OPTN Vascularized Composite Allograft Transplantation Committee
Meeting Summary
November 15, 2023
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 11/15/2023 to discuss the following agenda items:

1. New Project Ideas
2. Donation and Allocation of VCA Organs in Clinical Practice

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

1. New Project Ideas

The Committee reviewed the different types of Committee projects and discussed potential new project ideas.

Summary of discussion:

There were no decisions regarding this item.

A member noted the existing perception that uterus transplantation is experimental. They noted that ovarian tissue transplantation is no longer considered experimental by the American Society for Reproductive Medicine (ASRM) since they have surpassed over 100 transplants. The Vice Chair agreed, voicing their frustration with the definition of the standard of care, as well as the definitions of research and experimental procedures across clinical VCA care. They commented that recommendations and definitions are issued by specific transplant institutions and programs but feel that acceptance at the societal level will help strengthen the argument that VCA transplants instead are standard of care. They asked if there was any progress within the uterus field surrounding this topic. A member explained that there is an ASRM opinion piece being drafted that focuses on uterus transplants no longer being considered experimental. They mentioned that they are soon petitioning the American Medical Association (AMA) to have uterus transplantation adopted as a Category One Current Procedural Terminology (CPT) code, which means that the procedure will be defined as a common procedure. It is currently listed as a Category Three CPT code, which is a temporary code used for emerging and experimental services and technologies.[1] The Chair expressed that the advocacy work suggested should come from professional societies rather than the OPTN, which is a venue for policy development. However, they did recognize that the field of uterus transplantation is struggling with issues the overall VCA transplant community experiences, one of the main ones being the balance between innovation and regulation. The Chair suggested that the Committee potentially meet with the OPTN Ethics

[1] https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/list-cpt/hcpcs-codes

Committee to develop a white paper that questions at what point regulation is important to ensure safety but does not inhibit innovation.

Another potential project the Chair suggested to impact advocacy would be through capturing the voice of donor families and recipients and recipient families. They noted that people often listen more to patient stories rather than stories from medical professionals and believe that could be an effective mechanism for advocacy but were unsure how to develop it into an OPTN Committee project. A member voiced their support for this topic and suggested an approach to this topic could be by requiring approval for a program and making a statement noting that since 2014, the OPTN has mandated oversight of these clinical procedures. A member expressed their approval of this idea, noting that a statement like that would be incredibly strong, adding that including a framework to show the maturity of a newer field in transplant surgery would be welcomed. They reaffirmed the desire to create a white paper, adding that it could remind the transplant community that the Committee is not reinventing the wheel with VCA transplantation, as it is rooted in solid organ transplantation foundation. They indicated that within the next five years, it is likely that uterus transplants will only be available to those who can afford to pay out of pocket since institutional funding is running out. A member agreed, flagging that it is not just uterus transplant programs that are running out of funding and are a huge obstacle for the entire VCA transplant field.

The Vice Chair mentioned precedents that may be useful, giving the example of robotic surgery, noting that robotic procedures were once seen as experimental, but are now accepted as part of the standard of care. A HRSA representative reminded the Committee that the OPTN does not have statutory or regulatory authority to address the standard of care and medical coverage in that limited concept. They added that the OPTN has a lot of leverage by using data collection, specifically with the waiting list and transplants that are performed on any organ, including VCA organs. They continued, emphasizing that by collecting the data, especially outcomes data and allograft functionality, the data and analysis compiled can be used to demonstrate the type of candidates that are appropriate for VCA transplants and how that selection process is conducted in terms of evaluations. The data can also be used as evidence and support for professional societies to CMS or commercial payors, which can be instrumental for the VCA community.

A HRSA representative suggested collaborating with the OPTN Ethics Committee to create an analysis of different challenges that come up in the VCA community, approaching it from a candidate selection from the waiting list perspective, rather than an allocation policy perspective. They also recommended potentially developing a guidance document, which differs from policy but still falls into the scope of the Committee.

The Vice Chair echoed earlier sentiments, noting that collecting data could be useful to inform the AMA codes, and could be supplemented with peer-reviewed literature and clinical trials. A HRSA representative affirmed this idea, noting that data collection is within the scope of the OPTN.

Next steps:

The Committee will continue to explore potential projects to focus on next year.

2. Donation and Allocation of VCA Organs in Clinical Practice

The Committee continued previous discussions regarding programming considerations for VCA organs in the OPTN Computer System.

Summary of discussion:

Decision #1: For uterus transplantation, the Committee recommended that the OPTN Computer System just list “uterus”, rather than listing “uterus”, “cervix” and “vagina” as 3 individual body parts.

Decision #2: For head and neck organs, the Committee advised that individual body parts should be included in the OPTN Computer System, as the body part is procured on a candidate-by-candidate basis.

A member suggested that organ-specific questions should be directed to members of the Committee who specialize in the specific field that is being asked about. The Vice Chair clarified that UNOS IT is asking if it is beneficial to have the body part of organs listed in the OPTN Computer System, or if having just the organ will suffice. They commented that this applies to most organs and will help improve the OPTN Computer System. A member commented that for the uterus, this would cause more confusion and potential errors since procurement teams take the uterus, cervix, and small portions of the vagina, and there will never be instances where only the uterus is procured. They worried that asking about specific body parts in the uterus may cause mistakes in the OPTN Computer System, such as forgetting to click a checkbox. They added that the only thing that may vary is the amount of vasculature, as the amount procured varies between deceased and living donors. The Vice Chair commented that they are not necessarily discussing blood vessels.

The Vice Chair questioned the impact of one procurement team going to recover and leaving other tissues and structures that are potentially eligible for allocation. A member emphasized that vaginas would never be procured by themselves, as there is no ethical framework for that, and the vagina is part of the cervix. They continued, remarking that the cervix is part of the uterus, therefore there is no reason to transplant just the cervix.

A member of the Committee who specializes in face transplantation raised that for head and neck transplantation, it would be helpful to list out each body part, as the body part procured is circumstantial based on the candidate's injury. They elaborated that sometimes candidates may only need a partial face transplant, therefore they may not need every single body part that head and neck encompass.

The Vice Chair raised the question if a candidate registers for different body parts, then the procurement team doesn’t procure everything they selected in the OPTN Computer System, will that prevent other potential candidates from being able to accept those? They commented that decisions relevant to which body parts and how much tissue to procure are frequently made in the operating room during organ recovery and sometimes are not made before procurement. The Chair affirmed that like other organs, this type of information is helpful to collect, especially since it is relevant to allocation efficiency and utility and can potentially help reduce non-use. They mentioned that this seems theoretical right now and they will have to decide and implement this, but trying to avoid errors in the data collection when they do happen will be important.

Next steps:

The Committee will continue to help provide information regarding the donation and allocation clinical practices for VCA organs in the OPTN Computer System.

Upcoming Meeting

- January 24, 2024, at 4:00 PM ET (teleconference)

Attendance

- **Committee Members**
  - Sandra Amaral
  - Vijay Gorantla
  - Alexa Blood
  - Brian Berthiaume
  - Christina Kaufman
  - Elizabeth Shipman
  - Elliott Richards
  - Gerald Scott Winder
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Caitlyn Nystedt
- **UNOS Staff**
  - Asma Ali
  - Catherine Parton
  - Emily Howell
  - Houlder Hudgins
  - Jesse Howell
  - Kayla Balfour
  - Kelley Poff
  - Kristina Hogan
  - Krissy Laurie
  - Laura Schmitt
  - Leah Nuñez