

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
March 29, 2019
Chicago, IL**

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

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee met via Citrix GoTo in Chicago, IL State on 03/29/2019 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Data Update
3. Update VCA Transplant Outcomes Data Collection
4. Public Comment Review & Project Finalization
5. Uterus Transplantation Update
6. Scientific Forum

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

1. Policy Oversight Committee Update

UNOS staff will provide an update from recent POC discussions.

Data summary:

- UNOS staff presented an update from the POC, reminding members about POC role, OPTN Strategic Plan, recent work and new approved projects.

Next steps:

- Staff will keep the VCA committee updated on the living donor guidance document on social media and living donation.

2. Data Update

UNOS staff will update the latest data on VCA candidate registrations, removals, transplants, and recipient data.

Data summary:

Research Staff presented an update on VCA data, the presentation was split into four sections, VCA Waiting list, Transplants, Patient & Graft Survival and Graft Function.

- VCA Waiting list
 - The following are the figures presented by staff:
 - VCA Candidates added Waiting List from 7/3/14 – 2/28/19
 - By VCA type and Year of listing
 - VCA Waiting List by Month since 7/3/14
 - Current VCA Waiting List as of 3/1/19
 - By VCA type
 - By Waiting time
- VCA Transplants
 - VCA Waiting Times for Transplanted VCA Recipients
 - VCA Transplants in the U.S. through 2/28/19

- VCA Patient & Graft Survival
 - Head & Neck Transplants in the U.S. by years since transplant
 - Upper Limb Transplants in the U.S. since July 3, 2014 by years since transplant
 - Upper Limb Transplants in the U.S.
 - By graft time
- VCA Graft Function
 - Staff reminded members what data the OPTN collects for face graft function and upper limb graft function. In addition updated OPTN data collected for face and upper limb was shown.

Summary of discussion:

- The committee was appreciative of the update and thanked staff for their work.
- The major concern for members was the alarming amount of missing data. The committee had several questions and comments:
 - The reason behind the missing data was brought up and staff clarified, that is due to the difficulty of transplant hospitals to submit the completed data forms.
 - Members questioned how to improve this; what leverage can we take, possibly bring it to Membership and Professional Standards Committee (MPSC)?
 - A manpower issue; not all hospitals have a dedicated data person who has the skill to complete them.
- Some solutions discussed were:
 - Have guidelines for VCA data entry to help aid personnel; a webinar of some kind.
 - Suggested a notification system in DonorNetSM to notify transplant staff that their form needs to be completed,
 - Member asked how the OPTN asks for data and staff described the process, highlighting that UNOS staff sends reminder emails when forms are not filled in timely manner. Following this, a suggestion was made for UNOS to send a stronger reminder to a majority of transplant staff. Members emphasized that from their perspective, the leadership of transplant hospitals would like to know who is not completing forms. They stressed that the data is a necessity to move the VCA transplant field forward.
 - Several members expressed a need for a mechanism of escalation when hospitals consistently have missing data.
 - i.e: phone call, then a letter, then it should go higher such as the MPSC.
 - Staff will facilitate a discussion with MPSC and VCA leadership for further discussion of this topic.
 - A member commented that in the future the committee will need a “bigger stick” to close the gap in the data set, possibly even going as far as to say that certain transplant programs will not get organ offers because they have missing data and that will cause a change in membership status by the MPSC.
- A member asked if there was a “real time” report of VCA transplants done. Staff clarified that there is a report, and it can be distributed to the committee members.

Next steps:

UNOS staff will facilitate a discussion between the MPSC and VCA leadership, create a plan to solve the gap in the data and send members a weekly report of VCA transplants.

3. Update VCA Transplant Outcomes Data Collection

The Committee will hear an update re: POC and Executive Committee discussions, and begin in-depth project discussions. VCA specific breakout groups will be tasked with identifying what outcome measures are needed to build depth in recipient outcomes.

Data summary:

- Project plan
 - Gather input from committee member and develop more detailed data set for head & neck, upper limb and uterus.
 - Review the current baseline data set.
 - Seek feedback from VCA transplant Community.
 - Engage other OPTN Committees.
- The primary goal of this project is to improve patient outcomes.
- Reviewed OPTN data submission requirements.

Summary of discussion:

- The committee then broke out into three groups to review current data collection and considered prioritizing other data points, psychosocial tools, & time of collection. Another focus was on the data collected in the OPTN VCA Transplant Recipient Follow-up (TRF) form and Transplant Recipient Registration (TRR) form.
 - **Upper limb**
 - **Additions to forms**
 - Grip strength and pinch strength
 - Function: measurement of joints
 - Nail changes
 - Two- Point Discrimination test
 - Total active motion
 - A question about whether the patient could live independently(yes/no)
 - Additional questions about hygiene practices, independent dressing
 - Cold intolerance
 - Secondary surgery
 - Question: bone union/or bone malunion
 - Infection section
 - Add osteomyelitis
 - **Remove**
 - Semmes Weinstein Monofilament Test (from TRF)
 - Carroll test (from TRF)
 - **Head and Neck**
 - **Additions**
 - Links to international registry
 - Patient reported outcomes
 - Appearance
 - Smile, spontaneous blinks
 - Kidney function (to the TRF)
 - **Remove**
 - Cognitive development

- Simply QRL
- Skin grafts
- Pregnancies
- Sensitization
- Psycho-social consult (from TRF); several members were split on what to do here, the SF12 (Physical Health and Mental health) was suggested instead.
- **Uterus**
 - **Additions**
 - To TRR
 - Donor Type
 - To TRF
 - Positive HCG
 - Miscarriage
 - Expected Due Date
 - Psychological complications
 - Dates for embryo transfer
 - Consider something on psychological complication DSM V diagnosis with or without admission.
 - Add a special form for pregnancy
 - Complete at heartbeat
 - Complications of pregnancy
 - Need to seek input from high risk pregnancy clinicians for more details.
 - Add special form for delivery
 - Complete at delivery
 - Complications of delivery to mom and baby
 - Procedure type
 - Graft removal
 - Transfusions
 - Length of stay of (LOS) for Mom
 - LOS baby
 - Infant information –apgar, weight, length
 - Recommend to follow recipient for 2 yrs post graft removal-include questions about the infant. (The committee had a long discussion about the right to follow up on infants from a transplanted uterus)
 - Recommendations for additions to Living Donor registration (LDR) and follow up (LDF) information.
 - LDR-age at donation, gravity/parity, hormonal preparations pre-donation, relationship to recipient
 - LDF- Kidney function surgical complications , kidney ultrasound
 - **Remove**
 - From TRR
 - Previous skin grafts
 - Inpatient hospitalization prior to transplant
 - Life support
 - Tolerance used
 - Cognitive development

- Motor development
- SF 36
- multiple graft recipient
- topical immunosuppressive medications
- From TRF
 - Topical immunosuppressive medications
 - Cognitive development
 - Motor development
 - SF 36
- Other notes:
 - Do not duplicate data collected in TCR.
 - Recommended one form for common items then VCA specific items.
 - Discuss a need for health literacy assessment.

Next steps:

- UNOS staff will survey the VCA data subcommittee for a monthly meeting plan.
- The committee needs to evaluate the OPTN definition of Graft Failure.

4. Public Comment Review & Project Finalization

The Committee will discuss the feedback received on the proposal to *Eliminate the Use of Regions in VCA Distribution*. At the conclusion of the discussion, the Committee will vote whether to recommend the proposal to the OPTN/UNOS Board of Directors.

Data summary:

- UNOS staff presented an overview on the outcome of public comment and votes from regional meetings to the committee.
 - What groups commented on the proposal.
 - Sentiment of the proposal by state, OPTN region and Member type.
 - Two additional figures presented were sentiment by VCA programs only and by organ procurement organizations (OPOs) with VCA experience.
- Themes from public comment period are as follows:
 - Support to broaden the reach of VCA distribution
 - Sensitive to specific cases to maximize utilization
 - Allow for flexibility to take into account special geographic considerations
 - Not decrease utilization of organs
 - Diversity in feedback re: 750 NM
 - Supported
 - Unrealistic and too great of a distance
 - Alternatives suggested – 500 NM or 250 NM
 - There is a lack of sufficient data necessary to inform evidence-based policy.
 - The OPTN should continue to collect data and monitor VCA transplant outcomes to evaluate the proper distance.

Summary of discussion:

- Three choices were discussed, first being 250 NM, 500 NM, and 750 NM.
 - For 250 NM
 - VCAs would have a shorter flight and ischemic time.
 - For 500 NM
 - In support of 500NM
 - Less restrictive than 250NM

- OPOs perspective
 - Believes it is cumbersome to offer far away from local area.
 - The VCA waiting list is an excel spreadsheet and therefore is not located in UNet®. Which makes it a manual process for OPOs.
 - Would like to see a smaller local circle to promote efficiency.
- Most VCA transplants are done due to local relationships. Also keeping it local will keep cold ischemic time low.
- A member commented that there is no data to show either 500 NM or 750NM as a strong option, however majority of public comments are in support of 500 NM and it is similar to the distance in heart policy.
- Several members agreed that 500 NM would currently be the best choice, while more data and experience is collected to allow for possible expansion in future.
- In terms of flight time; the difference between 500 NM and 750NM is negligible, however ground transportation time and probability of an airport near the donor hospital are important factors.
- For 750 NM:
 - Some transplant hospitals IRBs (Internal review boards) don't allow their hospitals to travel far away (750 NM).
 - Unfunded VCAs programs don't have the financial resources (restrictive based on cost) to fly that long/far away; it would be easier if it were local/ drivable distance.
- UNOS staff asked HRSA staff to weigh into the discussion of mileage. Their response was supportive of a smaller mileage such as 250/500NM due to the lack of current data to make a compelling argument and be in compliance to the final rule for longer distances such as 750 NM.
- The VCA committee voted in favor for recommending this proposal for consideration by the OPTN Board of Directors in June 2019. (13 yes; 0 no; 1 abstained)
- Other comments made:
 - A tiered method was suggested, with concentric circles at 250 NM, 500 NM, and 750 NM. UNOS staff clarified that this would be a substantive change to what was originally proposed and would require this proposal to go back for public comment.
 - Possibly differentiate distances between VCA types in the future.
 - Members stressed that mileage importance depends where you are located in the US.
 - Members also explained that it is the prerogative of the transplant hospital to decline an offer or expand the circle of candidates.
 - Member asked about the possibility of altering VCA policy in the future to get more points for highly sensitized patients.

Next steps:

- UNOS staff will prepare the briefing paper consistent with the Committee's discussions.
- Consideration by OPTN Board Ad-hoc Policy Working Group early-May 2019.
 - Review & offer recommendation to the Board
 - Recommend either the consent or discussion agenda
- OPTN Board consideration June 10, 2019

5. Uterus Transplantation Update

A member will share current insights on uterus transplantation, current challenges, and key issues, and future considerations

Data summary:

- The committee member discussed a meeting later this calendar year where representatives of patients groups and insurance companies will be present to discuss funding options for future uterus transplants.

6. Scientific Forum

The Committee will discuss the emerging role of device perfusion in organ transplantation, and what role this may have in VCA transplantation

Data summary:

- The Vice Chair gave a research presentation about device perfusion project in porcine limbs, the progress made so far and what is needed in the future.

Next steps:

- The Chair asked the committee if they would like to write a manuscript about the data across the VCA types of the first 5 years of VCA transplantation.

Upcoming Meeting

- May 8th, 2019