

OPTN Vascularized Composite Allograft Committee

Meeting Summary

November 9, 2021

Conference Call

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

Introduction

The Vascularized Composite Allograft Committee (the Committee) met via Citrix GoToMeeting teleconference on 11/09/2021 to discuss the following agenda items:

1. Proposal: *Modify Graft Failure Definition for VCA*

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

1. Proposal: *Modify Graft Failure Definition for VCA*

The project will exclude planned removal of a vascularized composite allograft (VCA) when the graft is no longer needed from the definition of graft failure, modify the policy definition of graft failure, and modify the data collection surrounding graft failure to more accurately collect data on graft failure. The project is anticipated to be included during the Winter 2022 public comment cycle.

Data summary:

The Committee reviewed the updates to the current graft failure definition within VCA.

- For all organs except pancreas and covered VCA, graft failure occurs when one of the following occurs
 - A recipient's transplanted organ is removed
 - A recipient dies
 - A recipient is placed on chronic allograft support system

The Committee proposes a VCA-specific graft failure definition.

- Covered VCA graft failure occurs when any of the following occur:
 - A recipient re-registers for the same covered VCA
 - A recipient dies
 - An unplanned removal of a covered VCA
- Planned removal of a VCA graft occurs when
 - A graft is removed with the intent of removal recorded either pre-transplant or at the time of transplant

The Committee then reviewed the changes within the causes of death in the transplant recipient follow-up (TRF) form and the transplant recipient registration (TRR) form. Primarily, these are removals of causes of death that the Committee had found to be redundant, but there was one addition of "maternal/obstetric mortality, other".

Finally, the Committee reviewed the proposed definitions and updates to data fields on TRRs and TRFs. Notably, the Committee confirmed the changes to the Uterus TRF that updates the data field to allow for graft removal. Furthermore, the Committee was reminded that the interim report of graft failure

would not be updated based on a previous meeting in which the Committee determined that planned graft removal should only be reported on the TRRs and TRFs.

Summary of discussion:

A Committee member inquired whether other organs had a “Non-adherence” category for cause of graft failure, to which the Vice Chair replied there was. It was briefly explained the reasoning behind the definition of graft removal, which was based off a previous Committee meeting in which concerns were expressed about programs “gaming” the system.

With no further discussion, the Committee unanimously supported sending the proposal to the Winter 2022 public comment cycle (14 yes, 0 abstain, 0 no).

The last point of discussion for the Committee, following the approval of the proposal for public comment, was whether there should be any specific questions for the community. The Vice Chair mentioned that, earlier, the Committee had discussed how best to record data on uterus recipients who want to retain the uterus following a live birth with the intent of a second birth. The concern within the Committee is, if the graft fails during term for a second child, by the prior discussion, the graft would be considered a failure, even if one successful delivery occurred. A number of Committee members concurred that one successful delivery should constitute a graft success, regardless of what happens with the graft while attempting a second child. A member emphasized that, with live birth being the end goal, the definition of graft failure or success should be closely considered from what a patient would consider as success or failure, and they would want community feedback on that question. Finally, one member considered that this question could be posed to the OPTN Ethics Committee, as well, for feedback. The Chair summarized the discussion at the end, noting that, ultimately “the overall goal is to capture and track organ failures”, and posing the question to staff if they had any suggestion or how to accurately capture the data within UNetSM.

UNOS Staff noted that the best solution may be to separate the graft status field from the hysterectomy or removal question.

The HRSA representative also noted that both sending that question out for public comment and separating the fields were good ideas, as, anecdotally, successful live births should not somehow become reported as failures.

Next steps:

Staff will bring potential phrasings of the specific public comment question to the next Committee meeting. Additionally, during public comment, the Committee will consider presenting to the OPTN Ethics Committee to garner feedback.

Upcoming Meeting

- December 1, 2021

Attendance

- **Committee Members**
 - Bohdan Pomahac
 - Sandra Amaral
 - Brian Berthiaume
 - Bruce Gelb
 - Amanda Gruendell
 - Deborah McRann
 - Donald Rickleman
 - Elizabeth Shipman
 - Patrick Smith
 - Simon Talbot
 - Stefan Tullius
 - Mark Wakefield
- **HRSA Representatives**
 - James Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Raelene Skerda
- **UNOS Staff**
 - Kristine Althaus
 - Sarah Booker
 - Isaac Hager
 - Krissy Laurie
 - Janis Rosenberg
 - Leah Slife
 - Susan Tlusty
- **Other Attendees**