

**OPTN/UNOS Minority Affairs Committee
Meeting Summary
November 19, 2014
Conference Call**

**Meelie Debroy, MD, Chair
Jerry McCauley, MD, Vice-Chair**

Discussions of the full committee on November 19, 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 at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Guidance on Informed Consent for Living Donors Representing Vulnerable and High Risk Populations

UNOS staff presented data and the results of a literature review previously requested by the Committee. The Committee members plan to reconvene the working group to talk about recommendations for living donor informed consent with relation to vulnerable populations.

Review of Public Comment Proposals

2. Pediatric Transplantation Committee: Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18

The Committee was generally in support of this proposal because of the positive impact that it would have on pediatric liver candidates, which the Committee feels is a vulnerable patient population.

The Committee did raise a question about whether a candidate who is removed from the liver waiting list as a pediatric candidate and then is re-listed as an adult can petition and be eligible to have their previous waiting time reinstated. The Pediatric Committee representative stated that they thought the candidate would not be eligible to petition for this waiting time, that the candidate's waiting time would start from the date of re-listing, but that he would double check this for the Committee.

3. Operations and Safety ('Ops and Safety'): Proposal to Allow Collective Patient and Wait Time Transfers

In general, the Committee agrees that an option for collective transfers is a more efficient way to transfer patients. However, the Committee members expressed significant concern with this proposal.

One member was concerned about instances where two hospitals are merging because a larger one has acquired a smaller one and how patients will be protected from just being swept up. A representative from the Ops and Safety Committee responded that the current OPTN Bylaws requires the hospital to notify the patient in this instance and make clear the options that are available.

Another member expressed concern with the deadlines for completing evaluation and bulk transfer, especially for centers that already have a full load of patients. The Ops

and Safety representative responded that the proposal only requires the transplant program to update the OPTN Contractor on progress and communicate an estimated timeframe for completing all transfers. When it became clear, however, that the progress update is required on each patient, the Committee expressed some concern that this requirement may be too onerous and may discourage programs from accepting large numbers of patients. The Committee members asked that Ops and Safety consider a 120 day deadline instead of 90 days. There was also a suggestion that Ops and Safety consider some requirement that the program prioritize transferring certain patients first, especially the patients with more urgent statuses and longer accrued waiting times.

4. Kidney Transplantation Committee: Proposal to Convert OPTN KPD Operational Guidelines into OPTN policy

The Committee was generally supportive of this proposal with no specific feedback.

5. Organ Procurement Organization (OPO) Committee: Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

The Committee was largely supportive of this proposal but did have a couple of questions. The first question was whether the IRB requirement is going to be run as a national pilot program or whether it was up to individual institution IRBs. The OPO Committee representative responded that it would be individual IRBs approving the transplant center and that approval would be based on whether they meet the criteria being developed by the National Institute of Health (NIH).

There were also some questions about the timing of the release of the new criteria. The OPO representative responded that the NIH had at one point mentioned a summer 2015 timeframe but there hasn't been final confirmation.

One member asked whether there would be a minimum experience requirement; will the program be required to demonstrate a certain number of transplants into HIV positive candidates in order to participate in the study. The OPO representative stated that there will likely not be a number requirement, just that the transplant program demonstrate experience with HIV recipients.

Another member asked whether any specific testing for HIV is required. The OPO representative responded that part of the research protocol deals with viral loads and other factors on the donor and recipient.

There was also a question about who would bear the cost of this research. The OPO representative responded that there is an assumption that individual institutions are going to bear the cost of the research.

6. MPSC: Proposal to Implement Pre-Transplant Performance Review

The Committee had some concerns that these changes could shift the current risk aversion from the post-transplant setting to the pre-transplant setting and this could negatively impact patients. The Committee commented that it hoped the MPSC would consider these unintended consequences when making a final decision on this proposal.

7. Vascular Composite Allograft (VCA) Committee: Implement the OPTN's Oversight of VCAs

The Committee was generally supportive of this proposal. Some members questioned whether more specific membership requirements are needed to ensure individuals performing VCA transplants are qualified. The VCA Committee representative explained that the VCA Committee is currently developing more detailed membership requirements.

Upcoming Meeting

- March 23, 2015