OPTN Vascularized Composite Allograft Transplantation Committee
Genitourinary Membership Requirements Workgroup
Meeting Summary
December 21, 2020
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 12/21/2020 to discuss the following agenda items:

1. Overview of Project Plan
2. Overview of Existing VCA Membership Requirements and Living Donor Requirements
3. Review/Finalize Project Form
4. Open Forum

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

1. Overview of Project Plan

A Co-Chair presented an overview of the project plan.

Summary of discussion:

The workgroup will develop a proposal for consideration by the VCA Committee in June 2021, with the goal of releasing the proposal for public comment in August 2021. Members did not have any questions or comments.

2. Overview of Existing VCA Membership Requirements and Living Donor Requirements

UNOS staff presented an overview of general membership requirements for transplant programs, existing membership requirements for VCA transplant programs, and requirements specific to programs performing living donor recovery of certain organs.

Summary of discussion:

A Co-Chair explained that the workgroup will focus primarily on the section of the bylaws specific to VCA unless the workgroup identifies any other section of the bylaws that should be modified for genitourinary transplant programs. Additionally, the requirements identified by the workgroup for genitourinary transplant programs will be inserted into the existing appendix for VCA membership requirements. Members did not have any questions or comments.

3. Review/Finalize Project Form

The Workgroup reviewed the project form in preparation for review by HRSA, the Policy Oversight Committee (POC), and the Executive Committee for project approval.

Summary of discussion:

A Co-Chair explained that the Workgroup must identify a key metric for the project for POC review. This project aligns with the strategic plan goal to promote living donor and transplant recipient safety, so the proposed key metric is to evaluate the number of patient safety reports relative to the volume of approved genitourinary transplant programs. This metric will demonstrate that programs are adhering to the updated requirements, which are intended to protect living donor and transplant recipient safety.

A member asked if the genitourinary membership requirements will only include requirements for uterus, or if the requirements would also apply to penis transplant programs, and if so, if the workgroup roster includes a urologist. A Co-Chair confirmed that the requirements will apply to penis transplant programs as well, and that the workgroup includes a urologist. A Co-Chair said that the workgroup will also consider additional expertise needed for penis transplant programs.

Next steps:

The project form will be submitted to HRSA, the POC, and the Executive Committee for review and project approval.

4. Open Forum

The Workgroup discussed general considerations that should be taken into account in the development of more specific requirements for genitourinary transplant programs.

Summary of discussion:

A Co-Chair said that it is important to appoint people in the key transplant personnel roles to do the work that they are intended to do, whereas with the current requirements, it feels like programs might have to name someone to a key position just to meet the requirements. The workgroup should seek to avoid key personnel appointments that are "in name only." A member asked if the Co-Chair was concerned about excluding people from key positions if a certain specialty was designated as a requirement for a position. The Co-Chair said the goal would be to avoid having to name a nephrologist as the primary physician for a uterus transplant program just because the nephrologist meets the requirements, particularly since it is important to ensure that the obstetrics and gynecology (OB/GYN) experience is represented within the team. The Co-Chair noted that the workgroup will also want to ensure that immunosuppression expertise is covered by the requirements.

The Co-Chair said that the workgroup will need to consider what additional support is needed and whether that should be folded into these requirements, for example, follow-on care for pregnancy, delivery, and care for newborns after transplant. A member said that some of these items may be requirements for the team rather than requirements specific to the primary physician or primary surgeon. A member suggested looking at the current composition of genitourinary transplant programs, and that the workgroup take caution not to limit program growth by pigeonholing a role with specific requirements that may work well for one program but might not be applicable for another program. Instead, the workgroup should focus on covering the bases of knowledge and skills. A Co-Chair agreed, and said that since this is a novel field, the requirements should not be overly burdensome but should ensure that the patients are taken care of.

A member observed that the current membership requirements for key transplant personal tend to be rooted in training paradigms which are well-established for other types of transplant, but less so for VCA and genitourinary transplants. There are dedicated fellowships in transplantation for a variety of specialties, but the member was unaware of any type of designated transplant fellowship within

OB/GYN as a discipline. Accordingly, the workgroup needs to establish requirements that are appropriately stringent but also flexible enough to allow room for programs to develop experience.

Members agreed that incorporating maternal and fetal medicine expertise is necessary for uterus transplant programs, and that having adequate support for in vitro fertilization is also a critical component to ensure a successful uterus transplant outcome. A member said that the expertise related to safety should be a major consideration for the leadership positions. For example, while IVF is a critical component for a successful uterus transplant, it is probably the maternal-fetal medicine specialist and the transplant surgeon who play the largest role in patient safety for uterus transplants.

A member noted that uterus transplant teams are very large, and there will be requirements for expertise and requirements for leadership, which sometimes may overlap and sometimes may not. It may be appropriate to establish a different model for uterus transplant programs than what is currently used for other transplant programs. A Co-Chair agreed that the workgroup may want to consider if it would be appropriate to add key personnel requirements. For example, liver transplant programs are required to have a director of anesthesia, which is not a complicated application but asks the programs to attest to certain requirements. A member said the workgroup should consider what the program needs to be able to accomplish versus what the leadership should do. Members agreed that it may be appropriate to have alternate routes besides designated fellowships to determine whether personnel are qualified, for example, letters testifying to relevant experience.

A Co-Chair said that the workgroup should consider the roles of the primary surgeon and primary physician and how they should be distinguished, noting that the workgroup can develop more specific requirements for these roles as needed. The Co-Chair said that with the current requirements, the people selected for their program to be the primary physician and primary surgeon could essentially fill either role, so it might be worth exploring further what those roles really should entail. UNOS staff noted that Appendix D of the OPTN Bylaws list some requirements of the primary physician and primary surgeon roles pertaining to their leadership responsibilities. UNOS staff said that when the VCA Committee initially developed membership requirements, the idea was that the primary physician would manage immunosuppression. Accordingly, the requirement was written very broadly so that a surgeon or a physician could fill that role as appropriate.

A Co-Chair said that for the living donor recovery requirements, the workgroup may need to require surgical expertise relevant to the approach, for example, open hysterectomy versus minimally invasive hysterectomy. A member was not aware of any programs performing living donor penis transplants but noted that it could happen in the future as part of gender reassignment surgeries. A Co-Chair suggested that the workgroup consider whether it would be appropriate to require that transplant hospitals with living donor VCA programs be approved for another type of living donor transplantation, since the VCA program would benefit from having the resources, infrastructure, and support of another established living donor program.

UNOS staff noted that the Membership and Professional Standards Committee (MPSC) is currently working on a separate project to revise membership requirements, so UNOS staff supporting this workgroup and the MPSC will coordinate closely to ensure the proposals are not in conflict. One of the MPSC's proposals is slated for public comment in January 2021 and includes some revisions to Appendix D, including removing the role of the program director. The MPSC is also releasing a request for feedback in January 2021 regarding the training and experience requirements for primary surgeons and primary physicians that may be of interest to the workgroup. The MPSC tentatively plans to release an additional proposal for public comment in August 2021.

Next steps:

UNOS staff will send out materials to the Workgroup prior to the next call. The Workgroup will discuss primary surgeon requirements for genitourinary organ transplant programs during their next meeting on 1/18/2021.

Upcoming Meetings

- January 18, 2021
- February 15, 2021

Attendance

- **Workgroup Members**
    - Nicole Johnson, Co-Chair
    - Stefan Tullius, Co-Chair
    - Sanjeev Akkina
    - Linda Cendales
    - PJ Geraghty
    - Stevan Gonzalez
    - Paige Porrett
    - Debra Priebe
    - Mark Wakefield
- **HRSA Representatives**
    - Jim Bowman
    - Raelene Skerda
- **UNOS Staff**
    - Kristine Althaus
    - Sally Aungier
    - Nicole Benjamin
    - Elizabeth Miller
    - Sharon Shepherd
    - Kaitlin Swanner
    - Jen Wainwright