

OPTN/UNOS Living Donor Committee
Meeting Summary
April 20, 2015
Chicago, IL

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Discussions of the full Committee on April 20, 2015 summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available on at <http://optn.transplant.hrsa.gov/>.

Committee Projects

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

Under the current reporting system using the Living Donor Feedback 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 Living Donor Feedback 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. Vote 17-0-0

2. Proposal to Clarify the Status of Domino Donors

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

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 an FMEA for its ABO Proposal, which was distributed for spring 2014 public comment, and an 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

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 first quarter of 2015.

Implemented Committee Projects

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

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 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.

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

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

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

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.

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

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 donor 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.

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

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.

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

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.

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

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.

Review of Public Comment Proposals

12. The Committee provided comment on three proposals during the spring 2015 public comment cycle.

- Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)
- ABO Blood Type Verification (Operations and Safety Committee)
- Membership Requirements for Vascularized Composite Allograft Programs (VCA)

Other Significant Items

13. 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.

14. Imminent Death Donation Work Group

The Committee is participating on a work group, led by the Ethics Committee, that is examining the ethical considerations of imminent death donation. At this point, the path forward is unclear, as some members of the work group may not support IDD under any circumstances. In response the work group has identified the ethical or practical 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; and
- 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.

15. 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.

Upcoming Meeting

- October 19, 2015 – Full Committee Meeting