

**OPTN/UNOS Patient Affairs Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, Georgia**

**Kristie Lemmon, MBA, Chair
John Fallgren, RN, BS, Vice Chair**

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This report reflects the work of the OPTN/UNOS Patient Affairs Committee from October 2014 through April 2015.

Action Items

1. Clarify Policy Language and Process for Individual Wait Time Transfer

Public Comment: January 27 – March 27, 2015

The Patient Affairs Committee (hereafter, the Committee) proposes modifications to Policy 3.6.C: *Waiting Time Transfers* to clarify the process for individual waiting time transfers and provide guidance for calculating waiting time in various scenarios, such as when a candidate transfers between two current registrations or from a removed registration. This proposal promotes the efficient management of the OPTN by describing the responsibilities of both transplant programs and the UNOS Organ Center in the transfer process. By defining waiting time that is eligible for transfer, this proposal also ensures that waiting time transfer calculations are accurate and that the process is fair for all candidates.

Any candidate on the waitlist can potentially transfer waiting time to another transplant center. Each year during the period of 2011-2013, fewer than 3,000 people (< 2% of candidates) transferred primary waiting time. About 2% of kidney candidates consistently transfer waiting time each year, which may be attributed to longer overall waiting times and the relative importance of waiting time, historically, in kidney versus other organ allocations systems. This proposal requires minimal resources to implement, since it seeks to clarify policy and does not change the current individual waiting time transfer process.

Overall public comment for this proposal was favorable. The Minority Affairs Committee expressed concern that the proposed policy disadvantages some patients by defining gap time as ineligible for transfer. However, this is not a change from current policy. Additionally, as a practical matter, this impacts less than 1% of the waiting time transfers conducted each year. After reviewing the evidence, the Committee decided not to modify the proposed policy in regards to gap time. The Committee plans to share the results of this analysis with the Minority Affairs Committee and anticipates working with both the Minority Affairs and Transplant Coordinators Committees to educate about best practices in waiting list management, including preventing gap time when possible.

The Committee made minor post-public comment modifications to the proposed policy language, including changes to formatting and a requirement for the new transplant program to document that it notified the patient of the outcome of the transfer request. The need for documentation was explicit in the public comment narrative but omitted from the policy language. In an email vote completed April 8-10, 2015, the Committee unanimously voted in support of the amended language (15-Support, 0-Oppose, 0-Abstentions).

RESOLVED, that Policy 3.6.D (Waiting Time Transfers) is modified, as set forth in Exhibit A, effective September 1, 2015.

Committee Projects

2. The Patient's Guide to Referral to Kidney Transplantation

Public Comment: N/A

Board Consideration: N/A

Several Patient Affairs Committee members collaborated with the Minority Affairs Committee to develop an early referral to transplantation resource for dialysis patients. For more information see the **OPTN/UNOS Minority Affairs Committee Report to the Board**.

3. Update "What Every Patient Needs to Know" Brochure

Public Comment: N/A

Board Consideration: N/A

"What Every Patient Needs to Know," a resource for transplant candidates, recipients, and their families, is one of the most popular educational resources designed and distributed by UNOS. The Committee was responsible for a rewrite of the publication in 2010 and now must periodically review its content. In collaboration with the Transplant Coordinators Committee, the Patient Affairs Committee revised the waiting list section to improve candidates' understanding of the waiting list, including how the match run is performed and what it means to be in inactive status. The Committee also clarified the waiting time transfer section, updated data, ensured information regarding kidney paired donation programs was current, and made the resources section available online. The Committee anticipates the new version will be available in print in June.

Committee Projects Pending Implementation

None

Implemented Committee Projects

None

Review of Public Comment Proposals

The Committee reviewed 9 of the proposals released for public comment from September – December 2014 and January – March 2015.

4. Proposal for Informed Consent for Kidney Paired Donation (Kidney Transplantation Committee)

After listening to a presentation of the proposal, the Committee expressed support without further discussion.

5. Improving the OPTN Policy Development Process (Executive Committee)

The Committee believes that the new policy development process tracks will serve the community well by making the OPTN more nimble and responsive. It supports this proposal.

6. Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs) (VCA Committee)

The Committee appreciates the separate donor authorization process for VCA and supports this proposal.

7. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (OPO Committee)

This proposal was released for public comment twice. After listening to a presentation of the proposal during fall 2014 public comment, the Committee expressed support without further discussion.

After listening to a presentation of the proposal during spring 2015 public comment, the Vice Chair of the Committee asked if there would be required types of HIV testing, including two test verification and protocol to rule out false positives. The OPO and DTAC Liaisons explained that OPOs and transplant hospitals participating in the study would be responsible for establishing research protocols. OPOs can work with their laboratories to understand how to resolve false positives based on the particular tests they use.

The Vice Chair also asked for clarification that this research study will allow HIV-positive living donation. The OPO Liaison confirmed that this is likely. Another Committee member asked if living donation is safe for an HIV-positive person, or if living donation could compromise their health. The OPO Liaison explained that, as with any living donor, extensive medical evaluation and informed consent will determine an HIV-positive person's eligibility to donate.

8. Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18 (Pediatric Transplantation Committee)

After listening to a presentation of the proposal, the Committee expressed support without further discussion.

9. Proposal to Require Re-Execution of the Match run when a Deceased Donor's Infectious Disease Results Impact Potential Recipients based upon Screening Preferences (Disease Transmission Advisory Committee)

After listening to a presentation of the proposal, a transplant coordinator on the Committee asked if a patient admitted to the hospital as a back-up to the primary patient would remain as back-up regardless of if that patient appeared on the re-executed match run. In this instance, the patient, their family, and the transplant hospital have expended resources to admit the back-up patient. The DTAC Liaison explained that only the primary patient's offer would be honored and that the DTAC believed others would be best served on the new match run to avoid human error.

10. Membership Requirements for Vascularized Composite Allograft Transplant Programs (VCA Committee)

The Committee appreciates the standard of patient safety the proposed requirements establish.

11. ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)

After listening to a presentation of the proposal, one Committee member commented that these requirements could wait until the implementation of TransNet. The Operations and Safety Committee Liaison explained that TransNet has been voluntarily launched among OPOs, and she anticipates 45 to 50 participating OPOs by the end of the year. She is uncertain how long it will take to disseminate to individual transplant hospitals.

A transplant coordinator on the Committee commented that, although unintentional ABO-incompatible transplantation is rare, the impact is devastating. Therefore, she believes these precautions are necessary.

OPTN/UNOS Patient Affairs Committee

Other Committee Work

None

Meeting Summaries

The Committee held meetings on the following dates:

- October 20, 2014
- January 21, 2015
- February 11, 2015
- March 11, 2015
- March 30, 2015

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=14>.