

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

**Richmond, VA
June 26, 2007**

**Robert S. Brown, Jr. MD, Chairman
Michael Wachs, MD, Vice Chair**

*The following are the OPTN/UNOS Living Donor Committee's recommendations
regarding living donor follow-up to the Board of Directors.*

1. Living Donor Follow-up Period.

Since its October 20, 2006 meeting, the Committee has investigated extending living donor follow-up to two years. Based on those discussions, the Committee proposed and unanimously recommended the following modifications to OPTN/UNOS Policies 7.1.5 and 7.3.2

****RESOLVED, that the following modifications to Policies 7.1.5 and 7.3.2 shall be approved and implemented pending distribution of appropriate notice and programming in UNetsm, if and as applicable:**

7.1 REPORTING DEFINITIONS

7.1.5 The follow-up period for living donors will be a minimum of ~~one~~ two years.

7.3 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT REGISTRATION FORMS AND SUBMISSION OF LIVING DONOR REGISTRATION FORMS

7.3.2 Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Recipient ~~Transplant~~ centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The recipient transplant center must submit LDF forms for each living donor at six months, one year and two years from the date of donation.

Committee Vote: 20 in favor, 0 opposed, 0 abstentions.

This policy modification will fulfill an OPTN contractual obligation to collect information on all living donors at the time of donation and for at least two years after the donation. The Committee is recommending that the two-year Living Donor Follow-up (LDF) form include the same data elements that are currently being collected at one-year post donation. The longer follow-up period will provide valuable information on the experience, safety, and health implications for living donors. Transplant center compliance with living donor follow-up is especially important since no alternative source of data exists.

This additional data collection is in accordance with the OPTN Principle of Data Collection to “ensure patient safety when no alternative sources of data exist.” The “operational statements for data collection” approved by the Board in December 2006, also state that (1) the OPTN will only collect data that is contracted by HRSA, and (2) that data for specific populations (e.g., Living Donors) may constitute exceptions to the Principles of Data Collection. There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement. (Exhibit A)

2. Living Donor Follow-up Forms.

Since its October 20, 2006 meeting, the Committee examined living donor follow-up. During a review of Living Donor Follow-up forms (LDF) 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 Living Donor Registration (LDR) 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:

- attempts to contact a donor classified as “lost to follow-up”;
- the date and the living donor’s status during the most recent contact between the donor and the recipient transplant center; and
- whether living donor organ recovery and transplant of that organ occurred at the same center.

Proposed changes to the LDF and LDR are in accordance with the Principles of Data Collection and operational statements for data collection approved by the Board in December 2006. Expanded and improved living donor follow up will provide valuable information on the peri-operative experience and short-term health and safety implications for living donors. Center compliance in submission of LDR and LDF forms is especially important since no alternate source of data exists (Exhibit B).

****RESOLVED, that changes to the LDF and LDR forms set forth below shall be approved and implemented pending distribution of appropriate notice and programming in UNetsm, if and as applicable:**

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.

Committee Vote: 20 in favor, 0 opposed, 0 abstentions

3. Reporting Adverse Events in Living Donors.

Under current policy, transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the center becomes aware of these events. This proposed policy modification defines living donor "native organ failure" as (1) placing living liver donors on the National Transplant Waitlist and (2) living kidney donors requiring dialysis. This proposal limits the reporting period to five years, which will provide valuable information on the short-term health and safety implications for living donors, while limiting the burden of data submission for transplant centers.

The Board of Directors resolved that transplant centers must immediately report any live donation-related deaths and organ failure that occur within the first six months post-transplantation to the Membership and Professional Standards Committee (MPSC). In response, the Committee proposed a policy that would require immediate reporting of serious adverse events in living donors prior to normal reporting on the Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) forms. The policy was effective pending appropriate notice and simultaneous with public comment, which ended July

2006. The Committee further modified the policy language to clarify that adverse events in living donors would be reported through the UNetSM Patient Safety System. This system became operational in January 2007.

After review of this policy, the MPSC recommended that the Committee further clarify the policy to define organ failure and to limit reporting to five years. The Committee defined “organ failure” as either listing for transplant in liver donors or need for dialysis in renal donors. The Committee agreed to limit the reporting requirement to five years (Exhibit C).

****RESOLVED, that the following modifications to Policy 7.3.3 shall be approved and implemented pending distribution of appropriate notice and programming in UNetsm if and as applicable:**

7.3.3 Submission of Living Donor Death and Organ Failure Data. Transplant programs must report all instances of live donor deaths and failure of the live donor’s native organ function within 72 hours after of the programs ~~knowledge~~ becomes aware of the live donor death or failure of the live donors’ native organ function. Live donors’ native organ failure is defined as listing for transplant for liver donors and the need for dialysis in renal donors. These events will be reported to the MPSC for further review and reporting to the Board. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of five years from the date of the donation. The MPSC will review and report all adverse events to the Board.

Committee Vote: 19 in favor, 1 opposed, 0 abstentions