

# **Meeting Summary**

# OPTN Vascular Composite Allograft Transplantation Committee Meeting Summary October 26, 2020 Conference Call

Bohdan Pomahac, MD, Chair Sandra Amaral, MD, Vice Chair

#### Introduction

The OPTN Vascular Composite Allograft Transplantation Committee (the Committee) met via Citrix GoToMeeting on 10/26/20 to discuss the following agenda items:

- 1. Review Programming VCA Allocation in UNet<sup>SM</sup> proposal
- 2. Policy Oversight Committee Update
- 3. VCA in UNet Project Work
- 4. Review top project ideas
- 5. Membership requirements for genitourinary programs

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

# 1. Review Programming VCA Allocation in UNet<sup>SM</sup> proposal

#### Summary of discussion:

The Committee took a vote to approve sending the *Programming VCA Allocation in UNet* proposal to the OPTN Board of Directors in December 2020

All (19)- Approve, 0 – Oppose, 0 - Abstain

The Committee discussed other public comment feedback which suggested that uterus transplantation should be removed from VCA because it is a solid organ. Members discussed that the OPTN Final Rule does not identify uterus as an organ separate from VCA at this time. Members expressed they do not believe the Committee should spend time trying to change this part of the Final Rule because they are still able to work on uterus specific projects and develop uterus policy.

#### Next steps:

The Committee will hold a discussion on uterus- specific projects later in the meeting.

# 2. Policy Oversight Committee Update

# Summary of discussion:

A member suggested the Committee consider what role VCA could play in the strategic policy priorities (continuous distribution, efficient matching, and multi-organ allocation), now or in the future. A member said the Committee could start considering the constructs that should be used for continuous distribution of VCA. The Committee reviewed the efficient matching workgroup recommendations prioritized by the Policy Oversight Committee (POC). Members did not think that VCA needed to be involved at this stage in the work moving forward. The Chair asked if members involved in uterus transplantation should be involved in the projects related to biopsies, but members said that uterus transplant programs have not found biopsies to be useful. However, members said that other types of

image sharing would be helpful, for example, the ability to view computed tomography (CT) scans. UNOS staff shared that UNOS recently released new capabilities for image sharing, and the POC workgroup recommendation is specific to biopsy image sharing. Members said that the multi-organ transplantation work is important but it may be too early to pull in VCA at this time.

#### Next steps:

The Committee is slated to start work with continuous distribution in 2023. The Committee has the bandwidth to work on other projects between now and then.

#### 3. VCA in UNet Project Work

# Summary of discussion:

The Committee reviewed the VCA types established by *Policy 1.2: Definition of VCA* and discussed how variations within each organ type (anatomic components) would be presented in UNet.

The Committee discussed efficiency and utilization within the UNet system. Currently anatomic components within UNet are selected by whole body part and use the "Other" text field to indicate the exact anatomic component for recovery. A member asked if this method is the best way to utilize VCAs, as the surgeon may only need a portion of the whole requested body part. UNOS staff confirmed that the "other" text field is to be used for this purpose rather than a picklist that limits what a surgeon may select. A member expressed that the numbers of these highly specific VCA transplants are likely to be low over the next five years. This member believed the way the Committee decided to identify anatomic components will accurately capture the necessary information, but that this method could be reassessed in the future.

A member asked how sentinel flaps would be recorded in the UNet system. UNOS staff asked if these sentinel flaps should be considered separate organs and explained that if placed under the musculoskeletal composite graft VCA type, sentinel flaps would be considered separate organs with separate data collection and follow ups. The Committee agreed that this was not the desired outcome, unless the sentinel flap was the primary VCA to be transplanted. Members discussed that sentinel flaps that are not the primary VCA could be added to the "Other" text field of the primary organ type. If the sentinel flap was the primary VCA, this would be indicated by selecting the musculoskeletal composite graft VCA type. Another idea was to add sentinel flap as an option under every VCA type. The Committee and UNOS staff will gather more information and revisit this topic to resolve remaining questions.

Members discussed data requirements for adding/updating candidate records in Waitlist. The Committee determined that the system should require data to be entered for "acceptable donor age range" and "maximum distance organ recovery team will travel". They also discussed which screening criteria do and do not apply for each VCA type. Members eliminated donor weight from the screening criteria. Members determined that a single range/response was sufficient for all VCA donors and that local vs. import should not be programmed into the VCA donor acceptance criteria screening.

#### Next steps:

The Committee and UNOS staff will gather more information on sentinel flaps and revisit the topic.

# 4. Review top project ideas

#### <u>Summary of discussion:</u>

A member expressed that the Committee should embrace project ideas involving genitourinary policy, as the number of these procedures are increasing. A member asked how the Committee would go

about revising membership requirements for genitourinary programs. UNOS staff explained that this project could focus on membership specifications for uterus programs but would also include criteria that could apply to all genitourinary organ transplant programs as currently these requirements are rather general in OPTN policy.

The Committee also discussed projects that aim to examine VCA transplant outcomes. A member expressed that the Committee should continue work on their *Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients* request for feedback that went out for public comment in January 2020. Members agreed with the overall purpose of collecting data on these children, but voiced concern over foreseen feasibility and ethical barriers. A member suggested that the VCA Committee could partner with the Pediatric Committee to work on this project. UNOS staff added that the Ethics Committee should be involved. Members also expressed interest in a project that would define uterus graft failure in order to establish more structure surrounding uterus outcomes. The Committee had previously expressed interest in pursuing a project to increase awareness of VCA donation and transplantation, but decided that it may be more important at this time to pursue the project on graft failure.

#### Next steps:

The Committee continued their discussion on membership requirements for genitourinary programs in more detail.

# 5. Membership requirements for genitourinary programs

#### Summary of discussion:

The Committee discussed the need for membership requirements for genitourinary programs. Members agreed that the current membership requirements do not reflect the expertise needed for genitourinary transplantation, like uterus. A member said that many of these programs are started out of the hospital's OB/GYN departments, but current membership requirements do not include a role for that expertise. The development of these requirements will help establish a framework for hospitals interested in starting a uterine transplantation program.

#### Next steps:

The Committee will form a workgroup for the *Membership Requirements for Genitourinary Programs* project and continue conversations on projects that measure VCA outcomes.

# **Upcoming Meeting**

November 18, 2020 (teleconference)

#### **Attendance**

# • Committee Members

- o Sandra Amaral
- Linda Cendales
- o Lori Ewoldt
- o Bruce Gelb
- o Vijay Gorantla
- o Lawrence Gottlieb
- o Darla Granger
- o Liza Johannesson
- o Nicole Johnson
- o Alexander Maskin
- o Debbi McRann
- o Gary Morgan
- o Debra Priebe
- o Bohdon Pomahac
- o Paige Porrett
- o Patrick Smith
- o Simon Talbot
- o Stefan Tullius
- Mark Wakefield

# • HRSA Representatives

o Jim Bowman

# SRTR Staff

o Bryn Thompson

# UNOS Staff

- o Kristine Althaus
- o Nicole Benjamin
- o Brooke Chenault
- o Elizabeth Miller
- o Kelley Poff
- o Sharon Shepherd
- o Leah Slife
- o Kaitlin Swanner
- Susan Tlusty
- o Jen Wainright
- Karen Williams

# • Other Attendees

o Robert Goodman (visiting board member)