

Living Donor Committee Update

Connie Davis, MD
Chair

Board Meeting
June 28-29, 2011

Evaluation of OPTN Living Donor Data

The LD Committee continues to evaluate available living donor data in an attempt to establish performance metrics for living donor transplant programs.

However, no performance metrics have been developed because the data submitted on Living Donor Follow-up (LDF) forms are too incomplete for analysis.

Why Do We Need Living Donor Data?

Pre-Donation Issues

- Demographics - who becomes a living donor
- Health status and medical screening of donors

Living donation involves risk – helps quantify short term risk

- Peri-operative complications
- Post-donation adverse events

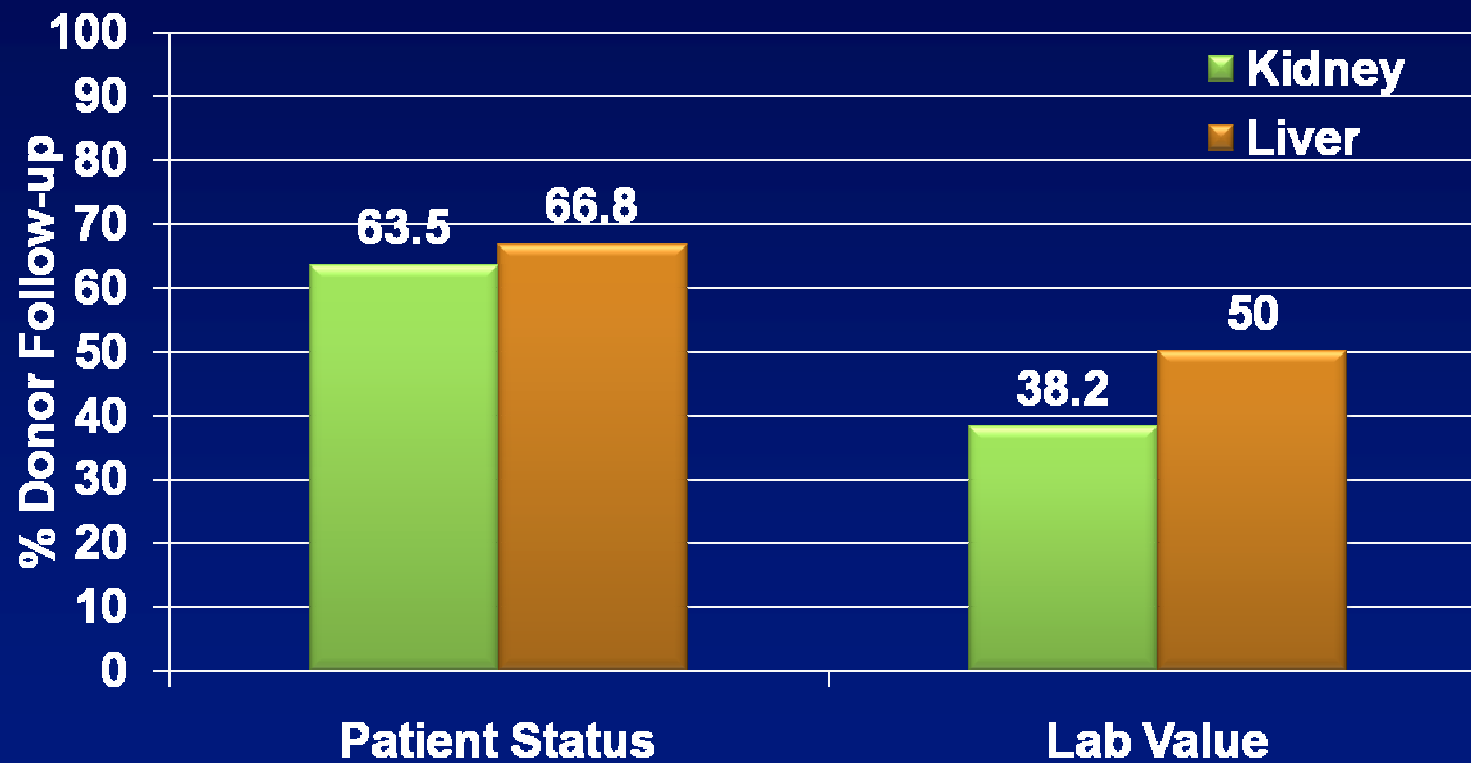
Reducing risk and quality improvement

Programs Notified Regarding the Status of their F/U

In each of the past three years, the Committee has provided 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:

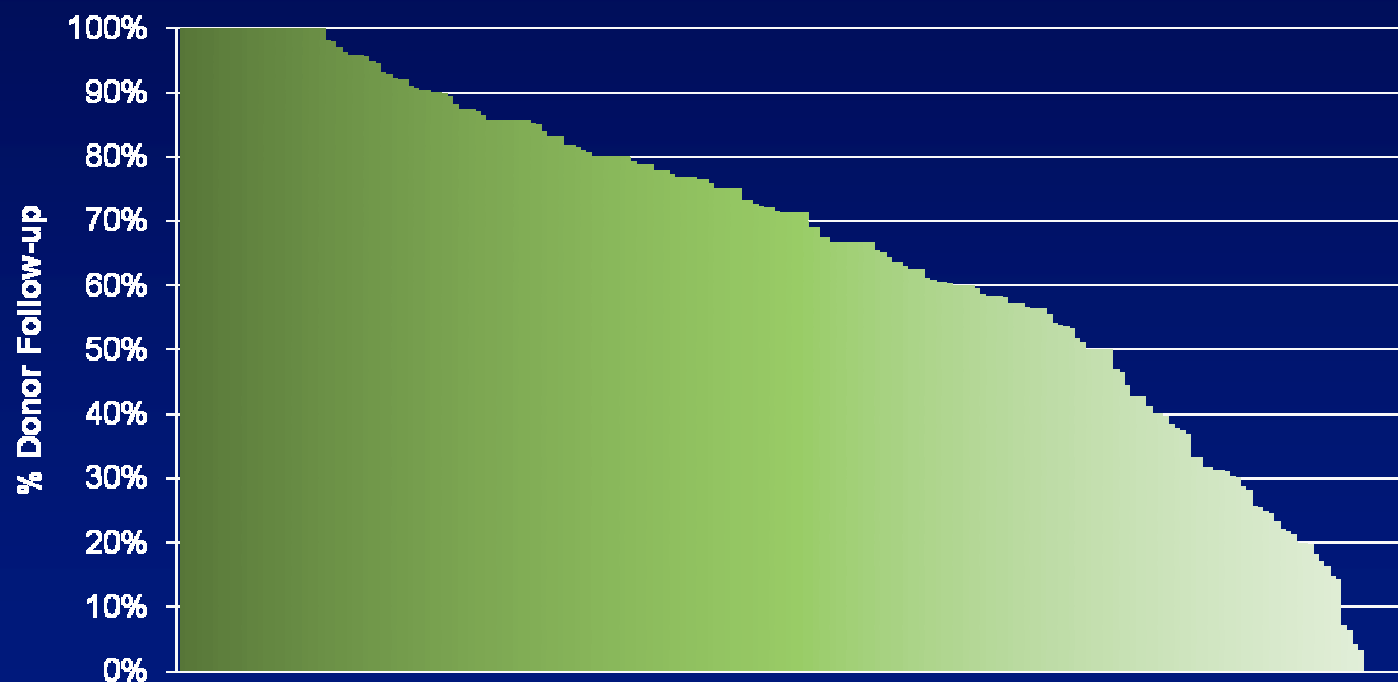
- % of living donors who have a 1 year LDF form with a known patient status (alive or dead; NOT lost-to-follow-up) dated within 2 months of the 1 year anniversary of the donation (10-14 months post-donation)
- % of living kidney donors who have a numerical serum creatinine / bilirubin value on a 1 year LDF form with a known patient status (alive or dead; NOT lost-to-follow-up) dated within 2 months of the 1 year anniversary of the donation (10-14 months post-donation)

Percent of Living Kidney and Liver Donors who have a Validated 1 Year LDF Form with Lab Values or a Known Patient Status (Alive or Dead, Not Lost-to-Follow-up) Dated within 2 Months of the Donation Anniversary – National Numbers



Cohort : July 1, 2008 – June 30, 2009

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 Center

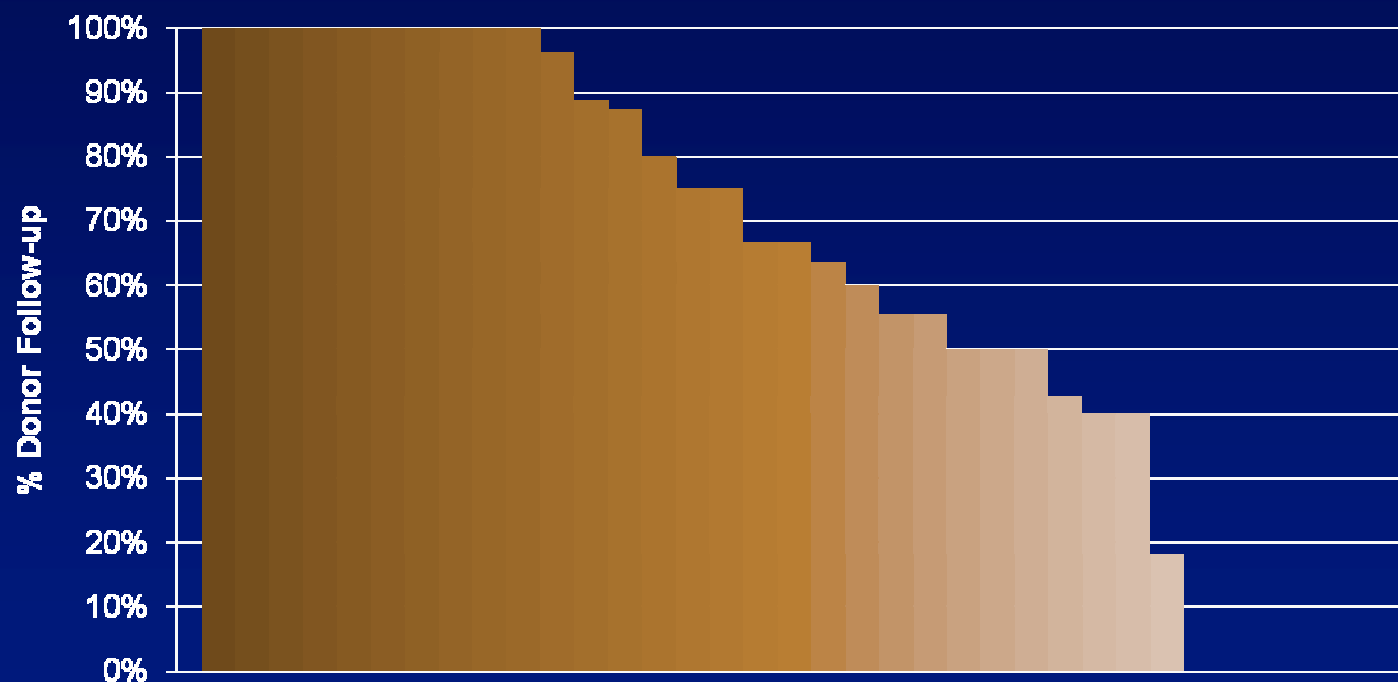


Note: Each bar represents 1 center. Includes living kidney donors who donated between 7/1/08 and 6/30/09. 26 centers reported status for 100% of their donors. 8 centers (blank area on right side of graph) reported status for 0% of their donors.

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Percent of Living Liver Donors who have a Validated 1 Year LDF Form with a Patient Status (Alive or Dead, Not Lost-to-Follow-up) Dated within 2 Months of the Donation Anniversary by Center



Note: Each bar represents 1 center. Includes living liver donors who donated between 7/1/08 and 6/30/09. 10 centers reported status for 100% of their donors. 6 centers (blank area on right side of graph) reported status for 0% of their donors.

Establishing a Threshold for Submission of Living Donor Follow-up

In November 2009, the OPTN/UNOS Board resolved that the LD Committee should develop a policy proposal to establish a threshold for acceptable submission of living donor follow-up.

Such a proposal is currently out for public comment and may be considered by the Board in November.

Establishing a Threshold for Submission of Living Donor Follow-up

The Board directed the LD 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 made it available to all living donor programs in March, and it is available on the OPTN website.

<http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=7>

Living Donor Committee Action Items

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Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy.

Modifications to Policy 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D(2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants; UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver Transplants Recovery

Living Donor Committee

Membership and Professional Standards Committee

Joint Work Group Review of the Bylaws

- A work group (with representatives from the Living Donor, Membership and Professional Standards, Liver, Kidney, Transplant Administrators and Transplant Coordinators Committees) was charged with clarifying which hospital is responsible for pre- and post-donation living donor-related activities when:
 - Donation takes place in one institution and the transplant in another; or
 - The donor participates in paired donation at a hospital geographically removed from his or her local transplant hospital.

Joint Work Group Review of the Bylaws

- The work group determined that the recovery hospital should be the entity responsible for the completion of the living donor evaluation, including the provision of the independent donor advocate. Any testing performed at another hospital should be considered preliminary screenings and done to avoid inconveniencing the donor. The decision on the suitability of the living donor is the responsibility of the hospital that performs surgery on that donor. Therefore, the evaluating hospital and the recovery hospital are in essence the same hospital.

Joint Work Group Review of the Bylaws

- The work group proposed that the recovery hospital be the hospital that is responsible for the living donation process, which includes consent, medical and psychological evaluation, perioperative, and follow-up reporting.

Public Comment Response Tally

Type	Response Total	In Favor	In Favor As Amended	Opposed	No Comment
Individual Comments	46	91.3%	0	6.52%	1
Regional Comments	11	100%	0	0%	0
Committee Comments	7	100%	0	0%	0

Board Consideration

- On March 10, 2012, the results of public comment were reported to the MPSC.
- The MPSC was informed that the LD Committee would likely recommend the proposal be considered by the BOD without modification.
- The Living Donor Committee reviewed the results of public comment during its April 3-4, 2011 meeting, and supported sending the proposal for consideration by the Board without modification.

Policy Proposal

7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNetSM, beginning January 1, 2003.

All OPOs are responsible for submission of patient level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms.

Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory.

Policy Proposal

7.0 DATA SUBMISSION REQUIREMENTS (cont)

Recipient transplant centers are responsible for submission of Recipient Feedback information, ~~Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms,~~ Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, or transplanted ~~or followed~~ at the center.

Transplant centers that recover living donor organs are responsible for submitting Living Donor feedback information, Living Donor Registration Forms, and Living Donor Follow-up Forms for each living donor whose organ was recovered at that center within the time frame established in Policy 12.8.3 or who is being followed at that center. The transplant center that intends to recover the living donor organ is responsible for generating the Donor ID and reporting whether the recovery procedure occurred.

Policy Proposal

- Policy 12.6 Center Acceptance of Living Donor Organs.

Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals that are approved to perform living donor recovery for that organ. If the OPTN does not have approval criteria for a living donor recovery hospital associated with a particular organ (e.g., lung, heart, intestine, or pancreas), then Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals that have an approved transplant program for that organ.

Policy Proposal

■ 12.8 Reporting Requirement

Reporting Requirement. Refer to Policy 7.0 (Data Submission Requirements) for the member that is responsible for submitting living donor forms.

12.8.1 to 12.8.3 No Change..

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 that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or ~~by~~ within six weeks following the transplant date, whichever is first. ~~The recipient~~ Transplant centers that recover living donor organs must submit LDR forms for each living donor at six months, one year and two years from the date of donation.

Existing Bylaws – Proposed Changes

- Please refer to the public comment document (pages 43 -51) to review all proposed changes to the bylaws.

Bylaw Proposal

- UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney ~~Transplants~~ Recovery: Kidney transplant programs that perform living donor kidney ~~transplants~~ recovery (“kidney recovery hospital”) must demonstrate the following:
 - Under the proposal, all references to “Kidney transplant programs that perform living kidney transplants”, “center”, and or “transplant program” are changed to read kidney recovery hospital(s)

Bylaw Proposal

- UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver ~~Transplants~~ Recovery: Liver transplant programs that perform living donor liver recovery (“liver recovery hospital”) must demonstrate the following:
- Under the proposal, all references to “Liver transplant programs that perform living liver transplants”, “center”, and or “transplant program” are changed to read liver recovery hospital(s)

DONATE



LIFE

OPTN

UNOS **DONATE**
LIFE