

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

### **Meeting Summary**

**January 12, 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 1/12/2022 to discuss the following agenda items:

1. OPTN Board Meeting Debrief
2. Public Comment Preview
3. CMS Request for Information
4. Monitoring Report: *Eliminate Use of Regions in VCA Distribution*

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

#### **1. OPTN Board Meeting Debrief**

The Chair and Vice Chair debriefed the Committee on the discussion related to the *Establish Membership Requirements for Uterus Transplant Programs* which was approved at the December 2021 OPTN Board of Directors (Board) meeting. Themes of the discussion were around understanding the nuances between the different procedures and balancing access for new programs versus living donor safety. While there was an amendment put forward that would have allowed a pathway to become a primary living donor uterus surgeon without direct living donor recovery experience, it was not approved. The Vice Chair noted that it was concerning that there was an apparent lack of understanding around uterus transplantation by and it was suggested that more education be done regarding uterus (and VCA) for Board members. The Chair and Vice Chair thanked the Committee and Workgroup for all the hard work that was needed throughout the process.

#### **2. Public Comment Preview**

The Committee reviewed the timeline and upcoming projects that will be included in the Winter 2022 public comment cycle. Committee members were encouraged to attend their virtual Regional Meeting and review any public comment proposals of interest on the OPTN website.

#### Summary of discussion:

The Chair asked for some background on the OPTN Living Donor Committee's proposal *Modify Living Donor Exclusion Criteria* and it was explained that it aims to adjust some of the malignancy and diabetes exclusions which would allow for additional living donors. The Chair felt that the Committee providing feedback was not necessary for this proposal since there was nothing specific regarding living donor uterus and members agreed.

### 3. CMS Request for Information

The Centers for Medicare and Medicaid Services (CMS) has a request for information (RFI) which contains specific questions regarding VCA<sup>1</sup>:

- Should the CMS definition of organs include VCAs?
- Would certain organ procurement organizations (OPO) be advantaged or disadvantaged if VCAs were counted as organs for OPO performance metrics?
- Given low transplant volume, should CMS establish survey and certification requirements for centers that transplant VCAs? If so, what health and safety aspects specific to VCA should be considered?

The Chair requested the Committee's feedback on these questions and asked if the Committee should craft answers which could be included as part of the OPTN Executive Committee's response.

#### Summary of discussion:

Regarding whether or not the CMS definition of organs include VCA, the Chair felt that it should. It was noted that when CMS issued their proposed rule for OPO performance metrics in 2020, there were a few organizations that submitted comments that VCA should be included in their definition but CMS felt that was not in the scope of what they were doing at that time which may be why they are requesting more information. A HRSA Representative mentioned that they are unbiased, but if reimbursement is important, then the VCA community should support having CMS consider VCAs as organs, and if there are going to be certification requirements, then the OPTN and CMS should be aligned. Members also agreed that the VCA community initially advocated for VCAs to be considered organs and that there should be consistency between the OPTN and CMS.

A member stated that currently from the OPO perspective VCA procurement counts as an unexpected organ recovery so it helps OPO metrics and would make up for an organ that could not be placed. The Chair said that VCAs should be counted, but in a way that would not negatively impact OPOs that are not in areas with VCA programs, and members agreed.

Regarding whether or not CMS should establish survey and certification requirements for hospitals that transplant VCAs, a member suggested not responding with a definite yes or no, but rather offering that if there are specific outcome requirements, that VCA be excluded based on low volumes which is already the practice for other low volume organ types (i.e. heart-lung, intestine, pancreas). The member also explained that the CMS survey does not really focus on outcomes, but more on quality assurance and performance improvement (QAPI) that the program has in place for each organ type. The Chair added that even if outcomes are not part of the survey and certification, at least CMS can ensure that the proper infrastructure is in place. A member stated that the OPTN is more focused on outcome metrics which would still be the case and reminded members that low volume organ types are currently excluded from outcomes for CMS. Another member noted that since CMS is returning to state-based surveyors, there may be differences in what is being surveyed.

The Chair asked if there were overall thoughts from the Executive Committee's response regarding these questions and it was clarified that the specifics on that area of the response were not available

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<sup>1</sup> Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities, Federal Register, accessed on February 8, 2022, <https://www.federalregister.gov/documents/2021/12/03/2021-26146/request-for-information-health-and-safety-requirements-for-transplant-programs-organ-procurement>

yet, but the Committee could offer their input. Overall, the Committee noted that OPTN and CMS often do not align and this seems like an area where they should align.

#### **4. Monitoring Report: *Eliminate Use of Regions in VCA Distribution***

In June 2020, 500 nautical mile (NM) circles replaced OPTN Regions in VCA allocation. Post-policy implementation data runs from June 18, 2020 through September 30, 2021 and the metrics include the size and composition of the VCA waiting list and deceased donor VCA transplants. During the pre-policy era, six of the eight transplants were within 500 NM of the donor hospital and all three transplants during the post-policy era were within 500 NM. The median number of days on the waiting list between listing and transplant were similar in both pre-policy (307 days) and post-policy (299 days). However, more time and data are needed to assess the true impact of this policy change due to the low volume of deceased donor VCA transplants.

##### Summary of discussion:

The Chair asked about prioritizing discussion around abdominal wall after seeing the number of candidates and a member said it would be beneficial since multi-organ policy does not include abdominal wall so candidates wait for a while, since abdominal walls are typically transplanted with another organ. The Chair asked if the Committee could get outcome data and compare it to cold ischemic time to see if that is a predictor of outcomes. UNOS Research staff explained that it can be included in the future monitoring reports. A member mentioned that it did not seem like the 500 NM circle would stop anyone from taking organs from further away, but right now it is such a small sample size. The Chair asked if there were any donors who were offered VCA organs but did not accept them, or if there are data on the discard rate for VCA. A member added that when match runs are in DonorNet<sup>®</sup>, those data would be available but are unfortunately not available retrospectively. A member noted that discard rates would also be helpful in informing performance metrics.

##### **Upcoming Meetings**

- February 9, 2022
- March 9, 2022

## Attendance

- **Committee Members**
  - Bohdan Pomahac, Chair
  - Sandra Amaral, Vice Chair
  - Mark Wakefield
  - Brian Berthiaume
  - Donnie Rickelman
  - Patrick Smith
  - Darla Granger
  - Debbi McRann
  - Lori Ewoldt
  - Simon Talbot
  - Debra Priebe
  - Gary Morgan
  - Vijay Gorantla
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kaitlin Swanner
  - Krissy Laurie
  - Sarah Booker
  - Leah Slife
  - Susan Tlusty
  - Isaac Hager