

**OPTN Living Donor Committee
VCA Workgroup
Meeting Summary
April 22, 2020
Conference Call**

Stevan Gonzalez, MD, Chair

Introduction

The Living Donor Committee VCA Workgroup met via Citrix GoToMeeting teleconference on 04/22/2020 to discuss the following agenda items:

1. Summary of Committee Feedback and Policy 14 Drafting

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

1. Summary of Committee Feedback

The Chair reviewed feedback received from the Living Donor Committee.

Summary of Data:

The Living Donor Committee reviewed the current draft of the Policy 14 changes during their April 20 meeting and offered the following feedback:

Regarding the proposed update to *Table 14-1: Requirements for Living Donor Informed Consent under Potential Psychosocial Risks, 15.b.iii:*

- Since this section of Policy applies to all living donors, this would be a significant administrative burden for transplant programs as they would have to update their informed consent materials
- The edited language is too generic for specific emotional stress and grief that would be unique to uterine donors
- Recommend keeping "if the transplant recipient dies" as it is important to discuss this risk with the donor
- Recommend making language more specific and including in the VCA specific section on uterus

Regarding the proposed table addition to *Policy 14.3: Informed Consent:*

- Committee thought the format of the table was fine
- Suggest adding psychosocial risk for uterine donors
- One suggestion to change "uterus" to "reproductive organ" (ex. testicular transplant)

Regarding the proposed table addition to *Policy 14.4: Medical Evaluation Requirements for Living Donors:*

- Suggestion to add bacterial vaginosis to the list of transmissible disease screening
- Align language with recommendations on the VCA Data Collection Workgroup's proposed update to the LDR form
- Match anatomic assessment language to similar language for liver and kidney already in Policy
- Remove consultation with gynecological surgeon as it's not required for other organ types

Summary of Discussion:

The Workgroup continued discussing elements in the proposed table for *Policy 14.3: Informed Consent*.

Table 14-X: Additional Requirements for the Informed Consent of Living VCA Donors

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:
Disclose to all living VCA donors	Potential financial impacts: <ul style="list-style-type: none"> • Procedure may not be covered by health insurance
Disclose to all living non-uterine VCA donors	There are surgical, medical, psychosocial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, <i>all</i> of the following: <ul style="list-style-type: none"> • Potential medical or surgical risks: <ul style="list-style-type: none"> ○ Loss of function ○ Physical disability ○ Physical disfigurement
Disclose to all living uterine donors	There are surgical, medical, and psychosocial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, <i>all</i> of the following: <ul style="list-style-type: none"> • Inability to bear children • Potential medical or surgical risks: <ul style="list-style-type: none"> ○ Need for hormonal replacement therapy ○ Pain or discomfort with intercourse ○ Ureteral/bladder injury or dysfunction ○ Bowel injury

A Workgroup member suggested removing “potential” from “Potential risks” within the table as it is redundant. Additionally, they suggested stating “inability to bear children” as an absolute factor rather than listed as a potential risk. The Living Donor Committee Chair stated inevitabilities are not separated from risks in other sections of informed consent policy.

The Workgroup discussed whether “bowel injury” should remain as a potential risk for uterine donors as it’s not listed as a risk for other organ types. A workgroup member commented that “bowel injury” probably is included on the surgical consent. The Workgroup determined “bowel injury” was specific and unique enough to uterine donation to remain in the table as a potential risk due to the location of the uterus in relation to the rectum.

The Workgroup discussed other potential psychosocial risks for uterine donation. A Workgroup member suggested potentially including consideration for the donor’s future spouse or partner. The Workgroup Chair mentioned they’re not aware of this scenario being mentioned in any existing literature. Another workgroup member mentioned they feel confident issues like this would be part of the psychosocial assessment for living donors. Another workgroup member asked if language should be added regarding the parental rights of the donor. UNOS staff suggested consulting with the UNOS legal team before including this language in policy. A HRSA representative commented parental rights laws tend to be state-based and also suggested consulting with the UNOS legal team.

The Living Donor Committee Chair suggested adding “Additionally” in front of “Disclose to all living non-uterine VCA donors” and “Disclose to all living uterine donors” to provide more clarity. The Workgroup agreed with that suggestion.

The Workgroup then discussed whether to expand “uterus” to “reproductive organ”. The Workgroup requested to see new drafts of the informed consent tables with options for covering “all reproductive organ”.

The Workgroup then discussed elements in the proposed table for *Policy 14.4: Medical Evaluation Requirements for Living Donors*.

Table 14-X: Additional Requirements for the Medical Evaluation of Living Uterus Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Uterine-specific medical history	Gynecological and obstetric history including prior childbirth
Uterine-specific tests	<ul style="list-style-type: none"> • Pelvic exam • Pap smear • Fungal screening
Anatomic assessment	<p>A radiological assessment must be performed to determine if the uterus is anatomically normal</p> <p>Consultation with a gynecological surgeon</p>
Transmissible disease screening	<p>Testing must include all the following:</p> <ul style="list-style-type: none"> • Chlamydia • Gonorrhea • HPV • Herpes (HSV-2)

The Workgroup agreed with the Committee’s recommendations to align the requirements with the recommendations on the VCA Data Collection Workgroup’s proposed update to the LDR form, change the anatomic assessment language to match other sections of policy as well as the removal of “consultation with a gynecological surgeon”. Bacterial vaginosis will also be added under transmissible disease screening.

Next Steps

The Workgroup’s feedback will be used to produce new draft tables for the Workgroup to review and discuss further.

Upcoming Meeting

- May 6 – Teleconference