

## **OPTN Vascular Composite Allograft Transplantation Committee**

### **Meeting Summary**

**November 18, 2020**

### **Conference Call**

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

#### **Introduction**

The OPTN Vascular Composite Allograft Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 11/18/2020 to discuss the following agenda items:

1. VCA in UNet<sup>SM</sup>: Transplant Program Inactivity
2. Sentinel Flaps
3. New Project Work

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

#### **1. VCA in UNet<sup>SM</sup>: Transplant Program Inactivity**

The Committee discussed transplant program inactivity requirements and the removal of exclusions that would require VCA to align with these requirements.

##### Summary of discussion:

A member explained that voluntary short-term inactivation status regulations are in place for scenarios in which a program does not have the ability to transplant a specific organ for no more than 14 days. Inactivation turns off a program's waiting list so they will not receive offers for organs they are unable to transplant. Programs can voluntarily inactivate through UNet and are required to notify patients of a coverage plan during the inactivation period.

A member pointed out the "Notice to the Patients of Long-term Inactive Status" (B) section and commented that this may be difficult to abide by, as unexpected events like prolonged illness of a primary surgeon could cause a program to need to inactivate on a long-term basis. UNOS staff responded that while 30 days notice is preferred, the requirement is to notify patients no later than 7 days after the inactivation. They added that reactivation is a fairly swift process following a voluntary long-term inactivation status.

A member asked why 14 days was selected as the threshold for temporary vs. long-term inactivation. UNOS staff responded that 14 days was selected as vacation timeframes are usually not more than 2 weeks long. The Final Rule does require that the OPTN is notified when a program becomes inactive. 14 days was selected as the longest period of time that could be justified to provide some flexibility to the hospital.

A member asked if these reporting requirements would apply to a VCA program who had no patients on the waiting list. UNOS staff responded that if there were no candidates on a program's VCA waiting list, then the program would not be receiving offers and would not have any patients to notify, but the program would have to report that information to the OPTN. A member added that the purpose of these requirements is to increase organ placement efficiency and let patients know if they do or do not

have access to organ offers. HRSA staff explained that transplant program inactivity is a bigger concern for high-volume kidney or liver programs, who may have many patients in various stages of evaluation.

Members agreed that VCA should align with the OPTN Bylaws, *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

Next steps:

The Committee agreed that VCA transplantation needs to align with transplant program inactivity bylaws. The MPSC is working on a proposal to revise membership requirements and will remove this exclusion in one of their upcoming proposals, most likely the proposal slated for public comment in August 2021. This change could be aligned with the implementation of VCA in UNet.

**2. Sentinel Flaps**

Suggested guidance for membership requirements: Ask programs to apply for musculoskeletal composite graft segment if they want to use skins flaps not covered under their program approvals.

Summary of discussion:

The Committee continued their discussion on sentinel flaps. A member asked if there would be any significant cost related to procuring these flaps if they are considered a separate organ. This member believes that if there is, procedures involving flaps may decrease in frequency. The Committee expressed the need to delineate what each sentinel flap would be used for, as some flaps are functional while others are used for monitoring the function of a primary organ. Some members suggested that if the flap is to be used for tissue coverage, then it should be considered a separate organ for which programs could be charged. Additionally- they expressed that if the flap is to be used to monitor rejection of a primary VCA transplant, then it should not be considered a separate organ or create costs for the program.

UNOS staff asked if the Committee would have any interest in a project that examines VCA policy for any areas where sentinel flaps should be treated differently than other VCAs. This is because sentinel flaps are otherwise subject to all policy requirements pertaining to all VCA or all organs, as stated in *Policy 1.2: Definition of VCA*. This means that all candidate registration, packaging/labeling, and data reporting required for other organs would also be required for sentinel flaps. Members expressed feelings that these requirements would be excessive for flaps. The Committee agreed that any approved VCA transplant program should be able to do sentinel flap procedures, particularly since most VCA surgeons are plastic surgeons.

A member questioned how much authority the Committee has to decide how sentinel flaps should be reported, as the Final Rule already defines the characteristics of VCA that fall under the purview of the OPTN. A representative from HRSA said he was not sure if sentinel flaps meet the homologous use criteria outlined in the Final Rule definition of VCA, since sentinel flaps are sometimes used solely for the purpose of monitoring rejection rather than any structural or reconstructive function. The HRSA representative will report this back to his team and work with UNOS to find a resolution to this authority question.

Next steps:

The Committee will continue discussions on VCA membership requirements for sentinel flaps.

**3. New Project Work**

The Committee will discuss new project work at the next meeting.

### **Upcoming Meetings**

- December 9, 2020 (teleconference)
- January 13, 2021 (teleconference)

## Attendance

- **Committee Members**
  - Sandra Amaral
  - Lori Ewoldt
  - Lawrence Gottlieb
  - Darla Granger
  - Nicole Johnson
  - Gary Morgan
  - Bohdan Pomahac
  - Paige Porrett
  - Debra Priebe
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kristine Althaus
  - Demi Emmanouil
  - Kelley Poff
  - Tina Rhoades
  - Sharon Shepherd
  - Kaitlin Swanner
  - Susan Tlusty
  - Jen Wainright
  - Marta Waris
  - Karen Williams
- **Other Attendees**
  - Robert Goodman (visiting board member)