

At-a-Glance

Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors

- **Affected and Proposed Policies:** 14.1 (Required Protocols for Recovery Hospitals), 14.4 (Medical Evaluation Requirement for Living Donors), 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements, 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 14.7 (Placement for Living Donor Organs), 14.8 (Packaging, Labeling and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), and 14.9 (Reporting Requirements)

- **Living Donor Committee**

This proposal would modify existing policy and establish new policy requirements for the psychosocial and medical evaluation of all types of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and is based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee. Policy to standardize the medical evaluation of living kidney donors has already been established. This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for the psychosocial and medical evaluation for all living organ donors.

- **Affected Groups**

Directors of Organ Procurement
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

In 2012, there were 5867 living organ donors including 5619 living kidney donors, 246 living liver donors, and two living lung donors.

Between 2007 and 2012 there were seven living lung donors, five living intestinal donors, and one living pancreas donor.

The proposed policy would affect all living donors and their living donor transplant recipients.

- **Compliance with OPTN Strategic Plan and Final Rule**

The proposed changes are consistent with the strategic plan goals to:

- Optimize a safe environment for living donor transplantation through improved living donor informed consent
- Improve living donor psychosocial and medical evaluations through development and enactment of policies to protect patient safety and preserve the public trust
- Identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

- **Specific Requests for Comment**

The Committee is requesting specific feedback on elements of the proposal determined to be problematic for members to implement, and especially feedback from living lung, living intestinal and living pancreas donors programs because of low volume of these types of transplants. For any identified problem please consider providing potential solutions for the Committee to consider.

Proposal to Modify or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors

New Proposed Policy: 14.1 (Required Protocols for Recovery Hospitals), 14.4 (Medical Evaluation Requirement for Living Donors), 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements, 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 14.7 (Placement for Living Donor Organs), 14.8 (Packaging, Labeling and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), and 14.9 (Reporting Requirements)

Living Donor Committee

Public comment response period: March 14- June 13, 2014

Summary and Goals of the Proposal

This proposal would modify existing policy and establish new policy requirements for the psychosocial and medical evaluation of all types of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and is based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee. Policy to standardize the medical evaluation of living kidney donors has already been established. This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for the psychosocial and medical evaluation for all living organ donors.

Background and Significance of the Proposal

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, (in accordance with section 121.8 of the final rule). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that is done for policies on deceased organ donors and deceased donor organ recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

In July 2009, the Committee released Guidelines for the Medical Evaluation of Living Liver Donors for public comment. Overall public comment supported the resource. Most comments in opposition to the resource questioned if UNOS should be involved in developing this type of resource rather than specific criticism of the content of the resource. The ASTS provided a statement opposing the resource stating it was “beyond the scope of the OPTN/UNOS mission”. The committee revised the proposal and approved sending the guidelines to the Board for consideration. The Board approved the resource during its November 16, 2009 meeting. Since Board approval, the resource has been available on the [OPTN website](#).

In December 2009, HRSA informed the OPTN that although helpful, the voluntary guidelines for the medical evaluation of living donors developed to date were not sufficient and policies were still required. In 2010, a Joint Society Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS and HRSA) formed to make recommendations on any

OPTN policy under development that has the potential to prescribe medical care, and would make its first recommendations on OPTN policies in development for the medical evaluation of living kidney donors. This Steering Committee preferred developing policy recommendations for living kidney and living liver donor psychosocial and medical evaluation as separate projects and favored addressing living kidney donor psychosocial and medical evaluation first and living liver donor psychosocial and medical evaluation as a future project.

The Joint Society Policy Steering Group formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented societies to develop recommendations for the medical evaluation of living kidney donors. The Committee used the JSWG's position paper to create proposed new policy requirements for the medical evaluation of living kidney donors. The proposed medical evaluation requirements were distributed for public comment between September 16, 2011 and January 12, 2012, approved by the OPTN/UNOS Board of Directors on November 12, 2012, and became effective on February 1, 2013.

Similarly, for this proposal a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed a JSWG to develop recommendations for the medical evaluation of living liver donors. This work group held its first meeting on August 7, 2012 and after several months of work sent preliminary proposed policy recommendations to the leadership of the transplant professional societies on December 1, 2012 for an initial review.

After receiving feedback from the parent societies, the JSWG met to revise their initial policy recommendations for psychosocial and medical evaluation of living liver donors. The JSWG modified their policy recommendations and sent the revised recommendations back to the parent societies for approval on April 1, 2013.

On April 8, 2013, the Chairperson of the JSWG attended the Committee meeting and gave a presentation on the work of the JSWG and its preliminary recommendations for living liver donor consent policy development.

After these preliminary recommendations were approved by each of the parent societies, the Committee considered the policy recommendations in the development of these proposed policy requirements for the medical evaluation of living liver donors.

The Committee met by teleconference on June 10, 2013 to consider if a policy proposal for the psychosocial and medical evaluation of living liver donors should be distributed for public comment. The Committee determined that they wanted additional time to review the final recommendations from the JSWG and consequently the Committee agreed to delay the proposal until some future public comment cycle.

During subsequent review of the proposal, a subcommittee of the full Committee considered if common elements in existing policy for the psychosocial and medical evaluation of living kidney donors and proposed policy for the psychosocial and medical evaluation of living liver donors could be extended to apply to other types (pancreas, intestine, and lung) of living organ donors. The subcommittee determined that as currently proposed the medical evaluation of living pancreas, intestine and lung donors would not be addressed in any policy, and likely would not be addressed in a separate policy development process because the low volume of these types of transplants.

The subcommittee understood that proposed new general policies for the medical evaluation of other types of living donors was a new concept that had not been previously considered by either JSWG or any organ specific committee. In response, this committee sent letters to fourteen OPTN Committees asking those committees to comment or identify concerns regarding the plan to modify or propose psychosocial and medical evaluation requirements for all types of living donors.

The full Committee met on September 16, 2013 and reviewed responses from five (Operations and Safety, Membership and Professional Standards, Pancreas, Ethics, and Disease Transmission Advisory Committee) committees which had responded before the deadline. Each of these committees supported the plan to propose psychosocial and medical evaluation requirements to include all types of living donors. Based on this feedback the Committee agreed to prepare a policy proposal for public comment that would include psychosocial and medical evaluation requirements for all types of living donors.

On December 12, 2013, the Committee met by web conference review final draft policy language for this proposal and to consider if the proposal should be distributed for public comment. The Committee chair lead a review of the proposed policy language and the committee discussed and came to consensus on a few remaining issues with the proposed policy language. The Committee voted to approve sending the proposal for public comment.

Specific Feedback and Collaboration

The proposal is based on recommendations from a Joint Societies Work Group composed of representatives of the AST, ASTS and NATCO. The recommendations from the workgroup were approved by the leadership of the parent organizations. Living Donor Committee representatives participated in this process. The Committee sent a memorandum to fourteen other committees requesting feedback on the plan to propose medical and psychosocial evaluation requirements for all categories of living donors. The memorandum included information on what medical and psychosocial evaluation requirements would be proposed for all living donors and what medical and psychosocial evaluation requirements would be specific to living kidney and living liver donors. Seven committees responded to the memorandum by the requested deadline, and each of the responses supported the plan to propose medical and psychosocial evaluation requirements for all categories of living donors. None of these Committees responded with specific concerns over any of the proposed requirements not being appropriate for a particular category of donor.

Disease Testing

In August 2013, the Ad Hoc Disease Transmission Advisory Committee (DTAC) provided recommended changes to the current requirements for infectious disease testing in potential living kidney donors. The DTAC recommendations specified that the proposed changes to infectious disease testing would be appropriate for all types of living organ donors. The DTAC recommendations included:

- An addition that testing be completed by a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using a FDA-licensed, approved, or cleared test. This will allow requirements for deceased and potential living donors to be more closely aligned and enhance patient safety by preventing the use of test kits not recognized by the FDA. Please note, this language would allow the use of screening or diagnostic tests.

- Removal of requirement for Hepatitis B surface antibody testing. This test is not related to potential for donor-derived transmission, but rather for healthcare of a living donor. While it indicates whether a donor has been immunized for Hepatitis B, it is of no value for donor selection, and is not required for deceased donor testing.
- Removal of specific rapid plasma regain (RPR) testing requirement for syphilis. In its place, any FDA-licensed, approved or cleared syphilis test may be used. This same change has been recommended for deceased donors and will be going out for public comment this fall. The DTAC agreed that either test type would be appropriate because both all treponemal and non-treponemal test types approved by the FDA provide accurate results. The RPR requirement is somewhat outdated based upon advances in the testing industry.
- Requirement for living donor hospitals to develop a written protocol for identifying and testing potential donors at risk for transmissible seasonal or geographically defined endemic disease as part of their medical evaluation process. While the DTAC is supportive of removing the specific requirements for Chagas, West Nile Virus, and Strongyloides that appear in current living donor kidney policy, it recognizes that these and other diseases must be considered as a potential risk factor in some living donors. Developing internal policy on how to address these concerns will give living donor centers more flexibility in how they want to incorporate this important process into evaluation and make compliance monitoring more straightforward for OPTN staff.

Clinical Social Workers Qualifications and Existing Policy Clarifications

The existing policy requirements for the psychosocial evaluation of living kidney donors require that the evaluation be conducted by a psychiatrist, psychologist or clinical social worker. Since enactment of the policy, the committee has received questions regarding the definition of “clinical” social worker. To clarify existing and future policy requirements, the Committee has proposed clarifying the requirement to be a master’s prepared social worker or a licensed clinical social worker which is consistent with CMS requirements.

The current policy for the medical evaluation of living kidney donors includes a goal statement.

The Committee understands that policy must be monitor able and measureable, and goal statements are neither, consequently the goal statement is proposed for elimination.

“Potential Living Donors” Terminology

Under this proposal all references to “potential living donors” would change to read “living donors” in current and future policy. The Committee is proposing this change because the term “potential living donor” is not defined in policy and programs define “potential living donors” differently. Committee members questioned which elements of current living donor informed consent and medical and psychosocial evaluation policy are required at various stages of the donor evaluation process. Committee member questioned if a program could be cited for an incomplete informed consent or medical evaluation of a potential donor who discontinues the evaluation process prior to donation. The Committee understands that programs must fulfill all current and approved future policy requirement for the medical and psychosocial evaluation only for actual living donors and consequently favors removing all references to potential donors.

Living donor program site surveyors were consulted and supported removing all references to potential living donors from policy. The site surveyors commented that they review the medical

records of living donors, and would only review a potential donor medical record on rare occasions and for small volume programs with an insufficient number of actual living donor medical records available for review.

Domino Donors

The Committee considered but did not support requiring these proposed new psychosocial and medical evaluation requirements for domino liver donation. The Liver and Living Donor Committees may propose new policy requirements for domino liver donation as a separate and future project.

Requirements for all Living Donors

At this time, living kidney donor recovery programs must follow OPTN policies for the psychosocial and medical evaluation of potential living kidney donors. However under current policy, living liver donor recovery programs are required to develop and follow their own center specific protocols for the psychosocial and medical evaluation of potential living liver donors. Programs which perform living lung, intestine or pancreas donor recovery are not required to follow any OPTN policy or develop and follow their own center specific protocols for the psychosocial and medical evaluation of potential living organ donors.

This proposal was originally intended to expand the same level of detail concerning the psychosocial and medical evaluation of living kidney donors to living liver donors. It is now expanded to include all living donors. Under this proposal, all existing policy requirements for the psychosocial and medical evaluations of living kidney donors were compared to the (JSWG) recommended requirements for living liver donors. The common elements in existing living kidney donor policy and recommended requirements for living liver donors are proposed as new requirements for all categories of living donors. The proposal would lead to some standardization of the psychosocial and medical evaluation process for all potential living donors.

The proposal contains additional elements as components of the medical evaluation specific to living kidney and liver donors. In general the additional elements address specific testing required for the psychosocial and medical evaluation of living kidney and liver donors. The Committee considered but did not propose any additional requirements for the psychosocial and medical evaluation of living lung, pancreas, or intestine donation because the volume of living lung, pancreas, and intestine donation is so low that the value of additional testing may not be substantiated. Given the low volumes, there is limited published data on required testing and there is unlikely to be a consensus conference for the development of an expert opinion.

Supporting Evidence

**Table 1. Living Donors in the US by Volume and Type of Donor
January 1, 2007 – December 31, 2012**

| Year of Donation | Kidney | Liver | Lung | Intestine | Pancreas |
|------------------|--------|-------|------|-----------|----------|
| 2005 | 6573 | 323 | 2 | 7 | 2 |
| 2006 | 6436 | 288 | 5 | 4 | 1 |
| 2007 | 6043 | 266 | 6 | 1 | 0 |
| 2008 | 5968 | 249 | 0 | 0 | 1 |
| 2009 | 6387 | 219 | 1 | 2 | 0 |
| 2010 | 6277 | 282 | 0 | 1 | 0 |
| 2011 | 5771 | 247 | 2 | 1 | 0 |
| 2012 | 5619 | 246 | 2 | 0 | 0 |

Data subject to change based on future data submission or correction.

Expected Impact on Living Donors or Living Donation

A standardized medical evaluation process should improve the transparency of the living donation process and could improve the confidence of living donors with regard to the safety of living donation. Over time, analysis of the living donor psychosocial and medical evaluation process could contribute to improved donor evaluation process and improved donor care and outcomes.

Expected Impact on Specific Patient Populations

There should be no impact on the candidate pool. However, the proposal has the potential to affect all living liver donors.

In 2012, there were 5867 living organ donors including 5619 living kidney donors, 246 living liver donors, and two living lung donors.

Between 2007 and 2012 there were seven living lung donors, five living intestinal donors, and one living pancreas donor.

The proposed policy would affect all potential living donors, all living donors, and their recipients.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

| <i>HHS Program Goals</i> | <i>Strategic Plan Goals</i> |
|----------------------------------|--|
| Patient Safety | The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors |
| Best Use | To achieve the best use of donated organs, the OPTN will refine policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit |
| Operational Effectiveness | The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit |

Plan for Evaluating the Proposal

The Committee will request annual blinded reports on the number of centers found out of compliance during UNOS living donor program audits, and will evaluate if the policy requirements for the medical and psychosocial evaluation of living donors need clarification on revision to aid centers with compliance.

Additional Data Collection

The proposal does not require changes to the OPTN data collection system.

Expected Implementation Plan

If this policy proposal is ultimately approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the medical evaluation of living kidney donors. UNOS Living Donor Programs Auditors will evaluate center compliance. The proposal will not require programming in UNetSM.

Communication and Education Plan

The proposal addresses both modifications to existing policy and new requirements. Its applicability to all potential living donors requires an above-average effort to ensure that living donor transplant programs are aware of the requirements. Communication and education efforts will address the details of the new and revised requirements and support members who may need to revise their individual protocols.

Information about the new requirements would be included in an ongoing effort to provide educational webinars to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/blog article
- Notification to a listserve group for transplant administrators

Monitoring and Evaluation

At living donor recovery hospitals, UNOS site surveyors may:

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address PKD screening for living kidney donors.

Review the living donor recovery hospital's internal policies, procedures and/or protocols and/or interview relevant staff to determine that the hospital has a process for determining if a potential donor is at increased risk for TB.

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference, to obtain evidence that the hospital's standard practice is:

- That those performing the medical evaluations are physicians or surgeons.
- That those performing the psychosocial evaluations are psychiatrists, psychologists, masters prepared social workers or licensed clinical social workers.

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor medical evaluation was completed.

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation

- That there are results for all required tests.
- That an evaluation of the potential donor included all required assessments

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that they include protocols for screening for:

- Cervical cancer
- Breast cancer
- Prostate cancer
- Colon cancer
- Lung cancer

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation.

Policy Proposal

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

In this proposal the existing policy requirements for living kidney donor psychosocial and medical evaluation, and new proposed psychosocial and medical evaluation requirements for all other categories of living donors are integrated and presented in a table format. Under this integration, many existing policy requirements for the psychosocial and medical evaluation of living kidney donors are proposed as new policy requirements for all categories of living donors. Some existing policy for the donor psychosocial and medical evaluation of living kidney donors is specific to kidney donation and cannot be extended to other types of living donors. Consequently, the proposed policy contains donor psychosocial and medical evaluation requirements for all categories of living donors, followed by existing requirements specific to living kidney donors and next new proposed requirements specific to living liver donors.

14.1—Required Protocols for Recovery Hospitals

14.1.A Required Protocols for Kidney Recovery Hospitals

~~Kidney recovery hospitals must develop and comply with written protocols to address all phases of the living donation process.~~

14.1.B Required Protocols for Liver Recovery Hospitals

~~Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process. Specific protocols must include the evaluation, pre-operative, operative, and post-operative care, and submission of required follow up forms at 6 months, one-year, and two-years post donation.~~

~~Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocols. This documentation must be maintained by the recovery hospital.~~

14.5₁ Psychosocial Evaluation Requirements for Living Donors

14.5.1.A Living ~~Kidney~~ Donor Psychosocial Evaluation Requirements

~~The~~ living kidney-donor psychosocial evaluation must be performed by a psychiatrist, psychologist, ~~or clinical social worker~~ master's prepared social worker or licensed clinical social worker. Documentation of the psychosocial evaluation must be maintained in the living donor record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as ~~potential~~ risks for poor psychosocial outcome
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the U.S. PHS Guideline (Policy 3.1.1.4)
3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency

4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the ~~potential~~ living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the ~~potential~~ living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the ~~potential~~ donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the ~~potential~~ living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the ~~potential~~ living donor understands the potential financial implications of living donation

14.4 Medical Evaluation Requirements for Living Donors

14.4.B Living ~~Kidney~~ Donor Medical Evaluation Requirements

A medical evaluation of the ~~potential~~ living kidney donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. ~~The goals of the medical evaluation are all of the following:~~

- ~~1. To assess the immunologic compatibility of the living donor to the recipient~~
- ~~2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney.~~
- ~~3. To determine if there are diseases present that may be transmitted from the living donor to the recipient~~
- ~~4. To assess the anatomy and function of the living donor's kidneys~~

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in Tables 14-26 through 14-9 below.

Table 14-26: Requirements for Living Kidney Donor Medical Evaluations

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|---|---|
| <p>A General living donor history</p> | <ol style="list-style-type: none"> 1. A personal history of significant medical conditions which include but are not limited to: <ol style="list-style-type: none"> a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer <u>including melanoma</u> 2. History of infections 3. A kidney-specific personal history including: <ol style="list-style-type: none"> a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections 4. Active and past medications with special consideration for known nephrotoxic <u>and hepatotoxic</u> medications <u>or chronic use of pain medication</u> 5. Allergies 6. An evaluation for coronary artery disease |
| <p>General family history</p> | <p>The living donor's family history of coronary heart disease and cancer</p> <ul style="list-style-type: none"> • <u>Coronary artery disease</u> • <u>Cancer</u> |
| <p>Kidney-specific family history</p> | <p>The living donor's family history of:</p> <ul style="list-style-type: none"> • Kidney disease • Diabetes • Hypertension • Kidney Cancer |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|---|--|
| Social history | <p>The living donor's history of:</p> <ul style="list-style-type: none"> • Occupation, • Employment status, • Health insurance status, • Living arrangements, and • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Criteria to assess increased risk for disease transmission behavior as defined by the PHS Guideline <u>Policy 1.2 (Definitions)</u> |
| Physical Exam | <p>A physical exam of the living donor including:</p> <ul style="list-style-type: none"> • Height • Weight • BMI • <u>Vital signs</u> • Examination of all major organ systems • Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring |
| General laboratory and imaging tests | <ul style="list-style-type: none"> • Complete blood count (CBC) with platelet count • Blood type and <u>subtype as specified in <i>Policy 14.4.A (Living Donor Blood Type Determination)</i> and its subsections</u> screen • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, albumin, calcium, phosphorus) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG) |
| Other metabolic testing | <ul style="list-style-type: none"> • Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|------------------------------------|---|
| Kidney-specific tests | <ul style="list-style-type: none"> ● Urinalysis or urine microscopy ● Urine culture if clinically indicated ● Measurement of urinary protein and albumin excretion ● Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection ● Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history ● Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring: <ul style="list-style-type: none"> ○ Calcium ○ Oxalate ○ Uric acid ○ Citric acid ○ Creatinine ○ Sodium |
| Anatomic assessment | <p>An assessment to determine:</p> <ul style="list-style-type: none"> ● Whether the kidneys are of equal size ● If the kidneys have masses, cysts, or stones ● If the kidneys have other anatomical defects ● Which kidney is more anatomically suited for transplant. <p>The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.</p> |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|--|---|
| Transmissible disease screening | <p>Infectious disease testing must <u>be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using a FDA-licensed, approved, or cleared test.</u> Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV 1, 2 (Human Immunodeficiency Virus) antibody testing 4. HepBsAg (Hepatitis B surface antigen) 5. HepBcAB (Hepatitis B core antibody) 6. HCV (Hepatitis C Virus) antibody testing 7. Syphilis testing 8. HepBsAB (Hepatitis B surface antibody) 9. RPR (Rapid Plasma Reagin test for syphilis) <p>For tuberculosis (TB), living donor recovery hospitals must determine if the potential donor is at increased risk for this infection, and if so testing must include <u>either</u>:</p> <ul style="list-style-type: none"> • Screening for latent TB using either intradermal PPD • Interferon Gamma Release Assay (IGRA) |
| Endemic transmissible diseases | <p><u>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</u></p> <p>For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for:</p> <ul style="list-style-type: none"> • Strongyloides • Trypanosoma cruzi • West Nile |

| This evaluation must be completed: | Including evaluation for and assessment of this information: |
|------------------------------------|---|
| Cancer screening | <p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) <u>or the U.S. Preventative Services Task Force</u> to screen for:</p> <ul style="list-style-type: none"> • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Skin cancer • Lung cancer |
| Exclusion criteria | <p>Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</p> <p>Kidney recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</p> <ul style="list-style-type: none"> • Is both less than 18 years old and mentally incapable of making an informed decision • HIV • Diabetes • Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality |

14.4.C Required Medical Evaluation Protocols for Liver Recovery Hospitals Additional Requirements for the Medical Evaluation of Living Kidney Donors

~~Liver recovery hospitals must develop and comply with written protocols for the medical evaluation of potential living donors that must include, but are not limited to, all the following elements:~~

- ~~1. A thorough medical evaluation by a physician or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which must include a screen for any evidence of occult liver disease.~~
- ~~2. A psychosocial evaluation of the potential living donor by a psychiatrist,~~

psychologist or social worker with experience in transplantation must be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate the potential living donor for signs of potential coercion to donate.

3. Screening for evidence of transmissible diseases such as cancers and infections.
4. A radiographic assessment to ensure adequate anatomy and volume of the donor and the remaining liver segment.

Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors

| <u>This evaluation must be completed:</u> | <u>Including evaluation for and assessment of this information:</u> |
|---|--|
| <u>kidney specific donor history</u> | <p>A personal history of significant medical conditions which include but are not limited to:</p> <p>A kidney-specific personal history including:</p> <ol style="list-style-type: none"> a. <u>Genetic renal diseases</u> b. <u>Kidney disease, proteinuria, hematuria</u> c. <u>Kidney injury</u> d. <u>Diabetes including gestational diabetes</u> e. <u>Nephrolithiasis</u> f. <u>Recurrent urinary tract infections</u> |
| <u>Kidney-specific family history</u> | <ul style="list-style-type: none"> • <u>Kidney disease</u> • <u>Diabetes</u> • <u>Hypertension</u> • <u>Kidney Cancer</u> |
| <u>Physical Exam</u> | <ul style="list-style-type: none"> • <u>Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring</u> |
| <u>Other metabolic testing</u> | <ul style="list-style-type: none"> • <u>Fasting blood glucose</u> • <u>Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)</u> <p><u>Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals</u></p> |

| <u>This evaluation must be completed:</u> | <u>Including evaluation for and assessment of this information:</u> |
|---|--|
| <u>Kidney-specific tests</u> | <ul style="list-style-type: none"> • <u>Urinalysis or urine microscopy</u> • <u>Urine culture if clinically indicated</u> • <u>Measurement of urinary protein and albumin excretion</u> • <u>Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection</u> • <u>Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history</u> • <u>Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:</u> <ul style="list-style-type: none"> ○ <u>Calcium</u> ○ <u>Oxalate</u> ○ <u>Uric acid</u> ○ <u>Citric acid</u> ○ <u>Creatinine</u> ○ <u>Sodium</u> |
| <u>Anatomic assessment</u> | <p><u>Determine:</u></p> <ul style="list-style-type: none"> • <u>Whether the kidneys are of equal size</u> • <u>If the kidneys have masses, cysts, or stones</u> • <u>If the kidneys have other anatomical defects</u> • <u>Which kidney is more anatomically suited for transplant.</u> |

14.4.D Additional Requirements for the Medical Evaluation of Living Liver Donors

Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors

| <u>This evaluation must be completed:</u> | <u>Including evaluation for and assessment of this information:</u> |
|---|--|
| <u>Liver specific family history</u> | <ul style="list-style-type: none"> • <u>Liver diseases</u> • <u>Bleeding or clotting disorders</u> |
| <u>General laboratory and imaging tests</u> | <ul style="list-style-type: none"> • <u>Hospitals must develop and follow a written protocol for hypercoagulable state evaluation</u> |
| <u>Liver-specific tests</u> | <ul style="list-style-type: none"> • <u>Hepatic function panel</u> • <u>Ceruloplasmin in a donor with a family history of Wilson’s Disease</u> • <u>Iron, iron binding capacity, ferritin</u> • <u>Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype</u> • <u>must develop and follow a written protocol for testing for genetic diseases</u> • <u>Hospitals must develop and follow a written protocol for screening for autoimmune disease</u> • <u>Hospitals must develop and follow a written protocol for pre-donation liver biopsy</u> |
| <u>Anatomic assessment</u> | <p><u>A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor.</u></p> <p><u>The evaluation must include at least all of the following:</u></p> <ul style="list-style-type: none"> • <u>Assessment of projected graft volume</u> • <u>Donor’s remnant volume,</u> • <u>Vascular anatomy</u> • <u>Presence of steatosis</u> |

14.4 E Living Donor Exclusion Criteria

Table 14-9: Living Donor Exclusion Criteria

| | |
|---|---|
| <p><u>Exclusion criteria for all Living Donors</u></p> | <p><u>Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</u></p> <p><u>Living donor recovery hospitals must exclude all donors who meet <i>any</i> of the following exclusion criteria:</u></p> <ul style="list-style-type: none">• <u>Is both less than 18 years old and mentally incapable of making an informed decision</u>• <u>HIV</u>• <u>Active malignancy, or incompletely treated malignancy</u>• <u>High suspicion of donor coercion</u>• <u>High suspicion of illegal financial exchange between donor and recipient</u>• <u>Evidence of acute symptomatic infection (until resolved)</u>• <u>Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality</u> |
| <p><u>Additional Exclusion Criteria for Living Kidney Donor</u></p> | <p><u>Kidney recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</u></p> <ul style="list-style-type: none">• <u>Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage</u>• <u>Diabetes</u> |

| | |
|--|---|
| <u>Additional Exclusion Criteria for Living Liver Donors</u> | <p><u>Liver recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</u></p> <ul style="list-style-type: none"> • <u>HCV RNA positive</u> • <u>HBsAg positive</u> • <u>Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes</u> • <u>Expected donor remnant volume less than 30% of native liver volume</u> • <u>Prior living liver donor</u> |
|--|---|

14.65 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the Living Donor Feedback Form. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the Living Donor Feedback Form with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

14.76 Placement of Living Donor Organs

14.76.A Prospective Crossmatching prior to Kidney Placement

A prospective crossmatch is mandatory for all potential kidney living donor recipients. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are outlined in Policy 4: Histocompatibility.

14.76.B Placement of Non-directed Living Donor Kidneys

Prior to determining the placement of a non-directed living donor kidney, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney is allocated, the recovery hospital must document how the organ is allocated and the rationale for allocation.

This requirement does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation (KPD) arrangement.

14.76.C Transplant Hospital Acceptance of Living Donor Organs

Transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member recovery hospitals that are approved to perform living donor recovery for that organ type. If the OPTN does not have approval criteria for a living

donor recovery hospital for a particular organ type, then transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals with current transplant program approval for that organ type.

14.87 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue typing specimens, or vessels that are recovered from living donors according to Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage when either of the following occurs:

- Living donor organs, tissue typing specimens, or vessels are recovered and must be transported outside the recovery hospital
- A living donor organ requires repackaging by a transplant hospital for transport outside the transplant hospital

14.87.A Living Donor Vessel Recovery and Transplant

A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

14.87.B Living Donors Vessel Storage

Any vessels recovered from living donors must be stored according to Policy 16.7: Vessel Recovery, Transplant, and Storage.

14.98 Reporting Requirements

Members are responsible for submitting living donor forms according to Policy 18.5: Living Donor.