

OPTN Vascular Composite Allograft Committee

Meeting Summary

April 3, 2020

Conference Call

Linda Cendales, MD, Chair

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Introduction

The OPTN Vascular Composite Allograft Committee (the Committee) met via Citrix GoTraining on 04/03/2020 to discuss the following agenda items:

1. COVID-19 Update
2. VCA Data Update
3. Updates to VCA Transplant Outcomes Data Collection
4. Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients
5. Programming VCA Allocation in UNet
6. Update on VCA Living Donor Workgroup
7. Update on Eliminate the Use of Regions in VCA Distribution
8. Update on List Covering Body Parts Pertaining to VCA and other VCA Membership Projects

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

1. COVID-19 Update

The Committee heard an update on the UNOS and OPTN responses to the developing COVID-19 situation.

Summary of discussion:

Members discussed the current activity levels and contingency plans of their respective active VCA programs. Members reported that most of their programs are not screening patients or proceeding with VCA procedures. Some are following the American College of Surgeons (ACS) guidelines regarding scheduling/performing surgeries and largely VCA would not fit into a life-saving surgery category. They might resume following ACS recommendations.

The Committee discussed the proposal of requiring local recovery surgeons. The VCA Committee does not support a mandate for local recovery surgeon use due to the need for specific expertise that might be required but not be available (e.g. hand, face recovery). They support a strong recommendation to use local recovery surgeons when local expertise is available to conduct recoveries to minimize the risk of COVID-19 transmission. They request that if local recovery becomes an emergency policy mandate that local VCA recovery be excluded from the mandate. They also have some concern that ER policy mandating local surgeon recovery could become permanent. This type of mandate could be harmful to the VCA field.

Next steps:

UNOS staff will communicate this feedback to the Executive Committee before this issue is considered later in the day.

2. VCA Data Update

UNOS Research fielded questions from Committee members on current VCA data.

Summary of discussion:

A member asked when the last VCA transplant was performed. There have been two VCA transplants this year, one from a living donor and one from a deceased donor. Another member asked if the current active/inactive program list was up to date.

Next steps:

UNOS research will follow up to answer these questions.

3. Updates to VCA Transplant Outcomes Data Collection

The Committee discussed public comment feedback on this proposal.

Summary of discussion:

The Committee reviewed comments on skin changes with acute rejection and agreed with comments that recommended retaining this field on the Transplant Registration Follow-up (TRF) form for head and neck. Committee members also decided to retain the Hemoglobin A1c field on the TRF for head, neck, upper limb, and uterus.

The Committee discussed which psychosocial assessment should be included on the TRF and if this assessment should be optional or required by the OPTN. Public comment was generally supportive of this data collection. The Committee noted that there are no psychosocial assessments tailored for assessing the quality of life of VCA recipients but agreed on the importance of conducting psychosocial assessments. Since there is not a tailored instrument available, the Committee agreed that it would be beneficial to use a general instrument in the interim. The Committee decided to replace the 36-Item Short Form Health Survey (SF-36) with the 12-Item Short Form Health Survey (SF-12) on the TRF for head and neck and upper limb as it is short and easy to use. They also agreed to remove the SF-36 from the TRF for uterus due to public comment and member feedback opposing mandated use of a specific psychosocial assessment for uterus recipients. These psychosocial evaluations will not be required per OPTN policy for transplant programs to complete, but the data fields will be required on the TRF instrument. This means that the transplant programs must provide an answer, even if that answer is that the psychosocial assessment was not completed.

The Committee discussed additional suggested data elements. There were no significant changes based on these suggestions as more consensus is needed among the community.

The Committee also made language additions to the definition of data elements. Additions are as follows:

- Two-Point Discrimination: "Please record the two-point discrimination from the most sensate area of the hand (for upper limb) or face (for head and neck)"
- Hot and Cold Sensation: "0- Lips not included in graft"
- Ability to Open and Close Eyelids: "0- Eyelids not included in graft"

The Committee discussed feedback on data elements that could be added to the TRR or TRF for other VCAs in the future. A member suggested considering the Sexual Health Inventory for Men (SHIM) as a measure of function for penis and including information on urethral strictures.

Next steps:

The Committee then voted to send the proposal to the Board of Directors (BOD). The results of the vote were 14/15 in support. One abstention. The BOD will vote on this proposal at their meeting in June 2020.

4. Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients

The Committee reviewed public comment feedback on this request for feedback

Summary of discussion:

There was general support for measuring outcomes with some concerns.

Members talked about the possibility of working alongside an organization such as the American Society for Reproductive Medicine (ASRM) and leverage information from their registry.

The Committee discussed the benefits and drawback of collecting data on children born to uterus recipients. The potential for a “lack of normalcy” in the lives of the families who have a child born from a transplanted uterus was discussed throughout public comment. The Committee reported that this lack of normalcy is a byproduct of having a child born from a transplanted uterus. This byproduct should be weighed against the OPTN’s duty to monitor transplant outcomes.

Next steps:

The BOD will receive a brief update on the request for feedback at their meeting in June 2020. A follow-up project may also be considered for public comment in Spring 2021.

5. Programming VCA Allocation in UNet

The Committee heard an overview of this project and reviewed the proposed policy changes.

Summary of discussion:

A member asked if the Committee could give input on what media capabilities UNet may need such as the ability to upload Computed Tomography (CT) scans and Electromyography (EMGs). UNOS Information Technology (IT) responded that they will need help with testing in the future.

Members asked about the time limit for surgeons to accept or decline an organ. Surgeons would have one hour to submit a provisional yes or organ offer refusal. If a surgeon who gave a provisional yes becomes primary, they will have 30 minutes to submit an official yes.

Next steps:

The Committee will discuss this project in more detail during their next meeting. It will also go to the Executive Committee for approval on April 20, 2020.

6. Update on VCA Living Donor Workgroup

The Committee heard an update on the progress of the VCA Living Donor Data Collection Workgroup.

Summary of discussion:

There was no discussion.

Next steps:

The VCA Living Donor Data Collection Workgroup will continue work on this project during their next meeting on April 13, 2020.

7. Update on Eliminate the Use of Regions in VCA Distribution

The Committee heard an update on Eliminate the Use of Region in VCA Distribution.

Summary of discussion:

There was no discussion.

Next steps:

The target implementation date for this project is June 2020.

8. Update on List Covering Body Parts Pertaining to VCA and other VCA Membership Projects

The Committee heard an update on the implementation of List Covering Body Parts and other VCA Membership Projects

Summary of discussion:

A member confirmed that this project will define and cover eight different body parts, including registration and data collection.

Next steps:

The target implementation date for this project is June 2021.

Upcoming Meetings

- May 13, 2020 (Teleconference)
- June 10, 2020 (Teleconference)