OPTN Vascularized Composite Allograft Transplantation Committee
Genitourinary Membership Requirements Workgroup
Meeting Summary
February 17, 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 02/17/2021 to discuss the following agenda items:

1. Primary Surgeon Requirements

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

1. Primary Surgeon Requirements

The Workgroup discussed requirements for the primary surgeon of a genitourinary organ VCA transplant program.

Summary of discussion:

Overview of Primary Surgeon Requirements for Upper Limb & Head and Neck Transplant Programs

The primary surgeon requirements for upper limb and head and neck transplant programs have three main components: (1) general requirements regarding degree, licensure, and credentialing, as well as observation of multi-organ procurements; (2) board certification requirement, which can be met by American board certification or an alternative to American board certification; and (3) experience requirements, which can be met though completion of an Accreditation Council for Graduate Medical Education (ACGME) fellowship; completion of another fellowship that meets OPTN criteria; or a minimum clinical experience pathway.

The Co-Chair noted that there is no ACGME fellowship specific to genitourinary organ transplants and asked if that means the primary surgeon for a genitourinary organ transplant program can only qualify via the clinical experience pathway. UNOS staff said that the Workgroup had previously identified some appropriate fellowships for the experience requirement but the Workgroup could also work on defining a clinical experience pathway. A member said that for organs that have a low case volume, like intestine and VCA, having parallel paths to qualify may be the best approach to help new programs get started.

A member clarified that for genitourinary organ transplant programs, a suitable ACGME fellowship would not be a fellowship specific to uterus transplant, for example, but fellowships that would be relevant, like plastic surgery, urology, or gynecology. If the workgroup follows the same structure as the upper limb and head and neck requirements, then a primary surgeon could meet the experience requirements either by completing a fellowship in a field specified by the workgroup, or through a clinical experience pathway. A member said that the Workgroup needs to find a balance that will let qualified people in the door to start doing these transplants and support growth in the field, but will not allow inexperienced people to do these transplants, since that could result in negative outcomes that

would harm the field as a whole. The member thought that providing multiple pathways to meet the experience requirements strikes the right balance.

A member said that the clinical experience pathway allows someone who comes from a residency program and does not have a fellowship – ACGME or otherwise – but has gained appropriate experience to be eligible for primary surgeon. The three pathways seem like a reasonable approach to balance the somewhat conflicting goals of ensuring a level of experience while allowing for growth in the field.

A member asked what the clinical experience pathway would look like. A member said the kidney and liver requirements are very prescriptive in terms of numbers of procedures. The Workgroup reviewed the minimum experience requirements for upper limb and head and neck. A member explained that these requirements were based on the number of procedures that fellows are required to submit for their certificate of qualification. The procedures include complex reconstructive surgeries that are relevant to these types of transplants and a smaller but meaningful number of transplants.

Board Certification Requirement

The Workgroup reviewed the board certification options they had identified previously:

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

The Workgroup supported these board certification options. When asked if any boards should be added or removed from this list, a member said that it depends what is being transplanted. UNOS staff said that this raises the question of whether these requirements should be bifurcated in some way, perhaps based on whether the program intends to perform uterus or penis transplants. A Co-Chair agreed that the expertise required for uterus and penis transplants are very different.

A member asked if certification from the American Board of Surgery alone is sufficient, but acknowledged that the experience requirements could balance the more general board certification requirement. A Co-Chair thought that American Board of Surgery certification would be sufficient.

A member asked if it would be appropriate to include the American Board of Orthopedic Surgery, in the event that an orthopedic surgeon had experience in a hand or upper limb VCA transplant program. A Co-Chair was not sure about this since uterus and penis transplants are very different from hand or limb. The member said he was envisioning a situation in which a reconstructive orthopedic surgeon with microvascular expertise was part of a hand transplant team, and perhaps the hospital wants to start a penis transplant program. In this case, if the orthopedic surgeon had the interest and the microvascular expertise, the member was wondering if it would be appropriate for the surgeon to be the primary surgeon for that penis transplant program. A Co-Chair thought that would be acceptable. A member said that it makes more sense to allow a microvascular orthopedic surgeon to be the primary surgeon than someone with certification from the American Board of Surgery who might not have clinical experience with genitourinary organs. A member said that their program is doing this in a way by designating their upper limb transplant surgeons as primary surgeons of other VCA transplant programs because of their expertise in transplant. The member noted that the primary surgeon for the transplant program is not necessarily the lead for the transplant surgery. A member said he had suggested this approach so that the requirements would be inclusive, even if this situation is uncommon. A Co-Chair thought this would be appropriate with an emphasis on the reconstructive and microsurgery experience, and that the one person designated as the primary surgeon may not have all of the clinical expertise required for the transplant procedure.

Experience Requirements – Fellowships

The Workgroup reviewed the fellowship options they had identified previously:

- Gynecologic oncology
- Transplant surgery
- Microsurgery

Some members were not clear on why the gynecologic oncology fellowship would be appropriate. A member said that gynecologic oncology is the most relevant fellowship for uterus transplant because they are the surgeons trained to perform radical hysterectomies. The member agreed that it doesn't really make sense for penis transplantation, so it depends on whether the Workgroup intends to develop separate requirements for uterus and penis transplantation or whether the requirements should be combined for all genitourinary organs. The member said people might have been confused because they associate the gynecologic oncology fellowship more with administration of chemotherapy, but that is the fellowship that requires the most surgical experience out of the gynecologic fellowships. A member said he had previously brought up maternal-fetal medicine (MFM) but he realized it just happened to be at his institution that they have gifted surgeons with MFM fellowships that handle complicated placental cases, but in many other places, the gynecologic oncology specialists handle those cases, so the gynecologic oncology fellowship seems appropriate.

A member suggested adding reconstructive urology, which is a separate non-ACGME fellowship orchestrated by the American Urological Association via the Society of Genitourinary Reconstructive Surgeons that would be very appropriate for penis transplantation.

A member suggested adding vascular surgery as an option. A member said that there was a period of time in solid organ transplant when vascular surgeons were heavily involved, but the focus of VCA transplants is more on microsurgery, so the member did not think it should be included.

The Workgroup reviewed the OPTN criteria used to identify acceptable fellowships for upper limb and head and neck programs other than those that are ACGME-approved. A member noted that not all of the fellowships identified by the Workgroup are ACGME-approved, including the transplant surgery fellowship. For transplant surgery, one gets a certificate from the American Society of Transplant Surgeons (ASTS). UNOS staff said the Workgroup does not necessarily have to follow the same dichotomy of ACGME-approved and non-ACGME fellowships, so the Workgroup could identify non-ACGME fellowships that are appropriate for fulfilling this requirement. The question is whether there are other fellowships that would be appropriate that would fulfill the OPTN criteria. The member said there is such a wide variety of fellowships that it may be hard to determine which other pathways would be appropriate and how to identify them. A member said that the reconstructive urology fellowship is not ACGME and does not have the track record of ASTS, but they have a formal match process and provide a completion certificate. The member believed that all of the programs participating in penile transplant have fellowships in this arena, since it requires the convergence of a urology program large enough to have a reconstructive focus, along with a transplant program. UNOS staff offered to do some more research in this area so that the Workgroup can revisit whether these additional criteria is needed.

Experience Requirements – Minimum Clinical Experience Pathway

UNOS staff asked if there are certain resources the Workgroup should reference as a baseline for determining what should be included in an experience pathway. This would allow surgeons to qualify as the primary surgeon based on their clinical experience, even if they have not completed one of the fellowships identified by the Workgroup. A member said that it is helpful to know that the upper limb

and head and neck requirements were developed based off of existing fellowship requirements, since that provides a potential framework.

For uterus, the Workgroup might be able to use the transplant fellowship requirements for liver, kidney, and pancreas as a reference. The gynecologic oncology fellowship might serve as a reference in terms of the number of hysterectomies that should be performed. A member said it might be hard to set a minimum number of uterus transplants since the case volume worldwide is low. The member suggested that surgeons could supplement transplant experience with cases of radical hysterectomies, but that would only apply to gynecologic surgeons. General surgeons would not have performed those procedures either. The member said it is hard to identify other procedures that would be appropriate besides retrieval of the organ and the transplant itself; there might not be substitute procedures as there seems to be for upper limb and head and neck. A Co-Chair agreed that a radical hysterectomy seems to have the most in common, but procurement and transplant include other aspects that would not be covered. The numbers listed for upper limb and head and neck procedures seem far-fetched to be reachable in preparation. The Co-Chair recommended listing radical hysterectomies but was not sure if abdominal organ transplant experience would be relevant, or what number of procedures would be helpful. There would need to be something else to include some sort of exposure to uterus transplantation. A member agreed that uterus transplant and uterus retrieval should be listed, but any case number requirement over five would be near impossible. The member could not think of any other procedures that would be appropriate, except perhaps multi-organ procurement, but that does not say anything about experience with uterus transplant. A member said the Membership and Professional Standards Committee (MPSC) is trying to reduce the number of multi-organ procurement requirements for other specialties.

A member pointed out that this pathway is for the group of people who have not done a fellowship, so for uterus transplant, there may be some value in having experience with a kidney, liver, or pancreas transplant. For penile transplant – there are case minimums for the fellowships, and relevant procedures include urethroplasty, penectomy for penile cancer, and reimplantation for trauma. The member agreed there should be some minimum requirement for experience with the actual procedure.

A member said she saw this pathway as applying more to foreign-trained medical professionals, since people trained in the U.S. will likely meet the requirements for board certification and have completed a relevant fellowship. The member suggested that if a foreign-trained surgeon is coming to the U.S. to start one of these programs, the surgeon likely has previous exposure to this procedure, so it may be appropriate to require experience with uterus transplant or penis transplant as part of this pathway. A Co-Chair suggested that a case minimum between three and five would be more realistic for these procedures, rather than more than five. A member agreed and said that requiring a number above five would probably be impossible for almost anyone, if they are not coming from one of the larger centers. The member suggested that radical hysterectomies could substitute experience in uterus transplantation. For example, if a surgeon has only participated in one uterus transplant and three to five are required, perhaps the surgeon could substitute with radical hysterectomies. However, the member thought that at least some uterus transplant experience should be required, so a surgeon could not qualify based solely on experience with radical hysterectomies. A Co-Chair said the same could be apply for abdominal organ transplants, and noted that it would be rare for someone to have both experience in abdominal organ transplants and experience in radical hysterectomies. Members supported this approach.

Other Primary Surgeon Requirements

The Workgroup discussed whether there should be any additional requirements for the primary surgeon of a genitourinary organ transplant program. A member noted that in the VCA membership

requirements being implemented,[1] genitourinary organ transplantation falls under "other VCA" transplant programs, for which the team must demonstrate experience in microvascular surgery, but experience in uterus transplantation is not a qualifying criteria. The member said that it does not really make sense to require experience that does not include experience with the actual organ being transplanted. UNOS staff noted that the Workgroup does not need to carry those requirements forward in these updated requirements for genitourinary organ transplant programs.

A member said that there is great interest in making sure there is some way to showcase the experience in uterus transplant or penis transplant as appropriate. The member noted that based on Workgroup discussions so far, the primary surgeon must meet all of the general requirements; the primary surgeon must have board certification or meet the alternative requirements to U.S. board certification; and the primary surgeon must either have completed a designated fellowship or meet the criteria of the clinical experience pathway. The member pointed out that someone could meet all these requirements to be the primary surgeon of a penis transplant program without any actual experience in penis transplantation. The member asked if the primary surgeon should have some experience – defined loosely – with this set of transplants, even to have watched one. A member said that it would be good for the primary surgeon to have some relevant clinical experience. A member suggested adding a requirement for the primary surgeon to at least have seen one of the relevant transplants.

A member said that for upper limb, a surgeon can be the primary surgeon without participating in or observing upper limb transplant, but one of the requirements is that they have observed at least two multi-organ procurements. At the time, the VCA Committee felt that was appropriate because there were not enough transplants yearly to provide that experience. That does not exclude them from being very capable of leading a hand or upper limb transplant program. The same rationale was used for head and neck transplant programs.

A member asked whether that is the best approach to take for genitourinary organ transplantation. The member was uncomfortable with the idea of letting someone be the primary surgeon if they have not at least seen one of these transplants. The member recognized these are not high volume transplants but wanted to make sure that when the OPTN certifies these programs to do transplants, it does so with a safety lens of ensuring the individuals are appropriately trained. A member responded that the idea for upper limb wass that there are many components to an upper limb transplant surgery, including patient evaluation and immunosuppression, and one surgeon may not have experience in all aspects of the surgery. Many of the techniques used in an upper limb transplant surgery are standard of care for other procedures. The member noted that people may also have lots of training and experience in the necessary techniques through cadaver labs, so people can be experts technically for this role without having performed one of these transplant surgeries. The member expressed concerns about the low case volume for VCA transplants and limited opportunities to observe a surgery, and noted that observation alone does not make a person qualified to do the surgery. A member said her goal is not to put up barriers for people in the field but felt that there are a sufficient number of programs doing uterus transplant that people interested in entering the field should have the opportunity to observe and at least discuss the procedures with the programs doing these transplants.

A Co-Chair asked the Workgroup whether they believe there are differences between uterus transplantation and upper limb transplantation in terms of how technical components are valued relative to other aspects of transplantation. HRSA staff said this is a good question, because reimplantation has been performed in the reconstructive and orthopedic fields for decades, but there is

[1] "Vascularized Composite Allograft Membership Changes," OPTN, Combined Policy Notice, accessed February 22, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf

probably no analogy to reimplanting a uterus. HRSA staff noted that there is a distinction between the requirements specifically for the primary surgeon and the requirements for a transplant program as a whole, which include facility requirements and ancillary staff support. HRSA staff suggested that the OPTN consider if it would be appropriate to require some member of the transplant program to have experience in the procedure, if not the primary surgeon. A Co-Chair agreed there should be some sort of small minimum, which could be a compromise between establishing that expectation of experience without hindering growth in the field.

Next steps:

Members agreed to share the case minimum requirements for related fellowships with the Workgroup prior to the next call. The Workgroup will continue working on the clinical experience pathway, along with the primary physician and other transplant program requirements.

Upcoming Meetings

- March 15, 2021
- April 19, 2021

Attendance

- **Workgroup Members**
  - Stefan Tullius, Co-Chair
  - Sanjeev Akkina
  - Linda Cendales
  - 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
  - Sharon Shepherd
  - Leah Slife
  - Kaitlin Swanner
  - Jen Wainwright
  - Marta Waris
  - Karen Williams