

At-a-Glance

- **Proposal to Improve the Reporting of Living Donor Status**
- **New Proposed Policy:** 12.8.3.1 (Reporting Requirements)
- **Living Donor Committee**

The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. The transplant community must collectively improve patient information on the LDF form to allow for meaningful analyses to objectively study the short-term effects of living donation. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. **Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months).** Follow-up information on donors is especially important in 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, it will not be possible to answer questions and address concerns.

- **Affected Groups**

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

- **Number of Potential Living Donors Affected**

In 2009, there were 6609 living donors, and the proposed policy has the potential to affect all living donors.

- **Compliance with OPTN Strategic Goals**

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

- Optimize a safe environment for living donor transplantation through improved living donor follow-up reporting
- Improve follow-up reporting through clarification of the policies in order to protect patient safety and preserve the public trust

- **Specific Requests for Comment**

Should living donor transplant programs be required to know and report the status of their living donors for the first two year post donation? Why or why not?

Proposal to Improve the Reporting of Living Donor Status

New Proposed Policy: 12.8.3.1 (Reporting Requirements)

Living Donor Committee

Summary and Goals of the Proposal:

The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. The transplant community must collectively improve patient information on the LDF form to allow for meaningful analyses to objectively study the short-term effects of living donation. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. **Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months).** Follow-up information on donors is especially important in 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, it will not be possible to answer questions and address concerns.

Background and Significance of the Proposal:

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 this work by comparing data on the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms to attempt to assess change in living donor health between donation and follow-up. Unfortunately, these metrics could not be calculated because the data submitted on LDF forms were too incomplete for analysis.

Specifically, the Committee is concerned with the number of living donors who are designated as "lost to follow-up" or whose status (alive or deceased) is not reported on LDF forms submitted at the time points required by OPTN policy. During an early review of such forms, the Committee noted that many forms were incomplete or many living donors were listed as "lost to follow up." To improve living donor data submission, the Committee recommended increasing options for reporting donor status on the LDF form to include:

- (1) Living: Donor seen at transplant center;
- (2) Living: Donor status updated by verbal or written communication between transplant center and donor;
- (3) Living: Donor status updated by other health care facility;
- (4) Living: Donor status updated by other source (example: 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 (if selected the transplant center is required to document their efforts to contact the donor).

In June, 2007, the Board of Directors approved this change to the LDF forms that became effective March 31, 2008.

The Committee sponsored new bylaws which require transplant centers:

- To develop and once developed, comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, preoperative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-year post donation.
- To disclose to prospective living donors that centers are required to submit LDF forms addressing the health information of each living donor at 6 months, one year, and two years after donation, and centers are required to develop a plan to collect the required follow-up information for each donor. Under the bylaws, transplant centers must have written protocols with a plan to collect follow-up information about each donor.

The Board approved these bylaws at its September 2007 meeting. ((ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS, Designated Transplant Program Criteria XIII. Transplant Programs) that require Kidney (and Liver) Transplant Program that Perform Living Donor Kidney (or Liver) Transplants).

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 reasonable measures were taken to contact donors. Additionally, this committee's review found that completing two data elements (status and date of status) on the form enabled a center to meet requirements for completion of the form. The presentation concluded with a request to the MPSC to do the following:

- Determine a minimum threshold for categorizing living donors as "lost to follow-up" on LDF forms;
- Strengthen reporting requirements so that 6 month, one-year, and two-year LDF forms are submitted at appropriate times; and
- Commit to an annual review of the status 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 included the following:

- Enforce a minimum standard for submission of complete LDF forms.
- Require, as prescribed in existing policies, that LDF forms must be submitted at 6 months, one year, and two years after donation, and that the data submitted reports an accurate and up to date donor status.
- Investigate any living donor transplant program that categorizes more than 10 percent of its donors as "lost to follow-up."
- State that the absence of additional funding specific to living donor follow-up is not an acceptable excuse for failing to complete the follow-up forms. Transplant 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 in the future.

In addition and concurrent with the work done by the Living Donor Committee, in June 2007, the OPTN/UNOS Board approved a resolution from the Policy Oversight Committee stating that, “Resolved, that a joint OPTN committee be established to evaluate the use of living donor data.” As a result, the Living Donor Data Task Force (LDDTF) was established in late 2007. The Task Force consisted of 19 members with varied expertise with living donation. Members were involved with:

- OPTN/UNOS Living Donor and Policy Oversight Committees, Kidney Paired Donation Working Group, and Board of Directors;
- ASTS and AST;
- Adult to Adult Living Donor Liver Transplantation Cohort Study (A2All), Renal and Lung Living Donors Evaluation Study (RELIVE), New York Center for Liver Transplantation, Living Donor Organ Network, the National Kidney Foundation; and
- Clinical, Social Work/Psychology, patients, and donors.

The LDDTF was asked to take an objective look at the various needs for living donor follow-up data and to propose an appropriate approach for each need. Final recommendations for consideration by the Board of Directors included the following:

- As currently collected, the OPTN/UNOS data are incomplete beyond the point when the discharge form is submitted (up to 6 weeks post donation, but much earlier for most donors) and therefore useless for research or making conclusions about living donor safety.
- There exists strong support for the following:
 - a. 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. Requiring 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. Developing a self-reporting mechanism for donors of a longer duration than that required of centers.

In addition to the aforementioned activities, for each of the past two years, the Committee sent each living donor transplant program an electronic letter containing data on the status of that program’s living donor follow-up, which reported the following metrics:

- The percentage of 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 (i.e., donors who are not categorized as “lost to follow-up”)

- 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

In November 2009, the Committee reported its continuing efforts towards improving Living Donor Follow-up to the OPTN/UNOS Board. During the meeting, the Board resolved that the Committee should develop a policy proposal to establish a threshold for acceptable submission of living donor follow-up.

During this same meeting, the Board directed the Committee to develop and disseminate a resource outlining best practices for the submission of living donor follow-up based on its review of high performing programs. The Committee has completed work on this resource and is planning to provide the resource to all living donor transplant programs this spring. The resource is intended to for transplant centers' voluntary use. Ideally, it should lead to review, discussion, and the generation of ideas within individual transplant programs as to how best to develop or further tailor their own strategies to promote optimal follow-up of living donors.

The Committee met in September 2010, and reviewed past, current, and planned future activities to improve living donor follow-up. The Committee considered trying to improve living donor follow-up by defining and proposing better enforcement of a "complete" LDF form, specifically defining a complete LDF as any one-year LDF form with a numerical serum creatinine for living kidney donor (or bilirubin for living liver donors) and with a known patient status (alive or dead) at least 300 days post donation. The Committee supports the collection of clinical data on living donors for a minimum of two years. However, the Committee understands that there is a lack of consensus on the value of clinical data on living donors during the early post operative period, and consequently anticipates there would be resistance or opposition to new requirements to obtain and report lab results for living donors for up to two years at this time. As proposed, the policy should lead to more complete although still minimal information on the status of living donors at one and two years post donation. The Committee considers this proposal to be a first step toward improving overall reporting of living donor follow-up.

Also during it September 2010 meeting, the Committee did endorse developing a policy proposal to establish a threshold for the percentage of living donors that any program can categorize as "lost to follow-up" i.e. donor without a valid status (alive or dead) and accurately reported at required post operative internals. The Committee supported establishing a 10% maximum threshold for categorizing donors as "lost to follow-up".

It may be helpful for living donor programs to understand the anticipated timeline for this policy proposal. If this proposal receives favorable public comment, it would not be considered by the OPTN/UNOS Board before November 2011. If the policy proposal is considered and approved by the Board, the policy would be expected to take effect in January 2012. As proposed, the new reporting requirement would only apply to living donors who donate an organ beginning in January 2012. For living donors who donate an organ beginning in January 2012, transplant centers would first be required to report their donor's status (alive or dead) in July 2012, and no center would be out of policy **before September 2012** for not reporting their donor's status.

Supporting Evidence and/or Modeling:

Transplant center compliance with OPTN policies regarding submission of 1 year LDF forms is high (99.5% for kidney donors and 99.1% for liver donors for those who donated between July 1, 2007 and June 30, 2008). Despite these high rates of compliance with OPTN policy, by one year post-donation,

some donors are listed as lost to follow-up or do not have an up-to-date patient status (alive or dead) or clinical lab values included in their follow-up forms.

For the most recent available cohort (those who donated between 7/31/07 and 6/30/08), only 56.4% of kidney donors had a valid status (alive or dead; not lost to follow-up) on their 1 year LDF form with a patient status date within two months of the donation anniversary (see Table 1 for national medians and Figure 1 for data by program), and only 31.4% had a valid serum creatinine lab value on their form. Using the same metrics for the same cohort, 69.6% of liver donors had a valid status (alive or dead; not lost to follow-up) (see Table 1 for national medians and Figure 2 for data by program), and 52.2% had a valid bilirubin lab value on their form.

Table 1. Follow-up of Living Kidney and Liver Donors

For living donors who donated from 7/31/07-6/30/08*	Median for all US Centers
% of living kidney donors who have a validated 1 year LDF form with a known patient status (alive or dead) dated within 2 months of the donation anniversary	61.8%
% of living liver donors who have a validated 1 year Living Donor Follow-up form with a known patient status (alive or dead) dated within 2 months of the donation anniversary	75.0%

*Note: Excludes donors whose organs were recovered at another center.

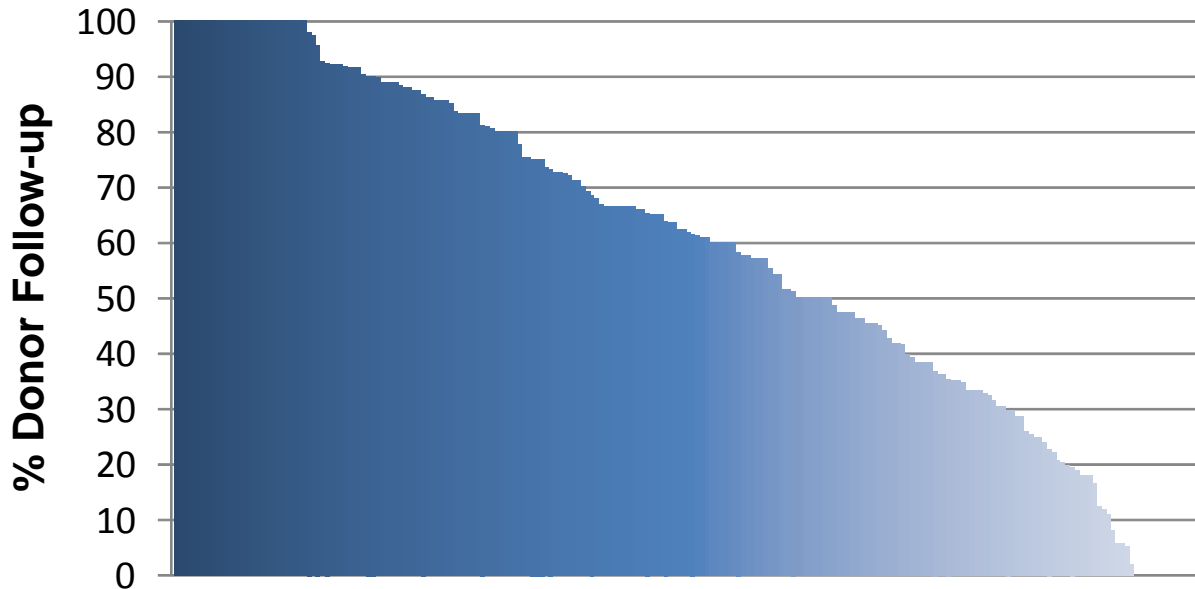


Figure 1. Percent of living kidney donors who have a validated 1 year LDF form with a known patient status (alive or dead, not lost-to-follow-up) dated within 2 months of the donation anniversary, by program

Note: Each bar represents 1 program. Includes living kidney donors who donated between 7/1/07 and 6/30/08. 29 programs achieved 100% follow-up (left side of the graph) while 15 programs had 0% follow-up (blank area on right of graph).

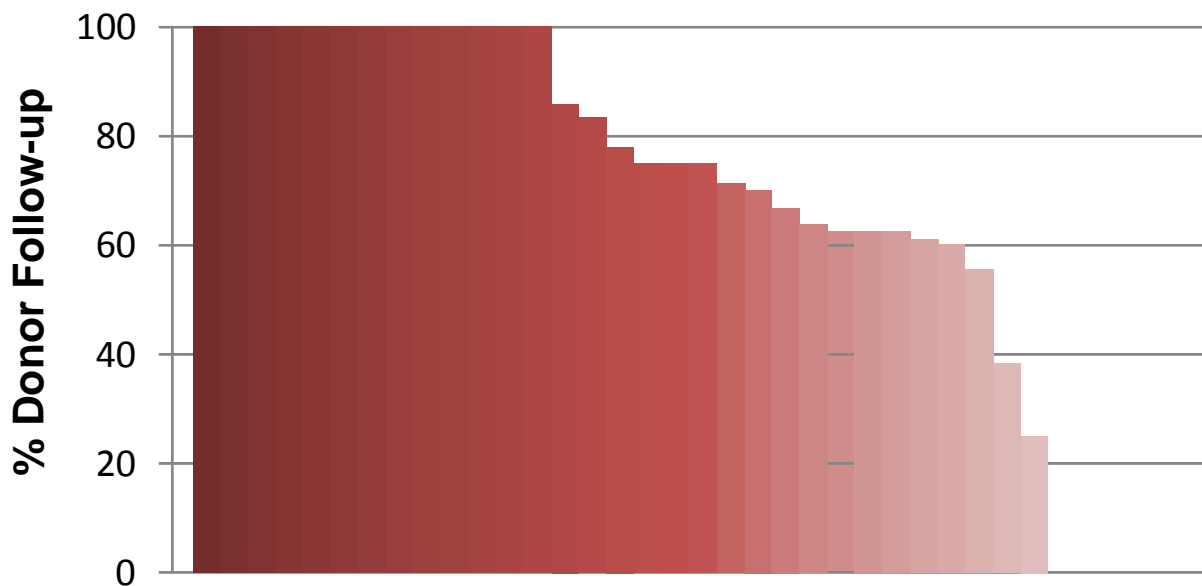


Figure 2. Percent of living liver donors who have a validated 1 year LDF form with a known patient status (alive or dead, not lost-to-follow-up) dated within 2 months of the donation anniversary, by program

Note: Each bar represents 1 program. Includes living liver donors who donated between 7/1/07 and 6/30/08. 14 programs had 100% follow-up (left side of the graph) while 5 programs had 0% follow-up (blank area on right side of graph)

Expected Impact on Living Donors or Living Donation:

Requiring transplant programs that recover living donor organs to report an accurate and current status for at least 90 % of their donors at the required reporting intervals should result in more complete and useful data on living donors.

Expected Impact on Specific Patient Populations:

There should be no impact on the candidate pool. However, the proposal has the potential to affect all living donors. In 2009, there were 6609 living donors.

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

The policy proposal will promote patient safety through improving short term follow-up reporting for living donors.

Plan for Evaluating the Proposal:

- ***What questions or hypotheses are guiding the evaluation of the proposal?***

Will overall required living donor follow-up reporting improve if programs are required to an accurate and current status on 90% of living donors at the required reporting intervals?

- ***Policy Performance Measures:***

The Committee will continue to monitor and/or report the aggregate and/or center specific percentage of living donors categorized as lost to follow-up on an annual basis.

- **Time Line for Evaluation:**

The Committee will monitor the percentage of living donors who are categorized as lost to follow-up or who do not have an accurate and current status at the required reporting intervals on an annual basis.

Additional Data Collection:

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

Expected Implementation Plan:

Transplant hospitals will continue to report living donor follow-up at 6 months, 1 year, and 2 years from the date of donation. The proposal does not require programming in UNetSM.

Communication and Education Plan:

Since this proposal does not require a significant behavioral change on the part of transplant center professionals and no programming changes are involved, we will employ our standard communication methods.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Relevant staff at transplant centers (emphasis on living donor programs)	e-newsletter/member archive	30 days after the board votes to approve the policy change.
System notice	Relevant staff at transplant centers (emphasis on living donor programs)	e-mail	30 days before policy is implemented and again on the day of implementation.
Blurb in e-newsletter about letters from the living donor committee mailed to the tx admins containing their follow-up form stats.	All relevant staff at transplant centers.	e-newsletter and accessing URL of member archive	March issue of the e-newsletter
Feature article in the UNOS Update highlighting centers effective at submitting living donor follow-up forms.	All relevant staff at transplant centers	Print copy by U.S. Mail and Update section of UNOS website.	March/April issue of UNOS Update
Blurb on TX administrators listserv.	Transplant Administrators	Electronic list serv	Post implementation of policy change.

Monitoring and Evaluation:

The UNOS Research Department will run the following semi-annual reports for the Living Donor Committee, starting 14 months after implementation of this policy. The cohort for these reports will include only living donors who donated after implementation of the policy. The first report will be generated 14 months after implementation so that analyses can include the cohort of donors who donated in the first 6 months after implementation and have reached the 6 month anniversary of their donation. An additional two months (for a total of 14 months) are required before generation of the report to allow for the 60 day time window for status dates.

- The number and percent of each program's living donors who do not have a valid patient status (alive or dead) and/or have a patient status that is not dated within 60 days of the donation anniversary.
- Discrepancies between reported living donor patient status fields (alive or dead) and deaths reported on the Social Security Death Master File

To evaluate overall member compliance levels with this policy over time, the Living Donor Committee will review blinded center data for all centers.

Policy or Bylaw Proposal:

12.8.3 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. [No Change]

12.8.3.1

Transplant centers that recover living donor organs must report an accurate and timely patient status (alive or dead) for at least 90 % of their living donors at the required reporting intervals (6 months, 1 year, and 2 years post-donation). Living donor information collected within 60 days of the six-month, one year, and two year anniversary of donation is considered timely.