

**OPTN Ethics Committee  
Meeting Summary  
August 22, 2024  
Webex Meeting**

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

## **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 08/22/2024 to discuss the following agenda items:

1. Transparency in Allocation Out of Sequence (AOOS)

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

### **1. Transparency in Allocation Out of Sequence (AOOS)**

**No decisions were made.**

The transparency and respect for persons topic group held discussion for the white paper on AOOS in progress.

#### Presentation Summary:

Respect for persons involves obligation to respect the intentions of the donor:

- System of allocation in place to procure and manage organs to maximize their potential
  - Potential life of graft after transplant
  - Best organ for patient and best patient for organ
- Distribution in ways that are fair and equitable
- Avoid non-use whenever possible (high priority)

Respect for persons requires that the organ allocation process be “fair”

- Where fairness can be defined as an optimal balance of utility and equity
- Fair has traditionally been defined by the match run

OPTN Policy 5.4.B.3: OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run. Match run is fairly effective at assuring equitable allocation, but has not been as successful at optimizing utility (avoiding non-use). This has led to the development of alternative methods by OPOs and transplant centers in a good faith effort to improve efficiency and fairness. Many AOOS protocols ad-hoc and lack transparency, bypass standard practices, and may lead to unintended consequences. Respect for persons means that patients should have full access to information that might impact decisions that are under their control. Prospective recipients should understand and be empowered to act on the choices available to them, enabling them to optimize their chances of receiving an organ that is compatible with their needs and preferences.

Transparency requires that the process by which organs are allocated be coherent and clearly articulated in published documents that are available to the public. The public needs to be able to trust

that these protocols have been developed following strict rules of accountability, but this does not necessarily imply that individual patients need to fully understand the details of the allocation process in order to have trust in the system.

Valid alterations made to allocation policy and to the match run are not “exceptions” or “violations” of the allocation system – rather, they represent the current, legitimate system of allocation. How do we view AOOS in this context?

Summary of discussion:

A member asked if an element of transparency is following the system as agreed upon through policy and told to prospective recipients, and stated that the AOOS process seems to step outside of this. The group leader agreed, stating that the system is in constant evolution but that the important part to prospective recipients is that the allocation process is adequately vetted and consistent from candidate to candidate. The system may not be the same over time because policy requires changing, but the public should trust that at any time, there is a consistent, legitimate process in place and individuals are not making decisions on the fly. The group leader stated that a transparent system would mean that every time a decision is made about how the organ is going to be allocated, it ought to be auditable in the sense that there is a track record of each decision that is made, and that AOOS seems to contradict this principle. A member stated that the balance of equity and utility have been defined that in a certain way and it seems like with respect to the out of sequence question, respect for persons requires following unless there are appropriate justified exceptions following that system. From there, the question would be what are the justified exceptions to the rule?

A member stated that AOOS does not seem to be highly correlated with reducing non-use and that lower KDPI kidneys are often being AOOS. This member expressed that this is concerning from a transparency standpoint, because the public does not understand that “exceptions” to the rules are being made so frequently or how this impacts them as a potential recipient.

Members discussed a “single river” concept of refining the match run through policy, versus a “two river” concept wherein there are parallel allocation systems, one for the match run, and one for the process of allocating out of sequence. The group lead stated that the single river concept is best because the two rivers concept opens up the possibility for patients to rightly say that they would have gotten an organ if their OPO/transplant center followed the match run, but because they allocated using an alternate pathway, they did not. The Chair recommended raising this in the paper, and then arrive at conclusions together as a Committee. The group lead acknowledged that there are different types of AOOS events, but that the worry is having a system with a sentiment that “when we really need to, we can AOOS,” without defining what those types of situations would be and what guardrails should be in place. A member expressed concern about the number of AOOS events increasing over time, and that OPOs have their own set of rules they are operating under that were not created following any sort of policy-making, public-facing process. This member stated this is because of underlying inefficiencies within the allocation system.

A member asked how the Committee is defining “maximize donor potential.” Members discussed that this entails both maximizing the number and quality of organs from donors, but also maximizing life from the perspective of how that graft will do for the recipient. The Vice Chair added that in some senses, the allocation system is based around reducing waitlist mortality more so than overall post-transplant function. A member who is a donor mom indicated that sometimes, the idea that the organs go to the sickest patients versus the ones who may have the best outcomes long-term can be hard to grapple with.

Next steps:

None

**Upcoming Meeting(s)**

- September 19, 2024

## Attendance

- **Committee Members**
  - Sena Wilson-Sheehan
  - Sanjay Kulkarni
  - Andy Flescher
  - Andrew Courtwright
  - Laura Jokimaki
  - Lois Shepherd
  - Oluwafisayo Adebiji
  - Jennifer Dillon
  - Laura Madigan-McCown
  - Lisa Paolillo
  - Felicia Wells-Williams
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
  - Arjun Naik
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kieran McMahon
  - Katrina Gauntt
  - Laura Schmitt
  - Carlos Martinez
  - Cole Fox
- **Other attendees**
  - Julie Spear