

Meeting Summary

OPTN Vascularized Composite Allograft Transplantation Committee Genitourinary Membership Requirements Workgroup Meeting Summary April 20, 2021 Conference Call

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Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee's Genitourinary Membership Requirements Workgroup met via Citrix GoTo teleconference on 04/20/2021 to discuss the following agenda items:

- 1. Living Donor Recovery Requirements
- 2. Uterus Primary Surgeon Experience Requirements

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

1. Living Donor Recovery Requirements

The Workgroup reviewed the current requirements for living donor kidney and liver components to provide context for possible living donor uterus component requirements. The Workgroup discussed experience that would be necessary for the living donor surgeon and other personnel requirements for a living donor uterus component.

Summary of discussion:

Living Donor Uterus Surgeon Key Personnel

The Workgroup was asked for input on whether or not there should be a requirement for programs performing living donor recovery of uterus to have "surgical resources on-site for open or laparoscopic living donor uterus recoveries," as is required for kidney. A member noted that it is rare for a uterus program to have the option to perform both laparoscopic and open uterus recoveries. Another member stated that it may be appropriate to have similar language to living donor kidney since both types of procedures require different experience from the surgeon. A Co-Chair asked for clarification on why the language is specific for kidney and not liver recovery and another member explained that the language for liver was implemented before laparoscopic techniques were utilized for liver recovery. The Workgroup discussed the benefit to keeping language less defined to leave the onus of how the procedures are performed and credentialing of the surgeons performing the procedures (whether open or laparoscopic) on the transplant hospital. A member noted that the distinction for kidney is in the Bylaws due to the risk of exsanguinating hemorrhage during a nephrectomy which is different from uterus recovery. It was also clarified that the specific open and laparoscopic requirements for kidney and the two on-site surgeons requirement for liver were included due to the possibility for complications that may arise during those procedures. Members agreed that it seemed reasonable to leave the language less defined with no additional requirements for open versus laparoscopic experience and supported requiring only one on-site living donor uterus surgeon.

Living Donor Uterus Clinical Resources

The Workgroup was asked to provide feedback on requirements for living donor uterus clinical resources, living donor psychological evaluation, and having an independent living donor advocate as it aligns with the proposal to add living VCA donation to *Policy 14: Living Donation*. A member stated that Policy 14 should absolutely be inclusive of uterus donation and a Co-Chair agreed. It was clarified that the Policy 14 proposal that adds VCA was delayed in December 2020 from going to the OPTN Board of Directors, but now that the OPTN VCA Committee is moving forward with the Policy and Bylaw Clarification proposal, the Policy 14 proposal should also move forward for approval in June 2021 with an approximate implementation of September 2021. The Workgroup supported requiring the same clinical support for living uterus donors that is currently outlined in Policy 14.

Living Donor Uterus Surgeon Experience Requirements

The Workgroup discussed experience requirements for a primary living donor uterus surgeon. A member stated that the individual in the role could either be trained as a surgical obstetriciangynecologist (OB/GYN) or a transplant surgeon. A Co-Chair asked if a current living donor liver surgeon would be capable of a uterus recovery and a member clarified that uterus and liver recovery are different procedures, so the individual should have experience with uterus specifically. A member stated that the requirements for living donor uterus surgeon should reflect OB/GYN or GYN oncologist training to best serve the protection of the donor. The member recommended either completing a gynecologic oncology fellowship or completing a number of radical hysterectomies. A member was cautious of excluding abdominal transplant surgeons completely and another member suggested including a number of hysterectomies to meet requirements. A member additionally explained that hysterectomies are a high volume procedure at most hospitals and surgeons should have the opportunity at their programs to gain the experience. Another member asked for clarification on how these proposed individuals would gain experience with OB/GYN specific post-donation complications and a member stated the simplest path would be to partner with the OB/GYN department at their transplant hospitals. The member asked how these requirements would be enforced, and it was clarified that historical precedence for that already exists in OPTN Bylaws in the form of a letter of support from the appropriate hospital department head.

A Co-Chair asked for feedback on whether or not an individual right out of a gynecologic oncology fellowship would need an additional procedural requirement and a member stated that there is a high case count within the fellowship, but if they are using either a transplant fellowship or transplant clinical experience pathway, they would need an additional procedural requirement. The Workgroup noted that if an individual did not complete a fellowship, but had the clinical experience, they would have to be board-certified by the American Board of Obstetrics and Gynecology or American Board of Surgery, or meet a foreign equivalent.

The Workgroup discussed volume requirements for the procedures and a member stated that radical hysterectomy or living donor recoveries should be accepted, but simple hysterectomies are not complex enough of a procedure. A member supported a volume of 10 radical hysterectomies, but needed more information on how often that procedure is performed in order to gain experience. Another member clarified that they are a relatively common procedure, but are mainly performed robotically and it would be difficult to gain experience in the role of primary surgeon, but may be reasonable accept co-surgeon or first assist roles.

¹ "Modify Living Donation Policy to Include Living VCA Donors," OPTN, accessed May 17, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/modify-living-donation-policy-to-include-living-vca-donors/

The Workgroup supported that the individual filling the role needed to be either someone:

- with experience/fellowship as a gynecologic oncologist or
- a transplant surgeon (including specified board certification) with the needed number of required living donor uterus recoveries or radical hysterectomies
 - o For transplant surgeon pathway requirements, the Workgroup discussed 10 radical hysterectomies and/or living donor uterus recoveries as a possible volume requirement

2. Uterus Primary Surgeon Experience and Uterus Program Requirements

The Workgroup reviewed the feedback from Workgroup and VCA Committee members regarding overall uterus program and primary surgeon requirements.

Summary of discussion:

The Workgroup continued to support focusing on requirements for uterus transplantation rather than the broader category of female genitourinary organ transplantation. The Workgroup discussed the need for microsurgery/plastic surgery experience and option for an orthopedic surgeon pathway and members noted that keeping the microsurgery experience and orthopedic pathway made sense for broader genitourinary organ programs, but not for uterus transplant programs. The Workgroup discussed the types of transplant surgeons that would qualify for primary uterus transplant surgeon and supported including abdominal organ program pathways. However, a Co-Chair noted that requirements should not exclude existing uterus transplant surgeons and asked if they would be excluded in the proposed language. It was clarified that current requirements are for general genitourinary organ programs, so requirements would need to be inclusive of individuals who meet the soon to be implemented genitourinary organ program requirements.

The Workgroup discussed the acceptable timeframe for procedural logs and supported a timeframe of within the last five years since the experience would be recent and that would allow for enough time to meet the volume requirements.

The Workgroup also discussed the volume requirements for each type of procedure and the role of the surgeon in the pathway options. Members felt the case numbers were reasonable, but discussed how to manage the gynecologic oncology minimum experience pathway based on previous feedback. It was suggested it might be appropriate to accept cases in which the applicant was the co-surgeon or first assistant as they are usually actively involved in the procedure. However, leaving the requirement to be primary surgeon may be appropriate if the proposed surgeon is utilizing clinical experience pathways to meet requirements since they may lack the training experience.

Upcoming Meeting

May 17, 2021

Attendance

• Workgroup Members

- o Nicole Johnson, Co-Chair
- o PJ Geraghty
- o Paige Porrett
- o Debra Priebe
- o Liza Johannesson
- o Stevan Gonzalez
- o Steve Potter

• HRSA Representatives

- o Marilyn Levi
- o Shannon Dunne

UNOS Staff

- Kristine Althaus
- o Nicole Benjamin
- o Sharon Shepherd
- o Kaitlin Swanner
- o Marta Waris
- o Karen Williams
- o Krissy Laurie