

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
August 8, 2018
Conference Call**

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

Introduction

The VCA Committee met via teleconference on August 8, 2018 to discuss the following agenda items:

1. Public Comment Proposal - *Frameworks for Organ Distribution*
2. Project Discussion – *Eliminate the use of Regions in VCA Allocation*

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

1. Public Comment Proposal - Frameworks for Organ Distribution

The Committee heard a presentation on the OPTN/UNOS Ad Hoc Geography Committee’s proposal *Frameworks for Organ Distribution*.

Summary of discussion:

The goal of this concept document is to identify a single, preferred distribution framework to be used across organs. The three frameworks include:

- Fixed distance from a donor hospital
- Mathematical Optimization
- Continuous Distribution

Members discussed each model and commented that simplicity in a model was very relevant for VCA currently. Members noted the fixed distance model appeared to hold the most potential for VCA transplantation in the very near term. One member cautioned against choosing distances that were not directly connected to elements of the OPTN Final Rule as this approach could be considered arbitrary. Members verbalized agreement with this sentiment, noting it was important to use the OPTN data currently available and other data that was readily accessible. The timeframe for policy changes does not permit an exhaustive review of all available data. Another member verbalized the use of the fixed distance framework may require periodic amendments to OPTN policy language to reflect advances in technology and medical care. One guest attendee from the OPTN/UNOS Transplant Coordinators Committee shared the fixed distance model has increased the travel and cold ischemic times for deceased donor lungs, and a similar effect may be seen from using this model with other organs. One member noted that a fixed distance circle located near a coastline of national boarder would extend over areas where there are no transplant programs or candidates waiting for a transplant. UNOS staff acknowledged this factor, noting one of the other models may be better suited to account for this geographic issue.

Members discussed the mathematical optimization model briefly, expressing the complexity of this model was not well-suited for VCA at this time. This approach may be better suited for organs with greater experience and greater case volumes. One member shared this model appeared to still have the potential for transplant candidates being “stuck on the edges” of boundaries, even if only be a few miles. Another member shared that this model may engender

problems for a transplant hospital in proximity to an under-performing OPO and this may create unintended inequities in organ distribution.

Members discussed the continuous sharing model briefly, also expressing this model was not well-suited for VCA at this time. Members expressed the body of data to make informed decisions on this model was still accumulating, the field is currently working towards consensus on definitions of success and definitions of outcomes, and the idea of “medical urgency” in this model was not a good match for VCA transplants. UNOS staff shared that other metrics, such as waiting time, could be considered in this model in lieu of “medical urgency”.

Despite the complexity of the mathematical optimization and continuous distribution models, members felt each had promise for VCA allocation in the future and once the numbers of VCA transplants increase. The Committee commended the Geography Committee for their forward-thinking work, and appreciated the opportunity to provide feedback on this concept document.

Next steps:

UNOS staff will draft a response on the proposal from the VCA Committee and share with leadership for review. Thereafter, it will be posted on the OPTN website.

The Chair thanked UNOS staff for the presentation and segued to the next topic on the agenda.

2. Project Discussion – Eliminate the use of Regions from VCA Allocation

Members began discussions on a project to remove the use of regions from OPTN Policy 12.2 *VCA Allocation*.

Summary of discussion:

UNOS staff shared an update with the Committee regarding the need to amend OPTN Policy 12.2 *VCA Allocation*. This OPTN policy currently uses OPTN regions as the first level of VCA distribution. A recent directive from the Secretary of Health and Human Services (HHS) requires any OPTN policy that uses Donation Service Areas (DSAs) or regions be amended to be in compliance with the OPTN Final Rule. Committee members were apprised of the potential for such a project during their June and July 2018 conference calls. Members verbalized understanding of the need to execute this policy language amendment project and temporarily pause other project development discussions.

Over the course of the discussions, UNOS staff reinforced that it would not be defensible to simply use data describing the current function of the VCA allocation policy in order to derive distances for VCA distribution. The rationale to use an identified distance(s) must be data driven and linked to the OPTN Final Rule. UNOS Research staff then shared a report on OPTN data for VCA transplantation, including:

- VCA transplants to-date
- VCA distribution rates since July 3, 2014
- Travel distances for VCA procurements
- VCA cold ischemic times (CIT) since July 3, 2014

Members expressed their appreciation for this first batch of data. One member asked, what role international VCA data could play in this discussion. UNOS staff will explore this idea and provide an update at a future call.

At the conclusion of the presentation, the Chair verbalized the creation of a Subcommittee as a next step to meet weekly with the goal to develop the needed changes to VCA allocation policy. Volunteers were asked to respond back to the UNOS staff liaison as soon as possible. Also, volunteers were sought to help with literature review for papers/manuscripts from the orthopedic

and reconstructive surgery realms that talk about ischemic time and outcomes. These data will help with the future Subcommittee discussions and policy development.

Next steps:

UNOS staff will solicit volunteers for the VCA Geography Subcommittee. Members were asked to review pertinent literature from the orthopedic and reconstructive surgery communities and share with the Committee.

With no further business to discuss, the call was adjourned.

Upcoming Meeting

- Full Committee Conference Calls -- Second Wednesday of each month from 4-5PM (Eastern)
- VCA Geography Committee Conference Calls – Weekly on Fridays from 11 AM-12 PM (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)