

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

Post-public comment action

- 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

Product

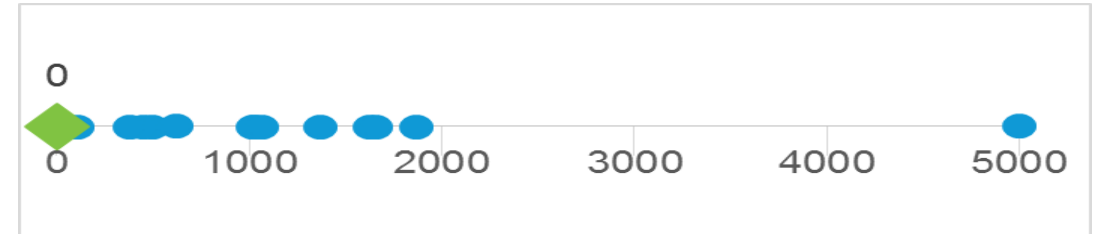
Changes to OPTN Policies & Bylaws

Target Population Impact:

*VCA Donors, Transplant Candidates, and Recipients
OPOs and Transplant Hospitals*

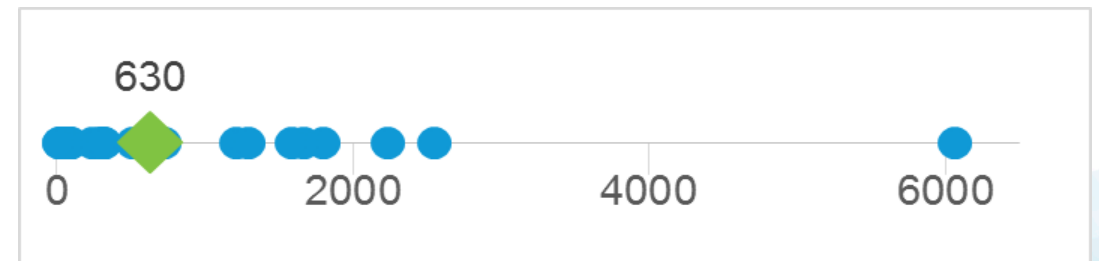
Total IT Implementation Hours

0/16,680



Total Overall Implementation Hours

630/23,685



Board Policy Group Recommendation

- 2-Approve without further discussion
- 2-Approve but discuss
- 0-Denial but discuss
- 5-No recommendation but discuss

Resolution 18 (page 83)

- 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.

Amendment 1

- Lines 350-351
- Strike
- This policy does not apply to VCA organ offers; instead, members must document VCA offers according to *Policy 18.1: Data Submission Requirements*.
- Insert
- This policy does not apply to VCA organ offers; instead, members must document VCA offers according to *Policy 12.2: VCA Allocation*.