OPTN Vascularized Composite Allograft Transplantation Committee
Genitourinary Membership Requirements Workgroup
Meeting Summary
May 24, 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 05/24/2021 to discuss the following agenda items:

1. Review of Uterus Transplant Program Requirements

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

1. Review of Uterus Transplant Program Requirements

The Workgroup reviewed the proposed requirements for uterus transplant programs.

Summary of discussion:

Primary Physician General Requirements

The Workgroup reviewed the three current pathways qualify as the primary physician of a VCA transplant program and discussed the proposed pathway option that would allow for an obstetrician-gynecologist (OB/GYN) to act as primary physician for a uterus transplant program.

A member noted that the board certification requirements for the OB/GYN pathway mirror one of the current pathways for the VCA primary physician, expect that it is specific to OB/GYNs and requires OB/GYN board certification from either the American Board of Obstetrics and Gynecology, Royal College of Physicians and Surgeons, or a foreign equivalent.

A member asked for clarification regarding whether or not a program with a transplant surgeon as a primary physician would have to demonstrate OB/GYN experience similarly to how a program with an OB/GYN trained primary physician would have to demonstrate experience in immunosuppression. It was clarified that OB/GYN is required as a field of additional medical expertise under the primary surgeon requirements, so all uterus transplant programs will be required to have both OB/GYN and immunosuppression expertise.

The Workgroup discussed the need to specify completion of an appropriate fellowship or residency as part of the OB/GYN pathway. Members noted that OB/GYN board certification requires successful completion of a residency program, and a fellowship is not necessary for this role, so a separate requirement for completion of residency in conjunction with board certification would be redundant.

Recipient Care

As currently written in the proposal, if an OB/GYN is filling the role of primary physician, the program must designate a transplant surgeon or physician that will assist with transplant-specific recipient care.

Previously, proposal language allowed for an OB/GYN to meet requirements for recipient care if they demonstrated adequate experience with immunosuppression. Members mentioned that there is concern that an OB/GYN would not gain enough experience with immunosuppression due to low patient volumes with uterus transplant programs. A Co-Chair stated that over time as these programs increase volume, OB/GYN trained physicians could possibly fill the role. Members supported having collaboration with a transplant surgeon or physician to assist with recipient care if the program has an OB/GYN trained primary physician.

Living Donor Recovery Requirements

The Workgroup reviewed the requirements for uterus living donor components such as recoveries being performed at designated uterus transplant programs, having clinical resources to perform medical and psychosocial evaluations of living donors, and having an independent living donor advocate.

The Workgroup discussed the potential options for a living donor uterus surgeon to meet requirements. An attendee stated that the fellowship option should not be limited to gynecologic oncology (GYN-ONC) since minimally invasive trained surgeons could also perform these procedures. An attendee suggested removing the section referencing GYN-ONC fellowships since qualified individuals could meet requirements by demonstrating experience. A member asked for clarification on how these pathways are outlined for kidney and liver living donor surgeons. It was clarified that living donor kidney surgeons have requirements specific to open and laparoscopic recoveries and liver living donor surgeons must meet primary liver transplant surgeon requirements in addition to the living donor requirements. An attendee asked why liver living donor surgeons must meet the primary liver surgeon requirements and kidney living donor surgeons do not and HRSA staff clarified that there are kidney surgeons trained as urologists that have the skill to recover kidneys, but do not have the qualifications to meet the primary kidney surgeon requirements. An attendee noted that that same logic should be applied to uterus, as in having the skill to perform the uterus recovery and not necessarily meet requirements of primary uterus surgeon.

The Workgroup was asked for feedback on whether the procedures listed in the experience pathway (at least 10 complex hysterectomies, living donor uterus recoveries, or some combination thereof) should include a minimum requirement to have performed at least two uterus recoveries. A Co-Chair asked for clarification on how an individual could meet the living donor uterus recovery experience requirements. It was clarified that an individual could perform the listed procedures as primary surgeon, co-surgeon, or first assistant. An attendee supported requiring a minimum number of uterus recoveries specifically due to vessel preservation that is unique to uterus recovery. An attendee noted that it would be difficult for an abdominal transplant surgeon to act as primary surgeon on living donor uterus recoveries and members supported including the role of co-surgeon to meet the minimum requirement of performing two living donor uterus recoveries since the necessary skills are still acquired in that role.

A member asked for clarification on whether the primary surgeon and primary living donor surgeon would be filled by two distinct individuals or whether one person fill both roles. A Co-Chair stated they could be two separate and distinct roles, but if one person meets all requirements, they could fill both roles. A Co-Chair asked if a letter of commitment or letter of reference specific to the primary living donor surgeon would be appropriate. A member noted that there are separate living donor policies which apply to any living donor and suggested focusing on what is appropriate for OPTN Bylaws without being redundant regarding OPTN Policy.

The Workgroup supported limiting the living donor uterus surgeon requirements to procedures only (rather than including fellowship options), which include demonstrating experience as the primary surgeon, co-surgeon, or first assistant by completion of at least ten complex hysterectomies, living

donor uterus recoveries, or some combination thereof, within the last five years, with at least two of the ten procedures being living donor uterus recoveries performed as primary or co-surgeon.

Medical Expert Support

The Workgroup reviewed the proposed additional medical expertise to be included as part of the primary surgeon requirements. Feedback from the Workgroup was requested on the addition of uterus transplantation to the list of required expertise. It was clarified that as written the primary surgeon and primary physician could come from backgrounds that are not specific to uterus transplantation. Members thought it would be appropriate to include uterus transplantation expertise in case both primary positions are filled by individuals trained in abdominal transplant.

Primary Surgeon Requirements

A member suggested removing the 15 complex hysterectomy option for clinical experience and require that the demonstrated experience be specific to uterus transplant. Another member asked how an abdominal transplant surgeon would meet requirements if that is removed, and it was clarified that those surgeons could qualify under the fellowship pathway. Members noted that it might be a barrier to new programs to remove the 15 complex hysterectomy clinical experience option and the Workgroup supported leaving this clinical experience option in the proposal.

Next Steps:

A summary of the proposed requirements will be shared with the Workgroup prior to a review of the proposal by the VCA Committee on June 9, 2021.

Upcoming Meeting

- June 9, 2021 (Committee)

Attendance

- **Workgroup Members**
  - Nicole Johnson, Co-Chair
  - Stefan Tullius, Co-Chair
  - Paige Porrett
  - Liza Johannesson
  - Steve Potter
  - Mark Wakefield
  - Sanjeev Akkina
  - Lawrence Gottlieb
  - Deb Priebe
- **HRSA Representatives**
  - Jim Bowman
- **UNOS Staff**
  - Kristine Althaus
  - Nicole Benjamin
  - Kaitlin Swanner
  - Marta Waris
  - Karen Williams
  - Krissy Laurie
  - Leah Slife
  - Sarah Booker
- **Other Attendees**
  - Kate O'Neill
  - Elliott Richards