

OPTN/UNOS Vascularized Composite Allograft Transplantation Committee
Meeting Summary
April 24, 2015
Conference Call

Sue McDiarmid, M.D., M.B.A., Chair
L. Scott Levin, M.D., FACS, Vice-Chair
Richard Luskin, M.P.A., Vice-Chair

Discussions of the full committee on April 24, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Membership Requirements for VCA Transplant Programs

The Membership Requirements for VCA Transplant Programs proposal was out for public comment from January 27, 2015 to March 27, 2015. The proposal included amendments to OPTN Bylaws, Appendix J. The Committee discussed the public comments received in response to the proposal and amendments to the proposal. The Committee unanimously approved the final proposal and recommended it to the Board (Yes – 14, No – 0, Abstain – 0).

Additionally, the Committee unanimously supported and recommended to the Board that the current requirements of Appendix J be effective until such time as the new proposal is implemented (Yes – 14, No – 0, Abstain – 0).

UNOS staff presented the Committee with a proposed approach to handling VCA program applications under the new bylaw requirements. This could be akin to histocompatibility laboratory applications, using an ad-hoc subcommittee composed of MPSC and Histocompatibility Committee members. The VCA Committee favored this approach and will solicit volunteers for the ad-hoc subcommittee at a later date.

2. Guidance Document for VCAs from Living Donors

The Chair provided a synopsis from a Working Group of members from the VCA, Living Donor, and Ethics Committees. Based on public comments received from during the fall 2014 public comment period, this Working Group collaborated on a Guidance Document for VCAs from Living Donors. The intent of this document is to:

- address some general considerations regarding VCA types that may be suitable to consider from living donors,
- provide guidance regarding criteria for living VCA recovery programs,
- provide recommendations on the informed consent and medical and psychosocial evaluation of living VCA donors, and
- lead to future policy development.

The Committee discussed the guidance document at length and approved the document, allowing the Chair edit privileges in the coming days, and recommended it to the Board (Yes – 11, No – 0, Abstain – 2).

3. VCA Data Collection and Submission

UNOS staff provided an update to the Committee regarding background elements to the VCA Data Collection and Submission proposal. The U.S. Office of Management and Budget approved VCA Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms in February 2015. This Board will consider the VCA Data Collection and Submission proposal in June 2015. If the Board approves the proposal, the OPTN/UNOS Executive Committee will review all Board-approved projects and prioritize projects for implementation. UNOS staff have a paper-based data collection plan ready, should an extended time period be experienced between Board approval and IT implementation of VCA Data Collection.

4. VCA Graft Failure Definition

The Committee discussed and came to a consensus to accept the current definition of “Graft Failure”, knowing the first two end-points were most appropriate for VCA recipients. Additionally, the Committee agreed to put the project on hold and revisit after a period of data collection.

Other Significant Items

5. Data Advisory Committee update

Data Advisory Committee Chair provided the VCA Committee with a project update regarding OPTN Data Release Policy and Review of OPTN Dataset.

6. Policy Oversight Committee- Length of Committee Terms

UNOS staff shared a presentation from the OPTN/UNOS Policy Oversight Committee (POC) regarding length of committee terms. The Committee held a discussion on the topic and supported three year terms for at-large VCA Committee members, and VCA Committee Chair and Vice-Chair.

7. OPTN Strategic Plan update

The UNOS Policy Director presented an overview of the draft OPTN Strategic Plan. The goals of this strategic plan are to set the priorities for the organization and to ensure everyone is working towards a common goal. The Executive Committee did not want a lengthy transition period and wanted the OPTN to pivot in the summer of 2014. Impact of this pivot will likely not be felt by the VCA Committee as the current projects clearly focus on the first two key goals of the Strategic Plan.

8. Future Committee Projects

The Committee discussed several ideas for future projects:

- a. Revisit VCA allocation,
- b. Gather data on instances where VCA authorization was obtained from deceased donors, but VCA allocation was unsuccessful,
- c. Develop strategies to optimize VCA procurement from deceased donors,
- d. Review policy/bylaw exemptions for VCAs,
- e. Discuss uterus transplantation,
- f. Discuss collaboration with VCA registries outside the U.S., and
- g. Discuss any potential role of OPTN in the payer landscape for VCA transplants.

Upcoming Meetings

- May 19, 2015 11-12 (Eastern) conference call
- June 16, 2015 12-1 (Eastern) conference call
- July 2015 (conference call to be determined)
- August 2015 (conference call to be determined)
- September 2015 (conference call to be determined)
- October 2015 (in-person meeting to be determined)
- November 2015 (conference call to be determined)
- December 2015 (conference call to be determined)