

**SELECTED RECOMMENDATIONS OF THE
OPTN/UNOS LIVING DONOR COMMITTEE TO THE
BOARD OF DIRECTORS**

SUMMARY

I. Action Items for Board Consideration

- The Board of Directors is asked to approve the Resource Document for the Medical Evaluation of Living Kidney Donors (Item1, Page 4)

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OPTN/UNOS LIVING DONOR COMMITTEE TO THE
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**Orlando, FL
February 20-21, 2008**

**Robert S. Brown, Jr. MD, Chairman
Andrew Klein, MD, Vice Chair**

*The following report represents the OPTN/UNOS Living Donor Committee's
recommendations regarding a Resource Document for the
Medical Evaluation of Living Kidney Donors.*

1. **Medical Evaluation of Living Kidney Donors** – The OPTN/UNOS Ad Hoc Living Donor Committee was formed in 2002 and identified “establishing minimum criteria for donor work-up” as a priority for its future work. This Committee developed a set of minimal guidelines for potential living kidney transplant recipient and donor evaluations, which included provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. Those guidelines are available on the OPTN.

In January 2007, the OPTN/UNOS President sent a letter to all transplant programs that perform live donor transplants requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The letter explained that federal regulation now required the Organ Procurement and Transplantation Network (OPTN) to develop policies for the equitable allocation of living donor organs. The Living Donor Committee planned to use these protocols to make recommendations to the OPTN/UNOS Board of Directors regarding new living donor guidelines. These recommendations are intended to ensure that individual institutions' living donor evaluation protocols consistently meet the needs and interests of potential living donors. Additionally, institutions may choose to compare their protocol against this set of recommendations that reflect the consensus of expertise among medical professionals involved in living donor transplantation

Committee Members reviewed and assessed all submitted protocols. Their evaluation revealed wide variation in the medical evaluation of potential living kidney donors. Some centers did not have written guidelines for the medical evaluation of a living donor. Additionally, the Committee reviewed recommendations from the American Society of Transplantation (AST) and the Report of the Amsterdam Forum on the Care of the Live Kidney Donor; completed an extensive literature review; and completed a focused survey of 16 large transplant centers in the development of these guidelines.

Based on the information reviewed, the Committee developed a set of recommendations for the medical evaluation of living kidney donors. At its June 2007, meeting, the Committee approved sending the Guidelines for the Medical Evaluation of Living Kidney Donors for public comment. The Guidelines for the Medical Evaluation of Living Kidney Donors were released for a 30-day public comment beginning on July 13, 2007.

The Living Donor Committee met by Live Meeting on August 14, 2007, to review public comment and to consider proposed modifications to the proposed Medical Evaluation Guidelines. Based on the comments received, the Committee agreed to make the guidelines less prescriptive, and agreed to refer to the proposal as “recommendations” rather than “guidelines.” Final proposal language was drafted for consideration by the Board.

A document entitled Recommendations for the Medical Evaluation of Living Kidney Donor was presented to the OPTN/UNOS Board during its September 18, 2007, meeting in Los Angeles. During that meeting, the Living Donor Committee Chair agreed that the document could be renamed a Resource Document rather than Recommendations. After extensive discussion and lack of consensus, the Board agreed to table this proposal until its next meeting in February 2008. In the interim, this Committee was charged to seek additional input from stakeholders including but not limited to the AST and ASTS. Within days after the Board meeting, OPTN President, Tim Pruett, MD., sent notification to the AST and ASTS requesting each organization to provide specific comments to the Living Donor Committee, which could be considered at the Committee’s upcoming meeting in October.

At its October meeting, the Committee reviewed all comments received to date and further revised the resource document in preparation for re-release for public comment. The Resource Document was sent for a special 30-day public comment period on November 12, 2007

The Living Donor Committee met by Live Meeting in December 18, 2007, to review public comments and made modifications to the proposed Resource Document. A summary of the public comment and Committee’s responses are included in the briefing paper. **Exhibit A**

During that meeting, the Committee agreed to offer the professional transplant societies an additional opportunity to provide feedback during a conference call to be scheduled at some future date. The Committee charged a small subset of its members to review any future public comment, and to prepare a final version of the Resource Document for the next Board of Director’s meeting.

The AST and ASTS participated in a Live Meeting to review this proposal on a January 4, 2008. A final version of the proposal was prepared after that meeting and follows:

***** RESOLVED, that Resource Document for the Medical Evaluation of Living Kidney Donors set forth below, is hereby approved, effective February 21, 2008:**

OPTN/UNOS Resource Document for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

Summary and Goals

In June 2006, a HRSA Federal Register Notice stipulated that the OPTN develop guidelines for the living donor and that the guidelines be given the same status as those for deceased donor organs. In response, the The OPTN/UNOS Living Donor Committee has developed a resource document rather than guidelines, about the living donor evaluation for both to help transplant professionals and medically evaluate potential living donors. Both new and existing living donor transplant programs can use these suggestions when developing medical evaluation protocols for their. This resource document will also inform and educate potential living donors. Potential living donors can also use this document to learn about the types of medical tests they can expect if they choose to proceed with living donation. Living

donor candidates who have questions about this about their own medical evaluations. This document should discuss it with their physician and/or transplant team.

This resource should not be considered an official medical guideline and it was originally released for public comment in July 2007 as *Guidelines for the Medical Evaluation of Living Kidney Donors*. Based on the input from the community, the document is not intended to be medically prescriptive. It being resubmitted after extensive revision. The Living Donor Committee is also not OPTN/UNOS now seeking public comment on this revised resource document. Please note that this resource document is not policy and does not carry the monitoring implications of as policy.

The Living Donor Committee hopes that transplant centers will voluntarily adopt the suggestions in this resource with the ultimate goals of both standardizing and improving to improve the care and follow-up of all living donors. living donors by providing this information for the voluntary adoption by transplant centers.

Introduction

All transplant programs that perform living donor kidney transplants are required to develop protocols to evaluate potential donors. The donor evaluation should include psychosocial and medical components. These evaluations will help determine if an individual whether a prospective donor is a suitable donor. The psychosocial evaluation should uncover any psychosocial barriers to donation (e.g., lack of social support to aid in their post operative recovery). The medical evaluation should uncover any unforeseen kidney disease or conditions other illnesses that significantly increase the risk of could lead to future kidney donation compared to the normal population. The evaluation disease. It should also detect diseases that would require treatments that could damage the donor's remaining kidney (e.g., cancer, severe vascular disease). Additionally, the medical evaluation screens for diseases that the donor could transmit to the potential recipient. This is an important step because the recipient must take immunosuppressive medications and certain transmitted diseases could cause serious life threatening conditions. Lastly, this evaluation should define the anatomy of the potential donor's kidney donor so the medical team can properly plan the donor surgery and transplant.

The donor evaluation process may uncover or clarify conditions that the potential donor may not have known about, such as cancer or others (such as HIV and other contagious diseases) that may have to be reported to health agencies, depending upon state law. The donor evaluation will include HLA testing, which could reveal the true identity of family relationships about. These discoveries may bring unexpected decisions before the donor and medical team. Both the potential donor and the medical team should discuss the risk and whether to proceed with who is to accept the risk of these findings if the evaluation process donor is still considering donation. Prospective living donors are willing to undergo varying degrees of personal risk to provide an organ needed by a known or unknown transplant candidate, and this difference needs to be taken into consideration when deciding to proceed with donation. 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.

As a means to obtaining accurate medical information and personal characterization of each living donor, it must be recognized that every potential living donor is unique, and no single evaluation protocol will ever be appropriate or applicable to all living donors. The evaluation needs to be a living process following the findings for each prospective donor. Physician knowledge and experience are important components in this process, and medical judgment of involved professionals will always need to direct the course of the evaluation.

The final decision to donate is based upon the medical test results, assessment of risk based upon current medical knowledge, donor psychological set point, and the relationship of the donor to the prospective recipient. This decision-making process is a nuanced one and also incorporates donor autonomy. Donor autonomy is determined by the donor's understanding of the risk, their relationship to the recipient, and benefit that they may accrue by donation. The fact that many medical conditions have not been fully evaluated in the setting of unilateral nephrectomy is recognized, as is the fact that the precise risk for the donor may not therefore be amenable to assessment or calculation. The weighing of the risk of donation to the benefit to the recipient of transplantation in the final analysis is the choice of the donor with the concurrence of the health care team involved with the care of the donor.

It is important to note that the potential donor can stop the evaluation or donation process at any time. If the potential donor does not wish to proceed with the evaluation, the medical team should state that the potential donor is not an acceptable candidate without providing specific reasons for this decision.

This resource document presents a list helpful menu of tests and procedures that many transplant programs have used in varying circumstance to assess health risk of living donors, transplant graft survival risk, and the risk of communicable disease. Towards the end of this document are listed medical conditions that are currently thought to be potential barriers to living kidney donation due to a high risk of developing kidney dysfunction. This list is subject to change as improved medical treatments become available.

It is acknowledged that currently there is no level A evidence (randomized controlled trials) that support the use of any of the testing listed below in the setting of the living donor evaluation. Instead, most of the information has been gleaned from a review of experienced center practice, articles by experienced clinicians in the practice of living kidney donor evaluation, retrospective cohort studies on living donor outcomes, studies evaluating samples of previous living donors at various times post donation, and by case reports of disease transmission from donor to recipient. These case reports were taken from the literature on deceased as well as living donation. Finally, many of the tests are adopted from general medical practice such as the cardiovascular evaluation appropriate for surgery and cancer screening recommendations. In summary, all pertinent information has been reviewed in the preparation of this document. However, even if all of this information is applied in the form of the most thorough medical evaluation and psychosocial assessment, potential living donors must realize that there is no guarantee and never will be that the living donor procedure can be performed without some risk for death, end stage renal disease and the development of de novo diseases that may affect kidney function. Some of this risk may come from the performance of the medical evaluation testing itself.

1. LIVING DONOR PSYCHOSOCIAL EVALUATION

The goals of the psychosocial evaluation are:

- To explore the rationale seeks to identify significant issues in the donor's cognitive, psychological, behavioral 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. financial composition that might place them at risk as an organ donor.
- To determine whether the 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).

- ~~To verify that the potential donor understands that they are **free to withdraw from** ~~an step 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 jeopardizing confidentiality or care, providing specific reasons for this decision. The following are goals of the psychosocial evaluation.~~
 - a. ~~To identify~~Identify and appraise any potential risks for poor psychosocial outcome, including risks related to the individuals individual's psychiatric history ~~or~~ social stability, and financial status.
 - ~~To establish the presence or absence of a current and/or prior psychiatric disorder and refer for professional assessment if there is concern for a significant psychiatric disorder.~~
 - ~~To determine~~ Ensure that the prospective donor is presented information about ~~comprehends~~ the risks, benefits, and potential outcomes of the donation for herself or himself and the recipient in a manner, and that is understandable to the potential donor.
 - ~~To determine that the potential~~the donor understands that there are few published reports on long-term psychosocial and health outcomes for living donors.
 - ~~To assess~~Assess the potential donor's capacity to make the decision to donate and ability to cope with the major surgery and related stress.
 - b. ~~To review the donor's~~Assess donor motives and the degree to which the donation decision is made free of guilt, undue pressure, enticements, or impulsive responses.
 - c. ~~To review~~Review lifestyle circumstances (e.g., employment, family relationships, insurance risk, or support systems)relationships) that might be affected by donation.
 - ~~To determine if~~Ensure that the prospective donor's cognitive status and capacity to comprehend information are not compromised and would ~~do not~~ interfere with judgment and increase ~~determine~~ risk for exploitation.
 - d. ~~To review~~ 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.
 - e. Review the nature and degree of emotional 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.
 - f. ~~To identify~~ 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). 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.~~

- g. ~~To identify the~~ assess donor's knowledge about, ~~understanding,~~ and preparation for the ~~procedure, and to explore~~procedure. 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)
- ~~To assess~~Assess the prospective donor's knowledge 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).~~follow-up.~~
 - ~~To determine~~Determine that support systems ~~are in place~~ and the existence of~~ensure~~ a realistic plan for donation and recovery are in place, with adequate social, emotional and financial support and resources.
 - ~~To determine~~Determine whether the prospective donor understands the impact of donation on his or her ~~is financially stable and free of~~ financial status. Specifically, the prospective donor ~~hardship~~ has resources available to cover financial obligations for expected and unexpected donation-related expenses and is able to take time away from work or established role, including unplanned extended recovery time. It is optimal for the prospective living donor to have~~time;~~ and~~has~~ disability and health insurance.
 - ~~To advise the~~The prospective donors ~~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.

LIVING KIDNEY DONOR MEDICAL EVALUATION

The goal of the medical evaluation is to determine that ~~assure~~ the donor, as much as is currently possible, ~~that they~~ will have adequate kidney function to sustain him or herself ~~them~~ throughout the rest of his or her~~their~~ life and that the risks associated with the performance of the donor nephrectomy procedure are acceptable. This means looking for unsuspected primary kidney disease in the donor as well as any diseases that would require two kidneys ~~normal kidney function~~ in order for the donor to undergo treatments of the disease (eg., cancer or autoimmune diseases). Additionally, the medical evaluation needs to assess the risk of transmission of disease to the recipient that would negatively impact his/her life. Finally, the evaluation is meant to determine if there are medical conditions that would require special management during and after the donor surgery.

This resource document is subject to change as new medical knowledge becomes available and therapies improve. The OPTN/UNOS Living Donor Committee will frequently review ~~and~~ update this document based on advancement in medical knowledge and in consultation with experts.

Medical Evaluation

Blood tests are one of the first steps in the evaluation and will include:

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

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

Other early steps in the evaluation can include obtaining a general history and physical examination to determine risk for kidney and heart disease, infection and cancer:

Conduct a general history with a focus on the following:

- Personal History

Kidney family history of kidney disease, proteinuria

Kidney injury

Diabetes

Hypertension

Cardiovascular disease

Lung disease

Cancer

Chronic infection

Smoking

Nephrolithiasis

Recurrent urinary tract infections

Gout or other arthritis

Gestational diabetes or multiple miscarriages

- Birth hypertension (high blood pressure)

- gestational diabetes

birthweight of offspring over 9 pounds

Clotting/Thromboembolic Disorders

Bleeding Disorders

Use of nephrotoxic medications

Dental illness

Neurological illness

Other illnesses/conditions for which they have received treatment (women) including psychiatric illness

- Family history:

Kidney disease

Diabetes

Hypertension

Gestational diabetes

Clotting clotting disorders or deep venous thrombosis

Cancer

Heart disease

Lung disease

Nephrotoxic medications are medications that can damage the kidney. Some of the most common medications that are associated with kidney damage and are sold over the counter are non-steroidal anti-inflammatory agents such as ibuprofen, naproxen, and indomethacin. These medications have been shown to acutely decrease kidney function, and there is data from large cohort studies that long-term use may also cause permanent kidney damage. Thus the need for continued long-term non-steroidal anti-inflammatory agents may be an issue raised by the team evaluating a prospective living kidney donor.

- ~~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~~

~~If poor dentation is found on physical exam, a more extensive dental evaluation if poor dentation is found during the exam may be required.~~ Risk for dental injury is increased at the time of surgery if the prospective donor has serious gum disease and/or tooth decay.

The Medical Psychological Evaluation and Social History usually should include questions concerning:

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

Excessive use of alcohol has been associated with liver disease and high blood pressure. Smoking is associated with the development of lung disease, cancer (lung, kidney), and heart disease. Use of drugs such as cocaine and amphetamines is associated with the development of kidney damage. Some treatments used for the treatment of mental illness (lithium) may cause kidney dysfunction.

The Basic Physical Exam begins with the tests listed below. Other more thorough physical examination and medical testing with a specific focus on areas peculiar to kidney donation will often be part of the medical evaluation.

- Blood pressure (Measure after sitting for 5 minutes, take twice at the same visit, obtain 2 different assessments of blood pressure on different days, recommendation as of the Joint National Commission VII on Hypertension guidelines). It may however be preferable to perform a 24-hour blood pressure monitor as cohort studies show improved accuracy for determining the correct blood pressure category with 24-hour monitoring. High blood pressure is a leading cause of progression of underlying kidney disease. It may also be a primary cause of kidney disease but this has not been firmly proven due to difficulty separating out high blood pressure from kidney disease. Additionally, high blood pressure is associated with heart disease and strokes such that people will often die before developing kidney disease in the setting of high blood pressure.
- Height

- Weight

Calculated 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 (obesity is associated with an increased risk of renal failure)~~
- A complete physical exam looking a search for evidence of heart, lung, liver, and blood vessel disease, as well as ~~and~~ abnormal lymph nodes, masses and large spleen

General Laboratory Tests are ordered as part of the assessment of to determine overall health, kidney status, risk for bleeding during and after surgery, and pregnancy status, and may include:

- CBC with platelet count
- Prothrombin Time/Partial Thromboelastin Time (more detailed evaluation with history of coagulation ~~disorders/e.g., disorders/i.g.,~~ bleeding or clotting problems)
- ~~Comprehensive comprehensive~~ panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for women < 55 years old

Tests to evaluate the Cardiovascular –Heart and Pulmonary Systems include:~~Blood Vessel tests~~

- Chest X-Ray
- Electrocardiogram (ECG)
- Evaluation for coronary artery disease, as suggested by the American Heart Association and the American College of ~~Physicians~~Cardiology,
- Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association appropriate for perioperative management of asthma or other clinical findings
- Vascular duplex or angiography of carotids, abdominal and extremity vessels if clinically indicated. Peripheral vascular disease is associated with intrarenal vascular disease for cerebral nervous system, gastrointestinal or peripheral limb symptoms

The Renal Focused Evaluation is used to determine the presence of underlying kidney disease in the donor and predict post donation kidney function in the donor and recipient. Tests used in the renal examination may include:

- Urinalysis with Microscopy
- Urine culture if clinically indicated
- Measurement of protein excretion
- Measurement of glomerular filtration rate

- Screening Urinalysis—look for protein and cells in the urine with additional workup if microscopic hematuria is detected or evidence of renal calculi are found on imaging studies (calcium, oxalate, etc)
- 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, iothexol 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 Polycystic Kidney Disease (PKD) as indicated by family history. If history, perform an ultrasound to detect cysts if the prospective donor is over age 30, this is usually accomplished with an ultrasound. In those under age 30, 30-years-old, genetic testing remains the gold standard, even though CT and MRI scanning may detect much smaller cysts if younger than ultrasound as only US has been directly correlated with genetic testing age 30.

The Metabolic Focused Evaluation includes tests to determine:

- Fasting blood glucose
- Uric acid (High uric acid levels are associated with the metabolic syndrome and independently with reduced kidney function)
- Uric acid
 - Cholesterol Levels (Cholesterol, Triglycerides, HDL Cholesterol, LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated to aid in risk assessment for cardiovascular disease and the metabolic syndrome
- Number Determine the number of elements of the metabolic syndrome present, consent for risk if ≥ 3 risk actors (central obesity, high blood pressure BP $>130/85$, fasting blood glucose $\geq 100\text{mg}/\text{dl}$, triglyceride levels $> 150\text{mg}/\text{dl}$, HDL < 40 for a man and $<50\text{mg}/\text{dl}$ for a woman) the more metabolic syndrome traits present the larger the risk for microalbuminuria and kidney disease. This risk is most pronounced (3-4 fold increase) with 3 or more traits.
- 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 and perhaps kidney disease. Many programs would perform a glucose tolerance test in such individuals. Diabetes is a key risk to assess because diabetes is the number one cause of end-stage kidney disease. About 30-40% of people who develop diabetes will develop kidney failure.

The Anatomic Assessment is used to determine

Determine which kidney is most anatomically suitable for transplantation (typically dependent upon the number of arteries going to safest to remove and which kidney has the kidneys) and

whether the kidneys are equal sized or have masses, cysts, or stones. The donor should preferably keep the best function. The kidney with the fewest issues, best function should preferentially remain with the donor. Also, the anatomic evaluation may determine the presence of abnormal liver, nodes, adrenal glands, and spleen.

- 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 performed by some programs necessary to evaluate the liver for fatty infiltration to access for and unexpected abnormalities of the liver, pancreas, and spleen if a full abdominal CT or MRI is are not performed. Non-alcoholic steatohepatitis (NASH) is a common cause of cirrhosis, but the best screening test to evaluate the presence and severity of fatty infiltration and fibrosis is not yet established. Testing for NASH is generally reserved for those with elevated liver enzymes.~~
- 1. ~~Renal scan if there is concern about glomerular filtration rate or for marked size — discrepancy in kidneys on imaging if not already determined by the CT scan.~~
- **Screening for transmissible infectious diseases is used to identify determine the risk of passing the donor developing an infection or related kidney disease as well as infection transmission to a recipient. This screening may also identify a condition that may require donor treatment or may increase the risk of donation. Infectious disease**CMV,
- ~~EBV~~
- ~~HSV, VZV (herpes group virus testing typically includes testing for the following: if intended recipient is negative for exposure to these viruses~~
- CMV (Cytomegalovirus)- antibody test, for recipient safety in order to risk stratify and guide appropriate prevention strategies
- EBV (Epstein Barr Virus) – VCA or EBNA antibody test performed if the recipient is EBV seronegative to clarify the risk for post transplant lymphoproliferative disease
- HSV (Herpes Simplex Virus), VZV (Varicella Zoster Virus) testing would be done for recipient safety if the recipient is seronegative, although the risk of transmission is low and usually covered by the perioperative antiviral prophylaxis. Many professional in the infectious disease community recommend not screening for HSV and VZV.
- HIV 1,2 (Human Immunodeficiency Virus) testing may impact donor health and recipient safety. Testing for antibody is likely acceptable although there is discussion about recommending nucleic acid testing for all donors given the earlier detection time.
- HIV 1,2 (human immunodeficiency viruses)HTLV I (Human AND HTLV II (human T-cell Lymphotropic Virus) antibody testing leukemia virus)
- HBsAg (Hepatitis B surface antigen) important for donor and recipient safetytest), high potential for hepatitis B transmission from donors who are HBsAg positive.
- HBcAB (Hepatitis B core antibody) standard donor screening test and may identify early donor infectiontest), current infection if present with HBsAg or serologically resolved remote infection (HBcAB total IgG+/- HBsAB); this latter situation also poses a risk for disease transmission.
- HBSAB (Hepatitis B surface antibody) standard donor screen to separate out early from later infectiontest) as well as those who have had an immune response to the hepatitis B vaccination.

- HCV (Hepatitis C Virus) important for donor and recipient safety, third generation EIA testing is acceptable. Nucleic acid testing is useful if the antibody testing is indeterminate, there is a risk for false positive testing.
- ~~HCV (hepatitis C virus)~~
- RPR (Rapid Plasma Reagin Test for syphilis) or Syphilis EIA - important for donor and recipient safety
- Exposure (based upon medical history) Related Testing
 - Tuberculosis, level of evidence case reports of transmission from donor to recipient. Additionally, there is the possibility of ureteral stricture from tuberculosis in the donor. Many programs but not all, screen donors for tuberculosis using intradermal testing, although there is also potential for using a blood test (quantiferon) which might be better for someone who has had BCG (since those people will be negative if not infected). High-risk donors (e.g. from endemic areas, people working in jails with clients with a high rate of TB) who are negative on their first PPD should have a second test. Even so transmission may be low from PPD positive donors who do not have active infection as determined by a negative CXR, negative excretory urogram and a negative urine microscopic examination.
 - Toxoplasmosis level of evidence case reports of transmission. During new infection, transmission is low if recipients are treated with trimethoprim-sulfamethoxazole. Many infectious disease professionals do not think the very low risk of transmission warrants testing for toxoplasmosis in living kidney donors.
- ~~Tuberculosis~~
- ~~Toxoplasmosis (depending upon exposure risk)~~
- Geographically determined testing, level of evidence case reports of transmission
 - Coccidioidomycosis –risk of transmission from donors not established
 - Strongyloides test with an ELISA +/- stools from donors from endemic areas, some infectious disease professionals do not believe testing is indicated in donors due to the very low risk of transmission
 - Trypanosoma cruzi test donors from endemic areas
 - Malaria test symptomatic individuals by evaluating 3 evening blood smears
 - HHV-8 donors from endemic areas donating to a seronegative recipient should have their serostatus evaluated. If recipients are not screened however, then there is little value in screening the donors.
- Special Circumstance level of evidence case reports of transmission
 - West Nile Virus (WNV) there is no consensus on testing at this time, but testing might include focusing on donors from endemic areas during WNV season with both nucleic acid and antibody assays. It should be mentioned that there have been several false positive tests from the major labs performing donor tissue testing. If a donor is positive, defer donation for a month.
 - ~~Malaria~~
 - ~~HHV-8~~
 - ~~Chagas disease~~
- ~~Consider West Nile, HHV-6, and Lyme disease~~

b. Cancer Screening

Cancer screening is an important health assessment for all people, but is especially important during evaluation process as it seeks to prevent possible transmission to give the transplant a potential recipient a cancer from the donor. The screening further seeks to prevent any potential donor who

might need both kidneys to help tolerate future medical treatments. The screening tests follow the practices advised by the American Cancer Society. Testing to be performed depending upon gender, age, or family history includes:

- Cervical Cancer Screening
- Breast Cancer Screening
- Prostate Cancer Screening
- Colon Cancer Screening

Screening for cancers that is not part of routine practice or the formal American Cancer Society Schedule

- Renal Cell Cancer Screening – this will be accomplished by the anatomic testing performed for the donor surgery although very small tumors may only be detected at surgery. Detection of renal cell cancer is important as this cancer in a donor necessitates removal of kidney tissue as a primary treatment to improve their survival and kidney cancer can be transmitted to the recipient. Additionally, the incidence of kidney cancer is increasing in our society partially due to the increase in obesity.
- Lung Cancer Screening in those at highest risk (usually older and long smoking history), may include chest CT – evidence based upon a study by Infante et al 2007, and information on the National Cancer Institute sponsored trial is detailed on the website www.cancer.gov/cancertopics/pdq/screening/lung/Patient/page3 and www.cancer.gov/nlst and www.cancer.gov/nlst/what-is-nlst. Lung cancer is the second leading cancer in men and women but the leading cause of cancer related death in the United States; screening in the past with CXR and or cytology has not proven effective at decreasing mortality.
- ~~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

POTENTIAL BARRIERS TO LIVING DONATION

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

- Inability to give informed consent: Age < 18 years, mentally incapable to make an informed decision, or uncontrolled psychiatric illness
- Uncontrollable Age < 18 years
- Uncontrolled hypertension (hypertension not controlled to <130/85 mmHg) in anyone, hypertension with evidence of end organ damage (eye ground changes, thickened heart muscle), hypertension in a non-Caucasian (as high blood pressure is associated with a more significant effect on progression of kidney disease in the non-Caucasian population), or taking more than one or more anti-hypertensive medication. Caucasians with well controlled high blood pressure on medications who are over age 50 and have been considered kidney donors at several programs.
 - Diabetes (diagnosis of diabetes)
 - History of substantial or recurrent thrombosis or embolism
- Bleeding disorders
 - ~~Uncontrollable Uncontrolled psychiatric illness~~
 - Morbid obesity

- Clinically significant Coronary and/or Peripheral Vascular 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)
- History of melanoma
- History of metastatic cancer
- Bilateral or recurrent nephrolithiasis
 - 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 $< 40 \text{ cc/min/1.73m}^2$ (based upon Thiel in Living Donor Kidney Transplantation, editors Gaston and Wadstrom, 2005)
 - Clinically significant peripheral vascular disease
 - Proteinuria (protein in the urine) $> 300 \text{ mg/24 hours}$, excluding postural proteinuria
 - Human Immunodeficiency Virus~~HIV~~ infection
 - Hepatitis C Virus infection
 - Hepatitis B Virus infection (Hep B cAB ok if recipient immunized and counseled about risk, as long as there is no active disease in the donor)

Medical Issues Requiring Special Emphasis during~~During~~ an Evaluation

- Obesity Determined BMI (excluding muscular individuals) $> 35\text{kg/m}^2$ which may increase the future risk for~~of~~ diabetes, hypertension, and chronic kidney diseasein the future
- Medications causing Kidney Dysfunction
- Age 18-21 years old ; older age relative to the medical condition
- ~~Obesity~~
 - 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 findingsand
 - Mild sleep apnea without pulmonary hypertension

LIVING DONOR FOLLOW-UP

The donor should expect certain questions to be asked during follow-up. ~~Examples of questions that might be asked include:~~

~~i. Psychosocial Questions:~~

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- ~~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 is required to submit Living Donor Follow-up forms to UNOS for know about your experience?~~

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

ii. Life Style Advice:

Following donation, a minimum of two years on each donor should consider the following general advice about healthy-living donor. All living These measures are meant to help limit the development of obesity, high blood pressure and diabetes, the major risk factors for kidney donors are disease and kidney disease progression. encouraged to maintain lifestyle choices that will protect their overall health and in particular kidney health. It is advisable to establish a health evaluation schedule as recommended by the American College of Physicians. The following is a possible care plan outline.

- 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

Medical Evaluation after Living Donation:

Following kidney donation, donors should consider knowing the following information about themselves and have basic evaluations performed to make sure that their kidney function remains normal. Donors must be responsible for their own healthcare after donation and should have the following tests annually after donation.

- Bloodblood-pressure
- Height,height, weight and waist circumference.
- An age appropriate physical exam
- Laboratory studies including:
 - a. Urinalysis
 - b. Urineurinalysisurine albumin:creatinine ratio
 - c. Serum serumcreatinine
 - d. Fastingfasting blood glucose
 - e. Lipidlipid profile

End Notes

¹The OPTN originally released this document for public comment in July 2007 as Guidelines for the Medical Evaluation of Living Kidney Donors. Based on input from the community, we made extensive revisions and are after resubmitting it as a resource document for public comment.

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