

**OPTN Vascularized Composite Allograft Committee**  
**Meeting Summary**  
**September 22, 2023**  
**Detroit, Michigan**

**Sandra Amaral, MD, MHS, Chair**  
**Vijay Gorantla, MD, PhD, Vice Chair**

## Introduction

The OPTN Vascularized Composite Allograft (VCA) Committee (the Committee) met in Detroit, Michigan on 09/22/2023 to discuss the following agenda items:

1. Review Public Comment Analysis: *Update Guidance on Optimizing VCA Recovery*
2. Gift of Life Effective Practices
3. VCA Data Update
4. VCA in UNet
5. VCA Application Update
6. Efficiency Discussion and New Project Ideas

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

### 1. Review Public Comment Analysis: *Update Guidance on Optimizing VCA Recovery*

#### Summary of discussion:

The Committee discussed feedback from public comment and the themes that arose. They proposed potential changes to the guidance document.

The Committee discussed the public comment feedback from their guidance document. There were four major themes that came out of the feedback: cost and insurance; Organ Procurement Organizations (OPOs) and credit for VCAs; education and access; and family considerations.

**1. Cost and Insurance:** Members discussed the financial aspects of VCA transplantation, considering the implications for both patients and healthcare providers. The absence of a standardized fee for VCA transplantation and the requirement for OPO engagement approval. Members recognized that each VCA transplant was unique in terms of expectations, requirements, and costs and this in turn would make standardizing fees difficult.

**2. OPOs and VCA Credit:** There was a consensus that OPOs should receive proper recognition and credit for their role in placing VCA organs. The lack of acknowledgment was a matter of concern. One recommendation was to include VCA performance evaluations. Another member brought up whether the Medicare Cost Reports could incorporate VCAs, as providing OPOs with appropriate credit might increase engagement.

**3. Education and Access:** The group discussed the need to enhance education and accessibility related to VCA experiences. They recognized that a lack of information often left both transplant centers and OPOs unsure of where to start.

**4. Family Considerations:** Family dynamics and decision-making in the context of VCA donation and transplantation were also a significant point of focus. The group addressed the need to balance the desire to promote VCA with respecting the decisions of donor families.

Furthermore, the meeting participants emphasized the importance of raising awareness about VCA and leveraging media coverage. They discussed the creation of educational tools to spread the word about VCA.

Members discussed public comments that addressed the psychological implications of VCA, highlighting that more patient stories might benefit attitudes towards VCA. Additionally, the Committee agreed that there must be a focus on striking a balance between promoting VCA and respecting donor family decisions. It was emphasized that VCA should not compromise the recovery of solid organs.

The issue of state restrictions regarding donor transportation was raised, highlighting the need for clear coordination in the guidance. There was discussion of an incidence where a donor could not be transported across state lines due to state law, however, the Committee agreed that this guidance document might not be the correct place for this information at this time. It was recommended to investigate this further for a potential future project if it fell under the Committee's and OPTN purview.

Members also discussed the importance of mentorship and having program "champions" to advocate for building and supporting a VCA program at OPOs and transplant programs.

The meeting concluded with discussions on mentorship, program initiatives, and the need to further explore patient and donor family experiences.

Next steps:

Staff will summarize and develop the feedback and ideas from the Committee and incorporate it into the guidance document.

**2. Gift of Life Effective Practices**

The Committee heard a presentation from a representative from the Gift of Life Donor Program OPO, this representative shared their best practices and insights related to VCA recovery.

Summary of discussion:

No decisions made; the Committee held a discussion about VCA best practices from an OPO perspective. The discussion revolved around key points that shed light on the program's significant involvement in VCA coordination and their early entry into this field.

The representative revealed that the Gift of Life Donor Program had coordinated a total of eleven local and two import VCA recoveries, underlining their active role in VCA procurement. What made their involvement even more notable was the fact that they had embarked on their journey in the VCA field as early as 2011. This was a time when the OPTN had not yet established a formal list for VCA donors.

During the discussion, participants raised several questions and sought clarifications on various aspects of VCA coordination. One member inquired about the program's collaboration with local OPOs and transplant centers. The representative explained that, typically, they primarily worked directly with the transplant center itself. Only when they engaged with an out-of-region transplant center did they interact with the corresponding OPO, and even then, their involvement was minimal.

The group also explored the logistics of transporting deceased donors across state lines, an essential aspect of VCA donation. The representative shared an example of successfully transporting a patient

from Delaware to New York City, emphasizing the importance of extensive coordination with the Medical Examiner's office and the coroner's office to ensure a smooth process.

A member inquired about Gift of Life's ability to conduct VCA donations outside of the Donor Service Area (DSA). In response, the representative clarified that the decision to extend their reach beyond the DSA was at the discretion of individual transplant centers. Several factors influenced this decision, such as the distance the VCA could travel and the staffing capabilities of the center. The stability of the donor was a key consideration in determining whether to move them.

The conversation turned to the tracking and credit mechanisms for VCA donations, both at the national level and internally. A member question prompted the representative to acknowledge that VCA was not routinely included in their observed organ utilization. They encouraged further inquiries via email to obtain a more comprehensive understanding of how OPOs received credit for their involvement in VCA procurement.

Lastly, the Chair discussed the goal of the Committee's guidance document, which aimed to ensure the sustainability of the VCA field. They shared feedback indicating that VCA was perceived as a rare and complex event for OPOs and sought advice on how to motivate other organizations to get involved. In response, the representative stressed the importance of collaboration and the willingness to share policies and procedures with other OPOs. It was highlighted that building a VCA program required dedication and a commitment to expanding donor opportunities, as each donor had the potential to help multiple individuals.

Next steps:

This presentation might serve as valuable insight into future projects that the VCA Committee might pursue.

**3. VCA Data Update**

A research staff member presented updates on VCA data.

Summary of discussion:

No decisions made; the Committee discussed data updates about VCA transplantations.

One member initiated the discussion by inquiring about the absence of genitourinary (GU) transplants on the list and specifically whether there were any penile transplants in progress. The research staff member confirmed that there were currently no GU transplants, including penile transplants, on the list. The Chair continued the conversation by asking about the number of transplants and additions to the registration list. The research staff member provided insight, stating that there had been 120 individuals added to the waiting list since the OPTN began overseeing VCA in 2014. It was expressed that OPOs were running their lists but were not seeing any recipients, raising questions about the status of these potential transplant candidates. Research staff acknowledged the concern and mentioned that they would investigate which recipients were inactive or how long they had been on the waiting list.

A member brought up that not all patients were listed for deceased donor transplantation if a living donor (LD) was already available for them. They inquired whether the list was inclusive of LD registrations. Research staff expressed uncertainty about whether the data included all types of donor registrations. The Vice Chair raised a concern about the accuracy of the numbers presented, wondering if they were under-representative. One member, however, suggested that the numbers might be over-representative.

Another member added to the discussion by raising questions about the registrations and their differentiation. A different member emphasized that while the previous slide displayed all the registrations of recipients, it lacked differentiation.

The conversation then took a turn towards uterine transplants. An inquiry was made about the registration process for uterine LD (living donor) transplants, specifically whether the rules applied similarly to other LD transplants like liver or kidney. A member confirmed that the same rules were applicable to uterine LD registrations as to other LD transplants.

Next steps:

Research will review the available data further to answer Committee questions.

**4. VCA in UNet**

IT staff presented about the recent integration of VCA into UNet and the changes that have come about with this shift.

Summary of discussion:

The Committee discussion revolved around the logistical aspects of VCA organ eligibility, the evolving nature of the field, and the allocation and transplantation challenges it presents.

A member, addressing the logistical standpoint, raised a question about how OPOs would determine if a VCA organ was eligible to be placed on the waiting list. They pointed out that the terminology and highly specified terms in the process might be confusing for those not deeply familiar with the field. The Chair, in response, explained that the terms and criteria for VCA organ eligibility were clearly defined in OPTN policies, aiming to provide guidance and clarity. The member further emphasized the complexity of the evolving field, acknowledging that VCA allocation and transplantation might not necessarily follow the same principles as kidney and liver. They expressed skepticism that these terms and criteria alone could magically resolve the intricate issues associated with VCA allocation.

The Vice Chair added to the discussion, shedding light on the intricacies of VCA procurement. They explained that certain VCA organs, like the vascularized thyroid and parathyroid, were challenging to resect. Sometimes, these organs cannot be separated, while other times they can. One member highlighted an essential aspect of VCA procurements—some of them occurred solely for research purposes. This nuance could affect the allocation process, as listing for certain organs might not yield any results if the procurement were primarily for research. They proposed the idea of listing all VCA types and inquired if there were any constraints on doing so.

It was clarified that it was possible to list all VCA types by selecting all the checkboxes in the system, indicating that there were no inherent limitations in listing all available options.

A member introduced a question related to inactive listings. They raised a scenario where some patients were pending insurance authorization, and in the past, it was considered inappropriate to list patients in such a situation. Given the transition to electronic systems, they wondered if there had been any changes in this regard.

A staff member responded by confirming that it was permissible to list inactive patients and added that the system allowed for the inclusion of reasons for their inactive status. Furthermore, they noted that even while inactive, patients could still accrue waiting time if they were listed, addressing the concerns surrounding insurance authorization and listing practices.

Lastly, members discussed their feedback on the UNOS Connect Course, highlighting a need for greater specificity and advanced content, especially for experienced VCA users in UNet. A member found the course to be elementary and lacking in unique information about listing VCA organs like uterus, face, and limb. Additionally, there was limited coverage of VCA living donor registration, with only a PDF link provided. As VCA programs continue to develop, the feedback suggested a demand for more comprehensive and tailored education in these areas.

Next steps:

None at this time, but as VCA in UNet develops further the Committee will be asked for additional feedback.

## **5. VCA Application Update**

The Committee received an update about the application process for transplant centers to found VCA programs.

Next steps:

Future updates will be presented to the Committee as needed.

## **6. Efficiency Discussion and New Project Ideas**

The Committee discussed potential new projects and ideas that relate to efficiency in the transplant system.

Summary of discussion:

Several topics related to policy work and potential projects were discussed. The discussion also encompassed ideas aimed at advancing the field of VCA and its recognition as a standard of care.

Staff outlined various aspects of policy work, including guidance documents, concept papers, policy change proposals, and white papers for the Committee to consider.

A member introduced the idea of addressing the barriers to creating and expanding VCA programs. They noted the importance of UNet in facilitating relationships with insurance companies and allowing VCA programs to present their qualifications. However, they highlighted the absence of a formal section for VCA within UNet and suggested that the OPTN Transplant Administrators Committee (TAC) might be better suited to handle this.

The conversation shifted to recipient data collection, with a member raising questions about who determines and revisits these data, especially considering the evolving nature of uterus transplants and research. Other members agreed that regular review of recipient data was essential, especially for VCA programs that were continuously changing.

One member introduced the idea of tracking children born of uterus transplant recipients, highlighting the potential to gather valuable data that could influence the field of uterus transplantation. However, the Chair pointed out the challenges of collecting data from the children, as they are not able to consent, and the responsibility falls on the uterus recipient to engage in data collection. Another member suggested collaborating with the transplant pregnancy registry, which focuses on medications and outcomes of children from all types of transplants, not just uterus. They also mentioned the more successful tracking efforts in Europe and the need for better data collection in the USA.

The discussion then turned to limb loss and preservation registries. A member introduced the idea of using a national limb loss and preservation registry to identify potential candidates for limb

transplantation. They mentioned that the registry could provide data on procedures, prosthetics, and other relevant information. The Vice Chair inquired about the preservation aspect, and the member explained that the registry encompassed various types of limb loss, including genetic causes. It was noted that the Mayo Clinic had a contract with the registry, allowing any center or program to push data to the registry through Mayo.

The Chair highlighted the importance of tracking and data to demonstrate the safety and effectiveness of VCA. They suggested that the OPTN could potentially lead the way in the development of VCA, particularly by partnering with other registries to refine research questions. The discussion also touched on the need for patient stories, the perception of VCA as experimental, and the transition to VCA being considered a standard of care, which may be influenced by insurance companies and healthcare systems.

Next steps:

The Committee will review the ideas again at later meetings and continue the discussion about potential new projects to increase efficiency and awareness of VCA transplantation.

**Upcoming Meetings**

- October 25, 2023
- November 15, 2023

## Attendance

- **Committee Members**
  - Sandra Amaral
  - Vijay Gorantla
  - Brian Berthiaume
  - Alexa Blood
  - Amanda Grendell
  - Joseph Max Hendrix
  - Christina Kaufman
  - Todd Levy
  - Gregory McKenna
  - Richard Redett
  - Elliot Richards
  - Charlie Thomas
  - Anji Wall
  - Gerald (Scott) Winder
- **HRSA Representatives**
  - Marilyn Levi
- **UNOS Staff**
  - Kelley Poff
  - Stryker-Ann Vosteen
  - Lauren Mauk
  - Catherine Parton
  - Jesse Howell
  - Marta Waris
  - Kristina Hogan
- **Other Attendees**
  - Caitlin Clarke, Gift of Life Philadelphia