OPTN Vascularized Composite Allograft Transplantation Committee
Genitourinary Membership Requirements Workgroup
Meeting Summary
January 20, 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 01/20/2021 to discuss the following agenda items:

1. Review Primary Surgeon Requirements
2. Review Current Requirements for VCA Primary Surgeons
3. Develop Primary Surgeon Requirements for Genitourinary Organ Transplant Programs

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

1. Review Primary Surgeon Requirements

UNOS staff presented an overview of general primary surgeon requirements in the OPTN Final Rule[1] and the OPTN Bylaws[2] that apply to all transplant programs.

Summary of discussion:

A Co-Chair asked if the program director is the director for all VCA transplant programs at a transplant hospital, whereas the primary surgeon is selected specifically for the type of VCA transplant program (e.g. genitourinary). UNOS staff explained that each transplant hospital must apply to have a designated transplant program for each VCA type they plan to transplant, and each of those programs must have a designated program director, but one person can be the program director for multiple programs. Each program can also have a different program director if desired. UNOS staff noted that the Membership and Professional Standards Committee (MPSC) has been working on a proposal that would eliminate the program director role but retain both the primary physician and primary surgeon roles. One person can also serve as the primary physician or primary surgeon for multiple transplant programs.

A member asked how the Workgroup should think about the changes they propose in relation to the changes under consideration by the MPSC, in terms of when the different changes might be rolled out, and whether the Workgroup should assume that the changes proposed by the MPSC will be implemented. UNOS staff said that the changes proposed by the MPSC have not yet gone out for public comment and have not been approved by the Board, so the Workgroup should from the language currently in the OPTN Bylaws. Additionally, the MPSC proposal was originally expected to go out for public comment during the Winter 2021 cycle but was delayed, so UNOS staff are not sure yet when this proposal will go out for public comment. Accordingly, the VCA proposal could go to the Board before the

[1] 42 CFR §121.9
[2] OPTN Bylaws, accessed February 15, 2021, https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf

MPSC's proposal has been approved by the Board. UNOS staff will coordinate and keep the Workgroup updated in terms of where the proposals stand and what is included in the MPSC proposal. A member from the MPSC said that based on historical precedent, the MPSC does not expect major concerns in public comment, and expects their proposed changes will be approved by the Board. A Co-Chair said it seems like most of the changes proposed by the MPSC would not conflict with the scope of the VCA workgroup's project. UNOS staff noted that HRSA has not yet expressed any specific concerns about the MPSC's proposal that might impact the VCA proposal and promised to provide updates as more information becomes available.

2. Review Current Requirements for VCA Primary Surgeons

UNOS staff presented an overview of the current requirements being implemented[3] for the primary surgeons of VCA transplant programs, including for upper limb, head and neck, abdominal wall, and "other" VCA transplant programs.

Summary of discussion:

A member asked who established the requirements for the foreign equivalency pathway for those who are not board certified. UNOS staff explained that those requirements were developed by the VCA Committee in 2014 and 2015. The member asked if these requirements can be revisited since the requirements used to be much simpler. UNOS staff explained that when VCA were first added under OPTN purview, there was a need to put something in place as a placeholder for the VCA membership requirements. This was the requirement to submit a letter of notification to the OPTN, which is what is in the current OPTN Bylaws. The membership requirements being implemented in 2021 are more aligned with the requirements for other OPTN transplant programs.

A member noted that the current requirements for the primary surgeon of "other VCA" transplant programs includes a requirement to perform pre-operative evaluation of at least 3 potential VCA transplant patients. A member said this assumes that the program is in existence and asked how this impacts new programs that have not done this type of transplant before, and whether the implication is that those programs should have started to evaluate potential VCA patients prior to program approval. A Co-Chair agreed the Workgroup has to consider how to handle situations in which programs did not have the opportunity to evaluate patients or did not complete a specific fellowship because there is not a fellowship specific to these types of transplants. The member expressed concern that this is a barrier. The Vice Chair of the VCA Committee acknowledged the concern but said that even with other new transplant programs, there is always a balance between making sure people have the right experience and promoting innovation. The Vice Chair noted that this is just for the requirements for the primary surgeon and that the expectation has generally been that at least one person at the program knows what they are doing. The language is written broadly to allow for evaluation of any potential VCA transplant patient, so it could be a patient other than a uterus candidate. The Vice Chair said that whether or not this is appropriate is a different question. The member agreed it is logical to require at least one person from the team to have experience from another VCA transplant program, but wanted to clarify the expectations from the OPTN. A member noted that the requirement to conduct pre-operative evaluation is very nonspecific. A member agreed and said that "potential VCA transplant patient" also is not very specific. A Co-Chair said this leads to a broader question about the workgroup's philosophy for developing the requirements for genitourinary transplant programs, and whether the workgroup believes that there are enough programs in existence that it is reasonable to expect that the

[3] "Vascularized Composite Allograft Membership Changes," OPTN, Combined Policy Notice, accessed February 15, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf

key transplant personnel at new programs would have received training at an existing genitourinary organ transplant programs, or if this is still so new that people interested in starting a program do not need to have had previous experience in genitourinary organ transplantation.

A member asked if the requirement for pre-operative evaluation of at least 3 potential VCA transplant patients applies to either the primary surgeon or the primary physician, or to both. The member says it makes sense to have one person who has met this requirement but maybe not both of them. UNOS staff said the requirement is just for the primary surgeon. A Co-Chair said this is another question the workgroup should consider, as to whether this requirement should apply to the primary surgeon or the primary physician, since both would be involved in patient evaluation. The Co-Chair recommended revisiting this question when the Workgroup discusses the primary physician requirements. The member asked whether this requirement could be written to apply to either the surgeon or the physician. UNOS staff explained that in its current state, the requirement applies only to the primary surgeon, so the MPSC could not approve a person as the primary surgeon of an "other VCA" transplant program without this experience. A Co-Chair said that for uterus transplantation, it would be appropriate for any requirement for pre-operative evaluation of patients to be fulfilled either by the primary surgeon or the primary physician. A Co-Chair noted that other organs don't necessarily have a pre-operative evaluation requirement for the primary surgeon.

A Co-Chair asked whether the Workgroup must apply the same requirements for "other VCA" transplant programs to genitourinary organ transplant programs. UNOS staff explained that the Workgroup can pull together whatever requirements they think are appropriate for a genitourinary organ primary transplant surgeon. The requirements for "other VCA" transplant programs were written broadly to apply to any other type of VCA that did not have specific requirements, so the requirement for pre-operative evaluation was an effort to include some sort of experience requirement. A Co-Chair said that since the Workgroup is establishing new requirements for genitourinary organ transplant programs, they are not beholden to the requirements being implemented for "other VCA" transplant programs. A member asked if the Workgroup will be developing requirements broadly for genitourinary organ transplant programs or requirements that are more specific to the type of genitourinary organ being transplanted, e.g., uterus or penis. UNOS staff said the Workgroup can decide whether broader requirements for genitourinary organs are appropriate or whether there should be requirements that are more specific to the type of genitourinary organ being transplanted.

3. Develop Primary Surgeon Requirements for Genitourinary Organ Transplant Programs

The Workgroup discussed requirements that should apply to the primary surgeon of a genitourinary organ transplant program.

Summary of discussion:

UNOS staff reviewed the structure of the primary surgeon requirements for head and neck and upper limb programs, which includes requirements for board certification; a foreign equivalency pathway in the event a surgeon is ineligible for U.S. board certification; and experience requirements. For the experience requirements, the primary surgeon must have completed a fellowship that meets the criteria in the Bylaws or completed a minimum experience pathway, which requires two years of consecutive and independent practice in the field and completion of a minimum number of related procedures. A member asked if the minimum experience requirements are bound by a time limit. There is no time limit listed in the requirements being implemented.

A Co-Chair recommended sticking within the same framework for head and neck and upper limb programs. A member agreed that it will be less confusing if the genitourinary organ requirements follow the same framework, unless the Workgroup has a good reason to deviate from this framework.

Board Certification Requirement

The Workgroup identified the following boards as appropriate for the primary surgeon of a genitourinary organ transplant program:

- American Board of Surgery
- American Board of Obstetrics and Gynecology
- American Board of Urology
- American Board of Plastic Surgery

A member said it depends on the type of transplant. For reconstructive genitourinary organs, the surgeon is generally a plastic surgeon or a urologist, and perhaps occasionally a gynecologist. Hysterectomies are almost always performed by a gynecologist. The member said a gynecologist should be involved for uterus transplantation but a gynecologist would not necessarily have the expertise to perform reconstruction of male genitourinary organs.

A Co-Chair said the primary surgeon should be distinguished from the primary donor surgeon for uterus transplantation. The primary surgeon would need to have transplant surgery experience and the primary donor surgeon would need to be a gynecologist, or a surgeon with experience in hysterectomy. A member said this raises a good point about the diversity of the operations but noted that the primary surgeon role is an administrative leadership program responsibility role. The member said there is a lot of clinical expertise that goes into making a uterus transplant program or any other VCA transplant program work, because there is a need for diverse team members because of the diversity of the surgeries. However, the member recommended that the Workgroup build flexibility into the primary surgeon requirements because whoever is designated as the primary surgeon will not be the only person who performs the operations, but rather, the primary surgeon should be the person who has the appropriate expertise to be the administrative leader of the program. The member was open to the idea that the primary surgeon of a uterus or penis transplant program could be anyone who is board-certified in their field of expertise. The member recommended including any boards that would be suitable so that a program could choose a transplant surgeon or a gynecologist to fill the primary surgeon role as the administrative program leader who is responsible in the eyes of UNOS. A Co-Chair agreed. A member said that this approach does not align with the current requirements for head and neck and upper limb transplant programs. A member said that may be a flaw with the current requirements for head and neck and upper limb.

A Co-Chair asked if the requirements should be written so that either the primary surgeon or the primary physician has transplant experience. Members agreed that both the primary surgeon and the primary physician do not need to have transplant experience, but that at least one of them should have that experience. UNOS staff said there is some precedent for conditional requirements so it would not be a problem to include that type of provision in the bylaws. A member suggested that “transplant experience” should be defined at some point so there is not confusion about what that means. UNOS staff agreed, on behalf of the MPSC and the members who review these applications. A Co-Chair suggested defining transplant experience as meeting the requirements for the primary surgeon or primary physician of another program, since that language is included elsewhere in the bylaws, but the Co-Chair was not sure if that would be too prescriptive.

Experience in Place of Board Certification

UNOS staff reviewed the foreign equivalency pathway for upper limb and head and neck primary surgeons, which includes additional experience requirements for those who are ineligible for U.S. board certification:

- Acting as first-assistant or primary surgeon on procurement
    - Upper limb and head and neck: at least 1 VCA procurement
- Pre-operative evaluation of potential transplant patients
    - Upper limb: at least 3 potential upper limb transplant patients
    - Head and neck: at least 3 potential head and neck transplant patients
- Acting as primary surgeon for transplant
    - Upper limb: at least 1 upper limb transplant
    - Head and neck: at least 1 head and neck transplant
- Post-operative follow-up of a recipient
    - Upper limb: at least 1 upper limb recipient for 1 year post-transplant
    - Head and neck: at least 1 head and neck recipient for 1 year post-transplant

A member said that having foreign credentialing similar to a board certification would make more sense than having experience with procurement. A Co-Chair agreed that being certified by the boards identified by the Workgroup would not necessarily equate to meeting these experience requirements. The Vice Chair said the purpose of the board certification or equivalent is to have some assumption of competence based on some required certification. A member said that board equivalency is subjective but it is important to have a mechanism for program leaders who are not board-certified to show their equivalency in some sort of detailed way, similar to what is required for hospitals or state licensing boards. A member asked if there could be three categories: (1) board certification in the U.S., (2) an equivalent to board certification from abroad, and (3) an experience pathway. An MPSC member suggested that it would make sense to stay aligned with the categories currently outlined in OPTN bylaws, both from an enforcement standpoint and from an implementation standpoint.

A Co-Chair asked if the Workgroup could forgo the experience requirements for genitourinary organ transplant programs, so that the foreign equivalency pathway just requires (1) that the member is ineligible for U.S. board certification; (2) that the member provide a plan for continuing education; and (3) that the member provides two letters of recommendation. The Co-Chair noted that there will be a separate opportunity to establish experience requirements for the primary surgeon. UNOS staff explained that these are the requirements are consistent with the foreign equivalency pathway for most organs, whereas the extra experience requirements were added for upper limb and head and neck. UNOS staff confirmed that the Workgroup does not need to include experience requirements for the genitourinary organ primary transplant surgeon foreign equivalency pathway if the Workgroup does not think they are appropriate. The Workgroup agreed to exclude the experience requirements from the foreign equivalency pathway and focus on experience requirements separately. A Co-Chair suggested that, if some of these criteria are included in the experience requirements, it would be challenging for new programs to complete pre-operative evaluations or post-operative follow-up, but it might be appropriate to have requirements related to procurement and transplant.

Fellowship Requirements

The Workgroup reviewed the current fellowship requirements for the primary surgeons of upper limb and head and neck programs. A member noted that completing a fellowship in hand surgery or head and neck surgery does not mean that the person has any experience with transplant, unless the fellowship was completed at a center that has a transplant program. The member suggested requiring both a fellowship and completion of a transplant. A Co-Chair agreed that transplant experience should be included.

The Workgroup identified the following fellowships as appropriate for the primary surgeon of a genitourinary organ transplant program:

- Gynecologic oncology
- Transplant
- Microsurgery

A member said that surgeons trained in hysterectomies complete a residency, and asked whether that would be considered adequate experience. A member said that is not a fellowship and that they may or may not be qualified to be the primary surgeon for a uterus transplant program. The member agreed that the fellowship might not be necessary since the board certification meets the basic competency requirement, and the other experience gained afterwards is what matters. The member said that a maternal-fetal medicine fellowship would not make sense as a requirement because it is not related to surgery. A Co-Chair said that maternal-fetal medicine training could be covered under other requirements for the transplant program rather than under the requirements for primary surgeon.

Next steps:

The Workgroup will continue discussing primary surgeon requirements and start discussing primary physician requirements on their next call.

Upcoming Meetings

- February 17, 2021
- March 15, 2021

Attendance

- **Workgroup Members**
  - Nicole Johnson, Co-Chair
  - Stefan Tullius, Co-Chair
  - Sanjeev Akkina
  - Sandra Amaral
  - PJ Geraghty
  - Stevan Gonzalez
  - Lawrence Gottlieb
  - Liza Johannesson
  - Paige Porrett
  - Steve Potter
  - Debra Priebe
  - Mark Wakefield
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Kristine Althaus
  - Sally Aungier
  - Nicole Benjamin
  - Elizabeth Miller
  - Sharon Shepherd
  - Leah Slife
  - Kaitlin Swanner
  - Marta Waris
  - Karen Williams