

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**October 17<sup>th</sup>, 2022**

### **Conference Call**

**Nicole Turgeon, MD, FACS, Chair**

**Jennifer Prinz, RN, BSN, MPH, CPTC, Vice-Chair**

## **Introduction**

The Policy Oversight Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/17/2022 to discuss the following agenda items:

1. Overview of Vice-Chair Selection Process
2. New Project Review: *Identify Priority Shares in Kidney Multi-Organ Policies*
3. Pre-Public Comment Preview

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

### **1. Overview of Vice-Chair Selection Process**

Staff provided a summary of the Committee Vice-Chair selection process, desired candidate qualifications, and the timeline for selection.

#### Summary of discussion:

There was no discussion surrounding this item.

#### Next steps:

Interested members will update their volunteer interest form and submit them to the OPTN.

### **2. New Project Review: *Identify Priority Shares in Kidney Multi-Organ Policies***

The purpose of the Multi-Organ Transplant (MOT) Committee is to improve equity and efficiency in multi-organ transplant policy. The Vice-Chair of the MOT Committee provided details about their new project's purpose.

#### Data summary:

The proposal will establish an updated framework for multi-organ allocation that addresses:

- Required MOT shares vs. single organ offer acceptance
- When kidneys should be offered to single organ candidates before multi-organ candidates
- How to determine which kidney to offer to which candidate (including laterality)
- Promoting consistency in OPO practice while leaving flexibility for dynamic allocation circumstances

The rationale for this proposal is that:

- Multi-organ transplantation tends to pull lower KDPI kidneys away from kidney-alone candidates
- Metrics will assess impact of policy on improving equity in access for these populations

### Summary of discussion:

The Vice-Chair of the MOT Committee provided the disclaimer at the conclusion of her presentation that much of how multi-organ allocation is currently performed may change with the implementation of continuous distribution. However, because of the wait time until continuous distribution is implemented, the MOT Committee felt it was important to bring this project forward for consideration.

A member agreed that continuous distribution will be an entirely different method of allocating, but thought that the impetus of the proposal was to devise multi-organ policies that could be applied both in the current allocation system and the future continuous one. A second member supported this perspective, and added that it may be worthwhile to implement this policy ahead of continuous distribution to help inform how that allocation style should allocate to multi-organ candidates.

With no further discussion, the Committee unanimously approved endorsing the project to the Executive Committee for approval (11 yes, 0 no, 0 abstain).

### Next steps:

The MOT Committee will apprise the Committee of any updates that require guidance or oversight from the Committee.

### **3. Pre-Public Comment Preview**

The Chair provided an overview of three projects identified for discussion in the Committee that will be available for public comment in the winter cycle of 2023. Staff provided a brief overview of the rest of the projects afterwards.

The function of this review is not to provide an opinion on the whether to approve the project for public comment, but to ensure the sponsoring committee has addressed feedback from the Committee during their evidence gathering stage of development and provide recommendations on areas for greater clarity prior to public comment.

### Data summary:

The following projects anticipate being available for public comment during the winter cycle of 2023:

- *Expanding Simultaneous Liver-Kidney Required Allocation*
  - This proposal will align simultaneous liver-kidney (SLK) allocation policy with heart-kidney and heart-liver policy by increasing the distance over which both the liver and kidney must be offered as mandatory share from 250 to 500 nautical miles.
  - A data request has been submitted to determine the number of candidates listed for SLK and the proportion that receive SLK transplant over time
- *Optimizing Usage of Offer Filters*
  - This proposal will increase the usage of offer filters through an “opt-out” system, and automatically applying offer filters for all transplant programs when implemented.
  - This was chosen to precede a second proposal from the Operations & Safety Committee on redefining provisional yes and organ offers, as it was felt that the offer filters proposal may address some of the problems the second paper sought to correct.
- *Redefining Provisional Yes and the Approach to Organ Offers*
  - This proposal would reframe current allocation priority into a three-tiered system that includes policy requirements at each tier. This was done to ensure programs perform and accurate and timely evaluation of all organ offers.
  - The scope of the project has been narrowed to address only kidney, and to focus on enhancements to the current match system rather than a redesign of allocation.

- *Ethical Implications of Normothermic Regional Perfusion*
  - This white paper will refrain from endorsing Normothermic Regional Perfusion (NRP), given concerns related to the dead donor rule, but may come to the conclusion that NRP is ethically permissible. It will also highlight the areas of consensus and outline varying positions.

Summary of discussion:

*Expanding Simultaneous Liver-Kidney Required Allocation*

There was no discussion surrounding this item.

*Optimizing Usage of Offer Filters*

There was no discussion surrounding this item

*Redefining Provisional Yes and the Approach to Organ Offers*

Multiple members supported the change in timeline as well as the change in scope of the project.

Given the change in scope of the project, the Chair requested that the Committee return with the updated goals of their project once those had been determined for the Committee to return.

The Chair also requested any additional information from the Vice-Chair of the Operations & Safety Committee on the enhancements considered. The Vice-Chair responded that much of the feedback from the community gathered during public comment supported a more automated match run, as well as tools to improve efficiency; these sentiments were also echoed by members of the Workgroup. They added that much of the reason the Workgroup was moving away from enforcing policy at specific steps during the organ offer review process was the difficulty in tracking compliance.

*Ethical Implications of Normothermic Regional Perfusion*

A member felt that the most important outcome of the white paper should be to determine what evidence would be necessary to consider NRP as an ethical possibility. They explained that, regardless of the decision of the paper, there should be a recommendation for a standard of practice such that there is a clear path forward for programs considering NRP. The current state is very ambiguous and programs are performing it at different times with different sets of considerations.

A second member emphasized that there should be a clear outcome from the paper. They expressed concern that a white paper that remained ambiguous on guidance could be worse than the OPTN producing no guidance on it. The Vice-Chair of the Ethics Committee responded that white papers produced by their committee often provide competing arguments within the same paper in order to show an accurate framing of the ethical issues considered. Because of this, it is often difficult for the Ethics Committee to outright determine a result of their deliberation. They felt that this did not forego clarity in the resulting paper, but it would forego uniformity in the outcome. A member suggested that the Committee could put forward a series of circumstances in which NRP is and is not acceptable, such that they do present a unified decision within a set of constraints. The Ethics Vice-Chair agreed that this would be a desirable outcome, but still may be difficult given the diversity of opinions shared on their committee.

The Vice-Chair asked whether the Ethics Committee was focusing on considering NRP from an ethical perspective or a legal perspective. The Ethics Vice-Chair replied that they absolutely were focusing on the ethical implications, but there was intersection between the two. For example, if the committee did decide that it was not ethical, it would then need to be considered from the legal perspective. In

addition, if it was considered ethical but in a set series of circumstances, the guardrails would need to also be considered from the legal perspective.

The Chair posed two questions, wondering, first, if the Ethics Vice-Chair felt that their committee needed more time, and, second, whether more time would change anything in their deliberations. The Vice-Chair responded that the option of more time may be beneficial, so as to fully examine the issue without fear of having to determine a result. In addition, it may be useful to provide updates to the Committee to ascertain what the anticipated outcome of the white paper is.

With no further discussion, the Chair requested the Ethics Committee report out to the Committee on their progress at a later date to determine if the project needs a timeline update.

Next steps:

The Ethics Committee will provide an update to the Committee at a later date.

**Upcoming Meeting**

- November 14, 2022

## Attendance

- **Committee Members**
  - Nicole Turgeon
  - Jennifer Prinz
  - Natalie Blackwell
  - Andy Flescher
  - PJ Geraghty
  - Matt Hartwig
  - Jason Huff
  - Jim Kim
  - Kimberly Koontz
  - Brad Kornfeld
  - Scott Lindberg
  - Jondavid Menteeer
  - Gerald Morris
  - Dolamu Olaitan
  - Stephanie Pouch
  - Jesse Schold
- **HRSA Representatives**
  - Vanessa Arriola
- **SRTR Staff**
  - Ajay Israni
  - Ryo Hirose
- **UNOS Staff**
  - James Alcorn
  - Sally Aungier
  - Matt Belton
  - Roger Brown
  - Matt Cafarella
  - Liz Robbins Callahan
  - Amber Fritz
  - Isaac Hager
  - Darby Harris
  - Kristina Hogan
  - Morgan Jupe
  - Krissy Laurie
  - Taylor Livelli
  - Keiran McMahon
  - Tina Rhoades
  - Laura Schmitt
  - Susie Sprinson
  - Lisa Stocks
  - Kaitlin Swanner
  - Susan Tlusty
  - Joann White