

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, GA**

**Sue V. McDiarmid, M.D., Chair
L. Scott Levin, M.D., FACS, Vice Chair
Richard S. Luskin, M.P.A., Vice Chair**

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This report reflects the work of the OPTN/UNOS VCA Committee during December 2014 to June 2015..

Action Items

1. VCA Implementation

Board Approval: [June 2014](#) (Approved with a sunset)

Public Comment: [September – December 2014](#)

On June 24, 2014, the OPTN/UNOS Board of Directors approved the VCA Implementation proposal with a sunset date of September 1, 2015. This proposal was approved pending public comment in the fall of 2014. The delay in public comment solicitation was due to the pending change to the OPTN Final Rule that included VCAs under the definition of “covered human organs” on July 3, 2014.

The fall 2014 public comment period saw 32 responses from the transplant community and public, with some opposition to the VCA Implementation proposal. The Committee discussed at length the common themes that were identified in the public comment submissions. These concerns centered on:

- The potential for living VCA donors,
- The allowance of “authorization”, and not “informed consent” for VCA donation, and
- Potential risks, needed safeguards, and impact of donation on a living VCA donor.

The Committee discussed amendments policy/bylaw language and the implications of the sunset provision approved by the Board in June 2014. After careful review, the Committee recommended the proposal for consideration by the Board of Directors (Yes – 10, No – 0, Abstentions – 0).

RESOLVED, that modifications to OPTN Policies 1.2 (Definitions), 2.2.12 (OPO Responsibilities), 2.15.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 12 (Allocation of Vascularized Composite Allografts) 14.5 (Registration and Blood Type Verification of Living Donors Before Donation), 18.1 (Data Submission Requirements), 18.2 (Time Data Collection), and 18.3 (Recording and Reporting Outcomes of Organ Offers); and OPTN Bylaws, Appendices D.2 (Program Requirements), D.4 (Transplant Program Director), D.5 (Transplant Program Key Personnel), D.6 (Changes in Key Transplant Program Personnel), D.9.A (Functional Inactivity), D.10.A (Transplant Program Performance), D.10.B (Notification Requirements for Waiting List Inactivation), D.10.G (Relocation or Transfer of Designated Program), K.1 (Transplant Program Inactivity), K.2 (Short-term Transplant Program Inactive

Status), K.3 (Long-term Transplant Program Inactive Status), and M (Definitions), as set forth in Exhibit A, are hereby approved, effective September 1, 2015.

2. VCA Data Collection and Submission

Public Comment: [September – December 2014](#)

To date, there is no systematic, centralized data collection for VCA transplants in the U.S. This proposal addresses the first attempt to collect transplant and follow-up data on VCA recipients for the immediate purposes of evaluating outcomes and ensuring patient safety. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. Additionally, this project updates data submission requirements in OPTN Policies 18.1 and 18.2. The project addresses the following topics:

- Specific data elements to be collected on VCA recipients at transplant and follow-up,
- Members responsible for submitting VCA organ transplant candidate, recipient, and donor data, and
- The time period that VCA organ transplant candidate, recipient, and donor data must be submitted to the OPTN.

The VCA Data Collection and Submission proposal was out for public comment from September 29, 2014 to December 5, 2014. The fall 2014 public comment period saw 10 responses from the transplant community and public. The Committee carefully considered the common themes that were identified in the public comment submissions, including requiring the collection of VCA donor and candidate HLA type. OPTN data collection forms were reviewed by the Office of Management and Budget (OMB) in July 2014. OMB approved the forms for VCA data collection in March 2015. After careful review, the Committee recommended the proposal for consideration by the Board of Directors (Yes – 10, No – 0, Abstentions – 0).

RESOLVED, that changes to Policies 18.1 (Data Submission Requirements) and 18.2 (Timely Collection of Data) as set forth in Exhibit B, are hereby approved, effective pending implementation and notice to members.

3. Membership Requirements for VCA Transplant Programs

Public Comment: [January - March 2015](#)

In response to changes in the OPTN Final Rule, the OPTN Board of Directors approved minimal VCA transplant program membership requirements that will expire on September 1, 2015. There are no specific requirements in current policy language for VCA transplant experience for the primary physician and primary surgeon at a VCA program. The VCA Committee has proposed minimal certification, training, and experience for individuals serving as VCA primary physicians and surgeons. Additionally, the proposal requires a VCA transplant program have a program director, akin to the requirement for other solid-organ transplant programs.

The Membership Requirements for VCA Transplant Programs proposal was out for public comment from September 29, 2014 to December 5, 2014. The fall 2014 public comment period saw 11 responses from the transplant community and public, and presentations at 10 regional meetings. The Committee carefully considered the common themes that were identified in the public comment submissions, including requirements for primary surgeons and concerns regarding living VCA donors. After careful review, the Committee recommended the proposal for consideration by the Board of Directors (Yes – 14, No – 0, Abstentions – 0).

RESOLVED, that changes to Bylaws, Appendix J, as set forth In Exhibit C in lines 7-264, are hereby approved, effective pending implementation and notice to members.

FURTHER RESOLVED, that the current Bylaws Appendix J, as forth In Exhibit C lines 265-293, are effective until lines 7 – 264 are implemented.

4. Guidance Document for VCAs from Living Donors

Public Comment: N/A

The fall 2014 public comment period saw 32 responses from the transplant community and public, with some opposition to the VCA implementation proposal. The Committee discussed at length the common themes that were identified in the public comment submissions. Chief among these concerns were the:

- Potential for living VCA donors, and
- Potential risks, needed donor-safeguards, and impact of donation on a living VCA donor.

The Committee considered these comments very seriously, and has collaborated with the OPTN/UNOS Living Donor and Ethics Committees on the development of a Guidance Document. This guidance document was designed to create public transparency about what an OPTN members' intentions would become, and the associated risks to a living donor for VCA. The intention of such a document is that it may lay the ground work for future policy/bylaw language on membership, informed consent, and medical and psychosocial evaluation requirements. This is similar to the process used to develop the current policy requirements for living kidney donation. After careful review, the Committee recommended the proposal for consideration by the Board of Directors (Yes – 11, No – 0, Abstentions – 2).

RESOLVED, that the Guidance Document for VCAs from Living Donors, as set forth in Exhibit D, are hereby approved, effective June 2, 2015.

Committee Projects

5. VCA Graft Failure Definition

The Committee discussed the need for a VCA-specific definition of “Graft Failure” during their meetings on December 9, 2014 and April 24, 2015. The consensus of the committee was the intended goal of a VCA transplant would need to be considered when deciding if a graft had failed. The Committee acknowledged that standard outcome instruments could be used, but the issue of validation may be challenging due to low numbers of VCA transplants. Additional work on a VCA-specific graft failure definition is on-hold and will take place in the future following a period of data collection.

For more information, see the Committee meeting summaries from [December 9, 2014](#).

Committee Projects Pending Implementation

None

Implemented Committee Projects

The [Guidance Document on VCA Donor Authorization](#) approved at the November 2014 Board meeting was posted on the OPTN website.

Review of Public Comment Proposals

The Committee reviewed one of the policy proposals released for public comment from January – March 2015.

6. Operations and Safety Committee: ABO Blood Type Policy Modifications

The Committee reviewed and supported the proposal from the Operations and Safety Committee to modify OPTN policy language regarding ABO blood typing.

Other Committee Work

7. Informed Consent and Medical/Psychosocial Evaluation Requirements for Living VCA Donors

The Guidance Document for VCAs from Living Donors may serve as the basis for future policy on informed consent and medical/psychosocial evaluation requirements for living VCA donors. The Joint Societies Steering Committee indicated in April 2015 they would be interested in collaborating on such policy development. This project has not yet been considered by the OPTN/UNOS Policy Oversight Committee.

8. Future projects

The Committee identified potential future projects:

- Revisit VCA allocation
- Gather data on instances where VCA authorization was obtained for deceased donors, but VCA allocation was unsuccessful
- Develop strategies to optimize VCA procurement from deceased donors
- Review policy/bylaw exemptions for VCAs
- Uterus transplantation
- Collaboration with VCA registries outside the U.S.
- Identify role of OPTN in the payer landscape for VCA transplants.

Meeting Summaries

The Committee held conference calls/meetings on the following dates:

- January 20, 2015 (conference call)
- February 17, 2015 (conference call)
- March 17, 2015 (conference call)
- April 24, 2015 (meeting, Chicago, IL)
- May 19, 2015 (conference call)

Meetings summaries for the Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=140>.