Introduction

The Living Donor Committee (the Committee) met via Citrix GoToTraining teleconference on 04/20/2020 to discuss the following agenda items:

1. VCA Data Collection Workgroup Update
2. COVID-19 Discussion
3. Living Donor VCA Policy 14 Project Update

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

1. VCA Data Collection Workgroup Update

The Chair of the VCA Data Collection Workgroup presented an update to the Committee on the current status of the project to update Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) forms to include living VCA donors.

Summary of Data

The presenter reviewed current proposed data elements for the LDR to include:

Pre-donation

- Infectious disease screening
  - HPV, HSV-2, gonorrhea, chlamydia
  - Vaginal candidiasis, bacterial vaginosis, trichomoniasis
- Uterine Imaging
- Medical History
  - Gravidity and parity
  - Spontaneous and therapeutic abortion
  - Prior full term live births

Surgical Information

- Intended procedure type
- Conversion from robotic to open
- Operative time
- Intra-operative complications
  - Ureter laceration
  - Anesthetic complications
  - Vessels Repaired

Post-Operative
• Length of ICU Stay
• Hospital Stay

Post-Operative Complications
• Wound infection
• Ureterovaginal fistula
• Nocturia
• Meralgia paresthetica
• Bladder hypotonia
• Other

The presenter also reviewed possible data elements for the LDF:
• Activity level
• Duration of sick leave
• Complications since uterus donation
• Menopausal symptoms
• New onset psychological symptoms
• Other complications
  o Dyspareunia, sexual dysfunction, vaginal pain, pelvic pain, other

Summary of Discussion
A Committee member asked if there are any considerations for vascular or neurological injuries as a result of VCA donation. The presenter explained some more general components and complications that are applicable to VCA could be added. The presenter asked the Committee if adding a free text field for other complications would be sufficient. A Committee member commented a free text field wouldn’t provide guidance to programs on what should be reported and is difficult to analyze from a data collection perspective.

The Chair commented that including “ureter laceration” under “intra-operative complications” would result in programs only reporting lacerations and may result in confusion from programs on what counts as a laceration. The Chair suggested changing the language to “ureter injury”. Additionally, the language “vessels repaired” could use more clarity to prevent confusion. The Chair also suggested under “prior full term live births”, there should be specificity between vaginal and caesarian section births.

The Committee asked if there’s any laboratory data that should be collected. The presenter informed the Committee there was discussion on this within their workgroup but they ultimately did not find an equivalent lab test for uterus specifically that would be captured in addition to general lab values.

Next Steps
The presenter will take all feedback back to the VCA Data Collection Workgroup. They will send the updated draft forms and send back to the Committee for another review.

2. COVID-19 Discussion
Committee members introduced themselves and commented on how the COVID-19 crisis is affecting them and their hospitals if applicable. A number of committee members said their hospitals had halted their living donor transplants and limited their evaluations. Some other programs are still conducting living donor transplants although being selective on which ones are scheduled. A number of committee members also reported doing more telehealth evaluations.
3. Living Donor VCA Policy 14 Project Update

The Living Donor VCA Workgroup (the Workgroup) Chair presented an update on the project to update Policy 14 to include living VCA donors.

Summary of Data and Discussion:

The Committee reviewed select sections of the current draft policy including proposed changes to OPTN Policy 14.3: Informed Consent and OPTN Policy 14.4: Medical Evaluation Requirements for Living Donors. The Workgroup had discussed updating language in Table 14-1: Requirements for Living Donor Informed Consent:

- Original language: “15.b.iii: Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies”
- Proposed language: “15.b.iii: Feelings of emotional distress or grief if the transplant does not result in a successful outcome” or “15b.iii: Feelings of emotional distress or grief if the transplant recipient does not experience a successful outcome”

It was noted this section of the policy would apply to all living donors. Committee members commented this change could be an administrative and financial burden for transplant hospitals as it could mean they would have to update their informed consent materials. Committee members also suggested the proposed language is too generic for the specific emotional stress and grief that would be unique to uterus donation. Committee members also said the language “if the recipient dies” should not be removed from the informed consent language as it is important to talk to donors about the potential death of the recipient. In summary, the Committee recommended drafting more specific language unique to uterus and add it to the VCA section of the Informed Consent policy.

The Committee then reviewed the proposed new table addition for living VCA donors under OPTN Policy 14.3: Informed Consent:

<table>
<thead>
<tr>
<th>The recovery hospital must:</th>
<th>These additional elements as components of informed consent for living VCA donors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclose to all living VCA donors</td>
<td>Potential financial impacts:</td>
</tr>
<tr>
<td></td>
<td>• Procedure may not be covered by health insurance</td>
</tr>
<tr>
<td>Disclose to all living non-uterine VCA donors</td>
<td>There are surgical, medical, psychosocial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, <strong>all</strong> of the following:</td>
</tr>
<tr>
<td></td>
<td>• Potential medical or surgical risks:</td>
</tr>
<tr>
<td></td>
<td>o Loss of function</td>
</tr>
<tr>
<td></td>
<td>o Physical disability</td>
</tr>
<tr>
<td></td>
<td>o Physical disfigurement</td>
</tr>
</tbody>
</table>
The recovery hospital must:
The Committee indicated the table format was easy to follow. A committee member suggested other reproductive organ transplants (ex. testicular transplant) would have similar potential risks to uterus donors and questioned if that category should be expanded to cover all living reproductive organ donors.

The Committee then reviewed the Workgroup’s current draft of a new table to be added to OPTN Policy 14.4: Medical Evaluation Requirements for Living Donors:

<table>
<thead>
<tr>
<th>This evaluation must be completed:</th>
<th>Including evaluation for and assessment of this information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine-specific medical history</td>
<td>Gynecological and obstetric history including prior childbirth</td>
</tr>
</tbody>
</table>
| Uterine-specific tests            | • Pelvic exam  
|                                  | • Pap smear  
|                                  | • Fungal screening  |
| Anatomic assessment               | • A radiological assessment must be performed to determine if the uterus is anatomically normal  
|                                  | • Consultation with a gynecological surgeon |
A HRSA representative recommended adding bacterial vaginosis to the transmissible disease screening requirements. The Committee also recommended to edit the radiological assessment requirement language to match similar language in other sections of Policy 14.4 and to remove the requirement to consult with a gynecological surgeon as it’s inconsistent with other sections of policy.

Next Steps

The Workgroup will align the medical evaluation requirements with the VCA Data Collection Workgroup’s proposed changes to the LDR and LDF forms. The Workgroup will review and incorporate the Committee’s feedback during their next meeting on April 22.

Upcoming Meeting

- May 20 - Teleconference