

**OPTN/UNOS Living Donor Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, GA**

**Mary Amanda Dew, PhD, Chair
Krista Lentine, MD, PhD, Vice Chair**

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This report reflects the work of the OPTN/UNOS Living Donor Committee between September 2014 and April 2015.

Action Items

1. Proposal to Improve UNetsm Reporting of Aborted Procedures and Non-Transplanted Organs

Public Comment: January 27 – March 27 2015

Under the current reporting system using the Living Donor Feedback (LDF) form there is a potential for recovery hospitals to underreport aborted living donor recovery procedures and living donors whose organs are recovered but are not ultimately transplanted.

Current OPTN/UNOS policy requires living donor recovery programs to register a living donor using the LDF form prior to the donor organ recovery procedure. The LDF form requires the transplant program to enter a response to the question “Aborted procedure after donor received anesthesia?” before the form can be successfully submitted. Options for responding to this required question include “Yes,” “No” or “N/A.” A message on the form instructs the user to select “N/A” to complete the form prior to surgery and to modify the form to “Yes” or “No” after surgery. However, OPTN policy does not specifically require the transplant program to update the response post operatively.

Additionally, Policy 18.5.D (Reporting of Non-transplanted Living Donor Organs) requires members to report whenever a living donor organ is recovered but not transplanted through the Improving Patient Safety Portal. However, current OPTN/UNOS policy does not specifically require updating the Living Donor Feedback (LDF) form if a living donor organ is recovered but not utilized. Consequently, if a living donor organ is recovered but not transplanted and the LDF form is not updated post operatively, the Living Donor Registration and Living Donor Follow-up forms would not generate and the living donor could be lost to follow-up.

This proposal was distributed for public comment and all responses were reviewed by the Committee. The Committee supported sending this proposal for Board consideration **(Exhibit A)**.

RESOLVED, that Policies 18.1 (Data Submission Requirements) and 18.6 (Reporting of Living Donor Adverse Events) are modified as set forth in Exhibit A, effective September 1, 2015.

Committee Projects

2. Clarify the Status of Domino Donors

Public Comment: August 2015 (Estimated)

Board Consideration: December 2015 (Estimated)

There are inconsistent practices regarding whether domino donors are considered as living donors or recipients for policy requirements and compliance. Current OPTN policy addresses the allocation of domino donor hearts, but does not address domino liver donation. The need to develop policy addressing domino liver donation has become more apparent and important as proposed new policies for living liver informed consent, medical evaluation, and follow-up are in effect.

In late 2014, the Living Donor Committee in consultation with representatives from the Thoracic, Operations and Safety and Liver Committees along with UNOS staff collaborated to draft proposed policy language for domino donation. During this process, the Living Donor Committee consulted surgeons and medical staff from hospitals experienced with domino liver donation. The Committee prepared to send a domino donation policy proposal for public comment in early 2015.

In late 2014, the Membership and Professional Standards Committee (MPSC) was asked to consider if domino donation should be limited to hospitals designated as UNOS approved living donor recovery hospitals and whether or not existing policy might need to be modified. In response the Living Donor Committee agreed to delay public comment on this proposal while the MPSC considered member requirements for domino donation. The MPSC ultimately did not support limiting domino donation to UNOS approved living donor recovery programs, but rather endorsed acceptance and transplantation of any domino donor organ recovered at an OPTN member transplant hospital with current designated transplant program approval for that organ type.

The Committee considered feedback from all other committees returning comments on the proposal. During its April 2015 meeting, the Committee considered proposed draft policy language, but questioned if the proposal should be revised to also address other types of therapeutic (e.g. organ donation to treat a health condition) living organ donation. The Committee is planning to finalize a policy proposal for the next public comment period.

3. New Requirements for the Transport of Living Donor Organs

Public Comment: August 2015 (Estimated)

Board Consideration: June 2016 (Estimated)

The Living Donor Committee first discussed this topic in May 2010 and determined that OPTN policy had very specific requirements for organ packaging living donor organs, but policy does not have specific requirements for how packaged living donor organs must be transported if they are transported out of the donor recovery center.

During its April 2011 meeting, the Committee approved a set of [*Recommendations to Reduce Transportation Delays or Failures for Living Donor Organs*](#). The recommendations included requiring a courier to accompany any transported living donor organ and making OPOs responsible for the packaging and transport of living donor organs. Additionally, in spring 2011, the Committee released a proposal for public comment titled [*Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels, and Tissue Typing Material*](#). Under the proposal, the packaging and shipping requirements for living

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donor organs were updated to mirror the packaging and shipping requirements for deceased donor organs. The Board approved the proposal in November 2011.

During its April 2012 meeting, the Committee discussed a new HRSA-sponsored project to investigate electronic tracking of donated organs. The Committee determined it should delay work on requirements for the transport of living donor organs until this project concluded to avoid any duplication of effort.

The Ad-Hoc Organ Tracking Committee reported its final recommendations to the Board in June 2013. A member of the Ad-Hoc Organ Tracking Committee provided an overview of the project to the Committee in June 2013 and verified that the current project would not include the packaging and transport of living donor organs.

In response, the Committee resumed work on this project during its fall 2013 meeting. Recently, the leadership of the Committee has discussed if this project might benefit from a Failure Mode Effects Analysis (FMEA). The Operations and Safety Committee (who is collaborating on this project) used a FMEA for its ABO Proposal, which was distributed for spring 2014 public comment, and a FMEA was performed in the HRSA-sponsored project to investigate electronic tracking of donated organs. The Committee anticipated that components of the FMEA for electronic tracking of donated organs could be utilized in the development of new requirements for the transport of living donor organs. UNOS staff received FMEA training in late September 2014.

In February 2015, the Committee formed a work group to address the transport of living donor organs. The work group includes representatives from the Operation and Safety, OPO, and Transplant Coordinators Committees. The work group is meeting two times each month and is using the Healthcare Failure Modes and Effect Analysis (HFMEA) methodology to identify all potential failure points in the transport of living donor organs.

Committee Projects Pending Implementation

4. Modify the Patient Safety System for Living Donor Events

Public Comment: [March 5 – April 16, 2010](#)

Board Approval: November 2010

Implementation: Spring 2015 (Estimated)

This project would update the Improving Patient Safety Portal for better reporting of non-utilized and redirected living donor organs. Under this project, the portal would be modified to include specific fields for reporting non-utilized and redirected living donor organs. This project is scheduled for implementation in the second quarter of 2015.

Implemented Committee Projects

5. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of Living Donors

Public Comment: [March - June 2014](#)

Board Approval: November, 2014

Implementation: February 1, 2015

This proposal modified existing or established new policy requirements for the psychosocial and medical evaluation of living donors. This proposal was in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it was based on recommendations from a Joint Societies Steering Committee, composed of

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representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors had already been established. This proposal modified some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and established new requirements for living liver, lung, intestine, and pancreas organ donors.

The Committee has not been notified concerning any problem with this policy since implementation.

6. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of Living Donors

Public Comment: [March - June 2014](#)

Board Approval: *November, 2014*

Implementation: *February 1, 2015*

This proposal modified existing or established new policy requirements for the informed consent of living donors. This proposal was in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it was based on recommendations from a Joint Societies Steering Committee, composed of representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors had already been established. This proposal modified some elements of existing policy for the informed consent of living kidney donors and established new requirements for living liver, lung, intestine, and pancreas organ donors.

The Committee has not been notified concerning any problem with this policy since implementation.

7. Proposal to Require Reporting of Aborted Living Donor Organ Recovery Procedures

Public Comment: [March - June 2014](#)

Board Approval: *November, 2014*

Implementation: *February 1, 2015*

The OPTN relies on the UNetsm Improving Patient Safety Portal for notification of patient safety concern and living donor adverse events. Under this proposal, an aborted living donor organ recovery procedure became a new category of living donor adverse event that recovery hospitals are required to report through the UNetsm Improving Safety Portal. Additionally, the proposal clarified current living donor adverse event reporting requirements by elimination of some redundant sections of policy.

The Committee was notified that the MPSC is monitoring this new policy requirement and that the MPSC has contacted programs found to be out of compliance.

8. Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

Public Comment: [September 2011 – January 2012](#)

Board Approval: *November, 2012*

Implementation: *February 1, 2013*

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The project improved living kidney donor follow-up by establishing minimum threshold for collecting and reporting living kidney donor follow-up. Under Policy 18.5 (Reporting Requirements after Donation) living kidney donor recovery hospitals must report accurate, complete and timely donor status and clinical information for at least 60% of their living kidney donors who donated after policy implementation date. Living kidney donor recovery hospitals are also required to report laboratory data on at least 50% of their living kidney donors who donated after the policy implementation date. Under the policy, the required threshold donor status, clinical information, and laboratory data increase over time.

Preliminary 6-month follow-up results for living kidney donors who donated after February 1, 2013 reveal that 71.7% of recovery hospitals achieved the 60% clinical data threshold and 75.1% of recovery hospitals achieved the 50% lab data threshold. These rates reveal ongoing improvement in follow-up rates, for comparison, living kidney donor follow-up rates averaged 42.5% in 2009.

9. Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors

Public Comment: [September 2011 – January 2012](#)

Board Approval: [November, 2012](#)

Implementation: February 1, 2013

The project improved and standardized the informed consent process for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Steering Committee representing the AST, ASTS, and NATCO and fulfill a HRSA requirement to develop policies for living organ donors and living organ donor recipients.

During the Committee's spring 2015 meeting, a representative from UNOS' Department of Member Quality provided a report on member compliance with informed consent requirements. Based on this report, programs not meeting all informed consent requirements continues to be the most common policy violations, 47% of all violations, are identified during site surveys.

10. Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors

Public Comment: [September 2011 – January 2012](#)

Board Approval: [November, 2012](#)

Implementation: February 1, 2013

The project improved and standardized the psychosocial and medical evaluations for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Steering Committee representing the AST, ASTS and NATCO and fulfill a HRSA requirement to develop policies for living organ donors.

During the Committee's spring 2015 meeting, a representative from UNOS' Department of Member Quality provided a report on member compliance with medical evaluation requirements. Based on this report, problems with the medical and psychosocial evaluations continue to be identified during site surveys.

11. Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up

Public Comment: January - March 2012

Board Approval: November, 2013

Implementation: February 1, 2014

The project improved living liver donor follow-up by establishing minimum threshold for collecting and reporting living kidney donor follow-up. Under Policy 18.5 (Reporting Requirements after Donation) living liver donor recovery hospitals must report accurate, complete and timely donor status and clinical information for at least 80% of their living kidney donors who donated after policy implementation date.

Living liver donor recovery hospitals are also required to report laboratory data on at least 70% of their living liver donors who donated after the policy implementation date. These rates reveal ongoing improvement in follow-up rates, for comparison, living kidney donor follow-up rates averaged 31.6% in 2009.

Review of Public Comment Proposals

The Committee has reviewed 3 of the 13 proposals released for public comment from January – March, 2105.

12. Proposal to Address the Requirements Outline in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)

A subcommittee of the Living Donor Committee limited its review of the proposal to aspects of the proposal relevant to living donors.

The subcommittee supports the proposed policy modification of Table 14-9 (Living Donor Exclusion Criteria) which would be modified to read:

- HIV, unless the requirements for a variance are met, according to Policy 15.5 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

The Committee is concerned that the proposal does not address any special informed consent and medical evaluation requirements that may be necessary for potential HIV positive living donors.

Additionally, the Committee is concerned that the proposal does not address post-donation follow-up requirements for HIV positive living donors. The two years of required follow-up for living donors required under current policy is unlikely to be sufficient to understand the longer term effects of organ donation for HIV positive living donors.

13. ABO Blood Type Verification (Operations and Safety Committee)

The Committee limited its review of this proposal to those elements addressing living donation. The Committee responded that the proposal should specifically address how induction of anesthesia is defined, how it needs to be documented, and how it would be evaluated during site surveys. ABO verification should be required after the patient is in the operating room to align with CMS requirements.

14. Membership Requirements for Vascularized Composite Allograft Programs (VCA)

The Living Donor Committee (LDC) reviewed the bylaw proposal including the background section and was concerned that the VCA committee was endorsing VCA living donation and VCA living donor transplants without any membership criteria, training requirements or

limitations on the types of living VCA organ recovery that could be performed at OPTN member hospitals.

The proposed bylaw language is silent on living VCA donation. However, the background of the proposal states *“limiting the proposed VCA membership criteria to only instances of deceased donor VCA transplantation would leave a gap in ensuring patient safety of living donors, should such cases occur in the future... Therefore, any VCA recovery from a living donor must take place at a transplant hospital that is approved for VCA transplantation involving grafts from deceased donors.”*

Since the proposed and existing bylaw language is silent on VCA living donation and transplantation, the VCA committee is noting that existing Policy 14.6.C should be sufficient to provide oversight of the practice of VCA living donation. The relevant section of 14.6.C states *“If the OPTN does not have approval criteria for a living donor recovery hospital for a particular organ type, then transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals with current transplant program approval for that organ type.”*

Policy 14.6.C was written prior to OPTN’s oversight of VCA transplants and VCA living donation. The LDC is concerned that Policy 14.6.C is therefore not sufficient for a nascent field whose boundaries have not yet been defined. The LDC understands that regulatory oversight should not stand in the way of innovation and would recommend that until such time as the OPTN develops the necessary VCA living donor policy(s) (for informed consent, psychosocial and medical evaluation and follow-up), any VCA living donation should only be performed at a transplant hospital approved for VCA transplantation and should be within an institutional review board (IRB) approved research protocol.

The LDC notes that the proposed bylaw requirements for VCA transplantation are focused on the safety of the transplant recipient rather than the safety of the (living) donor, and thus do not appear to consider the safety of living donors other than to support efficacy of the transplant for the recipient.

The LDC opines that if VCA living donation and transplantation is to be permitted with OPTN oversight, then at a minimum, Appendix J must be modified to include membership criteria for hospitals that perform living donor VCA recovery and VCA living donor transplants. Furthermore, the VCA Committee should consider whether the proposed bylaw must include language describing the minimal certification, training and experience for individuals serving as VCA primary physician and surgeons for living donor VCA recovery.

Other Committee Work

15. VCA Guidance Documents

Committee members are participating on a multi-committee work group developing a resource to provide guidance on living VCA donation, including program requirements and donor informed consent; medical and psychosocial evaluation; and post-donation follow-up. This guidance document is in response to the comments submitted by the Living Donor Committee to the VCA Committee’s public comment proposals, as noted above.

16. Imminent Death Donation Work Group

The Committee is participating on a work group, led by the Ethics Committee, which is examining the ethical considerations of imminent death donation. At this point, the path forward is unclear, as there is no consensus on the workgroup regarding when, if ever, IDD may be appropriate. In response the work group has identified the ethical or practical

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concerns that may need to be addressed in order for IDD to be considered as a potential new option for organ donation, including:

- Would IDD violate the Dead Donor Rule
- How should the option for IDD be introduced to the donor family
- Who would provide surrogate consent
- Concerns with public perception
- Possible restriction to only circumstances when DCD is unlikely to be successful, versus consideration of DCD after recovery of a single kidney through IDD

The work group is expected to prepare a report outlining areas of concern and proposed solutions that will be provided to the Committees represented on the work group for review and feedback.

17. Letters to Living Donor Recovery Hospitals

In January 2015, the Committee coordinated sending a letter to each living donor recovery hospital meeting or exceeding the new minimum requirement for living donor follow-up. The letter reported each hospital's level of follow-up compared the new minimum threshold required in policy.

Meeting Summaries

The committee held meetings on the following dates:

- April 20, 2015

Meetings summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=59>.