

Implementation of OPTN's Oversight of Vascularized Composite Allografts

*Vascularized Composite Allograft Transplantation
Committee*

Sue V. McDiarmid, MD, Chair

L. Scott Levin, MD, FACS, Vice Chair

Richard S. Luskin, MPA, Vice Chair

June 23 – 24, 2014

Richmond, VA

VCA Transplants performed in USA: 11 programs

28 Transplants

6
Face

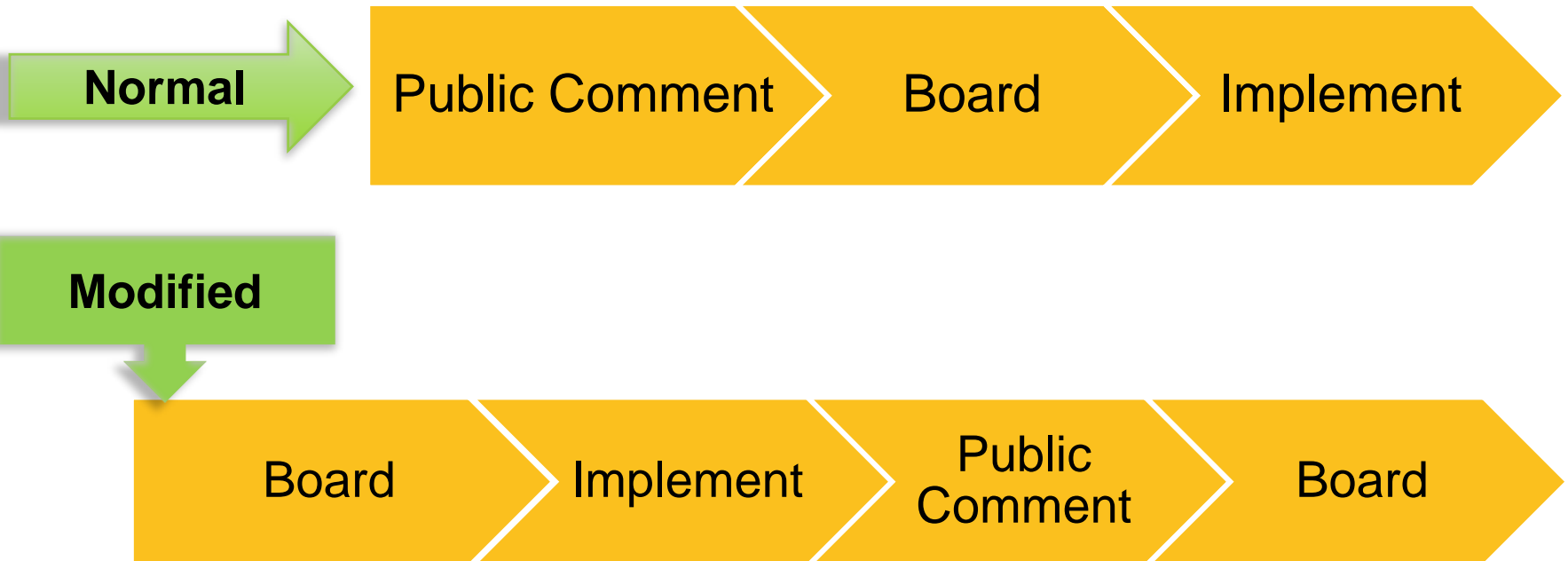
7
Double
Hand

14
Single
Hand

1
Multiple
VCA
(Face &
Double
Hand)

VCA and the OPTN

- Final Rule effective July 3, 2014
Oversight of VCA falls under the OPTN
- Core group of policies to establish framework for VCA recovery and transplantation



VCA Committee Composition (18)

- Sue V. McDiarmid, M.D. – UCLA (C)
- L. Scott Levin, M.D., Univ. of Pennsylvania (VC)
- Richard S. Luskin, M.P.A., New England Organ Bank (VC)
- Charles E. Alexander RN, M.S.N., M.B.A., Living Legacy Foundation of Maryland
- **Gerald Brandacher, M.D., The Johns Hopkins Hospital**
- **Warren Breidenbach, M.D., Univ. of Arizona**
- **Linda C. Cendales, M.D., Duke University Hospital**
- **Eric Elster, M.D., Captain, U.S. Navy**
- **Lindsay Ess, VCA transplant recipient**
- John J. Fung, M.D., Ph.D., The Cleveland Clinic Foundation
- **Christina L. Kaufman, Ph.D., Jewish Hospital**
- David M. Klassen, M.D., Univ. of Maryland Medical Center
- **W. P. Andrew Lee, M.D., The Johns Hopkins Hospital**
- Marlon F. Levy, M.D., Baylor All Saints Medical Center
- Kenneth F. Newell, M.D., Ph.D., Emory University Hospital
- **Bohdan Pomahac, M.D., Brigham and Women's Hospital**
- Kathy Schwab, RN, CCTC, Mayo Clinic
- Robert M. Veatch, Ph.D., Georgetown Univ.

OPTN Policy & Bylaw application

Specific VCA Policies

applicable to specific types of VCA transplants

General VCA Policies

applicable to all VCA transplants but not other organ transplants

General OPTN Policies

applicable regardless of organ type

Action Items for Board Consideration

1. Definition
2. Allocation
3. Remove Policy 5.9 – Allocation of Other Organs
4. Membership
5. Donor Authorization
6. Other policy and bylaw modifications

Definition of a VCA

- Final Rule definition changed the definition of organ to include VCAs
 - Nine criteria in Final Rule definition
- Synchronize OPTN definitions with Final Rule
- Committee vote (16 Support, 0 Oppose)

OPTN Policy 1.2 - Definitions

• Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

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; and
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

OPTN Policy 1.2 - Definitions

• Organ

A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

OPTN Bylaws, Appendix M - Definitions

Designated Transplant Program

An organ-specific program that has been approved by the MPSC to as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, ~~and~~ intestines, and vascularized composite allografts. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

OPTN Bylaws, Appendix M - Definitions

Organ

~~Organ means a~~ A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft . Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended “For use in organ transplantation and labeled “For use in organ transplantation only.”

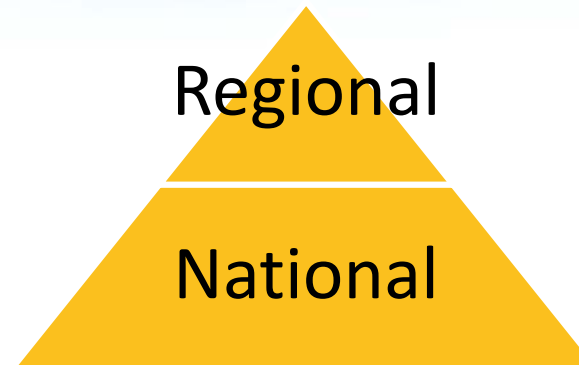
OPTN Bylaws, Appendix M - Definitions

Vascularized Composite Allograft (VCA)

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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; and
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

VCA Organ Allocation



- Committee considered prioritization based on other factors (sensitivity, 0-ABDR match, geographic parameters, etc...), but insufficient data to add these elements currently
- Needed to include physical 'match' concept
- **Prioritized by waiting time & blood type compatibility**
- **First level allocation will be Regional, then National**

OPTN Policy 12 – Allocation of Vascularized Composite Allografts

12.1 Waiting Time

Waiting time for VCA candidates begins when the candidate is registered on the waiting list. For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

12.2 VCA Allocation

The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:

1. Candidates that are within the OPO's region.
2. Candidates that are beyond the OPO's region.

Within each classification, candidates are sorted by waiting time (longest to shortest).

When a VCA is allocated, the host OPO must document 1) how the organ is allocated and the rationale for allocation and 2) any reason for organ offer refusals.

Committee Vote: 15 support, 0 oppose

Remove Policy 5.9 – Allocation of Other Organs

- Was created to allow for allocation of organs not specified in other policies
- Policy is outdated, never programmed, and functionally problematic for VCA allocation
- This part was sponsored by the OPO Committee.
- Committee Vote (15 Support, 0 Oppose)

VCA program membership criteria

- Letter of assurance from local OPO to provide VCAs
- Letter of notification from the transplant hospital must be signed by *all* of the following individuals:
 - The chief administrative officer for the institution
 - A reconstructive surgeon
 - A transplant specialist
- Would not negatively impact currently operating VCA transplant programs
- There was a need to document who would be accountable for VCA program performance

Amendment – OPTN Bylaws, Appendix J

J.1 The letter of notification from the transplant hospital must include the name, contact information, and signatures for *all* of the following individuals:

1. The chief administrative officer for the institution.
2. A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.
3. A transplant physician or transplant surgeon at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation.

Committee Vote: 11 support; 0 oppose

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OPTN Bylaws, Appendix D.2 – Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HHS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program ~~for at least one of the organ types involved in multi-visceral transplant~~. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

VCA Donor Authorization

- Policy requires a separate authorization for VCA donation
- UAGA allows consideration of a further gift, therefore OPOs can seek authorization for VCA donation in the setting of general registry information
- Policy does not conflict with state laws, the UAGA, or the efforts of the donation community

OPTN 2.12.C – Authorization Requirement

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

Committee Vote: 15 support, 0 oppose

Authorization Process for VCA

- Committee felt strongly that education of OPO staff, donor hospital staff, requestors, and general public was essential to ensure full understanding of the request for VCA donation and that consent would not be ‘assumed’ unless specifically documented by potential donor
- As well, approaching a family for authorization for VCA donation should not jeopardize authorization for life saving solid organ donation.
- The Committee has submitted to the Board the draft of a document that will serve the basis of a formal Guidelines for VCA Authorization Document that the VCA Committee will write and then submit for comments from the appropriate other committees – with emphasis on OPO, Ethics, Patient Affairs committees

Other policy and bylaw modifications

- Exemptions for certain OPTN Policies and Bylaws that are logistically problematic for VCA.
- Exemptions will be removed as programing enhancements are made to incorporate VCA into WaitlistSM, DonorNet[®], and Tiedi[®]
- Committee Vote (14 Support, 0 Oppose)

Other VCA Committee Initiatives

- **Data Collection**
 - Data Registry and collection subcommittee formed
 - Goal to develop the data elements required for submission to the SRTR
- **Membership Criteria**
 - Subcommittee formed to specify surgeon and transplant specialist qualifications, key elements of VCA programs etc
- **Monitor effects of policies adopted especially allocation**
- **Promote public awareness**

Strategic Plan Alignment

- Goal – Promote the efficient management of the OPTN
- Objective – Improve responsiveness of OPTN policy to a changing environment

Resolution 21

RESOLVED, that additions and modifications to Policies 1.2 (Definitions), 2.2 (OPO Responsibilities), 2.12.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 12.1 (Waiting Time), 12.2 (VCA Allocation), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.3 (Recording and Reporting the Outcomes of Organ Offers, and Bylaws Appendices D (Membership Requirements for Transplant Hospitals and Transplant Programs), D.2 (Designated Transplant Program Requirement), J (Membership Requirements for Vascularized Composite (VCA) Transplant Programs, K (Transplant Program Inactivity, Withdrawal, and Termination), M (Definitions), as set forth in Resolution 21, are hereby approved, effective July 3, 2014.

FURTHER RESOLVED, these additions will expire on September 1, 2015. *Page 104 of Board book

Resolution 18

RESOLVED, that Policy 5.9 (Allocation of Other Organs) be rescinded, as set forth in Resolution 18, is hereby approved, effective July 3, 2014, and shall expire on July 1, 2015.

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