Kidney and Pancreas Transplant Program
Policy and Procedure Manual

Site: Weill Cornell Medical Center
Title: Protocol for Kidney Transplant Patient Evaluation and Selection

POLICY:

This protocol must be used when determining a patient's suitability for placement on the kidney transplant waiting list and/or for living donor kidney transplantation.

PURPOSE:

To provide patient selection criteria which ensure fair and non-discriminatory distribution of donor kidneys.

APPLICABILITY:

All Renal Transplant Physicians, Transplant Coordinators and other Clinical Staff.

PROCEDURE:

1. All potential renal transplant candidates must be selected based on the following inclusion and exclusion criteria:

   a) Eligibility
      1) All patients with chronic kidney disease with actual or estimated glomerular filtration rate ≤ 20 mL/minute.

   b) Contraindications

   The following conditions are contraindications to renal transplantation, if active at the time of transplantation. Patients with these conditions may be added to the waitlist to accrue waiting time while the conditions are being addressed and/or the appropriate clearances are being sought:

      1) Active Infection

      (1) Such as active tuberculosis, untreated diabetic foot ulcers, catheter infections within 2 weeks of transplant, febrile illness. Patients may be transplanted after documented eradication of the infection after antimicrobial therapy has been completed.
      (2) Human Immunodeficiency Virus (HIV) positive patients, except if they meet all of the following criteria:
         - On Highly Active Anti-Retroviral Therapy (HAART) regimen

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- Undetectable viral load
- CD4 count > 200/mm^3
- No active opportunistic infection

2) Active cancer

(1) For patients with a past history of a malignancy, cases will be reviewed on a case by case basis and an appropriate disease free interval will be used to reduce the risk of recurrence.
(2) Some incidental cancers found during the evaluation process may not require a waiting period (examples include in situ or non-invasive bladder papillomas, localized prostate cancer, basal cell carcinoma, less than 5 cm renal cell). All will be evaluated on a case-by-case basis.
(3) When needed, we will seek the guidance of an appropriate specialist (ie. oncologist, surgical oncologist, hematologist, etc.)

3) Cerebrovascular Disease:

(1) Patients with risk factors for cerebrovascular disease or known cerebrovascular disease may be referred to a neurologist or vascular surgeon for clearance.

4) Liver Disease

Patient with cirrhosis, hepatitis B, and/or hepatitis C require Hepatology clearance.

5) Ischemic Heart Disease

Patients with unrevascularized significant coronary artery disease.

6) Cognitive Dysfunction

If patient cannot understand informed consent then there must be a sufficient support system for the patient before and after the transplant.

7) Noncompliance

A patient with a history of noncompliance with medical care must be evaluated by the transplant psychiatrist, show improvement in this behavior under the care of a specialist and receive clearance from the transplant psychiatrist.

8) Active drug or alcohol abuse

Patient must be evaluated by the transplant psychiatrist and a detailed treatment plan developed. Patient will be eligible for transplant once cleared by the transplant psychiatrist.

9) Social

(1) Patients are excluded if they cannot show that they will be able to obtain medications after the transplant (such as those who have no prescription drug coverage).

(2) Patients that live in unsafe environments (homeless or in unsanitary shelters) are not optimal candidates for transplant and immunosuppression.

10) Psychiatric Illness

Patients with significant mood or anxiety disorder, psychosis, substance abuse, or severe personality disorder will be referred for psychiatric diagnosis, treatment, and follow-up in preparation for potential transplant and must be cleared by the transplant psychiatrist.

2. All potential renal transplant candidates must be evaluated based on the following pre-transplant evaluation protocol:

a) The initial evaluation is a multidisciplinary effort which includes the following:

1) Nephrology consultation
2) Transplant Surgery consultation
3) Social Work Evaluation (SW to indicate the length of time in which the psychosocial evaluation is deemed to be current)
4) Nutritional Assessment, if nutrition risk is identified by clinical team
5) Pharmacy screening
6) Financial Evaluation
7) Laboratory Testing
   a) Including, but not limited to: histocompatibility testing, ABO verification on two separate dates, serum chemistry (BUN and creatinine), hematology, viral serologies, tuberculosis (Quantiferon Gold) (if no PPD available).
      - ABO's received from outside sources (ie. patient, external organizations) must be primary source documentation in order to be utilized (ie. Information that comes from the lab/facility who did the testing and contains patient identifiers (name, DOB), date of specimen collection and date of final result).

b) Additional testing may be performed based on patient's underlying disease and/or co-morbid conditions
c) All patients with a history of thrombosis (regardless of suspected cause) should receive a hypercoagulable work-up.

b) If indicated, renal transplant candidates may be referred to the following specialists or others as deemed necessary during the pre-transplant evaluation:

1) Cardiologist
2) Gastroenterologist/Hepatologist
3) Hematology
4) Urologist
5) Psychiatrist

c) All renal transplant candidates are required to undergo the following diagnostic tests at initial evaluation and at every re-evaluation, as well as any additional testing deemed necessary by medical condition:

1) Chest x-ray
2) EKG
3) CT Scan of abdomen/pelvis (with IV contrast if patient is on dialysis)

d) A colonoscopy is required of all kidney transplant candidates over age 45, and should be repeated according to the advice of the gastroenterologist.

e) An MRI or CT of the Brain may be required of some renal transplant candidates with a diagnosis of polycystic kidney disease.

f) A mammogram is required of all female renal transplant candidates over age 40, and should be repeated annually.

g) A pap smear is required of all female renal transplant candidates who are sexually active and/or over age 21, and should be repeated every 3 to 5 years, unless otherwise clinically indicated.

h) A PSA is required of all male renal transplant candidates over age 50 (African American candidates over age 45), and should be repeated at re-evaluation.

i) Low dose chest CT scan for patients aged 50 to 80 with a smoking pack year history of 20 years or more.

j) If indicated by the patient's history and/or if any abnormalities are found during routine testing, further diagnostic tests may also be required.

k) If a patient is deemed as a suitable candidate for renal transplant, a confirmatory ABO testing is required prior to their placement on the UNOS Kidney Transplant Wait List (as outlined in NYP Policy T600)

l) If the patient is scheduled to receive a transplant from a live donor, the following are required:

1) Final cross match, blood type and screen, and subtyping (if applicable) drawn within 14 days of transplant

i. Blood type compatibility of donor and intended recipient documented in recipient EMR and signed by transplant coordinator and two attending level physicians

2) Preadmission testing

3) Physical examination by transplant surgeon

3. Re-Evaluation Process

a. Patients who are active (status 1) on the waiting list should be re-evaluated at least every two years, or possibly more often if they have diabetes mellitus, are 65 years of age or older, and/or if have medical conditions that might require more frequent evaluation.
b. The frequency of re- evaluation visits for patients who are inactive (status 7) will be determined on a case-by-case basis.
c. During re-evaluation, patients will be evaluated by a transplant coordinator, transplant physician, and financial coordinator, and will be referred to other disciplines, as necessary.

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RESPONSIBILITY:

NYP/Weill Cornell Medical Center Kidney and Pancreas Transplant Program

REFERENCES:

CMS Condition of Participation for Transplant Center Certification 482.90: Patient and Living Donor Selection

NYP Hospital Policy 20102f Nutrition Intervention for Solid Organ Transplant Patients

Policy Dates:

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