

OPTN Ethics Committee

Meeting Summary

April 28, 2021

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 04/28/2021 to discuss the following agenda items:

1. Committee vote to submit CAT Rewrite white paper to OPTN Board of Directors for approval
2. Ethical Considerations of Continuous Distribution in Organ Allocation project
 - a. Presentation: Continuous Distribution: Tradeoffs through Optimization
 - b. Questions and answers regarding presentation, and discussion of revised outline

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

1. Committee vote to submit CAT Rewrite white paper to OPTN Board of Directors for approval

Following the feedback and recommendations submitted during public comment, the Committee modified the Revise General Considerations in Assessment for Transplant Candidacy white paper and UNOS staff disseminated the final copy to members ahead of this meeting.

Summary of discussion:

The Chair asked if there was anyone on the call who had questions or comments about the white paper, but no one did. The Chair called the vote and two members seconded it. The vote occurred vocally - 15 members voted yes, 0 voted no, and 0 abstained. The Committee unanimously approved to present the paper to the OPTN Board.

Next steps:

UNOS staff will proceed with the process of submitting the white paper for the OPTN Board's consideration during their June 14th meeting.

2. Ethical Considerations of Continuous Distribution in Organ Allocation project

The Chair introduced the white paper the Committee is developing, titled *Ethical Considerations of Continuous Distribution in Organ Allocation*. This paper will be the first part of a multi-paper project and is slated to go out for public comment in August 2021.

Data summary:

Ted Papalexopoulos and Nikos Trichakis, from the Massachusetts Institute of Technology's Operations Research Center, presented an analytics framework for policy development. The motivation for this project is to identify how optimization and artificial intelligence (AI) can help inform Continuous Distribution policy development.

Summary of discussions:

A member asked for the presenters to elaborate on what factors were considered when developing the post-transplant outcomes variable. MIT used the same model for Lung transplantation currently used by the simulator allocation mockup which is comprised of a proportional hazards model that tries to estimate survival after receiving a transplant. The presenters compared the days a patient would live with a transplant to the days they would live without a transplant to quantify the net benefit of receiving a transplant. The member countered that the weight of the variable should differ based on the organ being discussed. There was no opposition to this statement, but the presenters wanted to continue moving forward as this point would be addressed later on in the presentation.

A member inquired if the presenters could identify how much of the improvements depicted were attributed to each factor as the percentage of deaths on the waitlist decreased. MIT explained they had previously conducted research on how organ transplants could be optimized through tradeoff curves, which was a somewhat simplified version of Continuous Distribution.

A member added that as an Ethicist, there is great benefit from working backwards based off the desired outcomes in order to identify how to best achieve those outcomes. Additionally, it was noted that this method is agnostic to what the outcomes of this model are. Instead, this allows the organ specific Committees to decide what the goals and guardrails are and MIT's optimization system will develop the most optimal way to achieve that and identify where the tradeoffs will lie. The presenters clarified that in their collaboration with the OPTN Lung Transplantation Committee they developed additional tradeoff curves that looked at alternative factors, aside from what is shown on the slides representing median transport distance.

A member responded that as Ethicists, they should be discussing desired outcomes primarily instead of attributes or their weights. A member countered that it's not necessarily that they should not look at attributes at all, but instead should look at how the outcomes identify shifts in the attributes as opposed to how attributes shift the outcomes. By working backward from the outcomes, it allows for a stronger Ethical argument for a shift to Continuous Distribution. Ultimately, the members came to the consensus that attention still needed to be paid to the attributes in order to identify which tradeoffs would be tolerable.

In terms of the importance of geography, a member emphasized the necessity for it to be at the forefront of the utility argument. The MIT presenters responded that the primary emphasis on geography is in terms of equity and their data shows that constraints on geography should be expanded from what they currently are but it will eventually reach a point of diminishing returns. The farther the organ travels it is likely that both costs of transportation and risks of transplantation will increase. The presenter tended to agree with a member's observation of geography's importance by placing the framework in the scope of utility first and then adjusting for equity.

A member encouraged the group to remember that the data being presented has been prepared specifically for lung transplantation so the tradeoffs for other organs or multi-organ transplantation may look different. Additionally, the curves presented to the Ethics Committee have some existing guardrails in place that have calculated the presented tradeoff curves.

A member inquired on the role which pediatrics plays in these tradeoffs. The presenters detailed their previous analysis of the pediatric priority and established a 20% weighted guardrail for pediatric candidates within the data that was presented. The Chair noted that the ethical reconsideration of these factors allows the community to place constraints on how high or low a score can vary. The presenters clarified a member's inquiry that the parameters on pediatric priority exist as a desired outcome as opposed to an attribute.

A member posed the question ‘do we measure what matters, or does what we measure matter?’ This question was aimed to realize that this work can only be guided by existing data, thus restricting analysis to what can realistically be analyzed at this time.

A member commented that when considering post-transplant survival, one variable that must be considered are outcomes that are longer than one year. While the current focus has been on one year outcomes, it is insufficient to accurately indicate the success of a transplant. The presenters informed the group that the OPTN Lung Transplantation Committee has pushed to expand their data collection to five year outcomes moving forward. Although this data does not currently exist, the SRTR was able to simulate a model based on expected outcomes, however the MIT presenters proceeded with the existing one year outcomes data for this presentation.

Next Steps:

The Chair encouraged members to email leadership or UNOS staff if they had any additional questions regarding today’s presentation. Committee leadership will be in contact with members to update them on the outline for the Continuous Distribution white paper and next steps.

Upcoming Meetings

- May 20, 2021
- June 17, 2021
- July 22, 2021
- August 19, 2021

Attendance

- **Committee Members**
 - Aaron Wightman
 - Amy Friedman
 - Catherine Vascik
 - Colleen Reed
 - David Bearl
 - Elisa Gordon
 - Andrew Flescher
 - George Bayliss
 - Giuliano Testa
 - Glenn Cohen
 - Keren Ladin
 - Mahwish Ahmad
 - Roshan George
 - Sanjay Kulkarni
 - Tania Lyons
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Eric Messick
 - Laura Schmitt
 - Rebecca Murdock
 - Roger Brown
 - Ross Walton
 - Susan Tlusty
- **Other Attendees**
 - Ehab Saad
 - Nikos Trichakis
 - Sena Wilson-Sheehan
 - Ted Papalexopoulos