OPTN Vascularized Composite Allograft Transplantation Committee
Vascularized Composite Allograft – Living Donor Data Collection Workgroup
Meeting Summary
April 13, 2020
Conference Call

Linda Cendales, MD, Chair

Introduction

The Vascularized Composite Allograft (VCA) – Living Donor (LD) Data Collection Workgroup of the OPTN VCA Committee met via Citrix GoTo teleconference on 04/13/2020 to discuss the following agenda items:

1. Review OPTN Data Collection Principles
2. Review Draft Living Donor Registration (LDR) with Uterus-Specific Data Elements

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

1. Review OPTN Data Collection Principles

The Chair led the Workgroup in a review of the OPTN Data Collection principles and the Data Advisory Committee's Data Element Standards of Review Checklist, noting that the Workgroup should identify the minimal amount of new data fields that align with the strategic goal of living donor safety. There were no questions from the Workgroup.

2. Review Draft LDR with Uterus-Specific Data Elements

The Chair led the Workgroup in a review of a draft LDR prepared by the Chair and UNOS staff based on previous Workgroup discussions and relevant literature. The draft LDR was emailed to the Workgroup prior to the call and several members provided comments or questions for consideration by the Workgroup.

Summary of discussion:

Pre-Donation Uterus Clinical Information

The proposed data elements to add to this section included several tests for infectious diseases (human papillomavirus, gonorrhea, chlamydia, and candidiasis), as well as uterine imaging and prior full term live births.

The Workgroup discussed whether data collection via the LDR should align with the proposed policy requirements for medical evaluation of living uterus donors under development by the Living Donor VCA Workgroup. A member suggested collecting data only on required testing. UNOS staff recommended aligning data collection with policy requirements because it may be difficult to collect data on topics without associated policy requirement, particularly with regard to infectious disease testing. The Workgroup agreed with this approach.

The Workgroup agreed to add herpes (HSV-2) to the uterus-specific infectious disease testing section of the LDR because the Living Donor VCA Workgroup included it in their Policy 14 draft. A member questioned whether transplant programs should have the option to select "UNK/Cannot Disclose" for disease testing results. UNOS staff noted that this formatting was used for consistency with the other

infectious disease testing on the LDR for all organs. UNOS staff advised maintaining this consistency, noting that the "UNK/Cannot Disclose" option is rarely used and does not negatively impact data quality. UNOS staff also noted that any criteria that would be considered exclusionary under Policy 14 would not necessarily need to be collected on the LDR since people with those characteristics would not be permitted to be a donor. The Chair agreed, but noted that exclusionary criteria is largely determined by transplant programs, and recommended retaining these infectious disease tests on the LDR.

The Workgroup agreed to add a follow-up question to the data elements for testing of gonorrhea, chlamydia, and candidiasis to ask whether the donor was treated. HRSA staff also recommended adding bacterial vaginosis, trichomoniasis, and an option for "other" because some of these conditions have been associated with fetal demise. HRSA staff also noted that it is important to conduct a urine culture because a positive result is associated with premature labor and other complications.

The Workgroup noted that the "uterine imaging" section allows transplant programs to indicate if a donor has a retroverted or double uterus. The Workgroup discussed whether they need to add any granularity to this section, but agreed to leave it more open-ended with the option to submit a brief clinical narrative of any abnormal findings.

The Workgroup agreed that, in addition to collecting information on prior full term live births, the LDR should also collect information on gravidity; parity; spontaneous abortion (miscarriage); and therapeutic abortion. The Workgroup agreed to collect these data as continuous variables. A member noted that gravidity and parity can be very different from prior full term live births, which is important given that the purpose of a uterus transplant is to achieve pregnancy. Another member noted that some living donor programs are hesitant to accept uterus donors that have had a lot of instrumentation of the endometrial cavity due to either spontaneous or therapeutic abortion because it is not clear how much risk is conferred to the recipient. The member said it might be important to collect this information to understand how it impacts transplant recipient outcomes. The member noted that there is some controversy in the field about whether it is appropriate to use a nulliparous donor, so this data collection will help the OPTN to gather information on processes that are not yet standardized. Members agreed that this data collection will not impose too much burden on transplant programs because they will already be collecting this information as part of routine medical evaluations.

Uterus Surgical Information

The proposed data elements to add to this section included intended procedure type, conversion from robotic to open, operative time, intraoperative complications (including ureter laceration and anesthetic complications), and vessels/nerves/tissue from outside the donated graft repaired. The Workgroup agreed to eliminate a proposed data element for "estimated blood loss" because the current LDR includes a data element for "non-autologous blood administration," which captures the same information. The Workgroup affirmed that it is important to document whether a donor received a transfusion as it will impact future medical care decisions for the donor. The Workgroup agreed to work on the language referring to "vessels repaired" to better capture the intent of this data element.

Uterus Post-Operative Information

The proposed data elements to add to this section included length of intensive care unit (ICU) stay, hospital stay, and duration of sick leave. A member said it is unlikely that "duration of sick leave" would be known at the time the LDR is submitted, which is at time of hospital discharge. The Workgroup agreed to remove this data element from the LDR.

Uterus Related Post-Operative Complications

The proposed data elements to add to this section included wound infection, ureterovaginal fistula, nocturia, meralgia paresthetica, bladder hypotonia, and other complications. The Workgroup did not have any changes to this section. The Workgroup discussed the "any readmission after initial discharge" question on the LDR. UNOS staff noted that this question no longer makes sense on the LDR, since the LDR is submitted at initial discharge, but the Workgroup agreed that it is out of scope for this project to make any changes to the existing LDR. The Workgroup agreed that any information that needs to be collected after initial discharge should be reflected on the Living Donor Follow-up (LDF) instrument.

Organ Recovery

The Workgroup agreed that "extra vessels" should be added to the drop-down menu for "organ(s) recovered." Even though it is rare to remove extra vessels from a living donor, the Workgroup felt it was important for transplant programs to have the ability to document the recovery of extra vessels if it occurs.

Next steps:

The Workgroup will discuss the draft LDF at their final meeting on May 4th. UNOS staff will also share the latest draft of Policy 14 produced by the Living Donor VCA Workgroup with the VCA-LD Workgroup.

Upcoming Meeting

- May 4, 2020