



Pediatric Nephrology & Transplantation

Transplant Candidate Education Program — Confirmation of Education

The Transplant Candidate Education Program was developed to fully inform you and your family about the evaluation process to receive a kidney transplant from a living donor or to be placed on the waiting list for a deceased donor organ. The selection criteria (the things that would qualify or disqualify you for a transplant) were discussed with you. The risks and benefits of organ transplantation and information about the surgical procedure were also reviewed. In addition, alternative treatments, your rights as a transplant recipient, and insurance and confidentiality issues were discussed. The following information will outline what you and your family have learned in the Transplant Candidate Education Program.



Overview

A. Participation

Your and your family's participation in this evaluation process is completely voluntary. You and your family are free to withdraw from the evaluation process at any time. In addition, if and when you are found eligible for a transplant, you and your family have the right to refuse transplantation at any time, including when you are called in to receive a transplant.

B. Treatment Alternatives

Persons with kidney failure have several options:

1. Dialysis: Hemodialysis or Peritoneal Dialysis
2. Kidney Transplantation - Kidney may come from:
 - a. Deceased donor kidney
 - b. Living donor

(i) Compatible Donor

- (A) Related: blood or genetically related
- (B) Unrelated: emotional connection (e.g., family friend)

(ii) Incompatible Donor

- (A) Living Donor Kidney Exchange Program: for recipients with medically acceptable living donors who are incompatible by blood type or crossmatch, recipient/donor pairs are entered into a registry for an exchange match.
- (B) Program for Incompatible Transplants: for recipients with willing living donors who have incompatible blood type or crossmatch compatibility issues. Recipients receive medical therapies before and after transplant to significantly increase the likelihood for a successful transplant outcome.

C. Recipient Benefits

According to the most recent United Network for Organ Sharing ("UNOS") Scientific Registry for Transplant Recipients data:

1. On average, children who receive a kidney transplant have significantly increased life expectancy compared to children who are maintained on dialysis while waiting for a kidney.
2. On average, diabetic transplant recipients live longer than diabetic patients who are maintained on dialysis.
3. Most transplant recipients report an enhanced quality of life through improved health and energy.
4. These benefits may vary depending on the age and other medical conditions of the transplant recipient.

Additional Information

The following organizations and associated web sites provide general information, frequently asked questions and patient testimonials about kidney transplantation:

- A. www.optn.org – The Organ Procurement and Transplantation Network (OPTN): The unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984.
- B. www.unos.org – United Network for Organ Sharing (UNOS): The organization contracted to administer the OPTN. UNOS has also developed a website specifically for patients and families at www.transplantliving.org
- C. www.sharenj.org – The Sharing Network: The non-profit, federally certified organ procurement organization (OPO). An OPO is a program that acquires and coordinates placement of donated organs for patients on national transplant waiting lists.
- D. www.kidneyfund.org – American Kidney Fund (AKF).
- E. www.a-s-t.org – American Society of Transplantation.
- F. www.kidney.org – National Kidney Foundation.
- G. www.saintbarnabas.com/services/renal/index.html – Saint Barnabas Health Care System Renal and Pancreas Transplant.

The Evaluation Process

A. Eligibility/Ineligibility

The evaluation process determines if you are medically eligible to receive a kidney transplant and includes an assessment to make sure that there are no psychological or social barriers to transplantation. The goal of the evaluation process is to make sure your health status is optimal and that you would be able to be safely transplanted. If a new health problem is found during the evaluation, you may be referred back to your nephrologist or the appropriate medical specialist. If a serious health problem is found it is possible that you may be ineligible to receive a transplant.

B. Education Session

The Education Session includes a discussion of the following topics:

1. Selection criteria (disqualifying conditions) and testing requirements needed for medical clearance

2. Tissue-typing and crossmatching (i.e., checking to see if your tissue/blood matches the donor)
3. How the wait list works including multiple wait listing and transfer of wait time
4. Living and deceased donor organs: types and issues specific to each type
5. Your and your family's responsibilities in preparation for and after you receive a kidney transplant
6. What happens when an organ becomes available
7. Overview of the transplant surgery
8. The general hospital experience
9. Common immunosuppressant medications and their side effects
10. Post Transplant Care - visits to the transplant clinic
11. Possible transplant complications: (e.g. rejection, infection)
12. Financial considerations
13. Healthy lifestyle following transplantation

C. Individual Evaluations

The following individual evaluations are also part of the evaluation process:

1. Nursing Assessment
 - a. Review of required laboratory and diagnostic testing
 - b. Discussion of immunization history and needs to be communicated to pediatrician
 - c. Education/discussion about the option of living donation
 - d. Discussion of learning needs in preparation for understanding medication administration after transplantation
 - e. A review of compliance with your current medical regimen (e.g., medication; dialysis)
2. Physician Evaluation
 - a. History and Physical
 - b. Education/discussion including:
 - (i) risks and benefits of transplantation
 - (ii) option of living kidney donation
3. Social Work Assessment
 - a. A thorough discussion of your psychological and social history
 - b. A discussion of how transplantation may impact on school life
 - c. A discussion of the possible psycho-social risks including possible emotional, financial, and physical stressors that receiving a transplant may pose to you and your family
 - d. Education/discussion about the option of living donation
 - e. Review of your current insurance status and future insurability issues
4. Nutrition Assessment
 - a. Nutrition assessment and education aimed at achieving and maintaining optimal nutritional status for transplantation
 - b. Education and discussion of possible dietary needs after transplant

D. Overview of Requirements for Medical Clearance

1. Basic Testing (within the last 12 months)
 - a. Medical History and Physical – from referring nephrologist
 - b. Chest X Ray
 - c. Electrocardiogram (EKG)
 - d. Complete blood work results from your dialysis unit or MD office
 - e. Serologies: Hepatitis B and C, and HIV, EBV, CMV, Rubella, Varicella, RPR
 - f. Social Work Assessment from dialysis unit – if you are on dialysis
 - g. Medical Evidence Report (MER) from your dialysis unit - if you are on dialysis
2. Cancer Screening
 - a. PAP smear for sexually active females
3. Cardiac Testing: Echocardiogram and cardiology consult may be required for all patients with any of the following:
 - a. Abnormal electrocardiogram (EKG)
 - b. History of hypertension
 - c. History of diabetes
 - d. History of cardiac problems such as heart attack, angioplasty, stent placement, bypass surgery, valve replacement

4. Other Testing that may be required based on your medical history:
 - a. Blood clotting tests
 - b. Lung Function Tests
 - c. Ultrasound of liver/kidney
 - d. Peripheral Vascular studies
 - e. Others as recommended by transplant physician or required by your insurance company

E. Recipient Selection Criteria

Absolute contraindications or disqualifying conditions for kidney transplant include:

- Serious heart disease, ejection fraction (EF) less than or equal to 30%
- Serious psychiatric illness (uncontrolled with medication)
- Severe mental retardation and/or multiple congenital abnormalities associated with severe limitation (cases to be discussed by the hospital's bioethics committee)
- Chronic infections (unresolved)
- Advanced Pulmonary Disease
- Advanced Liver Disease (i.e. Cirrhosis of the liver)
- Metastatic Cancer
- Chronic proven non-compliance with medication and/or prescribed treatment(s)
- Active drug abuse
- Active vasculitis
- Active infection (i.e. peritonitis, abscess)
- Absence of funding for transplant procedure, hospital charges and/or medications
- Multiple co-morbid conditions which, in combination, would make transplantation too high risk for the patient.

F. Yearly Updating of Tests

Your transplant coordinator will inform you and your family which tests need to be updated yearly and will help you with this requirement. It is your and your family's responsibility to make sure your testing is up to date.

G. Tissue Typing Overview:

1. Blood Group compatibility:

	Recipient	Donor must be
Blood type	A	A or O
Blood type	B	B or O
Blood type	O	O
Blood type	AB	A or B or AB or O

2. Tissue Typing and Crossmatching

- a. Tissue typing is done to determine your genetic markers (or your HLA – Human Leukocyte Antigens).
- b. Panel Reactive Antibody (PRA) measures whether you have formed antibodies to other people's HLA as a result of previous blood transfusions, pregnancies, or transplantations.
- c. Crossmatching is the most important test to determine compatibility. Blood is mixed from the potential recipient and the potential donor.
 - (i) A positive crossmatch means there was a reaction upon the mixing of the bloods. The donor therefore may not be able to donate to the recipient.
 - (ii) A negative crossmatch means there was no reaction and the recipient and donor are compatible.

H. Monthly Blood Specimen

Once you are active on the transplant waiting list, one red top tube of blood must be sent to The Sharing Network on a monthly basis. If you are on dialysis, your unit can send this in for you. If you are not on dialysis, you or your family must have this tube drawn and sent directly to The Sharing Network. Your transplant coordinator will teach you exactly how to fulfill this very important responsibility. If a current blood tube is not at The Sharing Network at the time a deceased donor kidney is identified for you, you may lose the opportunity to receive that kidney.

I. Activation on the Waiting List

To become active, you must complete all of the evaluations and diagnostic tests required and be considered medically and psychosocially eligible. You will be sent an official letter from your transplant coordinator informing you that you are now active on the transplant waiting list. In addition, your nephrologist and your dialysis unit (if applicable) will be notified.

J. The Waiting List

When a deceased donor organ becomes available, you must be blood group compatible. A list of potential blood group compatible recipients is generated based on a point system. The points are allocated based upon time waiting, quality of match, high recipient PRA (Panel Reactive-Antibody) and pediatric recipient status. If you are on this list, you or your family will receive a phone call from a transplant coordinator. To be considered for this kidney you must be medically stable with no active infections and have your monthly blood specimen at The Sharing Network. You or your family will receive detailed information and instructions from the transplant coordinator. Every available deceased donor kidney generates a different list of potential recipients. Therefore, there is no way to tell your “position on the list” until a particular kidney becomes available.

As soon as a center accepts you as a transplant candidate, your “waiting time” begins.

Under Organ Procurement and Transplantation Network (OPTN) policy, you can list at more than one transplant center (multiple-list) as long as you don't choose two transplant centers in the same local area. As with any transplant listing, you must be evaluated and accepted by a transplant center. You or your family should also check with your insurance provider to see if there are costs associated with multiple listing that may not be covered. In addition, you or your family would need to maintain current lab results and contact information for each transplant program where you're listed.

The longest amount of time you have waited at any center is called your ‘primary waiting time’. If you list at multiple centers, your waiting time at each center will start from the date that center listed you. OPTN policy allows you to transfer your primary waiting time to another center where you are listed, or switch time waited at different programs. You are not allowed to add-up or split your total waiting time among multiple centers. Any request to transfer or switch waiting time must be approved by the transplant center(s) involved, and may require a written request from the patient.

Each patient will be provided with a pamphlet entitled “Questions and Answers for Transplant Candidates and Families about Multiple Listing and Waiting Time Transfer” for detailed information pursuant to OPTN and UNOS policy.

K. Living Donors

If you have a living donor, he/she may contact your transplant coordinator. Once it is determined that you are a candidate for transplantation, any willing living kidney donors that you identify will proceed with their education and evaluation. Living donors may be related to you by blood or may have an emotional connection with you (e.g., family friend). Another type of living donor is called an “altruistic donor”. This type of donor has offered their kidney to someone they do not have an emotional relationship with and in some cases to someone they do not even know. Altruistic donors may specify who they want to give their kidney to or may decide to donate it to the next qualified waiting list recipient.

It is our policy to discourage recipients from the use of the internet or ads to solicit donors due to the potential for unethical interactions or possibly illegal arrangements. It is often impossible for the transplant team to discern the nature of these interactions or arrangements. For this reason, we will not evaluate potential living donors who were solicited through the internet or ads. Likewise, we will not evaluate donors outside of the U.S. who are not related to you.

L. Deceased Donors

1. Deceased donor organs are obtained from individuals after their death whose next of kin has given permission to have their organs donated.
2. Deceased donor organs are most often from persons with brain death. Brain death means that there is no brain function but the heart is still beating so that the blood supply is still flowing to all of the body's organs. Deceased donor organs may also come from non-heart beating donors. This means the organs were donated after cardiac death has occurred. This is referred to as donation after cardiac death (DCD). Cardiac death means the patient is without oxygen and the heart has stopped beating.
3. At the time an organ becomes available, the transplant coordinator will provide you with general information about the deceased donor organ such as age of the donor, sex, cause of death, as well as any known risk factors (discussed below). Before deciding to accept the donor organ, you may wish to speak to the transplant physician on-call, if there are any additional concerns or questions. The risks and benefits of accepting the donor organ will be

reviewed with you at the time of admission by the transplant physician.

4. Remember, you and your parents/guardian have the right to refuse a deceased donor organ offer at any time.

M. Organ Risk Factors

1. Organ risk factors that could affect the success of the transplant or the health of the transplant recipient include but are not limited to, the donor's history, the condition or age of the organ used, and/or the recipient's risk of contracting an infectious disease.
2. The Organ Procurement Organization is responsible for the medical/social evaluation of each potential donor to reduce the risk of transmission of any donor illness. If a donor's social history indicates that the donor could potentially be in a "window period" for transmission of HIV, Hepatitis C, Hepatitis B or other infectious disease, you will be notified of the risk of contracting these diseases. A window period for transmission means that the donor may test negative for the disease but a review of social and/or behavioral history of the donor may indicate that he/she may have recently become infected and therefore may be infectious to others. In this situation, the transplant physician will discuss this potential risk with you.
3. A candidate who is positive for Hepatitis C virus in the blood may be offered kidneys from deceased donors who are also Hepatitis C antibody positive. The benefit of this is that waiting time is decreased significantly for patients accepting Hepatitis C positive donor kidneys. The risks of being transplanted with a Hepatitis C positive kidney include:
 - a. Worsening of liver function
 - b. Infection
 - c. Decreased survival of the transplanted kidney

N. Financial Considerations

Transplantation is an expensive undertaking that requires a serious commitment. It represents a partnership between you, your physicians, and the transplant team. Therefore, it is important for you to understand the terms and conditions of your current insurance and to keep apprised of any changes that may occur with your coverage. The Financial Coordinator and Transplant Social Worker will explain

the financial considerations involved in transplantation and verify your health insurance coverage both initially and periodically. However, it remains your responsibility to be aware of any changes to your insurance coverage and to contact the Financial Coordinator immediately. Failure to do so may jeopardize your ability to receive a transplant.

Most patients with Chronic Kidney Disease are eligible to receive Medicare benefits through the federal ESRD Medicare Program. Medicare may cover most of the costs related to transplantation, if you are eligible; however, there are many expenses that will need to be coordinated with other insurance coverage such as private insurance, a Medi-Gap plan or Medicaid. This has been reviewed with you and your family and you have been given additional information appropriate to your circumstances if necessary.

In some situations, Medi-Gap premiums are subsidized through grants obtained by the dialysis unit. This assistance will terminate after transplantation so it is important to plan appropriately. Patients also need to understand that Medicare or other disability entitlements such as Medicaid, may be affected by transplantation. For example, Medicare benefits terminate three years after a successful transplant if there are no other qualifying disabilities.

O. Hospital Admission

If you are receiving a kidney from a living donor, your surgery will be planned to coordinate with school and work schedules. One week prior to surgery, the donor, recipient, and family members will attend a "Family Meeting". At this meeting the surgical procedure for both the donor and recipient will be reviewed. The risks and benefits of receiving this living donor organ will have been reviewed with you by this time. Your medical suitability to undergo the transplant operation will be re-evaluated. A significant change in the candidate's health status may, in certain circumstances, lead to postponement or possibly cancellation of the transplant surgery.

If you receive an organ from a deceased donor you will be admitted to the hospital as directed by the pediatric nephrologist. You or your family will need to bring your

insurance cards and your medication list with you. When you arrive, you will have necessary laboratory and medical testing done. You will be admitted by the transplant physician who will review the known risks and benefits of that donor organ with you and your family. You will meet the surgeon and anesthesiologist at this time also. If there is a research protocol for which you are being considered, this will be discussed with you and your family at this time. If you and your parents/guardian choose to participate, the transplant physician will take informed consent for the research protocol at this time.

P. Patient Rights and Grievance Process

The New Jersey State - Ambulatory Care Patient Bill of Rights outlines your rights as a patient at our health care facility. All patients are asked to sign an acknowledgment form stating their receipt of these rights.

In addition to the grievance procedures listed on the New Jersey State –Ambulatory Care Patient Bill of Rights, patients with chronic kidney disease have several other alternatives. If a grievance or complaint cannot be resolved to the patient’s satisfaction through the Transplant Department Administrator and/or the Medical Center’s Patient Satisfaction Department, the patient or family may contact the Trans-Atlantic Renal Council per their ESRD Consumer Complaint/Grievance Procedure at 1-888-877-8400.

In addition, UNOS provides a toll-free patient services line to help transplant candidates, recipients, and family members understand organ allocation practices and transplantation data. You or your family may also call this number to discuss a problem you or your family may be experiencing with your transplant center or the transplantation system in general at 1-888-894-6361

Q. Transplant Services Received at a Non-Medicare Certified Facility

The Renal and Pancreas Transplant Centers of Saint Barnabas Health Care System are Medicare approved facilities. However, you should know that if the transplant recipient were to receive his/her transplant at a non-Medicare approved transplant center it could affect the recipient’s ability to have immunosuppressive drugs paid for under their Medicare Part B.

The Transplant Surgical Procedure

A. Prior to Transplant

In preparation for surgery, you may expect to have blood drawn to determine whether or not dialysis treatment is necessary before your surgery. In addition, an electrocardiogram (EKG) will be done to ensure your cardiac status is stable. An IV line will be started in your arm. Antibiotics and anti-rejection medications will be administered through the IV.

B. The Transplant Operation

You and your family will meet the transplant surgeon who will discuss the technical aspects of the operation with you and your family and will ask you and/or your parents/guardian to sign an informed consent. You and your family will also meet the anesthesiologist who will discuss the use of anesthesia during surgery, the insertion of a tube/catheter in a large vein in the neck and the potential need of blood transfusion in case of bleeding. When you are taken to the operating room you will be given general anesthesia. The average length of surgery is 4 to 5 hours. The catheter will then be inserted into a large vein in your neck. It will provide a way to administer medications, fluids, and possible blood products prior to, during, and after surgery. And lastly a tube will be inserted into your bladder to allow the bladder/ureter incision to heal, to help pass urine and monitor urine output.

After the transplant operation is completed, you will be brought to the pediatric intensive care unit where you will stay until the transplant physician decides that you can be transferred to the Pediatric Step-Down Unit.

C. The Hospital Stay

Because your immune system will be suppressed by medications, you should have as few visitors as possible. To further prevent infection, flowers are not allowed. You will remain in the hospital until discharged by your physician (the average length of hospital stay is 5 to 7 days). Before you are discharged all the tubes, IV’s and catheters placed during surgery will be removed. The pediatric nephrology nurse will teach you and your family how

to ensure you receive appropriate care following transplantation. This may include how to obtain, organize and take your medications, how to monitor your Blood pressure at home if needed, about follow-up appointments, signs of rejection and other warning signs to watch for at home. You will receive an educational manual named Planning for Home that has been prepared especially for you and your family. It will help you understand the best way to take care of yourself and your new transplant.

D. After Transplant

After you are discharged home, you will receive follow up care in the Saint Barnabas Pediatric Nephrology Clinic. Initially, you will be seen several times per week. Gradually, the length of time between visits will increase depending on your particular situation. Several months after successful transplantation, you may return to your own kidney doctor (nephrologist) for monthly check ups with only periodic monitoring at the Saint Barnabas Clinic. Some nephrologists prefer that their patients return to them even sooner and this decision will be made by you, your parents/guardian, your transplant doctor and your nephrologist.

E. Medical/Surgical Risks and Complications

There is no guarantee that the transplanted organ will work immediately or even work at all. Following is a list of uncommon but known complications of kidney transplant.

1. Potential surgical complications can include, but are not limited to:
 - a. Clotting of transplanted kidney. This means that the transplanted kidney fails to work at all in the recipient due to a blood clot in the kidney. This occurs in 1 to 2 % of the cases. The recipient may then require a second surgery in an attempt to correct the problem or remove the kidney if the problem is not correctable.
 - b. Urine leakage requiring repair
 - c. Rupture of transplanted kidney
 - d. Collection of fluid around transplanted organ with or without a blockage
 - e. Bleeding requiring a transfusion and/or a re-operation to drain collected blood and stop bleeding
 - f. Wound infection
 - g. Wound separation requiring repair or wound care
 - h. Death
 - i. Unexpected complications related to the actual operation
 - j. Femoral (a large nerve supplying the leg on the side of the transplant procedure) nerve injury resulting in permanent leg weakness.
2. Potential medical complications can include, but are not limited to:
 - a. Respiratory problems requiring the need for ventilatory support
 - b. Acute rejection:
 - (i) The recipient's immune system recognizing the donor's kidney is called rejection. The majority of rejection episodes are successfully treated with medication and kidney function returns to normal
 - (ii) A kidney biopsy is the best way to diagnose rejection. The risk associated with this procedure are bleeding and infection.
 - c. Infection other than wound infection
 - d. Delayed or slow transplant kidney function that may require dialysis
 - e. Medication related complications such as unexpected side-effects
3. Potential long term transplant complications can include, but are not limited to:
 - a. Chronic rejection
 - b. Complications related to long-term immunosuppression such as osteoporosis and increased risk of cancer and infection
 - c. Development of new onset diabetes

Program Plan of Coverage

The Pediatric Transplant Program is covered by two Board Certified Pediatric Nephrologists and at least 2 Board Certified Surgeons who specialize in pediatric transplantation and participate actively in the clinical activities of the Program. Physicians are selected and overseen by the Chief of the Transplant Division, Chair of the Department of Pediatrics and Director of

Transplant Surgery based on qualifications, experience, and the needs of the Program. The Pediatric Nephrologists and Transplant Surgeons cover all areas of transplant patient care including pre-transplant, in-patient services, post transplant clinic, transplant research and emergency room care/admissions.

The Pediatric Nephrologists and Transplant Surgeons also provide on-call coverage after hours for the Program. Coverage consists of a Transplant Surgeon and a Pediatric Nephrologist available 365 days/year, 24 hrs/day, 7 days /week. All post transplant patients will have access to routine care during normal business hours and will have access to urgent care 24 hours a day, 7 days a week. Additionally, The Chief of Transplant is generally available by beeper, 24 hours a day, 7 days a week and provides back up coverage and consultation to both the Pediatric Transplant Program and to Transplant Coordinators who are on-call for organ allocation issues.

All patients who are associated with the Transplant Program (evaluation patients, active UNOS wait list patients and post transplant patients) will be notified in writing, by the Chief of the Transplant Division or his designee, of any circumstance which would impact their ability to receive a transplant or subsequent care at this center. Such circumstances may include, but are not limited to, loss of Medicare certification, notification by UNOS of an adverse action imposed upon the center, unavailability of a transplant surgeon, or a disaster situation requiring transfer of patients due to the center's temporary or permanent closing. In the event of a disaster, written notification may be delayed due to the effects of the disaster. In this event, patients are instructed to contact the UNOS Patient Services line for immediate assistance at 1-888-894-6361.

Confidentiality

All communication between a patient and Saint Barnabas Health Care System are confidential. Health Care System personnel who are involved in the course of your care may review your medical record. They are required to maintain confidentiality as per law and the policy of this Health Care System. If you do become a transplant candidate/recipient, appropriate medical information which will include your identity, will be sent to The Sharing Network and UNOS and may be sent to other places involved in the transplant process as permitted by law. In addition, your parents will be provided with information regarding your care and treatment.

Accessing Updated Information

Technology in the field of transplantation is always improving as science evolves, new medications are developed and advanced techniques are implemented. As such, it is important that you and your family keep abreast of the most up to date information as it relates to your pending transplant. Please be sure to visit our website at www.saintbarnabas.com/services/renal/index.html to access information. The Transplant Candidate Education Program as well as National and Center specific outcomes will be updated regularly. You and your family may also contact your transplant coordinator at any time to request a mailed copy.

Recipient Outcome Information

In general, outcomes for transplant recipients are excellent. The Scientific Registry of Transplant Recipients (SRTR) publishes updated reports every six (6) months on activities at each transplant center and organ procurement organization in the United States. This can be accessed by visiting their website at www.ustransplant.org.

You will be given a document which represents the most current national and center-specific data obtained from the UNOS Scientific Registry for Transplant Recipients at the time of your initial evaluation.