

OPTN Vascularized Composite Allograft Transplantation Committee

Meeting Summary

September 8, 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 09/08/2021 to discuss the following agenda items:

1. Public Comment Update
2. Vice Chair Nomination Process
3. VCA in UNetSM Update
4. Graft Failure Definition and Data Collection

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

1. Public Comment Update

UNOS staff presented a public comment update for the *Establish Membership Requirements for Uterus Transplant Programs* proposal. Initial feedback included the Membership and Professional Standards Committee's (MPSC) sentiment to consider the use of "donor hysterectomy" versus "radical hysterectomy" and adding more detail regarding the medical expert support requirements. However, it was clarified during their Committee meeting that the rationale behind using radical hysterectomies to meet the requirement is that the volume for donor hysterectomies is currently low and may create too much of a barrier for new programs while still requiring similar skills needed to perform these procedures.

The OPTN Regional Meeting sentiment thus far was presented and overall the sentiment was generally supportive of the proposal with only one oppose submitted. A reminder was also given for the upcoming VCA National Webinar scheduled for September 22, 2021 where feedback on the proposal will also be encouraged.

Summary of discussion:

A member asked for clarification on whether or not the proposal was being presented or was on the Regional Meeting consent agenda and it was clarified that the proposal is included on the consent agenda.

2. Vice Chair Nomination Process

UNOS staff briefly covered the Vice-Chair nomination process including nomination and selection goals as well as the timeline for the new Vice-Chair candidate appointment. It was noted that targeted outreach will be sent to anyone who served on the Committee for the last five years and the Committee was encouraged to send any possible recommendations to UNOS staff.

Summary of discussion:

The Chair asked if the Committee should be soliciting names as part of the upcoming meeting agendas and it was clarified that it will not be part of the agenda, but UNOS staff will send out information as applicants submit their interest.

3. VCA in UNetSM Update

UNOS staff provided an update on the scheduling of VCA being implemented into UNetSM. It was explained that due to the WaitlistSM redesign project, which will affect all organ groups including VCA, it would be beneficial to implement VCA in UNetSM when the redesign can be included instead of implementing and then have to include the redesign at a later date. If VCA in UNetSM was implemented without the Waitlist redesign, VCA would continue to be different from other organ types so the revised implementation date would mean consistency across organ types. The revised implementation date for VCA in UNetSM would be March 2023 instead of June 2022.

Summary of discussion:

The Chair noted that this would probably be a more efficient way to implement the changes, but it is a little disappointing that this will be pushed by another eight months. It was clarified that this is a conservative estimate and they may be able to implement sooner, but did not want to be too aggressive and disappoint the Committee by delaying it in the future.

4. Graft Failure Definition and Data Collection

The Chair revisited the previous discussion regarding the current graft failure definitions and how covered VCA could differ, and the Committee also further discussed how uterus would have its own relevant definitions. Updates to the current definition could include language to distinguish both pancreas and covered VCA which would have additional graft failure definitions outside of the standard criteria. The inclusion of covered VCA could further specify “covered VCA other than uterus” and uterus separately.

The Committee also reviewed OPTN data collection on graft failure and discussed possible relevant options for including uterus to data collection. The Committee revisited the options for causes of graft failure and the previously proposed changes of using the language of non-adherence versus non-compliance.

Summary of discussion:

A member noted that it may be possible for other VCA types including abdominal wall and musculoskeletal graft segment to be transplanted with the intent to remove the graft depending on the success of the procedure which would be a similar situation to removing a uterus graft after a successful birth. SRTR staff stated that when planned or unplanned graft removals are being defined it is important to be very granular with the definition since there is some concern with interpretation, gaming of the system, and getting good information. They suggested that any removal planned or unplanned have documentation that is codified so that the MPSC and compliance staff can determine if the criteria were met (i.e. previously documented on a medical chart). The Chair agreed that one possible mechanism would be that the transplant program would have to indicate whether the allograft is planned to be removed before or at time of transplant, but acknowledged there is a chance that programs may indicate that regardless to avoid reporting a failure. HRSA staff mentioned that while it would require some administrative burden it may alleviate manipulation of the system if you ask for submission of the removal date and if there is a trend of non-removal of the grafts a program indicated would be removed it might raise concern. SRTR staff noted that the Committee may want to consider endpoints or goals of

the types of VCA transplants so that data collection can report actual outcomes relative to a successful transplant definition. The Chair explained that the VCA community has struggled to define the degree of success versus failure in both hand and face transplantation and it will probably move toward patient reported outcomes and measures that have not yet been developed. Committee members supported trying to keep definitions more black and white so there is less room for interpretation and would result in less variability across programs.

The Vice Chair mentioned that there is potential for a uterus transplant to be both a success and a failure and explained that someone could have a successful live birth and intended to try for a second birth which was unsuccessful. A Committee member stated that having one successful birth should be seen as a success of the graft overall. Another Committee member asked if the birth was a success but the mother died in childbirth would that be seen as a success or a failure and it was clarified that the program can indicate that the graft was functioning at the time of death. The Chair asked if there was anything to capture cause of death for the uterus field and it was clarified that primary cause of death would be collected.

The Committee discussed combining thrombosis and ischemia into one “vascular complications” category. The Chair supported this since there are many different types of vascular issues that are not limited to thrombosis and ischemia. The Committee was asked for feedback on whether or not there should be drop downs that are more granular to choose from and the Committee supported leaving it more generic.

Upcoming Meeting

- October 7, 2021 (Committee, virtual in-person)

Attendance

- **Committee Members**
 - Bohdan Pomahac, Chair
 - Sandra Amaral, Vice Chair
 - Mark Wakefield
 - Debra Priebe
 - Amanda Gruendell
 - Brian Berthiaume
 - Donnie Rickelman
 - Elizabeth Shipman
 - Patrick Smith
 - Darla Granger
 - Debbi McRann
 - Lori Ewoldt
 - Lawrence Gottlieb
 - Liza Johannesson
 - Simon Talbot
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
 - Ryo Hirose
- **UNOS Staff**
 - Kristine Althaus
 - Kaitlin Swanner
 - Krissy Laurie
 - Sarah Booker
 - Leah Slife
 - Alex Tulchinsky