

OPTN Ethics Committee

Meeting Summary

June 17, 2021

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 06/17/2021 to discuss the following agenda items:

1. Welcome & Reminder about onboarding and continuing education requirements
2. Goodbye to departing Committee members
3. Ethical Considerations of Continuous Distribution in Organ Allocation

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

1. Welcome & Reminder about onboarding and continuing education requirements

UNOS staff reminded members about the continuing education modules, conflict of interest document, and confidentiality agreement that are required for ongoing Committee service. These modules can be accessed on UNOS Connect.

2. Goodbye to departing Committee members

The Chair highlighted the accomplishments and contributions of the outgoing members and thanked them for their years of hard work and dedication. Outgoing members' term will conclude on June 30, 2021.

3. Ethical Considerations of Continuous Distribution in Organ Allocation

In preparation for the Committee's formal vote, the Chair gauged member's sentiment through a poll asking "Do you support sending the white paper, *Ethical Consideration of Continuous Distribution in Organ Allocation*, to the Policy Oversight Committee to proceed with public comment?" The initial, informal vote was conducted via SurveyMonkey and resulted in 10-1 in support. The Chair went through each section of the document to provide an overview to the Committee.

Summary of discussion:

A member shared concern that due to the length of the paper and the limited time to review the document in its entirety they are not necessarily as familiar with the final version of the paper as they would ideally like to be. The Chair empathized with that sentiment and inquired if it would be possible for members to vote after the meeting to allow for more time to review the document. UNOS staff responded that procedurally all of members needed to vote together during the meeting.

A member suggested including, in the normative justification section, a rationale for why a change in framework is necessary and beneficial for the transplant community. The Vice Chair noted that the background section was excluded from this draft but acknowledged the benefit of adding a few sentences to provide clarity to the reader. UNOS staff confirmed the background section would be included in the document that is sent out for public comment.

In reference to the section titled *Known Data Gaps May Disadvantage Certain Populations*, a member commented that the artificial intelligence and machine learning literature has shown that the underinclusion of certain groups in a data set is likely to make the algorithm or prediction less accurate for that group. However, it does not necessarily mean the data set will produce worse outcomes for that group in allocation because sometimes underinclusion results in greater allocation. The purpose of sharing this literature is to say that the issue is accuracy and does not directly cause maldistribution.

To resolve this, the Chair suggested adding a title sentence that said “Lack of data or inadequate data about underrepresented groups may reduce accuracy of modeling potentially affecting outcomes for these groups in ways that are difficult to anticipate.”

A member added that they may need to later elaborate on the subtle point that moving to a national plan of allocation will result in practical problems around sharing national resources. The chair suggested monitoring the public comment feedback to determine if this is confusing to OPTN members, and if so, whether more information about statistical fairness in machine learning is needed.

In reference to the section titled *Allocation Changes Will Inevitably Harm Groups Experiencing Limited Transplant Opportunities*, a member commented that while the paragraph is an accurate reflection of the sources referenced the title of the section is inaccurate. The member noted that it is not actually inevitable and instead attention should be paid to try to avoid this. Another member agreed with this comment and the Chair agreed to revise the title.

The words ‘will inevitably’ were replaced with the word ‘may’ so the new title reads as *Allocation Changes May Harm Groups Experiencing Limited Transplant Opportunities*.

UNOS staff informed the Committee that references to regions or Donation Service Areas (DSAs) as an allocation unit have been removed or rephrased to geographic area or geographical proximity. These terms have been edited to reflect current allocation policy.

A member commented that the paper does not reflect the quality of inputs impacting the quality of outputs. For example, the ischemic time or Kidney Donor Profile Index (KDPI) will impact the post-transplant outcome. The member suggested that this point could be integrated in either the data or machine learning section. UNOS staff informed the Committee that distinguishments on quality have not been included for the Lung Committee’s upcoming proposal, but the Kidney Committee is discussing distinguishments for KDPI.

A member inquired how informed consent will occur for patients when considering factors such as the impact of ischemic time on an organ offer. The Vice Chair countered that while this paper does not address the potential cost to the patients, the continuous distribution framework factors this in when determining the Composite Allocation Scoring (CAS).

UNOS staff responded to this informing members that in developing its proposal the Lung Committee spent extensive time analyzing geography, ischemic time, and post-transplant outcomes in order to develop two rating scales related to geography. The first one is proximity efficiency which is related to the cost of transporting organs and the other is a combination of factors related to the Final Rule including the efficient matching of organs. In combining these rating systems the Lung Committee developed an S-shaped curve for distance where there is a steeper drop off when the impact of ischemic time plays an influential role.

A member added that some of the concerns mentioned could be alleviated through an alternative distribution scheme that is separate from how the offers are allocated. The member noted that it is essential to have these high level cross Committee conversations but the practical implementation and execution remains unknown. The Chair agreed with these statement and reinforced the Committee’s

decision to separate this analysis into two papers wherein the first addresses theoretical ethical factors and the later address practical ethical considerations.

The formal vote to submit the paper for public comment was called and seconded. The Committee unanimously voted in support, 12-0.

Next steps:

UNOS staff informed the Committee that the paper will go to the Policy Oversight Committee (POC) for final review on July 14th before public comment begins on August 3rd.

Upcoming Meetings

- July 15, 2021
- August 19, 2021
- September 16, 2021
- October 21, 2021
- November 18, 2021
- December 16, 2021

Attendance

- **Committee Members**
 - Aaron Wightman
 - Amy Friedman
 - Andrew Flescher
 - Catherine Vascik
 - Colleen Reed
 - David Bearl
 - Earnest Davis
 - Elisa Gordon
 - George Bayliss
 - Giuliano Testa
 - Glenn Cohen
 - Keren Ladin
 - Mahwish Ahmad
 - Michael Davis
 - Roshan George
 - Tania Lyons
- **HRSA Representatives**
 - Chris McLaughlin
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Eric Messick
 - James Alcorn
 - Kristina Hogan
 - Laura Schmitt
 - Rebecca Murdock
 - Ross Walton
 - Susan Tlusty
- **Other Attendees**
 - Ehab Saad
 - Melissa Anderson
 - Sena Wilson-Sheehan
 - Thao Galvan