

OPTN/UNOS Vascularized Composite Allograft Transplantation Committee
Meeting Minutes
July 11, 2018
Conference Call

Linda C. Cendales, M.D. – Chair
Bohdan Pomahac, M.D. – Vice Chair

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee met via conference call on July 11, 2018, to discuss the following agenda items:

1. Welcome and Introduction of New Members
2. Impact of Geography Discussion & Critical Comment to Department of Health and Human Services (HHS)
3. Project Brainstorming

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

1. Welcome and Introduction of New Members

The Chair welcomed everyone to the new term of the Committee, and introduced two new members. Both members bring a wealth of expertise to the Committee and will be serving three year terms as at-large representatives.

2. Impact of Geography Discussion & Critical Comment to Department of Health and Human Services (HHS)

UNOS staff provided an update re: the impact of discussion on use of Donation Service Areas (DSAs) or regions in organ allocation policies.

Summary of the Discussion

The Committee was previously briefed on June 13, 2018 to ensure the Committee was aware of the discussions. On June 25, 2018, the OPTN response to HHS was that the use of DSAs and regions really was not rationally determined or consistently applied. The OPTN/UNOS Liver and Intestine Committee is moving forward with a plan to eliminate the use of DSAs and regions in liver distribution, and it will be done in a very quick manner hoping to have Board consideration in December of 2018.

UNOS staff then shared the implications for the VCA Committee. OPTN Policy 12.2 *VCA Allocation* uses regions as the first level of allocation. As a result, the Committee needs to temporarily pause work on the future project on *VCA Transplant Outcomes* and develop amendments to OPTN Policy 12.2 to ensure compliance with the OPTN Final Rule. UNOS staff affirmed this is not an opportunity to radically modify the VCA allocation policy. The goal of the discussion would be to have a bit of language voted on in the next few months that could go out for public comment in January of 2019.

With the intent of informing future discussions on these policy amendments, UNOS staff then asked the members to share their respective experiences with VCA offers and distances traveled for successful VCA recoveries. Members commented that they are receiving offers from OPOs with donors with good clinical profiles, but these are frequently declined due to distance. There was variability shared regarding the distances recovery teams were willing to consider offers, from no further than immediate adjacent states to distances up to 1,000 nautical miles from the VCA program. Successful VCA transplants were also recovered over varying

distances. However, the primary considerations appeared to be based on the clinical decision making of the teams (e.g.: appropriate match for the potential recipient, within acceptable cold ischemic times, etc...), the distance from the transplant center to avoid long ischemia times (e.g. a transplant center from Philadelphia declined an offer from Texas, another center in Durham declined an offer from California, and a center in Baltimore has declined offers due to distance), and within the parameters of their institution's Institutional Review Board (IRB). Whether the donor was located inside or outside the same region of the VCA program did not appear to play a role in whether to accept or decline a VCA offer.

Members revisited issues of VCA priority (whether candidates with certain sequella should have higher priority over other candidates), the matter of long waiting times for some VCA candidates due to sensitization or matching challenges, and the need to identify more deceased VCA donors. Some members shared the practice of VCA transplantation is still very young, and a body of data needed to inform future policy decisions (re: candidate priority and the role of candidate sensitivity) was accumulating.

UNOS staff shared that the Committee did discuss the heart allocation model in 2014; allocation begins within a 500 nautical miles radius of the donor hospital/recovery facility. The Committee felt this approach had promise, but more time was needed to gather donor and recipient information, and get an understanding of the transplant outcomes.

Near the conclusion of the call, UNOS staff recommended the concept of removing "region" as the first level of VCA distribution. The change would mean deceased VCA donors and potential recipients would continue to be matched based on ABO compatibility between the donor and potential recipient. Removing region as the first level of VCA distribution would mean potential recipients would be ranked nationally based on waiting time. UNOS staff commented this change would ensure compliance with the OPTN Final Rule, can be accomplished within the constraints mentioned above, and would be minimally impactful to VCA transplant programs. VCA transplant programs would continue to receive offers, and transplant teams would continue to determine acceptance based on the considerations above. This change would be consistent with the current manner of VCA allocation once an OPO moves outside their respective region.

One member asked whether the OPTN was tracking all VCA offers, whether they result in a transplant or not. UNOS staff responded that Organ Procurement Organizations (OPOs) are required to tell OPTN how their staff allocated VCAs by sending a copy of the VCA candidate list with either bypass codes or refusal, whatever the reasons are. However, this is only done in circumstances when a VCA is successfully allocated for transplant. The VCA candidate lists are not required to be sent to the OPTN in all instances when VCA donation is screened. Some OPOs are good about sending this level of information, but other OPO do not send this information. Members verbalized their concern that that some OPOs may not be entirely familiar with the process of referring a VCA donor. UNOS staff indicated that the Committee's recent guidance to *Optimize VCA Recovery from Deceased Donors* is available on the OPTN website, and a companion education module for OPOs will be developed.

At the conclusion of the call, members were asked to give this model some careful thought, and discussions would resume on the August 8th call.

Next Steps:

UNOS Research will gather available data on three areas; VCA distribution (local, regional, national), distances traveled by VCA recovery teams, and cold ischemic times reported to the OPTN. These data will be reported on August 8th.

3. Project Brainstorming

The project brainstorming discussion was tabled for a future call/meeting.

Upcoming Meetings/Calls

- Conference Calls -- Second Wednesday of each month from 4-5PM (Eastern)
- In-person meetings (O'Hare Hilton--Chicago, IL)
 - October 12, 2018, 9 AM - 3 PM (Central)
 - March 29, 2019, 9 AM - 3 PM (Central)