

## *At-a-Glance*

- **Proposed Guidance for the Medical Evaluation of Living Liver Donors**
- **Living Donor Committee**
- This resource is a voluntary set of recommendations for OPTN member transplant hospitals to use when developing their program-specific living liver donor medical evaluation protocols.

This resource is not a policy or bylaw. The OPTN contractor will not monitor adherence to these guidelines.

- **Target Audience for the Guidelines**

Living Liver Donors  
Candidates for Living Liver Donation  
Transplant Administrators  
Transplant Coordinators  
Transplant Physicians and Surgeons  
Transplant Program Directors  
Living Liver Donor Family Member  
General Public

## **Proposed Guidance for the Medical Evaluation of Living Liver Donors.**

### **Sponsored by the Living Donor Committee**

#### **Summary and Goals of this Resource:**

The OPTN/UNOS Living Donor Committee developed this resource to assist transplant professionals to medically evaluate potential living liver donors. This guidance document can also inform and educate potential living liver donors about their own medical evaluations. The intent of this resource is to improve the medical care and follow-up of living liver donors. Each OPTN member transplant hospital that evaluates potential living liver donors can choose to adopt the guidance herein. The OPTN/UNOS Board of Directors previously approved a similar resource for the medical evaluation of living kidney donors.

**Please note that this resource is not policy and therefore does not carry the same monitoring implications.**

#### **Rationale for this Resource:**

On June 16, 2006, the Health Services and Resources Administration (HRSA) published a notice in the Federal Register in which the Secretary of the Health and Human Services (HHS) directed the OPTN to develop policies regarding living organ donors and organ donor recipients. The notice stated that the consequence of centers not complying with living donor policy matches that of centers not complying with deceased donation policy; and, that the emphasis of living donor guidelines and policies should be “to promote the safety and efficacy of living donor transplantation for the donor and recipient.”

In January 2007, the OPTN/UNOS President requested from transplant programs that perform living donor transplants copies of their informed consent, medical evaluation, and living donor follow-up protocols. The Living Donor Committee used these protocols to make recommendations to the OPTN/UNOS Board of Directors regarding new living donor policies or guidelines. After deliberations during several OPTN/UNOS Board of Directors’ meetings, in June 2008, the OPTN/UNOS Executive Committee approved recommendations for the medical evaluation of living kidney donors for public comment. The Living Donor Committee intended for clinicians to voluntarily use this *Guidance for the Medical Evaluation of Living Kidney Donors*.

In September 2007, the OPTN/UNOS Board of Directors approved new bylaws (Attachment I, Appendix B) that require transplant programs that perform living donor transplants to develop and follow written protocols that address all phases of the living donation process. These protocols must address the medical evaluation of the potential living organ donor; pre-operative, operative, and post-operative care of the living donor; and, the submission of living donor follow-up data.<sup>1</sup>

The Committee now proposes a similar resource for living liver donation. This resource includes information that transplant programs can use to develop their own program-specific living liver donor medical evaluation protocols. This resource includes information gathered from a survey of 11 living liver transplant programs (see Exhibit A). This resource is also based on an extensive literature review, as well as recommendations from the *Vancouver Forum on The Care of the Live Organ Donor Lung, Liver, Pancreas and Intestine*; *New York’s Committee on Quality Improvement in Living-Liver Donation*; and the *Adult-to-Adult Living Liver Transplantation Cohort (A2ALL)* studies. Additionally, the Committee sought

input from the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), and the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee during the development of this resource. All comments were considered by the Committee and most were incorporated into this resource.

Centers can opt to use this resource to develop medical evaluation protocols for potential living liver donors. This resource is not intended to be a standard of care. UNOS will not use this resource to assess member compliance of policy or bylaw. The Committee acknowledges that no single evaluation protocol will ever be appropriate or applicable to all potential living liver donors. Additionally, the Committee recognizes that medical judgment of involved transplant professionals will direct the appropriate course for the medical evaluation. The Committee proposes these guidelines as an important step in protecting the health and safety of all living liver donors.

**Expected Impact on the Strategic Plan:**

The proposed guidance document addresses the following strategic plan goal:

- Optimize a safe environment for living donor transplantation

Transplant programs may use this resource to develop or refine their own program specific protocols for the medical evaluation of potential living liver donors.

**Communication and Education Plan:**

If approved by the Board of Directors, the transplant community will receive information regarding this new resource.

## Guidance for Developing Program-Specific Living Liver Donor Medical Evaluation Protocols

### I. *Guidance for Creating Your Pre-Evaluation Guidance Protocol*

Each potential donor is unique and no single evaluation protocol is applicable to all living donors; however, transplant centers must inform potential living donors about all phases of its evaluation protocol. The donor evaluation includes psychosocial and medical components, which should help determine if an individual is a suitable for living donation. The psychosocial evaluation should determine the presence of psychosocial problems that might complicate donation (e.g., lack of social support to aid in the individual's post operative recovery). The medical evaluation may uncover conditions that could significantly increase the risk of donation to the potential living liver donor. The evaluation should also screen for diseases that the donor could transmit to the potential recipient, which is particularly important since the recipient will be taking immunosuppressive drugs. Lastly, this evaluation should define the anatomy of the liver so that the surgical team can assess the anatomical suitability of the organ and properly plan the surgery.

To the extent possible and early in the medical evaluation process, the transplant team should inform both the potential living liver donor and the intended recipient of alternatives to living donation. The team should also inform the potential living liver donor and intended recipient of donor and recipient outcomes at the institution compared to national outcome data. The evaluating transplant center should include a donor advocate or donor advocate team to assist the donor throughout the process.

It is important to inform the potential living donor that he/she can stop the medical evaluation or living donation process at any time. If a potential living donor chooses to not proceed with the evaluation or donation process, the center may state that the living donor did not meet the program's criteria for donation to help avoid difficult social situations.

#### Communicating Donor Risk

Living liver donation involves risk. Most of the medical risks and complications associated with the partial hepatectomy procedure occur in the peri-operative period. These risks are relatively well known and can include:

- Risks associated with anesthesia;
- Surgical complications such as liver failure, blood loss, bile leak, blood clots, infection, pain, hernia; and less frequently bile duct stricture<sup>(2,3,4,5)</sup>;
- Death - the risk of dying from living donor surgery is estimated to be between 0.1%-0.3% and possible as high as 0.5% when donating right lobe<sup>(4)</sup>; or,
- Overall Donor Morbidity is estimated to be approximately 35 %<sup>(5)</sup>.

Since there has been no national and systematic long-term data collection on the risks associated with living organ donation, the risk of long-term liver-related complications is not well known. However, recent OPTN data reveal that:<sup>(6)</sup>

- Five living liver donors were listed for liver transplant between 4/1/1994 and 11/30/2008.
  - Two were between 18-34 years of age, two between 35-49 years of age, and one was between 50-64 years of age.

- All living liver donors were placed on the liver transplant waiting list within 20 days after donation.
- Diagnoses of the five donors at time of listing were sub-fulminant hepatic failure (2), Budd-Chiari syndrome (2), and other (1).
- One living donor died after being placed on Waitlist<sup>SM</sup>, three candidates received deceased donor liver transplants within 4 days after listing, and one candidate was removed from the Waitlist<sup>SM</sup> due to improved health.
- 3.4 % of the living donors required re-operations within 6 weeks of donation in 2007.
- 7.4 % of the living donors required readmissions to hospital within 6 weeks of donation in 2007.

The concern about the long-term risk of living liver donation has to be balanced against the benefit of transplantation for the recipient. It is difficult to assess long term risk to the living liver donor due to lack of data. Donors have reported chronic problems including bile strictures, re- operations, and chronic pain.

It is clear that those patients who remain on the Waitlist<sup>SM</sup> and have an increase in their Model for End-Stage Liver Disease (MELD) score have an increased risk for death as compared with patients who are transplanted.

The potential living liver donor and the medical and surgical team should discuss these risks and whether the risk of partial hepatectomy to the living donor is warranted when compared with the benefit the recipient will receive from transplantation.

#### Risks of Living Liver Donor Evaluation

Risks associated with medical evaluation may include:

- Mild to severe allergic reaction due to exposure to contrast materials used in abdominal imaging.
- The discovery of infections or malignancies unknown to the potential donor.
- Complications from liver biopsy (if needed) ranges from 0.2% and 1.79%.<sup>(7)</sup>
- The discovery of diseases that must be reported to health agencies.
- HLA testing (if performed) could reveal the true identity of family relationships, and create issues that the donor or other family members may not wish to be exposed. Test results may require unexpected decisions of the donor and medical team.
- Test results may require the need for additional testing and treatments, which may become the financial responsibility of the donor or donor's insurance.

Physician knowledge and experience are important components in this medical evaluation. The involved professionals' medical judgment will always need to direct the course of the evaluation. The health care team should be judicious in selecting of screening tests and cautious about interpreting any findings.

## Decision Regarding Donation

The final decision regarding whether the living liver donor can donate an organ is based upon:

- The medical test results;
- The donor's psychosocial evaluation;
- Assessment of risk based upon current medical knowledge;
- Willingness of the donor to proceed after receiving education about the entire donation process; and,
- Confirmation that the donor is an acceptable candidate based on the medical evaluation.

The living liver donor should make the decision to donate with the help of his/her family, friends, the independent donor advocate (IDA), and the medical/surgical team.

In cases of directed donation, if an individual decides to donate, the transplant team should consult with the potential recipient to determine if all parties agree to proceed with transplantation. Under these circumstances, the transplant team should inform the donor and recipient of the risks of both procedures (e.g. severity of recipient illness, donor anatomy, etc).

Some living donors may be willing to accept relatively greater degrees of personal risk to give an organ to a transplant candidate in need. Transplant teams should consider the special circumstances of each potential donor when deciding about candidacy for donation.

Transplant candidates may also vary in the degree of risk they are willing to take (e.g., risk for communicable disease or substandard donor organ quality).

## ***II. Evaluation Guidance***

This resource provides a list of tests and procedures that may be necessary for assessing the medical and psychosocial suitability of a potential living liver donor. Transplant centers can use this list as a guide.

To date, no randomized controlled trials have been conducted to determine the tests required to evaluate a living liver donor. The process described in this resource represents the general medical practice of existing OPTN member transplant programs which assess living donors.

This resource will be modified over time as improved screening tests become available. At all times, the transplant program should assess the risk of the screening procedures versus the benefit of information received. Again, transplant centers should view the process outlined below as a suggestion. Opinions on what process to follow will vary.

## Psychosocial Evaluation

As required in the bylaws (Attachment I, Appendix B), a psychosocial evaluation should be performed by a professional approved by the current OPTN/UNOS bylaws. The person performing this evaluation should have experience in transplantation. This person may be a psychiatrist, psychologist, or social worker. The psychosocial evaluation should <sup>(2, 3, 8, and 9)</sup>.

- Review psychosocial issues that might complicate the living liver donor's recovery and identify potential risks for poor psychosocial outcome.
- Attempt to identify factors that warrant educational or therapeutic intervention before donation. If the evaluating professional suspects current or prior psychiatric disorders, including those related to substance abuse, this professional should provide the necessary referrals to the potential donor for further psychological or psychiatric evaluation.
- Determine the potential donor's understanding of the short- and long-term medical risks associated with living donation.
- Allow the transplant program to explore the reason(s) why the potential donor volunteered to donate. The program should attempt to determine that the potential donor's decision to donate is not due to coercion.
- Determine the potential donor's ability to make an informed medical decision, and cope with the emotional and physical consequences of a major surgery. The potential living donor should have a realistic outlook about donation and recovery, with social, emotional and financial support available as needed.
- Review the financial circumstances of the potential living liver donor (e.g., employment, insurance coverage, etc). Where applicable, the program should investigate the potential donor's understanding of the possible financial implications of living donation and the availability of financial resources.
- Inform the potential donor that he/she may experience problems in obtaining future disability benefits or health insurance following donation.
- Inform the potential donor that health information obtained during his/her medical evaluation will be subject to the same patient confidentiality regulations as regular medical records.

### ***III. Donor Medical Evaluation***

The OPTN/UNOS bylaws state that a physician or surgeon experienced in living donation should perform a thorough medical evaluation. The goal of the medical evaluation is to: <sup>(1, 2, 3, 5, 10, and 11)</sup>

- Assess the compatibility of the potential donor to the recipient.
- Assess the general health of and surgical risk for the potential donor.
- Include screening the potential donor for conditions that increase the donor's surgical risk for liver resection (this may include underlying liver disease, HBV, HCV, HIV, coagulation disorder).
- Perform tests on the potential donor to prevent potential transmission of donor-derived diseases to the recipient.
- Assess the anatomy of the potential donor's liver, and assess the likelihood of successful transplantation of the partial liver graft given recipient anatomy, diagnosis, and disease severity.

Due to time constraints, in fulminant liver failure, some tests may not be possible to perform. But, but all safeguards (e.g., communication of risk, psychosocial evaluation etc.) should be in place including the use of an IDA.

The Living Donor Committee will consult with relevant experts in the transplant community to periodically review and update this resource.

## Components of the Medical Evaluation

### 1. General Medical History

Physicians should assess the potential living liver donor for:

- Significant medical conditions such as hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, history of cancer, history of infections, hematologic disorders, and bleeding/clotting disorders;
- Smoking, alcohol and drug use/abuse, including intravenous drug use/abuse, and other high risk behavior(s);
- Medications consumed currently and in the past (hepatotoxic, chronic use of pain medications, other);
- Allergies;
- Family history (coronary artery disease, cancer, other);
- Liver specific personal history: Risk factors for viral hepatitis, history of abnormal liver enzymes, Diabetes, Fatty liver disease, Jaundice, bleeding, and pruritis; and,
- Liver Specific Family History: liver disease, autoimmune disease, diabetes, and viral hepatitis

### 2. Social History

A mental health professional should conduct a full psychosocial evaluation of the potential donor. Part of the medical evaluation should attempt to determine psychosocial concerns that may warrant further investigation. Special emphasis of this evaluation may be on:

- Employment, health insurance status, living arrangements, and social instability that may make donation difficult;
- Psychiatric illness, alcohol or substance abuse, depression, and suicide attempts; and,
- Motivation for donation.

### 3. Physical Exam

- Height, weight, and body mass index (BMI); and
- Examination of all major organ systems.

### 4. Liver-specific Exam

- Assess for stigmata of liver disease
  - Hepatomegaly
  - Splenomegaly
  - Spider angiomas
  - Edema
  - Palmar erythema

### 5. General Laboratory Testing

- CBC with platelet count

- Prothrombin Time , INR, Partial Thromboelastin Time
- Coagulation profile ( consider factor 5 liden)
- Comprehensive panel (electrolyte, BUN, creatinine, calcium, phosphorus,)
- HCG quantitative pregnancy test for women < 55 years old
- Age and gender appropriate cancer screening tests  
The transplant program may choose to follow the screening recommendations from the American Cancer Society. <sup>(12)</sup>
- Chest X-Ray
- Electrocardiogram (ECG)
- Evaluation for coronary artery disease, as suggested by the American College of Physicians <sup>(13)</sup>
- Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association. <sup>(14)</sup>

#### 6. Liver-specific Testing

- Hepatic function panel
- ANA
- Cerulaplastin
- Iron, Iron Binding capacity, ferritin
- Alpha 1 antitripsin level and phenotype <sup>(15)</sup>
- Smooth Muscle antibody
- Anti mitochondrial Antibody
- Consider Hemachromatosis gene testing

#### 7. Immunological Testing

- ABO blood group typing

#### 8. Metabolic Focused Testing

- Fasting blood glucose
  - The evaluation team may consider fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated.
  - If the potential donor does not meet the definition of diabetes but has a family history of diabetes or characteristics of metabolic syndrome, he/she should receive counseling about risk for developing diabetes and perhaps non-alcoholic fatty liver disease. <sup>(16)</sup>

#### 9. Anatomic Assessment:

Surgeons may use this assessment to determine if the liver is anatomically suitable for transplantation into the recipient, and to assess the adequacy of the donor's residual liver volume. Evaluation would include assessment of projected graft volume, donor's remnant volume, and vascular anatomy. Pre-operative imaging of the potential donor's biliary anatomy is recommended.

Based on these findings, the surgeon can determine the suitability of the liver, and any additional risks associated with anatomical variants. The radiologic imaging may reveal unexpected findings

that will need to be investigated. These findings may be related or unrelated to the organ of interest.

- The test of choice will depend upon the local radiological expertise and surgical preference, but may include CT angiogram, MR angiogram or angiogram, used singly or in combination. An assessment for steatosis should be undertaken. <sup>(17,18)</sup> A liver biopsy may be warranted if the imaging suggests significant fatty liver in the potential donor.

## 10. Liver Biopsy

Liver biopsy may be indicated at the discretion of the center. Indications for a biopsy may include: <sup>(2,19)</sup>

- Abnormal liver function tests;
- Steatosis on imaging;
- BMI >30;
- Genetic relation to a person with autoimmune or genetic liver disease;
- HBV core positive serology; and,
- Prior history of alcohol abuse.

## 11. Transmissible disease testing:

This screening is used to identify the risk of transmitting an infection or disease to a recipient. This screening may also identify a condition that may require the donor to seek treatment or may increase the risk of donation. Infectious disease testing typically includes testing for the following: <sup>(20)</sup>

- CMV (Cytomegalovirus);
- HIV 1, 2 (Human Immunodeficiency Virus);
- HTLV 1 (Human T-cell Lymphotropic Virus) antibody testing;
- HBsAg (Hepatitis B surface antigen)\*;
- HbcAB (Hepatitis B core antibody)\*;
- HBSAB (Hepatitis B surface antibody);
- HCV (Hepatitis C Virus)\*\*; or,
- RPR (Rapid Plasma Reagin Test for syphilis)

\*HBV DNA should be considered if HbcAB is positive or in high risk individuals.

\*\*HCV RNA should be considered in high risk individuals.

Depending on transplant program preference and donor risk profile, physicians may test for other diseases such as:

- EBV (Epstein Barr Virus) – VCA or EBNA antibody test may be performed if the recipient is EBV seronegative E
- Lyme disease for donors from endemic areas
- Strongyloides for donors from endemic areas
- Tuberculosis

- Trypanosoma cruzi for donors from endemic areas
- West Nile for endemic areas
- Toxoplasmosis: Transmission is low if recipients are treated with trimethoprim-sulfamethoxazole <sup>(21)</sup>

## 12. Cancer screening:

Cancer screening tests should follow the practices advised by the American Cancer Society (ACS) Screenings that should be performed based on gender, age, or family history include:

- Cervical cancer;
- Breast cancer;
- Prostate cancer;
- Colon cancer; and,
- Skin cancer.

Lung cancer screening is not currently recommended by the ACS, but could be considered in the older patient with a long smoking history.

## **IV. Possible Exclusion Criteria**

A variety of criteria may make an individual unsuitable for living liver donation. Some of these may include: <sup>(2, 3, 5, 8, 11, 22, 23, 24)</sup>

- Age < 18 years of age, or mentally incapable to make an informed decision;
- Upper age limit >60 years of age;
- Diabetes;
- Significant history of thrombosis or embolism;
- Bleeding disorders;
- Uncontrollable psychiatric illness;
- Active TB or untreated TB infection;
- 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;
- Vascular or biliary abnormalities in the donor liver that make the likelihood of successful transplantation low or increase the risk in the potential donor;
- HIV infection;
- Hepatitis C virus infection;
- Active hepatitis B virus infection;
- Fatty liver disease( >20% steatosis);
- Asymptomatic ZZ alpha 1 antitripsin genotype;
- Multiple or complex upper abdominal surgeries;

- Recipient graft to body weight ratio (GBWR); or,
- Donor remnant volume less than what is considered appropriate.

#### Living Donor Follow-up

The living donor organ recipient's transplant center is required to submit information to UNOS about the status of each living donor for a minimum of two years. UNOS will use any information received to determine if living donors experience short term health complications and how living donation may impact quality of life. Follow up information submitted by transplant centers is the only method currently available to obtain information on living donors. (To clarify, the recommendations in this resource are provided assist transplant centers with the development of their center-specific medical evaluation protocols. UNOS will not use this resource to assess the medical evaluation protocols of members for policy compliance).

#### Medical Evaluation after Living Donation

Following partial liver donation, the living donor should remain informed about his/her health and have basic medical evaluations performed as listed below:

- An age appropriate physical exam;
- Laboratory studies that include: CBC with platelets, hepatic function panel, creatinine level, and PT/INR; and,
- Radiological imaging.

All living liver donors should be encouraged to maintain lifestyle choices that will protect their overall health and in particular, their liver health. These donors should be advised to consider vaccination for Hepatitis A and B. Living Liver donors should be advised to establish a health evaluation schedule as recommended by the American College of Physicians. However, these evaluations may become the financial responsibility of the living liver donor.

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