

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
February 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 February 10, 2017 to discuss the following agenda items:

1. Update from VCA Membership Working Group
2. VCA Donation and Transplantation Consensus Conference

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

1. Update from VCA Membership Working Group

The Vice-Chair shared an update from the Membership Working Group following a conference call on January 26, 2017.

Summary of discussion:

During the last update to the Committee on January 20, 2017, members asked for more information about the continuing education pathway that may be considered for VCA transplant programs. The Working Group met by conference call on January 26, 2017 to consider this feedback and to derive a list of board certifications that would be applicable in VCA transplantation.

The Working Group developed a list of board certifications that could be considered, in alignment with OPTN Policy 1.2 (Definitions) for Vascularized Composite Allograft:

- **Upper limb**
 - American Board of Plastic Surgery, American Board of Orthopedic Surgery, American Board of Surgery, or American Society for Surgery of the Hand Certificate of Advanced Qualification (CAQ)
- **Head and Neck**
 - American Board of Plastic Surgery, American Board of Oral and Maxillofacial Surgery, or the American Board of Surgery
- **Genitourinary organs**
 - American Board of Obstetrics and Gynecology, American Board of Urology, or American Board of Plastic Surgery
- **Glands**
 - American Board of Surgery
- **Musculoskeletal Composite Graft Segment**
 - American Board of Plastic Surgery, American Board of Orthopedic Surgery, or American Board of Surgery
- **Lower Limb**
 - American Board of Plastic Surgery, American Board of Orthopedic Surgery, or American Board of Surgery
- **Abdominal Wall**
 - American Board of Surgery, American Board of Plastic Surgery

- **Spleen**
 - American Board of Surgery

The Working Group agreed that continuing education equivalent to the *maintenance* of the board certification above was appropriate. Further, this is consistent with requirements for all solid organ transplant programs.

UNOS staff and the Vice Chair reminded members that the scope of discussions at this early stage was to clearly identify the problem, consider alignment with OPTN Strategic Plan including a “Primary Goal”, and to hypothesize a high-level solution to the problem. Once these elements were diligently discussed, it would be appropriate for the Committee to consider whether to hand-off to the OPTN/UNOS Policy Oversight Committee (POC) and request additional resources to develop the project. If approved by the POC, the Working Group could then develop this project, including specific language for public comment.

At the conclusion of the update, the Vice-Chair asked the Committee; is this project appropriately developed for POC consideration in March 2017, or is additional time needed for the Committee and Working Group to develop this project? The Chair thanked the Vice-Chair for the update and reminded the Committee that the intent of this project is for VCA transplantation to be in lock-step with their solid-organ counterparts in the U.S. who lead programs, but are not U.S. board eligible. Thereafter, he opened the floor for questions.

The Committee held a lengthy discussion to gain greater understanding of the scope of the project and the next steps. Members were in general agreement with the described board certifications for each Covered Body Part that appear in OPTN Policy 1.2. However, there was opposition to including the CAQ for upper limb transplant programs. It was felt this professional society credential was not equivalent to board certification. Members felt it was important to uphold the uniformity of board certification and not mix in societal membership. Other members on the call felt the changes proposed by the Working Group were rational, based on precedent in other OPTN Bylaws, and this was an uncomplicated project.

Over the course of the discussion, a motion was made to recommend the project for POC review. However, the divergence of opinions and the desire for greater understanding shared by the Committee resulted in the motion being withdrawn. The Chair asked UNOS staff to circulate to the Committee the developed project form that catalogs all discussions on the project (problem statement, alignment with the OPTN Strategic Plan, and high-level solution). Further, he asked the Committee to diligently examine the project form and share feedback with leadership and UNOS staff.

Next steps:

- The Vice Chair will work with UNOS staff to update the project form consistent with the aforementioned discussion.
- UNOS staff will send a PDF of the project form to the Committee for their review. This form will be discussed during a future conference call.
- The Committee will discuss this project at a future conference call and consider whether to submit to the POC.

2. VCA Donation and Transplantation Consensus Conference

The Committee began early discussions on a consensus conference to address VCA donation and transplantation. The goals of this, and future discussions, is to identify the obstacles facing VCA programs and strategies to move the field forward.

Summary of discussion:

The Chair made introductory remarks on the topic of a consensus conference for VCA donation and transplantation. Historically, the first VCA Consensus Conference was convened on November 11, 2011 (coordinated by the Hospital of the University of Pennsylvania and The Johns Hopkins Hospital). The passage of time has seen an increase in hospitals performing VCA transplants and inclusion under the OPTN. With this in mind, many members of the Committee verbalized their support for another consensus conference. The Chair shared his opinion that, of all the current challenges for the field, changes to the payer landscape for VCA transplantation is critical for future progress. Further, he felt it would be ill-advised to approach the Centers for Medicare and Medicaid Services (CMS) with a request for reimbursement.

Earlier informal discussions with members noted that a consensus conference small intestine transplantation with the National Institutes of Health (NIH) preceded a decision for financial reimbursement. This precedent and the experience for small intestine could be informative for VCA transplantation. With emphasis on collaboration among the VCA community and diligence, the Chair felt progress could be made on a reimbursement model.

The Committee then discussed potential invitees for such a conference, including:

- American Society for Transplantation
- American Society for Transplant Surgeons
- American Society for Reconstructive Transplantation
- Association of Organ Procurement Organizations
- North American Transplant Coordinators Organization
- Health Resources and Services Administration
- Organ Procurement and Transplantation Network
- Scientific Registry for Transplant Recipients
- Centers for Medicare and Medicaid Services
- National Institutes of Health
- U.S. Department of Defense
- Healthcare payers
- Transplantation researchers
- Medical ethicists

The Chair concluded his remarks with the belief that the Committee should be the key driver for such a conference. Following his comments, he opened the floor for discussion. The Committee held a lengthy discussion on the topic, including whether there was sufficient case volume to inform payers. Members felt there was decent case volume in the U.S. to-date, but international cases would be useful in these discussions. Additionally, the care needed to be exercised by focusing on the number of *recipients*, rather than the number of *transplants*. The rationale for this was that some recipients may have received multiple VCA transplants (e.g.: bilateral upper limbs). One member recommended the leading message should be with the VCAs that have the greatest depth of clinical experience, rather than all VCAs. Presenting an all-inclusive proposal to payers would present its own challenges.

The Committee also considered the historical parallels between small intestine and VCA transplantation. One member felt that Kareem Abu-Elmagd, M.D., Ph.D., would have a great deal of insight to share from his efforts to get Medicare approval for intestine transplants. The Chair asked UNOS staff to facilitate contact with Dr. Abu-Elmagd in the coming weeks.

UNOS staff shared that a conference whose key goal to change the payer landscape for VCA transplantation was likely outside the purview of the OPTN/UNOS. The Chair acknowledged this position and indicated his willingness to meet with whomever may be the appropriate entity to

move on this issue. Further, he felt there was good alignment with between increasing VCA transplants by addressing funding issues and Goal I of the OPTN Strategic Plan.

Next steps:

- UNOS staff will discuss this off-line and consult with colleagues at HRSA on the matter of a consensus conference. An update will be provided to the Chair and Vice Chair ASAP.
- The Committee will continue to discuss a consensus conference on future calls/meetings.

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

Upcoming Meetings

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

Attendance

- **Committee Members**
 - L. Scott. Levin, M.D., FACS, Chair
 - Linda C. Cendales, M.D., Vice-Chair
 - W.P. Andrew Lee, M.D., At-large
 - Kenneth Newell, M.D., At-large
 - Mary Pappas, RN, B.S.N., CCRN, At-large
 - James R. Rodrigue, Ph.D, At-large
 - Matthew D. Scott, At-large
 - Scott M. Tintle, M.D., At-large
 - Andreas Tzakis, M.D., At-large
- **HRSA Representatives**
 - Shannon Dunne, J.D.
 - James Bowman, M.D.
- **SRTR Staff**
 - Jessica Zeglin
- **OPTN/UNOS Staff**
 - Christopher L. Wholley, M.S.A.
 - Melinda Woodbury
 - Jennifer Wainright, Ph.D.
 - Elizabeth Miller, J.D.
 - Darren DiBattista