

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
August 9, 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 August 9, 2017 to discuss the following agenda items:

1. Introduction of new members
2. Guidance to OPOs to Optimize VCA Authorization and Recovery – Update from OPO Guidance Subcommittee
3. Align VCA Membership Requirements with Solid Organ Membership Requirements – Update from Membership Subcommittee

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

1. Introduction of new members

UNOS staff reviewed a roster and photographs of the Committee members.

2. Guidance to OPOs to Optimize VCA Authorization and Recovery

The Chair of the OPO Guidance Subcommittee shared a brief status update on the project.

Summary of discussion:

The Chair of OPO Guidance Subcommittee provided a brief overview of the project to help on-board new members of the Committee. This included:

- Goal – increase deceased VCA donation
- Justification – the VCA Committee coordinated a national survey in 2016 to identify barriers to VCA authorization and recovery. The identified barriers included many that could be addressed by sharing effective practices and providing educational resources.
- Project scope – address knowledge gap with OPOs re: VCA authorization and donation. A guidance document is under development to share effective practices as learned by OPOs with a history of successful VCA recoveries. The intended audience for this guidance are those OPOs who do not have protocols/SOPs in place for VCA donation, or those OPOs “on the fence” on the topic.

The Subcommittee Chair update to the Committee following a conference call on July 14, 2017. The call focused on the following:

- Updates to contacts with external subject matter experts (SMEs)
- Detail the ask for SMEs and timeline for contributions
- Need to update AST, ASTS, ASRT, NATCO, & AOPO

UNOS staff then reviewed the project timeline with the Committee. No roadblocks were anticipated between with the future milestones. The Subcommittee Chair commented that he was very happy with the progress to-date and acknowledged that more development lay in the months ahead.

At the conclusion of the presentation, the Committee held a short discussion on the project. Members verbalized their support for this project and appreciation for the Subcommittee's efforts to-date. Members on the call also volunteered to help in the months ahead. The Subcommittee Chair commented that one of the most important needs from the Committee is to ensure the guidance articulates the benefits from VCA transplantation. This sentiment will be compelling for OPOs to further consider participating in VCA donation.

Next steps:

- The OPO Guidance Subcommittee will continue to develop the project and collaborate with external SMEs.
- Project updates will follow at future Committee calls and meetings.

3. Align VCA Membership Requirements with Solid Organ Membership Requirements

UNOS staff shared an update from the Membership Subcommittee's recent call on July 21, 2017.

Summary of discussion:

The Membership Subcommittee met by conference call in July 2017 to resume discussions on aligning the membership requirements for VCA transplant programs with those membership requirements of their solid organ counterparts. UNOS staff developed a new grid to compare the requirements for key personnel at kidney transplant programs to the requirements for key personnel at VCA transplant programs. This the intent of this grid is to show the dis-similarities and goal of adding, not removing or decreasing the stringency, of the requirements for VCA programs. Additionally, the grid is intended to help with messaging the intent of the proposal to those individuals who may be less familiar with the nuance of OPTN membership requirements.

	Primary Transplant Surgeon – Kidney	Primary Transplant Surgeon – VCA	Primary Transplant Physician – Kidney	Primary Transplant Physician - VCA
Medical Degree (MD or DO)	✓	✓	✓	✓
On hospital's medical staff	✓	✓	✓	✓
Review by credentialing committee	✓	✓	✓	✓
Board certification	✓	✓	✓	✓
<i>Accepts foreign board certification</i>		✓		

	Primary Transplant Surgeon – Kidney	Primary Transplant Surgeon – VCA	Primary Transplant Physician – Kidney	Primary Transplant Physician – VCA
Alternative pathway for board certification	✓		✓	✓
Fellowship training	✓	✓	✓	✓
Alternative pathway for fellowship training	✓	✓	✓	✓

The grid highlights the absence of an option for the primary transplant surgeon of VCA programs, and the continued allowance of foreign board certified individuals in the same position.

The Subcommittee also discussed the following elements during the July 21st call:

- *Letters of recommendation* – members discussed whether two letters (consistent with other solid organs) or three to four letters of recommendation would be appropriate. The concern was if two letters were required and one of the letters submitted *not* in support, then the application may be viewed unfavorably. Thus, requiring three letters may be prudent. It was determined that it would be unlikely an individual would submit unfavorable letters or recommendation, and being consistent solid organ was acceptable. However, the Subcommittee was in wide agreement that recommendation letters needed to be from VCA program directors, not program directors of solid organ transplant programs.
- *Continuing Education (CE) requirements* – members discussed the pluses and minuses of requiring CE credits from specific boards. Some members felt it was important to require CE from the board specific to the member’s area of expertise and relevant to their program for which they lead. Others raised the option of allowing CE credits from other organizations (may be less expensive, or more convenient for the provider) that were germane to the area of practice, e.g.: infectious disease, immunosuppression, etc...). At the conclusion of the discussion, members acknowledged this was a philosophical discussion that had implications beyond the project at hand. However, members felt comfortable allowing broad CEs that were germane to the individual’s scope of practice.
- *Requiring completion of board examination* – one member felt it was important for non-board certified/eligible individuals to complete (and pass with a minimum score) a continuing education written exam from a board related to their clinical practice. Others on the call felt this was a good idea, but such exams are not consistently offered by all medical boards. Further, this is not required for solid organ. The Subcommittee acknowledged that requiring such an exam was not possible at this time.

UNOS staff then reviewed then reviewed the pathway requirements below:

- Ineligible for U.S. board
- Provide a plan for continuing education that is comparable to American board maintenance of certification. Specific boards are outlined in bylaws.
- At least 60 hours of Category I CME credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment minimum score 75%.
- Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital.
- If not adhered to plan, 6 month grace period is permitted
- If not completed in grace period, matter referred to MPSC

The aforementioned pathway requirements are nearly identical to those for solid organ programs. At the conclusion of the Subcommittee's discussion, members felt these requirements would allow appropriately qualified individuals to lead VCA programs while excluding less qualified individuals.

Committee members thanked UNOS staff for the update and discussed the presentation. One member shared, the OPTN/UNOS Membership and Professional Standards Committee (MPSC) has attempted to derive a consistent approach to determine qualifications to serve in key personnel positions at organ transplant programs. In doing so, a pathway was created to standardize review for those individuals ineligible for U.S. boards. The typical OPTN pathway to demonstrate qualification includes a training pathway, an experiential pathway, or a certification pathway. Other members verbalized that the board certifications shared by the Subcommittee should be from those organizations that were affiliated with the American Board of Medical Specialties (ABMS). There are a handful of unaffiliated organizations in existence that refer to themselves as "medical boards". The general public is likely unaware of the distinction between those affiliated and unaffiliated board organizations. The Committee asked the Subcommittee to investigate if the American Board of Oral and Maxillofacial Surgery was an ABMS-affiliated board. If not, the Subcommittee should consider whether to include this organization on the list.

One member verbalized his concern that the approach of listing specific American medical boards was too granular at this early stage for VCA transplantation. This degree of specificity could engender confusion with the MPSC. Further, he suggested a single strata for VCA transplant programs. This may include the requirement that the primary transplant surgeon be board certified by an ABMS-affiliated board with no further specification.

One member did share some historical context on the proposal with new Committee members. Some Committee members have felt that board certification was essential for key personnel at VCA transplant programs. Others on the Committee have the opinion that board certification (either U.S., Canadian, or from other nations) was not necessary, and could limit participation of innovative and qualified surgeons. It was his opinion that the current proposal would potentially allow an individual without *any* verified training or board certification to lead a VCA transplant program. Further, even with the reference letters embedded in the proposal, hesitancy persists among some members of the Committee to allow non-board certified individuals to serve as key personnel of VCA transplant programs.

One member asked a clarification question; is the alternative pathway intended to allow innovative surgeons who are not board certified to lead programs in the U.S.? Another member responded that the rationale has always been to not disallow well-qualified surgeons, e.g.: from Europe, from serving in key personnel positions. The position of the OPTN has always been to have broad access for individuals that wish to be considered for key personnel positions knowing these individuals will be diligently reviewed by the MPSC *prior* to being approved. Examples of this approach were seen in the development of living kidney and liver donation. Almost none of the innovative leaders developing these clinical practices outside the U.S.

would have met the formal training requirements, but clearly had tremendous experience. Thus the need for experience-related pathways. The OPTN has encountered many instances when a physician or surgeon from outside the U.S. was recruited to serve in a key personnel position at an OPTN member transplant hospital. The use of board certification is the standard used to validate if a physician or surgeon is qualified. However, if a physician or surgeon that has tremendous experience, but not board certification, these alternative pathways have been leveled to allow a mechanism to vet this person (case experience, leadership experience, productivity, etc...). With regard to solid organ, the MPSC decided it was unrealistic to verify the equivalency of foreign board certification. Thus, the change to remove "foreign equivalent" and addition of the CE pathway before the Committee.

The Committee members then reviewed the list of specific boards for each VCA type. Members felt the American Board of Surgery should be included for genitourinary organs, and American Board of Otolaryngology (previously added, but omitted in error).

UNOS staff then reviewed the project timeline with the Committee. No roadblocks were anticipated between the conference call the milestones ahead.

Next steps:

- The Membership Subcommittee will meet by conference call on September 6, 2017 to discuss the feedback from the Committee.
- Target for full Committee review and assess readiness for public comment is October 2017.

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

Upcoming Meeting

- September 13, 2017 4-5 PM (Eastern)
- October 18, 2017 9 AM-3 PM (Central) Chicago, IL
- November 8, 2017 4-5 PM (Eastern)
- December 13, 2017 4-5 PM (Eastern)
- January 10, 2018 4-5 PM (Eastern)
- February 14, 2018 4-5 PM (Eastern)
- March 14, 2018 4-5 PM (Eastern)
- April 6, 2018 9 AM-3 PM (Central) Chicago, IL
- May 9, 2018 4-5 PM (Eastern)
- June 13, 2018 4-5 PM (Eastern)

Attendance

- **Committee Members**
 - Sandra Amaral, M.D.
 - Chris Curran, CPTC, CTBS, CTOP
 - Linda Irwin, RN, ANP, CCTC,
 - Sheila Jowsey-Gregiore, M.D.
 - Andrew Lee, M.D.
 - Timothy Pruett, M.D.
 - Matthew Scott
 - Maria Siemionow, M.D., Ph.D.
- **HRSA Representatives**
 - Joyce Hagar
- **SRTR Staff**
 - Bryn Thompson
- **OPTN/UNOS Staff**
 - Christopher L. Wholley, M.S.A.
 - Jennifer Wainright, Ph.D.
 - Anne Paschke
 - Sharon Shepherd
- **Other Attendees**
 - Wendy Dean, M.D.