

NOTE: At its September 2007 meeting, the Board of Directors approved only the “Introduction” and “Purpose” sections of the proposed resource document. The Board further directed that the resource document should be further revised, resubmitted for public comment, and presented to the Board in February 2008 for final adoption.

Resource Document for the Medical Evaluation of Living Kidney Donors

Purpose

The OPTN/UNOS Living Donor Committee developed this resource document to help transplant professionals medically evaluate potential living kidney donors. This resource document will also inform and educate potential living donors about their own medical evaluation.

Introduction

All transplant programs that perform living donor kidney transplants are required to develop protocols for the medical evaluation of their potential donors. An important step in the medical evaluation of living kidney donors is education about the medical evaluation process.

Prospective living donors are willing to undergo varying degrees of personal risk to provide an organ needed by a known or unknown transplant candidate. Likewise, transplant candidates are willing to undergo varying degrees of communicable disease and organ quality risk from acceptance of the prospective living donor’s gift of his or her organ. Every potential living donor is unique, and no single protocol will ever be appropriate or applicable to all living donors. Physician knowledge and experience are important components in the evaluation of potential living kidney donor, and medical judgment of involved professionals has primacy in all cases.

This resource document is intended as a helpful menu of tests and procedures that have been used by many transplant programs in varying circumstances to assess health risk of living donors; to assess transplant graft survival risk and the risk of communicable disease to the organ recipient; and to assess the psychological health of the potential donor.

This resource document will require review and revision on a regular basis to reflect changing medical knowledge, experience and practice.

It is hoped that this resource document will be useful to both medical professionals and living donors considering living donation.

LIVING DONOR PSYCHOSOCIAL EVALUATION

The potential donor can stop the evaluation or donation process at any time. The medical team should inform the potential donor that if this occurs, the medical team will state that the potential

donor is not an acceptable candidate without providing specific reasons for this decision. The goals of the psychosocial evaluation are:

- a. To identify and appraise any potential risks for poor psychosocial outcome, including risks related to the individuals psychiatric history or social stability.
- b. To ensure that the prospective donor comprehends the risks, benefits and potential outcome of the donation for herself or himself and the recipient, and that the donor understands that the data on long-term donor psychosocial outcomes are sparse.
- c. To assess the donor's capacity to make the decision to donate and ability to cope with the major surgery and related stress.
- d. To assess donor motives and the degree to which the donation decision is made free of guilt, undue pressure, enticements or impulsive responses.
- e. To review lifestyle circumstances (e.g., employment, family relationships) that might be affected by donation.
- f. Ensure that the prospective donor's cognitive status and capacity to comprehend information are not compromised and do not interfere with judgment and determine risk for exploitation.
- g. Establish the presence or absence of current and prior psychiatric disorder, including but not limited to mood, anxiety, substance use and personality disorders. Review current or prior therapeutic interventions (counseling, medications); physical, psychological or sexual abuse; current stressors (e.g. relationships, home, work); recent losses; and chronic pain management. Assess repertoire of coping skills to manage previous and current life or health-related stressors.
- h. Review the nature and degree of closeness (if any) to the recipient, (i.e. how the relationship developed); and whether the transplant would impose expectations or perceived obligations on the part of either the donor or the recipient.
- i. Explore the rationale and reasoning for volunteering to donate, i.e. the "voluntariness," including whether donation would be consistent with past behaviors, apparent values, beliefs, moral obligations or lifestyle. Determine whether the potential donor's decision would be free of coercion, inducements, ambivalence, impulsivity or ulterior motives (e.g. to atone or gain approval, to stabilize self-image, or to remedy a psychological malady).
- j. To identify any factors that warrant educational or therapeutic intervention before donation can proceed. It is important to identify donors with anxiety, depression or other mental conditions which may make them unsuitable as living donors
- k. Donor knowledge, understanding and preparation: Explore the prospective donor's awareness of the following:
 - any potential short and long-term risks for surgical complications and health outcomes, both for the donor and the transplant candidate

- recovery and recuperation time
- availability of alternative treatments for the transplant candidate
- financial ramifications (including possible insurance risk)

Assess the prospective donor's understanding, acceptance and respect for the specific donor protocol, e.g. willingness to accept potential lack of communication from the recipient and the donor's willingness to undergo future donor follow-up.

l. Determine that support systems are in place and ensure a realistic plan for donation and recovery, with adequate social, emotional and financial support and resources. Determine whether the prospective donor is financially stable and free of financial hardship; has resources available to cover financial obligations for expected and unexpected donation-related expenses; is able to take time away from work or established role, including unplanned extended recovery time; and has disability and health insurance.

m. The prospective donor should be advised that the information contained in the report will be subject to the same regulations as regular medical records and may not be additionally protected. In order to protect the donor, whenever possible the more sensitive questions should be at the end of the psychosocial evaluation. Therefore, if the evaluator determines earlier in the evaluation that the individual is not an appropriate candidate, the more sensitive questions will not be asked and the answers will not appear in the report.

2. LIVING KIDNEY DONOR MEDICAL EVALUATION

In addition, the goal of the evaluation is to ensure that medical conditions that require treatment that necessitate all of the donor's renal function are not present. At this time, these conditions include HCV, HIV, cancer and vascular disease. Lastly, the evaluation needs to assess the risk of transmission of disease to the recipient that would negatively impact his/her life. This resource document is subject to modification as new medical knowledge becomes available and therapies improve. This resource document will be frequently reviewed and updated for advancement in medical knowledge.

Evaluation

a. Donor typing to determine the risk for acute transplant failure

- ABO blood group typing x 2
- Human Leukocyte Antigen (HLA) typing
- Cross match

b. General History and Physical Examination

Conduct a general exam as well as a history with a focus on the following:

- family history of kidney disease
- diabetes
- hypertension (high blood pressure)
- birth weight if possible
- gestational diabetes
- birth weight of offspring (for women)
- clotting disorders or deep venous thrombosis
- use of NSAID's anti-inflammatory agents (e.g., ibuprofen, indomethacin),
- urinary tract infections
- nephrolithiasis (kidney stones)
- chronic infections
- kidney injury
- cancer
- heart disease
- lung disease

Determine if prospective donors have had a recent dental evaluation.

Physical Examination to include:

- blood pressure (x3 at 3 different times; if possible it is preferable to perform a 24-hour blood pressure monitor)
- height
- weight
- calculated body mass index
- a search for evidence of heart, lung, liver and blood vessel disease, and abnormal lymph nodes and large spleen

Medical Psychological Evaluation and Social History should include questioning about:

- alcohol intake
- smoking history
- substance use and abuse
- history of mental illness and treatment used

c. General Laboratory Tests

- CBC with platelet count
- Prothrombin Time/Partial Thromboelastin Time (more detailed evaluation with history of coagulation disorders)
- comprehensive panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test women < 55 years old,
- SPEP in those over 60

d. Cardiovascular – Heart and Blood Vessel tests

- Chest X-Ray
- Electrocardiogram (ECG)

- ECHO or ETT as indicated by history and physical examination
- Pulmonary function tests for smokers as appropriate for perioperative management of asthma or other clinical findings
- Vascular duplex or angiography if clinically indicated for cerebral nervous system, gastrointestinal or peripheral limb symptoms

e. Renal Focused Evaluation

- Urinalysis – look for protein and cells in the urine
- Perform urine culture (if symptoms are present or urinalysis is abnormal)
- Protein excretion: 24 hour urine for protein and/or microalbumin excretion or protein:creatinine ratio and/or albumin:creatinine ratio x 2, if one is abnormal repeat again. If protein is detected, evaluate for postural proteinuria by collecting split urine over 24 hours (8 of those hours recumbent, 16 active)
- Serum creatinine
- Glomerular filtration rate (GFR) measurement – clearance testing, 24 hour urine for creatinine clearance measurement or preferably a measured clearance using urine or plasma clearance of iothalamate, iothalamate or other suitable marker. GFR should be expressed per 1.73m^2 . Calculated GFR measurements using the serum creatinine are not felt to be adequate. GFR should be within 2 Standard Deviations for age or be calculated to be at $40\text{cc}/\text{min}/1.73\text{m}^2$ at age 80
- Screen for PKD as indicated by family history, US if over 30 years old, genetic testing if younger than age 30.

f. Metabolic Focused Evaluation

- Fasting blood glucose
- Uric acid
- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, LDL Cholesterol)
- Determine the number of elements of the metabolic syndrome present, consent for risk if ≥ 3 risk factors
- If the risk of diabetes is higher than the general population by presence of a first degree relative with diabetes or the presence of metabolic syndrome characteristics but the prospective donor does not meet the definition of diabetes, they should be counseled that they are at an increased risk to develop diabetes

g. Infection

- CMV, EBV
- HSV, VZV (herpes group virus testing) if intended recipient is negative for exposure to these viruses
- HIV 1,2 (human immunodeficiency viruses)
- HTLV I AND HTLV II (human T-cell leukemia virus)
- HBsAg (Hepatitis B test)
- HBcAB (Hepatitis B test)
- HBSAB (Hepatitis B test)

- HCV (hepatitis C virus)
- RPR (for syphilis)
- Tuberculosis
- Toxoplasmosis (depending upon exposure risk)
- Geographically determined testing
 - Coccidiomycosis
 - Strongyloides
 - Trypanosoma cruzi
 - Malaria
 - HHV-8
- Consider West Nile and HHV-6

h. Anatomic Evaluation

Determine which kidney is the safest to remove and which kidney has the best function. The kidney with the best function should preferentially remain with the donor. Also determine the presence of abnormal liver, nodes, adrenal glands and spleen.

1. The test of choice will depend upon the local radiological expertise and surgical preference but may include CT angiogram, MR Angiogram or angiogram. An abdominal ultrasound may be necessary to evaluate the liver for fatty infiltration and unexpected abnormalities of the liver, pancreas and spleen if a full abdominal CT or MRI are not performed.
2. Renal scan with differential renal function.

i. Cancer Screening

Conduct a cancer screening which attempts to determine if the donor does not need both kidneys to help with tolerance of anti-cancer treatment and that the donor does not have a tumor that would be transferred to the recipient.

Testing to be performed depending upon gender, age or family history includes:

- PAP for all women
- Mammogram for all women over 40 years old or according to family risk
- PSA for all men over 50; for all African American men over 40 or if from a high risk family
- Colonoscopy for all donors over 50 years old or younger according to family history
- Consider chest CT to evaluate for lung cancer in potential donors with long- term and current smoking history.

3. POTENTIAL CONTRAINDICATIONS TO LIVING DONATION

a. The following reasons could exclude a living donor candidate from donating based upon scientific data medical risk, psychological assessment and/or consensus on best practice:

- Age < 18 years
- Hypertension BP > 130/90 in someone younger than 50 years old, evidence of end organ damage, non-Caucasian, on three or more anti-hypertensive medications

- Diabetes (diagnosis of diabetes)
- History of thrombosis or embolism
- Uncontrolled psychiatric illness
- Obesity Determined BMI (excluding muscular individuals) $> 35\text{kg/m}^2$ which may increase the risk of diabetes and hypertension in the future
- Coronary Artery Disease
- Symptomatic Valvular Disease
- Chronic lung disease with impairment of oxygenation or ventilation
- Recent malignancy, or cancers with long times to recurrence e.g., breast cancer
- Urologic abnormalities of donor kidney
- Creatinine clearance $< 80\text{ ml/min/1.73m}^2$, or projected GFR with removal of one kidney at 80 years old of $< 40\text{ cc/min/1.73m}^2$
- Peripheral vascular disease
- Proteinuria $> 300\text{ mg/24 hours}$
- HIV infection
- Hepatitis C Virus infection
- Hepatitis B Virus infection
- Medications causing Kidney Dysfunction

b. Medical Issues Requiring Special Emphasis During an Evaluation

- Age 18-21 years old ; older age relative to the medical condition
- Obesity (BMI 30-35)
- Kidney stones
- Distant history of cancer
- Psychiatric Issues
- Renovascular Disease
- Thin basement membrane disease
- Prior valve surgery
- Moderate Cardiac Valvular Disease with otherwise normal echocardiographic findings and
- Mild sleep apnea without pulmonary hypertension

c. **Appendix** – Suggested Approach for Long-term Living Kidney Donor Follow-up

i. Psychosocial Questions:

How have you been feeling, both physically and emotionally since your surgery?

Was your experience, both at the time of transplant and now, what you expected it would be?

Have your relationships with significant people in your life been impacted by your donation and if so, how?

Is there anything that you think would be useful for the transplant center to know about your experience?

Do you have any concerns that you would like to share or questions that you would like to ask?

If desired or needed, your social worker can refer you to resources for support or counseling; do not hesitate to ask for help.

ii. Life Style Advice:

Exercise at least 4 times a week for 30 minutes
Eat a balanced and appropriate caloric diet
Avoid saturated and trans fats
Eat plenty of fruits and vegetables
Get plenty of rest
Talk to your doctor before taking any over the counter medication or supplement for more than a few weeks

iii Medical Evaluation Focus:

1. Yearly blood pressure measurement
2. Yearly height, weight and weight circumference
3. Age appropriate physical exam
4. Laboratory yearly:
 - a. urinalysis,
 - b. urine albumin:creatinine ratio
 - c. serum creatinine
 - d. fasting blood glucose
5. Additional Laboratory:
 - a. Optimally, yearly lipid profile