OPTN/UNOS Living Donor Committee
Meeting Summary
March 7, 2016
Chicago, IL

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

Discussions of the full Committee on March 7, 2016 are summarized below. All committee meeting summaries are available at *http://optn.transplant.hrsa.gov/*.

Committee Projects

1. Removing Disincentives For Candidates to Consider Living Donation

The Committee continued preliminary work on a new project to improve understanding about living donation among transplant candidates and their support communities, and remove barriers and disincentives to identification of potential living donors by transplant candidates. As currently planned, the project would result in two deliverables including a 1) patient-centered pamphlet designed to inform transplant candidates about effective strategies for improving pursuit of living donor transplantation and facilitate discussion with their transplant center and other healthcare providers, and 2) a white paper summarizing the literature evaluating potential strategies, which would be directed at transplant centers, dialysis centers and other providers involved in the care of patients with end-stage organ failure.

During discussion of this project, committee members noted that it would be important to consider a future project to revise the Living Donor Brochure, available on the OPTN website, because it is outdated in some ways. The current project on removing disincentives is seen as complementary to this existing brochure.

2. Modification of Existing and Potential New Requirements for the Informed Consent of Potential Living Donors

The Committee continued preliminary work on a proposed project to update current and potentially add new living donor informed consent requirements to OPTN Policy 14 to address:

- New evidence published on donor health outcomes
- Consensus-based recommendations from the transplant professional societies
- Release of living donor program-specific reports by the SRTR
- Persistent questions and areas poorly understood by transplant centers, encountered during living donor programs site surveys

During discussion of this project, committee members suggested that it would be important to consider a future project to develop a plain language version of the informed consent policy requirements as an informational brochure for potential living donors.

Committee Projects Pending Implementation

3. Proposal to Establish and Clarify Policy Requirements for Domino Donors and Non-Domino Therapeutic Donors

This proposal focused on modifications to OPTN Policy 14 by establishing and clarifying policy requirements for transplant centers evaluating potential domino donors and non-domino therapeutic donors. The project was approved by the Board in December 2015 and will be implemented pending programming currently scheduled for fall 2016.

4. Proposal to Improve UNet[sm] Reporting of Aborted Procedures and Non-Transplanted Organs

Under current policy, aborted procedures and non-transplanted organs may not be reported through the UNet[sm] at the time of the event and consequently may be under reported. This proposal was approved by the Board in June 2015, and will be implemented pending programming scheduled for April 2016.

Review of Public Comment Proposals

5. Improving Post Transplant Communication of New Donor Information

Following a presentation of the briefing paper developed by the Ad hoc Disease Transmission Advisory Committee, the Living Donor Committee voiced concerns that it was not consulted during the development of this proposal which, if approved, would modify existing policy requirements for living donor recovery hospitals.

The Committee questioned why the proposal would modify existing requirements for living donor recovery hospitals, when the FMEA process used to inform policy development was limited to deceased donor disease transmission events. Put another way, if the FMEA did not involve any living donor cases, the Committee questioned how it would be known or asserted that the revised policy would be adequate for those instances involving living donors.

The Committee noted that the section of the briefing paper concerning how members would implement the proposal does not address any impact or changes required for reporting by living donor recovery centers. It is not clear whether recovery centers are expected, for example, to develop additional reporting protocols beyond what they currently follow.

6. Standardize an Organ Coding System for Tracking Organs: Requirements for OPO TransNet Use

Following a presentation of the briefing paper developed by the Operations and Safety Committee, the Living Donor Committee responded that an organ coding system for tracking organs should be the standard for the packaging, labeling and shipment of all—both deceased and living donor—organs. Thus, the technology must be extended to address the packaging and shipment of living donor organs. Transplant hospital or OPOs should not be expected to use an automated system for the packaging, labeling and shipment of deceased donor organs and a manual system for the packaging, labeling and shipment of living donor organs.

Other Significant Items

7. Update on Strategic Plan Alignment and POC Update

The Vice Chair provided an update on the status of the strategic plan and on the status of current and proposed new projects under review by the Policy Oversight Committee meeting.

8. Consider Changes to the Committee's Mission Statement

The Committee reviewed its mission statement and determined the statement was still consistent with the strategic plan and did not need substantive revision at this time.

9. Proposal to Establish a Living Donor Registry (SRTR)

A representative of the Scientific Registry of Transplant Recipients (SRTR) explained that HRSA has charged the SRTR with conducting a feasibility study for a living donor registry. Under the current proposal, transplant hospitals would be required to register all potential living donors evaluated at the program including those that 1) become donors, 2) are approved to donate but do not donate, and 3) are not approved to donate. The transplant hospital would report the reason for not donating. The SRTR would obtain follow-up information, report to transplant programs and report to the general public. As proposed, the Living Donor Registration (LDR) form would be extended to all potential living donors evaluated at a transplant hospital and the form would need to be modified to capture the reason(s) a potential donor does not donate. The SRTR requested that the Committee prepare a concept document providing an overview of this proposed registry, and the changes that would be required within OPTN Policy in order to develop the registry, for public comment in August 2016.

The Committee had concerns with the proposed feasibility study including:

- The proposed registry should actually "follow" living donors and not be limited to merging CMS and NDI data to see who develops ESRD or died 10 to 20 years later.
- Requiring centers to submit forms on all potential donors could deter some potential donors from proceeding with the living donor evaluation.
- There would be difficulty in obtaining a consistent sample because some centers use online screening programs, or require some testing to be done before a potential donor comes to the center, in order to screen out potential donors who have co-morbidities that would make them poor choices as donors.
- Some members opined that the project was research rather than a true registry. To the extent that it is a research activity, it is not appropriate to modify OPTN policy in order to conduct the project.
- The VA doesn't participate in CMS, so promises of CMS reimbursement for the extra data submission won't help all programs.
- There was concern that donors would choose centers based on the results of this registry's findings.
- The proposed plan could require centers to change the timing of their data collection/submission for actual donors.

Upcoming Meeting

- October, 2016