

**OPTN Ethics Committee  
Meeting Summary  
August 15, 2024  
Webex Meeting**

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

## **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 08/15/2024 to discuss the following agenda items:

1. Expeditious Taskforce Rescue Pathways Workgroup
2. Data Request Results and Discussion

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

### **1. Expeditious Taskforce Rescue Pathways Workgroup**

**No decisions were made.**

A representative who serves on both the Ethics Committee and the Expeditious Taskforce gave an update on the work of the Rescue Pathways Workgroup.

#### Presentation Summary:

The Workgroup is testing potential improvements to allocation policies through a policy variance. Out-of-sequence allocation of kidneys is currently happening, but the process is not standardized across organ procurement organizations (OPOs). The Workgroup developed a protocol to test a potential rescue pathway idea for kidney donor profile index (KDPI) kidneys 75% and up.

The group selected OPOs based on high potential, non-use rate, out of sequence allocation, geography, and size. Transplant programs were chosen based on proximity to the OPO and potential for increasing out of sequence acceptance. Stopping rules will be implemented to monitor the proportion of transplants for females, non-white, and pediatric candidates. The protocol aims to reduce offer burden, non-use of organs, cold ischemic time, and improve organ placement.

#### Summary of discussion:

A member asked if at-risk groups such as non-white, females, and pediatric candidates will be monitored throughout the protocol to make sure that the proportion of high KDPI kidneys being allocated to these populations is not increasing, as this would be an equity concern.

#### Next steps:

None

## 2. Data Request Results and Discussion

No decisions were made.

The Committee heard the results of the data request they submitted about measures of interest regarding allocation out of sequence (AOOS).

### Data Summary:

Many of the committee data OPTN questions were addressed in OPTN presentation provided in June. Updated excel documents with donor and recipients' characteristics based on the committee's indicated cohort and few additional characteristics not included prior.

- Bypass codes 799, 861, 862, 863
- Transplant/Recovery from July 2021 – December 2023
- Donors who were transplanted only
- New Donor Characteristic : Biopsy
- New Recipient Characteristic : Cold Time, Distances from Recipient zip code to Transplant Hospital, and On dialysis

Conclusions differed slightly as described below:

### **Donor Characteristics:**

When looking at just donors who were recovered and transplanted some differences were more prominent (ex. donor age, Kidney Donor Risk Index (KDRI), Donor Creatinine, etc). Characteristics largely identified through the age adjusted analysis. A greater proportion of AOOS kidneys tended to be biopsied (In Sequence (AIS): 43%, AOOS: 70%)

### **Candidate Characteristics:**

CPRA shift seen was likely influenced by the new policy implemented on January 26th, 2023.

AOOS recipients

- received kidneys with a slightly longer cold time ( AOOS : 24 hrs, AIS : 19 hrs)
- were slightly less likely to be on dialysis (AOOS : 75%, AIS : 81%)
- lived in ZCTA that were slightly closer to the transplant hospital (AOOS : 17 NM, AIS : 22 NM)

### **Data presented also included:**

- Average number of Registrations bypassed in AOOS events
  - Median Number of Registrations Bypassed: 395
  - Median Number of Refusals before First Bypass: 35
- 1 year graft survival for AIS vs AOOS
  - By KDPI: no statistically significant difference between AIS and AOOS
  - Donor Type: no statistically significant difference between AIS and AOOS
- Non-Use Rates for AOOS kidneys
  - By KDPI: overall, 27.1%. As KDPI increases, nonuse increases.
  - Donor Type: DCD donors had a slightly higher nonuse rate when compared to non-DCD donors
  - Blood Type: relatively similar across blood types, with a slightly higher proportion for AB donors
  - History of Diabetes: nonuse higher for kidneys from donors with a history of diabetes

- Donor Terminal Creatine: donors with a terminal creatinine of greater than or equal to 1.5 had a higher overall non-use rate

#### Summary of Discussion:

A member asked about the counterfactual question of about whether very high out of sequence placement OPOs are not seeing a change in their nonuse rate because it just stays stable no matter what you do or whether it would have been higher if they hadn't been engaged and out of sequence allocation. Research staff responded that this is difficult to analyze but the Kidney Committee has looked at some of this in a recent data request that is available to the Committee.

The Chair asked about race and gender, and research staff responded that these measures are included in the spreadsheets sent to the Committee, but that there are no statistically significant differences in race between donors AIS and AOOS. The Vice Chair asked about race within individuals who are listed for preemptive kidney transplants. This was not included in the original analysis but can be provided to the Committee. The Vice Chair also asked if it is possible to tell when an OPO uses an expedited liver pathway versus an OPO who allocates a liver strictly out of sequence. Research staff responded that yes, this was monitored for in a liver monitoring report, and the report showed that the pathway was somewhat underutilized, possibly because it was required to be used after cross-clamp.

A member asked if part of the analysis considered insurance. This was not in the original request; however, it can be provided to the Committee subsequently. A member asked about urban versus rural, and staff responded that the closest approximation of this would be how close or far the recipient lives to the transplant center for allocation based on zip code. A member asked if there was any possible additional information to provide about geographic disparities.

The Chair asked why 1-year was chosen for graft survival, and staff responded that there hasn't been enough time that has passed to analyze past 1-year for the influx of AOOS events that began in 2023. A member asked about death on the waiting list for those bypassed due to AOOS, and staff responded that was not included in the analysis.

#### Next Steps:

Research staff will follow up with the additional clarifications requested.

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

- August 22, 2024

## Attendance

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