

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
January 9, 2019
Conference Call**

**Linda Cendales, M.D., Chair
Bohdan Pomahac, M.D., Vice Chair**

Introduction

The VCA Committee met via Citrix GoTo teleconference on 01/09/2019 to discuss the following agenda items:

1. Update from OPTN/UNOS Board of Directors Meeting
2. Project Discussion: VCA Transplant Outcomes

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

1. Update from OPTN/UNOS Board of Directors Meeting

The Committee will debrief from the OPTN/UNOS Board of Directors meeting held in Dallas, TX (12/3/18-12/4/18)

Data summary:

UNOS staff highlighted some key points that the VCA committee should be aware of following the December 2018 Board of Directors meeting:

- Proposals on the consent agenda was passed in a block vote with 37 votes for yes, 0 votes for no, and 1 for abstain (37-0-1).
- The discussion agenda included *Changes to Islet Cell Program Requirements* (37-1-1 inclusive of one amendment), *Frameworks for Organ Distribution concept document* (36-1-0 supporting the continuous distribution model) and *Eliminate the Use of DSAs or Regions in Liver Distribution* (30-7-2 supporting the Acuity Circle (AC) model). The latter proposal garnered lengthy discussion, including amendments.

The BOD addressed other important business, including electing another at-large member, approved nominees for board vacancies, approved minutes from June 2018 Board meeting, approved a revised OPTN operating budget for the 2019 fiscal year, and a reduction in the candidate registration fee.

The Chair thanked UNOS staff for the update. With no questions from members, he segued to the next item on the Committee's agenda.

Summary of discussion:

The Chair thanked UNOS staff for the informative update. She then shared her thoughts from her attendance at the Board meeting including:

- The Pancreas Committee was discussing very similar concerns as the VCA Committee. As a group, there is a lot of similarities and lessons that can be learned from the Pancreas Committee's discussions.
- The compelling and dutiful remarks during the liver discussion shared by transplant recipients and donor family representatives on the BOD.

The Chair then segued to the next agenda item.

2. Project Discussion: VCA Transplant Outcomes

The Committee briefly reviewed project development to-date and discuss remaining elements to make the project “POC-ready” for February 2019.

Data summary:

- A. UNOS staff presented some concerns that the committee expressed at the 2018 in person meeting.
 - A need to gather more clinically relevant data on success and outcomes from VCA programs.
 - To collect this data in a unified manner.
 - Potential gaps in data collection across all VCA types.
 - A need to engage expertise from urology and obstetrics and gynecology (OB/GYN) fields.
- B. UNOS staff showed the Committee two summary documents to illustrate what VCA recipient information is being collected. This included the current Transplant Recipient Registration (TRR) Form and the Transplant Recipient Follow-up (TRF) form for VCA.

Summary of discussion:

Members discussed several elements pertaining to this project. These included:

- Clarification of when VCA data reporting to the OPTN was mandatory.
- Preliminary discussions on data elements to capture (e.g.: history of prior skin graft procedures)
- How to capture genitourinary transplant outcomes, and what these outcomes may include.
- The need to capture great depth of information on psychosocial health of VCA recipients.
- What role, if any, the OPTN plays in collecting data on the health of babies born to uterus transplant recipients.
- The administrative process to amend existing forms approved by the U.S. Office of Management and Budget (OMB), or submit new forms for OMB review.
- Future data requests were made:
 - A request at the next meeting to have a summary of this data on all the VCA transplants done since 2014?
 - How many VCA transplants were performed in the last 6 months?

At the conclusion of the discussion, members felt the initial project scope was defined and supported. The Committee unanimously recommended this new project be considered by the OPTN/UNOS Policy Oversight Committee (POC) at their next conference call. UNOS staff affirmed they would perform the necessary administrative work to put this project before the POC. The Chair and Vice Chair thanked members for their diligent discussions on this project. A status report will be provided at the next conference call or meeting.

Next steps:

UNOS staff will:

- Provide follow-up information on data submission compliance rate requirements, and review summary lists shared with the Committee.
- Prepare the project form consistent with today’s discussion and share with leadership for review.

The committee will review tables of TRR and TRF and consider what data elements are needed.

With no further business to discuss, the conference call was adjourned.

Upcoming Meeting

- March 29th 2019 In Person Full Committee Meeting , Chicago, IL