

**OPTN Ethics Committee
Meeting Summary
November 21, 2024
Webex Meeting**

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

Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 11/21/2024 to discuss the following agenda items:

1. Review Revised Draft of Ethical Analysis of Allocating Organs Out of Sequence (AOOS)

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

1. Equity in Allocation Out of Sequence (AOOS)

The Committee further revised the white paper.

The Committee continued discussion for the white paper on AOOS in progress, with a focus on the conclusions section.

Presentation Summary:

The Chair overviewed the main changes since the prior draft:

- Conclusions section added
- Background section reorganized
 - Covers differences between standard allocation and AOOS
 - Role of open offers section added
 - OPTN policy-making process, regulatory framework, and procedural justice covered in greater detail
- Idea of the future of AOOS introduced earlier
 - Over time we will build policies to better account for the organs that are currently being allocated out of sequence to ensure that they are transplanted, so there will be less need for AOOS as a workaround
- References to the utility of AOOS reframed slightly to better align with data
- Appendix A describes factors that may have contributed to rise in AOOS
- Glossary terms added

Summary of discussion:

The Committee focused on the conclusions section during the discussion:

Informing the public, in particular potential transplant recipients, about AOOS as a possibility should be a priority.

A member suggested linking the idea of the match run more clearly in this conclusion, and this change was made. A member expressed concern about this conclusion and asked what, if any, action items

there would be from knowing about AOOS as a possibility for a patient. This member described that it is not an option to “opt out” of AOOS, and the Chair responded that even though there may not be anything that an individual patient could do with the information, it is still important for this knowledge to be public in support of transparency. The Vice Chair stated that the true impact of AOOS is still unknown, both in terms of public perception and of outcomes for those bypassed. Another member stated that the allocation system is not reducible to simply the idea of the match run, and that it is important for patients to understand that the system is complicated, and that there may be elements of the system that may not benefit them as an individual in every instance. This member stated that anytime there is allocation of a scarce resource, it is important to understand that the system aims to distribute the benefits/burdens of the system. In transplant, this means that for an individual patient, AOOS may or may not affect them, and they should understand this as a condition of entering onto the waitlist. A member described that this may be misunderstood by the community. The Committee will ask for public feedback on this topic during public comment.

Further data and analysis are required to fully understand the ethical implications of AOOS. Understanding what makes an organ hard-to-place and at risk of nonuse will support more robust and comprehensive allocation policies.

A member asked about if the definition of AOOS needed to be further refined, and the Committee discussed the challenges with defining AOOS.

Ultimately, the option of an “expedited pathway” should be able to be identified in a consistent manner and, over time, become part of normal allocation policy. To this end, in the future there may be opportunities to standardize the allocation of certain organs that are currently being placed out of sequence by developing policies that address allocation of organs at greater risk of nonuse.

Members felt that this conclusion was appropriate and did not have concerns.

While AOOS remains as a practice to alleviate the pressures that end up in nonuse, it should not come to be regarded as a catch-all solution. The OPTN should continue to identify which aspects of AOOS present issues of greatest potential concern and attune monitoring to these aspects.

A member described that it is hard to think about this conclusion because there is so much that is unknown about AOOS, and what we do understand is sometimes conflicting and non-intuitive. The Chair explained that the paper has been revised to more clearly reflect that the utility aspects of AOOS are mixed according to currently available data. A member stated that people on the front lines *do* understand the specifics of how AOOS is impacting the system. This member explained that standardization and monitoring of concerning instances of AOOS is important now and into the future.

The Committee also discussed the section of the paper that describes the OPTN data request it submitted. Members discussed that although the bypass codes used to identify AOOS may not contain as much detail as would be ideal, it is likely out of scope of the paper to discuss this much further.

Next steps:

The Committee will vote on the paper at the next meeting.

Upcoming Meeting(s)

- December 19, 2024

Attendance

- **Committee Members**
 - Sena Wilson-Sheehan
 - Andy Flescher
 - Laura Jokimaki
 - Lois Shepherd
 - Gloria Chen
 - Laura Madigan-McCown
 - Lisa Paolillo
 - Joel Wu
 - Shelia Bullock
 - Bob Truog
 - Sanjay Kulkarni
 - Julie Spear
 - Felicia Wells-Williams
- **HRSA Representatives**
 - none
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kieran McMahon
 - Katrina Gauntt
 - Cole Fox
 - Kristina Hogan
- **Other attendees**