

## **OPTN Ethics Committee**

### **Meeting Summary**

**April 21, 2022**

**Conference Call**

**Keren Ladin, PhD, Chair**

**Andy Flescher, PhD, Vice Chair**

### **Introduction**

The Ethics Committee met via Citrix GoToMeeting teleconference on 04/21/2022 to discuss the following agenda items:

1. Social Determinants of Health Presentation
2. Review and Discussion of *Transparency in Program Selection* white paper

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

#### **1. Social Determinants of Health Presentation**

Two members of UNOS Research presented an update on the Social Determinants of Health (SDoH) project. In fiscal year 21, UNOS Research partnered with LexisNexis to link approximately 112,000 OPTN records of adult kidney candidates to current address records and patient and geographic-level SDoH measures. They analyzed linked data and felt confident that it could be used to further study SDoH factors in transplant. Subsequently, two studies were developed and are being funded by the Health Resources and Services Administration (HRSA).

#### Summary of discussion:

##### *Study 1: Population-based Analysis of Social Determinants of Health and the U.S. Kidney Waitlist*

A member inquired if county-level data provided the amount of granularity that is necessary to understand the population needs, especially with respect to counties that encompass extremely large and diverse populations. The presenter responded that they have been able to link this data to larger SDoH data sets to consider both the candidate and county-level data. The OPTN data was aggregated with county-level data from the Centers for Disease Control (CDC) to understand the level of disease burden.

A member asked if waitlist data is what the OPTN ought to be looking at, noting that SDoH information may be more valuable to understanding the limitations of those who are unable to access transplant and suggested looking at transplant referral or organ failure data. Unfortunately, the OPTN is not currently collecting referral or organ failure data, so the county-level data allows the research team to consider if the number of patients on the waitlist is proportional to the population with consideration of the CDC data.

With regard to the multi-varied analysis, a member suggested the group ought to look at the intersectionality of patient experiences specifically noting gender and race. A presenter appreciated the sentiment expressed and ensured the Committee that they are looking at the different interactions between the variables and not the variables alone.

## *Study 2: Social Determinants of Health and Kidney Waitlist Outcomes*

A member asked if SDoH affect outcomes or are a proxy for markers associated with outcomes of transplant. The presenter noted that at this time the group is limited in looking at the association of SDoH and weak outcomes, as opposed to the casual relationship.

### **2. Review and Discussion of *Transparency in Program Selection* white paper**

The Vice-Chair introduced the white paper and provided background on the project. Two main questions were posed to the Committee. First, how to better define or clarify potentially frail patients? Second, how best to invoke the Scientific Registry of Transplant Recipients (SRTR)? Members were also asked to share any literature that would be pertinent to the paper to bolster a few remaining citations.

#### Summary of discussion:

A member informed the Committee that there is a clinical definition of frailty but was curious if there was a patient definition of frailty, noting that many patients may not be aware that they would be determined to be frail. A member suggested breaking down the clinical definition of frailty into the components that the patient does understand about themselves and their condition. A member added that the components of frailty would be helpful for a patient to know to better understand the impact of their individual characteristics, but urged that the definition in the white paper ought to be clinical.

A member noted that the SRTR is currently undertaking projects to better understand what information patients are looking for and urged that invoking SRTR should not be as controversial as some may think. A member responded that the charter of the SRTR is only to analyze and provide the data collected by the OPTN without a specific audience thus noting that the paper may be asking the SRTR to do something that it is not designed to do. A member noted how valuable it would be to provide patients with more information regarding the referral process and timeline. A member distinguished that the paper addresses what information and data would be essential to inform a patient's decision, which are starkly different from metrics. A member also noted that metrics are not neutral and data aspires to be neutral but often falls short of doing such.

A member responded that it may not be sufficient to urge for increased access to data, but instead argue for what data would be useful for patient decision making. It was noted that little research has been done to better understand what data patients want other than wait time information. The workgroup has been challenged in not being able to understand what patients want, which is why they provided outlined experiential examples to consider what information could be helpful in those scenarios. A member noted how strongly these challenges are linked to disclosure and paternalism, which are identified in the complicating question section, and the importance of informed consent to develop a dialogue and better understand the needs of the patient. A member responded that the purpose of the paper is not to understand what information the patient wants, but instead outline what information is ethically just for the patient to have.

#### Next steps:

Members are asked to send any outstanding comments or references to UNOS staff. The Transparency workgroup will meet next week to consider the feedback from the Committee. The Ethics Committee will vote on the final draft of the white paper for public comment during their June meeting.

### **Upcoming Meetings**

- May 19, 2022
- June 16, 2022

## Attendance

- **Committee Members**
  - Aaron Wightman
  - Andy Flescher
  - Catherine Vascik
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Ehab Saad
  - George Bayliss
  - Roshan George
  - Sanjay Kulkarni
  - Sena Wilson-Sheehan
  - Tania Lyons
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Alex Garza
  - Anne Zehner
  - Catherine Parton
  - Cole Fox
  - Kim Uccellini
  - Kristina Hogan
  - Laura Schmitt
  - Nikki Johnson
  - Tatenda Mupfudze
  - Trenece Wilson
- **Other Attendees**
  - Bob Troug
  - Dave Weimer
  - Jennifer Dillon
  - Megan Urbanski