

OPTN Vascularized Composite Allograft Transplantation Committee

Meeting Summary

March 4, 2024

Houston, Texas

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

Introduction

The OPTN Vascularized Composite Allograft (VCA) Committee (the Committee) met via WebEx teleconference on 03/04/2024 to discuss the following agenda items:

1. OPTN Data Advisory Committee Pre-Waitlist Data Collection Project Update
2. OPTN 2024-2027 Strategic Plan
3. Standardize the Patient Safety Contact and Reduce Duplicate Reporting Presentation
4. The First Partial Face and Vascularized Eye Transplant: Presentation
5. Clarify Requirements for Pronouncement of Death Proposal
6. VCA in Clinical Practice: Donor Side
7. VCA Data Update
8. Update: OPTN Expeditious Task Force
9. Project Brainstorming
10. Outgoing Committee Member Recognition

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

1. OPTN Data Advisory Committee Pre-Waitlist Data Collection Project Update

The Committee received a presentation by the Data Advisory Committee (DAC) about their Pre-Waitlist Data Collection project.

Summary of discussion:

There were no decisions regarding this item.

A member noted the importance of having the VCA expertise included in future project iterations. They continued, underscoring the importance of including the VCA patient population, as they are often viewed as the "other" population and want to be sure that the VCA perspective is included. The Vice Chair echoed previous sentiments, adding that potential VCA candidates do not follow the same referral process that other organ-specific candidates do. They added that each transplant program has different thresholds of inclusion and exclusion criteria, and although the VCA community is working towards standardization, the thresholds are still variable.

A member questioned how payment will be tracked and how granularly it will be approached. They added that collecting Federal Emergency Services as a sub-topic and the reason for denial or not having access would be helpful. A member commented that quarterly reporting is highly preferred to what is currently done. They also asked if a source of income is requested. The Vice Chair of the OPTN Data Advisory Committee (DAC) said that it will not be included in the first set of data elements, however, they would like to revisit for subsequent evolutions of these data elements.

The Chair indicated that they were overall supportive of the concept of obtaining these data, however, they expressed their concern for workforce demand, as more data means that someone will have to enter that data. They recommended that the OPTN Data Advisory Committee (DAC) creatively advocate for transplant centers to have the resources and staffing to enter these data.

Next steps:

The Committee hopes to be involved in a future iteration of the OPTN Data Advisory Committee's Pre-Waitlist Data Collection Project.

2. OPTN 2024-2027 Strategic Plan

The Committee received a presentation regarding the OPTN 2024-2027 Strategic Plan sponsored by the OPTN Executive Committee. The proposal is out for public comment until March 19, 2024.

Summary of discussion:

There were no decisions regarding this item.

The Committee had no feedback regarding the OPTN 2024-2027 Strategic Plan proposal.

Next steps:

A public comment will be posted to the OPTN website on behalf of the Committee.

3. Standardizing the Patient Safety Contact and Reduce Duplicate Reporting

The Committee received a presentation regarding the *Standardize the Patient Safety Contact and Reduce Duplicate Reporting* proposal sponsored by the Ad Hoc Disease Transmission Advisory Committee. The proposal is out for public comment until March 19, 2024.

Summary of discussion:

The Committee is supportive of the *Standardizing the Patient Safety Contact and Reduce Duplicate Reporting* proposal.

A member expressed their gratitude and support for this proposal, highlighting the amount of time that will be saved with this standardization. The member continued, noting that their organ procurement organization (OPO) spends a lot of time with post-procurement reporting of cultures and the patient safety contact often says they do not deal with this.

Next steps:

Feedback will be summarized and posted on behalf of the Committee on the OPTN website.

4. The First Partial Face and Vascularized Eye Transplant: Presentation

The Committee received a presentation about the first partial face and vascularized eye transplant performed by Dr. Bruce Gelb, a former member of the Committee.

Summary of discussion:

There were no decisions regarding this item.

A member asked if there were rehabilitation efforts in place to prepare for if or when the patient gains vision in the transplanted eye. Dr. Gelb responded, noting that it is currently unknown if the recipient

will regain sight in the transplanted eye and the priority is to ensure that the recipient keeps vision in his native eye. A member asked if the eye is consistently covered. Dr. Gelb replied that the recipient cannot currently close the eye, but he will likely be able to by the end of the year. He added that for corneal protection, the recipient uses eye drops and an eye patch. The Vice Chair asked the recipient when cross-clamping occurred. Dr. Gelb stated his institution decided to procure all VCA organs before cross-clamping. The Chair asked if the recipient experienced any sensitivity. Dr. Gelb responded that they were referred to the recipient early enough to prevent any sensitivity.

A member commented that an important factor in VCA transplantation is an early referral of potential candidates, which is a significant gap in the community. They advised that a solution would be getting VCA personnel to potential recipients early, which is critical not just to expanding the field, but also to best serving patients. Dr. Gelb agreed, highlighting that frequently, the media and self-referrals are two of the largest referral sources for VCA transplants and a different approach that may increase awareness for VCA transplants is contacting level one trauma centers to ensure they know that VCA transplant could be a potential option for some of their patients. A member emphasized a point mentioned in the presentation, which was that VCA transplantation is not always the best course of treatment for certain individuals.

A member questioned how Head and Neck recipients emotionally handle their transplant. Dr. Gelb replied that most of them handle it very well and the quality-of-life aspect drastically improves. He continued, adding that most of the issues arise in the intermediate/long-term phase of recovery and that the screening process for potential VCA recipients is very integral to ensuring optimal mental health outcomes following the VCA transplant. He noted that a particularly unique challenge of VCA transplant is the media, as these transplants are often headlines in news stories, thus ensuring that potential VCA recipients are aware of this is extremely important when screening individuals.

A member commended Dr. Gelb and his team for not just the success of the transplant, but also for the leadership structure that has been fostered at his institution. They added that the organizational structure of the surgical and medical teams seemed to be an asset to this transplant. Dr. Gelb agreed, noting that a principle they enforce in their team is to give credit where it is deserved, which doesn't often occur in medicine. He noted that when talking to his team in this way, he's noticed an impact of a more positive workplace, but his team members are more open to correction for improvement.

A member, who is a psychologist, noted the inspiration they felt when hearing this presentation and felt that other areas of transplant need to hear this as well. They added their appreciation for how Dr. Gelb and his team approached the transplant of the mindset that transplant fixes the crisis, but it does not fix the problem, thus having mental health and other social services are vital aspects to transplantation.

Next steps:

The Committee will continue to consider ways to support the expansion and growth of VCA transplants, including vascularized eye transplantation.

5. Clarify Requirements for Pronouncement of Death Proposal: Presentation

The Committee received a presentation regarding the *Clarify Requirements for Pronouncement of Death* proposal, that is currently out for public comment by the OPTN Organ Procurement Organization (OPO) Committee.

Summary of discussion:

The Committee was supportive of this proposal.

The Chair expressed their approval for this proposal, appreciating how straightforward the proposed policy changes are.

Next steps:

Feedback will be summarized and posted to the OPTN website on behalf of the Committee.

6. VCA in Clinical Practice: Donor Side

The Committee reviewed the different types of Committee projects and discussed potential new project ideas.

Summary of discussion:

There were no decisions regarding this item.

A member voiced their concern that the Donor Disposition Form will not match the Anatomical Gift Form (AGF), which the member’s organ procurement organization (OPO) fills out. The form is standardized amongst solid organs, but for VCA, OPOs must fill it in the “other” box. The member added that OPOs would adopt this form once it went into the OPTN Computer System. The Chair recommended that the data fields match between the OPTN Computer System and what OPOs see for VCA Donor Organ Disposition Forms. The Vice Chair commented that the Donor Disposition Form should match what was done when the Committee worked on Disposition in the OPTN Computer System from a candidate perspective.

Next steps:

OPTN Contractor staff will continue to develop VCA in clinical practice from a donor perspective and will continue to engage the Committee in decision-making regarding how fields are displayed in the OPTN Computer System.

7. VCA Data Update

The Committee received an update surrounding VCA data, including how many VCA transplants were completed in the United States last year.

Summary of discussion:

There were no decisions regarding this item.

The Chair suggested displaying a map to show where the active programs are and what organs they transplant, as well as where VCA transplants are happening. The Vice Chair suggested including a legend with the graphs so they can better interpret the visuals provided. The Chair flagged that there have not been any upper limb transplants since 2020, and questioned why the numbers for upper limb transplants are low. They added that the median waiting time for potential recipients would be helpful to see.

A member questioned when a VCA program is considered to be active in terms of the data. The OPTN Contractor responded that as long as they meet the requirements that are outlined in the OPTN Bylaws, they will remain active. The member continued, adding that more programs will continue to remain active on the OPTN front, however, they will not be performing transplants due to the lack of funding available for VCA transplants. OPTN Contractor staff noted that programs will have to be deemed “inactive” if they do not have any medical staff that meet the OPTN guidelines and bylaws for VCA transplant.

A member highlighted that a lot of surgeons who perform VCA transplants are also plastic reconstructive surgeons, so they will still have expertise. The Chair noted that it has been a few years since their program performed a VCA transplant, however, their program still can perform one, should another potential recipient need to be listed at their program.

Next steps:

The OPTN Contractor will continue to monitor the data and trends surrounding VCA transplantation.

8. Update: OPTN Expeditious Task Force

The Committee received a presentation regarding updates from the OPTN Expeditious Task Force.

Summary of discussion:

There were no decisions regarding this item.

The Chair referenced earlier conversations from the meeting, specifically regarding how to find candidates and refer them to VCA transplant, citing that this is a challenge for the field. They questioned if that would fit into the Task Force's initiatives. OPTN Contractor staff noted that the primary focus of the Task Force at this time is on kidney transplants, however, they are trying to think across the organ groups.

Next steps:

The Committee will continue to receive updates about the OPTN Expeditious Task Force as they become available.

9. Project Brainstorming

The Committee reviewed the different types of Committee projects and discussed potential new project ideas.

Summary of discussion:

There were no decisions regarding this item.

Limb Loss and Preservation Registry (LLPR)

This registry is a quality improvement initiative for those who have lost limbs or are going through limb preservation efforts. It collects data from hospitals and orthotics organizations, specifically on the social determinants of health. It is currently funded by the U.S. Department of Defense (DoD) and the National Institutes of Health (NIH); thus, program participation is currently free.

A member suggested leveraging the LLPR to identify individuals who may not know they are potential candidates for VCA transplant. They elaborated that this registry may also aid in understanding outcomes, as they encourage patient-reported outcomes via an online portal. A member said they were familiar with this registry and their institution considered using it, however, there was a fee to use it, so they decided to not move forward with it.

A member recommended that the Committee write a white paper or concept paper surrounding the registry to bring awareness to it. A member recalled when the Committee looked into using a database to track children born from uterus transplant recipients but determined that may not be in the scope of the Committee's work. They suggested that working with a database or registry like this is useful for sharing knowledge and expertise within the VCA community, as it would be helpful to have, especially

when trying to grow the field. The Committee agreed to continue to explore ways to fit the LLPR into an OPTN project.

Needs Assessment Idea

The Chair indicated that this would fit nicely into the previous discussion, whether it was through collaboration with a registry or something that the Committee develops. They added that this is one of the biggest challenges when it comes to VCA transplantation, as many potential VCA recipients may not even realize that VCA transplant is an option.

Review/Update Membership Requirements

A member voiced their concern that the medical director for VCA transplants must go on two donor recoveries. The Chair noted that is the requirement for all solid organs as well and believes that it is a valuable experience since medical directors will be able to conceptualize the organ donation and procurement process and some of the issues that arise during the process. A member asked if medical directors were involved in dealing with those issues. The Chair indicated that sometimes they are, but it's most valuable for contextualizing the process and for medical staff to understand what surgical staff do and vice versa.

Open Discussion

A member suggested creating a patient and provider-facing site that shows the active programs and lists contact information for those programs. After being shown the OPTN membership directory on the OPTN website, a member commented that the field is not big enough for the resource to be useful. They followed up indicating that it would be helpful to have a list of centers actively recruiting.

A member commented that although they find this resource helpful, they would appreciate if it were more robust and easier to locate. They added that on the Patient page of the OPTN website, there is no link for VCA patients, which is something that should be considered. A member agreed that it is challenging to find contact information for these programs and could leave someone frustrated, especially if they are not familiar with VCA and are trying to learn more. They added that although a VCA OPTN resource for patients and providers would be helpful, they encouraged other Committee members to think of creative ways to display this information. They suggested including a resource for providers that gives VCA specialists names and information so that they can receive referrals and inform them about the OPTN's process for VCA transplants. A member agreed, emphasizing the need for a reputable resource and location to inform others about VCA, especially as the field continues to grow since that will be harder for providers to keep track of.

A member suggested that VCA programs are more transparent about their data, specifically how many patients each program listed for each month. They added that having real-time information about each program will demonstrate which programs are active or inactive. The Chair liked the idea of becoming more transparent but cautioned the Committee that due to the small number of VCA transplants, the data could potentially become identifiable. A member advised using binary variables such as yes or no questions to provide information to accommodate for patient confidentiality. A member likened this issue to intestinal transplant programs, as they also have small volumes.

The Vice Chair raised the concern that with eye transplants now occurring, should there be a separate requirement for eye transplantation since it is different than face transplantation in terms of credentialing, as well as who these patients are, and metrics of success and failure. They added that they want to look at this idea proactively since eye transplantation currently falls under "Head and Neck" within the OPTN. They mentioned that the eye is not specifically mentioned, however, the

definition of “Head and Neck” includes “other vascularized structures”, which encompasses eye, but the Vice Chair is questioning if it should be explicitly mentioned.

A member agreed, citing that they always appreciate having expertise in designated areas. They added that there would be immediate value in helping grow the field by adding the expertise to help guide the initial endeavors. They noted that when other programs begin performing eye transplants, having the expertise to help shape the future would be beneficial. They suggested bringing in experts, including the NYU team, to begin thinking about what this expertise may look like in practicality. The Vice Chair suggested executing this idea in the form of a white paper, as it is a conceptualized future state in which eye transplants are regularly performed.

The Chair questioned if the appropriate vehicle for this idea is through the OPTN. A member agreed, adding that there is not much information out there for the Committee develop a white paper on the topic. The Chair indicated their uncertainty if this is the time to be doing this project, as there is still so much to be learned in the field.

Next steps:

The Committee will continue to brainstorm ideas for potential projects at future meetings.

10. Outgoing Committee Member Recognition

The Committee reviewed the different types of Committee projects and discussed potential new project ideas.

Summary of discussion:

There were no decisions regarding this item.

The Committee recognized the following outgoing Committee members: Amanda Gruendell, Elizabeth Shipman, Sandi Amaral, Donald Rickelman, and Brian Berthiaume and thanked them for their years of dedication to the Committee.

Upcoming Meetings

- April 25th, 2024, at 4:00 PM ET (teleconference)
- May 22nd, 2024, at 4:00 PM ET (teleconference)

Attendance

- **Committee Members**
 - Sandra Amaral
 - Vijay Gorantla
 - Brian Berthiaume
 - Charlie Thomas
 - Christina Kaufman
 - Elliott Richards
 - G. Scott Winder
 - Paige Porrett
 - Anji Wall (virtual)
 - Gregory McKenna (virtual)
 - Rick Redett (virtual)
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Asma Ali
 - Eric Messick
 - Houlder Hudgins
 - Jesse Howell
 - Kaitlin Swanner
 - Kayla Balfour
 - Kayla Temple
 - Kristina Hogan
 - Leah Nuñez
 - Morgan Jupe
 - Nadine Hoffman
 - Sevgin Hunt
 - Susan Tlusty
 - Tamika Watkins
 - Viktoria Filatova
- **Other**
 - Bruce Gelb (Former OPTN VCA Committee Member)
 - Dianne LaPointe Rudow (OPTN Executive Committee President)
 - Jesse Schold (Vice Chair, OPTN Data Advisory Committee)
 - Lara Danziger-Isakov (Chair, OPTN Ad Hoc Disease Transmission Advisory Committee)