

OPTN Vascularized Composite Allograft Transplantation Committee**Meeting Summary****May 12, 2021****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 05/12/2021 to discuss the following agenda items:

1. Update on VCA Policy/Bylaw Clarification
2. New Project Discussion and Project Form Review

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

1. Update on VCA Policy/Bylaw Clarification

The Committee received a brief update regarding minor changes to how the VCA Policy and Bylaw Clarification will be implemented. The clarification was split into two parts: language that will be effective immediately upon approval and language that will be effective when the VCA in UNet^{SM1} and Living Donor Registration/Living Donor Follow-up² projects are implemented. Language that will be effective immediately will include the list of covered body parts, bylaw/membership requirements, and the clarifications to the current policy language that will be removed in the future with the implementation of other proposals. Language that will be implemented in the future includes clarifications that will be added as part of the data collection proposals, but will not be effective until those data are being collected.

2. New Project Discussion and Project Form Review

The Chair facilitated discussion of the new VCA Committee project that may include policy changes, data collection changes, and the option to seek OPTN Board of Directors approval for the expedited pathway of changes to the list of covered body parts in OPTN Policy.

Summary of discussion:*VCA Graft Failure Definitions*

The Committee reviewed the current definitions for graft failure in OPTN Policy and discussed how it could be defined for VCA.³ The Chair referenced the Committee's previous feedback regarding VCA graft failure including use of "graft survival" or "graft removal" as alternative terms and inclusion of removal

¹ "Programming VCA Allocation in UNet," OPTN, accessed June 8, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/programming-vca-allocation-in-unet/>

² "Modify Data Collection on VCA Living Donors," OPTN, accessed June 8, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/modify-data-collection-on-living-vca-donors/>

³ "Policy 1.2 Definitions," OPTN, accessed June 8, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

of a uterus graft prior to a live birth.⁴ A member noted that the removal of a graft due to the patient requesting removal should still be seen as a failure since the patient may no longer adhere to immunosuppression and post-transplant care which will likely result in the removal of the graft. The Chair agreed that if a patient requests removal of a live graft, it may not be a biological failure but it is a failure of patient selection or indication. The Vice Chair mentioned that a non-functional graft that a patient still wants to retain may cause under reporting of graft failure since that graft is not functioning to the intent of the transplant. A member agreed that there is nuance to VCA graft failure and suggested the possibility of adding a category for functional failure. The Chair noted that it is difficult to tease out distinct categories since there are many facets to functional failure in VCA. A member asked when failure would occur in the instance of relisting or re-transplanting. The Vice Chair clarified that with kidney, need for re-transplant as indicated by return to dialysis is considered graft failure. The member thought re-transplant should also be considered graft failure for VCA. The Chair stated that preemptive re-transplanting should be avoided and suggested adding language to clarify that the re-transplant was unplanned.

The Vice Chair noted that there should be two options for uterus grafts, one that indicates a graft failure as removal before a live birth and one as a graft success as removal after a successful live birth since not all uterus graft removals are graft failures. The Chair mentioned that this addition could be specific to uterus similarly to how pancreas has specific graft failure definitions. Members supported data collection changes to align with a policy definition of graft failure specific to uterus, such as a drop down menu for uterus that has options for those two types of uterus graft removal.

A member suggested the following options for VCA graft failure: the graft is removed, recipient dies, and re-listed/re-transplanted, with an option for removal prior to live birth available for uterus. The Chair asked for clarification on whether or not recipient death was relevant and a member clarified that death with a functioning graft is the most common form of graft loss and is reported across organ types. Members clarified that the OPTN tracks all patient death in order to monitor whether certain centers are seeing higher than average, or higher than expected, recipient death rates. The Vice Chair asked for clarification on whether or not re-listing would be appropriate for VCA and members noted that for pancreas re-listing would be a failure which would be similar to keeping a VCA graft that is no longer functioning properly.

The Chair asked for Committee feedback on the options of graft removal, recipient dies, and a variation of re-listed or re-transplanted. Members felt that including re-listing as a cause of graft failure is reasonable, mirroring the definition for pancreas. A member asked for context for graft loss and patient death and a member clarified that reporting both graft loss and death to be consistent with other organ groups as well as have the ability to tease out if the patient death is related to the transplant (i.e. cancer as a complication due to transplantation).

The Committee supported three options to define graft failure for VCA with additional clarification for uterus:

- Graft is removed, recipient death, and patient re-registers for VCA type
- Uterus graft failure defined as graft removal prior to live birth

⁴ "VCA Committee Meeting Summary (4/12)," OPTN, accessed June 8, https://optn.transplant.hrsa.gov/media/4591/20210412_vca-committee-meeting-summary_final.pdf

Causes of VCA Graft Failure

The Committee reviewed a list of possible causes of graft failure as appropriate for VCA to be included as part of this project. The Committee discussed intra-operative failure (failure to perfuse) and if that would fall under “ischemia” and members thought that it would fall under that category with the “other, specify” as another option.

The Chair expressed concern over the “non-compliance: rehabilitation” cause because then it becomes easier to blame to the patient and the Chair was unsure that would lead to the failure of the graft. A member noted that may fall under “patient requested removal” and suggested combining all of the non-compliance type causes into one. The Vice Chair mentioned that this is an issue across organ types since the transplant program has somewhat of a bias in assessing these causes and reporting them.

The Vice Chair noted redundancy in some of the options was noted, such as “non-compliance: immunosuppression” and “chronic rejection” since the former would lead to the latter. Another member mentioned that noncompliance is a difficult term due to its negative connotation and suggested using loss of function terminology instead. HRSA staff noted that a loss of function cause may be too broad of a category in terms of data collection and suggested adding more specificity depending on what type of data the Committee is hoping to collect. Members suggested using inadequate function and possibly adding a drop down menu with more specific reasons for that loss of function. A member also noted that function has been difficult to define for VCA since each case is unique and the Chair agreed. The Chair asked for clarification on if there are similar noncompliance causes for other organ programs and it was clarified that there was more of a blanket cause of noncompliance. The Vice Chair stated that some programs are moving towards the term of non-adherence. Committee supported removing non-compliance in exchange for non-adherence and adding an option for general loss of function.

Wait Time Modifications

The Committee briefly reviewed the possible changes to include VCA in OPTN Policy 3.7.A to allow for a program to submit a request for waiting time modification and updating OPTN Policy 3.7.B so that if a candidate is registered for two VCA, the candidate’s waiting time for the second VCA would be adjusted to include the waiting time already accrued for the first VCA.

Multi-Organ Allocation

The Chair noted that multi-organ allocation of other organs is being worked on by the OPTN Ad-Hoc Multi-Organ Transplantation Committee where VCA would be included towards the end of the project. However, it was clarified that the proposed project updates could be implemented sooner and would not interfere with the Multi-Organ Committee’s work. The Vice Chair stated that the concern is a VCA pulling a vital organ, and asked how this could be operationalized where that is not the case. It was clarified that the intent would be for the vital organ to pull the VCA, which is most common with abdominal wall, and the Committee could propose that separately from the Multi-Organ Committee’s work. The Committee supported drafting language for VCAs being pulled along with vital organs and having the Multi-Organ and Organ Procurement Organizations (OPO) Committees review.

It was also noted that more involvement from OPOs with VCA is an area of improvement, but that the educational modules on UNOS Connect for VCA in UNetSM will make things clearer for OPOs.

Other Data Collection Changes – VCA in UNetSM

The Committee reviewed the addition of skin tone screening to WaitlistSM and DonorNet[®] since that would require the implementation of new data fields. The Chair noted that in concept it may be difficult

to standardize quality and lighting of images, but it is useful information for organ acceptance. A member requested that skin tone not be overcomplicated and referenced the use of a 40-option scale which led to patient expectations for their graft not being met.

Currently, DonorNet[®] has an organ data tab where information can be added for each type of organ, but since VCA is not yet in UNetSM, OPOs have been adding this information to the donor highlight section. The addition of comment boxes would allow for this information to be included by each VCA type.

Expedited Approval Pathway

The Committee reviewed the option to utilize the expedited approval pathway per the OPTN Bylaws, that states the Board may approve a “policy that includes specific policy language defining components of the policy that will be eligible for future expedited updates as well as the anticipated frequency of the updates” for any future changes to the list of covered body parts.⁵ These proposals may use shorter public comment periods and can be implemented more quickly.

Upcoming Meetings

- May 17, 2020 (Genitourinary Workgroup)
- June 9, 2020 (Committee)

⁵ “Article 11.8 Expedited Actions,” OPTN, accessed June 8, https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf

Attendance

- **Committee Members**
 - Bohdan Pomahac, Chair
 - Sandra Amaral, Vice Chair
 - Linda Cendales
 - Vijay Gorantla
 - Darla Granger
 - Nicole Johnson
 - Debbi McRann
 - Paige Porrett
 - Mark Wakefield
 - Patrick Smith
 - Bruce Gelb
 - Debra Priebe
 - Lori Ewoldt
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Christian Folken
- **UNOS Staff**
 - Kristine Althaus
 - Leah Slife
 - Kaitlin Swanner
 - Susan Tlusty
 - Jennifer Wainwright
 - Karen Williams
 - Krissy Laurie
 - Marta Waris
- **Other Attendees**
 - Amanda Gruendell
 - Brian Berthiaume
 - Elizabeth Shipman
 - Robert Goodman