

## **OPTN Ethics Committee**

### **Meeting Summary**

**August 17, 2023**

**Conference Call**

**Andrew Flescher, PhD, Chair**  
**Sanjay Kulkarni, MD, MHCM, Vice Chair**

### **Introduction**

The Ethics Committee met via Citrix GoTo teleconference on 08/17/2023 to discuss the following agenda items:

1. Welcome and announcements
2. Public Comment Presentation: Continuous Distribution of Hearts Update
3. New Project Brainstorm
4. Adjourn

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

#### **1. Welcome and announcements**

##### Summary of discussion:

The Committee Chair welcomed members and gave a few announcements.

#### **2. Public Comment Presentation: Continuous Distribution of Hearts Update**

The Committee heard an update on the OPTN Heart Transplantation Committee's progress in the development of continuous distribution.

##### Summary of presentation:

The presenter introduced the purpose, goals, current state versus future state, and timeline for the development of heart continuous distribution. The heart continuous distribution system will include additional consideration for congenital heart disease, hypertrophic/restrictive cardiomyopathy, cardiac allograft vasculopathy, and waiting time on left ventricular assist device (LVAD), as well as attributes for sensitization, pediatric candidates, proximity efficiency, and priority for prior living donors. An attribute for post-transplant survival is also under consideration, however, there is currently not an accurate measure for this. The presenter explained that the Committee would like to include data collection into the first iteration of continuous distribution so that an accurate measure of post-transplant survival could be developed for version 2.0.

The Committee was asked to provide input on the following questions:

- Are the identified attributes appropriate for the initial version of a continuous distribution of hearts allocation framework?
  - What attributes, if any, should be included that the Committee did not identify?
  - Has the Committee identified any attributes that should not be included?
- From the patient, family, and donor perspectives, what are the most important factors that the Committee should consider?

### Summary of discussion:

The Chair asked the presenter to elaborate on the incorporation of the prior living donor attribute into continuous distribution, and the presenter explained that this is an attribute aimed at recognizing their prior donation and the commitment that the transplant system will take care of them. A member stated that the attribute may disadvantage minority communities given the lower rates of living donation in these populations. A member asked how many prior living donors were heart transplant candidates in the past few years, and the presenter answered while they do not have that data today, it can be provided subsequently. A member stated that the goal for providing “appropriate” transplant access for certain populations may need further examination as to what “appropriate” means, who decides that, and which groups will receive priority.

Another member stated that some communities may see priority given to prior living donors as elitist. A member added that there are two components to the prior living donation attribute from an ethical perspective: gratitude and recognition for their living donation and priority given to these patients because living kidney donors do have a higher risk of developing end stage renal disease as a result of donation. This member continued that there seems to be an ethical basis for giving priority to living kidney donors who wind up on the kidney waitlist, but a less strong ethical basis for access to other organs. A member stated that considerations around transparency and public perception around this attribute is very important for the Heart Committee to consider.

The presenter asked the Committee to consider that this attribute is a part of the framework for each continuous distribution system being developed across organs, and if the Ethics Committee feels strongly that this warrants re-consideration, it would be helpful to develop a uniform stance. A member responded that these concerns have been raised before, but in the development of lung continuous distribution, the ultimate consensus was that although ethical concerns are present, the benefit of both incentivizing and protecting living donors justified the inclusion of this in the allocation score.

A member explained that from an ethical standpoint, there is strong justification for the prioritization of sensitized candidates in the first version of heart continuous distribution, explaining that sensitization is a paradigmatic example of biological disadvantage. The presenter explained how calculated panel reactive antibody (CPRA) works in heart transplant, and noted that the Heart Committee agrees that it is important to prioritize candidates with lower access to transplant because of sensitization. The presenter added that in current allocation, programs will sometimes submit pre-sensitized patients for exception requests. The Heart Committee intends to incorporate these exception requests into the continuous distribution system to ensure consistency and uniformity.

The Chair explained that there is ethical support for the inclusion of an attribute for post-transplant survival in the first version of continuous distribution, while acknowledging the logistical challenges. The presenter explained some of the challenges associated with the inclusion of this into the model, noting that data collection is the first step. A member asked if the connection between cold ischemic time and increased travel distances predicted under continuous distribution will be modeled and looked at by the Committee, and the presenter answered that this will be considered by the Committee, as they have a special focus on efficiency.

### Next steps:

This feedback will be summarized and recorded as a public comment from the Committee on the OPTN Heart Transplantation Committee’s concept paper.

### 3. Brainstorm New Projects

Members submitted new project ideas ahead of the call, and they were compiled and presented. Members weighed in to add detail to the ideas.

#### Summary of presentation:

The Chair briefly explained the policy development process and the OPTN Strategic Goals. Then, members were asked to introduce their new project ideas, which were as follows:

- White paper on ethical considerations involved in xenotransplantation
  - Given ongoing renal xenotransplants into deceased donors and calls for additional cardiac xenotransplantation candidates, the field appears to be evolving rapidly. Although there are numerous society guidelines regarding ethical considerations in xenotransplantation, an OPTN white paper would have particular standing in this area.
- Using deceased donor kidneys to initiate paired living donor exchange chains for magnified benefit
- End-of-chain kidney allocation best practices
- Ethical implications of accepting organs from anonymous altruistic donors with history of mental illness (anxiety, depression)
- White paper considering if it is ethically acceptable to accept multiple organs from altruistic donors (partial liver donation following kidney donation)
- White paper on access to becoming a living donor:
  - Showing difference between removing disincentives and adding incentives
  - Recent legislative proposals from various states regarding living donation
  - Utility and equity-focused
- Provide ethical guidance when considering transplant programs' vaccination policies & protocols
- Revisit imminent death donation, in the context of changing opinions, discussion of expanding donation with the emphasis on transparency, donor rights, and increased organ availability
- Examine ethical issues in crowdfunding for transplantation:
  - Crowdfunding raises issues in equity and access to care (when centers make raising funds a criterion for listing). There are also legal issues related to "valuable consideration" for living donors who crowdfund.
  - Transplant centers offer varying degrees of education and support for crowdfunding, but none of them have a formal policy about management of patient crowdfunding.
  - Ethical permissibility of conditional living donation
- White paper on split liver utilization, with a focus on utility

#### Summary of discussion:

The Chair thanked members for bringing their ideas to the table and asked that if any members have additional ideas or details to add to the currently proposed ideas, to please reach out to leadership and/or staff.

### 4. Adjourn

#### Summary of discussion:

Committee leadership gave a brief update on how public comment and regional meetings are going for the Normothermic Regional Perfusion (NRP) white paper, and thanked members for their hard work on the paper. The meeting was adjourned.

### **Upcoming Meetings**

- September 14, 2023 (teleconference)
- October 10, 2023 (in-person)

## Attendance

- **Committee Members**
  - Andrew Flescher
  - Sanjay Kulkarni
  - Keren Ladin
  - Andrew Courtwright
  - Carrie Thiessen
  - Ehab Saad
  - Erica Stohs
  - Felicia Wells-Williams
  - Laura Jokimaki
  - Laura Butler
  - Lisa Paolillo
  - Sena Wilson-Sheehan
  - Thao Galvan
  - Sheila Nichols Bullock
  - Lois Shepherd
- **HRSA Representatives**
  - Jim Bowman
- **UNOS Staff**
  - Kieran McMahon
  - Cole Fox
  - Kristina Hogan
  - Elena Liberatore
  - Rebecca Murdock
  - Eric Messick
- **Other attendees**
  - JD Menteer