OPTN Vascularized Composite Allograft Transplantation Committee
Meeting Summary
August 15, 2022
Conference Call

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

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee met via Citrix GoToMeeting teleconference on 08/15/2022 to discuss the following agenda items:

1. The First Successful Combined Full Face and Bilateral Hand Transplant
2. Breakout Sessions: Update Guidance on Optimizing VCA Recovery for Deceased Donors
3. Public Comment Proposal: Transparency in Program Selection
4. Overview of VCA in UNet^{sm}
5. Continuous Distribution Update
6. Research Orientation
7. Update on VCA Waiting List and Transplants
8. SF-12 Questionnaire Form

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

1. The First Successful Combined Full Face and Bilateral Hand Transplant

The Committee heard a presentation about the first successful combined full face and bilateral hand transplant, which included background information about the recipient of the face and bilateral transplant, the process, stakeholder engagement, and post-transplant results of the recipient.

Summary of discussion:

A Committee member stated that the recipient had burns all over his body, and his fingers were amputated. The member then questioned if the VCA transplant team was able to preserve any nerves and use them in the patient's hands for quicker functionality.

The presenter responded that nerve rehabilitation is performed in the forearm and stated that sensation comes back rapidly in VCA patients. In this circumstance, the patient was referred to VCA early and had some healing skin grafts when he was admitted to the hospital. The patient has tactile sensation in his proximal hand and currently has two-point discrimination sensation in his fingertips.

A member pointed out that historical protocol notes that prosthetics must be used for a minimum of 6-12 months. The member asked about the reasoning for using a prosthetic on a patient who has experienced significant burns.

The presenter explained that the rationale behind using prosthetics for 6-12 months is due to evidence that prosthetics can be equal to or better than a transplant and 6-12 months is an adequate timeframe for a patient to learn how to use a prosthetic. However, the patient who received a face and bilateral hand transplant had severe bilateral injuries, and there wasn't a prosthetic that could do the form and function needed. Another option was to transplant the right hand and use a prosthetic on the left hand.

Another member asked if there were discussions about using sentinel flaps to monitor rejection.

The presenter replied that using sentinel flaps was an option to monitor rejection; however, most biopsies are performed on the side of the neck with a transplant.

2. Breakout Session: Update Guidance on Optimizing VCA Recovery for Deceased Donors

Committee members split into breakout session groups to discuss the different sections of the guidance document to identify places that may need updating once VCA in the OPTN Computer System is implemented and presented their recommendations to the full Committee.

Summary of discussion:

Group 1: Strategic Decision to Participate in VCA Donation

Members in this group identified that language should be updated to refer to match runs rather than candidate list. Members of this group inquired about how to promote collaboration at centers that do not have a VCA program. The speaker of this group referenced the previous presentation, and pointed out that the VCA team who performed the transplant is an excellent example of what collaboration between OPOs and VCA programs should represent. The group speaker suggested recognizing participating OPOs and VCA programs using star ratings and Centers of Excellence. Another member emphasized that OPOs and VCA programs working jointly rather than individually is critical because it allows for clear communication and collaboration.

When locally relocating a donor from the OPO center to the VCA program, the group felt that OPO staff should travel to the VCA program or move the donor to an OPO with experience. The group suggested including language within this section regarding fostering mentorship amongst inexperienced OPOs.

Group 2: Planning and Hospital Partnerships

This group suggested adding metrics and stratification of hospitals to align with eligible donors focusing on the higher-rated donor hospitals. The group's speaker recommended adding guidance for limiting OPO and donor hospital personnel for privacy and recovery team focus and education. The group noted that it might be challenging to limit OPO personnel due to staff shift rotations every twelve hours.

Group 3: Family Support and Authorization Approach

The members of this group support the current VCA authorization approach, which states that effective VCA authorization practices show that VCA authorization should occur after authorization for organ and tissue donation. The group emphasized keeping the authorization forms separate. The members in this group also discussed if the VCA committee had previously surveyed or had previous projects asking family donors about their thoughts on time preference when asking for VCA authorization.

During the April VCA meeting, there was a recommendation that crossmatching should not be completed until the donor family has given consent. The group speaker stated that the timing of the crossmatch has not been problematic because VCA authorization does not preclude organ and tissue authorization. Crossmatch is already completed for solid organs before VCA recovery, so the group does not feel that there is a problem with completing crossmatch ahead of time with consent.

Another group member noted that there are educational resources available on VCA donation and transplantation, which have been effective in showing donor families how the VCA authorization process works and encouraged the Committee to reference these resources in the guidance document.

Group 4: Criteria for the Evaluation of Donors for VCA Transplantation

The members of this group agreed with the previous recommendations to update the language regarding Public Health Services (PHS) terminology. The group noted that the language within this section regarding VCA matching is specific to non-uterus VCAs, such as faces and hands. However, additional detail about matching all VCA types should be included with subsections that could provide examples of how to navigate through VCA recipient matching challenges. The group speaker added that a separate section that addresses the evaluation of the living donor should be included within the guidance document.

Next steps:

Seek OPTN Policy Oversight Committee for project approval and work on finalizing the updated guidance sections and language.

3. Public Comment Proposal: Transparency in Program Selection

The Committee heard a presentation from the OPTN Ethics Committee about the summer 2022 public comment proposal, Transparency in Program Selection.

Summary of discussion:

A member of the Committee asked if Medicare and Medicaid pay for VCA transplants.

A member of the committee replied that transplants are covered by Medicare and Medicaid on a case-by-case basis.

A member asked how this information is collected when asking the community what factors are important to patients when selecting a transplant program.

The presenter replied that the Ethics Committee includes donors, recipients, and family members of donors and recipients and their feedback was captured when creating the proposal. The speaker stated that comments have been collected on this proposal and much of the feedback has been from members of the community and recipients.

The presenter noted that for solid organs, such as kidney, patients may have the option of choosing between 2-3 kidney programs that are relatively close by, whereas VCA programs tend to be smaller. The speaker asked in terms of program selection, is the patient population likely to change in terms of choosing a center?

A member replied that an important consideration for patients is the duration that they will be spending at that center in the early post-transplant period. For example, if a patient must travel a long way they may be living at that center for a while. Another member noted that caregivers should be taken into consideration when selecting a transplant program.

The speaker asked the Committee about their thoughts on sharing listing criteria for VCA patients ahead of time.

A member stated that sharing listing criteria ahead of time can be challenging because VCA programs are unique and are patient specific. It was also noted that oftentimes, selection committee decisions are made based on a combination of factors, good judgment, and experience, and it is very challenging to be able to educate and explain the different factors ahead of time.

A member commented that another important factor to consider when selecting a transplant program is the level of expertise in reconstructive surgery outside of transplantation, which may affect how an

individual would choose a VCA center because sometimes the center is not performing VCA transplants, but instead reconstructive surgery.

The presenter asked if the Committee had any thoughts on that level of experience and expertise.

A member answered that the level of experience and expertise can be expressed through the composition of the team. Additionally, in some programs such as kidney or liver, patients will look at how programs compare by volume. However, most programs will not have a high volume but were selected due to the depth of expertise.

4. Overview of VCA in UNet

The Committee heard an overview of the VCA policy projects that are pending implementation and the system process changes as a result of these projects.

Summary of discussion:

A member of the Committee shared that at a conference, transplanted patients stated that they want more data on the quality of life and way to report patient outcomes. The member also commented that it is important to be specific about follow-up outcomes and functional status, such as the ability to drive, grip strength, or use a cell phone and be able to capitalize on patient engagement.

A Committee member asked, in terms of implementing VCA into the OPTN Computer System, if there will be a need to show the community how to navigate the new system, and if so, what educational resources would be helpful.

A member stated that some VCA programs are affiliated with transplant programs, therefore, the program has coordinators who are familiar with UNet. The member suggests that if a VCA program is affiliated then it may be helpful to recruit people who are familiar with the system. The member also suggested that a video or training be created for people who do not know how to use the OPTN Computer System.

A member commented that VCA programs may have 1–2-point people who enter information into the system and the people may have different positions.

A member asked when entering information into the current form, are electronic health records utilized so that they can seamlessly transfer over the information.

A member responded that some information will pull into the OPTN Data System from electronic medical records, but a majority of the data entry is manual.

5. Continuous Distribution Update

The Committee heard an update about Continuous Distribution.

Summary of discussion:

A member asked when the committee begins working on Continuous Distribution VCA, is it okay to have different scores for different VCA types?

The presenter replied that more discussion is needed when we begin to work on continuous distribution VCA. The presenter explained that kidney is rated based on their KDPI and has different match runs. Similarly, VCA could have a different match run for the different types of VCAs.

Another member asked when the Committee will begin working on Continuous Distribution VCA.

The presenter responded that Continuous Distribution VCA is slated for 2024.

6. Research Orientation

The Committee heard a presentation from the Research Department about their role in OPTN committee support.

7. Update on VCA Waiting List and Transplants

The Committee heard an update on the VCA waiting list and transplants.

Summary of discussion:

A member asked if patients on the waiting list data were active the whole time or were some inactive.

The presenter replied that the figure shown did not take into account the times a patient may have been registered but inactive on the waitlist.

A member asked if someone is receiving a uterus living donor, is that person listed on the deceased donor list as inactive, or are they not listed at all.

A member responded that at their center, the recipient is listed but the recipient is not set up for deceased donor transplant because there are lots of living donors.

A member asked if there is an understanding of why upper limb has been inactive for the last two years.

A member responded that it could be attributed to insurance issues and the slowness of reactivation since COVID.

8. SF-12 Questionnaire Form

The speaker informed the Committee about the evolution of the SF-36 questionnaire form to the SF-12.

Summary of discussion:

A member of the Committee asked questions from the SF-12 questionnaire form that can be retrieved and used from the SF-36 form.

The speaker replied that the SF-36 may be free, but the SF-12 may need to be purchased from the company that produced the form. The speaker stated that the SF-12 questions could be found within the SF-36 questionnaire form.

A member asked how the SF-12 would form be used.

The speaker answered that SF-12 would be similar to using the SF-36. The company has a computer-based way to scan in the form or an easy rubric for scoring the form. The speaker explained at their center, a bubble form format SF-12 form is used to fill out, then it is scanned into a machine and then generates the answers. The speaker also suggested calling the company that produces the SF-12 and receive additional details.

Upcoming Meeting(s)

- September 28, 2022
- October 26, 2022

Attendance

- **Committee Members**
  - Sandra Amaral
  - Vijay Gorantla
  - Amanda Gruendell
  - Anji Wall
  - Brian Berthiaume
  - Bruce Gelb
  - Bohdan Pomahac
  - Charlie Thomas
  - Christina Kaufman
  - Debra Priebe
  - Elizabeth Shipman
  - Liza Johannesson
  - Lawrence Gottlieb
  - Lori Ewoldt
  - Paige Porrett
  - Ryutaro Hirose
  - Stefan Tullius

- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Tamika Watkins
  - Kelley Poff
  - Lauren Mauk
  - Catherine Parton
  - Cole Fox
  - James Alcorn
  - Krissy Laurie
  - Laura Schmitt
  - MiYoung Kwon
  - Sarah Booker
  - Stryker- Ann Vosteen
- **Other Attendees**
  - Sheila Jowsey- Gregoire
  - Sena Wilson-Sheehan