OPTN Vascularized Composite Allograft Transplantation Committee
Meeting Summary
April 24, 2024
Teleconference

Sandra Amaral, MD, MHS, Chair
Vijay Gorantla, MD, PhD, Vice Chair

Introduction

The OPTN Vascularized Composite Allograft (VCA) Committee (the Committee) met via WebEx teleconference on 04/24/2024 to discuss the following agenda items:

1. Membership Bylaws Revisions Project: Potential Inclusion of OB/GYN in Appendix D Requirements

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

1. Membership Bylaws Revisions Project: Potential Inclusion of OB/GYN in Appendix D Requirements

The Committee discussed the OPTN Bylaws related to uterus transplantation, specifically whether the Primary OB/GYN should be subject to additional requirements in Appendix D that apply to the primary physician and surgeon. Changes to Appendix D could be incorporated into a project sponsored by the OPTN Membership and Professional Standards Committee.

Summary of discussion:

Decision #1: The Committee supported having an "on-site" provision within the OPTN Bylaws for the primary OB/GYN.

Decision #2: The Committee agreed that the primary OB/GYN's intended role should not include ensuring the operation and compliance of the program according to OPTN Bylaws, since those responsibilities can be handled by the primary surgeon and/or the primary physician.

Decision #3: The Committee supported including "primary OB/GYN" rather than "primary surgeon or primary physician" in Appendix D.2.B.1.b: Reinstatement of Previously Designated Key Personnel.

Decision #4: The Committee agreed that it is reasonable to include primary OB/GYNs in Appendix D.2.C: Program Coverage Plan.

When asked if the "on-site" provision within the Bylaws makes sense for the primary OB/GYN role, members agreed that having on-site OB/GYN is key to having a successful uterus transplant program. The Chair agreed, emphasizing that they would be concerned with not including this provision, and by not including it, potentially could cause harm. A member agreed, underscoring previous sentiments surrounding the diversity of obstetrics and gynecology needed for uterus transplantation cannot be encompassed in one OB/GYN practitioner, and current policies encompass that. They continued, mentioning that it is important to be mindful that there are current uterus transplant programs where obstetric and gynecologic care is not provided on-site, however, they do agree with the team leader being on-site. They mentioned that it is important to maintain the flexibility for providers to be able to provide care off-site, as long as the primary team leader is on-site at the transplant program. A member

agreed, comparing the on-site OB/GYN as the "quarterback," or someone who is the lead and is coordinating care. They recognized that it is important for the on-site OB/GYN to work closely with the recipient's care team, regardless of where they are located. A member, who is a uterus recipient, mentioned that they received a lot of care in their home state, which is different than where they received their transplant. They mentioned that thought this worked well from a patient perspective and that their care would be limited if they did not have the flexibility.

When asked if the primary OB/GYN's intended role includes ensuring the operation and compliance of the program according to OPTN bylaws, a member commented that it should. The Committee agreed that because an OB/GYN has a different training pathway than typical transplant physicians, they do not also need to fill the role of ensuring compliance with the OPTN Bylaws, as the primary surgeon or physician can perform that role. However, since the primary OB/GYN also could be the primary physician or surgeon, each program can divide up the labor for what fits their team the best, based on the composition of that team. Members agreed that flexibility within programs is important since uterus transplant programs are still in their infancy and trying to find a model that best fits their goals.

A member commented that Appendix D.2.B.1: Changes in Key Personnel is the substantive part of the regulation, adding that personnel changing without notification is worrying. Several other members spoke up to voice their support and agreement with the previous comment. The Chair voiced their opinion that "primary OB/GYN" should be included in Appendix D.2.B.1: Reinstatement of Previously Designated Key Personnel. Other members agreed, citing that this keeps the language consistent throughout the bylaws.

When asked about Appendix D.2.B.2: Programs or Components Without Key Personnel, one member noted that it is vital for a program to have an in-house OB/GYN in an active program, however, their subspecialty is not imperative. They said they strongly support at least one on-site OB/GYN to be included in the language. Several members agreed with the previous member's sentiments and supported the suggested change.

Regarding Appendix D.2.C: Program Coverage Plan, one member commented that it is reasonable to have the same requirement for the primary surgeon and primary physician to submit a detailed Program Coverage Plan to the OPTN and introduce "primary OB/GYN" where the primary surgeon/primary physician is written. One member agreed, highlighting that much of the language in the Appendix is focused on the time of transplant (organ acceptance, procurement, and transplantation) and therefore felt comfortable with the language including primary OB/GYN. When asked how to define "additional transplant surgeons" and "additional transplant physicians", one member pointed out that they need to figure out the exact language that would be used to substitute those terms and what services they would provide. A member agreed, voicing their concern for the term "credentialed," as institutions may struggle with that. The Chair suggested looking at the Bylaws outlining the necessary expertise for the primary OB/GYN to ensure consistent language. One member emphasized the need to define what services these positions would provide, as that will help with the definition.

Next steps:

The Committee will review the updated, proposed Bylaws when they become available.

Upcoming Meeting

- May 22, 2024, at 4:00 PM ET (teleconference)

Attendance

- **Committee Members**
  - Sandra Amaral
  - Alexa Blood
  - Amanda Gruendell
  - Anji Wall
  - Brian Berthiaume
  - Charlie Thomas
  - Elliott Richards
  - Paige Porrett
- **HRSA Representatives**
  - Jim Bowman
  - Shannon Dunne
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Asma Ali
  - Jesse Howell
  - Kaitlin Swanner
  - Kayla Balfour
  - Kristina Hogan
  - Marta Waris
  - Sharon Shepherd
- **Other**
  - Ericka Harrison (incoming Committee member)