

**OPTN/UNOS Vascularized Composite Allograft Transplantation Committee
Report to the Board of Directors
November 12-13, 2014
Saint Louis, Missouri**

**Sue V. McDiarmid, MD, Chair
L. Scott Levin, MD, FACS, Vice Chair
Richard S. Luskin, MPA, Vice Chair**

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This report reflects the work of the OPTN/UNOS VCA Committee during the June 2014 to November 2014 period.

Action Items

1. Guidance Document for VCA Deceased Donor Authorization

Public Comment: N/A

Concerns regarding the sensitivity of the approach to donation requests for VCA were identified by the Secretary of Health and Human Services in the Federal Register (Volume 78 Number 128, July 3, 2013). The Committee identified that preserving the public trust in the process of organ donation is of the highest priority. In June 2014, the Board adopted a policy requiring OPOs to receive specific authorization before recovering a vascularized composite allograft. The VCA Committee authored a “Resource Document for VCA Donor Authorization” and submitted this with the VCA briefing paper for the Board meeting in June 2014. Transitioning this to a formal guidance document is intended to provide support to Organ Procurement Organizations (OPOs) and other designated requestors, staff at local donor hospitals and administrators, as well as the general public. After careful review, the Committee voted to recommend the guidance document for consideration by the Board of Directors (9-Support, 0-Oppose, 0-Abstain).

RESOLVED, that the guidance document entitled, “Guidance for VCA Deceased Donor Authorization”, as set forth in Exhibit A, is hereby approved, effective November 13, 2014.

Committee Projects

2. Data Collection and Submission Requirements for VCAs

Public Comment: [September 29 – December 5, 2014](#)

Board Consideration: June 2015 (Estimated)

To date, there is no systematic, centralized data collection for VCA transplants in the U.S. This project addresses the first attempt to collect VCA donor, candidate, recipient, and follow-up data on VCA transplants for the immediate purposes of evaluating outcomes and ensuring patient safety. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. Additionally, this project updates data submission requirements in OPTN Policies 18.1 and 18.2. The project addresses the following topics:

- Specific data elements to be collected on VCA recipients at transplant and follow-up
- Members responsible for submitting VCA organ transplant candidate, recipient, and donor data

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- The time period that VCA organ transplant candidate, recipient, and donor data must be submitted to the OPTN

The Committee reviewed the OPTN Principles of Data Collection and draft VCA data elements during meetings and conference calls held during the period of February to August 2014. The draft data elements include, but are not limited to, general physical and mental health, VCA organ function, and major complications. The data collection intervals were modeled after those of other, non-VCA organs. OPTN data collection forms must be reviewed and approved by the Office of Management and Budget (OMB) and the lists of VCA data elements were submitted for OMB review in July 2014. UNOS staff anticipates OMB approval in March 2015.

For more information, see the Committee meeting summaries from [July 15, 2014](#) and [August 25, 2014](#).

3. VCA Graft Failure Definition

Public Comment: August 2015 (Estimated)

Board Consideration: December 2015 (Estimated)

The current definition of graft failure in OPTN Policy 1.2 is broadly written and not perfectly suited for VCA recipients. A VCA-specific definition of graft failure is needed. The VCA Data Subcommittee will draft language for consideration by the Committee in the Fall of 2014.

Committee Projects Pending Implementation

None.

Implemented Committee Projects

4. Implement the OPTN's Oversight of VCAs

Public Comment: [September 29, 2014 - December 5, 2014](#)

Board: June 2014

June 2015 (Estimated)

Implementation: [July 1, 2014](#)

In June 2014, the Board adopted several policies related to the OPTN's oversight of VCAs. They included:

1. Definition of a VCA
2. VCA membership criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

Because of the pending statutory change at the time, these policy changes were approved by the Board of Directors with a "sunset" date on September 1, 2015. These changes are currently out for public comment. Following public comment, the Committee and the Board will review and reconsider these proposals and public comments.

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The VCA Committee shared information about the implementation of VCAs under the OPTN at the following OPTN/UNOS Committee meetings:

- Patient Affairs Committee – August 7, 2014
- Histocompatibility Committee – August 12, 2014
- Living Donor Committee – September 8, 2014
- Ethics Committee – September 15, 2014

UNOS staff worked with the Committee to implement an interim system to gather data on VCA donors and candidates, facilitate and record VCA allocation efforts, and capture VCA transplants. This approach was required due to technical and time constraints of incorporating VCAs into the OPTN's existing electronic infrastructure. Additionally, UNOS staff developed help documents for the OPO and transplant community to facilitate VCA recovery and transplant. The interim system described above was shared with the transplant community via webinar on July 1, 2014.

Review of Public Comment Proposals

The VCA Committee did not review any of the proposals released for public comment in March 2014. The Committee has not yet reviewed any of the proposals released for public comment on September 29, 2014.

Other Committee Work

None

Meeting Summaries

The VCA Committee held meetings on the following dates:

- May 9, 2014
- July 15, 2014
- August 25, 2014
- September 24, 2014

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=140>

Guidance to Organ Procurement Programs (OPOs) For VCA Deceased Donor Authorization

Summary and Goals

On July 3, 2014, Vascularized Composite Allografts (VCAs) were added under the definition of “organs” in the OPTN Final Rule. The major impetus for this change was the recognition of the essential role OPOs play in the process of identifying potential VCA donors, requesting authorization, and safely and effectively distributing VCAs according to proposed fair and equitable allocation policies. The new definition includes limbs, faces, and other vascularized multiple-tissue allografts¹. OPTN policies and bylaws prior to this date defined organs to include: a kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract)². These human organs were likely the scope of the general public’s understanding of an organ that may be used in a transplant procedure. Additionally, these organs were likely those an individual considered when making a donor authorization decision-making in a recognized donor registry.

The OPTN/UNOS VCA Committee sought to ensure transparency in the donation request by requiring that authorization for VCA from deceased donors, whether given by the donor prior to death, or by family as surrogate decision makers after death, must be explicit and specific for VCA donation. Authorization for VCA donation should not be assumed under the general term “organ” donation.

The goal of this guidance document is to provide support to Organ Procurement Organizations (OPOs) and other designated requestors, transplant hospitals, staff at local donor hospitals and administrators, as well as the general public.

Background

The OPTN/UNOS VCA Committee’s highest priority is to preserve the public trust in the process of organ donation. Recently VCAs were designated “organs.” The transplant community must carefully consider how public trust can best be maintained while facilitating appropriate authorization for deceased VCA donation. The public and potential donor families are unlikely to know that VCAs are now regarded as an organ that may be donated for transplantation.

¹ [42 CFR §121.2 \(2014\)](#)

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ’s utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient’s organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

²[OPTN Bylaws, Appendix M, Definitions \(2014\)](#), [OPTN Policies, Section 1.2, Definitions \(2014\)](#)

The Secretary of Health and Human Services explicitly addressed concerns regarding the sensitivity of the approach for VCA donation requests in the Federal Register (Volume 78 Number 128, July 3, 2013) Action: Final Rule:

“...questions of public trust may arise if transparency is not kept at the forefront at every phase of the donation process. For this reason the Secretary encourages explicit consent for VCA from prospective donors (or next of kin) and as such consent be as clear and meaningful as possible...”

Authorization to recover donated organs is governed by state laws under the Uniform Anatomical Gift Act. OPTN/UNOS policies and bylaws should be consistent with state law. This includes the principle that prior authorization for organ donation is legally binding.

Accordingly, the VCA Committee intentionally crafted policy language that seeks to ensure transparency in the donation request by requiring that donor authorization for VCA, whether given by the donor prior to death, or by family as surrogate decision makers, must be explicit and specific for VCA donation. Authorization for VCA donation may not be assumed under the general term “organ” donation.

Taking into consideration these principles, the OPTN/UNOS Board of Directors adopted the following policy language:

Policy 2.15.C Authorization Requirement

Organ recovery teams may only recover organs that they have received authorization to recover. An authorized organ should be recovered if it is transplantable or a transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery. This policy does not apply to VCA transplants.

Recovery of vascularized composite allograft for transplant must be specifically authorized from the individual(s) authorizing the donation whether that is the donor or a surrogate donation decision maker consistent with applicable state law. The specific authorization must be documented by the host OPO.

The Committee recognizes the importance of a thoughtful education effort for OPOs and other designated requestors, transplant center staff, staff at local donor hospitals, and the public. The Committee developed this guidance document to aid in this educational effort and to provide best practices for OPOs.

Guiding Principles and Best Practices

- 1) If prior donor authorization is in place either through a recognized donor registry (DMV or otherwise) or other signed document recognized under applicable UAGA state law, it is recommended that the OPO staff determine if the authorization explicitly states the desire to donate a VCA. Currently, very few donor registries provide an opportunity to specifically authorize VCA, although this may change in the future. Donor authorization through the Department of Motor Vehicles donor registries currently does not include an

opportunity to specifically authorize VCA donation. If authorization for donation is requested from a surrogate decision maker, the donation request and authorization needs to explicitly and specifically identify VCA donation as compared to traditional solid organs or tissues.

- 2) In discussing general concepts of deceased organ donation with a potential donor family when no prior authorization for donation exists, authorization to recover VCAs should be addressed separately and sequentially. Otherwise, a donor family who is unaware of or uncomfortable with VCA donation may refuse to authorize recovery of any organs and tissues. OPOs with experience requesting VCA authorization have first obtained authorization for traditional whole organ and tissue donation followed by a separate discussion and specific request for VCA donation.

In all cases of VCA donation, the requestor must educate the donor's family about VCA donation and transplantation. The following key elements should be addressed:

- Clearly define and explain what a vascularized composite allograft is, the benefit to the recipient and exactly what may be recovered.
 - Clearly communicate that prior general authorization by the potential donor to recover "organs" does not include authorization to recover a VCA unless explicitly stated.
 - Be sure the next of kin understand that the donor will look very different after recovery depending on the VCA procured. Also tell the family, that if they request, the VCA surgical recovery team may perform re-construction in the preparation for the donor's burial. This may include a face mask molded from the donor's own features prior to procurement, or a prosthetic hand or upper extremity.
 - Clearly communicate that the donor's identity will be protected to the extent possible, but factors such as identifying skin markings, i.e. "birthmarks" and fingerprints for upper extremity procurements, may limit the ability to keep all donor information confidential. Further, the donor family will likely learn the recipient's identity if the recipient decides to be public about the VCA transplantation. This may unintentionally compromise the anonymity of the donor.
- 3) OPOs should develop a deceased donor authorization form that specifically identifies the option of VCA donation. Strong consideration should be given to a separate VCA donor authorization form that specifically acknowledges and documents that the family understands the relevant anatomical details of the VCA, the alteration in the physical appearance of the donor, and the possibility that donor anonymity may not be protected despite best intentions of the OPO.