

**OPTN Living Donor Committee
Meeting Summary
September 9, 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 09/09/2020 to discuss the following agenda items:

1. Public Health Service (PHS) Guidelines Proposal
2. Data Collection on Living Vascularized Allograft Composite (VCA) Donors Proposal
3. Public Comment and Other Updates
4. Open Forum

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

1. Public Health Service (PHS) Guidelines Proposal

The Chair of the OPTN Disease Transmission Advisory Committee (DTAC) presented *Align OPTN Policy with US Public Health Service Guideline, 2020* proposal to the Committee. Final Rule requires that OPTN policies are consistent with the PHS Guidelines. Updates include guidelines for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection.

Summary of discussion:

A member expressed support for the removal of the label "increased risk". The member asked for data regarding the number of patients who refuse an organ because it was labeled "increased risk". The DTAC Chair responded that data showed increased organ declines in kidney patients and pediatric patients. The DTAC Chair added that the data showed great diversity among regions and programs for utilization of "increased risk" organs. The member also asked for data on donor derived infections comparing use of "increased risk" and "non-increased risk" organs. The DTAC Chair responded that the vast majority of HBV and HCV transmission has occurred through organs labeled as "increase risk".

Another member asked if a hepatitis B surface antibody level is sufficient to document HBV vaccination status. The DTAC Chair responded yes, that is what is suggested. The DTAC Chair added that the level of 10 IU/L or greater is what is considered adequate by the Advisory Committee on Immunization Practices (ACIP). The member inquired whether it is considered a failure of providing optimal care to patients in the dialysis population, who have low levels due to the poor immunogenicity of the hepatitis B vaccine within that patient population. The DTAC Chair responded that documenting the effort of immunizing and re-immunizing will show that providers have tried their best as well as looking into new vaccines that could help get a robust response.

A member stated that their organ procurement organization (OPO) designates some organs as "OPO increased risk". This label is broader than HIV, HBV, and HCV infections, and includes cancers. The member inquired whether this topic was discussed during the development of this proposal. The DTAC Chair stated this proposal only addresses blood-borne diseases HIV, HBV, and HCV but expects there to

be further discussion on other potential risks. The member expressed disagreement regarding the ten-year storage of living donor samples. The member asked if there were plans on how to track samples in situations where programs close as well as cost of storage. The DTAC Chair agreed there should be plans to track samples and appreciated the feedback.

Another member asked how frequently are programs unable to follow up with a living donor when there might be a potential transmission. The DTAC Chair responded that currently there is no storage requirement for living donors, so a long-term storage makes it easier than potentially having to track down living donors. The DTAC Chair added that long-term storage allows for testing on samples given at the time of donation. Another member asked about the reasoning on deciding a ten-year storage as the time frame for living donor samples. The DTAC Chair responded that ten-year time frame was decided upon because that is the same as what is used for deceased donors. The member asked about the legality around a donor asking for access to their stored samples during the ten-year time frame. The DTAC Chair responded that there should be consent which outlines the acceptable uses of the stored sample during the ten-years but that is not included in the policy.

Align OPTN Policy with US Public Health Service Guidelines, 2020 Sentiment Vote

3 Strongly Support; 8 Support; 0 Neutral/Abstain; 2 Oppose; 0 Strongly Oppose

2. Data Collection on Living Vascularized Allograft Composite (VCA) Donors Proposal

The Chair of the VCA Committee presented the *Modify Data Collection on VCA Living Donors* proposal to the Committee. The purpose of this proposal is to improve the OPTN's ability to monitor patient safety through data collection on VCA living donors. The proposed data elements align with proposed policy changes included in the Living Donor Committee's proposal, *Modify Living Donor Policy to Include VCA Donors*.

Summary of discussion:

A member asked what the time frame is from evaluation to donation and if certain tests should be repeated after donation. The VCA Chair was not sure and will bring this back to the VCA Committee to discuss.

Another member asked if the proposed data is being added to the current liver and kidney living donor registration forms. The VCA Chair confirmed this. The member mentioned that these forms collect information on donation procedures that have started and then been aborted which is similar to the proposed data element of "post-operative complication". The VCA Chair appreciated the feedback and will make sure the VCA Committee reviews for clarity and redundancy. Additionally, the member asked for more information regarding the timing of when living donor registration forms are filled out. The VCA Chair responded the submission schedule will model other LDF form submission requirements.

Modify Data Collection on VCA Living Donors Sentiment Vote

4 Strongly Support; 6 Support; 1 Neutral/Abstain; 0 Oppose; 0 Strongly Oppose

3. Public Comment and Other Updates

The Committee was informed of the regional meetings that have occurred thus far, there has been overwhelming support for the Committee's proposal, *Modify Living Donation Policy to Include Living VCA Donors*.

4. Open Forum

A member requested an update on the Kidney-Paired Donation (KPD) Project Workgroup. Staff responded that when the KPD project restarts, the Committee will be provided updates.

Upcoming Meetings

- October 7, 2020 (teleconference)
- October 14, 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
 - Nahel Elias
 - Omar Garriott
 - Roberto Hernandez
 - Stevan Gonzalez
 - Vineeta Kumar
 - Pooja Singh
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bertram Kasiske
 - Michael Conboy
- **UNOS Staff**
 - Emily Ward
 - Kaitlin Swanner
 - Leah Slife
 - Lindsay Larkin
 - Matt Cafarella
 - Meghan McDermott
 - Sarah Booker
- **Other Attendees**
 - Marian Michaels
 - Sandra Amaral