

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
January 20, 2018
Conference Call**

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

Introduction

The VCA Committee met by teleconference on January 20, 2017 to discuss the following agenda items:

1. Public attitudes toward VCA donation and transplantation
2. Update from OPO Guidance Working Group
3. Update from VCA Membership Working Group

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

1. Public attitudes toward VCA donation and transplantation

James Rodrigue, Ph.D. shared a presentation on a survey his institution performed on public attitudes towards VCA donation.

Summary of discussion:

Dr. Rodrigue and colleagues at Beth Israel Deaconess Medical Center (Boston, MA) recently coordinated a public survey to assess attitudes on VCA donation and transplantation. This effort is in nice alignment with the education efforts of the Committee. Dr. Rodrigue shared a historical synopsis of public attitudes towards organ donation in the U.S. A Gallup survey in 2012 included two questions on VCA donation. This survey noted general support for hand and face donation. Despite this earlier inclusion of questions related to VCA donation and transplantation, Dr. Rodrigue was unaware of any full scale surveys about VCA donation and transplantation. Colleagues at Beth Israel Deaconess Medical Center created a survey in 2016.

[Specific content regarding the survey is not included in these minutes. The results under review for publication]

The Chair thanked Dr. Rodrigue for the very informative presentation and opened the floor for discussion. One member asked, would there be value in amending public registries to capture authorization for VCA donation? Dr. Rodrigue was cautious about doing this. He indicated discussions with OPO representatives noted that adding such an option at this early stage could dissuade organ donation. Another member shared that her experience has been that donor families "rise to the occasion" when approached. She has not seen the hesitancy to donate that is often reflected in surveys. A member shared his support for these comments, noting his experience has been the same. He commented that there could value in obtaining data from OPOs who have approached families for VCA authorization. This could show that a VCA approach does not dissuade families, contrary to the sensitivity shared by some OPOs. The HRSA liaison to the Committee complimented Dr. Rodrigue on the presentation and encouraged him to share this presentation to the OPTN/UNOS OPO and Ethics Committees.

UNOS staff liaison asked the Committee to carefully consider the data shared by Dr. Rodrigue with regard to future education efforts. Members have previously shared ideas to increase awareness of VCA donation and transplantation. However, many of the ideas centered on *how* to increase awareness, rather than the message. The efforts of the Committee would be most

impactful to focus on what the message would be, rather than how the message would be relayed; distinguishing between strategy and tactics.

Next steps:

- UNOS staff will facilitate discussions with OPO and Ethics Committee leadership on Dr.Rodrigue's presentation.

With no further discussion, the Chair segued to the next topic on the agenda.

2. Update from OPO Guidance Working Group

Christopher Curran, CPTC, CTBS, CTOP, provided an update from the working group exploring guidance to OPOs on Optimizing VCA Authorization and Donation from Deceased Donors.

Summary of discussion:

During the Committee's in-person meeting in Chicago, IL, a breakout group identified the need to provide guidance to OPOs to improve VCA donation. This group drafted a preliminary framework for the document at this meeting and the Committee was very pleased by this early progress. The Chair asked this group to continue meeting to develop this idea and report back to the Committee. Two conference calls were held in December 2016 and January 2017. Early discussions of the working group in December 2016 centered on the following:

- Problem statement
- Goals
- Framework for the guidance
- Timeline
- OPTN Committees to engage in development of the guidance
- External stakeholders to engage in the development of the guidance (AST, ASRT, AOPO, NATCO, etc...)
- Future presentation to OPTN/UNOS Policy Oversight Committee

The framework was discussed in more detail in January 2016. The general sense of the working group was to follow the donation process:

- Benefits of VCA transplantation
- VCA donation process and interface with solid-organ donation
 - Effective approaches to partnerships between OPOs and VCA transplant programs.
 - Hospital development before VCA donor cases
 - Identifying candidates on VCA list
 - Surrogate decision-maker authorization
 - VCA donor evaluation
 - Recovery considerations
 - Post-recovery considerations
 - Public education and media considerations
- How to institute a recovery protocol OPO

The working group had a short discussion on OPO expenses related to VCA procurements. The group felt it was outside the purview of this guidance to outline organ acquisition charges. Rather, the document will likely encourage OPOs to have an understanding of the impact of VCA procurement on OR time, transportation, etc... Further, working group members felt it was prudent for OPOs and VCA programs to have discussions on procurement costs to ensure these details are well understood.

Following the update from OPO Guidance Working Group, the Chair opened the floor for discussion. One member asked, do members of the working group feel that more time would be needed to develop the concept of this guidance document, or is it appropriate to approach the POC? The Working Group Chair responded that the framework for the document was well developed and it was his opinion that the time was appropriate to approach the POC to request additional resources to develop the project. The Chair verbalized his support for the working group's assessment and favored moving forward. Another member commented that it seemed like an excellent plan and the timeline was reasonable.

At the conclusion of the discussion, the Chair asked whether the Committee felt it was appropriate to approach the OPTN/UNOS Policy Oversight Committee (POC). The motion was made to refer this project to the POC for their consideration. This motion was unanimously approved (Yes – 10, No – 0, Abstain – 0).

Next steps:

- UNOS staff will arrange a conference call between the Working Group Chair and the Committee Vice-Chair to prepare for the POC discussion on February 16, 2017.
- The Vice Chair will update the Committee on discussions by POC in March 2017.

3. Update from VCA Membership Working Group

UNOS staff liaison updated the Committee on recent discussions from the Membership Working Group to align the VCA membership requirements with solid organ membership requirements.

Summary of discussion:

After the November 2016 in-person meeting in Chicago, the Membership Working Group was formed to further discuss the need for the VCA membership requirements to be aligned with solid-organ membership requirements. This working group met by conference call on January 4, 2016 to develop a project proposal. The working group developed a good understanding of the inconsistencies between the membership requirements for VCA and solid-organ, and affirmed that changes to OPTN Bylaws, Appendix J were prudent. The intent of this project is to use the language that appears in the membership requirements for solid-organs for U.S. board ineligible individuals and add this to the VCA membership requirements. Following this update UNOS staff asked for feedback from the Committee prior to discussing readiness for a vote.

The Chair thanked UNOS staff for the update and shared some thoughts from his participation with the working group. He felt it was important for the membership requirements for VCA programs to be as similar as possible to those requirements for solid-organs. If there were to be inclusion of a continuing education pathway, it would have to be extremely rigorous. Further, this could include attendance at in-person meetings, CME credits, etc... He felt that the instances this pathway would be used would be rare. However, there are members of the Committee that are foreign board certified or U.S. board ineligible that have been extremely prominent in VCA transplantation and helped advance the field. By not allowing these individuals to lead a VCA program would be a disservice to patients and composite allotransplant. However, the working group has not developed what the continuing education pathway would include.

UNOS staff shared the Board-approved language for the primary transplant surgeon of a kidney transplant program with the Committee. The intent of this was to show the language that was approved by the Board in December 2015 and where the language for VCA membership requirements could be drawn from. The Chair proposed to the Committee that the framework of the continuing education pathway should be as stringent, if not more stringent than solid-organ.

Following these comments, the Chair opened the floor for discussion. One member verbalized her general support for the concept, but expressed caution about the yet-to-be developed continuing education plan. The Chair shared his support for these comments. Further, he commented that it would be very challenging to prescribe CME requirements for each type of VCA. What may be more realistic is to develop CME requirements based on the list of Covered Body Parts in OPTN Policy 1.2.

Another member commented that he was in agreement with this project and did not think it would take months to develop. He supported the Chair's earlier comments that VCA should not be more forgiving or less forgiving than solid-organ. It was his opinion that the *type or mechanisms* of training and CME would not differ across body parts. However, the areas of focus would be specific to body parts and clinical practice. The depth of experience in VCA transplantation is not distributed over many teams in the U.S as compared to solid organs. It is important to not be a disservice to patients by being overly restrictive. Other members expressed caution at this early stage and wanted to know more about the continuing education requirements.

At the conclusion of the discussion, the Chair elected to table additional discussion on the project to allow the Working Group to respond to the Committee's questions: specifically, what would constitute appropriate continuing education for each type of Covered Body Part (OPTN Policy 1.2).

Next steps:

- The Working Group will meet by conference call to discuss the feedback from the Committee. An update will be reported during the February 10, 2017 conference call.

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

Upcoming Meetings

- February 10, 2017 (conference call)
- March 10, 2017 (conference call)
- April 7, 2017 (meeting in Chicago, IL)
- May 12, 2017 (conference call)
- June 9, 2017 (conference call)