

OPTN Vascularized Composite Allograft Transplantation Committee

Meeting Summary

August 11, 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 08/11/2021 to discuss the following agenda items:

1. VCA Membership Implementation Update
2. Summer 2021 Public Comment Items
3. Graft Failure Definition

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

1. VCA Membership Implementation Update

UNOS staff presented a post-implementation update of the VCA membership bylaws. There were 42 VCA programs across 21 transplant hospitals that gained approval (either through the June 2021 OPTN Board of Directors meeting or Membership and Professional Standards Committee interim approval) on implementation day. There were 19 VCA programs across 11 transplant hospitals that opted out of completing program requirements. It was noted that while there were some challenges during the beginning of the implementation process which included members that had either unfamiliarity with VCA or OPTN membership processes which created a learning curve, overall the implementation was successful as both UNOS staff and OPTN members became more familiar with the VCA membership bylaws and applications.

Summary of discussion:

A HRSA representative asked what "opting out" meant in terms of the implementation and if that meant they decided to no longer perform VCA transplants. It was clarified that those were programs that had VCA programs prior to the bylaw implementation and decided not to apply with the new requirements and therefore are no longer considered active programs. The Chair asked if there was interest in pursuing a survey to follow-up with the programs that opted out to help inform why some programs chose to no longer have those programs and UNOS staff stated that they are still looking into how that could be done and will update the Committee.

2. Summer 2021 Public Comment Items

High level overviews of a few of the items out for public comment were presented to the Committee:

OPTN Regional Review Project – Request for Feedback, OPTN Executive Committee

The purpose of the OPTN Regional Review project is to evaluate the structure, processes, performance, and effectiveness of the OPTN Regions. The review will consider current and future needs of the nation's donation and transplant community needs. The feedback provided as part of the request will be evaluated and will help inform any possible updates to the current regional structure.

Summary of discussion:

A member mentioned that the current OPTN Board of Directors (BOD) is rather large and supported a restructuring of the BOD. The Vice Chair noted that while the current regional structure is not perfect, they had concerns over some of the ideas shared by the outside consultant EY since it seems like they would create more silos among OPTN members. They also stated that while silos may occur with the current OPTN Committee structure, the current regional meetings provide an opportunity for stakeholders and other multidisciplinary individuals to voice their opinions, but they acknowledged there may be room for improvement.

Data Collection to Evaluate Organ Logistics and Allocation – Proposal, OPTN Operations and Safety Committee

The purpose of this proposal is to collect data on organ logistics and allocation to inform future policy development. The proposal includes modifications and removal of certain current data elements and proposes the addition of new data elements (organ check-out time, organ check-in time, and time of first anastomosis). The new data elements aim to provide a more accurate account of the timeline from organ recovery to organ transplant.

Summary of discussion:

The Chair noted that this information is usually recorded in some way, but it is being done informally so this proposal will help formalize the data that is being collected which is important for outcomes, complications, and graft survival.

Enhance Transplant Program Performance Monitoring System – Proposal, OPTN Membership and Professional Standards Committee (MPSC)

The MPSC currently uses one metric to identify underperforming transplant programs, which is one-year post-transplant patient and graft survival, and the current process does not apply to VCA. The proposed metrics will still not apply to VCA, but they aim to create a more holistic review of transplant program performance, identify real time patient safety concerns, continue to expand support and collaboration with transplant programs, and promote equitable access and increase the number of transplants.

Summary of discussion:

The Chair asked for clarification on the program criteria for identification ratios and what they mean practically and a member clarified that in terms of VCA they will not be relevant because of the low volumes. SRTR staff further clarified that solid organ programs have an expected rate of mortality on the waitlist, so a program would essentially need almost twice that expected rate to be flagged for performance monitoring. It was also mentioned that the 90-day graft survival is intended to capture perioperative outcomes and the one-year graft survival would actually exclude those first 90 days so that it is focused on the one-year outcomes. This proposal was shared with the VCA Committee to inform their work on updating the definition of graft failure and associated data collection for VCA.

3. Graft Failure Definition

The Vice Chair shared that the OPTN Policy Oversight Committee (POC) recommended approval of this project. The POC noted that with solid organs being re-registered for the organ is a graft failure and suggested the Committee consider whether re-registration for a uterus after a successful birth would not be a failure of the original graft.

The Committee revisited previous discussion regarding the current graft failure definitions and how covered VCA could differ, and the Committee also noted that uterus would have its own relevant definitions.

Summary of discussion:

Members noted that the policy definition of graft failure includes recipient death but OPTN data collection distinguishes between deaths caused by graft failure and deaths with functioning graft. The Chair stated that the same reporting option should be available for VCA and members agreed.

A member asked if re-registering for a uterus after a successful birth and removal count as a graft failure. A member suggested that it should be considered a failure since it may show a program's failure to properly assess the patient initially. The Vice Chair disagreed and felt that a patient's life stage or age may influence their decisions and should not necessarily reflect the transplant team's ability to assess the patient.

It was mentioned that the Committee previously discussed a timeframe for graft failure if the uterus is removed prior to a live birth (i.e. occurring prior to 23 weeks gestation or later) and Committee feedback was requested on whether or not there should be a gestation based threshold for determining uterus graft failure. It was noted that the issue that needs to be figured out is distinguishing between a graft failure and adverse birth outcomes. A member stated that 23 or 24 weeks is considered the standard for gestational viability. The member also mentioned that there is a timeframe between possible successful live births that should be considered and asked whether it would be considered graft failure if the graft failed between intended births. A member noted that the original definition supports that it would be a success because the outcome was a successful live birth. The Chair stated that since the graft needed to be removed before the patient's desired outcome that should be seen as a graft failure. The Vice Chair suggested that there should be a way for data to be collected to distinguish a single successful birth versus subsequent intended live births since knowing both could be important when evaluating safety and efficacy and members agreed.

SRTR staff noted that graft success is not the same as lack of graft failure. For example, if the metric is failure at one year, and it is defined as whether the graft is removed or the patient dies, it does not matter whether or not a live birth occurred, it would still be considered graft failure. For uterus, it is possible that a successful live birth has not occurred by that one year mark. A member stated that from a prospective patient perspective they are going to want to know how many successful births a program has, especially since they are responsible for the costs and SRTR staff clarified that the graft failure definition does not account for that at all.

Next Steps:

The Committee will continue the discussion of how graft failure should be defined for covered VCA and uterus during the next full Committee meeting.

Upcoming Meeting

- September 8, 2021 (Committee)

Attendance

- **Committee Members**
 - Bohdan Pomahac, Chair
 - Sandra Amaral, Vice Chair
 - Mark Wakefield
 - Debra Priebe
 - Amanda Gruendell
 - Brian Berthiaume
 - Donnie Rickelman
 - Elizabeth Shipman
 - Stefan Tullius
 - Vijay Gorantla
 - Patrick Smith
 - Bruce Gelb
 - Darla Granger
 - Debbi McRann
 - Lori Ewoldt
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Ryo Hirose
- **UNOS Staff**
 - Kristine Althaus
 - Kaitlin Swanner
 - Susan Tlusty
 - Krissy Laurie
 - Sarah Booker
 - Leah Slife
 - Marta Waris