

## **OPTN Ethics Committee**

### **Meeting Summary**

**April 15, 2020**

**Teleconference**

**Elisa Gordon, PhD, MPH, Chair**

**Keren Ladin, PhD, Vice Chair**

### **Introduction**

The OPTN Ethics Committee (the Committee) met via Citrix GoToTraining teleconference on April 15, 2020 to discuss the following agenda items:

1. Considerations in Assessment for Transplant Candidacy (CAT) Project Update
2. Facilitating Patient Navigation Project Update
3. Living Donor Project Update
4. Multi-Organ Project Update
5. Policy Oversight Committee (POC) Update

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

### **1. CAT Project Update**

The Committee received an update on this project

#### Summary of Discussion:

The subcommittee chair provided an update on the review of the Ethics Committee's 2014 white paper that is posted on the OPTN website.<sup>1</sup> The subcommittee will make recommendations to revise existing sections if needed and recommend the addition of several new sections. The subcommittee's initial recommendations and feedback from the Committee:

#### *Preamble*

- The subcommittee recommends revision to the preamble in order to provide clarity on the intent of the document. Additionally, the subcommittee recommends that justice and utility be better defined in the document.

#### *Life Expectancy*

- The subcommittee recommends no changes to this section.

#### *Organ Failure Caused by Behavior*

- The subcommittee recommends revising this section because it is broadly written. Additionally, the subcommittee recommends clarifying that organ failure caused by past behavior is a consideration but not a contraindication for being relisted for transplant. One member asked

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<sup>1</sup> <https://optn.transplant.hrsa.gov/resources/ethics/general-considerations-in-assessment-for-transplant-candidacy/>

how this applies to today's practice and whether there should be criteria included in the white paper.

### *Compliance/Adherence*

- The subcommittee recommends retaining this section but modifying the title since compliance has a negative connotation. They recommend replacing "compliance" with "non-adherence."
- A member noted that some kidney transplant recipients lose their medication coverage after a few years and simply cannot afford the medications. He recommended that the subcommittee consider this external factor since it is a financial issue not behavior. Committee members agreed to add this information to the document while noting that some transplant center's listing committees will consider this to determine if it might happen again. Another member noted there is a lot of non-compliance with teenagers or younger patients where behavior can be a factor.
- A member noted that a large number of liver transplants are performed for acute alcohol-induced liver failure. Therefore, the Committee needs to be careful about the implications of these white papers, especially without scientific evidence.
- Another member noted that the transition from pediatric to adult status has an impact as well. When a patient turns 18 years old, they might lose charity care under which pediatric patients are able to get more support. He noted that many centers have implemented an "adherence contract" of 6 months or so during which time they have to obtain funds/social support and show behaviors agreed upon to constitute adherence.

*Repeat Transplantation* – The subcommittee chair noted that age needs to be a factor along with the issues discussed previously.

*Alternative Therapies* – The subcommittee recommends removing this section since it is common practice for transplant programs to consider alternative therapies before proceeding to transplant.

### ***Proposed New Sections***

#### *Intellectual Disability*

- The subcommittee members agree that intellectual disability should not be the primary contraindication for transplant. One committee member noted that a good support system is important and that many individuals with intellectual disabilities have very strong support systems.
- One Committee member noted that the Office of Civil Rights (OCR) is working on guidance on this issue and the Committee could include a link to that guidance in the white paper if the guidance is released.
- The subcommittee chair also noted there is active discussion in the subcommittee about patients in a vegetative state.

#### *Financial Challenges*

- The subcommittee chair noted that this issue includes medications as well as other expenses related to transplantation. One member recommended adding medications to this section since it is so important to the longevity and success of transplanted organs.
- A member asked if there are OPTN discussions regarding patients that fall within this category. UNOS staff noted that the OPTN does not collect data on patients excluded during the transplant evaluation process. Another member suggested reaching out to the Transplant Administrators Committee or Data Advisory Committee about this issue.

### *Incarceration status*

- The subcommittee chair noted that, similar to the other issues discussed, incarceration status alone is not a rationale for excluding a patient from accessing transplant. The subcommittee has discussed including references to other documents.
- There was variability among committee members regarding access to transplant for prisoners. For example, one member noted there could be challenges getting inmates to appointments.
- A member noted that their transplant center does not accept patients or donors that are on probation due to the risk of induced non-compliance and bad outcomes for these patients. Another member noted that his transplant center will list patients on parole based on feedback from the probation officers.
- A member noted the importance of being educated about the transplant process and the legal/prison systems. He noted that there are differences between the state and federal prison systems that should be taken into consideration.

### *Social Support*

- The subcommittee chair noted that social support can be defined in many different ways such as church, friends, and families. One important population to consider are those that do not have a social support system and how to provide that support so they can have access to transplant. One member noted that there are programs, such as those for veterans, which provide assigned support.
- A member commented that the patient might be the one providing support. For example, they might be the sole support for children or the elderly. One member noted that their center does ask this question, especially if it is a patient with an aging parent or with young children.
- A member noted that listing committees have to make philosophical decisions and social support is an extremely important factor in the decisions. He noted that up to 20% of patients could be ruled out due to lack of social support. He provided an example of a kidney transplant recipient who cannot be discharged from the hospital because the social support is no longer available.
- A member commented that the duration of the social support is also very important. For example, some kidney transplant recipients only rely on this support for a couple of weeks. Another member noted that 6-8 weeks is standard for heart patients, which can be a burden.
- A member noted that some patients could be at a social disadvantage if they do not have a social support system. Additionally, the question was raised about how long transplant centers wait for the patients to obtain support.
- A member noted the importance of considering transparency around these factors. For example, when can patients be re-evaluated for listing and how do transplant centers communicate with patients about this process.
- A member asked about the ethical principles for denying transplantation for these situations and not just evaluating the medical considerations. The Committee Vice-Chair noted a recent article published in the American Journal of Bioethics that addresses this issue and requested that it be distributed to the committee members.

### *Immigration status*

- The subcommittee chair noted that the subcommittee discussed the model of providing a short statement along with references to other sources of information that would be beneficial to the community.

### *Vaccinations*

- The subcommittee chair asked if vaccinations should be included in the evaluation protocols. UNOS staff noted that the Health Resources and Services Administration (HRSA) is still reviewing the draft outline for a white paper addressing vaccinations. HRSA staff noted that vaccinations are part of the medical history used during the evaluation process and the subcommittee should continue to discuss it. He also recommended that the Ethics Committee work closely with the Ad Hoc Disease Transmission Advisory and Pediatric Committees since the public health infrastructure could affect access to vaccinations.

## **2. Facilitating Patient Navigation Project Update**

The Committee received an update on this project.

### Summary of discussion:

The subcommittee wants to provide guidance and education to help patients through the decision-making pertaining to organ transplantation process. There were no comments and questions about this project.

### Next steps:

- Finish outline and submit for internal review
- Incorporate feedback and project approval by the Policy Oversight Committee
- Finish drafting sections
- Review by full committee
- Submit project for public comment

## **3. Living Donor Project Update**

The Committee received an update on this project.

### Summary of discussion:

Currently, *Policy 14: Living Donation* does not cover living vascular composite allograft (VCA) donors. Committee leadership noted that as living uterus donation becomes more prominent, it would be important to update the policy to include living VCA donors to fill the gap that currently exists. Committee leadership also noted that this project is being developed concurrently with the VCA Committee's project to update the Living Donor Recipient and Living Donor Follow Up forms to include living VCA donors.

- There were no comments or questions about this project.

### Next steps:

- Continue working on this project

## **4. Multi-Organ Project Update**

The Committee received an update on this project.

### Summary of discussion:

The Ethics Committee's representative on this multi-disciplinary workgroup provided an overview of the early discussions. This workgroup is charged with evaluating and revising Policy 5.10.C: Other Multi-Organ Combinations. The workgroup is also using key recommendations from the Ethics Committee

White Paper to aid in their discussions.<sup>2</sup> This project is in the early phases of discussion with the goal of sending a proposal out for public comment in January 2021.

Next steps:

- The Ethics Committee will receive periodic updates on this project.

## **5. Policy Oversight Committee Update**

The Committee received an update on the work of the Policy Oversight Committee.

Summary of Discussion:

The Committee members provided initial feedback on the project ideas that might require participation by the Ethics Committee. The Committee identified the following projects:

- *Enhanced screening* – This is a current IT project to allow programs to set additional screening criteria. One member noted that there should be set guidance on transparency and how reevaluation will happen at specific time points since this impacts patients and transplant programs.
- *Improve pediatric offer acceptances* – This is a current collaborative improvement project to improve the acceptance practices of pediatric programs. A member asked if there was a way to track organs refused by pediatric programs and what the outcomes were if transplanted into adult candidates.
- *Best practices on getting to “yes”* – This is a potential improvement project to share OPO best practices.

Cross-committee collaboration – The Ethics Committee will provide periodic feedback on the Kidney Committee project “Improving access for pediatric and highly sensitized kidney candidates.”

Committee leadership also noted that they are working with the leadership of the Pediatric Committee on a project idea to address the ethical principles of pediatric allocation in the current system.

## **Upcoming Meetings**

- May 21, 2020 (Teleconference)
- June 18, 2020 (Teleconference)