VCA Implementation

VCA Committee
June 2015
The Problem

- Vascularized Composite Allografts (VCA) designated as organs under the OPTN Final Rule (July 3, 2014)

- OPTN policies and bylaws required modification to accommodate new organ type

- June 2014: Board approved VCA bylaws and policies with 18 month sunset provision
  - Released for public comment post-Board approval
Strategic Plan Alignment

Goal 1: Increase the number of transplants

• New class of “organ”

Goal 2: Increase access to transplants

• VCA allocation sequence
VCA Transplants in USA (1999-2014)

28 Transplants

6 Face
7 Double Hand
14 Single Hand
1 Multiple VCA (Face & Double Hand)
VCA Transplants (July 3, 2014-April 17, 2015)

4 Transplants

- 2 Head and Neck (Craniofacial)
- 1 Bilateral Upper Limb
- 1 Unilateral Upper Limb
VCA Candidates (As of April 17, 2015)

11 VCA Candidates

- 2 Abdominal Wall
- 1 Head and Neck: Craniofacial
- 1 Head and Neck: Scalp
- 4 Bilateral Upper Limb
- 3 Unilateral Upper Limb
Proposed Solutions

• Definitions of “organ” and “VCA”
• Allocation of VCAs
• Donor authorization to recover VCAs
• Exemptions from certain general bylaws and policies not applicable to VCAs at this time
Public Comment Themes

- Potential impact on living VCA donation:
  - Inclusion of possible living VCA donors
  - Appearance of allowing a surrogate decision maker to authorize living VCA donation
  - Concern of impact of donation procedure on living donor, including potential permanent disability
  - Limits on what VCAs could be recovered from living donors
  - Lack of safeguards for living VCA donors
Amended policy to clarify that authorization for VCA donation from surrogate decision-maker is valid only for deceased VCA donors

Committee declined to prohibit living VCA donation
  - Prohibition would require a change to the Final Rule

VCA, Living Donor, and Ethics Committees collaborated on Guidance Document for VCAs from Living Donors
  - Will collaborate to develop policy once more data are collected
Post-Public Comment Outreach

- Meeting with National Catholic Bioethics Center and National Catholic Partnership on Disability March 12, 2015
What Members will Need to Do

- OPOs must:
  - Grant staff access to Secure Enterprise to obtain OPTN VCA Candidate List
  - Obtain and document separate authorization to procure VCA organs for transplant
  - Allocate VCA grafts only from the OPTN VCA Candidate List
  - Record VCA allocation, including refusal and bypass reasons, and return the completed VCA Candidate List to the OPTN
    - vca@unos.org
What Members will Need to Do

- Transplant hospitals must:
  - Obtain OPTN approval for a VCA transplant program before registering a VCA candidate
  - Request VCA worksheets via email from OPTN
    - vca@unos.org
  - Use worksheets to register or remove a VCA candidate
# Overall Project Impact

<table>
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<tr>
<th>Product</th>
<th>Changes to OPTN Policies &amp; Bylaws</th>
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| **Target Population Impact:** | **VCA Donors, Transplant Candidates, and Recipients**  
**OPOs and Transplant Hospitals** |
| **Total IT Implementation Hours** | **0/16,680** |
| **Total Overall Implementation Hours** | **630/23,685** |
Board Policy Group Recommendation

- 2-Approve without further discussion
- 2-Approve but discuss
- 0-Decline but discuss
- 5-No recommendation but discuss
RESOLVED, that additions and changes to OPTN Policies 1.2 (Definitions), 2.2.12 (OPO 1 Responsibilities), 2.15.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.B 2 (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for 3 Acceptance), 12 (Allocation of Vascularized Composite Allografts) 14.5 (Registration and Blood 4 Type Verification of Living Donors Before Donation), 18.1 (Data Submission Requirements), 18.2 5 (Time Data Collection), and 18.3 (Recording and Reporting Outcomes of Organ Offers); and OPTN 6 Bylaws, Appendices D.2 (Program Requirements), D.4 (Transplant Program Director), D.5 7 (Transplant Program Key Personnel), D.6 (Changes in Key Transplant Program Personnel), D.9.A 8 (Functional Inactivity), D.10.A (Transplant Program Performance), D.10.B (Notification 9 Requirements for Waiting List Inactivation), D.10.G (Relocation or Transfer of Designated 10 Program), K.1 (Transplant Program Inactivity), K.2 (Short-term Transplant Program Inactive 11 Status), K.3 (Long-term Transplant Program Inactive Status), and M (Definitions), as set forth 12 below, are hereby approved, effective September 1, 2015.
This policy does not apply to VCA organ offers; instead, members must document VCA offers according to Policy 18.1: Data Submission Requirements.

This policy does not apply to VCA organ offers; instead, members must document VCA offers according to Policy 12.2: VCA Allocation.