

Quality of Life
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Pancreas and Islet Transplantation for Patients with Type 1 Diabetes



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Alliance Primary Care

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Transplant Services

 **University of Cincinnati
College of Medicine**

The University of Cincinnati and Health Alliance Transplant Services are pleased to provide this vital information about pancreas and islet transplantation for patients with diabetes. This booklet will provide an idea of the process before, during and after receiving a pancreas or islet transplant.

A dedicated team of physicians, surgeons, pharmacists and nurses are committed to providing excellent medical care. Diabetes is more than a disease, it is a personal battle every day. The University of Cincinnati and the Health Alliance are committed to winning the war against diabetes by focusing efforts on new and better ways of treatment. Our center is the only program in Cincinnati to perform pancreas transplant procedures. The pancreas transplant program was started in 1979 and represents part of a long tradition of providing the best and latest advances in medicine.

Recently, the University of Cincinnati and The University Hospital of the Health Alliance have invested considerable resources to develop an islet transplant program. This exciting procedure has shown great promise and provides a new approach for treating and potentially curing diabetes.

This booklet is intended to answer your questions and provide information to help individuals make informed decisions for a healthier future.

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Transplantation at The University Hospital

The first adult solid organ transplant procedure in Cincinnati was performed at The University Hospital in 1967. The University Hospital and University of Cincinnati College of Medicine then developed kidney, pancreas, liver and heart transplant programs. The transplant team at The University Hospital and University of Cincinnati College of Medicine has extensive experience in the use of anti-rejection drugs and providing medical care to transplant recipients. In addition, our programs offer advanced treatments and are at the forefront of many research areas in transplantation.

Staff involved in your care

The staff involved in your care includes surgeons, nephrologists (kidney specialists), endocrinologists (diabetes specialists), a registered nurse who serves as transplant coordinator, transplant pharmacists, renal (kidney) clinical nurse specialists (registered nurses specially trained in transplantation), a social worker, a dietitian, surgical and medical residents (physicians in training), a transplant administrator and laboratory personnel.

During your pre-transplant visit to The University Hospital, the transplant team will provide you with information about your pre-transplant evaluation, the operation, medications, hospital stay and financial considerations. Our goal is to treat you with consideration while providing excellent medical care. As a candidate for pancreas or islet transplantation, you and your family will be involved in all aspects of your evaluation and treatment process.

Definitions

Diabetes is a disease defined by the loss of the body's ability to control the glucose (sugar) levels in the blood. Exposure of the body to high glucose levels over several years or more leads to vascular disease, coronary heart disease, kidney disease and damage to eyes and nerves.

Glucose is the main sugar in the blood, released into the blood following digestion of food.

Glycemic Control is the control of the level of sugar (glucose) in the blood.

Insulin is a hormone produced by beta cells. The cells reside within islets of Langerhans within the pancreas. Insulin release maintains normal glucose levels by lowering the level of sugar within the blood.

Diabetes and its impact

The loss of glucose control in diabetics is caused by either a lack of insulin (Type 1 diabetes) or the body's resistance to the effects of insulin (Type 2 diabetes). Approximately 10 percent of diabetics have Type 1 diabetes and 90 percent have Type 2.

Type 1 diabetes is caused by the death of the insulin-producing beta cells in the islets of Langerhans in the pancreas. Beta cells sense the glucose level in the blood and produce an appropriate amount of insulin to metabolize sugar to be properly used by your body.

Type 1 diabetes mainly occurs in young people, although it may also occur in older adults. The symptoms usually appear quickly and include hunger, thirst, urination, weight loss and fatigue.

Type 2 diabetes is caused by the body improperly using insulin that is produced by the pancreas. The symptoms usually develop over a longer period of time and include increased hunger, thirst and urination, blurred eyesight, fatigue, numbness or tingling in hands or feet, frequent infections and slow healing cuts or sores.

No one knows for sure the exact cause of diabetes, but doctors believe the following factors are involved:

Heredity—a history of diabetes in your family

Stress—physical illness or injury

Viruses—may cause injury to the pancreas

Autoimmunity—the body's immune system destroys the islets of Langerhans by mistake.

- There are 16 million diabetics in the United States today, costing more than \$105 billion annually or about \$1 in every \$10 spent on health care.
- According to the World Health Organization (WHO), approximately 120 million people suffer from diabetes worldwide. This number will rise to over 250 million by the year 2025.
- There are 2,200 new cases of diabetes diagnosed every day in the United States.
- Diabetes is the leading cause of blindness, kidney failure and non-traumatic limb amputation.
- The rate of children with diabetes is 1.7 per 1,000, making it second only to asthma in chronic childhood illnesses.
- An American dies every three minutes from diabetes.
- Diabetes is the fourth leading cause of death by disease in the United States.

Insulin injections and insulin pumps

Insulin injection is the most common therapy for diabetes. The use of an insulin pump provides the delivery of small amounts of fast-acting insulin 24 hours a day into the body via a small needle or soft tube. Unfortunately, even the most careful form of insulin therapy cannot copy the precise blood sugar control that a working pancreas can. Insulin injections often offer poor glycemic control, placing a patient at significant risk of developing diabetic complications (blindness, kidney failure, limb amputation, vascular disease, coronary artery disease and cerebral artery disease).

Types of transplant procedures

Pancreas transplantation provides optimal glycemic control. Whole organ pancreas transplantation is performed by transplanting the entire pancreas, often simultaneously with a kidney transplant.

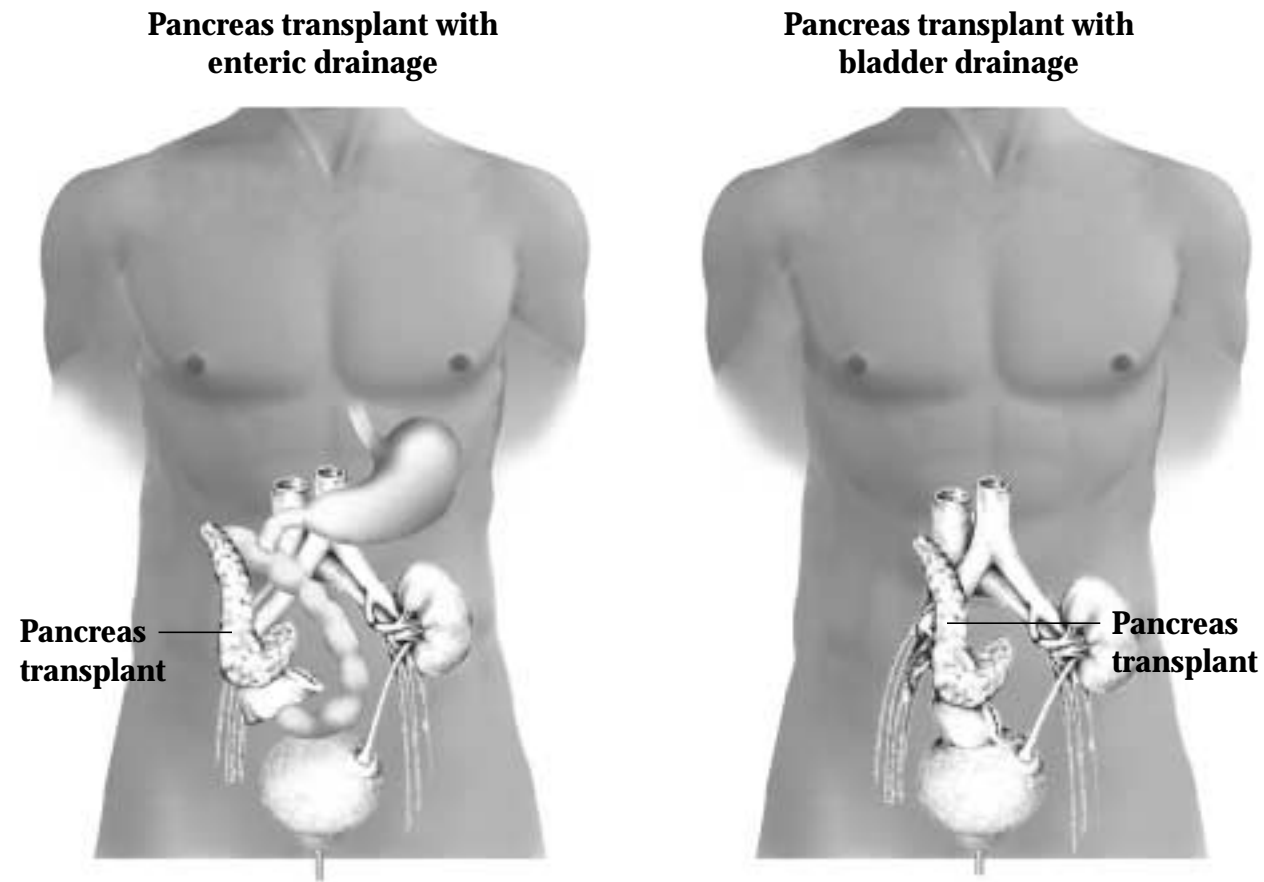
Whole organ pancreas transplantation is a major abdominal procedure that takes about two and a half hours to perform (five hours if performed simultaneously with a kidney transplant). Occasionally, pancreatic exocrine secretions (digestive enzymes produced by the pancreas) lead to post-operative complications.

A simultaneous pancreas/kidney transplant is currently the best solution for the return to normal activities with an increased quality of life for a patient suffering from both diabetes and kidney disease.

A pancreas or pancreas-kidney transplant can provide sustained and fully effective insulin secretion for many years. The benefits of a successful pancreas-kidney transplant include, in most cases, improved quality of life due to decreased dietary restrictions and normal glucose control with freedom from insulin injections.

The long-term goal of pancreas transplantation is prevention of late complications of diabetes such as kidney failure and damage to the eyes, nerves and blood vessels. A pancreas transplant will stabilize, and in a small number of patients, improve eye disease. Nerve disease also improves in most patients with a successful pancreas transplant. Additionally, there is evidence that the transplanted kidney is protected from diabetic damage by a successful pancreas transplant.

Your own pancreas is left in place, and the newly transplanted pancreas and kidney are placed in the left pelvic area, through a single midline incision. During the operation, the transplant surgeon will create a connection to allow the pancreatic digestive enzymes to drain (see figures below). Currently, the preferred method is to drain the pancreatic digestive enzymes into the intestine (enteric drainage) because this most closely follows how the body works.

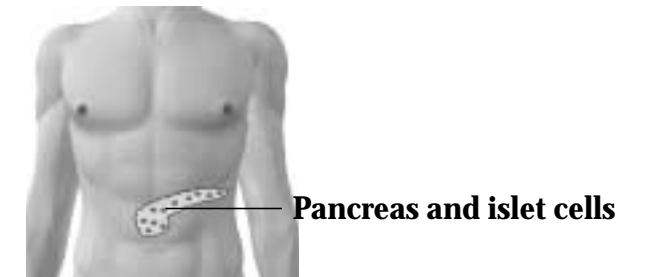


The results of pancreas transplantation for the treatment of diabetes are continuously improving. Ideal candidates are those who have insulin-dependent diabetes mellitus (Type 1 diabetes), and those who do not have severe damage to other organs.

Patient and graft (the transplanted kidney and pancreas) survival rates have improved substantially since physicians performed the first pancreas transplant in 1966. According to the UNOS (United Network for Organ Sharing) Transplant Registry, from 1996 to 1999 the one-year patient survival rate for pancreas-kidney transplants was 95 percent. The pancreas graft survival rate for the same time period was 85 percent.

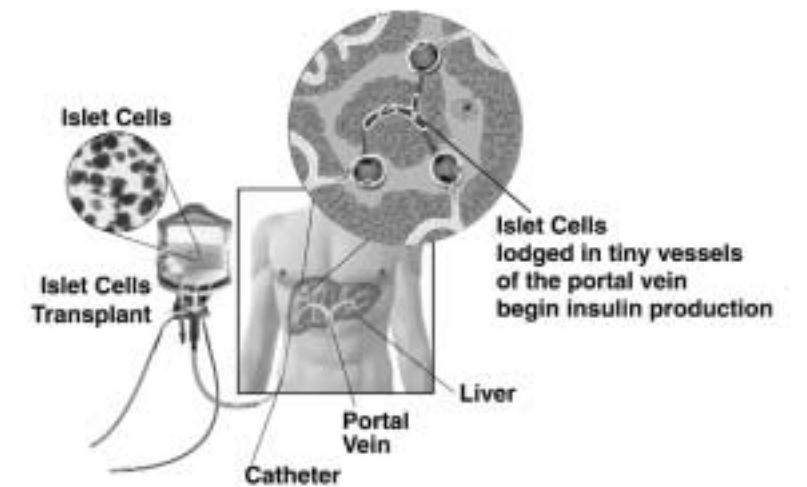
Islet transplantation is a minimally invasive procedure that requires a one-hour operation, a three-inch abdominal incision and a one-day hospital stay. Islets are obtained from a donor pancreas using a complex isolation and purification process in which enzymes break down the tissue surrounding the islets.

The islets of Langerhans are embedded within the pancreatic tissue and require a special, highly technical process to extract them from the pancreas.



Islets are usually transplanted by injecting them into the veins leading to the liver (the portal vein).

The islets migrate to the liver where they reside and produce insulin. Because pancreatic exocrine tissue is not transplanted during islet transplantation, complications related to digestive enzyme drainage are avoided.



Islets are injected directly into the portal venous system. If a patient is also receiving a kidney or liver transplant, the islets are injected directly into the portal vein at the time of surgery.



Incision for islet transplant

Incision for pancreas/kidney transplant

The decision about whether a patient should receive a pancreas or an islet transplant is complex and requires a full medical evaluation and input from several medical professionals. The final decision about whether a patient should receive a whole organ or islet transplant can be made only after a full medical evaluation is completed.

Finding out if you are a candidate

Islet and whole organ pancreas transplants can be performed under three types of circumstances, depending on the status of the transplant recipient's kidney. These include:

Islet Alone and Pancreas Alone Transplants are performed in patients who have no or minimal kidney disease.

Simultaneous Kidney/Islet and Pancreas/Kidney Transplants are performed in patients whose diabetic kidney disease has advanced to the point that they need dialysis or a kidney transplant.

Islet after Kidney and Pancreas after Kidney Transplants are performed in patients who have previously received a kidney transplant.

Patients are eligible for pancreas-kidney transplantation if they have Type 1 diabetes, are between the ages of 16 and 55 and have:

- Severe impairment of renal function.
- End stage renal disease requiring dialysis.

Patients are eligible for solitary whole organ pancreas transplantation if they have Type 1 diabetes, are between the ages of 16 and 55 and have:

- Autonomic neuropathy (degenerative disease of the nervous system which controls the function of glands, smooth muscle tissue and the heart). These patients usually experience loss of appetite, bloating after eating, nausea, vomiting, gastric discomfort, constipation or diarrhea and urinary bladder dysfunction.
- Poorly controlled diabetes, despite an appropriate insulin regimen. Such patients experience wide variations in their blood sugar.
- Repeated hypoglycemic (low blood sugar) episodes requiring emergency treatment.
- Repeated bouts of ketoacidosis (a condition where acid builds up in the blood).

Symptoms or conditions that would prohibit a pancreas or pancreas-kidney transplant include:

- Presence of active infection.
- Cancer that is not cured or does not have a high chance of cure.
- Alcoholism or other chemical dependency.
- Unstable or advanced heart disease.
- Presence of severe peripheral vascular disease (poor blood flow to arms and legs).
- Not complying with prescribed medication therapy.
- Severe lung disease.

What happens during the pre-transplant evaluation?

Potential recipients will receive a complete medical evaluation with a number of tests including: laboratory tests for viruses (hepatitis, herpes, AIDS, etc.), stomach X-rays, gallbladder ultrasound, bladder X-rays, EKG (heart rhythm), chest X-rays, dental evaluation, eye exam (to determine the status of eye disease) and a thallium stress test (heart treadmill). A pelvic exam with Pap smear and a mammogram are required for female candidates.

Other preliminary tests may include:

- Non-invasive vascular studies to determine the severity of diabetes complications on the blood vessels to your legs and brain.
- Electromyogram (EMG) to determine the severity of diabetes complications to the nerves of your extremities.

Your pre-transplant evaluation will include a visit to the pre-transplant center and a meeting with the transplant nephrologists and a transplant surgeon. If these physicians believe that you are a good candidate for a transplant, a member of the transplant team will be in contact with your primary care physician to begin scheduling the necessary tests.

If you pass the medical evaluation, your name will be placed on a computer recipient waiting list. You will be asked to carry a long-range pager so you can be reached quickly if a donor becomes available.

How are organs matched?

Several factors are considered when finding the best recipient for a pancreas or islet transplant. These include:

Blood compatibility-Recipients blood must be compatible with the donor.

Crossmatch-Crossmatching laboratory test that determines if the body has immune proteins (antibodies) that will attack the transplanted organs.

Tissue matching-Combinations of antigens (proteins found on the surface of blood cells) determine the uniqueness of a person's tissues and also provide a means to determine how well the transplant organ will match with the recipient.

Other major factors that determine who will receive a pancreas or islet transplant are the general well-being of the recipient, the current antibody level and the length of time on the list. Each time a donor organ becomes available, every person on the waiting list is matched for the organ based on these factors. Points are given for every factor, and recipients who have the best match and have been waiting the longest will have the greatest number of points, which gives them the greatest chance of receiving a transplant.

Waiting for a donor organ

Because we never know when a donor organ will be available, the patient who is to receive the transplant must be ready on short notice. Patients waiting for a pancreas or islet transplant must make several telephone numbers available to the transplant coordinator and wear a pager, so they can be alerted when an organ is available. All potential recipients must be prepared for immediate hospitalization.

You will be instructed not to drink or eat from the time you are notified of a pending transplant. Periodically check your finger stick glucose levels and notify the transplant team should your blood sugar rise over 300 or fall below 60.

You will be admitted to the transplant floor.

Care after surgery

Combined pancreas-kidney and solitary pancreas transplant patients are taken to the Surgical Intensive Care Unit (SICU) immediately after surgery. The average stay in SICU is one to two days. You are then transferred to the transplant unit. You will receive intravenous fluids since you will not be able to ingest fluids by mouth for some time. A nasogastric tube is inserted through your nose into your stomach during surgery to allow the intestines to rest. This tube is usually removed after three days. During surgery, a catheter is placed into your bladder to check urinary output.

Pain medications will be given as needed. The immunosuppressive drugs to help prevent rejection will be started during the surgery.

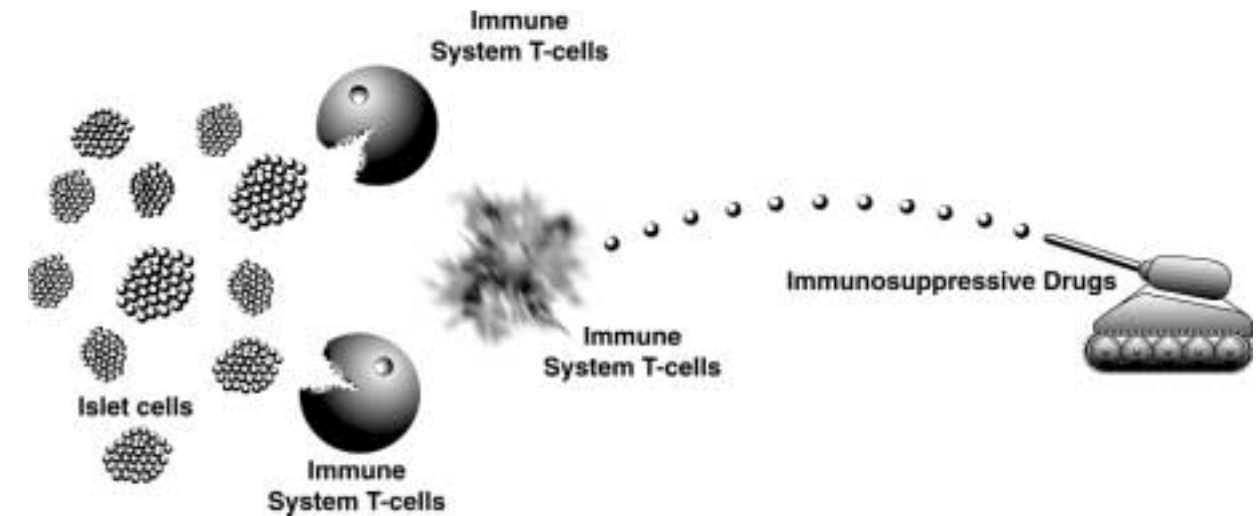
Blood sugars are checked frequently to assess the function of your new pancreas. Bed rest is ordered for approximately 24 hours, after which you may sit in a chair with assistance.

Two small drainage tubes are placed near the incision during surgery, and are removed before you go home.

You will have blood work done daily to check kidney function and pancreas function. Hospital stays usually average about seven days.

Medications after transplant

After your transplant, you will need to take several medications to prevent rejection and infection. Side effects usually depend on the dose of the drug and can be managed with dosage adjustment or changing to other medications.



While successfully transplanted patients may lead nearly normal lives, they must have a **life-long commitment to taking medications faithfully and having frequent check-ups.** Immunosuppressive drugs must be taken every day, and it is critical to never miss a dose. Research continues for improvement of anti-rejection medications and reductions of side effects.

Immunosuppressive therapy will lower the body's resistance to infection by altering the immune system. Patients should be aware of the increased incidence of infection and seek early treatment from the physician.

You should never avoid taking your medicine or reduce your dose on your own. To do so invites a great risk of rejection and losing your transplant. Your physician will be able to answer questions about specific side effects and adjust your medications if needed. A list of these medicines and some of their side effects is included below.

Trade Name	Generic Name	Side Effects
Neoral	Cyclosporine	flushing, kidney toxicity, hair growth, shaking, sleep disturbances
Prograf	Tacrolimus	flushing, kidney toxicity, shaking, sleep disturbances
CellCept	Mycophenolate Mofetil	nausea, diarrhea, abdominal pain, low blood counts
Imuran	Azathioprine	low blood counts
Rapamune	Sirolimus	diarrhea, high cholesterol
Deltasone	Prednisone	weight gain, acne, bone loss, cataracts, poor wound healing

Rejection or other complications

Rejection is the body's natural response to the presence of foreign tissue. Only about 20 percent of patients experience a rejection episode. Symptoms of rejection include fever, tenderness over a graft area and swelling of the hands and feet. The overwhelming majority of rejection episodes are reversed using anti-rejection medications.

It is understandable to be depressed or discouraged at the time of rejection, but you should realize that rejection episodes are a common part of the transplant procedure. If rejection occurs after you have gone home, the physician may want to readmit you to the hospital so you can be watched more closely during treatment.

Many transplant recipients experience complications besides rejection. Most are minor, but others may be serious. You will get very close medical supervision to detect and treat complications as soon as possible. It is vital that you notify your physician of any signs of infections, such as a cold, cough, sore throat, fever, chills and skin rashes. Infection can be a serious complication following a transplant, though most infections are effectively treated with antibiotics.

Rejection, infection and other problems can usually be treated quickly and effectively if detected early.

What to expect when you return home

Once you are home from the hospital, you can set goals for your return to an active life. Activities such as walking, jogging, hiking, bicycling, tennis, golf and swimming can help you regain your strength. Renewing intimate relationships, strengthening old friendships, meeting new people and returning to work will also help boost your self-confidence and sense of well-being.

It is important after your transplant to have regular checkups with physicians such as your ophthalmologist, gynecologist, dentist and dermatologist. Be sure to let them know that you have had a transplant and what medications you are taking.

Wear a bracelet or necklace designating that you are a transplant patient and give them your transplant physician's emergency phone number. Your dentist should be aware of your condition so that antibiotics can be used to prevent possible infection when dental work is done.

Many patients are able to return to work within a few months after the transplant. We can keep your employer informed about when you can return to work, and if there are any limitations on what you may do.

Currently, the Social Security Administration re-evaluates disabled people on a regular basis. It often determines that you are able to seek gainful employment one year after transplant. Therefore, it is important that you seek rehabilitation aid to develop job skills as soon as you are physically able. The transplant social worker and the financial counselor are always available at the hospital to assist you with problems or concerns related to returning to work.

After your transplant, you will receive low-fat, low-sugar diet guidelines. You will also need to drink extra fluids to prevent dehydration, especially in the summer. You will have a tendency to gain weight because of increased appetite from some of the medications. Excessive weight gain can increase your blood pressure, so it is important to keep your weight under control.

It is normal to have some emotional ups and downs during this process. However, it is important to keep a positive outlook. If you find yourself feeling down, please do not hesitate to talk about it with your nurse and doctors. The social worker can come to talk to you also. This feeling is a normal reaction for some people.

Follow-up visits to the outpatient transplant clinic

Your follow-up visits will be on the third floor of the Outpatient Building, located adjacent to The University Hospital. Immediately after you are discharged from the hospital, you will need to go to clinic on Monday, Wednesday and Friday. As you get stronger, the frequency of your check-up visits will decrease.

Please arrive between 8 and 8:30 a.m. on the day you are scheduled for clinic. Physicians, the transplant coordinator and, if appropriate, a dietitian and a social worker will see you during your visit. You will also need to go to The University Hospital or your local pharmacy to refill your prescriptions after you see the physician. Bring your medication list, Cyclosporine or Tracrolimus to each visit. You will be notified if a urine sample is needed.

At your follow-up visit you will sign the roster at the desk when you arrive and wait until you are called. A phlebotomist will draw your blood. You will be weighed, have your temperature taken and may be asked to provide a urine sample. Your name will be called when it is your turn to see the physicians.

Generally, you should be finished with the appointment by noon. Make sure you do not miss an appointment, because it is very important that your medical condition be carefully monitored.

Financial considerations

Along with receiving a bill for services provided by your transplant team, you may also receive separate statements for services provided by specialty physicians involved in your care and departments like Laboratory Medicine and Radiology, which conduct important testing during your hospital stay and outpatient visits.

Hospital costs related to the kidney transplant are usually covered by your insurance or Medicare.

The pancreas portion of the hospitalization is not always covered by private insurance. In some cases, Medicare does cover it. If your insurance company has a transplant "rider," pancreas transplants are usually covered.

For additional information or to schedule an appointment, call the Pancreas/Islet Transplant Program at 513-584-3581 or toll free at 1-866-268-4265. For assistance with insurance or billing, call 513-584-7709.

A Christmas Gift To Remember

Jeffrey Dunn

December 8 will forever be a special day for Jeffrey Dunn. It was on this day in 1997 that Jeffrey received the best Christmas gift of all—the gift of life.

After suffering from diabetes for 17 years, Jeffrey's kidneys had sustained serious damage. After being on dialysis for a year, Jeffrey was placed on the waiting list to receive a simultaneous pancreas/kidney transplant.



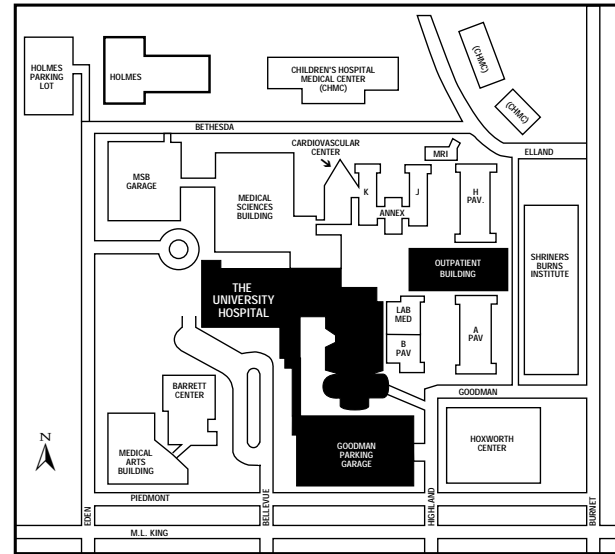
On the night of Dec. 7, 1997, Jeffrey, minister of music at Christ Temple Apostolic Church in Louisville, Ky., prayed that the organs would soon become available. "At that point, I was truly ready to receive the transplant," he said.

The next morning, Jeffrey received a phone call from a nurse who told him that a kidney and pancreas were available. "I was jumping up and down inside," says Jeffrey. "My wife and I were so excited. It felt like we had won the lottery!"

The transplant was performed the same day at The University Hospital. Jeffrey had no problems with rejection, and he went home from the hospital on Christmas Day. "I am so thankful to the Lord, who gave me the faith and trust that helped me through my surgery, and all the doctors and nurses who cared so diligently for me. They were true professionals who worked with dedication and expertise. My wife and I are also very thankful for our parents, Bishop Johnnie L. Johnson, First Lady Claire Johnson and the Bethlehem Temple Church family, who gave us their prayers, support and encouragement during my illness and surgery."

Today, as a musician, Jeffrey spends his time singing and playing instruments at his church. He also enjoys playing ball and riding roller coasters at the amusement parks.

"Being a transplant recipient has made me look at the world in a whole new light," says Jeffrey. "I am so thankful for the things I have, and I could never take anything or anyone for granted."



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