent Form

Combined kidney and pancreas transplantation

A Patient's side left / right or N/A

Consultant or other responsible health professional

Name and job title: .................................................................

☐ Any special needs of the patient (e.g. help with communication)? ........................................

Please use 'Procedure completed' stamp here on completion: ...........................................

B Statement of health professional (details of treatment, risks and benefits)

1 I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the hospital's consent policy. I have explained the procedure to the patient. In particular, I have explained:

   a) the intended benefits of the procedure (please state)

   To replace the function of your diseased kidney with normal function from a transplant kidney;
   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 should also increase your chances of living longer than if you had a kidney transplant alone;
   We expect eight or nine out of ten of our transplanted kidney and pancreas transplants to work at least one year after the transplant operation; we expect six out of ten to be still working after 10 years.

   b) 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

   • Approximately 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 kidney or pancreas transplants will become blocked following transplantation leading to failure of the kidney and/or 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.
   • After the operation, there is a 25 in 100 risk of acute rejection of the kidney or pancreas transplants requiring admission for treatment.
   • Chronic rejection of the kidney or pancreas. If this happens you would need to go back on dialysis and/or start back on insulin.
   • 2 to 3 in 100 patients will get recurrent autoimmune diabetes and need to return to insulin.
   • 1 in 100 patients may get nerve damage resulting in paralysis of the legs or arm
   • Wound infections, blood clot in the legs or on the lungs, fluid leak from drains and wound sites.
   • We take every effort to screen kidney 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 require further admissions to hospital in the months or years after transplant.

   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:

   .................................................................

   .................................
Consent Form

Combined kidney and pancreas transplantation

- d) any extra procedures that might become necessary during the procedure such as:
  - Blood transfusion
  - Other procedure (please state)

The following information leaflet has been provided:

Combined kidney and pancreas transplantation

Version, reference and date: CF170 version 9, February 2018

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.Y.Y.Y.Y.Y.Y

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

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
Consent Form

Combined kidney and 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. □ 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

5 Donor specific choices

We assume that you are willing to accept a kidney and 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. Kidneys and pancreases from such donors have equal long term outcomes, but are 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

Combined kidney and 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:
Consent Form

Combined kidney and pancreas transplantation

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

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: ___________________________