

**INTERIM REPORT of the
OPTN/UNOS POLICY OVERSIGHT COMMITTEE**
Teleconference on August 13, 2012

1. **Review of Public Comment Proposals:** The POC reviewed five proposals scheduled to be distributed for public comment in September 2012. The POC will provide feedback to the sponsoring committees and recommendations to the Executive Committee. Scores are included with each proposal and are based on six questions contained on the POC scorecard with a maximum score of 20.

- **Proposal to Substantially Revise The National Kidney Allocation System (Kidney Transplantation Committee)**

There was some concern about the four points given to a previous living donor and the impact on the waiting list. It was noted that the categorical priority which exists in the current system has not been modified and the main goal is to get prior living donors transplanted expeditiously if they need a kidney transplant. Prior living donors still receive priority at the local level and if not transplanted locally the additional four points will be added for allocation of a kidney at the regional and national level.

There was also concern raised about the language used to identify the individuals within the transplant program and HLA labs that must approve unacceptable antigens for candidates. Currently it states the “transplant physician” which could be a nephrologist and surgeon and a recommendation was made to broaden the definition and provide better guidance.

The POC approved this proposal moving forward to public comment by a vote of 10 in favor, 0 opposed, and 0 abstentions. Score: 18.4

- **Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion (Pancreas Transplantation Committee)**

One concern from a POC member was the potential for confusion for the patients and the administrative burden of providing multiple notifications. It was noted that most patients require multiple infusions and understand the process enough to avoid confusion. Additionally, it was noted that there is currently no standardized way of monitoring islet infusions because reporting is not required in OPTN policy. This proposal is intended to make it a requirement and allow the OPTN Contractor to track islet infusions which is important for patient safety and disease transmission.

The POC approved this proposal moving forward to public comment by a vote of 11 in favor, 0 opposed, and 0 abstentions. Score: 19.2

- **Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation (Thoracic Organ Transplantation and Membership and Professional Standards Committees (MPSC))**

The POC approved this proposal moving forward to public comment by a vote of 11 in favor, 0 opposed, and 0 abstentions. Score: 17.3

- **Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity (Membership and Professional Standards Committee (MPSC))**

There was some concern about the proposal not addressing the subsection of patients within a certain program and the MPSC staff noted that one purpose of this proposal is to get feedback from the transplant community on those kinds of issues. It was also noted that currently the OPTN does not have the authority to require notification when these small subsets do voluntarily inactivate or have functional inactivity. There was agreement that in order to avoid unnecessary work for the programs, a more precise definition of those subsets and who should be notified will be important moving forward. Another issue is defining what patients are considered pediatric and adult and a suggestion was made that the MPSC might want to consider seeking advice about what age you would be notified. For example, if you identify a pediatric program or adults program what happens to the teenagers that programs view differently?

Another issue the POC agreed should be clarified was the notification requirement once the threshold for inactivity is met based on the 28 days cumulative days within a 365 day period. It was not clear at what point individuals affected would be notified. The proposal states that no more than 7 days following the last date of the inactive period, however various scenarios were discussed that might lead to confusion. The MPSC staff agreed to update the proposal to clarify the timing of the notification and potential for repetitive notifications once the 28 day mark is reached.

The POC approved this proposal moving forward to public comment with the stipulation that the clarification be made in the proposal. POC vote: 11 in favor, 0 opposed, and 0 abstentions. Score: 11.5

- **Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)**
POC Comments

There was some concern about the goal of this proposal. It was noted that the main focus of the proposal was to get more consistent data reporting, eligibility reporting and conversion reporting. It was also noted that this data submission is currently required in policy and this proposal is an effort to improve on that data.

The POC approved this proposal moving forward to public comment by a vote of 10 in favor, 1 opposed, and 1 abstention. Score: 13.6

2. **Multi-Organ Allocation Policies:** The POC continues to work on this issue and is currently awaiting feedback from various committees. The POC asked the Ethics Committee to help establish some overarching ethical principles that can be applied universally across the various organ systems. The vice-chair of the Ethics Committee provided a brief overview of the memo

that was sent to the POC in response to that request. Some of the highlights of the memo include:

- There is a good understanding about utility within organ allocation, especially multi-organ allocation, but there seems to be less focus on equity. The memo addresses what equity means, how it is measured, the different perspectives on equity and a request that equity gets some recognition as we move forward.
- Although it is common to want to achieve both equity and utility it is hard to create the right balance. There are a few opportunities where different approaches to allocation would satisfy both equity and utility and one of them is allocating organs to children. There is definitely a concern that common scenarios tend to give multi-organ candidates higher priority than children and that would seem to violate both equity and utility. The Ethics Committee requests that the POC pay particular attention to the interest of children as these discussions move forward.
- Utility – this is usually looked at in terms of who will derive the most benefit from receiving an organ. This is commonly discussed in terms of life years or quality years.

The Ethics Committee is requesting that the focus be on both equity and utility and determine if multi-organ candidates should get priority over children. There was also some discussion about how multi-organ candidates fit within the proposed new kidney allocation system. It was noted that the kidney allocation is addressing issues a few levels below the “top buckets” but it is clearly something the POC will need to keep in mind as the discussions move forward. There was also a brief discussion about the concept of “lifesaving organ” versus non-lifesaving organ. The Ethics Committee did not want to remove the concept but they were uncertain how useful it is today. In essence all organ transplants have the capacity to prolong life and therefore are lifesaving to a certain degree. They did not have an opinion but noted further discussion will need to happen on this topic.

Since the POC has several new members, the committee leadership will work with UNOS staff to revise the roster for the multi-organ allocation subcommittee. This group will continue working on this issue

Carl Berg, MD, Committee Chair
Duke University Hospital

Robert A. Hunter, MPA
UNOS Staff, Policy Analyst

Attendance

Name	Position	August 13, 2012
Carl L. Berg, MD	Committee Chair	X
Yolanda Becker, MD	Committee Vice-Chair	
Jonathon A. Fridell, MD	At Large	X
Kristie A. Lemmon, MBA	At Large	X
Richard N. Formica, MD	At Large	X
Tim Shain	At Large	
Eileen Brewer, MD	At Large	
Meelie A. DebRoy, MD	At Large	X
David Mulligan, MD	At Large	X
Sean Van Slyck, MPA/HSA	At Large	X
Sandra Taler, PhD	At Large	X
Joseph Rogers, MD	At Large	
Nancy Metzler	At Large	X
Dolly Tyan, PhD	At Large	X
Theresa Daly, MS, RN, FNP	At Large	X
Laurie Williams, RN, BSN, CPTC	At Large	
Charles Mowll	At Large	
Peter Reese, MD	At Large	X
Daniel Kaul, MD	At Large	X
Robert Walsh	HRSA	X
Monica Lin, PhD	HRSA	X
Ba Lin	HRSA	X
Bertram L. Kasiske, MD, FACP	SRTR	X
Susan Leppke	SRTR	X
Robert Hunter	Committee Liaison	X
James Alcorn	Director of Policy	X
Jen Wainright, PhD	Research Policy Analyst	X
David Kappus, MS	Director, Membership	X
Heather Neal	Transplant System Performance Manager	X
Sally Aungier	Senior Membership Standards Advisor	X
Ciara Samana	Kidney Committee Liaison	X
Liz Robbins	Liaison, Thoracic Committee	
Cliff McClenney	Assistant Director, Regional Administration	
Vipra Ghimire	Liaison, Pancreas Committee	X