

**OPTN Ethics Committee  
Meeting Summary  
September 19, 2024  
Webex Meeting**

**Andy Flescher, PhD, Chair  
Sanjay Kulkarni, MD, Vice Chair**

## **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 09/19/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Equity in Allocation Out of Sequence (AOOS)
3. Public Comment Presentation: Kidney Continuous Distribution Update

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

### **1. Welcome and Announcements**

**No decisions were made.**

The Committee was provided an update about the Expeditious Taskforce. The Health Resources and Services Administration (HRSA) directed the OPTN to pause work on the rescue pathway protocol in response to a critical comment HRSA received regarding organ allocations out of sequence. A critical comment requires review and response from Health and Human Services (HHS). We are not sure how long the review process will take so we will update you when we know more.

Also, the Xenotransplantation White Paper was approved by the Policy Oversight Committee to move forward to the OPTN Executive Committee for final approval.

### **2. Equity in Allocation Out of Sequence (AOOS)**

**No decisions were made.**

The equity topic group held discussion for the white paper on AOOS in progress.

#### Presentation Summary:

Equity: Fairness in the pattern of distribution of the benefits and burdens of organ allocation

- Distributive justice: Requires fairness in the distribution of scarce resources so that patients of similar need have an equal opportunity to benefit from transplantation
- Formal equality of opportunity: developing rules and policies that equally apply to all patients
- Fair equality of opportunity: developing rules and policies that each individual has a fair chance to equally exercise opportunity within those rules and policies
- Procedural justice: Upholds a commitment to treating like cases similarly, transparently, and predictably – treating similar people similarly

The National Organ Transplant Act states the importance of “equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant.”

We are concerned not exclusively with the aggregate amount of medical good that is produced, but also with the way in which that good is distributed among potential beneficiaries. This does not mean treating all patients the same, but it does require giving equal respect and concern to each patient.

The following can be considered possible equity considerations in AOOS:

- Organ Procurement Organization (OPO) Based:
  - Same patient listed at different centers may not have the same access (based on which "aggressive" center the OPO has a relationship with)
  - Should ALL centers get notified of potential expedited offer? Should there be uniform criteria for centers receiving the expedited offer?
- Transplant Center Based:
  - Disparities in access to transplantation are potentially exacerbated by homegrown expedited lists maintained by transplant centers
  - Consider – what criteria and/or biases are impacting center decisions about which patient(s) to select for the expedited offer?
- System/Access Based:
  - Patients able to be listed at large, aggressive centers benefit (impacted by geography, payer)

The presenter also reviewed some summarized data from the prior OPTN data request submitted.

Summary of discussion:

A member noted that the volume of transplants performed by a hospital certainly has an impact on this topic, as there is concern for outcomes with more marginal organs if the denominator is smaller. The Vice Chair explained one question is if the aims of broader sharing/continuous distribution are being impacted by rising allocation out of sequence, noting that he has not seen analysis that could shed light on this.

A member explained that patients in rural areas may be more likely to be bypassed in favor of someone at the center who has less logistical considerations. A member asked if the inequities seen in the data request were happening at the OPO level or at the transplant center level. The presenter answered that it is a bit of both, because OPOs are choosing which centers to offer the organ to, and then the individual centers are choosing who to allocate that organ to once it is offered in an open offer. The Vice Chair explained the difference between allocations out of sequence that are open offers versus those that are not, and noted that this is an important distinction to make in the paper.

Next steps:

The Committee will continue to discuss equity in the next meeting.

**3. Public Comment Presentation: Kidney Continuous Distribution**

**No decisions were made.**

The Committee received a presentation on kidney continuous distribution from the OPTN Kidney Transplantation Committee.

### Presentation Summary:

The Committee heard a presentation by the Chair of the OPTN Kidney Transplantation Committee about their request for feedback out for public comment on kidney continuous distribution.

This paper builds upon the Kidney Transplantation Committee's previous request for feedback, and on the Committee's Continuous Distribution (CD) updates. This update provides the Kidney Committee's progress to date on the continuous distribution project, including their discussions regarding efficiency objectives. This includes reducing non-use of kidneys, reducing out of sequence allocation for kidneys, and consideration of an expedited placement pathway in the continuous distribution of kidneys. This update also includes discussions on continued modeling and optimization.

### Summary of discussion:

The Ethics Committee discussed the presentation and submitted the following official comment:

The OPTN Ethics Committee thanks the OPTN Kidney Transplantation Committee for their ongoing work on continuous distribution and for the opportunity to provide feedback. In general, the Committee is supportive of the concepts outlined in the update paper. In particular, ethics members offer the following points for consideration.

It is clear from the update that the Kidney Committee is highly focused on utility and avoiding non-use, as directed by the OPTN Board. Will this clear focus on avoiding non-use, improving post-transplant outcomes, and overcoming transportation burdens potentially diminish the attention to equity and transparency? The Committee emphasizes that these efficiency-related goals are important, but must be achieved in balance with equity and transparency.

The Committee also appreciates the Kidney Committee's work to better understand and define a hard-to-place kidney, and to propose systems for expedited placement. The Ethics Committee is currently undertaking an ethical analysis of organs allocated out of sequence, and notes that understanding some of the drivers and consequences of this will help create an efficient and balanced system for allocating hard-to-place organs.

Finally, the Committee recommends that the Kidney Committee consider monitoring and takeaways from the implementation of lung continuous distribution to inform policy development.

### **Upcoming Meeting(s)**

- September 26, 2024

## Attendance

- **Committee Members**
  - Sena Wilson-Sheehan
  - Sanjay Kulkarni
  - Andy Flescher
  - Andrew Courtwright
  - Laura Jokimaki
  - Lois Shepherd
  - Gloria Chen
  - Julie Spear
  - Oluwafisayo Adebisi
  - Jennifer Dillon
  - Laura Madigan-McCown
  - Lisa Paolillo
  - Felicia Wells-Williams
  - Matthew Wilkinson
  - Joel Wu
  - Shelia Bullock
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
  - Arjun Naik
  - Shannon Dunne
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kieran McMahon
  - Katrina Gauntt
  - Laura Schmitt
  - Kaitlin Swanner
  - Cole Fox
- **Other attendees**
  - Jim Kim