

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
October 12, 2018
Chicago, IL**

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

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee (Committee) met in Chicago, IL on October 12, 2018 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Update on OPTN Committee Projects Addressing the Use of DSAs or Regions in Organ Allocation Policy
3. Eliminate the Use of Regions in VCA Distribution
4. Project Discussion: VCA Transplant Outcomes
5. Latest VCA Data
6. Update from 2018 Chauvet Workshop
7. Committee Project Portfolio Review & Brainstorming
8. Update from American Society of Transplant Surgeons (ASTS) VCA Committee

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

1. Policy Oversight Committee Update

The Vice Chair shared an update from recent OPTN/UNOS Policy Oversight Committee (POC) conference calls.

Summary of discussion:

The Vice Chair began the presentation by briefly summarizing the purpose of the POC. He then shared an update of the POC's recent work, including:

- Help developing the response to HRSA re: use of DSAs and regions in organ distribution policies
- Consideration of six proposals for public comment (August-October 2018)
- Consideration of one proposal for special public comment (October 8-November 1, 2018)
- Review of two new projects from other OPTN committees

UNOS staff then profiled where the Committee's ongoing project appears in relation to other Goal Two projects (the "maturation chart"), and the raw project counts for the Committee.

The Chair thanked the Vice Chair and UNOS staff for their presentation and opened the floor for discussion.

Next steps:

The Vice Chair will continue to remain engaged with the POC and provide periodic updates to the Committees.

2. Update on OPTN Committee Projects Addressing the Use of DSAs or Regions in Organ Allocation Policy

UNOS staff provided an overview of other OPTN projects dealing with removing DSAs or regions from organ distribution policies.

Summary of discussion:

UNOS staff provided updates on the activities of the Kidney, Liver, and Thoracic Committees who are discussing how to amend respective sections of OPTN Policy to be in compliance with the OPTN Final Rule.

- *Liver*
 - Feedback will be sought during a special public comment period in October 2018 on fixed distance model.
 - Allocation to candidates within 150, 250, or 500 nautical miles (nm) based on urgent status listing and MELD/PELD scores before national allocation
 - Other policy changes will be made, including prioritizing livers from deceased donors < 18 years old to liver transplant candidates < 18 years old.
- *Thoracic*
 - Requested modeling from the Scientific Registry of Transplant Recipients (SRTR) on replacing DSA with 150, 250, 500 nm based distances from a donor hospital. This will be available in late-October 2018.
 - Public comment will be sought in January 2019.
- *Kidney/Pancreas*
 - Feedback is being sought on fixed distance model and a hybrid proximity points model. The Kidney Committee is awaiting SRTR modeling report on replacing DSA & region with 150, 250, 300, 500 nm, then national allocation based on ABDR match, CPRA, ABO identical/compatible. A hybrid model using points added to a kidney candidate's score based on proximity to a donor hospital was also requested. This model uses a single 500nm radius to replace DSA and region.
 - Public comment will be sought in January 2019.

The Chair thanked UNOS staff for the update and opened the floor for discussion. Members inquired how other committees were dealing with the issue of states that were near coastal or boarder areas. UNOS staff reported this was a short-coming in the fixed distance model. Other committees were aware of this short-coming, but it was a consistently applied organ distribution model that was in compliance with the OPTN Final Rule. The use of this model was accepted as a means to reduce the legal risk in the near-term, knowing future policy changes would move towards a more advanced model that would mitigate the impact of costal and boarder areas.

The Chair then transitioned to the next item on the agenda.

3. Eliminate the Use of Regions in VCA Distribution

UNOS staff and VCA Geography Subcommittee members updated the Committee on progress amending OPTN Policy 12 to remove the use of "regions" and replace with another geographic boundary.

Summary of discussion:

The Chair commended members of the Subcommittee and UNOS staff for assertively and diligently working on this project. The Chair shared the goal of this discussion was to approve draft changes to OPTN Policy 12.2 *VCA Allocation* and vote whether to solicit public comment on the draft changes. UNOS staff verbalized support for the Chair's comments and also

reminded the Committee was to draft policy language changes that were compliant with the OPTN Final Rule. A secondary consideration was to have language that had a measure of policy durability so frequent changes would not be required, and the language would keep pace with the clinical practice of VCA transplantation.

The VCA Geography Subcommittee has held weekly conference calls to discuss changes to OPTN Policy 12.2 *VCA Allocation*. The Subcommittee's early discussions centered on the three frameworks identified by the OPTN/UNOS Ad-hoc Geography Committee (fixed distance, mathematical optimization, and continuous distribution). While the Subcommittee members verbalized interest in a more advanced model of allocation, a fixed distance model was ultimately chosen. The rationale for this was the time constraints for development, and the relatively low case volume to-date low amount of VCA outcome data to make an informed policy decision on an advanced distribution model.

Subcommittee members diligently discussed the early desire in the field to keep cold ischemic times (CIT) as short as possible, and the clinical similarities of ischemic reperfusion injury effect on skeletal muscle and cardiac muscle. The latter was the rationale for using heart CIT tolerances of four to six hours. Members recognized that some VCA programs appeared to be traveling farther distances (based on OPTN data). But there was not yet a robust data set available through the OPTN or other sources (both domestically and internationally) correlating CIT and VCA transplant outcomes. Members discussed available literature reports of CIT in VCA transplantation, but these papers were also not able to correlate CIT and VCA transplant outcomes. Members did report there was some use in considering current clinical guidance from limb replantation/reconstruction that did correlate CIT with post-surgical outcomes. Members recognized weakness in direct correlation with VCA transplantation; the presence of high energy trauma preceding replantation and the absence of the same in VCA transplantation, and the use of preservation solutions in VCA transplantation and the absence of the same in replantation/reconstruction. As in transplantation of other organs, the available resources showed the least amount of CIT generally supported better outcomes.

The Subcommittee then discussed what distances may be appropriate. Three distances from a donor hospital were considered, 250 nautical miles (nm), 500 nm, and 750 nm. Members agreed that it was premature to develop different distances for each VCA type, and it was prudent to develop policy language that applied to all VCAs. There was diversity in opinions about which distance from a donor hospital may be appropriate. A 250 nm distance would keep initial offers close to a donor hospital and promote the optimal chance of VCA being accepted and transplanted with low CIT. Members shared that this was an option, but VCA programs reported good transplant results at distances greater than 250 nm. A 500 nm distance was also discussed and this had good initial support by Subcommittee members. This distance was approximately equal to one hour of flight time and members felt this would not substantially contribute to overall CIT in VCA transplants. One member did share that the 500 nm distance would have varying impact across the U.S. Some geographic areas would see an increase in access to VCA offers over the current regional allocation and some areas would see a decrease in access. Also, there issue of a lack of potential donors in coastal and boarder areas was shared. Based on discussion, some Subcommittee members felt it was reasonable to consider a 750 nm distance from a donor hospital. Members verbalized there was a small increase in CIT when travel by aircraft went from 500 nm to 750 nm. They felt this small increase would not impact graft outcomes. However, there was not consensus on this distance as some members felt 750 nm was excessive. The Subcommittee did also discuss distances greater than 750 nm. However, it was felt a larger fixed distance for VCA allocation would engender system inefficiencies for allocation and may have create a dis-incentive for organ procurement organizations (OPOs) screening deceased donors for VCA donation.

Members acknowledged it was important to move forward with a recommendation to the Committee. As a result, the Subcommittee asked the Committee to carefully consider replacing “region” in Policy 12.2 with either 500 nm or 750 nm fixed distance from the donor hospital.

The Chair thanked UNOS staff for the project update and opened the floor for discussion. Members held a lengthy discussion on the recommendations from the Subcommittee. This included:

- Uses of either 500 nm or 750 nm distances. Members verbalized the 500 nm distance may have a limiting impact on coastal and border states (organ donors are not identified outside these geographic boundaries). As flight time is one contributor to overall CIT and the flight time difference between traveling 500 nm and 750 nm was small, using 750 nm would be appropriate to compensate for the decreased donor availability that may impact some VCA programs from using 500 nm.
- The impact of the policy change to VCA programs located in smaller regions by transitioning to a 500 nm fixed distance (increased access to potential VCA donors), and the impact to those VCA programs located in larger regions by transitioning to a 500 nm fixed distance (decreased access to potential VCA donors).
- The need to not “dis-incentivize” OPOs by maintaining the current VCA allocation system in rudimentary state of function, and make enhancements to the system to enhance function.

UNOS staff reminded the Committee that the policy changes need to be in compliance with the OPTN Final Rule and reviewed the clauses. The Committee felt the data available in either OPTN or non-OPTN sources did not yet definitively correlate transplant outcomes with CIT. However, the available data did guide the Committee’s discussions, and the Committee was committed to making an informed discussion based on what was currently available. Thus, distribution within either a 500 nm or 750 nm distance followed by national distribution was consistent with 121.8(a) 1 (based on sound medical judgement), and 121.8(b) 3 (distributing organs over as broad geographic area as feasible). Also, the Committee felt by continuing the practice of a two-step allocation system and replacing “region” with a consistently applied geographic boundary was consistent with 121.8(a) 5 (avoid wasting organs, promote patient access to transplantation, and to promote efficient management of organ placement).

At the conclusion of the discussion, a majority of members supported seeking public comment replacing “region” with a single 750 nautical mile distance from a donor hospital. Members commented this distance was based on the data available, was the most inclusive based on the data, and based on input from experts on the Committee using sound medical judgement. UNOS staff shared that feedback in the proposal could be sought if the community felt another distance was appropriate. Members agreed with this approach and looked forward to reviewing feedback from the transplant community and other stakeholders.

Members then inquired whether other amendments to OPTN Policy 12.2 were being considered within the scope of this project. UNOS staff responded that other changes were not being recommended by the Subcommittee. If VCA offers were declined by for all transplant candidates within the new geographic boundary, allocation would continue to candidates outside the boundary.

A motion was made and seconded to approve policy language changes to OPTN Policy 12.2 as described above, and recommend to the POC that public comment be sought on the proposed changes (yes – 13, no – 0, abstain – 0).

Next Steps

UNOS staff will prepare the public comment proposal consistent with this Committee and Subcommittee's discussions.

The POC and Executive Committee will consider the recommendation for public comment in January 2019.

The Chair then transitioned to the next item on the agenda.

4. Project Discussion: VCA Transplant Outcomes

The Committee resumed discussions to develop a project on assessing VCA transplant outcomes.

Summary of discussion:

In July 2018, the Committee was asked to pause discussions on a project assessing VCA transplant outcomes and redirect to a project addressing potential noncompliance of VCA allocation policies with the OPTN Final Rule. As the Committee recently voted on draft language addressing the aforementioned compliance issue, members expressed interest in returning to the project development discussions.

The Vice Chair shared a brief development history to-date. This included:

- Good alignment of this project with priorities of the VCA transplant community.
- High level understanding with Subcommittee members where gaps in OPTN data exist.
- Understanding of the challenges posed by diverse functional goals across VCAs, and event across candidates within the same type of VCA.
- Acknowledgement that VCA transplant outcomes may not be seen for several months post-transplant.
- Some functional assessments may not be pertinent over time.

Earlier development discussions also addressed potential solutions for the problem. These included:

- Surveying VCA transplant programs in the U.S. to identify program-level feedback on outcome data collected.
- Modification of the current VCA Transplant Recipient Registration (TRR) and Transplant Recipient Feedback (TRF) forms to capture more clinically relevant transplant outcome data for abdominal wall, head and neck, and upper limb transplant recipients.
- Create a new form to capture recipient data for other types of VCA transplants.

The Chair thanked the Vice Chair for the synopsis and opened the floor for discussion. Members shared there were two parallel needs regarding VCA transplant outcome data, 1) the need to consistent gather more clinically relevant data on success and outcomes from VCA programs, and 2) the need to collect these data in a unified manner (VCA community, ASRT, and OPTN). Another consideration that was raised by reviewers and editors of a recent American Journal of Transplantation submission was to consider data reporting that was similar across all VCA types.

The Chair then mentioned a substantial gap in VCA data collection exists in the area of uterus transplantation. The OPTN does not currently collect data on living uterus donors or uterus transplant recipients. Members agreed with the Chair's comments, noting the gaps also exist for penis and abdominal wall transplants. One member commented that each VCA type would eventually need to have defined success, or failure, and outcomes. Another member shared the matter that transplant programs should be incentivized to submit data.

The Chair thanked members for their insightful comments. There was consensus on moving forward on a project that would 1) survey VCA transplant programs to identify what data they currently collect, 2) collect a consistent set of data on all VCA transplants, 3) ask members from the clinical areas of VCA transplant to identify pertinent outcome data, and 4) engage with VCA colleagues to identify definitions of success or failure, and VCA specific outcomes.

Next Steps:

UNOS staff will survey Data Subcommittee members and those Committee members interested in this project for available date/times for future conference calls. Initial goals will be to wrap up project development discussions to present to the POC in the coming months.

The Chair then transitioned to the next item on the agenda.

5. Latest VCA Data

UNOS staff shared the latest OPTN data on VCA donors, candidates, and recipients.

Summary of discussion:

UNOS staff profiled the latest VCA activity in the U.S. This included:

- VCA transplants in the U.S. since 1998
- Distances traveled for VCA recoveries since 1998 and 2014
- CIT reported for VCA transplants since 2014
- VCA sharing (local, regional, national)
- VCA waiting list trends since 2014
- VCA candidate waiting times since 2014
- Outcomes reported in head and neck, and upper limb transplants

The Chair thanked UNOS staff for this compelling data update and opened the floor for discussion. Members discussed the matter of funding for different components for VCA transplants. They requested future OPTN data on sources of payment for VCA transplantation. Members also shared challenges submitting the data to the OPTN. Given the relative infrequency of VCA data reporting (as compared to other organs), transplant program staff may be less familiar with the outcome data, where to locate within the medical record. UNOS staff agreed with this sentiment, but commented that VCA programs are improving with the completeness of data submission.

UNOS staff shared with members that gaps in data continue to persist. The issue is not non-compliance with OPTN data submission policies. Rather, the issue is with the completeness of the data submitted. Members agreed to collaborate with UNOS staff to fill the data gaps where possible. Further, they noted this helps illustrate the need for the Committee's next project.

Next Steps:

UNOS staff will continue to provide data updates to the Committee and report on progress obtaining pre-2014 VCA recipient follow-up data.

The Chair then transitioned to the next item on the agenda.

6. Update from 2018 Chauvet Workshop

One of the at-large members shared a synopsis of the biennial Chauvet Workshop.

Summary of discussion:

The purpose of the Chauvet Workshop was to discuss domains of evaluating VCA transplant patients from a psychology/psychiatry perspective. The exchange at the 2018 Chauvet

Workshop was described as excellent with continued discussion on elements to VCA transplant candidate evaluation and sharing on the U.S. experience.

Current challenges being discussed by the Workshop attendees were the need to develop testing instruments and a process to collect patient reported outcomes, ethical insights in VCA transplantation, educational opportunities, and the desire to share and learn from challenging cases.

The Workshop attendees also discussed the need for 360 degree buy-in; not just from the medical community, but from patients and their families, OPOs, and payers understand the value of VCA transplantation. To do so in the U.S. without European colleagues would be short-sighted, especially with the challenge of case volume that is slow to accrue. One idea shared was following the model of Standardizing Outcomes in Nephrology (SONG). This group developed a survey instrument that was understandable by patients, valuable to clinicians, easy to administer, no-cost to use, no specialized equipment, cross-cultural, and can be used to assess changes over time. This is intended to collect qualitative data from patients to assess their impression of their transplant outcome.

The speaker concluded by emphasizing the need for ongoing collaboration both domestically and internationally. The next Chauvet Workshop is tentatively planned for 2020 in the U.S.

The Chair thanked the speaker for the informative presentation and transitioned to the next item on the agenda.

7. Committee Project Portfolio Review & Brainstorming

UNOS staff facilitated a new project brainstorming session to identify problems facing the VCA transplant community and potential solutions from the OPTN.

Summary of discussion:

During the discussion, UNOS staff shared the span of potential OPTN committee projects. The Committee's earlier prioritization list was also shared, noting substantial progress in two areas and early discussions in one area. Committee members were asked to be mindful of these and other recorded ideas, then consider that issues were facing the VCA transplant community currently. Members were then assigned to one of three groups and asked to report back on new project ideas to Committee.

At the conclusion of the breakout activity, committee members shared several new project ideas:

- Guidance to transplant hospitals on expansion of services to include VCA transplantation.
- Collaboration with the Association of Organ Procurement Organizations (AOPO) to influence thought leaders in the OPO community to screen more potential donors for VCA donation.
- Amend organ and tissue donation registries to include option for VCA donation.
- Data collection on living uterus donation and transplantation, including the potential for patient-reported data.
- Enhance the VCA allocation system to remove barriers to OPO use, and integrate into UNetSM.
- Collect all VCA allocation efforts (not just on successfully allocated VCAs) to identify VCA donor potential.
- Expand awareness of VCA transplantation beyond the public and transplant community, e.g.: reach those medical specialties that may refer patients for VCA transplant evaluation.

- UNOS staff indicated this approach was not considered before, but should be discussed to identify potential opportunities.

Though not within the scope of a future Committee project, members were interested in presenting an update at the spring 2019 regional meetings. UNOS staff will explore this idea and provide an update to the Committee.

Next Steps:

UNOS staff will record the aforementioned project ideas. An online survey will be sent to members to identify the priority of the future work.

The Chair thanked members for their innovative thinking and transitioned to the next agenda item.

8. Update from American Society of Transplant Surgeons (ASTS) VCA Committee

The ASTS-VCA Committee will be coordinating a VCA Consensus Conference in the fall of 2019. They will be engaging VCA partners to have a dynamic discussion to advance the field, including indications and contraindications for VCA transplantation, outcomes, cost estimates, and cost comparisons with alternative care plans. Invitees would likely include the major transplant societies, ASRT, the OPTN, the Department of Defense (DoD), and payers. Please be on the lookout for more information on this opportunity.

Next Steps:

The Chair thanked the ASTS representative for this update and asked for future updates on the development of this conference.

Note - The scientific discussion was tabled in consideration of the short time remaining on the agenda. This will be shared at a future conference call or meeting.

The Chair and Vice Chair shared their deep appreciation to members for attending the meeting. Members verbalized their appreciation for the opportunity to engage with the Committee, and were energized about the future opportunities and project work. With no other business to discuss, the meeting was adjourned.

Upcoming Meetings

- Conference calls – 2nd Wednesday of each month from 4-5 PM (Eastern)
- In-person meeting – March 29, 2018 (Chicago, IL)