

## **OPTN Vascularized Composite Allograft Transplantation Committee**

### **Meeting Summary**

**March 9, 2022**

**Conference Call**

**Bohdan Pomahac, MD, Chair**  
**Sandra Amaral, MD, Vice Chair**

### **Introduction**

The Vascularized Composite Allograft (VCA) Transplantation Committee met via Citrix GoTo teleconference on 3/9/2022 to discuss the following agenda items:

1. In-Person Meeting Logistics
2. Public Comment Update
3. New Project: *Apply Transplant Program Inactivity Requirements to VCA*
4. Guidance on Optimizing VCA Recovery from Deceased Donors

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

#### **1. In-Person Meeting Logistics**

The meeting will be April 6<sup>th</sup> from 9am – 3pm CT at the Chicago O'Hare Hilton with an informal dinner option for the night before. Members that are planning to attend in-person were asked to fill out the survey regarding health and safety protocols sent via email prior to traveling. Members also reviewed the COVID-19 protocols for Winter 2022 OPTN Committee as resolved by the OPTN Executive Committee. As part of the resolution, virtual attendance will be an option for members who cannot travel to Chicago and members were asked to please let UNOS staff know as soon as possible if they will not be able to attend.

#### **2. Public Comment Update**

The Chair presented the public comment feedback received so far for the Committee's proposal *Modify Graft Failure Definition for VCA*. The feedback included what has been submitted through OPTN Regional Meetings, presentations to OPTN Committees, the OPTN VCA National Public Webinar, and the OPTN Public Comment website. Overall, the sentiment collected has been supportive for the proposal.

Specific comments included ensuring that it is not considered graft failure if a candidate registers separately for right and left upper limb, clarifying if it is graft failure if a recipient has a successful uterus transplant which is removed then later pursues another uterus transplant, clarifying how the OPTN will evaluate compliance, and clarifying how graft failure will be captured if the graft is not removed and the patient does not re-register for VCA.

#### Summary of discussion:

Regarding the comment on right and left limb registrations, it was clarified that those would be separate registrations so if a recipient has a left limb, registering for the right limb would not indicate a graft failure of the first graft.

The Chair asked for thoughts on the example of a patient requesting a second uterus transplant after a successful first uterus transplant and a member noted that they would need to fully conceptualize the example since that is not something that has been done. The Vice Chair added that the intent is to get the language right with the possibility of a successful uterus transplant after one already successful uterus transplant if that is something that may happen in the future. A member offered an example of a woman who had life changing events, such as divorce, and would want to pursue the second transplant with their new partner. Members felt if planned removal and graft failure were reported accurately, this case would not be flagged as a graft failure.

The Vice Chair covered the questions that were asked during the national webinar and it was clarified that the compliance piece of the proposal states that Member Quality does not plan to change their evaluation plan in response to the proposal, but Site Survey can ask to review any documentation in patient medical records, which could include documentation of planned removal.

### **3. New Project: *Apply Transplant Program Inactivity Requirements to VCA***

The Chair presented the overview of this proposal and how it would affect VCA programs. The Committee originally discussed removing the VCA exclusion from the OPTN Bylaw program inactivation requirements in November 2020 and the Committee supported having the OPTN Membership and Professional Standards Committee include this change in their upcoming proposal that has since been delayed. The Committee could endorse this proposal in Summer 2022 to make the change so it can be implemented with VCA in UNet<sup>SM</sup>.

The removal of the VCA exclusion in Appendix K would require that VCA programs notify the OPTN and their patients if the program meets either short-term or long-term inactivation, but would not establish functional inactivity requirements for VCA programs.

#### Summary of discussion:

A member noted that programs should have a standard requirement of notification if the program is not able to perform transplants and agreed that considering transplant volume requirements for VCA programs at this time would not be appropriate.

The Chair stated that VCA programs are unlike many solid organ programs in that they often only have one or two lead surgeons, so the short-term inactivation timelines may be too strict with travel and other obligations. A member added that if a transplant surgeon is out of town, they are likely still reachable and would fly back to perform the transplant if necessary so that would not count as an inactive day. It was clarified that VCA is not entirely unique in having only one surgeon available to perform transplants and that there are single surgeon solid organ programs. With single surgeon programs, they include that information in the program coverage plan to ensure patients are aware of the potential impacts to surgeon or physician availability. A member felt that the 15 consecutive days seemed reasonable, but raised concerns over the 28 cumulative days if there is only one surgeon at the program. They also added that the VCA waitlists are typically low in number so it should not be a large burden to notify their patients. Members discussed the nuance of how availability would be defined and a HRSA representative noted that the bylaw references inactivation of the program's waitlist counting towards a program's inactivation, not defining a surgeon's availability.

The Chair asked for clarification on the timeframe for notification to patients should a program anticipate that they will hit either the 15 consecutive or 28 cumulative days. It was clarified that the bylaw outlines the required timeframes for notification and in that example, the program would be required to notify patients "no more than seven days following the last day of the inactive period that caused the transplant program to exceed the inactive waiting list threshold". It was also mentioned that

while the requirement is no more than seven days after the last day, there is nothing barring a program from notifying their patients sooner if they anticipate that happening. A member stated that their impression was that programs needed to notify their patients any time their status was changed, and it was clarified that there is no requirement for that currently.

A member asked if there was any occurrence of VCA candidates utilizing dual-listing to mitigate the risk of temporary unavailability at either program. A member stated that some uterus candidates register at multiple transplant programs, and that would be an option for other VCA candidates. A member added that the spirit of this is to let the patient make the decision to dual-list, but present it as an option.

Overall, the Committee decided that the same standard of inactivation requirements should be applied to VCA programs and supported moving forward with this project.

#### Next steps:

Present to the OPTN Policy Oversight Committee and OPTN Executive Committee for approval and aim to send the proposal out for public comment in Summer 2022.

#### **4. Guidance on Optimizing VCA Recovery from Deceased Donors**

The Committee reviewed the current guidance document which was approved in 2018.<sup>1</sup> The current document includes references to the current VCA allocation process which will be outdated once VCA is in UNet<sup>SM</sup>. The Committee was presented with three options for discussion:

- Remove the guidance from the OPTN Website
- Remove outdated references
- New project – review the full document and update as needed

#### Summary of discussion:

A member offered to review the organ procurement organization (OPO) specific areas prior to the next Committee meeting to aid in discussion. The Vice Chair also added that when the document was created, uterus transplantation was not on the Committee's radar so the document should be updated to include that.

#### Next steps:

The Committee supported doing a deeper review of the current guidance document as part of a new project at the April Committee meeting.

#### **Upcoming Meetings**

- April 6, 2022 (Chicago)
- April 13, 2022 (Tentative)

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<sup>1</sup> Guidance on Optimizing VCA Recovery from Deceased Donors, OPTN, accessed March 29, 2022, [https://optn.transplant.hrsa.gov/media/2503/vca\\_guidance\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf)

## Attendance

- **Committee Members**
  - Bohdan Pomahac, Chair
  - Sandra Amaral, Vice Chair
  - Mark Wakefield
  - Brian Berthiaume
  - Donnie Rickelman
  - Patrick Smith
  - Simon Talbot
  - Debra Priebe
  - Paige Porrett
  - Bruce Gelb
  - Darla Granger
  - Debbi McRann
  - Lori Ewoldt
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kaitlin Swanner
  - Krissy Laurie
  - Sarah Booker
  - Catherine Parton
  - Kristina Hogan
  - Leah Slife
  - Robert Hunter
  - Sharon Shepherd
  - Susan Tlusty