

**OPTN Ethics Committee  
Meeting Summary  
January 21, 2021 11:00 – 12:00 PM, EST  
Teleconference Meeting**

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

## **Introduction**

The Ethics Committee met via Citrix GoTo 884-431-893 teleconference 1/21/2021 to discuss the following agenda items:

1. Public Comment and Regional Meetings – *General Considerations in Assessment for Transplant Candidacy*
2. OPTN Governance Training
3. Discuss *Ethical Analysis of Continuous Distribution in Organ Allocation*

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

### **1. Public Comment and Regional Meetings – General Considerations in Assessment for Transparent Candidacy**

UNOS staff introduced the start of public comment and provided instructions on accessing *General Considerations in Assessment for Transplant Candidacy* white paper and other public comment materials. During the next two Committee Meetings, UNOS Staff will go over comments submitted to date for the CAT Rewrite. The workgroup will reconvene at the conclusion of the public comment period to revise the white paper as needed.

Additionally, UNOS staff provided information on regional meeting dates, times, and how to register for the meetings.

### **2. OPTN Governance Training**

UNOS staff gave a presentation addressing policy development government and compliance with NOTA, Final Rule, OPTN Contract, and OPTN Policies and Bylaws. All Committee work must be authorized by and comply with these governing structures.

### **3. Discuss *Ethical Analysis of Continuous Distribution in Organ Allocation***

The Committee Chair introduced the purpose, reasons for the project and Committee considerations. The Chair also shared that the Policy Oversight Committee (POC) was supportive of the project, and requested a thorough ethical examination of the implications of rolling out continuous distribution. This analysis will not compare continuous distribution to other organ distribution methods, but instead analyze the ethical implications of continuous distribution and provide guidance to organ specific committees as they implement it.

#### Summary of Discussion:

Leadership shared ethical principles and precepts for consideration which led to a brief discussion of justice, equity, utility, and respect for persons. Leadership stated that these frameworks should be included in every ethical discussion, but the Committee is in no way limited to just these frameworks.

A member used the idea of guardrails to propose creating categories or a list of factors that are ethically important in the planning process as opposed to waiting for the data that new algorithms will provide after implementation. This would be a preemptive list that guides organ specific committees and provides them with considerations during their policy development process.

Following this, a member posed the question ‘what do we define as advantaged versus disadvantaged?’ They used wait time as an example to inquire if this would be impacted and whether or not algorithms have been established and data collected to answer this. As it stands, the Lung Committee is the farthest along in the development process and wait time is not highly considered for them, whereas it is a main focus for the Kidney Committee’s efforts. It was suggested to consider metrics developed by the SRTR and writings from UNOS Research Staff on equity across organ systems to gain a better understanding of what these definitions and metrics may be.

The discussion pivoted to the importance of a cross organ metric for comparison. While valuable, is it essential? Feedback was given that one of the core goals of continuous distribution is to have greater comparison across organs so that we can consider how the successes within one organ system can be implemented into another. A long term goal of the Ethics Committee is to consider if there should be a consistent balance of factors, such as waitlist urgency, post-transplant survival, efficiency in the system, patient access, etc., across all organ systems? Or would it be ethically sound for one organ system to value patient access over waitlist urgency, for example? Again, this would be a long term goal of the Committee as that data is not currently available.

Reexamining current capabilities, a member posed the question that without existing data on continuous distribution, what kinds of things go members of other committees, who are working on developing continuous distribution frameworks, need to be made aware of? Without final proposals to consider, it would be important for the Ethics Committee to provide guidance to specific organ Committees to ensure that disadvantaged groups are not alienated from the process and to consider how organ center could become overwhelmed with the change in volume.

A member shared that the Committee’s role is not to define advantaged versus disadvantaged, but instead to redefine it in terms that exceed just geographic focus. The Committee members agreed on the importance of providing a few metrics, focused on advantaged versus disadvantaged, that organ specific Committees need to consider as they move through the policy development process.

A member encouraged the Committee to not just stick to the metrics that the Ethics Committee typically focuses on but to consider other factors that have not been prioritized in the past and look beyond what we have done to see what we can do.

As the meeting concluded, the Committee agreed that the information on the slides reflected their conversation and there were no additional principles to add at the time. The Chair noticed that it may be difficult to think about all of these principles at the same time and suggested focusing on them one at a time. The Chair encouraged the Committee to continue to examine the continuous distribution framework in terms of identifying what we believe to be the strengths and challenges with a focus on justice and utility. The Chair noted that today’s conversation reflected concerns about increasing efficiency but potentially limiting equity so how are justice and utility in balance in this framework. The Chair’s concluding suggestion was to identify groups and consider guardrails for them and then identify metrics within a continuous distribution framework.

#### Next Steps:

If there are no other key guiding questions that the Committee would like answered, then UNOS staff will proceed with gathering information to share with the Committee for the next meeting and potential

internal discussions in the interim. The UNOS staff will prepare a brief presentation for the next meeting that outlines key strengths and potential challenges in framework with respect to justice, equity, and utility. This presentation will help guide the discussion and provide a better understanding of the ethical tradeoffs. Lastly, if members have inquiries for specific data that will help them better understand continuous distribution, please submit those requests to UNOS staff and leadership.

### **Upcoming Meetings**

- February 18, 2021
- March 18, 2021
- April 15, 2021
- May 20, 2021
- June 17, 2021

## Attendance

- **Ethics Committee Members**
  - Keren Ladin, Chair
  - Andrew Flescher, Vice Chair
  - Aaron Wightman
  - Amy Friedman
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - Glenn Cohen
  - Mahwish Ahmad
  - Sanjay Kulkarni
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Maryam Valapour
- **UNOS Staff**
  - Eric Messick
  - James Alcorn
  - Laura Schmitt
  - Rebecca Murdock
  - Ross Walton
  - Sarah Konigsburg
  - Susan Tlusty