

**OPTN Ethics Committee
Meeting Summary
April 15, 2021 11:00 – 12:00 PM EST
Conference Call**

**Keren Ladin, PhD, Chair
Andrew Flescher, PhD, Vice Chair**

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 04/15/2021 to discuss the following agenda items:

1. Revise General Considerations in Assessment for Transplant Candidacy white paper
2. Continue discussion: Ethical Considerations of Continuous Distribution in Organ Allocation
3. New project: *Transparency in Transplant Program Selection*

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

1. Revise General Considerations in Assessment for Transplant Candidacy white paper

The Committee Chair introduced the purpose of the paper and provided an overview of the feedback and sentiment provided during public comment.

Data summary:

Below is a summary of suggestions received during public comment:

- Addressing financial considerations and disabilities
- Specifically addressing pediatric population
 - o Collaborated with OPTN Pediatrics Committee leadership to identify additional considerations
- Providing more specific guidance to assist transplant program staff
- Call for broader collection of data about practices and outcomes

Summary of discussion:

Members inquired about immigration status within pediatrics. The Committee Chair clarified that the OPTN does not preclude pediatric candidates on the basis of immigration status. However, there is an ongoing concern that the parent or caregiver's immigration status will directly correlate to a pediatric candidate's ability to obtain insurance therefore limiting their access to medication and post-transplant care. One member included that parents are often living donors for their child so the parent's immigration or employment status may inhibit a child's access to transplantation, regardless of the child's citizenship status.

The member suggested the Committee acknowledge this challenge and prompt transplant centers to consider ways they can provide additional support and services. Since transplant centers do not ask about immigration status, it could be almost a year after first contact until they are informed of the potential candidate's immigration status. In these situations, where candidate families are afraid they will likely not ask for help so it's essential for the transplant centers to continue to share options for care or support and reassure families that their immigration status will not be shared externally. Ultimately,

the member urged the Committee to recognize that these barriers could be intrinsically unique to this population.

The Committee Chair clarified that the pending section on disability is focused on intellectual disability, as opposed to physical disability, per the comments submitted during the public comment cycle. Additionally, the Committee Chair responded to an inquiry submitted in the GoToMeeting chat function that inquired about the tone of the white paper toward social workers. The white paper has been revised to express concern for the challenges faced by social workers, who are advocating for their patients during an organ shortage, and that social workers should be given support and resources to this end.

Next steps:

The final version of the white paper will be circulated on April 19, 2021 for members to review. Please submit written comments and feedback to the leadership team. The Committee will reconvene on April 28, 2021 from 3:00 – 4:00 PM EDT to vote on the final version of the white paper.

2. Ethical Considerations of Continuous Distribution in Organ Allocation Project

The goal of Continuous Distribution framework is to improve efficient and equitable organ allocation, consistent with Final Rule allocation requirements. It includes the use of a comprehensive Composite Allocation Score. The Committee's objective is to analyze Continuous Distribution as an allocation framework based on ethical principles used in organ allocation, primarily: equity, utility, and respect for persons. The Committee Chair introduced the revised outline for the white paper and the Vice Chair discussed the normative justifications in the shift to Continuous Distribution.

Summary of discussion:

The conversation started with acknowledging that despite the OPTN Board charging the Committees to move forward with implementing Continuous Distribution there is a lot of work to be done to determine how the community moves forward with implementation. A member inquired if the purpose of this paper was to create an ethical analysis regarding what factors and weighting goes into developing the composite allocation score. The Chair clarified that Continuous Distribution will be split up into two white papers, wherein the Ethics Committee must first determine if this framework is ethically defensible and consistent with the principles of organ allocation. The second paper will dive deeper into analyzing, for example, the changes that the Lung Committee is making and what the implications are on equity and utility. The Committee will also consider not only how to determine the weights within the Composite Allocation Score, but also whose voices need to be heard in that development.

The Vice Chair discussed the myriad of challenges that exist with the move to Continuous Distribution and elaborated that this white paper would not be a position paper, but instead a judicious ethical analysis that addresses both theoretical and pragmatic challenges. Members delved into the issue of explaining the Composite Allocation Score to patients and the importance of being able to explain it in the simplest terms. A member identified this as a paradox for participating in the system. Despite the desire to increase patients' sense of autonomy, it is possible that the complexity of the system could overwhelm them. One member shared the dichotomy between what could be seen as patients gaming the system versus using their autonomy to appear more appealing as a patient. This is something that may not be as accessible for all patients but noted that the complexity of the system would hopefully not deter patients from participating.

UNOS staff shared that transparency in the Composite Allocation Score is fundamental for a patient's understanding of how it impacts them and the community to steering clear of systems that do not inherently promote transparency. The Vice Chair agreed with these concerns and the Committee's role

in expanding on these issues within the paper. The Vice Chair echoed the suggestion of members in developing a user friendly way for patients to understand the Composite Allocation Score.

Next Steps:

Committee leadership requested members to email them any additional comments, concerns, or objections they want considered in moving forward with this paper.

3. New project: *Transparency in Transplant Program Selection*

The Committee Chair introduced the new project and the progression of the topic into its current state. The objective of this project is to develop an ethical analysis that examines the case for the development and dissemination of patient-oriented pre-transplant metrics, including implications for equitable transplant selection and patient autonomy. The Committee is seeking input from DAC, MAC, PAC, and TCC as collaborating committees.

Summary of discussion:

Members brought up the issue of insurance and the limitations patients face in requesting a referral to a specific transplant center. Due to the structured manner of the referral process, one member inquired on the practicality of this type of project. The Vice Chair countered that the Ethics Committee could make a statement on what transplant centers can do to amplify transparency.

A member inquired about the viability of this project without speaking to patients and gaining a better understanding of what they want. The Committee Chair countered that the Committee can analyze what should be available, from an ethical standpoint, as opposed to what exactly is available. Instead, the Committee could provide suggestions on how to improve transparency and state that further research needs to be done to better identify what patients' needs are. With that being said, there is the potential to collaborate with the UNOS research team if the Committee decides this research would be invaluable white paper.

One member noted that some patients are able to find resources and do their own research prior to their referral appointment but is not common and comes from a point of increased access and privilege. A member suggested improving patient centered materials and promoting engaging and informative conversations about organ transplant options between patients and providers. Ultimately, there was a consensus on the importance of analyzing why patients should receive this information and proving suggestions on how to do so.

Next Steps:

Leadership requested members reach out to them if they are interested in participating in this workgroup. The Committee's goal is to have this white paper out for public comment in the January to March 2022 public comment cycle. In order to achieve this goal, the project form must be submitted for internal UNOS review by April 28, 2021 before presenting it during the Policy Oversight Committee (POC) meeting on May 12, 2021.

Upcoming Meetings

- April 28, 2021 – Review and Vote on Final CAT Rewrite White Paper
- May 20, 2021
- June 17, 2021

Attendance

- **Committee Members**
 - Keren Ladin, *Chair*
 - Andrew Flescher, *Vice Chair*
 - Mahwish Ahmad
 - George Bayliss
 - Lynsey Biondi
 - Glenn Cohen
 - Earnest Davis
 - Amy Friedman
 - Elisa Gordon
 - Sanjay Kulkarni
 - Tania Lyons
 - Colleen Reed
 - Catherine Vascik
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Sommer Gentry
 - Bryn Thompson
- **UNOS Staff**
 - James Alcorn
 - Eric Messick
 - Laura Schmitt
 - Susan Tlusty
 - Ross Walton
- **Other Attendees**
 - Ehab Saad