

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
March 10, 2017
Conference Call**

**L. Scott Levin, M.D., FACS, Chair
Linda C. Cendales, M.D., Vice Chair**

Introduction

The VCA Committee met via teleconference on March 10, 2017 to discuss the following agenda items:

1. VCA Donation and Transplantation Consensus Conference
2. Update on Guidance to Optimize VCA Authorization and Recovery
3. Align VCA Membership Requirements with Solid Organs

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

1. VCA Donation and Transplantation Consensus Conference

The Chair provided an update to the Committee on recent off-line discussions regarding a VCA Donation and Transplantation Consensus Conference.

Summary of discussion:

During the last conference call on February 20, 2017, members felt the pressing issue for this conference was addressing the payer landscape for VCA transplantation. UNOS staff cautioned that it may be outside the scope of the OPTN and VCA Committee to be the leading entity for such a conference. UNOS staff would follow-up with colleagues at the Health Resources and Services Administration Division of Transplantation (HRSA/DoT) on the matter.

The Chair then summarized a conference call with Committee leadership, UNOS staff, and HRSA/DoT representatives from February 23, 2017:

- HRSA/DoT expressed appreciation that the Committee comprises a critical core of the world's leading experts within the field
- Optimal approach to achieve coverage and reimbursement for VCA transplants is likely to be most successful through a more broad based, multi-pronged effort by the larger VCA community
- A more likely and successful pathway is the approach that has proven effective for similar transplant modalities in the past (other solid organs and bone marrow transplant). Specifically the CMS Coverage with Evidence Development (CED) mechanism.
- Both HRSA/DoT and its contractors (OPTN & SRTR) were prepared to assist, facilitate, and support the VCA community

Based on this counsel from HRSA representatives, the Chair and Vice Chair felt it was prudent to withdraw from the position that the VCA Committee is the principle driver for a VCA Donation and Transplantation Consensus Conference. The Chair felt it was best to reach out to leadership of the the American Society for Reconstructive Transplantation (ASRT), the American Society for Transplant Surgeons (ASTS), and American Society for Transplantation (AST) and appeal for their leadership on the matter.

The Chair shared that he has personally spoken with the President of AST, as well as the Chair of their VCA Committee. These discussions were describes as favorable, and both individuals are considering the matter. The Chair then opened the floor for discussion.

A member who is also the Chair of ASRT shared her support of the VCA Committee's efforts to facilitate this discussion. One of the agenda items discussed during the society's biennial meeting last year was VCA transplant funding. She agreed that the various transplant societies should lead this effort and shared her organization's complete support.

Next steps:

The Committee will receive an update during the April 7, 2017 in-person meeting in Chicago, IL.

2. Update on Guidance to Optimize VCA Authorization and Recovery

UNOS staff updated the Committee on recent discussions on this new project idea.

Summary of discussion:

On January 20, 2017, the Committee voted to send a new project to the OPTN/UNOS Policy Oversight Committee (POC). This project is intended to provide *Guidance to Optimize VCA Authorization and Recovery*. The POC discussed this project during a conference call on February 13, 2017:

- Agreed with the VCA Committee's position that the project is in alignment of Goal I of the OPTN Strategic Plan
- Supported the project moving forward to the OPTN/UNOS Executive Committee

The Executive Committee then considered this new project during a conference call on February 27, 2017. The project was also approved for further work by the Executive Committee.

Next steps:

- UNOS staff will coordinate future calls with the OPO Guidance Working Group.
- Routine updates will be shared with the Committee over spring and summer of 2017.

3. Align VCA Membership Requirements with Solid Organs

The Chair profiled recent activity of the Membership Working Group to align the VCA transplant program membership requirements with those of solid-organ programs.

Summary of discussion:

The Chair acknowledged the duration of discussions on previous calls and the principle of the discussions for the VCA membership requirements to be consistent with those of solid-organ transplant programs. To facilitate productive discussions, the Chair recognized members who had dissenting opinions on this project. These individuals shared:

- Disagreement with the rationale by MPSC, that there is no established means to evaluate training of individuals from countries without board certification process.
- Adopting these changes to VCA membership requirements would inject risk into the nascent state of VCA transplantation. It was prudent to mitigate the risk of unqualified individuals becoming leaders at VCA programs by higher standards in order to maintain public trust.
- Disagreement to the OPTN's position that it is difficult to assess comparability of foreign board certification to U.S. board certification.
- There is diversity across surgical techniques based on VCA types and each patient. Based on this, it is important to minimize the risk of an individual entering the VCA field who does not have verifiable training and board certification and jeopardize patients and the VCA field as a whole. Should there be the case for VCA to be different (higher bar) from solid organ?

- There are ample U.S. board-certified individuals for key personnel positions. Recruiting a foreign board-certified individual due to lack of U.S. board certified persons is not seen as a prevalent issue.

The Chair also recognized members who had supporting opinions on this project. These individuals shared:

- VCA transplantation does not have the same depth of field of surgeons (as compared to kidney or liver transplantation). By limiting who can lead VCA programs at this stage, this would effectively limit access to VCA transplantation. A nonboard certified individual who has contributed to VCA transplantation with responsible innovation should be allowed.
- Over-regulation is a greater threat to this developing field.
- Concern over how stark differences in membership requirements as compared to solid-organ transplant programs would be seen by payers. By being so different, this could negatively impact the payer discussions that are important to the Committee.
- It was important to legitimize the field by making VCA transplantation look like everything else, not higher or lower requirements.

After a lengthy discussion, the Chair thanked the committee for their open dialog. He valued the supporting and dissenting opinions and was optimistic that language amendments that satisfies everyone were possible. When appropriate for discussion, he felt a compromise may include board certification in the field or experience as demonstrated by performing VCA transplants (e.g.: hand or face transplants). The Working Group Chair then reminded the Committee that that the current discussion is about a request to POC to *develop criteria*, not vote on final language. Other members verbalized their support for this procedural vote to advance to the POC. One member noted that input from the Joint Society Steering Committee could be valuable in these discussions.

The Chair then asked the Committee to consider a motion to move forward with a request to the OPTN/UNOS Policy Oversight Committee (POC). A motion was made and seconded to move forward with a request for resources on this project to the POC. A request was made for a roll call vote; (Yes – 4, No – 3, Abstain – 2). Based on members comments in proximity to the vote, the Chair felt there was lack of understanding of the policy development process by members, and the motion before the Committee. UNOS staff clarified that moving forward at this stage did not require a quorum. Additionally, UNOS staff shared the requirements of electronic voting outside of an official meeting according to the Code of Virginia. Following this discussion, the Chair asked the Committee to reconsider the motion was made and seconded to move forward with a request for resources on this project to the POC. The Committee approved the motion (Yes – 7, No – 2, Abstain – 0).

Next steps:

The POC will consider this new project from the VCA Committee on April 20, 2016. UNOS staff will update the Committee during future calls/meetings.

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

Upcoming Meetings

- April 7, 2017 (meeting in Chicago, IL)
- May 12, 2017 (conference call)
- June 9, 2017 (conference call)