

OPTN Ethics Committee

Meeting Summary

August 19, 2021

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 08/19/2021 to discuss the following agenda items:

1. Call for Project Ideas
2. Public Comment Presentation: Ad Hoc International Relations Committee – *Guidance for Data Collection Regarding Classification of Citizenship Status*
3. Public Comment Presentation: Kidney and Pancreas Committees – *Update on Continuous Distribution of Kidneys and Pancreata*

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

1. Call for Project Ideas

The Chair provided a brief introduction to how the Committee manages multiple projects and considers their staggered timeline. UNOS staff provided additional context to considering and developing a project idea.

Next steps:

UNOS staff will send the SurveyMonkey link, the list of past white papers, and a blank and completed project form for their reference. Committee leadership expects every member to submit a new project idea. Members will provide an overview of their project idea during the September 21st meeting. During the October 29th meeting the Committee will discuss the project ideas in greater detail and determine which projects they would like to pursue.

2. Public Comment Presentation: Ad Hoc International Relations Committee – *Guidance for Data Collection Regarding Classification of Citizenship Status*

Barry Friedman, the Chair of the OPTN Ad Hoc International Relations Committee, presented *Guidance for Data Collection Regarding Classification of Citizenship Status* for the Ethics Committee's feedback.

Summary of discussion:

A member expressed concern that citizenship information could potentially be breached, specifically if the OPTN contract was held by an organization other than UNOS. UNOS staff informed the group that this data collection falls under all data security and compliance laws as any other identifiable health information. The presenter added that in cases of the contract for the Scientific Registry of Transplant Recipients (SRTR) switching contractors there are safeguards in place to prevent any potential mishandling of data or the integrity of the information. The HRSA representative on the call clarified that there is an extremely well built data security infrastructure to house and protect all UNOS data and this security would not diminish based on the recipient of the OPTN Contract.

A member added that in their region there was concern that non-US citizens would have to use private pay options, which can sometimes impact the amount of funding the center receives depending on the state, and therefore it disincentivizes centers from accepting these patients.

There was additional concern that access to transplantation would be diminished due to citizenship status. UNOS staff clarified that OPTN policy states that citizenship or residency status “must not be considered when allocating deceased donor organs to candidates for transplantation”¹. The presenter clarified that citizenship data is already being collected and this document provides guidance on how it can be done more consistently and accurately.

A member inquired if field testing had been done to determine if there were any negative impacts on undocumented persons. Unfortunately, this is not in the scope of the Committee. The member countered that if the outcome of this policy created an unintended negative impact on undocumented persons then they would have great concern and suggested engaging with immigration groups to gather their feedback.

Next steps:

UNOS staff will compile this feedback into the Ethics Committee’s official public comment.

3. Presentation: Kidney and Pancreas Committees – Update on Continuous Distribution of Kidneys and Pancreata

Dr. Rachel Forbes, the Chair of the OPTN Pancreas Committee, presented *Update on Continuous Distribution of Kidneys and Pancreata* for the Ethics Committee’s feedback.

Summary of discussion:

A member inquired what kind of ethical challenges the Kidney and Pancreas Committees grappled with when developing a continuous distribution framework? The presenter responded that individually each member has their own challenges but the allocation goes to Kidney-Pancreas first before going to the individual Kidney and Pancreas waitlists, so there is the question if the organ should go to a pediatric or highly sensitized and hard to match candidate first? The member responded that the value of the Ethics Committee lies in its ability to address ethical concerns that the organ specific committees have instead of necessarily initiating that conversation.

A member shared that this proposal should emphasize the role of organ donation in allocation as a way to maximize the quantity of transplants. The member noted that if the goal of this framework is to reduce the organ shortage then the system needs to rely on methods other than allocation changes.

A member expressed concern over the stewardship of organs when balancing multi-organ transplantation (MOT) with single organ transplantation (SOT) and how this will play a role in the continuous distribution framework. A member expressed concern that since the OPTN recently moved from regional allocation to a system based on nautical miles and is now developing a continuous distribution framework it creates the potential for the community to lose trust in the system. The presenter empathized with this concern and felt confident that by prioritizing community feedback in what the weight of these attributes should be, the Committee will be able to develop an allocation policy that is based on a mutual understanding.

From the perspective of patient justice and autonomy, a member inquired about who will be adjusting the weights, what the basis for adjustments will be, and how often this will occur once the policy is

¹ OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (September 2021).

implemented. The presenter responded that a detailed plan of the revision process will be detailed in the post-implementation monitoring plans for each organ's policy proposal.

A member asked how continuous distribution will improve access and risk adjust for disadvantaged groups, specifically those who are geographically far from a transplant center or those groups that do not have insurance. The presenter informed the Committee that risk adjustments are being made for insurance but this is something that could continue to be refined. The presenter clarified that the purpose of continuous distribution is not necessarily to affect vulnerable populations significantly but instead to ensure that organs are transplanted in the best recipient for that organ based on all relevant factors.

Attention was also paid to the need for risk adjustment for transplant centers that are geographically far away from airports and how that will impact its access to donor organs. A member asked how the system will prevent kidneys with a high Kidney Donor Profile Index (KDPI) from being offered repeatedly to the same population? The presenter agreed with these concerns and will share this feedback with the Kidney and Pancreas Committees.

Next steps:

UNOS staff will compile this feedback into the Ethics Committee's official public comment.

Upcoming Meetings

- September 21, 2021
- October 29, 2021
- November 18, 2021
- December 16, 2021
- January 20, 2022
- February 17, 2022
- March 17, 2022
- April 21, 2022
- May 19, 2022
- June 16, 2022

Attendance

- **Committee Members**
 - Amy Friedman
 - Andrew Flescher
 - Catherine Vascik
 - Carrie Thiessen
 - Colleen Reed
 - Ehab Saad
 - George Bayliss
 - Glenn Cohen
 - Keren Ladin
 - Lynsey Biondi
 - Melissa Anderson
 - Sanjay Kulkarni
 - Sena Wilson-Sheehan
 - Tania Lyons
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Eric Messick
 - Joann White
 - Kristina Hogan
 - Laura Schmitt
 - Meghan McDermott
 - Robert Hunter
 - Ross Walton
- **Other Attendees**
 - Barry Friedman
 - Dave Weimer
 - Rachel Forbes