

**OPTN Ethics Committee**

**Meeting Summary**

**October 29, 2021**

**Conference Call**

**Keren Ladin, PhD, Chair**

**Andy Flescher, PhD, Vice-Chair**

## **Introduction**

The Ethics Committee met via Citrix GoToMeeting teleconference on 10/29/2021 to discuss the following agenda items:

1. Social Determinants of Health Project Update
2. Present and Discuss New Project Ideas
3. Discuss Wait Time in Kidney Pancreas Continuous Distribution
4. Discuss Attribute Weighting in Kidney Pancreas Continuous Distribution
5. Transparency in Program Selection Project Update
6. Closing Remarks

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

### **1. Social Determinants of Health Project Update**

UNOS Research staff provided an update on the Social Determinants of Health project, which was a HRSA funded feasibility and suitability study.

#### Summary of discussion:

Members posed administrative questions to the presenter, such as the methods used by Lexis Nexis to gather data and how that data would be broken down geographically. UNOS Research staff informed the group that the vendor used proprietary technology tied to credit bureau data, then linked to publicly available data. The data can be broken down by state, region, county, etc. based on the parameters of the question. Echoing privacy concern previously shared by the Minority Affairs Committee, the presenter informed the Committee that this project has an Institutional Review Board (IRB) and complies with all privacy concerns.

The conversation shifted to additional populations of consideration, specifically living donors and pediatrics. A member inquired if UNOS Research considered analyzing living donors in addition to candidates. The presenter responded that the analysis of living donors was considered for a future project but was outside of the scope of this project. Members discussed whether this framework could fit an analysis of the pediatric population. The presenter responded that in order to obtain this information the data would need to connect the care provider with the child and it appears there is hesitancy on behalf of the data providers to make that connection for minors. Regardless, a member advocated for the necessity of collecting pediatric information sooner rather than later to provide adequate support for this vulnerable population. The UNOS Research Staff noted the complexity of identifying who was in the role of caregiver for the child.

A member inquired if this project would be able to provide information on the impact of continuous distribution on particular communities. While this could be possible, UNOS Research is approaching this

project as a way to review if this type of data can be used for policy, monitoring, and ongoing evaluation. A member asked if the long term goal of this project is to characterize local need versus global access, which the presenter responded that the primary focus is on communities and developing a better sense of how need can be calculated. The presenter highlighted that a key challenge of this data is that it is only accurate at the time of collection and requires ongoing data collection efforts to insure accuracy.

Next steps:

There are two potential future projects identified during this presentation. The team is awaiting feedback from HRSA and other stakeholders before proceeding with their potential next steps.

**2. Present and Discuss New Project Ideas**

In August, leadership requested members to submit their ideas for new Committee projects. Leadership selected four projects that fit within the Committee's scope, would have a sizeable impact, and were timely and relevant issue for the Ethics Committee to consider.

Summary of discussion:

*Higher Risk Living Donors Project*

A member inquired, from a procedural point of view, if the Committee should pursue topics that are being discussed elsewhere or if they should evaluate new issues that do not have previous consideration from the transplant community. The Chair responded that since people in the community are talking about an issue then it is clear that it is relevant to the community and the Committee's role is to offer ethical analysis to guide policy-making committees. A member asked for more explanation on the APOL1 gene and how it is diagnosed. The presenter provided background on APOL1 and informed the group that it has recently become clinically available as a blood test.

A member asked if this project would include other groups of high-risk living donors. The presenter suggested including others, such as young mothers donating to their child whom would need extensive follow up care. The Chair noted that this project could be broken down into two projects, wherein the first project analyzes the framework around living donors and their inherent risk and the second project being an ethical analysis on a specific case and how it should be handled within living donation. A member considered including an ethical analysis on how this could systematically disadvantage some patients.

*Exclusion of Inmates as Living Donors*

A member noted that there is a clear ethical dilemma but inquired how the community could ensure that inmates receive adequate follow up care. The presenter responded that since some states allow incarcerated individuals to be donors for their immediate family, there is a framework in place for that coordination of care. A member noted the importance of providing psychological support for inmates who decide to pursue living donation.

A member inquired if UNOS or HRSA may have any hard stops around this topic. UNOS staff identified this project as within scope for the Committee to consider. They highlighted the possibility for controversy when discussing inmates but noted that this is the forum to structure that controversy into a discussion. The Chair noted the possibility of combining this topic with the previous one to address a fundamental question about what the transplant community considers a high risk or vulnerable donor.

A member inquired if there was data on the states that limit living donation from incarcerated individuals or the number of inmates in these restricted states that want to be living donors. A member

noted that living donation from incarcerated individuals has occurred in the U.S. historically, referencing a specific example from a prolific program in Colorado in the 1960s.

### *Evaluation of Multiple Listings*

A member shared that they thought this topic was out of the question for the Ethics Committee to consider because it was up to the transplant center's discretion of whether or not to list a patient for transplant. UNOS staff informed the Committee that the OPTN has authority to address this topic. The National Organ Transplant Act (NOTA) allows the OPTN to set standards for wait listing candidates but the OPTN has allowed the community to set those standards themselves through transplant hospitals. UNOS staff noted that this has been a regular topic of discussion throughout the OPTN.

A member added that with heart transplant, multiple listing is extremely uncommon due. Additionally, a member shared their experience that some transplant centers are not as willing to send their records because they want to do their own evaluations. However, a member noted that most insurance providers will often only cover one transplant evaluation per year.

### *Reviewing Inactive Status Patients*

A member inquired how continuous distribution might impact the ways in which centers manage their waitlist. The presenter noted that the allocation framework will impact a transplant center's behavior, but the ethical issue of this project is independent of access to organs. The primary ethical argument is that the transplant center are responsible for resolving the issues that led a patient to be inactivated.

A representative from HRSA noted that the Collaborative Innovation and Improvement Network (COIIN) was a performance improvement program for kidney patients. The representative suggested that this methodology could be utilized for other organs.

A member inquired if the transplant program would be responsible for ensuring transplant protocol was completed or would they be responsible for coordinating care when chronic illness impeded transplant. The presenter responded that this would be imploring transplant centers to take over their patient's care coordination to ensure that they could get ready for transplant.

### Next steps:

Committee members were asked to submit their project ranking via Survey Monkey. Leadership will review the results to determine which project the Committee will address.

### **3. Discuss Wait Time in Kidney Pancreas Continuous Distribution**

Two Ethics Committee members shared their role and experience in acting as a liaison to the Kidney Pancreas Continuous Distribution Workgroup. In a recent workgroup meeting, a UNOS staff member presented options for converting wait time into an attribute of the Composite Allocation Score (CAS). UNOS staff presented these options the Committee for them to consider the ethical tradeoffs.

### Data summary:

Option 1 is a general waiting time rating scale; wherein as waiting time increases the points awarded will increase and every day of waiting time is equal. The main issue with this is weight dilution.

Option 2 is a no ceiling scale; wherein patients can exceed 100% of the determined threshold but very few patients will actually receive these points.

Option 3 is a scale with a ceiling; wherein as waiting time increases, the points awarded increase until a certain wait time is reached. Patients that exceed the wait time will still only receive 100% of the rating scale.

Option 4 is a linear to curve scale; wherein there is a 0-100 rating scale with a change from linear to curve line at a certain point.

Summary of discussion:

The Vice Chair identified this presentation as an ideal example of how the Ethics Committee could weigh in on a specific ethical issue related to continuous distribution on an as needed basis. The Vice Chair noted that this would be more relevant and timely insofar as to provide targeted answers to direct questions as opposed to try to address all areas of concern in a white paper.

A member proposed using a staggered weighting scale where years 0-4 were equal, 4-8 years was slightly higher, etc. The presenter shared that the workgroup discussed this point which posed the question why wait time was being considered. The workgroup could come up with different scales if wait time was being used as a surrogate for medical urgency or as a factor for equity in access. The member countered that by staggering the weight of the attribute it accounts for the patients worsening condition and the likeliness of them being well enough to recover from transplant.

A member inquired if, in a no ceiling system, are there a specific demographic of patients who are reaching 100%. UNOS staff replied that UNOS Research is working on analyzing this information. The presenter noted the role that time on dialysis plays into wait time to account for individuals who were late to referral and how this will be factor into wait time.

A member noted that wait time is not uniformly distributed in the country and that placing a cap on wait time may diminish the opportunity to mitigate unfair disadvantages that occur in a regional manner. UNOS staff shared that the majority of the Kidney Transplantation Committee members were not in favor of placing a cap on waiting time.

#### **4. Discuss Attribute Weighting in Kidney Pancreas Continuous Distribution**

UNOS staff discussed how utility and equity are balanced and maximized when selecting and prioritizing attributes for a continuous distribution allocation framework. Leadership posed questions to the Committee to gauge what tradeoffs they felt were appropriate when developing continuous distribution.

Summary of discussion:

The Vice Chair suggested that when factors that have traditionally been categorized as equity are shifted to utility, such as medical urgency, there is a possibility that utility could be emphasized over equity. UNOS staff noted that it is difficult to place attributes into just one category and placement can influence outcomes.

A member expressed concern about the accuracy of predictive models for determining allocation and suggested placing less weight of attributes with a higher degree of variability. A member asked if kidneys reserved for multi-organ transplantation would be factored into which organs were available and the presenter responded that this would be considered.

A member inquired if weight will be added for patients who receive a second or third transplant for the same organ type. The presenter responded that the Kidney Transplantation Committee has not discussed this as an attribute yet, but it could come up in the future. Members discussed that if multiple transplants were to be considered, how potential patient noncompliance or organ quality would be considered to determine the cause of graft failure.

The Chair asked the Committee if they would like to proceed on a second white paper, focusing on aligning the attributes with ethical principles and outlining the tradeoffs, or proceed in an advisory role

to the Kidney Committee on an as needed basis. With consideration of the timeline for Kidney and Pancreas allocation proposal, UNOS staff suggested working in an advisory role to provide timely and direct feedback. Members discussed what the Committees role as a consultant could look like and how a written response could be provided for each inquiry.

#### **5. Transparency in Program Selection Workgroup Update**

The workgroup co-chairs discussed the goal of this project, shared a high-level outline, and identified the main points for each section. The Chair asked the workgroup to present text for the Committee's feedback during the December 16 meeting.

#### **Upcoming Meetings**

- 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**
  - Aaron Wightman
  - Amy Friedman
  - Andy Flescher
  - Carrie Thiessen
  - Catherine Vascik
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Ehab Saad
  - George Bayliss
  - Glenn Cohen
  - Keren Ladin
  - Melissa Anderson
  - Roshan George
  - Sanjay Kulkarni
  - Sena Wilson-Sheehan
  - Tania Lyons
  - Thao Galvan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Abby Fox
  - Alex Garza
  - James Alcorn
  - Kristina Hogan
  - Laura Cartwright
  - Laura Schmitt
  - Lindsay Larkin
  - Susan Tlusty
  - Tatenda Mupfudze