

**OPTN Ethics Committee**

**Meeting Summary**

**October 16, 2024**

**In-Person Meeting**

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

## **Introduction**

The Ethics Committee (“Committee”) met in-person in Richmond, VA and via WebEx teleconference on 10/16/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Allocation Out of Sequence White Paper Discussion
3. Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation

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

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

#### Summary of discussion:

The Chair welcomed members to the call. Members participated in an icebreaker. There was a call for volunteers for an Organ Procurement Organization (OPO) Committee workgroup.

### **2. Allocation Out of Sequence White Paper Discussion**

The Committee discussed the first draft of the allocation out of sequence (AOOS) white paper and considered what the paper should conclude.

#### Presentation Summary:

The Chair reviewed the goals of today’s discussion:

1. Recap goal of paper
2. Overview each drafted section
3. Go through selected comments and resolve items through discussion
4. Discuss other components of the paper (glossary, any necessary appendices)

The Chair went through the charge of the Committee and reviewed information about the white paper approval process and lessons learned from past projects. The Committee reviewed the authority for the project as well as some updated information from the Membership and Professional Standards Committee’s (MPSC) report to the Board of Directors on review of AOOS events.

Staff provided a recap of the cohort of the OPTN data request that the Committee submitted and noted that where other literature is cited in the draft, it will be important to note that these sources most likely used a slightly different cohort and definition for their analysis. Staff noted that it would be appropriate to note this for readers, but that there were no areas of major concern where data is cited in the paper.

The Committee reviewed the outline of the paper and what each section aims to address.

## Summary of discussion:

### *MPSC review of AOOS events*

The Chair indicated that the MPSC's concern for the rise in AOOS and their call for standardization is helpful for the Committee's analysis. Staff clarified that the MPSC does not review AOOS events that do not result in a transplant, and that due to volume, the MPSC has a system in place to review a subset of allocations of exceptional concern.

### *Data review*

A member expressed concern that the utility analysis will be limited if the data is only capturing AOOS that resulted in a transplant. The Chair noted that it is appropriate to note this in the paper. The Vice Chair (VC) agreed noting that most analyses will underreport the level of AOOS that is happening. A member stated that one conclusion of the paper should be increased analysis, and possibly additional data collection, is needed to fully understand the scope of the issue and impacts, especially to understand AOOS events that did not result in a transplant.

### *Discussion of the match run*

A member indicated that if AOOS is protocolized such that it is a part of policy, then there is no need for the terms "exception" or "variance" to policy, because expedited placement would be within policy. Several members indicated that the framing of AOOS as an "acceptable exception to the rule" from the outset is confusing and limits the potential conclusions of the paper. Members discussed how the match run is probably best described as the outcome of or mechanism through which allocation policy occurs. Members addressed how starting out with the paper attempting to justify exceptions to the rule may need to be adjusted. Members agreed to add more detail to the section about the match run regarding policy development and regulatory frameworks for context. A member indicated that information about allocation policy development- both procedurally and substantively- is important for setting up the idea that AOOS has *not* followed the normal steps. Staff also recommended drawing a clearer distinction between the match run and allocation policy and the implications of each in terms of AOOS. A member described that the problems with AOOS are an absence of consistency and opacity in terms of process.

Members also discussed limited patient understanding (and in some cases, limited information shared to patients) regarding the match run and what this means for their transplant journey. The VC addressed "open offers" and noted that the concept of folding AOOS in the match run is problematic when you consider open offers. A member recommended that a threshold be set for which organs should qualify for an open offer. The VC also discussed how expedited placement protocols are currently limited in terms of feasibility and underutilized.

### *Comments on white paper draft*

Members addressed the following topics in a review of the draft:

- Defining AOOS
  - The Committee reached consensus to remove the idea of intent from the description of AOOS. The factors behind why an organ may be allocated out of sequence can be described in a narrative section for context.
- Members wished to add an appendix to describe what may occur in AOOS and how it differs from "standard" allocation, as well as a glossary.
- Members discussed the concept of procedural justice. Some members agreed that this point was addressed adequately in the transparency section, but several members advocated that the

concept of procedural justice should be its own section, or addressed in the background section, as this is a problem in it of itself.

- Members talked about how an AOOS event is referred to in the draft, as multiple terms are used, including “exception to the rule,” “deviation from policy,” “option,” and “policy violation.” A member stated that if AOOS is a deviation from policy that is accepted, then AOOS becomes de facto policy, regardless of whether it is actually in policy. Members discussed how it may be problematic if AOOS is de facto policy but has not gone through all policy-making procedures. The VC noted that there is a conceptual overarching duty on the part of OPOs and transplant centers to avoid non-use, which is consistent with regulatory requirements. Staff explained that making this distinction is probably needed in the paper, because the behavior of attempting to avoid non-use is not inappropriate because it is following the charge to avoid non-use. A member described that the duty to adhere to the match run is conditional, not absolute, because there are circumstances in which it would be more appropriate to *not* follow the match run in order to ensure that an organ is transplanted vs not used. The Committee agreed to not qualify the term of AOOS any further than stating that it is an AOOS event and an increasing practice. The Chair noted that it would be useful to describe that the practice of AOOS is happening de facto, and while not an official part of policy, it does not stand in contradiction to the goals of policy. However, the increasing practice does give rise to questions which should be examined in terms of implications and consequences.
- OPO versus transplant center role in AOOS
  - A member stated that both the organ procurement organizations (OPOs) and transplant centers have a role in all the issues that are covered in the analysis, especially the equity issues, but that it is important to make clear who is doing which part of the AOOS process. OPOs allocate organs, and transplant centers select an appropriate recipient for the organ.
  - A member from an OPO recommended making sure that the text does not read like AOOS is only an OPO problem, because it is a system issue. The Committee agreed that tone will be important.
- Equity versus equality: the Committee clarified the use of these two terms throughout the paper
- Geographic disparity
  - A member asked if the goal of moving away from donation service areas as a unit of allocation was intended to reduce geographic disparity, did it actually accomplish that? This member recommended adding data to get at the before/after to better understand how AOOS impacts geographic disparities.

The Committee also discussed the potential conclusions of the paper. The following points were mentioned:

*Transparency, respect for persons, and notification:*

- Public disclosure of the policy-making process and the existence of AOOS as a possibility is important for potential transplant recipients (PTRs) to understand. Individual notification would likely not be feasible, and may not be as relevant to transparency in considering whether a patient actually has a choice in the decision or not.
- Conclusions about what is required in terms of transparency must be understood in the context of allocation of a scarce resource. However, the VC stated that while this is true, it is important to note that as a society, we have already decided how to allocate the scarce resource and that is through the allocation policies.

- Members noted that it is challenging because there is limited patient understanding of what the “list” means already, and AOOS complicates this. Members discussed various ways that clinicians have conversations about the appropriate organ for an individual patient.
- Some members stated that each time a person is “skipped over” in AOOS, they should be notified. Other members disagreed, stating that this is not feasible and does not provide actionable information that would impact their autonomy, because offers are made to clinicians and not to patients. The VC summarized, stating that it is indisputable that not notifying patients when they are skipped limits their clinical decision making, however, it could be justifiable for the greater good to reduce non-use. Members discussed this, noting that a challenge arises when the organ in question is not a clinically reasonable option for the patient, because in this case, it would not be significantly limiting their autonomy because it was not a viable option to begin with. The VC explained that in his experience, the AOOS offers have already been determined to be transplantable. Staff recommended keeping the scope of this limited to transparency issues regarding AOOS, and noted that it is appropriate to note the limitations of the current system.
- The Chair recommended framing this in terms of “common good” issues and then issues concerning an individual. For example, the formal right that patients have to understand how allocation policy is made is a common good issue.
- The Committee reached consensus that it is appropriate to conclude that community-level education regarding the possibility of AOOS and how this may impact them is important. There was less consensus about the role of individual notification and disclosure, and how the burdens of this should be distributed.

#### *The future of AOOS*

- Members mentioned that it is not appropriate to have a deviation from allocation policy 20% of the time, and so the Committee should determine if the paper should conclude that the number of AOOS events should be reduced, or make sure that the instances in which an organ is allocated out of sequence are legitimized through policy change. A member recommended that you can create a pathway through fair procedures that there is agreement on, and then organs travel through that pathway such that these events are not deviations from policy.
- A member stated concern about legitimizing this, stating that the geographic disparity will not be addressed. The VC stated that if a pathway is built, then patients may not have an equal ability to access the organs through this pathway.
- A member stated that it is challenging to solve for AOOS when there is not consensus on what a “marginal” organ is, because you cannot identify which organs would be appropriate to expedite to reduce the risk of non-use. Another member cautioned that not all organs that are transplanted AOOS are marginal. The VC encouraged looking into the characteristics of the recipients of the 0-20% kidney donor profile index (KDPI) organs, especially to see if these people were highly sensitized. The Committee also recommended looking into when an AOOS event was an open offer, at what point this occurs, and how often this occurs.
- A member cautioned that if the Committee is recommending that the level of AOOS is reduced to an “acceptable” level, if there is not standardization, protocol, and transparency, then there is no acceptable level.
- The Chair explained that there needs to be better enforcement and monitoring of AOOS to the extent that it continues to exist. A member explained that the conclusions should be that the system should be more fair and transparent about AOOS, provide for better reporting and

monitoring, and try to reduce the overall instances where an AOOS event is “required” in the first place.

- A member explained it is challenging to determine the appropriate future of AOOS without a vision of a perfect system in place- how is the Committee determining success when it comes to AOOS?

Next steps:

The Committee will continue to revise the draft and consider the conclusions.

**3. Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation**

The Committee briefly discussed their next project, *Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation*.

Presentation Summary:

The Chair overviewed the project and the main questions the paper may address, including:

1. Should eligibility to participate in a xenotransplant clinical trial impact the eligibility for and timing of a patient’s initial waitlisting for a deceased donor allograft?
2. Should patients who receive a xenotransplant remain on the allograft waiting list?
3. How should prior receipt of a xenotransplant affect eligibility to be listed for a subsequent deceased donor allograft?
4. Should former clinical trial participants with a failed xenograft receive special consideration for subsequent receipt of a deceased donor allograft?

The Chair also noted that due to the OPTN authority on this topic, the paper may only address how xenotransplantation may interface with the human organ allocation system. Questions of the general ethicality of xenotransplantation are not within the scope.

The VC explained that the question of if prior xenograft recipients should be eligible for any sort of priority was misconstrued at the POC-level because of the example of prior living donor priority that was used. The VC described that this was not intended to equate these two situations in any way, just to provide an example, and that the Committee can consider other ways of making this point.

Summary of Discussion:

The Committee discussed the questions related to clinical trial eligibility and the authority and scope of the ethical analysis. The Committee decided that the questions as outlined in the project form may need to be rephrased and reconsidered for relevance as the project develops. A member highlighted the need to clarify the use of the term “priority,” indicating that special consideration for just being a participant in a clinical trial would be ethically different than accurately weighing the medical complexities that they would experience as a result of being a xenograft recipient within the allocation system.

The Committee wants to include the following stakeholders throughout project development:

- OPTN members who are experienced with review boards and exception requests
- Xenotransplant experts
- OPTN Disease Transmission Advisory Committee/infectious disease expertise

Next Steps:

The Committee will continue to discuss this project as the AOOS white paper wraps up.

## Upcoming Meeting(s)

- Nov 21

## Attendance

- **Committee Members**
  - Andy Flescher
  - Sanjay Kulkarni
  - Sheila Bullock
  - Gloria Chen
  - Lisa Paolillo
  - Laura Madigan-McCown
  - Julie Spear
  - Joel Wu
  - Andrew Courtwright
  - Laura Jokimaki
  - Fisayo Adebisi
  - Bob Truog
  - Lois Shepherd
  - Felicia Wells-Williams
  - Sena Wilson-Sheehan
  - Jennifer Dillon
- **HRSA Representatives**
  - Jim Bowman
  - Shannon Dunne
  - Arjun Naik
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kieran McMahon
  - Cole Fox
  - Kim Uccellini
  - Katrina Gauntt
  - Keighly Bradbrook
  - Linwood Butler
- **Other Attendees**
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