

OPTN Vascularized Composite Allograft Transplantation Committee

Meeting Summary

August 28, 2024

Teleconference

Vijay Gorantla, MD, PhD, Chair

Paige Porrett, MD, PhD, Vice Chair

Introduction

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (the Committee) met via in Richmond, Virginia on 08/28/2024 to discuss the following agenda items:

1. VCA Biannual Data Report
2. Open Discussion: Opportunities to expand VCA deceased donor donation
3. Proposal Overview: Revise Conditions for Access to the OPTN Computer System
4. Improvement of OPTN VCA Patient Resources
5. VCA Forms in OPTN Data System
6. Guest Speaker: First Larynx Transplant
7. Expeditious Task Force Update
8. Continuous Distribution Update
9. Open Forum

The following is a summary of the Committee's discussions.

1. VCA Biannual Data Report

No decisions were made.

Summary of Presentation:

A biostatistician staff member presented current VCA transplant and waiting list numbers. The staff member stated that there are 48 active VCA programs in 24 unique hospitals. Staff mentioned that not all regions have all types of VCA programs. In the past ten years, 138 registrations have been added to the VCA waiting list, which included 68 uterus registrations, 27 upper limb, 14 bilateral upper limb, 12 unilateral upper limb, and one combination bilateral and face. Head and neck included 17 face, 2 scalp, 2 face and scalp, 1 trachea, 1 larynx, 17 abdominal wall, and 3 penis registrations. As of current, there are 9 uterus, 3 neck, 3 face, 3 upper limb, and 2 abdominal wall candidates. There have been 121 registration removals.

Summary of Discussion:

There was no discussion by members.

2. Open Discussion: Opportunities to expand VCA deceased donor donation

No decisions were made.

Summary of Presentation:

The OPTN VCA Committee Vice Chair discussed fostering positive relationships with OPOs and expanding transplant regions beyond single states to serve more VCA candidates. The Vice Chair mentioned that these efforts are difficult given the small size of VCA programs. She also mentioned that not all OPOs keep lists for VCA donations. She discussed that there is room to increase communication and education to eliminate barriers, especially in emphasizing VCA transplants as transplants versus being defined as research.

Summary of Discussion:

A member responded that if an OPO doesn't have a VCA center, a center could reach out to adjacent OPOs. They continued that donor specific testing could get delayed if VCA isn't considered at time of workup, so their center is working on evaluation tip sheets. Further, they suggested having OPOs that can be contacted for reference information. They also stated that to complete advanced imaging for face donors, they move donors to their institution. Lastly, they added that VCA is a standard of care but there are still research elements, as there are for any transplant field.

Committee members mentioned that it is important to speak about VCA in terms of medical care with elements of research. A member discussed possibilities for transplants increasing given developing technologies. They mentioned the importance of collaboration with OPOs. A member discussed information deficits among OPOs regarding VCA transplantation. Another member said their center has only worked with VCA living donors.

A member asked if the VCA Committee would be willing to create materials to educate OPOs about VCA transplantation. They also mentioned that the field is rapidly developing, which makes educational materials hard to make. A member who works at an OPO stated that inclusion and exclusion criteria, as well as patient education, are the biggest barriers to OPO familiarity with VCA. The committee said they are interested in hearing patient family feedback. The OPO member said that regional meetings and OPO conferences are good ways to connect with OPOs.

3. Proposal Overview: Revise Conditions for Access to the OPTN Computer System

No decisions were made.

Summary of Presentation:

An OPTN NOOC committee member presented their current proposal.

Summary of Discussion:

A member asked if there would be guidance on levels of contractor access. The NOOC member stated that this proposal applies to contractors with PHI access.

4. Improvement of OPTN VCA Patient Resources

No decisions were made.

Summary of Discussion:

The committee discussed the current VCA resources available on the OPTN website and options for expanding educational materials. The Chair mentioned that there could be a VCA-specific webpage that could include subcategories for different types of VCA transplantation. He said this could also include connections to support networks, support services, financial information, and patient and/or caregiver testimonials, as well as an FAQ section.

Staff reviewed the OPTN website. Staff pointed out that there is currently a resource page for professionals, and that OPO resources could be included here. Further, staff stated that educational videos could be very important for patients and family support. The Vice Chair suggested ideas such as medication protocol, immunosuppression, length of procedure, blood type information, mental health and social support, and fertility and uterus transplant protocol. Another member said that social media is important, as well as follow-up videos that include resources on nutrition, mental health, and family support.

A member said videos can cause issues in a rapidly developing field. The Vice Chair suggested connecting the OPTN website with research program resources, as well as maintaining updated accessible resources. A member stated that it is important to remember search engines and which results come up. Another member reminded the committee of the importance of psychosocial evaluation and support which can make a difference in patient lives. A member said that videos may be snipped and reposted. Staff said they will discuss and outline limitations. A member suggested that regular VCA data be shared with the public.

5. VCA Forms in OPTN Data Systems

No decisions were made.

Summary of Discussion:

Staff reviewed implementation of VCA Transplant Recipient Registration and Transplant Recipient Follow-up forms in the OPTN data systems. Staff presented that historical VCA forms may appear in the OPTN system with extended due dates. The Chair stated that data entry prior to 2014 is voluntary. IT staff presented what members will see in the system to the committee. A member suggested attaching a paper burden estimate to the forms to help coordinators.

Staff showed OMB data burden estimates. The Chair suggested repetitious data collection to lessen burden. The Vice Chair asked the group if four months is an acceptable extended timeline to fill out historical data. Some committee members suggested 6 months, while others suggested 12 months. The committee settled on 6 months with a 3-month update to the Committee. They chose this to give enough time to large-volume centers while not prolonging the process of obtaining required VCA data.

6. Guest Speaker: First Larynx Transplant

No decisions were made.

Summary of Presentation:

A medical surgeon who led the first larynx transplant along with his medical team presented their experience. He stated that partnerships are an important part of transplantation, and that meetings were done monthly to prepare. The surgeon discussed the difficulties of doing a transplant type that had never been done before, as well as developing new policies around pre- and post- VCA. Policies included HLA agreements, graft failure definition, data entry updates, and education.

On the education side, a medical team member discussed transplant center impacts on nutrition, speech therapy, and care management. The team discussed the large amount of medical, administrative, and educational staff involved in the larynx transplant.

The medical surgeon discussed the clinical trial which was planned as 2 transplants a year for 5 years to study psychosocial and ethical standpoints. The surgeon discussed transplant criteria. A team member

also discussed staff education and re-education, as well as mock procurements and transplants. The team member discussed OPO education and connections. The surgeon mentioned surgical protocols and communication with other surgical teams during procurement, along with the recipient procedure and post-transplant care. A team member discussed that OPTN computer system elements for VCA, separate donor family consent, VCA-specific coding, and workflows for non-traditional teams were positives gained. The team covered barriers including offer turndowns, the OPTN computer system implementation period, and lack of public knowledge.

Summary of Discussion:

A committee member asked how larynx recipients are monitored post-transplant. They also asked whether donor gender factors into larynx transplant considerations, as well as medication effects on the body. The surgeon stated that gender affects voice pitch from the larynx and that monitoring is easier than some other transplants because it can be monitored through the nose, and biopsies can be done if needed. A presenter remarked that this particular recipient was on a consistent drug regimen without issues.

A committee member asked how different cell types can be monitored in VCA transplants. The surgeon discussed suturing techniques and thyroid monitoring. A member asked about biopsy tissues, and the surgeon replied that biopsies can be done through the stoma or trans-nasally.

A member discussed their own experience around patient choice and larynx transplants versus other larynx procedures. A member asked about donor screening with HPV status and age. A team member stated that they didn't screen for HPV and that age was collected.

7. Expeditious Task Force Update

No decisions were made.

Summary of Presentation:

The committee heard updates on the Expeditious Task Force.

Summary of Discussion:

The Vice Chair asked how policies are communicated to transplant center C-suites. The presenter stated that relationship building is important in this area. The committee discussed the importance of medical and hospital staff's opinions being heard and that hospitals expect detailed business plans. A member discussed disparities in pediatric subspecialties. A member replied that transplant center departments cannot work in isolation and that different areas are all important to the transplant process.

8. Continuous Distribution (CD) Update

No decisions were made.

Summary of Presentation:

The committee heard a presentation on CD updates.

Summary of Discussion:

The committee discussed difficulties of translating VCA into CD given the broad range of transplant types. A member asked about VCA's future inclusion in the Expedited Task Force updates. Another member added that uterus could be the main focus. The Vice Chair mentioned hopes for VCA to be

included within the CD updates by 2028. A committee member discussed clinical and legal definitions of VCA transplantation as it relates to the organ transplantation count and program burden under CMS.

Upcoming Meeting

- September 17, 2024, 5 PM ET, teleconference

Attendance

- **Committee Members**
 - Vijay Gorantla
 - Paige Porrett
 - Sandra Amaral
 - Todd Levy
 - Charlie Thomas
 - Elliott Richards
 - Christina Kaufman
 - Anji Wall
 - Gregory McKenna
 - Amanda Gruendell
 - Joseph Hendrix
 - Ericka Harrison
 - Sheila Advento
 - Eric Genden
 - Bruce Gelb
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Shannon Dunne
- **SRTR Staff**
 - Avery Cook
 - David Zaun
- **UNOS Staff**
 - Brooke Chenault
 - Susan Tlusty
 - Leah Nunez
 - Lindsay Larkin
 - Kristina Hogan
 - Desiree Tenenbaum
 - Miyoung Kwon
 - Erin Schnellinger
- **Other Attendees**
 - David Lott
 - Elizabeth Stearns
 - Girish Mour
 - Glen Kelley