

OPTN Ethics Committee

Meeting Summary

March 19, 2020

Teleconference

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Introduction

The OPTN Ethics Committee (the Committee) met via Citrix GoToTraining teleconference on March 19, 2020 to discuss the following agenda items:

1. Important Announcements
2. Public Comment Discussion: Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients – Vascular Composite Allograft (VCA) Committee
3. Public Comment Discussion: Addressing Medically Urgent Candidates in New Kidney Allocation Policy – Kidney Transplantation Committee
4. Continuous Distribution Update

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

1. Important Announcements

- In-Person Meeting in Richmond, Virginia - UNOS staff noted that the meeting has been changed to a virtual meeting and members will receive additional information once details are known. Members were told that no action is required by them regarding travel arrangements.
- Vice-Chair Nomination Process – UNOS staff noted that there are six Vice-Chair nominees that have submitted personal statements. The Committee will be provided with an opportunity to vote for the top three nominees who will then be interviewed by Ethics Committee leadership.

2. Public Comment Discussion: Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients

UNOS staff provided an overview of the VCA Committee's proposal.

Summary of discussion:

A member noted that mandatory reporting for something like this could be controversial. While parents can provide prospective consent, will there be an option to withdraw data once the child reaches a certain age?

A member commented their appreciation for the potential value of the data points, there was concern about the lack of consent ability for these children. Additionally, the parents could be conflicted about giving complete consent. The member noted that it is similar to consent for live donation where there is concern about the lack of objectivity about providing the information. That was the rationale for requiring an independent donor advocate for living donor and could be beneficial for these patients as well.

A member noted that it should not be mandatory as a condition for uterus transplant and there should be an option to opt out without affecting access to transplant.

A member noted that the uterus is being transplanted solely for the purpose of producing a child so the need to collect information is greater than other situations because we are trying to determine if it is appropriate.

Another member noted that if data is collected for research, it is different from clinical reasons.

The Committee discussed the length of time for the data collection. A member noted that uterus transplants are only being performed at a few centers nationwide. Most candidates relocated to the location of the transplant center and remain there for a considerable length of time. Some research studies collect data for five years, which is the more than the two years required by the OPTN. This does create some challenges once the mother moves away. The member also noted that a lot of mothers just want the normalcy of regular childbirth.

The Committee discussed the potential for adverse effects on children, particularly as they get older. For example, if a child knows they are part of a research study they may not feel normal.

A member noted that there are established neonatology clinical studies that require long-term follow up and consent from pregnant women.

A member noted that there should be rules for consent and withdrawal of consent.

Next steps:

The comments received by the Committee will be synthesized into a formal statement that will be posted to the OPTN website.

3. Public Comment Discussion: Addressing Medically Urgent Candidates in New Kidney Allocation Policy

The Committee reviewed and provided comments on the Kidney Committee's proposal.

Summary of discussion:

A member noted that it would be important for transplant programs to document why each dialysis access location could not be used and specify why the urgency status is being requested. One member expressed support for the proposal since it is a solution for a small number of patients. However, the OPTN should monitor the number of medically urgent candidates at transplant programs.

Next steps:

The comments received by the Committee will be synthesized into a formal statement that will be sent to the OPTN Kidney Transplantation Committee.

4. Continuous Distribution Update

The Committee received an update on the continuous distribution of lungs project.

Summary of discussion:

A member asked if there would be different attributes for the different organ types. UNOS staff noted that community feedback will be important and expressed interest in having the committee participate in the prioritization exercise.

Next steps:

The Ethics Committee will submit their input in a prioritization exercise. The committee will also receive periodic updates on this project.

Upcoming Meetings

- April 15, 2020 (Teleconference)
- May 21, 2020 (Teleconference)