

OPTN/UNOS Living Donor Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

Summary

Action Items for Board Consideration

- The Board of Directors is asked to approve new Policies 12.3.1 (ABO Identification) and 12.8.1.1. (Reporting Requirements) to require two separate ABO typings of living donors. (Item 1, Page 3)
- The Board of Directors is asked to approve an update to a resource titled “Guidance for the Informed Consent of Living Donors.” (Item 2, Page 5)
- The Board of Directors is asked to approve a resource titled “Guidance for the Medical Evaluation of Potential Living Liver Donors.” (Item 3, Page 10)

Other Significant Items

- Status of Living Donor Follow-up. (Item 4, Page 21)

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Matthew Cooper, MD, Chairman
Connie Davis, MD, Vice Chair

The following report is a summary of the Living Donor Committee's deliberations and discussions during its full Committee meetings held on February 23, 2009, May 18, 2009, and September 21, 2009 and Live Meeting held October 14, 2009.

1. Proposal to Improve the ABO Verification Process for Living Donors. Policies 12.3.1 (ABO Identification) and 12.8.1.1 (Reporting Requirements)

In June 2008, the Committee learned of a living donor transplant in which the living donor kidney was transplanted into an ABO incompatible recipient. The living donor was originally typed as blood type A2. The recipient was typed blood type O. In this case, the kidney of this A2 living donor was transplanted into a recipient with an O blood type; however, the recipient showed immediate signs of accelerated rejection of the transplanted kidney. After repeated blood typing and cross matching, the donor's ABO was typed as A1, and had a positive crossmatch with the kidney recipient's serum.

After considering this case, and reviewing existing policies, the Committee realized that existing policies for ABO verification are more stringent for deceased donors than for living donors. Policies 3.1.4.2 (Waiting List) and 3.2.4 (Match System Access) require deceased donors and candidates for receiving deceased organs to receive two ABO tests; however, no similar policy exists for living donors.

The Committee is only aware of this single instance of unintentional living donor and recipient ABO incompatibility and it is difficult to determine conclusively if other cases have occurred. Transplants in which the reported donor ABO differed from the reported recipient ABO may represent intentional "blood type incompatible" donation.

Although there is limited evidence to demonstrate persistent problems with the ABO verification process in living donation, the Committee determined that even one accidental case of ABO mismatch between a living donor and his or her recipient is unacceptable. The ABO verification process for deceased donors requires two ABO samples sent to two separate laboratories, or two samples from separate blood draws sent to the same laboratory. At present, there is no policy addressing the ABO verification process for living donors. In response, the Committee opined that the ABO verification process for living donors should be as stringent as the process for deceased donors.

According to the experience of transplant professionals serving on the Committee, it is standard practice for most programs to require potential living donors to receive two ABO tests. Therefore, the Committee embarked on an effort to include this requirement in policy to help prevent ABO mismatches in the future.

The Committee consulted the Operations, Transplant Administrators, and Transplant Coordinators Committees on this case and proposed policy. The Operations Committee and Transplant Administrators Committee both supported developing new and clearly defined policies for ABO typing and verification of a potential living donor and his/her recipient. The Operations Committee questioned why current policy would permit less stringent testing requirements for living donors, and commented that this proposed policy would improve living donor safety.

This policy proposal will help protect living donors by reducing the risk of having their organ(s) transplanted into an ABO incompatible recipient. The proposal also benefits the recipient by reducing the risk that he or she will not be compatible with the donor. Any reduction in donor risk optimizes a safe environment for living donor transplantation, protects patient safety, and will help preserve public trust.

This proposal was released for public comment period between July 10 and September 14, 2009. The Committee considered all public comments received on the proposal at its September 21, 2009, meeting. Overall, there was strong public support for the proposal (**Exhibit A**). In public comment, one person noted the proposal described an error in sub-typing which would not have been prevented if the donor had had only two initial ABO typings. The Committee agreed, and consequently changed the final proposed policy language to address sub-typing. The Committee approved the revised final version to be considered by the Board. Committee vote: 24-0-0

The following proposal is recommended for consideration by the Board.

**** RESOLVED, that new Policies 12.3.1 (ABO Identification) and 12.8.1.1 (Reporting Requirements), set forth below, are hereby approved, effective pending distribution of notice.**

12.3 Medical Evaluation of Living Donors

12.3.1 ABO Identification

The member transplant hospital must ABO type, and subtype if appropriate, each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.8.1 Reporting Requirements

12.8.1.1 The living donor transplant program must use the source documents from both ABO typings to enter the living donor's ABO on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO was correctly entered on the Living Donor Feedback Form. A transplant program must document that each ABO entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to UNOS the OPTN Contractor, upon request.

2. **Guidance for the Informed Consent of Living Donors**

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 Committee planned to use these protocols to make recommendations to the Board of Directors regarding new living donor policies and guidelines.

The Committee's evaluation of these protocols revealed wide variation in the consent process throughout the country. Some centers had no formalized guidelines for living donor consent. In an effort to provide Members with a shared knowledge base, the Committee used the 80/20 rule in evaluating submitted protocols. If the majority (or 80%) of programs had a particular element as part of their standardized consent processes, the Committee included that element in the final recommendations. The Committee reviewed and incorporated recommendations from a variety of sources, including the Advisory Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), and the State of North Carolina living donor statutes in the development of these recommendations. Based on the information reviewed, the Committee developed recommendations for the informed consent of living donors.

These recommendations titled, "Guidance for the Informed Consent of Living Donors" were distributed for public comment. In September 2007, the Board approved the resource, and instructed the Committee to review and update the resource as necessary and on a regular basis. Since Board approval, this resource has been available through the UNOS, OPTN, and Transplant Living websites.

In November 2007, the OPTN/UNOS President requested that the resource be modified to include two additional elements:

- Disclose that the medical evaluation of the potential donors could reveal conditions that must be reported to governmental authorities; examples include HIV and some venereal diseases; and
- Explain that some medical information about the potential donor may need to be disclosed to the intended recipient, and that some medical information on the intended recipient may need to be disclosed to the potential donor, to enable each party to evaluate if they should donate or receive the organ.

The Committee completed a first review and update of this resource which was approved by the Board in June 2009. That update focused primarily on adding provisions to address the special circumstances of nondirected living donors and considered living donors who may wish to participate in Kidney Paired Donation.

In response to recent publicized reports of the alleged sale of living donor organs, the Committee recommended that the resource be revised again to address valuable consideration. At its September 21, 2009, meeting, the Committee approved adding the following element to the Consent Guidelines:

- (r) Disclosure that the sale or purchase of organs is a federal crime, and it is unlawful for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.

Vote: 24-0-0

These voluntary recommendations are intended to help transplant programs develop living donor protocols, which consistently meet the needs and interests of potential living donors, and that reflect the consensus of expertise among medical professionals involved in living donor transplantation. (A Resource Impact Summary is provided as **Exhibit B**)

The Committee recommends the following for consideration by the Board.

**** RESOLVED, that modification to the “Guidance for the Informed Consent of Living Donors” set forth below, are hereby approved effective November 17, 2009:**

Guidance for the Informed Consent of Living Donors

Purpose

The Living Donor Committee developed this resource to help transplant professionals develop consent processes for all living donors.

Introduction

Education is important in the consent process for any potential living donor. The potential donor must understand all aspects of the donation process and understand the risk and benefit associated with being a living donor as well as center-specific risk factors. Most living donors give their organ to a family member or acquaintance. However, some living donors are nondirected and do not influence the placement of their donated organ. This resource contains some recommendations that only apply to nondirected donors. Above all else, the potential donor must understand that he or she may stop the evaluation or donation process at any time.

Living Donor Consent

The consent process for any potential living donor should include, but is not limited to:

- a. The assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time.
- b. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

The medical evaluation will be conducted by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post donation, which will include a screen for any evidence of occult renal and infectious disease and medical co-morbidities which may cause renal disease.

The psychosocial evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

- c. A disclosure that living donor transplant programs must provide an Independent Donor Advocate (IDA) whose responsibilities include but are not limited to the following.
- to promote the best interests of the potential living donor
 - advocates for the rights of the potential donor
 - assist the potential donor in obtaining and understanding information regarding the:
 - i) consent process
 - ii) evaluation process
 - iii) surgical procedure, and
 - iv) benefit and need for follow-up
- d. An evaluation of the potential donor's ability to comprehend the donation process, including procedures employed for both donor and recipient and possible outcomes.
- e. The provision of printed materials that explain all phases of the living donation process. Materials should be written at an appropriate reading level and provided in the potential donor's native language. When necessary, independent interpreters should be provided to make certain the potential donor comprehends all phases of living donation and its associated risks and benefits.
- f. The provision of education that discusses what remaining organ function will be left after the donation and what the impact on the donor might be.
- g. The provision of sufficient time for the potential donor to reflect after consenting to donate.
- h. Disclosure of alternate procedure or course of treatment of treatment for the potential donor and recipient including deceased donation. All potential donors should be informed if the intended recipient has or has not been listed for deceased donation. Pre-existing life threatening conditions of the potential recipient should be disclosed to the potential donor prior to obtaining consent.
- i. Explain that a decision by the potential donor not to proceed with the donation will not be disclosed without the prior consent of the potential donor.
- j. A determination that the potential donor understands that he or she will undertake risk and will receive no medical benefit from the operative procedure of donation.
- k. A disclosure that the potential donor's medical evaluation could reveal conditions that the transplant center must report to governmental authorities such as HIV or certain venereal diseases.
- l. An explanation that medical information on the potential donor may not be revealed to a potential recipient unless authorized by the potential donor. If the potential donor has a condition that might harm a recipient the medical team in charge of his or her evaluation will not allow the donation to occur.

m. A specification of the medical, psychological, and financial risks associated with being a living donor. These risks may be transient or permanent and include, but are not limited to the following:

i. Potential Medical Risks

- potential for surgical complications including risk of donor death
- potential for decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in their individual kidney function is to be discussed with each donor
- potential for organ failure and the need for a future organ transplant for the donor
- potential for other medical complications including long-term complications currently unforeseen
- scars
- pain
- fatigue
- abdominal or bowel symptoms such as bloating and nausea
- increased risk with the use of over the counter medications and supplements

ii. Potential Psychosocial Risks

- potential for problems with body image
- possibility of post surgery depression, anxiety, or emotional distress
- possibility of transplant recipient rejection and need for re-transplantation
- possibility that the transplant recipient will have a recurrence of disease
- possibility of transplant recipient death
- potential impact of donation on the donor's lifestyle

iii. Potential Financial Risks

- personal expenses of travel, housing, and lost wages related to live donation might not be reimbursed; however, the potential donor should be informed that resources may be available to defray some donation-related costs
 - child care costs
 - possible loss of employment
 - potential impact on the ability to obtain future employment
 - potential impact on the ability to obtain or afford health, disability, and life insurance
 - health problems experienced by living donors following donation may not be covered by the recipient's insurance
- n. Disclose that transplant centers are required to report living donor follow-up information for at least two years, so the donor should expect to be contacted by the transplant program regarding the current health status.
- o. Disclose that living donor follow-up is the best method for the collection of information on the health implications of living donation.
- p. Disclose that centers will specify who is responsible for the cost of follow-up care.
- q. The agreement of the potential donor to commit to post-operative follow-up testing coordinated by the recipient transplant center for a minimum of two years.
- r. Disclosure that it is unlawful for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.
- s. Disclosure that living donor follow-up is the only method for the collection of available information for the collection of short-term health implications of living donation.
- t. The stipulation that transplant centers will provide potential donors with both national and their center-specific outcomes from the most recent SRTR center-specific report. This information should include, but not be limited to 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.
- u. Disclose to all potential non-directed donors the following:
- i) the transplant program will determine who will receive the donated organ;
 - ii) the transplant center will take all reasonable precautions to provide anonymity for the donor and recipient;
 - iii) the transplant center should obtain a separate consent to allocate your organ to a paired donation system; and

- iv) the transplant center should disclose there is an increased risk associated with the transport of nondirected living donor organs and obtain additional consent to transplant the organ if it will not be transplanted at the recovery center.

3. Proposed Guidance for the Medical Evaluation of Potential Living Liver Donors

On June 16, 2006, the Health Services and Resources Administration (HRSA) published a notice in the Federal Register in which the Secretary of the Department of 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 Committee planned to use these protocols to make recommendations to the Board of Directors regarding new living donor policies or guidelines.

Based on the protocols received, the Committee developed a set of voluntary recommendations titled *Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols*. This resource was released for public comment in 2007, and was approved by the Executive Committee in June 2008.

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 obtained 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) Living Donor Subcommittee, the American Society of Transplantation (AST), and the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee during the development of this resource. All comments received prior to the public comment were considered by the Committee and most were incorporated into this resource.

This resource was released for public comment between July 10 and September 14, 2009. Overall public comment supported the resource (**Exhibit C**). 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.”

Post- public comment, the Committee arranged a conference call (October 1, 2009) between representative of the ASTS and the Committee to provide the ASTS another opportunity to provide specific feedback on the content of the resource. A final draft of the resource was reviewed and approved by the Committee during a Live Meeting on October 14, 2009. Committee vote: 15-0-0

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.

The Committee recommends the following for consideration by the Board.

**** RESOLVED, that the resource titled “Guidance for the Medical Evaluation of Potential Living Liver Donors set forth below, is hereby approved effective November 17, 2009:**

Guidance for the Medical Evaluation of Potential Living Liver Donors

Summary and Goals

On June 16, 2006, HRSA published a notice in the Federal Register in which the Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor recipients. The notice stipulated that noncompliance with such policies will subject members to the same consequences as noncompliance with policies regarding deceased donor transplantation. In response, the Board of Directors adopted changes to the Bylaws requiring transplant programs that perform living donor transplants to develop and follow written protocols that address all phases of the living donation process, including the evaluation, pre-operative, operative, and post-operative care, as well as the submission of data.

To assist members, the Living Donor Committee developed a non-exhaustive set of elements to serve as a resource that could be used by transplant programs in developing their own program specific living liver donor medical evaluation protocols, as required by the Bylaws. Since this resource is not considered OPTN or UNOS policy, it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, and it is not intended to be clinically prescriptive or to define a standard of care. This resource will not be used to determine member compliance with policies or Bylaws; rather it is a resource being provided to the members for examples and amplification of the elements mentioned in the Bylaws. It is intended for members’ voluntary use.

Both new and existing living donor transplant programs can use this guidance when developing medical evaluation protocols for their potential living donors

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 suitable for living donation. The psychosocial evaluation may reveal 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^(2,3,4,5);
- 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 the right lobe⁽⁴⁾
- If all complications are considered, from the most minor to the most severe, approximately 1 of every 3 donors will experience a complication based upon multicenter consortium data. The great majority (95%) are considered minor or with no permanent sequelae.⁽²²⁾
- Overall Donor Morbidity is estimated to be approximately 35 %⁽⁵⁾.

Recent OPTN data (6) reveal that: five out of 3632 (0.1%) living liver donors were subsequently 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 waiting list, three candidates received deceased donor liver transplants within 4 days after listing, and one candidate was removed from the waiting list due to improved health.

The A2ALL study has improved our understanding of the short and medium term risks associated with living liver donation. Donors have reported chronic problems including bile strictures, re-operations, and chronic pain. Although data collection is ongoing, our ability to quantify complications which may arise beyond 5 years is currently limited.

Risks of Living Liver Donor Evaluation

Some of the possible risks associated with the 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) range from 0.2% and 1.79%.⁽⁷⁾
- 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.

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 and psychological 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 considered 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 transplant programs that 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 processes 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 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 :^(2, 3, 8, and 9)

- 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.
- Attempt to 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 receive adequate educational material and engage in discussions that will enable the potential living donor to develop a realistic assessment regarding 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 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: ^(1, 2, 3, 5, 10, and 11)

- Assess the compatibility of the potential donor to the recipient.
- Assess the general health of and surgical risk for the potential donor.
- Screen the potential donor for conditions that increase the donor's surgical risk for liver resection
- Perform tests on the potential donor to identify the potential for 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, 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, clotting disorders, 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 should 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. Suggested General Laboratory Testing

- CBC with platelet count
- Prothrombin Time, INR, Partial Thromboplastin Time
- Coagulation profile (consider factor V Leiden, Prothrombin II gene mutation)
- Comprehensive panel (electrolytes, 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⁽¹²⁾
- Chest X-Ray
- Electrocardiogram (ECG)
- Evaluation for coronary artery disease, as suggested by the American College of Physicians⁽¹³⁾
- Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association⁽¹⁴⁾

6. Suggested Liver-specific Testing

- Hepatic function panel
- ANA
- Ceruloplasmin
- Iron, Iron Binding Capacity, ferritin
- Alpha 1 antitrypsin level and phenotype⁽¹⁵⁾
- Smooth Muscle Antibody
- Anti Mitochondrial Antibody

7. Immunological Testing

- ABO blood group typing as per OPTN/UNOS Policies for ABO confirmation

8. Suggested 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

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.^(17,18) 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:^(2,19)

- 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:

Screening tests are 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:⁽²⁰⁾

- CMV (Cytomegalovirus);
- HIV 1, 2 (Human Immunodeficiency Virus);

- 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

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
- Tuberculosis
- HTLV-1/2
- Additional infectious diseases endemic to certain geographic areas

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

IV. Possible Exclusion Criteria

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

- 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;
- 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);
- Vascular or biliary abnormalities in the donor liver that make the likelihood of successful transplantation low or increase the risk in the potential donor;
- Hepatitis C virus infection;
- Fatty liver disease (>20% steatosis);

- Asymptomatic ZZ, Z-null, null-null and S-null alpha 1 antitrypsin genotype; those with low Alpha 1 antitrypsin levels may have untype-able phenotypes and may be excluded.
- Multiple or complex upper abdominal surgeries;
- Recipient graft to body weight ratio (GBWR) < 0.8; or,
- Donor remnant volume less than 30% of native liver volume.

Living Donor Follow-up

The living donor organ recipient's transplant center is required to submit information to OTPN Contractor about the status of each living donor for a minimum of two years. 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 to assist transplant centers with the development of their center-specific medical evaluation protocols. This resource will not be used 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 with testing performed as would be appropriate for health maintenance and follow up of the donor according to the Recommendations from the United States Preventative Services Task Force (<http://www.ahrq.gov/clinic/pocketgd.htm>) and are in compliance with applicable reporting requirements.

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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4. Status of Living Donor Follow-up

One of the Committee's goals for the past several years has been to evaluate available living donor data and establish performance metrics for living donor transplant programs. The Committee began to address this work by comparing the variables on the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms that could be considered to monitor change in living donor health between donation and follow-up. Unfortunately, metrics were not identified because the data submitted on LDF forms was too inconsistent for comparison and analysis.

The Committee continues to be concerned with the number of living donors designated as "lost to follow-up" on LDF forms. During a review of such forms, the Committee noted that many forms were incomplete, contained suspicious data, and listed many living donors as "lost to follow up." The Committee discussed methods to improve living donor data submission and identified several potential changes to the LDR form and LDF as an important first step in improving overall living donor data collection.

The Committee recommended adding one new data element to the LDF form and three new data elements to the LDR form, which would document important information, including:

- New options for living donor status on the LDF will be:
 - (1) Living: Donor seen at transplant center;
 - (2) Living: Donor status updated by phone or email correspondence between transplant center and donor;
 - (3) Living: Donor status updated by other health care facility;
 - (4) Living: Donor status updated by transplant recipient
 - (5) Living: Donor contacted, declined follow up with transplant center;
 - (6) Dead;
 - (7) Lost: No attempt to contact donor; and
 - (8) Lost: Unable to contact donor (document)

If item 8 (Lost: Unable to contact donor) is selected, the transplant center will be asked to document their efforts to contact the donor.

- Changes to the LDR form will provide:
 - (1) the date of and the living donor's status during the most recent contact between the donor and the recipient transplant center; and
 - (2) whether living donor organ recovery and transplant of that organ occurred at the same center

In June, 2007, the Board of Directors approved changes to the LDR and LDF forms for implementation pending OMB approval of revisions to the forms. The new forms went into effect on March 31, 2008.

The Committee sponsored new Bylaws which required transplant centers to disclose they are required, at a minimum, to submit LDF forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. Under these Bylaws, transplant centers must have written protocols with a plan to collect information about each donor. The Board approved these Bylaws during its September 2007 meeting.

On July 22, 2008, the Committee Chair gave a presentation to the Membership and Professional Standards Committee (MPSC) on the current status of living donor follow-up. That presentation explained that the Committee's review of LDF forms revealed a large number of programs reported their donors as "lost to follow-up" when it is uncertain if realistic measures were taken to contact donors in this effort. Additionally, this Committee's review found that completing a single data element on the form enabled a center to meet requirements for completion of the form. However, submitting forms with such inadequate information is of limited value in our desire to collect data on short term follow-up after surgery and in counseling those individuals who seek our knowledge as to the risks of donation on their long term health.

The Committee believes the problem of categorizing living donors as "lost to follow-up" must be addressed especially in this important period in transplantation when the public and the media seek data on the safety of living donation. Often, untoward outcomes are reported without sufficient advice from the transplant community. Without accurate and comprehensive living donor follow-up data, it will challenge to answer questions and quell concerns. The presentation concluded with a request to the MPSC to:

- Determine a minimum threshold for categorizing living donors as "lost to follow-up" on LDF forms;
- Ensure 6 month, one -year and two-year LDF forms are submitted at appropriate times; and
- Commit to annual review of LD follow-up.

The MPSC agreed to study the issue through the formation of a joint workgroup with the Living Donor Committee. The MPSC Living Donor Workgroup on Data Submission Issues met for its first conference call on September 30, 2008. The workgroup agreed that as currently collected, the OPTN/UNOS data are incomplete beyond the point when the discharge form is submitted (up to 6 weeks post donation) and therefore not useful for research or making conclusions about living donor safety. Final recommendations of the workgroup were issued in January 2009, and reviewed by the Committee during its February 23, 2009, meeting. Final recommendations of the workgroup included the following:

- Enforce a minimum standard for submission of complete LDF forms (75%, to increase over time)
 - A definition for "completion" will need to be determined.
- Require as prescribed in existing policies, that LDF forms must be submitted at 6 months, one-year and two years post donation, and that the forms may not be submitted earlier than 60 days before any of these post-donation intervals.
- Investigate any living donor transplant program that categorizes more than 10 percent of its donors as "lost to follow-up."
 - Require that such programs develop and submit an action plan to achieve complete and timely submission of 75% of required LDF forms.
- State that a lack of additional funding specific to living donor follow-up is not an acceptable excuse for failing to complete the follow-up forms. Centers should consider

- living donor follow-up as a mandatory component of the recovery and/or transplant of living donors
- Support educational efforts to improve living donor follow-up data submission.
- Support the concept that completion of LDF forms and categorizing donors “as lost to follow-up” will become a metric for evaluating living donor programs at some point in the future

The document titled the LD/MPSC Workgroup Report to the MPSC is available (Exhibit D). After finalization of the report, the Committee elected to delay any further action until after the Living Donor Data Task Force (LDDTF) made its final recommendations to the Board which was planned to occur in February 2009.

The Board did not receive final recommendation of the LDDTF until its June 2009 meeting. Final recommendations of the LDDTF follow:

1. As currently collected, the OPTN/UNOS data are incomplete beyond the point when the discharge form is submitted (up to 6 weeks post donation) and therefore useless for research or making conclusions about living donor safety.
2. There exists strong support:
 - a. for using the OPTN/UNOS data supplemented by data from the SSDMF and NDI as the mechanism for tracking short- and long-term deaths.
 - b. for required center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration depending on whether funding is made available to the centers.
 - c. for development of a self-reporting mechanism for donors of a longer duration than that required of centers.
3. Uniform support for utilizing both OPTN/UNOS and non-OPTN/UNOS sources of data to determine donor risk for the purpose of generating accurate informed consent regarding medical and QoL issues.
4. Some support for a requirement for center-specific reporting of deaths and major complications.
5. Suggestions to investigate existing registries (LODN, LDAP) to determine how the OPTN could partner with and/or promote their efforts.

As an additional step toward improving the data submitted on LDF forms, the Committee arranged for a letter (EXHIBIT E) from the OPTN/UNOS President, to be sent to the primary transplant administrator of each living donor kidney and liver program. These letters were distributed (electronically) on February 17, 2009, and explained that the LDR forms and LDF forms are necessary to gather data about the short-term health of living donors. The letter stressed the need to collectively improve the completeness of these forms so that we can make meaningful analyses based on these data and objectively study the short-term effects of living donation.

The letter further reported that data on living donors who donated in 2006 and 2007 show that a large number of programs report many of their donors as “lost to follow- up,” and that Living Donor Committee would be taking steps to address the problem of categorizing living donors as “lost to follow-up” when they may not truly be lost. The Living Donor Committee believes that improved data collection is especially important during the current climate where the public and the media seek data on the safety of living donation. The Committee opines that without accurate and comprehensive living donor follow-up data, we will not be challenged to answer questions and address concerns.

Additionally, the letter reported center-specific data on submission of living donor follow-up compared to the national median. Specifically, the letter reported:

- The percentage of each program’s expected LDF forms submitted and validated within three month of the expected date.
- The percentage of LDF forms submitted and validated within six months of the expected date.
- The percentage of programs with who donors who have a validated one-year LDF form with a known patient status (dead or alive) at least 300 days post donation.
- The percentage of living donor who have a numerical serum creatinine (or bilirubin for liver donors) on a validated one-year LDF form with a known patient status (alive or dead) at least 300 days post donation.

The letter explained that the Membership and Professionals Standards Committee and Living Donor Committee were working jointly to:

- Establish a threshold percentage for categorizing living donors as “lost” on the LDF form
- Improve the submission of 6 month, one-year and two-year LDF forms at appropriate times
- Increase the number of required data elements that may need to be provided before LDF forms will be accepted through Tiedi®

Lastly, the letter announced that UNOS is hosting a national conference call with a visual portion of the meeting that can be accessed through Microsoft LiveMeeting. This event was intended to offer the transplant community guidance on how to accomplish better living donor data collection through the exchange of information and best practices.

The Webinar titled “Improving Living Donor Follow-up” was provided for the transplant community on March 24, 2009. OPTN/UNOS President at that time, Dr. Robert Higgins, opened the presentation attended by 190 participants. Dr. Matthew Cooper, Chair of the Committee and others presented information on the current status of living donor follow-up.

The Webinar also included presentations from four living donor programs (Swedish Medical Center, Henrico Doctors Hospital, the University of Wisconsin, and St. Joseph's Hospital) identified as having achieved high levels of living donor follow-up in the country. These programs were asked to share their strategies for successful follow-up with Webinar participants.

On May 18, 2009, the Committee heard a report on the success of the Webinar, and the Committee opined that it should continue to develop and offer educational initiatives to improve living donor follow-up in the future.

LIVING DONOR COMMITTEE	MONTH	OCTOBER	FEBRUARY
	DAY	6	23
		In Person	In Person
NAME	POSITION		
Matthew Cooper MD	Chair	x	x
Connie Davis MD	Vice Chair	x	x
Stefan Tullius MD, PhD	Regional Rep.	x	x
Burckhardt Ringe MD	Regional Rep.	x	x
Winston Hewitt MD	Regional Rep.	on phone	x
Nicolas Jabbour MD	Regional Rep.	x	x
Suzanne Fitzpatrick	Regional Rep.	x	x
Regina Klein RN, CCTC	Regional Rep.	x	x
Kay Catherine Kosberg RN	Regional Rep.	x	x
Warren Kortz MD	Regional Rep.	x	x
Dianne LaPointe Rudow Dr NP, CCTC	Regional Rep.	x	x
Shawn Pelletier M.D.	Regional Rep.	x	x
Sharon Alcorn RN	Regional Rep.	x	x
Mark Barr MD	At Large	x	x
Suzanne Lane Conrad RN, MS	At Large	x	x
Anne Courcier	At Large	x	x
Mary Amanda Dew Ph.D.	At Large	x	x
Oliver Hale	At Large	x	x
Andrew Klein MD, MBA	At Large	x	x
Mary Mason MSW	At Large	x	x
Alicia Munoz	At Large		
Stephanie Musselman DPT	At Large	x	x
Miguel Pineda	At Large	x	x
Agrippa Williams	At Large	x	x
Jane Zill LICSW	At Large	x	x
Michelle Desler M.S.	BOD - Liaison	x	x
Pam Gillette MPH, RN	At Large	x	x
Robert Brown Jr., MD, MPH	Ex. Officio	x	x
Bernard Kozlovsky MD, MS	Ex Officio	x	x
Valarie Ashby	SRTR Liaison		on phone
John Magee MD	SRTR Liaison	on phone	on phone
John Wolfe	SRTR	x	
Lee Bolton	Committee Liaison	x	x
Jennifer Wainright Ph.D.	Support Staff	x	x

LIVING DONOR COMMITTEE	MONTH		SEPTEMBER	OCTOBER
	DAY		21	14
	FORMAT (select)		In Person	Live Meeting
NAME	POSITION			
Matthew Cooper MD	Chair		x	
Connie Davis MD	Vice Chair		x	x
Ronald Perrone, MD	Regional Rep.		x	
Joseph Melancon, MD	Regional Rep.		x	
Karyn Hanley, RN, CCTC	Regional Rep.			
Nicolas Jabbour MD	Regional Rep.		x	x
Suzanne McGuire, RN, BSN, CCTC	Regional Rep.		x	x
Regina Klein RN, CCTC	Regional Rep.		x	x
Eugenia Steffens, RN, BS, CCTC, CNN	Regional Rep.		x	x
Christie Thomas, MBBS	Regional Rep.		x	x
Paul Gaglio, MD	Regional Rep.		x	
Tim Taber, MD	Regional Rep.		x	
Sharon Alcorn, RN, BSN	Regional Rep.		x	
Mark Barr MD	At Large		x	
Suzanne Lane Conrad RN, MS	At Large		x	x
Catherine Cullen	At Large		x	x
Mary Amanda Dew Ph.D.	At Large		x	x
Cynthia Forland	At Large		x	x
Oliver Hale	At Large		x	
David Hulme	At Large		x	
Andrew Klien, MD, MBA	At Large		x	x
Jerry Lee	At Large		x	
Stephanie Musselman, DPT	At Large		x	
Christina Pippin	At Large		x	x
Helen Sumut	At Large		x	
Amy Waterman, Phd	At Large		x	
Vicky Young, PhD	At Large		x	
Michelle Desler M.S.	BOD - Liaison		x	
Pam Gillette MPH, RN	At Large		x	
Mesmin Germain, MBA MPH	HRSA			
Bernard Kozlovsky MD, MS	HRSA		x	x
Valarie Ashby	SRTR Liaison			
John Magee MD	SRTR Liaison		x	x
Lee Bolton	Committee Liaison		x	x
Jennifer Wainright Ph.D.	Support Staff			