

**OPTN Vascularized Composite Allograft Transplantation Committee
Genitourinary Membership Requirements Workgroup
Meeting Summary
March 15, 2021
Conference Call**

**Nicole M. Johnson, MBA, RN, Co-Chair
Stefan Tullius, MD, PhD, Co-Chair**

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee's Genitourinary Membership Requirements Workgroup met via Citrix GoTo teleconference on 03/15/2021 to discuss the following agenda items:

1. Review of Project Plan
2. Primary Physician Requirements
3. Transplant Program Requirements
4. Review Primary Surgeon Requirements

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

1. Review of Project Plan

The Workgroup reviewed the genitourinary (GU) requirements project plan and timeline. The Co-Chairs proposed that the Workgroup focus on female GU/uterine requirements while leaving male GU/penis in the program category of "other" due to the low volume and current lack of expertise within the group to adequately outline requirements for a male GU/penis transplant program at this time. This would likely be a staggered approach where uterine transplant requirements will be completed and then the male GU/penis transplant requirements could be revisited when it is appropriate.

Summary of discussion:

A member asked for clarification on any possible future consequences with policy should the Workgroup move forward with a division of GU programs approach, and UNOS staff clarified that updates would be made to policy including updating the list of VCA program types and covered body parts while also fully separating the GU types for VCA in UNetsm to reflect these changes. A member asked if there was reason to not be inclusive of both GU types for this project at this time since the group may want to be sensitive to any barriers a male GU/penis transplant program may have to meeting requirements in the "other" program type. Workgroup leadership stated there is a significant enough difference between the two to justify separating them and felt it would be a disservice to write requirements for a male GU/penis program with the current volume and expertise levels. This was supported by another member agreeing that the pressure is higher to have specific requirements for uterus considering uterus transplants are currently occurring at a much higher volume. It was also discussed whether VCA male GU/penis programs would have any barriers meeting "other" VCA program requirements and the Workgroup concluded that there is not enough information to know for certain. The Workgroup supported moving forward focusing on VCA uterus program requirements and then revisiting VCA penis program requirements when more information is available to make more informed decisions.

2. Primary Physician Requirements

The Workgroup discussed different options for requirements of a VCA uterus program primary physician. Feedback was requested on what the Workgroup thought would be adequate primary uterus physician requirements.

Summary of discussion:

Experience in Immunosuppression

A member mentioned that there must be a requirement for someone on the VCA uterus program team to have immunosuppression experience. However, they noted that it does not necessarily need to be the primary physician, it could be the primary surgeon who meets that requirement. Workgroup leadership asked for clarification on how these programs would document who meets the immunosuppression experience requirements (whether it is the primary physician, surgeon, or someone else on the team) and how would that be tracked with any changes in personnel. UNOS staff explained there is no restriction for limiting this experience to only the primary physician and/or surgeon, but it would add a layer of complexity to the membership application process since more information would need to be submitted by the program to demonstrate they meet the immunosuppression requirements should there be a change in key personnel. Workgroup leadership asked how this approach would differ from solid organ transplant programs and UNOS staff stated there is an assumption that both primaries of those programs would have experience with immunosuppression because both of those positions are going to have training and experience specific to transplant which may not always be the case with VCA proposed key personnel. A member stated the Workgroup needs to define and build a route for how these programs would demonstrate any immunosuppression requirements without being a barrier to proposed primaries with more reproductive medicine backgrounds.

Allowance for an obstetrician/gynecologist (OB/GYN) to be a VCA Uterus Program Primary Physician

Workgroup leadership asked for feedback on what types of specific training and/or experience would be needed for an OB/GYN to meet VCA uterus program requirements. A member explained that the Workgroup should be mindful of any possible barriers for OB/GYNs trying to serve in leadership roles for these programs since in their opinion it is problematic that an OB/GYN cannot meet the current VCA physician requirements. The member felt it is necessary that there be someone on the team that has experience in reproductive medicine whether that is the primary physician or surgeon. Workgroup leadership agreed that an OB/GYN should have the opportunity to serve as either the primary surgeon or physician in these programs.

Overall Program Key Personnel Requirements

The Workgroup agreed that these programs need to require experience with immunosuppression and reproductive medicine. A member asked for clarification on whether or not the Workgroup could be more flexible with the primary surgeon and physician requirements and add more overall program requirements so that all necessary experience is captured within the multidisciplinary team. UNOS staff stated that if the Workgroup wanted to incorporate more requirements for the multidisciplinary team or for the overall program they could, but any requirements, however flexible for the primary surgeon and physician, need to be clear enough to review for the membership application process.

HRSA staff asked what has been successful in establishing these programs prior to the current requirements and members stated that they focused on assembling a team that meets all the combined experience to successfully and safely perform these transplants which is larger than a primary surgeon and physician. HRSA staff wanted clarification on if these programs would have access to transplant staff

outside of the VCA uterus program to support the VCA uterus program with immunosuppression and UNOS staff stated that is an option, but that would need to be documented in the application for review.¹

3. Transplant Program Requirements

The Workgroup reviewed the OPTN transplant program personnel requirements and discussed what needed to be included for VCA uterus programs.

Summary of discussion:

A member voiced concern over the overall medical expert support requirements since not all programs would have all of these available (such as a hepatologist), and suggested reshaping the requirements to be more inclusive. UNOS staff explained this is being revised to include language like “if applicable” or “as needed” to better match the requirements of the Final Rule.²

The Workgroup discussed additional expertise that should be added for VCA uterus programs. The Workgroup previously decided that expertise in gynecology/oncology, maternal fetal medicine, OB/GYN, and experience in uterus transplantation needs to be included. A member stated that reproductive endocrinology expertise needed to be added as a requirement. HRSA staff asked if urology would be included in the current requirements and Workgroup leadership stated that it would be covered in the requirements already outlined, but the Workgroup wanted to consider urology expertise in the event of complications.

4. Review of Primary Surgeon Requirements

The Workgroup briefly recapped and reviewed the requirements for primary surgeon as discussed so far.

Summary of discussion:

It was suggested that surgeons holding American Board of Urology certification should be accepted since this is a training path that some kidney transplant surgeons utilize, but that the fellowship in reconstructive urology should be removed as an option since that would be specific to male GU/penis transplant programs.

Next steps:

The Workgroup will discuss what it means to have experience in uterus transplant and come to a decision as a group.

Upcoming Meeting

- April 19, 2021

¹ Vascularized Composite Allograft Membership Changes (Not yet implemented OPTN Bylaw J.2), OPTN, June 1, 6, 12, 2018. Accessed April 12, 2021: https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf

² 42 CFR §121.9 (a)(2)(v)

Attendance

- **Workgroup Members**
 - Stefan Tullius, Co-Chair
 - Nicole Johnson, Co-Chair
 - Sanjeev Akkina
 - PJ Geraghty
 - Paige Porrett
 - Mark Wakefield
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **UNOS Staff**
 - Kristine Althaus
 - Sally Aungier
 - Nicole Benjamin
 - Sharon Shepherd
 - Leah Slife
 - Kaitlin Swanner
 - Jen Wainwright
 - Marta Waris
 - Karen Williams
 - Krissy Laurie