OPTN Vascular Composite Allograft Committee
VCA Uterus Transplant Outcomes Workgroup
Meeting Minutes
June 26, 219
Conference Call

Linda Cendales, MD, Chair
Bo Pomahac, MD, Vice Chair

Introduction

The VCA Uterus Transplant Outcomes Workgroup (hereafter referred to as the "Workgroup") met via conference call on June 26, 2019 to discuss the following agenda items:

1. Uterus-focused Review of VCA TRR and TRF Forms

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

1. Uterus-focused Review of VCA TRR and TRF Forms

Several Committee members, program directors of OPTN approved uterus transplant programs, and external subject matter experts (SMEs) from reproductive medicine and obstectricts/gynecology met by conference call to review potential changes to OPTN data fields pertaining to uterus transplant recipients.

Summary of discussion:

The Chair welcomed participants to the call and thanked them for their willingness to help with this important initiative. This project represents the first national data collection on uterus transpant outcomes in the U.S. Parallel discussions have taken place regarding other VCA types.

The Chair recalled early discussions on uterus recipient data from the Uterus Transplant Intersociety Roundtable in April 2016.[1] These data requirements would need to be balanced with the OPTN Principles of Data collection that serves five key purposes:

- Inform future policy decision-making for organ donation and transplantation
- Monitor OPTN member performance
- Determine if OPTN members are complying with policies
- Monitor for transplant patient safety when no other alternative sources of data exist
- Fufill requirements of the OPTN Final Rule

Participants discussed the right balance of changes, a key consideration of not creating data forms that were onerous to complete, and the timeframe to collect these uterus recipient data elements. Members felt it was important to adhere to the same general structure and cadence of transplant patient data submission.

Summaries of proposed data collection changes were emailed to workgroup participants for review prior to the call. Call participants held lengthy discussions in four areas:

[1] Centralized data collection is a requirement of the OPTN contract, essential to support scientific advancement of VCA transplantation, outcome measures for organ function, demonstrate success and fulfill a medical need. Uterus Transplantation Intersociety Roundtable, Chicago, IL, April 21, 2016.

Data elements to maintain

UNOS staff briefly profiled data elements that are intended to be left unchanged. This profile of data include recipient demographic information, provider information, graft function, and presence or absence of major complications. Call participants agreed with this general approach, but wanted to examine in more detail off-line.

Data elements to remove

The participants reviewed removing a small number of data elements from the Transplant Recipient Registration (TRR) form that may not be clinically applicable to uterus transplantation. These included:

- Hemoglobin A1C
- Cognitive Development
- SF-36
- Carroll Test
- Semmes-Weinstein Monofilament Test
- Previous skin grafts
- Inpatient hospitalization prior to transplant
- Patient on life support
- Prior blood transfusions
- Prior pregnancies
- Tolerance used
- Multiple graft recipient
- Topical immunosupression

There was general agreement with these changes. The workgroup members noted:

- There should be consideration whether instances of prior reconstructive gynecological procedures and type (e.g.: neovagina and instances of perioperative surgical complications or later obstetrical complications associated with the reconstruction), and prior pregnancies [pregnancy followed by hysterectomy due to malignancy or other OB/GYN etiology] should be captured.
- The need to maintain collection of recipient sensitizing events. The rationale for this was the incomplete understanding of immunological variables on graft function and graft rejection. Future changes to data collection in this area could be made if data showed prior sensitizing events was not meaningful in uterus transplantation.
- The “skin changes” should be removed from uterus data collection. There would be value in capturing if visual changes were noted on cervical examination.

Participants expressed the desire to to examine the proposed changes in more detail off-line and provide lists of options under each data element.

Data elements to modify

A workgroup member supported transition from the SF-36 to the SF-12. An alternative measurement tool, the Psycological General Well-being Scale, is being used in Europe but needed more review before the OPTN should consider using.

Data elements to add

The Workgroup the reviewed a list of potential data points on uterus recipients, including:

- Embryo transfer(s) and date(s)
- Date of positive pregnancy test result
- Date embryonic heart beat detected by ultrasound
- Estimated delivery date
- Miscarriage (y/n) and date (if applicable)
- Psychological disorder(s) pre-transplant (specify) – Perhaps Paitient Health Questionare – 2 use
- New onset maternal psychological disorder(s) (specify), admission for treatment (y/n)
- Pregnancy complications (specify) and gestational age (weeks/days)
- Maternal complications at delivery (specify)
- Delivery type (vaginal/ceserian) and date
- Hysterectomy (y/n) and date, performed following successful delivery or due to complication
- Blood transfusions required following delivery
- Length of stay (days)
- Post-delivery complications (specify)
- Surgical, medical, or psychological complications after hysterectomy (specify) and date

Workgroup members felt the list above was a good start, but there needed to be consideration to the right balance of data. Members were cautionary about collecting too granular a level of data as this may become less useful. One member noted that challenges may be seen in uterus recipients to engage in follow-up evaluations after hysterectomy, specifically to monitor the recipient's kidney function. The OPTN policy requirement for living donor follow-up of two years may be a realistic precedent.

Participants then discussed whether there was a need to collect health information on the children born to uterus recipients. This included what types of information may be appropriate (birth length and weight, gestational age (weeks/days), APGARs, whether NICU admission was required, length of stay, any birth complications, and presence of any congenital issues), the duration of a data submission requirement, experiences of invitro fertilization (IVF) registries in the U.S., and potential challenges for requiring this type of data. One member noted the data collection would also serve the purpose of conveying the safety and efficacy to the public. UNOS staff commented that a pre-condition to gathering data of this nature was the determination whether the OPTN has the purview by statute or regulation to collect the health information of children born to uterus transplant recipients. UNOS General Council is engaged with representatives of the Health Resources and Services Administration (HRSA) Division of Transplantation (DoT) to answer this question.

Next steps:

Tables summarizing the proposed changes, as well as TRR and TRF help documents will be sent to participants for their review. *Follow-up feedback should be emailed to UNOS staff coordinating the conference call by July 19, 2019.*

The Chair and Vice Chair expressed their gratitude to the participants for their engaging discussion, and looked forward to future interaction with the group. With no further business to discuss, the workgroup call was adjourned.

Attendance

- **Workgroup Members**
  - Linda C. Cendales
  - Bodhan Pomahac
  - Andreas Tzakis
  - Sheila Jowsey-Gregoire
  - Nicole Johnson
- **HRSA Representatives**
  - none
- **SRTR Staff**
  - none
- **UNOS Staff**
  - Christopher L. Wholley
  - Sakshi Thassu
  - Hannah Byford
  - Paula Dehetre
- **Other Attendees**
  - Katherine O'Neill, M.D. – Hospital of the Univ. of Pennsylvania Department of OB/GYN
  - Page Porrett, M.D. – Hospital of the Univ. of Pennsylvania Department of Surgery
  - Rebecca Flyckt, M.D. – The Cleveland Clinic Foundation Department of Women's Health
  - Simon Talbot, M.D. – Brigham and Women's Hospital Department of Surgery
  - Giuliano Testa, M.D. – Baylor Univ. Medical Center Department of Surgery
  - Liza Johannesson, M.D. – Baylor Univ. Medical Center Department of OB/GYN
  - Jessica Goldstein, RN – American Society for Reproductive Medicine
  - Elliott Richards, M.D. – The Cleveland Clinic Foundation Department of OB/GYN