

**OPTN/UNOS Kidney Transplantation Committee
Meeting Minutes
February 12, 2018
Teleconference**

**Nicole Turgeon, MD, FACS, Chair
Vincent Casingal, MD, Vice Chair**

Introduction

The OPTN/UNOS Kidney Committee met via teleconference on 02/12/2018 to discuss the following agenda items:

1. Public Comment Proposal Review: Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies (OPTN/UNOS Ethics Committee)
2. Public Comment Review: Clarify Informed Consent Policy for Transmittable Conditions (OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee(DTAC))
3. Public Comment Review: Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB (OPTN/UNOS Operations and Safety Committee)
4. Histocompatibility Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI) Work Group Update

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

1. Public Comment Proposal Review: Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies (OPTN/UNOS Ethics Committee)

The Ethics Committee Chair presented this white paper proposal to the Kidney Committee for feedback during the public comment cycle. The white paper defines and presents an ethical analysis of manipulation of the waitlist priority of the organ allocation system through the use of medically unnecessary interventions that are used to increase a transplant candidate's priority on the waitlist. The white paper delineates the potential harms to transplant candidates, the wait list as a whole, transplant providers, and transplant hospitals involved in the manipulation of the organ allocation system.

The Kidney Committee supported the concept of this ethical white paper and appreciated the thoroughness of the Ethics Committee's explanation of the issue. The Kidney Committee agreed that instances of manipulation of the organ allocation system need to be identified, addressed, and discussed by the transplant community. While it is understood that concepts in ethical white papers are not deemed policy and are used as guidance only, the Committee hoped that more light on this complex issue may lead to more identification and monitoring of manipulation themes and scenarios.

2. Public Comment Review: Clarify Informed Consent Policy for Transmittable Conditions (OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee(DTAC))

The DTAC Chair presented this proposal to the Kidney Committee for feedback during the public comment cycle. Current policy states that specific pre-transplant informed consent is required when, "The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, including HIV." The phrase "known medical condition" has led to questions and varying applications in practice. The Membership and Professional Standards Committee (MPSC) notes in a memo to the DTAC that broad interpretation of this policy would require specific informed consent for any positive serology, culture, or other donor test result and that this would be cumbersome without adding patient benefit.

The Kidney Committee supported the solutions proposed in this policy change. The Kidney Committee appreciated the attention to detail that the DTAC used when clarifying the existing problem and ways to improve the process. DTAC asked for specific feedback concerning the proposal and the Committee discussed the following questions:

Should the policy specify patient signature or documentation of discussion in medical record?

Several Committee members asked about the timing of the consent – during evaluation or in the moment of the organ offer. The DTAC Chair responded that while pre-consent may be a viable option, some offers come years after listing and candidate’s opinions may change over time, so consent at time of offer was still the most reasonable option. Some Committee members were in favor of documentation of discussion, while others favored signatures. The consensus of the Committee was to mirror the practices of the PHS increased risk guidelines.

Are conditions named in policy for candidate screening and re-executing the match run still applicable and complete?

The Kidney Committee was in broad agreement that conditions named in policy are still applicable and complete. There were no suggestions by the Committee for changes or removals.

3. Public Comment Review: Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB (OPTN/UNOS Operations and Safety Committee)

The Operations and Safety Committee Liaison presented this guidance document proposal to the Kidney Committee for feedback during the public comment cycle. Since the original guidance publication, the Operations and Safety Committee sponsored major revisions to ABO policies that were approved by the OPTN/UNOS Board of Directors and implemented in June 2016. During that process, the need was identified to revise the subtyping guidance, as many questions emerged related to subtyping. Questions and identified issues include lab result nomenclature, results interpretation, and incomplete knowledge of policy requirements.

The Kidney Committee supported this guidance document and appreciated the updates and improvements made to clarify ABO subtyping expectations. The Committee also thanked the Operations and Safety Committee for the opportunity to attend an informative webinar about the proposal prior to Committee discussion. Specific feedback questions were discussed by the Committee:

Is guidance sufficient for special considerations (red blood cell transfusions, neonates)? Do you need more detail or policy?

The Kidney Committee agreed that the guidance for special considerations was sufficient and no other detail or policy was needed as explanation. The Committee was thankful that pre-public comment feedback was addressed in the guidance document prior to presenting to the Committee.

Did we fail to address any other concerns?

The Kidney Committee unanimously agreed that there were no deficiencies in the guidance document, and that all updates were evidence-supported and well-organized.

4. Histocompatibility Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI) Work Group Update

The Histocompatibility Committee Chair discussed the progress of the CMS RFI Work Group in drafting an OPTN response. The majority of the discussion revolved around the RFI for physical versus virtual crossmatching. The Kidney Committee has three members on the work group. The draft response was sent to the Kidney Committee for input and suggestions. The Executive Committee will review the work group response and approve an OPTN response.

Upcoming Meetings

- March 12, 2018 In-Person in Chicago, IL
- April 9, 2018 Teleconference
- May 14, 2018 Teleconference