

**OPTN/UNOS Living Donor Committee  
Meeting Summary  
September 8, 2014  
Chicago, IL**

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

Discussions of the full Committee on September 8, 2014 are 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 Require the Reporting of Aborted Living Donor Recovery Procedures**

Under this proposal living donor recovery hospitals would be required to report aborted living donor organ recovery procedures within 72 hours of the event as Living Donor Adverse Events through the UNet<sup>SM</sup> Improving Patient Safety Portal. The Committee reviewed the development of this proposal and public comment submitted regarding the proposal. In response to public comment the Committee agreed that the phrase "receives anesthesia" in the original proposed policy language should be clarified to read "begun to receive general anesthesia." There were no other changes to the proposed policy language and the Committee approved sending the proposal for Board consideration. Vote 17-0-0

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

This proposal would modify existing or establish new policy requirements for the informed consent of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it is 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 has already been established. This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for living liver, lung, intestine, and pancreas organ donors

The Committee considered and addressed all public comment received on this proposal and voted in support of sending the proposal for consideration by the Board of Directors

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

This proposal would modify existing or establish new policy requirements for the psychosocial and medical evaluation of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it is 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 has already been established. This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for living liver, lung, intestine, and pancreas organ donors.

The Committee considered and addressed all public comment received and voted in support of sending the proposal for consideration by the Board of Directors.

### **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 Establish Minimum Requirements for Living Kidney Donor Follow-up**

The proposal was intended to improve living kidney donor follow-up by establishing minimum thresholds 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 thresholds for 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.

#### **6. Proposal to Establish for the Informed Consent of Living Kidney Donation**

The project was intended to improve and standardize the informed consent process for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Work Group representing the AST, ASTS and NATCO and fulfill a HRSA requirement to develop policies for living organ donors and

living organ donor recipients. The Committee will use reports on the number of transplant centers found out of compliance during UNOS Living Donor Program Site Surveys to evaluate the proposal. UNOS's Department of Evaluation and Quality will report on the level of compliance at the Committee's spring 2015 meeting.

#### **7. Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors**

The project intended to improve and standardize the psychosocial and medical evaluations for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Work Group representing the AST, ASTS and NATCO and fulfill a HRSA requirement to develop policies for living organ donors. The Committee will use reports on the number of transplant centers found out of compliance during UNOS Living Donor Program Site Surveys to evaluate the proposal. UNOS's Department of Evaluation and Quality will report on the level of compliance at the Committee's spring 2015 meeting.

#### **Review of Public Comment Proposals**

#### **8. The Committee had preliminary discussions regarding two proposals scheduled for the fall 2015 public comment cycle.**

- Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)
- Implementation of the OPTN's Oversight of Vascularized Composite Allografts (Vascularized Composite Allograft Committee)

#### **Other Significant Items**

#### **9. The Committee discussed several potential new areas of work including:**

- The development of policy, protocols or guidelines for the development of living donor selection committees
- Adding a routine toxicology screening to the existing living donor medical evaluation requirements
- Standardizing the process for providing an alibi for medical unsuitability

#### **Upcoming Meeting**

- April 20, 2015 – Full Committee Meeting