OPTN Living Donor Committee
Meeting Summary
October 14, 2020
Conference Call

Heather Hunt, JD, Chair
Titte Srinivas, MD, Vice Chair

Introduction

The Living Donor Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/14/2020 to discuss the following agenda items:

1. Update on Public Comment Proposal: *Align OPTN Policy with US Public Health Service Guideline, 2020*
2. Review of Public Comment Feedback
3. Public Comment Discussion: Post-Public Comment Changes
4. Public Comment Discussion: Other Topics

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

1. Update on Public Comment Proposal: *Align OPTN Policy with US Public Health Service Guideline, 2020*

The Chair presented an update on the OPTN Disease Transmission Advisory Committee (DTAC) presented *Align OPTN Policy with US Public Health Service Guideline, 2020* proposal. The requirement to store a living donor specimen for 10 years was an area of concern during public comment. Since public comment closed, HRSA communicated that OPTN policy must align with the PHS guideline, therefore the OPTN must adopt the 10-year storage period for living donor specimens. The DTAC requested to collaborate with the Committee on language to add to Living Donor Informed Consent policy regarding specimen storage and to provide feedback on the cost of storage as well as donor's privacy concerns.

Summary of discussion:

Informed Consent for Living Donors

The Committee agrees with adding language to Informed Consent policy, and recommends not specifying the storage duration in the event the 10 year requirement is updated. Committee members emphasized the language should make it very clear the specimen would only be collected at the time of donation.

Cost and Logistics of Storage

The Committee encourages consideration of costs to smaller programs who may not have capacity for the economic or logistical burden of long-term storage. Additionally, members requested more information on whether the recovering or recipient hospital would be responsible for storage in cases of paired exchange. Members also requested clarity on what qualifies as a 'specimen' according to proposed policy language.

Living Donor Privacy Concerns

The Committee expressed based on their experience in communicating with potential living donors, there is a valid concern for the impact this requirement will have on the potential living donor pool as some donors will not be comfortable with their samples being stored, particularly in minority communities.

Next Steps

The Committee will draft language for the Informed Consent policy and send all compiled feedback to the DTAC to help inform their proposal to the Board.

2. Review of Public Comment Feedback

The Chair presented a summary of public comment feedback on the *Modify Living Donor Policy to Include Living VCA Donors* proposal.

Summary of Data

Patient Safety and Program Compliance

The majority of the comments the proposal received were in support of including VCA within living donor policy for patient safety and establishing requirements for living donor VCA programs. The regions, committees, and most of the stakeholders who submitted comments are in overall support of this primary tenet of the proposal.

Additional Informed Consent and Medical Evaluation Requirements

Within the proposal, the community was asked their thoughts on the proposed requirements and if there were other items that should be included in the proposed Informed Consent and Medical Evaluation Requirements tables. The comments submitted in reference to the proposed requirements indicated overall support. Some committee members and societies offered additional recommendations as follows:

- Uncertain if the "decreased fertility" and "physical disfigurement" risks should be gender specific
- Recommendation to add "loss of identity" as a psychosocial risk
- Recommendation to add psychosocial risks related to surgical risk. For example, psychosocial risks related to physical disfigurement
- Recommendation to add potential for not only short term but also long-term consequences of urinary tract injury or dysfunction under "potential surgical risks"
- In the "potential financial impact", programs should be required to convey to the potential donor that there are degrees of financial risk involved

Toxoplasma Testing for All Living Donors

Another request for feedback was on the subject of toxoplasmosis testing and if it should be a required test for all living donors. There was minimal feedback from the regions on this question. The comments received were mixed with some in support of expanding the testing requirement and others either opposed or indicated they would only support if there were clear data to show it should be required.

- DTAC and PAC in support of requiring toxoplasma testing for all living donors
- AST in opposition to requiring toxoplasma testing for all living donors
- ASTS in support of requiring toxoplasma testing for uterus only

Timing of Transmissible Disease Testing for Uterus

The OPTN Disease Transmission Advisory Committee (DTAC) was instrumental in informing the medical evaluation requirements within the proposal. The DTAC submitted a comment recommending to amend the policy to specify timing for chlamydia, gonorrhea, trichomoniasis, and fungal testing. Specifically they recommend testing for these diseases should occur at both evaluation and recovery.

Ethics of VCA in Informed Consent

The proposal received three comments related to ethical concerns. Some VCA Committee members questioned if the Informed Consent table as proposed is appropriate at this time as other forms of genitourinary transplant have not been given the level of ethical consideration uterus has. An individual commenter stated the requirements should be limited to uterus at this time. Several Catholic medical associations submitted a collective comment opposing living VCA transplant, highlighting the need for more rigorous informed consent language and the lack of exclusion criteria for uterus.

Prior Living Donor Priority

Three comments were received requesting the Committee to consider whether a living VCA donor should receive prior living donor priority for kidneys like other organ types. The commenters were not clear on whether they should or should not be added.

3. Public Comment Discussion: Post-Public Comment Changes

The Committee discussed post-public comment changes to the proposed policy language in light of the public comment feedback.

Summary of Discussion

Ethics of VCA in Informed Consent

The Committee reviewed the VCA Committee's public comment questioning whether the Informed Consent table should be expanded to cover all genitourinary or restricted to uterus only. The Committee then reviewed the Informed Consent table as proposed compared to a table that is uterus specific. The Living Donor Committee VCA Workgroup (The Workgroup) Chair recognized the proposed table was a result of robust discussion within the Workgroup. The Workgroup's arrived at the proposed table with the goal of providing language broad enough to encompass where the field may evolve. A member commented the proposed table is not an attempt to influence the direction of the field of VCA, but would establish guardrails the two distinct types of VCA transplant. The Committee agreed to keep the Informed Consent categories as proposed.

The Committee then reviewed the collective public comment submitted on behalf of several Catholic medical associations and discussed whether exclusion criteria should be added for VCA/uterus. The Committee was informed the Workgroup did consider exclusion criteria for uterus and due to varying requirements in existing IRB protocols and feedback from uterus programs, decided not to propose exclusion criteria for uterus at this time. Additionally members commented the proposed policy is not meant to be prescriptive of medical practice but rather to provide guardrails that provide fundamental safety and protections for living donors. The Committee agreed with the Workgroup's decision not to include exclusion criteria in OPTN policy at this time, leaving inclusion and exclusion criteria to be determined by the hospital's specific protocols.

Additional Informed Consent and Medical Evaluation Requirements

The Committee considered the recommendations on the language within the proposed Informed Consent table. The Committee agreed gender-specific language for surgical risks as proposed should be removed from the proposed table to be consistent with the spirit of keeping the requirements broad

enough to be applicable to various types of genitourinary donation. The Committee recognized those surgical risks that were gender-assigned may need to be reworded to be broadly applicable.

The Committee then discussed whether to include language related to potential loss of identity or loss of gender identity as a psychosocial risk. Some members supported the inclusion of a psychosocial risk related to gender identity or gender fluidity within the language. A member commented this is a subject of discussion that is becoming more prominent in the medical community and literature. The Committee briefly considered including gender identity within the psychosocial evaluation requirements but recognized that policy section would apply to all living donors, which would be beyond the scope of the project. However, the Committee generally agreed more consultation with subject matter experts would be needed before adding such language to OPTN policy.

The Committee considered the recommendations to add additional language to the potential surgical risk of urinary tract injury or dysfunction to specify the potential for short term and long term consequences. Upon review of the table as proposed, the Committee felt the language "may be temporary or permanent" was sufficient.

The Committee also discussed the recommendation to add more language to the potential financial impact related to degrees of financial risk. The Committee agreed the language as proposed when combined with financial impact language in general informed consent language is sufficient.

Timing of Transmissible Disease Testing for Uterus

The Committee considered DTAC's recommendation to add timing requirements to chlamydia, gonorrhea, and trichomoniasis in addition to fungal screening as proposed. The Committee was informed adding the additional requirements would require further public comment as it was not included in the original proposal and could be an additional burden on programs. Additionally, the addition of the timing requirements would affect the data collection fields included in the VCA Committee's [NAME] proposal. The Committee agreed to consider these additional timing requirements as part of a future project.

Next Steps

Based on feedback from the group, the Committee will be presented with updated policy language for further review.

4. Public Comment Discussion: Prior Living Donor Priority

The Committee then discussed another topic raised from public comment feedback. Three comments were received requesting the Committee to consider whether a living VCA donor should receive prior living donor priority for kidneys like other organ types. The commenters were not clear on whether they should or should not be added. Current *Policy 8.5.E: Prior Living Organ Donors* lists kidney, liver segment, lung segment, partial pancreas, and small bowel segment for prior living donor priority.

Summary of Discussion

A member commented the original intention of the policy was to acknowledge the gift of living donation. Some members further commented they would be in favor of amending the policy to apply to all living donors.

Next Steps

The Committee will continue discussing prior living donor priority during the October 26 meeting.

Upcoming Meetings

- October 21, 2020 (teleconference)
- October 26, 2020 (teleconference, formerly in-person meeting)

Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Carol Hay
  - Carolyn Light
  - Heather Hunt
  - Jessica Spiers
  - Katey Hellickson
  - Mark Payson
  - Mary Beth Stephens
  - Nahel Elias
  - Roberto Hernandez
  - Stevan Gonzalez
  - Vineeta Kumar
  - Pooja Singh
  - Randy Schaffer
  - Titte Srinivas
- **HRSA Representatives**
  - Arjun Naik
  - Raelene Skerda
- **SRTR Staff**
  - Chris Folken
  - Bertram Kasiske
  - Michael Conboy
- **UNOS Staff**
  - Nicole Benjamin
  - Emily Ward
  - Kaitlin Swanner
  - Leah Slife
  - Lindsay Larkin
  - Matt Cafarella
  - Matt Prentice
  - Michelle Rabold
  - Sarah Booker
  - Shannon Edwards
  - Susan Tlusty
  - Tina Rhoades