

OPTN/UNOS Living Donor Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, VA

Summary

Action Items for Board Consideration

- The Board of Directors is asked to approve a proposal to amend the Bylaws to require transplant programs disclose it is unlawful to buy or sell human organs. Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Liver Transplantation. (Item 1, Page 3)

Other Significant Items

- The Committee continues its effort improve data submitted on living donor follow-up forms. (Item 2, Page 7)
- The Committee discussed plans for the Joint Society Policy Steering Group (Item 3, Page 10)
- The Committee considered several issues for future policy development. (Item 4, Page 11)
- The Committee reviewed the current status of organ transport and considered if new rules for the transport of living donor organ may be needed. (Item 5, Page 11)

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

**Richmond, VA
June 21-22, 2009**

**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 meeting held on May 17, 2010:

1. Proposal to Add a Valuable Consideration Disclosure to the Bylaws. Affected Bylaws: Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplantation

In 1984, the National Organ Transplant Act (NOTA), was enacted, which prohibits the sale or purchase of human organs in the United States. Violations are punishable by five years in prison and up to a \$50,000 fine.

Today, the disparity between demand for and the supply of organs available for transplantation continues to grow. The plight of those awaiting potentially lifesaving organ transplants is a probable contributing factor in a recent and highly publicized case of the allegedly illegal sale and purchase of living donor organs.

For the first time since NOTA was enacted, federal authorities charged an individual with violating the federal law prohibiting the sale or purchase of human organs in July 2009. Publicized reports state that the accused offered to obtain a living unrelated kidney from a donor in another country for \$160,000.

Upon notification of this case, the Living Donor Committee questioned if actions could be taken to limit or prevent the illegal sale and purchase of living donor organs in the future. Committee members opined that existing bylaws for kidney and liver transplant programs performing living donor transplantation should be modified to require centers to document that potential living organ donors are informed that the sale or purchase of human organs is a federal crime. Human organs are the kidney, liver, heart, lung, and pancreas, as defined in the OPTN Final Rule.

In September 2007, the Board of Directors modified the Bylaws to establish additional minimum criteria for granting designated program status to transplant programs that perform living donor liver transplants. The intent of these additional Bylaws was to require that transplant programs had essential elements in place for the evaluation, consent, and follow-up of living donors.

The new 2007 Bylaws required that transplant centers develop and, once developed, comply with written protocols for the informed consent and medical evaluation of potential living donors. Some of the elements required for consent protocols included disclosing the medical, psychological and financial risk associated with living donation; disclosing that the donor has the right to opt out of the donation process at any time; and the disclosure that the transplant center is required to submit follow-up forms on each living donor at 6 months, one-year and two-years post donation.

The Committee considered several ways to address the issue of valuable consideration for living donor organs. One option is to add a disclosure element in the bylaws that would require transplant centers to document that potential living donors understand that the purchase or sale of human organs is illegal. A second option would be to require that potential living donors attest that they are not participating in the sale or purchase of human organs. A third potential approach would be to add a requirement that the transplant center have both the potential living donor and candidate attest that they are not participating in the sale or purchase of human organs. The Committee and UNOS staff decided that the second and third options require more analyses and input from the transplant community before they can be considered.

The Committee recommended that the consent requirements in the bylaws be modified to require transplant centers disclose that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation.

This proposal was released for public comment between November 13, 2009, and February 5, 2010. The Committee considered all public comments received on the proposal at its May 17, 2010, meeting. Overall, there was strong public, regional, and other committee support for the proposal (**Exhibit A**). In public comment, many respondents were concerned with the requirement to document the potential donor “understands” that the sale or purchase of human organs is a federal crime, and opined it would not be possible to verify understanding. In response, the Committee agreed to remove that requirement from the proposal.

Additionally, some respondents were concerned that the proposal did not address organ recipients who may be involved in the purchase of human organs for transplantation. The full text of the proposal explained that the issue of potential recipients involved in the purchase of human organs had been considered by the Committee; however the Committee ultimately decided that any policy proposal involving recipients would need to involve multiple committees and other stakeholders and should not be addressed in this proposal. The Committee requests the Board consider if some other Committee(s) should address the issue of recipients involved in the purchase of living donor organs.

The Committee approved the revised final version to be considered by the Board. Committee vote: 20-4-0

The following proposal is recommended for consideration by the Board.

**** RESOLVED, that modifications to the Bylaw: Appendix B, Attachment I, Section XIII, C (2) (Kidney Transplant Programs that Perform Living Donor Kidney Transplantation) and Appendix B, Attachment I, Section XIII, C (4) (Liver Transplant Programs that Perform Living Donor Liver Transplantation), set forth below, are hereby approved, effective pending distribution of notice:**

Proposed Modification to Bylaws, Appendix B, Attachment I, Section XIII, C (2), Designated Transplant Program Criteria.

XIII. Transplant Programs.

- (1) Kidney Transplant [No Changes]**
- (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants**

a-b (iii) (4) [No Changes]

(iv) Informed Consent. Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. The protocol must include a plan to collect the information about each donor;
- (6) the telephone number that is available for living donors to report Concerns or grievances to the OPTN
- (7) documentation of disclosure by the transplant center program to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.
- (8) documentation that each potential donor understands that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

(3) Liver Transplantation [No Changes]

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a-b (iii) (4) [No Changes]

(iv) Informed Consent. Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. The protocol must include a plan to collect the information about each donor;
- (6) the telephone number that is available for living donors to report Concerns or grievances to the OPTN
- (7) documentation of disclosure by the transplant center program to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.
- (8) documentation that each potential donor understands that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

2. 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 the 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 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 be challenging 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. 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.

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 observations of the LDDTF follow:

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.

- There exists strong support:
 - a. for using the OPTN/UNOS data supplemented by data from the Social Security Death Master File (SSDMF) and the National Death Index (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.
- There is 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 Quality of Life (QoL) issues.
- There is some support for a requirement for center-specific reporting of deaths and major complications.
- The OPTN should 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 provided letters containing center specific data on the status of each program's living donor follow-up annually for the past two years. This year's letter (**EXHIBIT B**) was distributed (electronically) on March 12, 2010, and again explained that the LDR forms and LDF forms are necessary to gather data about the short-term health of living donors. 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. Without accurate and comprehensive living donor follow-up data, we will be challenged to answer questions and address concerns. This year's letter specifically 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 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 donors 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 (**EXHIBIT C**).

The letter invited each living donor program to participate in an electronic survey (**EXHIBIT D**) through which the Committee hoped to learn how centers conduct living donor follow-up, and specifically what obstacles centers encounter in their attempts to obtain follow-up. The letter explained that compiled results from the survey will be reported to the Board, and may help identify issues that could be addressed at the Board level to facilitate and improve living donor follow-up.

The survey was developed in response to the directive from the Board asking the Living Donor Committee to develop and disseminate a document outlining best practices for the submission of living donor follow-up based on its review of high performing programs. Before determining best practices it was necessary to determine common practices for living donor follow-up and to determine the common obstacles centers face in their attempts to obtain follow-up.

Preliminary survey results were reviewed by the full Committee at the May 17, 2010, meeting. The Committee requested further analysis of survey results to include: comparison of the sample to the larger group of all center with a goal of determining if there is any bias in the sample regarding basic center characteristics; determining which basic characteristics should be examined in relation to survey responses; and to analyze the responses to open-ended questions and consider how or if such data should be included in the report to provide further insights into the critical issues. The Committee anticipates writing a manuscript based on survey results for publication. A full report of survey results will be provided to the Board of Directors at the November 2010 meeting.

3. Joint Society Policy Steering Group

During the May 17, 2010 meeting, Walter Graham, UNOS Executive Director spoke with the Committee regarding a new process for incorporating clinical input into developing OPTN policies with the potential to direct or prescribe medical care through a Joint Society Policy Working Group. A synopsis describing why the Work Group was proposed and details on how the Work Group is anticipated to operate was available for Committee members to review prior to the meeting.

It was asked why the Joint Society Working Group was necessary especially in light of the Committee's past efforts to involve the professional societies in policies and resource development, or necessary when members of the ASTS, AST and NATCO are represented on the Committee.

As proposed, the Joint Society Working Group would be permitted to consider any policy proposals under development that may affect clinical practice, and questions were raised regarding how clinical practice would be defined. The Committee discussed how the Joint Society Working Group may create delays in the development of living donation policies, and whether or not the working group would be permitted to consider proposals in late stages of development. Mr. Graham and HRSA representatives at the meeting responded to all questions from Committee members.

4. Living Donation Policy Development

Also during its recent meeting, the Committee reviewed several policy proposals under development. The first proposal considered would clarify which transplant program is responsible for living donor follow-up and clarify which transplant program is required to fulfill elements of

the Bylaws that address living donation. After discussion, the Committee voted to finalize a proposal for fall public comment. Vote: 23-0-0

A second proposal under consideration would set minimum thresholds for the submission and completion of living donor follow-up reporting. Some committee members were uncomfortable with advancing this proposal until a definition for “completion” is better defined. The Committee recommended that the proposal needs further consideration.

The Committee was asked to consider if required living donor follow-up should be changed from 6, 12, and 24 months post donation to 3, 12, and 24 months post donation. This change is proposed because if the first required follow-up occurs at 3 months that follow-up visit would be covered under the recipient’s insurance. The Committee endorsed developing a proposal for fall public comment: Vote: 22-1-0

The Committee was asked to consider if the generation date of living donor follow-up forms should be changed so the forms are available prior the donation anniversary date. As proposed the follow-up form would generate at 10 and 22 months post donations instead of on the one and two year post donation anniversary date. The Committee endorsed developing a proposal for fall public comment. Vote: 23-0-0

Under current programming, if a center categorizes a donor as “lost to follow-up” no future follow-up forms are generated. The Committee discussed changing existing programming to have follow-up forms generate for all living donors at required follow-up intervals. The Committee endorsed developing a proposal for fall public comment. Vote: 23-0-0

5. Transport of Living Donor Organs

The Committee heard a presentation on organ transportation failures and delays. After discussion, the Committee agreed that new policies for the transport of living donor organs may need to be developed. A subcommittee will be assigned to consider the issue and to prepare recommendations for the full Committee.

LIVING DONOR COMMITTEE	MONTH	May
	DAY	17
	FORMAT (select)	In Person
NAME	POSITION	
Matthew Cooper MD	Chair	x
Connie Davis MD	Vice Chair	x
Ronald Perrone, MD	Regional Rep.	x
Joseph Melancon, MD	Regional Rep.	x
Karyn Hanley, RN, CCTC	Regional Rep.	x
Nicolas Jabbour MD	Regional Rep.	x
Suzanne McGuire, RN, BSN, CCTC	Regional Rep.	x
Regina Klein RN, CCTC	Regional Rep.	x
Eugenia Steffens, RN, BS, CCTC, CNN	Regional Rep.	x
Christie Thomas, MBBS	Regional Rep.	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	By phone
Catherine Cullen	At Large	x
Mary Amanda Dew Ph.D.	At Large	x
Cynthia Forland	At Large	x
Oliver Hale	At Large	
David Hulme	At Large	x
Andrew Klein, MD, MBA	At Large	By phone
Jerry Lee	At Large	x
Stephanie Musselman, DPT	At Large	x
Christina Pippin	At Large	x
Helen Smunt	At Large	x
Amy Waterman, Phd	At Large	x
Vicky Young, PhD	At Large	By phone
Michelle Desler M.S.	BOD - Liaison	x
Pam Gillette MPH, RN	At Large	x
Bernard Kozlovsky MD, MS	HRSA	x
Chris McLaughlin	HRSA	x
John Magee MD	SRTR Liaison	By phone
Walter Graham	UNOS Exec Director	x
Lee Bolton	Committee Liaison	x
Jennifer Wainright Ph.D.	Support Staff	x