

**OPTN Ethics Committee
Meeting Summary
July 18, 2024
Webex Meeting**

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

Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 07/18/2024 to discuss the following agenda items:

1. New Member Orientation
2. Discussion: Utility Topic Group

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

1. New Member Orientation

No decisions were made.

Presentation Summary:

New members participated in a brief orientation process.

Summary of discussion:

None

Next steps:

None

2. Discussion: Utility Topic Group

No decisions were made.

The utility-focused topic group held discussion for the development of the Committee’s white paper, Ethical Analysis of Allocating Organs Out of Sequence.

Presentation Summary:

The group leader began by introducing the goal of the utility topic group and discussion for the meeting, noting that the focus is on allocation out of sequence (AOOS) as it currently functions in the system. The OPTN Ethics definition of utility holds a practice to be right if it promotes as much or more aggregate net good than any alternative practice. Goods in this case may include patient survival, graft function, quality of life, efficiency in organ placement, and financial cost.

- Does AOOS as currently practiced result in more aggregate good(s) than the standard organ match? Are there modifications to AOOS that may result in improvements to utility?

The leader went through some of the intended utility benefits of AOOS:

- Decrease non-use to promote more transplants
 - Reduce wait time, reduce likelihood of waitlist death or removal
 - Reduce accumulation of comorbidities while waiting for transplant
 - Reduce donor family distress relating to non-use, allow for donation in context of donor family time constraints
- Improved efficacy in placement (independent of non-use)
 - Good faith efforts by organ procurement organizations (OPOs) to streamline hard-to-place organs
 - “Better than dialysis” kidneys
 - Open offers to find appropriate candidates who may be further down the list
- Financial and logistical benefits

The leader also discussed utility of AOOS in context of the National Organ Transplant Act (NOTA) and the Final Rule, as well as other points to consider in context of the following:

- Aspects of AOOS that may reduce utility of the practice
 - Prolonged ischemic times, related complications
 - Increased financial costs with longer travel distances, resources
- Non-use
 - No correlation between non-use rates and increases in AOOS, globally or among OPOs with high AOOS
 - Need data on if rates would have increased more without use of AOOS
- Does AOOS streamline allocation of hard-to-place organs?
 - KDPI 60-85% kidneys are the most common group for AOOS (note: need to opt-in for KDPI 85% +)
 - AOOS has been happening earlier and earlier in the match runs, especially for 0-20% KDPI kidneys

Summary of Discussion:

A member asked if the donor family perspective will be included in this section, and the leader agreed that this is a good that should be considered. The Vice Chair asked if donor families know if their family members’ organs were utilized or not, and if there is distress. An attendee stated that as a donor mom, the families know whether or not their loved one’s organs were placed and that distress does occur, and should be considered in this analysis. A member agreed, stating that this was consistent with the OPO perspective. Another member asked if another good that should be considered is distress on behalf of organ procurement professionals as a utility point, and members agreed this should factor in. The leader asked if these members knew of any literature on this topic to cite in the analysis.

The Chair asked if the analysis should consider the reality of turn-downs and allude to other system pressures that exist, including the phenomenon of “list-diving.” The Chair and the lead agreed that this is helpful context, but that it may not make sense to have it at the core of the analysis. A member asked if there are ways to discourage AOOS, and the lead and staff responded that while there have not been any action taken against those who allocate out of sequence, these are tracked and monitored within the OPTN by the Membership and Professional Standards Committee (MPSC).

The Vice Chair explained that the background section should address that AOOS is not new, it is just a response to a change in system pressure and set-up over time, and that it has become more of a prevalent concern in recent years. A member discussed the use of the word “appropriate,” noting that

each center may define “appropriate” differently. This member stated that in their center, providers sometimes define the “appropriate” candidate as one much further down the match run, because those higher up on the match run are more likely to get more offers as they are typically more medically urgent, so they would have another “shot” at an organ soon.

The leader discussed utility in context, noting that trust in the system is a utility consideration but that these transparency-focused utility concerns will be discussed in detail by that topic group. A member commented on there not being a correlation between AOOS and a reduction in non-use, noting that this does not line up with anecdotal evidence. A member asked if the organs transplanted through current AOOS are those that historically would never have been placed, or if they are more likely to be organs that would have been placed but perhaps with a longer cold ischemic time. The lead answered that to their understanding, cold ischemic time seems to be similar but that what is unknown is if the organs allocated out of sequence would have never been used. A research staff member also noted that the donor pool is expanding, shifting the groupings of kidney donor profile index (KDPI) and the marginality of the donors respective to each other from year to year. The leader stated that if the Committee believes that AOOS is justified on utility grounds, it will be important to understand and explain why non-use does not correlate.

A member discussed the rate of 0-20% KDPI kidneys being allocated out of sequence, noting that if even these “high-quality, easy-to-place” kidneys are being allocated outside the match run, this will be important for the public to understand. The leader agreed this will be important to explain, and that it raises concerns about the intent of the practice versus what is actually happening.

A member discussed procedural fairness as a consideration, explaining that there is a process of creating processes and policies for organ allocation that includes stakeholders and deliberation to produce the match run, and that AOOS sits outside this. The Chair responded that this may belong in the transparency section, and that the importance of the match run and its relevance will be explained at the outset of the paper, including why there is a deviation to the match run in this case. The Chair continued, explaining that the paper will describe how “rules to the exception to the rule” should be thought about. The member explained that procedural justice should be a consideration in its own right, not simply as a component of transparency. The Vice Chair agreed, stating that one question should be how often a system should tolerate variations or exceptions to policy if the goal of policy development is to build a set of policies that are sturdy.

Next Steps:

None

Upcoming Meeting(s)

- August 15, 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
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kristina Hogan
 - Kieran McMahan
 - Katrina Gauntt
 - Jamie Panko
 - Cole Fox
- **Other attendees**
 - Julie Spear