

INFORMED CONSENT FOR ADULT KIDNEY TRANSPLANT RECIPIENTS

Introduction

The UCSF Kidney Transplant Program was established in 1963. We have performed over 8000 kidney transplants. UCSF is a longtime leader in improving the way transplants are done, and making it possible for more people to receive one.

In order for you to make this decision about participating in the kidney transplant process at UCSF and having surgery to receive a new kidney, you must understand the risks and benefits. This process is known as informed consent. This consent form provides information about the kidney transplant process at UCSF and the surgery that will be discussed with you. Once all of your questions have been answered, you may sign this form showing that you are, of your own free will, choosing to participate in the kidney transplant process and become a candidate to receive a new kidney. You are free to ask any questions, change your mind, withdraw your consent at any time or opt out of the kidney transplant program at any time.

The Kidney Transplant Team

At UCSF, the care you receive will be given by a transplant team:

- Surgeons are the doctors who will put in your new kidney.
- Nephrologists, or kidney doctors, will take care of you and your new kidney after your transplant surgery.
- Transplant coordinators will be your main contact with the UCSF transplant team. They will answer your questions as you get ready for your transplant.
- Nurses will care for you in the hospital and in the clinic after your transplant.
- Social workers will focus on your non-medical needs during the transplant process, such as transportation, housing, and financial, family or community support.
- Financial counselors will help you understand your insurance plans and your financial responsibility.
- Administrative assistants will schedule your appointments, send letters and packets, and gather test results for review.
- Additional consults: you may be referred to other services for evaluation or consultation if the transplant team feels it is appropriate. Examples include a Pharmacist (for education and management of medication) or Registered Dietician (for nutritional assessment or education).

Confidentiality

UCSF complies with state and federal confidentiality laws. Except where allowed by law, communication between you and UCSF will remain confidential. This includes, but is not limited to, the potential donor. Similarly, you cannot receive medical information about the donor and his or her tests, unless the donor has given permission to share that information. However, under these laws, hospital staff who are involved in your medical care may review your medical record. They are required to maintain confidentiality according to the law and the policies of UCSF.

If you do receive a transplant, data about your case, which will include your identity, will be sent to the Organ Procurement and Transplantation Network (OPTN), the United Network for Organ Sharing (UNOS) and may be sent to other places involved in the transplant process as permitted by law.

The Evaluation Process

During your evaluation, you will meet with the kidney doctor, a transplant coordinator, a social worker and a financial counselor.

- The kidney doctor and transplant staff will discuss any medical problems that need to be evaluated before the transplant, such as heart disease, infections, bladder problems, ulcer disease or obesity.
- The social worker will meet with you to discuss transportation, housing, financial and family support needs with respect to transplant.
- A financial counselor will meet with you to assist you in understanding the covered benefits of your insurance policy. You should also contact your insurance company to make sure you understand your insurance benefits or whether you have insurance benefits related to kidney transplant.
- The transplant coordinator will arrange for a series of tests that are needed to decide on the best treatment for you.

You will have an opportunity to ask any questions. We encourage you to learn as much as possible about the transplant process before making a decision about whether you wish to agree to become a candidate for or receive a kidney transplant operation. You do not have to make a decision by the end of the evaluation session. You can let us know later.

National and Transplant Center-Specific Outcomes

During the evaluation process you will be provided with UCSF's most current outcome data as released by the Scientific Registry of Transplant Recipients (SRTR). The document provided to you will include UCSF's current 1-year post-transplant patient survival rate and 1-year post-transplant kidney survival rate. The document will also explain how these rates compare to the national average. If at any time you need help interpreting the report, please let your transplant coordinator know. You can visit the following websites for further information:

Scientific Registry for Transplant Recipients (SRTR) www.ustransplant.org
Organ Procurement and Transplantation Network (OPTN) www.optn.org

Special Programs

UCSF offers special kidney transplant programs such as: alternative living donor, extended criteria donor and high risk donor programs. These options will be discussed with you during your evaluation appointment.

After the Evaluation

About four weeks after your evaluation visit you will receive a letter that will tell you your blood type, whether you are considered to be a candidate for a transplant, and any tests that must be completed with your local physician.

Selection Criteria and Suitability for Transplant

Although a kidney transplant may be appropriate for many people with end stage kidney (renal) disease, there are certain conditions that may affect your eligibility for a transplant. Your suitability is determined by your current health condition, past medical history, psychosocial history, laboratory results, diagnostic data and financial status. Each patient's suitability for transplantation is discussed in our kidney transplant selection conference. UCSF's Kidney Transplant Program has established specific selection criteria. This list was included in the informational packet sent to you before your evaluation and is also available to you upon request.

Selection Conference

UNIT NUMBER

PT. NAME

BIRTHDATE

LOCATION

DATE

UNIT NUMBER

PT. NAME

BIRTHDATE

LOCATION

DATE

After all the details of your case are reviewed by the consulting transplant physician and nurse, your case is presented in detail at our selection conference. Transplant surgeons, kidney specialists, transplant coordinators, social workers and financial counselors are present and have input about your case. If more tests are needed to assess your health, they may be recommended.

The conference may decide that a kidney transplant is too risky for you and may lead to worse health than remaining on dialysis. These types of decisions are discussed with your own physician who will then discuss the decision with you. If the conference recommends that you not receive a kidney transplant, we can answer any questions you may have about this decision.

Post Transplant Regimen

After transplant, you will be asked to return to the transplant clinic frequently for lab tests, chest x-rays, clinic visits, and other diagnostic procedures to monitor how well your transplant is working. Please notify the UCSF transplant team now, or when you become aware of any problems you may have that would prevent you from keeping your appointments or taking medication.

Support Issues

It is essential that you are prepared for your post operative needs before you are called for your transplant. You will need to identify a support person(s) that will help you accurately follow your post-operative care program by supervising your medication, exercise program, diet and hygiene in the first weeks of your recovery after surgery. Your support person(s) will also need to provide transportation and accompany you to your laboratory and doctor appointments.

Financial Responsibilities

Your medical care after your transplant is very expensive; consequently, you must keep current with your insurance, what it covers, how it works, and your responsibilities. If, for example, your insurance requires authorization for you to come to clinic appointments, you must get the authorization from your primary care provider. Medications after transplant are not free and you will need to make arrangements to make sure they are available. You will need to keep your financial counselor and social worker informed about the progress of obtaining funds and about any changes in your insurance coverage.

UNIT NUMBER

PT. NAME

BIRTHDATE

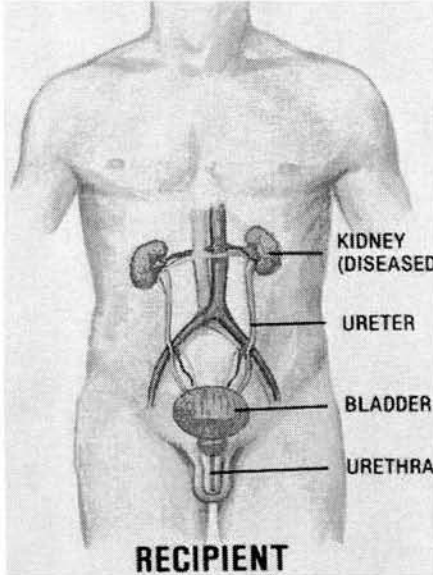
LOCATION

DATE

The Surgical Procedure

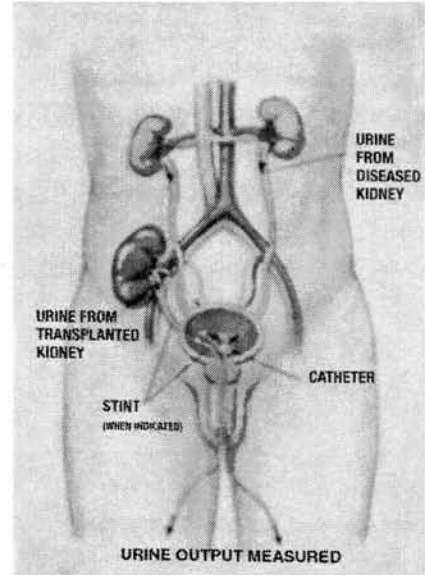
Surgery – What to Expect

Most people have two kidneys. They are in the back underneath your rib cage (see diagram on the left). They remove waste products, fluids, help produce blood cells and control your blood pressure. We do not usually remove your original kidneys during a transplant. If they must be removed, we will discuss this when we meet with you individually.



After your kidneys remove waste products and fluids, you end up with urine that must leave your body.

The ureter transports the urine from the kidney to the bladder. The bladder sits in your pelvic region and inflates like a balloon. When there is enough urine in your bladder, you feel pressure in your pelvic region to empty it.



Your new kidney will be placed in the front, lower pelvic region, usually on the right side near the appendix (**see diagram on the right**).

Sometimes the new kidney might be placed on the left side. The donor provides the kidney, the artery and vein that bring blood to and from the kidney, and the ureter, which transports the urine to the bladder.

After the transplant, you will wake up with an 8-inch, crescent moon-shaped incision in your pelvic region and a bladder catheter in place to measure how much urine your new kidney is making.

Surgical Risks

General Anesthesia

The transplant surgery will be done under general anesthesia. There are a number of known possible risks with any surgery done under general anesthesia. An anesthesiologist will explain these to you and you will need to sign a separate consent for anesthesia.

Blood Transfusions and Risk Involved with use of Blood or Blood Products

Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. You will be asked to sign a separate consent form at the time of surgery regarding transfusion risk.

Potential Surgical Complications

There are risks in all surgeries. Many complications are minor and get better on their own. In some cases, the complications are serious enough to cause death or to require another surgery or medical procedure.

Blood vessel clotting (thrombosis) occurs in a small percentage of kidney transplants. This is a clot that develops in one of the major blood vessels that goes to your kidney. Clotting can cause failure of the kidney transplant and most patients who develop a clot in the kidney will require another kidney transplant.

Some patients experience urinary or bladder complications such as leaks and narrowing (strictures). If this happens, tubes may need to be placed through the skin to aid in the healing process. In some cases surgery is necessary to correct the urinary and bladder leaks. Poor healing of the incision can lead to a bulging or hernia. More surgery may be needed to repair this.

Fluid can sometimes collect around the kidney, which can lead to problems with kidney function, or pressure in the area of the kidney. This problem, known as a lymphocele, may require additional surgery to repair.

Rarely, damage to nerves may occur. This can happen from direct contact within the abdomen or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases, these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.

Other rare, but possible, complications include: injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, heart attack, stroke, and permanent scarring at the site of the abdominal incision.

The doctors and nurses will watch you very closely after surgery. They will look for bleeding or wound healing problems, poor blood circulation to the kidney, and urine flow problems. If a problem develops, you may need to return to surgery.

Many patients ask whether they can die from a kidney transplant. The answer is yes. A kidney transplant is a surgical procedure, and sometimes complications develop. Most deaths, however, are caused by other medical problems, such as heart disease, diabetes and high blood pressure. The risk of dying from the surgery itself is low and happens in less than 1% of cases.

Medical Risks

Rejection - As a transplant recipient it is crucial that you take your anti-rejection medication and keep your medical appointments to decrease the risk of rejection. The risk of rejection never goes away. The signs and symptoms of potential rejection will be discussed with you while you are in the hospital.

Infections, High Blood Pressure, Diabetes, and High Cholesterol - The anti-rejection medicines sometimes can cause infections, high blood pressure, diabetes, high cholesterol or cancer. Patients commonly ask, "Well, I already have high blood pressure, diabetes, and high cholesterol. What does this mean for me?" It may mean that your medications will be changed. Diabetics who have not taken insulin before may need to do so after a transplant.

Opportunistic infections – These types of infections take advantage of weakened immune systems. Infections from bacteria, viruses, or fungi, are all possible after transplant. Specific viruses that transplant patients are more at risk to get include cytomegalovirus virus, Epstein-Barr virus, and polyoma BK virus.

- Cytomegalovirus (CMV) is a virus most adults have been exposed to in their lifetime. It is a virus which can present as an infection. A mild form could include fatigue. A serious form could cause severe illness and affect the kidney.
- Epstein - Barr virus (EBV) is a virus most adults have been exposed to in their lifetime. It can cause fever, sore throat or lymph node swelling in the neck. On rare occasions, high amounts of EBV in the body can lead to a type of lymphoma.
- Polyoma BK Virus can be present in the urine, blood or kidney after transplant. Most people are exposed to this virus during childhood but never feel sick. The virus may damage the transplanted kidney.

Cancer - Transplant patients probably are most concerned about the cancer risk. Your risk will be about 5% higher than that of the normal population. The two most common types of cancers that occur are lymphoma and skin cancer.

Sleepy Kidney - Sometimes a kidney doesn't work right away once it is transplanted. This is known as a "sleepy kidney" and it happens in 2 out of 10 transplants. It happens because the new kidney is outside the body for a period of time after it is removed from the donor. If your new kidney doesn't work right away, you may need dialysis during the time that the new kidney is "sleepy." This does not mean the new kidney is failing. It nearly always "wakes up." The time it takes to begin working may be as short as a couple of days, or could be as long as 6 weeks.

Recurrence of Original Kidney Disease - Some kidney diseases can reoccur in the new kidney. If that is a concern for you, we will discuss it when we meet individually.

Organ Donor Risk Factors There are several organ donor risk factors that could affect the success of your kidney transplant. These risks include, but are not limited to; the medical and social history of the donor; the age of the donor; the condition of the kidney used; or the possibility that you could be at risk of contracting HIV, hepatitis B virus (HBV), hepatitis C virus (HCV) or malaria if the donor is infected but the infection is not detectable at the time of donation. All donors are screened to prevent transmitting an infectious disease or cancer. These screening tests are not perfect, and on rare occasions, an infection or cancer can be passed on to the recipient.

When the time comes for you to receive an organ offer, the transplant team will discuss the possible risks associated with transplantation of that particular organ.

Psychosocial Risks

A serious illness can create many personal and family stresses. After your transplant, there will be different types of adjustments. You and your family can expect some ups and downs related to your physical condition as well as emotional reactions to this new phase in your life. Some possible side effects are depression, post traumatic stress disorder, generalized anxiety, anxiety regarding dependence on others and feelings of guilt. It is important that you notify your transplant team if you feel you may be experiencing any psychological side effects.

Financial Risks

After transplantation, some people lose eligibility for disability-based insurances like Medi-Care and Medi-Cal. Additionally, it is possible that future attempts to obtain medical, disability and life insurance may be jeopardized. If you think you are going to lose your insurance, talk with either the financial counselor or transplant social worker about what other coverage may be available. Do not wait to call until you have no insurance. You must plan ahead.

Transplantation by a Transplant Center Not Approved by CMS (Medicare)

If your transplant is not provided in a Medicare-approved transplant center, it could affect your ability to have your immunosuppressive drugs paid for under Medicare Part B. UCSF is a Medicare-approved transplant center. If at any time we lose our Medicare approval, we will notify you at least 30 days in advance and provide assistance if you choose to transfer to the waiting list of another Medicare-approved transplant center without losing the time you have accrued on the waiting list.

UNIT NUMBER

PT. NAME

BIRTHDATE

LOCATION

DATE

Benefits of Having a Kidney Transplant

A transplant is a good option for most patients.

- One reason is that transplantation may increase your lifespan. Studies have shown that patients who are carefully selected for transplant have an improved lifespan compared with patients who continue on dialysis.
- With hemodialysis and peritoneal dialysis, wastes are removed only during treatment. A transplanted kidney works 24 hours a day, 7 days a week, so waste products and fluids are continuously removed from your body.
- Another reason is because a transplant can improve your quality of life. For most patients, that means freedom to do things they enjoy, and the ability to return to work. This freedom comes with a responsibility though – to take medications as directed, maintain a healthy lifestyle, attend clinic appointments, and have all blood work completed.

Alternative Treatments

Kidney transplant may not be the right option for every patient. If the doctors who complete your evaluation feel that it is too dangerous for you to have a transplant, we will let you know, and you will continue on dialysis. If you feel that you do not want to take the risks of the transplant surgery or the anti-rejection medicines, you can continue with dialysis as you are doing now. If you are uncertain about the transplant option, it is also okay to go on the waiting list now, but change your mind later and be removed from the list.

Right to Refuse Transplantation

All transplant candidates have the right to withdraw his or her consent for transplantation at any time during the process.

Whom Do I Call if I Have Any Questions or Problems?

Please take your time to make your decision. Discuss it with your family and friends. Feel free to ask us questions also. For questions about the program, contact your pre-transplant coordinator at (415) 353-1551.

Signatures

UNIT NUMBER

PT. NAME

BIRTHDATE

LOCATION

DATE

I, the undersigned, have been informed about the UCSF Kidney Transplant Program purpose, procedures, possible benefits, risks and alternatives. I have received a copy of this consent document. I have been given the opportunity to ask questions and I have been told I can ask questions in the future. All of my questions have been answered to my satisfaction. I voluntarily:

agree _____ or do not agree _____ (initial appropriately) to participate in this program.

I am free to withdraw from the program at any time without need to justify my decision. I understand that I have the right to withdraw my consent at any time during this process. A withdrawal will not in any way affect my future treatment or treatment of my relative, friend or partner on the waiting list.

Printed Name of Patient

Signature of Patient

Date

Printed Name of Witness

Signature of Witness

Date