

**OPTN Ethics Committee  
Meeting Minutes  
November 21, 2019  
Teleconference**

**Elisa Gordon, PhD, MPH, Chair  
Keren Ladin, PhD, Vice Chair**

## **Introduction**

The OPTN Ethics Committee met via Citrix GoToMeeting teleconference on November 21, 2019 to discuss the following agenda items:

1. Public Comment Project Updates
2. New Project Ideas

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

### **1. Public Comment Project Updates**

The Committee received updates on the Minority Affairs Committee (MAC) Data Collection Project and the Organ Procurement Organization (OPO) Donation after Cardiac Death (DCD) Policy Review.

#### Summary of discussion:

##### MAC Socioeconomic Status (SES) and Access to Transplant

The MAC is developing a data collection proposal to begin collecting some of the significant data regarding transplant candidates socioeconomic status in order to better understand the issue of potential disparate access for individuals with low socio-economic background. The proposal will go out for the Spring 2020 public comment cycle.

The Committee Chair asked if there were any other social determinants of health that were considered. Are all of the new variables ones that transplant centers are going to have to ask the transplant candidates? UNOS research staff clarified that the data elements that are being proposed are commonly asked in most health surveys and is information that would have to come from the transplant candidates. From discussions with transplant social workers and other transplant center staff, the data elements being proposed are closest to what is already being asked during the financial assessment that occurs prior to listing. This information may already be available and should be easy to collect into the Transplant Candidate Registration (TCR) form.

The Committee Chair continued by asking if any other sources were used in this type of analyses. UNOS research staff replied that the data being proposed is more on a patient level. The data from other sources are more on a neighborhood level and may not necessarily apply to a patient level. The Committee Chair stated that this type of data may be helpful in a more supplemental and comprehensive way. UNOS research staff stated that neighborhood level data is readily available from other sources which wouldn't require it to be included.

A member asked if social support data was being collected. UNOS research staff stated that this information is not being collected systematically right now. The member continued that social support

data should be collected given that any economic hardships that the care provider experiences could also affect their ability to sustain that support long term.

Another member asked who would be responsible for collecting the data and completing the TCR form. UNOS research staff stated that the staff who collects this information tends to vary and that whatever process a center already uses – whether it is the financial coordinator or medical social worker – can be solicited from the patient and then passed on to the staff responsible for completing the TCR.

A member asked if this data would be collected on patients or potential donors. UNOS research staff clarified that the data being collected is being considered right now for potential donors on the TCR.

#### OPO Committee Review of DCD Policy

The OPO Committee is working on a project to review and revise the policy language of *Policy 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* in order to give OPOs and donor hospitals more flexibility to include donation discussion as part of end of life discussions. The project was recently approved by the Policy Oversight Committee (POC). During the POC meeting, additional projects were assigned to the OPO Committee. Due to this, the DCD policy review has been pushed back to the Fall 2020 public comment cycle. At this time, the OPO Committee is prioritizing their projects and will reach out to the Ethics Committee volunteers to join the Workgroup to help in the development of the project.

There were no comments or questions.

#### Next steps:

- Committee members will be updated on the progression of the featured upcoming projects and any additional involvement needed.

## **2. New Project Ideas**

The Committee reviewed and discussed new project ideas.

#### Summary of discussion:

##### Pediatric (Peds) Committee Project Collaboration

The Vice Chair provided the Committee with an update on a potential project collaboration with the OPTN PedsCommittee. The Peds Committee is interested in publishing a peer review manuscript aimed at the transplant community discussing the reasons to prioritize pediatric candidates and the concerns that pediatric candidates have that may or may not apply to adult candidates.

Additionally, there is a project idea to revisit the Ethical Principles of Pediatric Organ Allocation (Ethical Principles) white paper and systematically evaluate and address what changes may need to be made or what recent issues haven't adequately considered the needs of pediatric candidates.

UNOS staff explained that in order to move forward with the proposed projects, the Committee would first need to determine if the Ethical Principles white paper needs to be updated. If so, this would require the white paper to go through public comment and approval to the OPTN Board for any changes being made to the document. The decision made by the Committee on how to proceed with the current Ethical Principles white paper would determine the potential timeline for the Peds Committee's proposed projects.

A member stated that the current Ethical Principles white paper is not a bad document, but is not as sophisticated as the current literature. If information from the more sophisticated literature were

included, this would lead to conclusions, changes, or specifications that may not be appropriate to include in the white paper.

Another member stated that the Ethical Principles are fine and that there should not be any additional principles added. There should be explication of the implications particularly of the justice principle for pediatric patients. This would require looking into some sophisticated literature.

A member stated that there was no mention of the topic of re-transplantation in pediatrics and there needs to be some consideration on how many may be needed in this population.

The Vice Chair suggested that this be left as an open question and that UNOS staff could reach out to members to get additional feedback on whether the Ethical Principles white paper should be updated to determine next steps.

#### New Project Ideas:

The Committee Chair reviewed the new project ideas that the Committee discussed during their in-person meeting. Committee members reviewed the top three new project ideas:

- *Patients being informed of covert factors in donation and transplantation:* This project would address how much patients/potential patients should know about issues pertaining to the donation and transplantation process. Some topics include:
  - Is a particular transplant team relatively aggressive or conservative in accepting organs (e.g., PHS high risk, increased risk of delayed graft function)
  - Has a specific team been with a specific transplant facility for a long time? Do available outcome data represent the outcomes for that team? If they have recently arrived, what prior outcomes were available for that team's performance?
  - Is a center heavy handed with immunosuppression or does there tend to be a preference for minimization?
  - Does the team continue to follow recipients indefinitely or is long term care referred to local physicians (with or without transplant expertise)?

The Committee Chair suggested that there could be a list of questions provided for patients to help guide a conversation about the transplantation process. The Committee Chair voiced concern on the need for this type of education for patients. Is there any information that suggest the need for this type of education among patients? Have there been certain questions that patients have voiced in wanting to know?

A member asked if this information should be placed on a center website. From a coordinator's perspective, the questions posed have been asked by patients.

Another member stated that it would be helpful reaching out to patient advocacy groups to refine the questions and seeking additional information for what would help patients throughout the transplantation process.

A member voiced agreement that this information would be invaluable to patients. Having this information contextualized would help patients understand and guide them to making informative decisions. Additionally, there should be tracking of outcomes beyond the 1 year mark.

Another member voiced concern in addressing centers as conservative, aggressive or heavy handed. The Committee Chair stated that the language would be adjusted.

A member stated that if a patient hears less than perfect answers to their questions and have insurance related limitations on where they can go to be listed, this may cause additional frustration. Another member agreed with this and stated that transparency is always challenging.

A member stated that patients should have information and a lot of information is provided to patients during the evaluation. There is concern for the pediatric population, where access to transplant care is often limited to one center. If there is no other option, would this help the families or patients in these types of settings?

A member stated that another unintended consequence of the PR aspect of the transplant centers. This may change the behavior or transplant centers that could potentially present harm to patients rather than enhance their understanding and be a betterment to them.

Another member responded by saying that transplant programs may alter treatment protocols that are felt to be more effective for protocols that may be classified as something that does not have a negative connotation like aggressive.

The Committee Chair summarized that the concern would be the implication affecting physician practice. While transparency is a targeted ideal, there may be some consequences which is important to consider.

A member suggested that as there is variation among transplant centers on the perception of what constitutes as an aggressive and conservative center, this project should be more of a data driven response such as the percentage PHS high risk donors use.

The Committee Chair agreed with this and stated that once data is gathered, there would need to be interpretation of the data. The Committee was encouraged to volunteer being a part of a Workgroup to work on this project if they are interested.

- *Rewrite Considerations in Assessment for Transplant Candidacy (CAT):* This project would entail the review, update and revision of the CAT. There have been significant updates in current literature, which should be updated in the existing document as well as adding any additional topics that were not originally addressed.

The Committee reviewed the current CAT document. The issues identified with the current document is that it is very broad, doesn't clearly articulate the ethical controversies, and does not include current evidence.

A member asked that if the goal of revising this document is to create a paper of the same length or to go into the level of detail suggested in the discussion. Detailing the document would create a larger document.

The Committee Chair stated that there is a need to update the current document. The level of detail and how best to update this information would be based on the discussion and decision of the Workgroup.

The Committee was encouraged to volunteer being a part of a Workgroup to work on this project if they are interested.

#### Next steps:

- UNOS staff will reach out to the Committee for Workgroup volunteers and any additional feedback on the projects discussed during the meeting.

### **Upcoming Meetings**

- December 19, 2019
- January 16, 2020