

**OPTN Vascular Composite Allograft Committee  
VCA Living Donor Data Collection Workgroup  
Meeting Summary  
May 4, 2020  
Conference Call**

**Linda Cendales, MD, Chair**

## **Introduction**

The VCA Living Donor Data Collection Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference 05/04/2020 to discuss the following agenda items:

1. Review Draft Living Donor Follow- Up Form (LDF)
2. Review Data Element Analysis and Finalize Changes to the Living Donor Registration Form (LDR)

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

### **1. Review Draft Living Donor Follow-Up Form (LDF)**

The Workgroup completed their revisions to the LDF.

#### Summary of discussion:

##### Uterus Clinical Information

- The Workgroup determined that the "Activity Level" field should be removed as it is not relevant to uterus transplantation.

##### Complications Since Uterus Donation

- The Workgroup determined that they would add the "Complications Requiring Intervention" section of the form currently listed on the LDR to the LDF. These complications include: Wound infection, ureterovaginal fistula, nocturia, meralgia paresthetica, bladder hypotonia.
- Also added urinary tract infection to "Complications Requiring Intervention" on the LDF
- Other fields in this section: Dyspareunia, vaginal pain, pelvic pain, and other- specify
- Did not add "duration of sick leave" field to LDF. This field does not exist on any other follow-up form.

##### Menopausal Symptoms

- The Workgroup determined that this section did not require any changes.

##### New Onset Psychological Symptoms:

- A member expressed the importance of collecting psychosocial evaluation data in order to record any anxiety, depression, etc. that develop in uterus living donors after donation
- Members agreed to keep this section labeled "New Onset Psychological Symptoms" rather than change it to "New Onset Psychological Diagnoses" as symptoms is a better word for screening patients for psychosocial issues and does not required them to have been formally diagnosed by a medical professional
- The Workgroup determined that they would add the following data fields: Anxiety, depression, change in mood, change of eating habits, suicidal ideation, and other- specify

Next steps:

The LDF will be sent to the full VCA committee for feedback.

**2. Review Data Element Analysis and Finalize Changes to the Living Donor Registration Form (LDR)**

The Workgroup discussed the data element checklist and completed their work on the LDR.

Summary of discussion:

Data Element Analysis

- The data element analysis spreadsheet will be sent for the Data Advisory Committee's (DAC) review prior to the VCA Committee's presentation of this project to the DAC on May 11, 2020.

Pre- Donation All VCA Clinical Information

- The Disease Transmission Advisory Committee (DTAC) suggested screening for Toxoplasma IgG for all VCA donors. The Workgroup determined that they would follow this suggestion.

Pre- Donation Uterus Clinical Information

- The Workgroup determined that living uterus donors should be tested for vaginal candidiasis twice --once at the time of evaluation and again at the time of donation. It was noted on this portion of the form that vaginal candidiasis is also known as Gardnerella vaginalis.
- The Workgroup considered whether the "uterine imaging" data element should include more specific guidance as to what transplant programs should document in the "abnormal findings" section. A member said that while it is unlikely that a program will conduct a living donation procedure with a uterus that has an abnormal finding, the open text field provides programs with the opportunity to document any findings if they feel the need to do so. The Workgroup agreed not to make changes to this data element.

Uterus Surgical Information

- The Workgroup clarified that operative time should be counted as surgical time from skin to skin. The Workgroup determined that this portion of the form should be structured so that transplant programs enter the exact start and end times, so that UNet<sup>SM</sup> can calculate the operative time. This method will collect data as a continuous variable and offer more data analysis options than data collected as a categorical variable.
- The Workgroup determined that no changes should be made to the "Ovaries Removed" section of the LDR.
- The Workgroup decided that the "Ureter Laceration" data element under "intraoperative complications" should be changed to "Ureter Injury."

Uterus Post- Operative Information

- The Workgroup determined that the "Length of ICU Stay" response options that asked for a range of days (0 days, 1-3 days, etc.) should be changed to one box that must be filled in with the exact number of days. This collects that data as a continuous variable.
- The Workgroup added a fill in the box response option for any other post-operative complications.

Next steps:

The LDR will be sent to the full VCA committee for feedback.

## Upcoming Meetings

- None