OPTN Vascularized Composite Allograft Transplantation Committee
Meeting Summary
June 9, 2021
Conference Call

Bohdan Pomahac, MD, Chair
Sandra Amaral, MD, Vice Chair

Introduction

The Vascularized Composite Allograft (VCA) Transplantation Committee met via Citrix GoTo teleconference on 06/09/2021 to discuss the following agenda items:

1. Review of Proposed Uterus Transplant Program Requirements

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

1. Review of Proposed Uterus Transplant Program Requirements

The Committee reviewed and discussed the proposed uterus transplant program requirements. The proposal will split the VCA type "genitourinary organ" into three categories and will define membership requirements for uterus transplant programs.

<u>Summary of discussion:</u>

Primary Surgeon Clinical Experience Pathway

The Committee discussed defining "complex hysterectomy" terminology and whether or not these procedures would be adequate for primary surgeon experience requirements. The Chair noted that "complex hysterectomy" may be a problematic term since it is hard to define and it is not clear that these procedures would provide adequate experience. A member stated the originally discussed procedure type was radical hysterectomy and that the Genitourinary Membership Requirements Workgroup received outside perspective suggesting that the term "radical hysterectomies" may exclude surgeons who completed fellowships in minimally invasive surgery. The member also acknowledged that since "complex hysterectomy" is difficult to define, it may be appropriate to use radical hysterectomies as the required experience for primary uterus surgeons and the Chair agreed. The Committee was asked for clarification on how radical hysterectomies are performed and a member clarified that they are performed robotically or laparoscopically and are usually performed as part of a cancer diagnosis which means the gynecologist would be performing the procedure not a minimally invasive surgeon. Another member supported limiting the procedure type to radical hysterectomies and using case volumes that reflect fellowship requirements. The Committee supported including a clinical experience pathway for primary uterus surgeons that requires the completion of 15 radical hysterectomies.

Medical Expert Support

The Committee reviewed and discussed the areas where a primary surgeon must show proof of collaboration including areas specific to uterus transplantation including: gynecologic oncology, maternal fetal medicine, neonatology, obstetrics and gynecology, reproductive endocrinology, abdominal organ transplant, urology, and uterus transplant surgery. It was clarified that the names of the individuals collaborating with the uterus transplant program would be indicated on the membership application and the Committee supported this approach.

Key Personnel Structure for Uterus Programs

The Committee reviewed three options for key personnel structure including requiring a primary surgeon and primary physician with flexibility on who fills the roles (e.g. surgeons and physicians trained either in transplant surgery or obstetrics and gynecology), adding a third role specifically for a primary obstetrician and gynecologist (OB/GYN), or requiring an abdominal transplant surgeon to fill the primary surgeon role if the primary physician is an OB/GYN. Members discussed and agreed that these programs need to have personnel to meet requirements for both managing immunosuppression and OB/GYN experience. Members also noted that the first option is the most flexible, but the other options have a more formal position requirement which may be preferred considering the needed involvement with the program. A member stated that if patient safety is the primary goal, the option requiring a primary OB/GYN in addition to the primary surgeon and primary physician would be best because it requires all expertise in the form of positions needed for patient care. A member asked for clarification on whether or not the same person could fill multiple roles and it was clarified that currently one person could fill multiple roles, but only if they met all the requirements outlined for each position. The Committee supported including primary OB/GYN as a third position for uterus programs and that all three of the positions would need to be filled by at least two individuals. The language initially proposed for the OB/GYN primary physician pathway would be utilized and could be filled by either the primary surgeon and/or any board certified OB/GYN.

Living Donor Uterus Requirements

Committee members noted that these requirements should also include radical hysterectomies instead of complex hysterectomies to be consistent with other requirements. A member noted that the involvement in uterus transplant procedures may be difficult for some surgeons, but the Committee agreed that the high standard should be set for living donor components with patient safety being of utmost importance. It was also mentioned that experience gained in the role of co-surgeon in those procedures is acceptable which makes the requirement less of a barrier.

Update to the List of Covered Body Parts

The Committee reviewed the proposed changes to the list of covered body parts to be included in the uterus membership requirements proposal. The changes include splitting the “genitourinary organ” VCA type into three categories including uterus, external male genitalia, and other genitourinary organs. Since the OPTN defines membership requirements for VCA transplant programs by type, this change would also establish uterus, external male genitalia, and other genitourinary organ as distinct VCA transplant programs. The Chair noted that this is slightly based on anatomic division, but more so the practicality of what is currently being performed at transplant hospitals. A member mentioned that every covered body part needs development of data collection and noted that if a hospital is performing transplants outside of uterus and external male genitalia, the hospital would need the “other” category program to perform both (i.e. uterus and bladder). The Chair and a member mentioned they are trying to develop structure for VCAs that are currently being performed and the Committee would revisit the topic as other types of VCA transplantation become more common. Another member stated that this is the best compromise in current times and the Committee agreed.

Committee feedback was requested on the listed body parts for uterus programs and a member stated that vagina can be a problematic term since typically only the vaginal cuff is recovered. Another member noted that in terms of deceased donor recoveries, organ procurement organizations (OPO) aim to be completely transparent in terms of what is being recovered from the donor and suggested leaving vagina since that may be recovered. A member explained that they were referencing living donor recovery when suggesting vaginal cuff and agreed that vagina would be appropriate for deceased donor

recovery. HRSA staff noted that ureters are typically included with kidney recovered and not necessarily listed with deceased donor kidney recovery and members stated that OPOs try to be clear since VCAs are very specific and suggested that there could be historic background for why that specificity is not included with kidney recovery. Members agreed that for the policy language, using the term “vagina” rather than “vaginal cuff” is appropriate, and transplant programs can refer more specifically to the “vaginal cuff” when speaking with potential living donors.

Administrative Changes

The Committee reviewed changes to the language referencing the multi-organ transplant observations to allow additional options for uterus transplant programs. Also, the microvascular experience requirement for “other VCA” transplant programs is only noted as plural which has been interpreted to mean at least two, so the change in language will specify that the program needs to provide at least two documented procedures.

Public Comment Questions for the Community

It was mentioned that public comment is a good opportunity to get feedback from the community regarding the proposal.

A member suggested asking for feedback on the proposed changes to the list of covered body parts.

VOTE

Does the VCA Committee support sending this proposal forward for public comment in August 2021?

- The Committee voted in support with 12 yes, 0 no, and 0 abstentions.

Upcoming Meeting

- July 14, 2021 (Committee)

Attendance

- **Committee Members**
    - Bohdan Pomahac, Chair
    - Sandra Amaral, Vice Chair
    - Linda Cendales
    - Darla Granger
    - Nicole Johnson
    - Debbi McRann
    - Paige Porrett
    - Mark Wakefield
    - Patrick Smith
    - Debra Priebe
    - Gary Morgan
    - Liza Johannesson
- **HRSA Representatives**
    - Jim Bowman
    - Raelene Skerda
- **UNOS Staff**
    - Kristine Althaus
    - Leah Slife
    - Kaitlin Swanner
    - Susan Tlusty
    - Krissy Laurie
    - Marta Waris
    - Sarah Booker
    - Sharon Shepherd
- **Other Attendees**
    - Amanda Gruendell
    - Brian Berthiaume