OPTN Vascularized Composite Allograft Transplantation Committee
Meeting Summary
July 21, 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 07/21/2021 to discuss the following agenda items:

1. New Project Discussion
2. OPTN VCA Overview
3. Committee Updates

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

1. New Project Discussion

The Chair presented an overview of the previously discussed potential Committee projects:

- Graft failure definition and data collection
- Waiting time modifications
- Multi-organ allocation involving VCA
- Add comment boxes by VCA type in DonorNet®
- Add skin tone screening to DonorNet®
- Expedited approval pathway – list of covered body parts

The Committee was asked to prioritize the projects after the OPTN Policy Oversight Committee's recommendation to narrow the scope of the proposal to the most important component(s) due to the small population of candidates impacted by this "large" (as determined by UNOS resource estimates) project proposal.

Summary of discussion:

Members asked for more information on how the scale of a project and number of IT hours were determined and it was clarified that the hours make up effort for coding, designing, and testing of the changes regardless of how often those changes would be utilized. Estimated hours also include submitting proposed changes to the Office of Management and Budget (OMB) for approval. A member asked for clarification on if there was a target number of IT hours that the Committee should aim for with these projects and it was clarified that there is no target, but fewer hours would be easier to move forward with sooner.

Graft failure definition and data collection

The Committee discussed possible policy changes to the definition of graft failure as it pertains to VCA and uterus specifically. The Committee previously discussed that the graft failure definition for VCA could include if the graft is removed, the recipient dies, or the patient re-registers for the VCA type. For

uterus, the Committee previously discussed defining graft failure as graft removal prior to a live birth with a possible specification for 23 weeks gestation. Data collection changes could include data collected separately on planned uterus graft removal following a successful birth and modifying data on graft failure for other covered VCA types. A member stated that all projects should be prioritized by which will facilitate safer and more successful VCA transplantation, and suggested graft failure be prioritized due to aiding current VCA programs, transplant programs with interest in VCA, and payors. Another member added that the graft failure definition and associated data collection is a must have for VCA and should be prioritized over the other projects and the Chair agreed that transplant programs and payors need to know what is happening with these grafts.

Waiting time modifications

The Committee reviewed the possible policy changes that would be included in waiting time modifications for candidates who are registered for two VCA types, so that the waiting time for the second organ would be adjusted to include the waiting time accrued for the first organ. A member noted that this project would mostly be to align VCA with other organ types and that does not necessarily make it a priority over some of the other projects being discussed. Members also added that the current wait lists are small and this would be very rare so this should be a lower priority.

Multi-organ allocation involving VCA

The possible policy change would include updating *Policy 5.10 Allocation of Multi-Organ Combinations* so that a candidate who needs both a VCA and a lifesaving organ can pull the VCA from the same donor. There are VCAs such as abdominal wall, scalp, chest wall, and thymus that may be transplanted with solid organ types. A member stated that these transplants are going to be very infrequent events, so that should be considered when prioritizing. A member asked in what situations this would happen. The Chair said it would be rare and added that it could be difficult to figure out how prioritization would occur when the donor is not a VCA match due to skin tone or other quality, but is a solid organ match. Members noted that this requires more discussion on how this would implemented before moving forward with the project.

Add comment boxes by VCA type in DonorNet®

The Chair asked the Committee for feedback on whether or not this is needed before some of the other items and a member stated that if the comment boxes would allow for much more efficiency for VCA programs and Organ Procurement Organizations (OPOs) that should rank higher than some other projects. The Chair agreed since it will likely be frequently used. A member added that it may also inform future needs for data collection, since there may be trends in the information added to the comment boxes.

Add skin tone screening to DonorNet®

Committee members noted the large number of hours needed for skin tone screening and it was clarified that since this addition would involve modifications in Waitlist[SM] and in DonorNet® to screen candidates off of a match run, the project would require a larger number of IT hours. A member suggested standardizing the tool used for color matching (ex: numbered silicone prosthesis swatch) across centers as a solution in the interim. The Chair mentioned that the quality of imaging for matching has proven problematic due to all the variables when taking an image (camera quality, lighting, etc.), so a standardized swatch may simplify the issue. They also suggested that using a standardized tool instead of imaging may reduce the number of IT hours required. It was clarified that the free text box is still available, so that transplant programs could provide the desired skin tone based on the Fitzpatrick scale as they do currently, but it will not screen donors off of a match run. The Chair noted that the Fitzpatrick

scale has medical relevance, but is limited to a few color categories.[1] However, a prosthesis swatch may be much more precise for donor matching in terms of VCA. The Committee agreed that this project would need further discussion before moving forward, but expressed an interest in more information surrounding why this is a larger lift for IT and wanted to explain in more detail what the Committee is requesting with this project to ensure IT resources are utilized appropriately.

Expedited approval pathway – list of covered body parts

The Committee reviewed the process for utilizing the expedited approval pathway and how it has been used previously. It was explained that the Committee could pursue this option for updates to the list of covered body parts and that the first step in the process would be to get approval from the OPTN Board of Directors to use this expedited pathway should the list of covered body parts need to be updated more quickly. A member stated that it would be useful to have the approval and the Chair asked for clarification on how specific the request would have to be to make updates to the list of covered parts. It was clarified that if an entirely new category of VCA was required that may be out of the scope due to factors such as IT implementation, but would be more for additions to current categories of VCA programs.

Committee New Project Prioritization

The Committee supported prioritizing the projects as:

- 1: Graft failure definition and data collection
- 2: Add comment boxes by VCA type in DonorNet®
- 3: Add skin tone screening to DonorNet®
- 4: Multi-organ allocation involving VCA
- 5: Waiting time modifications

The Committee recommended holding off on exploring the expedited pathway until a change to the list of covered body parts is needed.

2. OPTN VCA Overview

The Committee received an overview of VCA then and now covering VCA milestones and Committee work including a more in-depth look at Committee projects that are pending implementation.

3. Committee Updates

The Committee welcomed new Committee members and was also informed of a volunteer opportunity for members to join the OPTN Fiscal Impact Group (FIG) which meets twice a year to evaluate the costs of implementation of public comment proposals on OPTN members.

Upcoming Meeting

- August 11, 2021 (Committee)

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[1] "Fitzpatrick skin phototype," arpansa, accessed August 18, https://www.arpansa.gov.au/sites/default/files/legacy/pubs/RadiationProtection/FitzpatrickSkinType.pdf?acsf_files_redirect

Attendance

- **Committee Members**
    - Bohdan Pomahac, Chair
    - Nicole Johnson
    - Paige Porrett
    - Mark Wakefield
    - Debra Priebe
    - Amanda Gruendell
    - Brian Berthiaume
    - Donnie Rickelman
    - Elizabeth Shipman
    - Simon Talbot
    - Stefan Tullius
    - Vijay Gorantla
- **HRSA Representatives**
    - Jim Bowman
- **SRTR Staff**
    - Bryn Thompson
    - Nick Salkowski
- **UNOS Staff**
    - Kristine Althaus
    - Kaitlin Swanner
    - Susan Tlusty
    - Krissy Laurie
    - Sarah Booker