

OPTN Vascularized Composite Allograft Transplantation Committee

Meeting Summary

April 12, 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 04/12/2021 to discuss the following agenda items:

1. VCA in UNetSM – Review of Body Parts
2. Policy/Bylaw Language Clarification
3. VCA Genitourinary Membership Requirements Update
4. OPTN Governance
5. New Project Discussion
6. Policy Oversight Committee Update

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

1. VCA in UNetSM – Review of Body Parts

The Chair presented a review of all of the VCA types comparing the policy language with proposed clarifications to what may be selected for each VCA type in UNetSM as previously discussed by the Committee. UNOS IT provided possibilities for added clarification to the selection options for each program for the Committee's to review.

Summary of discussion:

Head and Neck

A member asked if the proposed clarifications included any isolated part of the face such as the nose and the Chair clarified that would be included since if the nose was procured and offered for transplant, the remaining parts of the face would not be offered separately.

Abdominal Wall

A member asked for clarification in instances where the ischium would be utilized since that could fall within either abdominal wall or lower limb VCA programs. It was clarified that if the intent was that if you needed the ischium with the lower limb it was allowable with a lower limb program, otherwise these transplants would fall under abdominal wall programs. The Chair supported leaving the language as is, and if partial pelvis transplants become more common the Committee can revisit the need for clarification.

Genitourinary Organs

It was noted that there is some duplication regarding internal and external male and female genitalia, but a member stated that it may be easier for transplant coordinators to keep uterus and penis as a standalone option since that is a specific transplant type and would not include other VCAs. It was mentioned that UNOS IT could add options for internal and external genitalia so that it is exclusive of

both penis and uterus. A member suggested including vessels so that the OPO is aware they are also needed for the offer. The Chair pointed out that there is a free text box to add that vessels are needed.

Lower and Upper Limb

The Chair asked for feedback on whether or not there should be an option for “no preference” in reference to laterality since there are instances where either left or right can be utilized. The Committee supported including an option for “no preference” in addition to left and/or right.

Musculoskeletal Composite Graft Segment

A member asked if it was possible to include a mandatory text box since this VCA program type is a vaguer category and it was clarified that a text box was not the preferred option for initial graft type selection, but that after one of the graft types is selected there would be a text box to provide more detail/context. A member asked if the thymus would be permissible with chest wall since in pediatrics thymus would be procured with the chest wall and the Chair clarified that thymus would fall under the separate “gland” category. The Chair acknowledged that there are some instances where there is overlap between VCA programs but also noted that these instances are extremely rare and if the Committee finds that additional changes need to be made they can be addressed in the future.

2. Policy/Bylaw Language Clarification

The Committee received an update on the VCA policy and bylaw language clarification project which includes an exclusive list of covered VCAs. The Health Resources and Services Administration (HRSA) had provided preliminary feedback that the proposed approach for updating the definition of VCA was supported and the plan would be to send this to the OPTN Board of Directors (Board) in June 2021.

The Committee reviewed the language that would be presented and was asked to vote on whether or not they supported sending the VCA policy and bylaws clarification to the Board at their June 2021 meeting.

Summary of discussion:

A member asked what the process would be for a transplant hospital that wants to perform an “uncovered VCA” transplant and it was clarified that any VCA outside the covered VCAs listed would need to reach out to the OPTN and explain their intent, but policy would need to be updated before it would be permissible with the current language.

A member asked whether or not the separation of internal and external genitalia would be referenced in the policy and bylaw language or if the distinction for uterus and penis would only be made for VCAs in UNetSM. It was clarified that the distinction is not made in the policy and bylaw language, and there was Committee support for leaving the language as presented and only having the distinction in UNetSM.

The Chair asked for clarification on when a VCA primary surgeon would need to meet the requirement of participating in at least one covered VCA procurement and it was noted that that requirement was part of the alternate pathway for upper limb and head and neck programs.

The requirements listed in OPTN *Policy 15: Identification of Transmissible Diseases*, Table 15-2 “Host OPO Reporting Requirements...” were clarified for the Committee for when respiratory and urine cultures would apply for the appropriate VCA programs. Respiratory cultures would be reported to head and neck VCA programs and urine cultures would be reported for genitourinary organ programs and the reporting would be done by the OPO directly to the VCA program.

The Committee supported sending the policy and bylaws clarification to the Board at their June 2021 meeting with 15 members voting yes, 0 voting no, and 0 abstaining.

3. VCA Genitourinary Membership Requirements Update

A Workgroup Co-chair presented an overview of the working draft of proposed changes which included establishing separate transplant program types for uterus versus other genitourinary organs, updating primary surgeon requirements as needed for uterus transplantation, updating primary physician requirements to allow for OB/GYN trained individuals to fill the role, adding requirements for living donor uterus recovery, and administrative changes to streamline the application process. It was clarified that these changes would not be included in the updated policy and bylaw language that is being sent to the Board in June 2021, but would be a separate update proposed for public comment in August 2021 and sent to the Board in December 2021.

The Committee reviewed two options for how to split genitourinary organs into separate program types, which included the Workgroup-preferred option of uterus and other genitourinary organ programs, and an alternate option of female genitourinary organs and male genitourinary organs.

Summary of discussion:

Separating Genitourinary Programs

The Chair noted that the two options combine program types that may not require the same expertise, but recognized that uterus and penis transplants are the obvious standalone transplant programs since they are the types being performed currently. Members discussed the option of having uterus, penis, and other genitourinary organ programs because uterus and penis have more distinct practice which makes it more approachable to develop policy around. Committee feedback was requested on how penis transplant programs would be developed since the two transplants that have been performed so far have varied in what they included as part of the graft. The Committee noted that in some cases, penis transplant would need both a penis program and an “other genitourinary organ” program to cover all the VCAs needed for the transplant. A member noted that a future conversation for the Committee would be how germline tissue would be handled in transplant. The Committee supported separating the genitourinary programs as uterus and “other genitourinary organ” with the possible addition of a penis/external male genitalia program. Members stated that it is easier to write policy and bylaws around what is more commonly done currently (i.e. uterus) and that this topic would have to be revisited as other transplant volumes increase.

Uterus Primary Surgeon Requirements

Committee members thought it would be appropriate for uterus primary surgeons to have some requirement for uterus transplant experience specifically. The Vice Chair noted that from the patient perspective it would be important to include uterus-specific experience. Another member agreed and mentioned that the group needs to be specific, but not to the point that the requirements are too restrictive for new programs. A member stated that since uterus transplant is a growing field, having uterus transplant-specific experience for a primary surgeon would not be an impossible requirement.

Uterus Additional Expertise Requirements

The Chair recognized that there are ways to bypass the need for microsurgery experience, but supported having a designated team member to give assistance for microsurgery as needed due to a number of complications in previous uterus transplants stemming from vascular issues. A member agreed that this would be beneficial even though most of the vessels in uterus can be connected without the need for a microscope, as it is important for the team to demonstrate experience with revascularization. A Workgroup Co-chair stated that this is a topic that has not been covered by the Workgroup in detail yet, but will be a future discussion.

The Vice Chair asked if there should be a pediatric expertise requirement, specifically expertise in neonatology. UNOS staff offered to provide more detailed information on the scope of what can be added as a requirement and would provide that information in a future meeting.

4. OPTN Governance

UNOS staff gave a presentation outlining the National Organ Transplant Act (NOTA), the Final Rule, the OPTN contract, OPTN Policies and Bylaws, and how each relates to governance and authority. This was to help the Committee members understand how the four governing structures impact their role while serving on the Committee.

Summary of discussion:

The Chair asked for clarification in practical terms regarding how UNOS relates to the OPTN contract and the alluded changes to how OPTN committees discuss, develop, and present committee projects. It was clarified that the difference is that the authority to pursue committee work is being specified earlier in the process so that the process is more collaborative and supported up front and that will include a more in depth discussion about authority at the beginning of project development.

The Chair asked if there were previous issues with authority or compliance and it was clarified that there were barriers due to differences in interpretation between UNOS and HRSA later in the project development process that would delay projects, so those conversations are happening earlier. These changes were already being developed for the future, so the timeline is only shifting up and this is also standard practice of many government agencies.

5. New Project Discussion

The Chair presented on possible future Committee projects that stem from past Committee discussions around the future implementation of the VCA policy and bylaw language. These projects could include changes to policies and data collection.

Summary of discussion:

Definition of Graft Failure

The Committee considered that different definitions would need to be applied for certain VCA types. The Chair thought that in terms of many VCAs, partial or full removal of the graft would be considered a graft failure with uterus being the exception. A member asked if there was a consensus from the combined International Society of Vascularized Composite Allotransplantation and American Society for Reconstructive Transplantation Workgroup on this topic. The Chair noted that how success would be quantified and qualified regarding VCA transplant is an ongoing discussion, but that level of specificity would likely be different than the definition of graft failure in policy for Committee project purposes.

The Committee discussed the nuance of defining graft failure and survival with the example of a hand transplant that is still a living graft, but is not functional for the patient. In this case, some patients may choose to leave the graft and others may want it removed in favor of a prosthesis. It was noted that the term “graft survival” may be more appropriate for VCA since functional outcomes can have considerable variation and it may be easier to conceptualize graft survival (e.g. tissue is alive and not necrotic) rather than graft failure due to the differences in patient perception.

Overall, members supported keeping definitions more “black and white” with a possible definition of presence or absence of the graft, however the Committee noted the importance of the patient’s perspective of the outcome when considering these definitions.

The Committee supported pursuing a Committee project that included updating the definition and data collection of graft failure as it pertains to VCA and specifically addressing uterus transplant removal post-child birth being a success of the graft.

Waiting Time Modifications

For most organs, current policy allows for a candidate's transplant program to submit a request for waiting time modification through an application or an expedited process should the candidate be listed for a second organ. These policies currently do not apply to VCA. The Chair noted that this would be fairly uncommon for VCA currently, but the Committee saw the benefit to including VCA to this policy so that VCA is aligned with other organ types.

Multi-VCA Allocation

The Committee discussed instances where a candidate needing a solid organ transplant and also a VCA, and whether or not it be in policy that both organ types have priority to come from the same donor. The Committee felt that this should apply, especially in instances of abdominal wall, or a chest wall transplanted with a heart. However, the Committee did not support policy changes where the VCA pulls the vital organ since VCA is often life-enhancing while the vital organ is life-saving. Members noted that the VCA may not be a match since there may be instances where the donor does not match the criteria needed for the VCA (i.e. male donor and female recipient). A member also supported language for candidates listed for multiple VCAs receiving all VCA types from the same donor.

HRSA staff asked if there was a concern for recipient sensitization if the vital organ and VCA are done at separate times, Members confirmed that it is generally beneficial from a sensitization standpoint for a candidate to receive multiple organs from the same donor. VCA allocation does not currently consider candidate sensitization but this could be added when VCA shifts to continuous distribution.

Other Data Collection Changes – VCA in UNetSM

These changes could include adding skin tone screening and comment boxes by VCA type in DonorNet[®].

Expedited Approval Pathway for the List of Covered Body Parts

These proposals may use shorter public comment periods and the Committee supported this use in the future since the VCA field is developing and new body parts may need to be added quickly.

6. Policy Oversight Committee Update

The Vice-Chair presented an overview of the Policy Oversight Committee's (POC) role in policy development including POC's current workgroups and project work. This includes the alignment of committee projects with broader OPTN strategic goals.

Summary of discussion:

The Chair asked for information on the Technology Tools Workgroup and if their project for image sharing include the needs for matching for VCA. It was clarified that the imaging is being rolled out in phases to all organ procurement organizations (OPO), but that the workgroup is currently focused on biopsy imaging. However, there should be updates for the project in May 2021.

Upcoming Meetings

- April 20, 2020 (Genitourinary Workgroup)
- May 12, 2020 (Committee)

Attendance

- **Committee Members**
 - Bohdan Pomahac, Chair
 - Sandra Amaral, Vice Chair
 - Linda Cendales
 - Vijay Gorantla
 - Lawrence Gottlieb
 - Darla Granger
 - Liza Johannesson
 - Nicole Johnson
 - Alexander Maskin
 - Debbi McRann
 - Paige Porrett
 - Mark Wakefield
 - Gary Morgan
 - Patrick Smith
 - Simon Talbot
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kristine Althaus
 - Leah Slife
 - Kaitlin Swanner
 - Susan Tlusty
 - Jennifer Wainwright
 - Karen Williams
 - Krissy Laurie
 - Rebecca Murdock
 - Tina Rhoades
 - Nicole Benjamin
- **Other Attendees**
 - Donald Rickelman
 - Amanda Gruendell
 - Brian Berthiaume
 - Elizabeth Shipman
 - Robert Goodman