OPTN Vascularized Composite Allograft Committee Meeting Summary October 13, 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 10/13/2021 to discuss the following agenda items:

1. Review of the Public Comment Feedback on Proposal: Establish Membership Requirements for Uterus Transplant Programs

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

1. Review of the Public Comment Feedback on Proposal: Establish Membership Requirements for Uterus Transplant Programs

The Committee reviewed changes to the primary surgeon requirements for a living uterus donor recovery proposed at the prior Committee meeting on October 7, 2021. A brief recap of the changes was provided by the Chair for those unable to attend at the aforementioned meeting. The Chair began by highlighting the largest proposed change in reaction to the public comment feedback, the primary living donor surgeon requirements for programs to be able to perform living uterus donor recoveries. The proposed change would state that, in the role of primary, co-surgeon, or first assist, the surgeon must have performed ten radical hysterectomies or living donor uterus recoveries as primary, co-surgeon, or first assistant. In addition, their experience must comprise at least one of the following as primary or co-surgeon:

- Two living donor uterus recoveries
- One living donor uterus recovery, one deceased donor uterus procurement, and at least one direct observation of a living donor uterus recovery
- Two deceased donor uterus procurements, as well as two direct observations of living donor uterus recoveries

This change reflects the feedback that "it may be very hard to perform two living donor uterus recoveries as a first surgeon or co surgeon, given that it's virtually impossible to scrub in any other hospital than your own, even across the street". A summary of discussion surrounding this change is recorded below:

A Committee member inquired as to how these procedures would be documented, and it was noted that the transplant program of the primary surgeon would be responsible for the documentation, as well as recording the recovery details (date, location, primary surgeon, and the UNOS ID). The member then inquired as to how procedures performed or observed outside of the United States would be recorded, stating that the current majority of living donor uterus transplants are not performed within the U.S. The Chair agreed that, in the early stages of this field, experience cannot be limited only to OPTN-designated transplant hospitals. The Committee agreed with the principle that experience should

not be constricted to procedures performed within the OPTN and found no OPTN bylaw that excluded foreign experience due to lack of a UNOS ID. The documentation, therefore, will require the unique medical identifier of the procedure if no UNOS ID exists, in alignment with current bylaw J.2.D, which necessitates: "The dates of the procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN". Finally, a member questioned whether animal procedures should be included in the surgical requirements, speculating that a number of procedures have been performed in animal models, which can be somewhat similar to humans. A second member rebutted that, while animal procedures were instrumental to the establishment of the field, "the field has surpassed that [point]". In addition, they also noted that, in the case of baboon recovery as a human analogue, this procedure is fairly rare and would be harder to witness than a human living donor recovery. The Committee agreed that animal procedures should not be included within the updated requirements.

Vote

The Committee unanimously supported sending the proposal to the OPTN Board of Directors at their December 2021 meeting (13 yes, 0 no, 0 abstain).

Upcoming Meeting

• November 9, 2021

Attendance

- Committee Members
 - o Bohdan Pomahac, Chair
 - o Sandra Amaral, Vice Chair
 - o Amanda Gruendell
 - o Brian Berthiaume
 - o Bruce Gelb
 - o Debra Priebe
 - o Donald Rickelman
 - o Elizabeth Shipman
 - o Lawrence Gottlieb
 - o Liza Johannesson
 - o Lori Ewoldt
 - o Mark Wakefield
 - o Stefan Tullius
- HRSA Representatives
 - o Jim Bowman
- SRTR Staff
 - o Bryn Thompson
- UNOS Staff
 - o Krissy Laurie
 - o Roger Brown
 - o Sarah Booker
 - o Leah Slife
 - o Kristine Althaus
 - o Rebecca Murdock