

**OPTN/UNOS Living Donor Committee
Meeting Minutes
July 11, 2018
Conference Call**

**Randy Schaffer, M.D., Chair
Heather Hunt, Vice Chair**

Introduction

The Living Donor Committee met via teleconference on 7/11/2018 to discuss the following agenda items:

1. New Committee Member Welcome
2. Region 6 Representative Search
3. OPTN/UNOS Living Donor Committee In-Person Meeting
4. Updates on the Liver & Intestinal Committee and Ad Hoc Geography Committee
5. Discussion on Maintenance Dialysis Clarification Project
6. Final Questions or Comments

The following is a summary of the Committee's discussions.

1. New Committee Member Welcome

The Chair welcomed the four new members of the Living Donor Committee: Jane Forbes, Carolyn Light, Nahel Elias, and Rita McGill.

2. Region 6 Representative Search

Dr. Kayvan Roayaie, the representative for Region 6, has taken a new position outside of Region 6. Leadership is currently being presented options to take his place through the regional appointment process.

3. OPTN/UNOS Living Donor Committee In-Person Meeting

Committee members are reminded that in-person meetings require attendance to the extent possible. These meetings take place over the course of a day, and dinner is provided the night before for those who arrive early. Travel should be arranged through UNOS site, and Committee members will receive an e-mail from UNOS Meeting Partners to book their travel. Currently, the date for the Living Donor Committee In-Person meeting is Monday, October 15 from 8am to 3pm Central Time in Chicago, Illinois. Please mark your calendars now to ensure attendance.

4. Updates on the Liver & Intestinal Committee and Ad Hoc Geography Committee

Summary:

The Department of Health and Human Services received a critical comment from a law firm in New York City, which asked for an inquiry into Donor Service Areas (DSAs) and Regions as units of liver allocation and subsequently to remove them as they violate the National Organ Transplant Act (NOTA) and the Final Rule, 42 C.F.R. § 121.5(c). The Liver and Intestinal Committee was tasked with responding. The Liver Committee is currently working on finding ways to remove regions and DSAs from allocation policy. The Board did approve the Geographic Principles of Organ Distribution that was completed by the Ad Hoc Committee on Geography. These principles restate NOTA and the Final Rule, which designates deceased donor organs as national resources. However, these principles also provide four reasons as to why geographic constraints may be applied consistently and rationally. This is the guiding

principle for all organ committees moving forward. Given emergency lung allocation changes last year and now liver currently, the Kidney Committee, the Pancreas Committee, the VCA Committee, the Operations and Safety Committee, the Thoracic Organ Transplantation Committee, the Liver & Intestinal Transplantation Committee are all currently re-evaluating allocation policies based on DSAs and regions.

These emergency measures may have some impact on the Living Donor Committee, even if the impact is secondary. Currently, these events do not directly impact the LDC, but the Committee is aiming to go before the Policy Oversight Committee (POC) and the Executive Committee (ExCom) in August with a new project proposal for approval. Other Committees, especially organ-specific committees, have had to put other work on hold to work on reviewing the allocation systems. LDC projects may undergo increased scrutiny during project approval in order to ensure enough resources exist to tackle new projects. As of now, however, there should be little impact on the Committee's new project.

Summary of discussion:

Committee members asked about the outside timeframe by which the geography issues may interrupt other committees' work and ExCom's concern about the impact of the geography work. UNOS staff stated that the Liver Committee will have a special round of public comment in October and their work will go through to the Board in December 2018. All other organ-specific committees will have seek spring 2019 public comment with work through to the Board by June 2019.

5. Discussion on Maintenance Dialysis Clarification Project

Summary:

Members have raised questions regarding the meaning of the phrase "begins dialysis" in Policy 18.6. Specifically, it is not currently clear whether the phrase "begins dialysis" requires reporting chronic dialysis representing end-stage renal failure and/or acute dialysis.

In addition, there are several other areas within policy language, TIEDI, and the Patient Safety Portal which refer to the decrease or loss of renal function in a living donor using inconsistent terminology. For example, Policy 18.6.A requires recovery hospitals to report any "living kidney donor who is listed on the

kidney wait list or begins dialysis within 2 years after organ donation" as a "living donor event" in the Patient Safety Portal within 72 hours after the hospital is aware of the event. UNOS must then notify HRSA of the event within 24 hours of it being reported through the portal.

- The checkbox in the Patient Safety Portal is labeled as "Loss of native organ function." Prior versions of policy included "failure of the living donor's remaining organ function" (February 1, 2014 rewrite version) and "failure of the living donor's native organ function" (January 31, 2014 pre-rewrite version). In these cases, policy 1.2 defined this as "listing for transplant or the need for dialysis in kidney donors" but did not specify acute versus chronic dialysis.
- The Living Donor Follow-up (LDF) form reporting (Policy 18.5.A) queries centers about related clinical events at 6 months, 1 year, and 2 years post-donation. Among the choices are "5. Kidney complications" and "6. Maintenance dialysis." Under choice "5. Kidney complications" are the options "Added to UNOS TX candidate waiting list" and "Other, specify." This section does not specifically mention "acute dialysis" as an option.

- Regarding the LDF's item "6. Maintenance dialysis," UNet Help documentation offers a definition of "Maintenance dialysis" as "if the donor was on maintenance dialysis (22 sessions in a 3-month period)," but this definition is not codified elsewhere within OPTN/UNOS policy.

Clarifying when transplant hospitals should report chronic versus acute dialysis in the sections of policy and harmonizing terminology on forms will help centers accurately report living donor events. In addition, greater clarity in reporting will improve safety reviews and the understanding of clinical events after living donation.

Next Steps:

The process for the future will be as follows: The Committee has generated the problem statement, identified strategic goal alignment, prioritized, and will reach out to UNOS staff for resource estimates on what this would entail. There will be an internal team meeting next week where this will be further discussed. The aim is an August POC/ExCom review and if it goes through, the Committee will hammer out details and plan of attack to clarify language, finalize Living Donor Form, and clarify Patient Safety Portal.

Upcoming Meetings

- August Monthly Call
- In-Person Meeting October 15, 2018