

OPTN Vascularized Composite Allograft Transplantation Committee Meeting Summary February 12, 2020 Conference Call

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Introduction

The OPTN Vascularized Composite Allograft Transplantation Committee (the Committee) met via Citrix GoToTraining teleconference 02/12/2020 to discuss the following agenda items:

- 1. "Modify Data Collection on Living Donors" Project
- 2. Update on VCA Public Comment proposals
- 3. Membership Changes Timeline

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

1. "Modify Data Collection on Living Donors" Project

The Committee discussed feedback from the Data Advisory Committee's (DAC) problem analysis checkpoint and voted to send this project forward to the Policy Oversight Committee (POC).

Summary of discussion:

The Committee reviewed the DAC's feedback questions and discussion:

- Why don't we collect specific clinical data for all living donors?
 - The prevalence of living uterine donation continues to increase, while the number of other types of living donation have remained very few.
- Who would look at these data and how would findings be used?
 - UNOS research monitors procedure outcomes and risks through data analysis at 6 months, 1 year, and on an annual basis thereafter to assess patient safety.

"Modify Data Collection on Living Donors" was unanimously endorsed by DAC at the problem analysis checkpoint.

The Committee reviewed the content of "Modify Data Collection on Living Donors" project form. Members agreed on a solution that focused on developing data requirements for living VCA donors and specific clinical information for living uterus donors. The Committee unanimously supported sending this project to the POC.

Next steps:

"Modify Data Collection on Living Donors" will be presented to the POC for approval on February 21, 2020 and is projected to be heard by the Execrative Committee on February 25, 2020. The next required OPTN DAC checkpoint is during the evidence gathering period of the policy development process.

1. Update on VCA Public Comment proposals

The Committee discussed the public comment to date on "Update to VCA Transplant Outcomes Data Collection" and "Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients".

Summary of discussion:

Each public comment document has received one comment on the OPTN website. Both comments were generally supportive and offered insight on posed feedback questions and requests. The comment on "Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients" supported the follow up of children delivered from a transplanted uterus for a maximum of two years including only information gathered at routine pediatric visits. A member commented that this follow up period was especially short considering the Committee had discussed following these children from a range of two to eighteen years after birth.

A HRSA representative indicated an updated memo related to collecting data on children of uterus transplant recipients will be submitted to the OPTN soon.

These public comment proposals have been supported and passed by all three regional meetings held at this point in the cycle. A member suggested asking the American Society of Pediatrics to comment on these proposals.

Next steps:

The Committee will review more public comments received on these documents later in the cycle.

2. Membership Changes Timeline

June 2021 is the implementation date on the membership changes timeline.

Upcoming Meetings

- March 11, 2020 (Teleconference)
- April 3, 2020 (In- Person)