

**OPTN Patient Affairs Committee
Meeting Summary
September 1, 2020
Conference Call**

**Darnell Waun, R.N., M.S.N., Chair
Garret Erdle, M.B.A., Vice Chair**

Introduction

The Patient Affairs Committee (PAC) met via Citrix GoToMeeting teleconference on 09/01/2020 to discuss the following agenda items:

1. Public Comment Presentation and Discussion: Modify Living Donation Policy to Include Living Vascularized Composite Allograft (VCA) Donors
2. Board of Directors and Committee Recruitment and Nomination
3. Public Comment Presentation and Discussion: Update on the Continuous Distribution of Organs Project
4. HRSA Web Update Discussion
5. Next Steps

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

1. Public Comment Presentation and Discussion: Modify Living Donation Policy to Include Living Vascularized Composite Allograft (VCA) Donors

The Chair of the Living Donor Committee presented the *Modify Living Donation Policy to Include Living VCA Donors* proposal. The purpose of this proposal is to expand living donor policies to include living uterus and other living VCA donors in order to ensure safety.

Summary of discussion:

Overall, PAC members agreed with the *Modify Living Donation Policy to Include Living VCA Donors* proposal. PAC members suggested the proposal could expand inclusion to other VCA living donors. For example, in regards to genitourinary, further inclusion for potential living donor testicular transplants. Members inquired whether the proposal should include other fertility related risks based on gender, such as "decreased fertility" for males and "physical disfigurement" for female.

Members expressed concern regarding insurance coverage. The Living Donor Committee Chair responded that there is not practical experience yet for analyzing insurance coverage. Since these transplants are still in the clinical trial phase, the programs are covering most or all of the cost.

Members emphasized their concern for patient's sense of identity. The members recommended adding "patient sense of identity" as a potential psychosocial risk. Additionally, the members wondered whether language regarding psychosocial risks related to surgical risk should be expounded. For example, psychosocial risks related to physical disfigurement. The Living Donor Committee Chair responded that this was not discussed and they will relay the feedback.

Members agreed with the requirement for toxoplasma testing for all VCA living donors. Members inquired whether there are additional tests needed for genitourinary non-uterus living donors that should be included within the proposal. Members suggested the proposal should outline tests that were

discussed but not included in order for a lay audience to understand. Staff responded that tests related to uterus transplants are included because that is the information that is currently available. Literature is not yet available for other living donor VCA organ transplants.

For the non-genitourinary category, members wondered whether language should be included to communicate the fact that there are a lot of unknowns because it is new and evolving.

Members asked how many donors are projected to be impacted by this proposal. The Living Donor Chair responded that exact numbers are not yet available but are projected to be small. Members suggested the proposal include an education plan for implementation. The Living Donor Committee Chair responded that since uterus transplants are minimal, the education would rest in the programs involved; and if the population continues to increase, then the OPTN may develop and promote educational materials. Additionally, members advocated for a broader involvement of living donors during the proposal development.

A member asked what mechanism is established to update the risks listed in the informed consent. The Living Donor Committee Chair said that depending on the changes, potential updates would have to be submitted for public comment.

Modify Living Donation Policy to Include Living VCA Donors Sentiment Vote:

5 Strongly Support; 5 Support; 1 Neutral/Abstain; 0 Oppose; 0 Strongly Oppose

2. Board of Directors and Committee Recruitment and Nomination

PAC reviewed the OPTN recruitment and Board of Directors nomination process.

Summary of discussion:

A member asked about the time commitment for volunteering on the Board of Directors. Staff responded patient and donor affairs representatives serve three year terms. Requirements for conference calls are similar to other OPTN Committee involvement. Additionally, there are in-person conferences, twice a year, which last two to three days. Staff explained there is the additional opportunity to become involved with Board Committees, such as the Finance Committee, which would require further time commitment.

3. Public Comment Presentation and Discussion: Update on the Continuous Distribution of Organs Project

The Chair of the Lung Transplantation Committee presented an *Update on the Continuous Distribution of Organs Project*. The purpose of this project is to move towards a broader distribution framework by considering multiple patient factors all at once with an overall score rather than placing candidates into prioritized categories.

Summary of discussion:

Members agreed with the work done thus far on the *Update on the Continuous Distribution of Organs Project*. Members suggested working with other organ-specific committees to discuss other potential attributes.

Members emphasized the need for the proposal language to be modified in order for lay audiences to understand. Members suggested inserting a glossary, creating a high level summary, and giving more context to the visuals.

Members asked for more context regarding the equity and ethics of this project. Staff responded that the Ethics Committee has been engaged in development and will continue to be engaged. Additionally,

the analytical hierarchy prioritization (AHP) exercise allows for the ethical and values laden considerations to be pulled to the forefront of discussion. The AHP exercise is open for everyone in the community to input their opinions regarding ethical considerations.

Members suggested sharing raw data as well as real world application for the community to better understand the impact of a new allocation system. Staff responded a tool is being created to show how changes to the weights of different attributes changes the impact to candidates.

Members suggested reconsidering the “1-year post-transplant survival” attribute and measuring benchmarks farther out from surgery to create an impetus to look longer-term and have higher standards. The Lung Chair responded that the Continuous Distribution project allows for changes to be made and reanalyzing the “1-year post-transplant survival” measurement is an attribute that is under consideration for potential changes in the future.

Members suggested engaging the Ethics Committee for further discussions regarding prioritizing prior living donors. The Lung Chair emphasized that the Committee felt that prior living donation was important enough to include as an attribute but that the AHP exercise will give a better picture of the weight of the importance.

Members inquired whether there could be more explanation and visibility regarding the attributes that were excluded. Additionally, members asked what the process will be for considering future attributes.

Members asked for more insight regarding how the attributes are converted into points, considering some are value-based judgements while others are data-driven decisions. Staff responded that currently, attributes, which are a part of the current lung allocation score (LAS), have clinical data to score each individual patient. From that clinical data, rating scales are created for each specific attribute. The values part will come from weighing the different attributes against each other, through the AHP exercise.

Members asked about the timeline regarding the results of the AHP exercise as well as data on the potential impact of the Continuous Distribution project. Staff responded it will be an iterative process where the Lung Committee reviews feedback and analyzes potential changes. The Lung Committee will submit a modeling request to SRTR. Based on the report, a policy proposal will be developed.

4. HRSA Web Update Discussion

The Division of Transplantation is responsible for overseeing initiatives to increase organ donation registration. Part of these initiatives include maintaining the English and Spanish websites, organdonor.gov and donaciondeorganos.gov. HRSA overviewed four webpages; *The Deceased Donation Process*, *The Living Donation Process*, *Who Can Donate?*, and *How Organ Donation Works*. HRSA requested feedback on language used as well as potential improvements.

Summary of discussion:

Members stated that the new *Deceased Donation Process* webpage is more user friendly. Members suggested including a summary about the impact of organ donation. Another member suggested to avoid exclusionary language.

A member liked the conciseness of the information on the *Living Donation Process* webpage. Another member suggested highlighting the success and safety of the living donation process in order to make individuals comfortable.

On the *Who Can Donate?* Webpage, in regards to a sentence stating, “only a few health problems would prevent a person from donation an organ”, a member asked if the sentence means there are a few

situations which would make an organ not useable. The member emphasized the difference between the decision to make their body available for donation versus deciding to donate an organ. Another member suggested highlighting that everyone has the ability to sign up to become a potential donor.

A member expressed the name change from *How Organ Donation Works* to *How Does the Process Work* might not be specific enough. A member suggested that tissue transplantation processes should be captured on this webpage.

5. Next Steps

Official PAC feedback for *Modify Living Donation Policy to Include Living VCA Donors* and *Update on the Continuous Distribution of Organs Project* will be composed and posted on the respective OPTN Public Comment webpages. PAC members are encouraged to post individual public comments. Public Comment closes October 1, 2020. PAC members are also encouraged to share information about the OPTN Board and Committee Nomination process with their networks.

Upcoming Meetings

- October 20, 2020 (teleconference)
- November 17, 2020 (teleconference)

Attendance

- **Committee Members**
 - Anita Patel
 - Christopher Yanakos
 - Darnell Waun
 - David Skinner
 - Diego Acero
 - Earl Lovell
 - Eric Tanis
 - Garrett Erdle
 - James Sharrock
 - Julie Siegel
 - Kenny Laferriere
 - Marvin Lim
 - Molly McCarthy
 - Phil Williams
 - Sarah Koohmaraie
- **HRSA Representatives**
 - Jim Bowman
 - Melanie Deal
- **SRTR Staff**
 - Allyson Hart
 - Katie Audette
- **UNOS Staff**
 - Anna Wall
 - Craig Connors
 - Elizabeth Miller
 - James Alcorn
 - Kaitlin Swanner
 - Lindsay Larkin
 - Sara Rose Wells
 - Sarah Booker
 - Meghan McDermott
 - Sara Rose Wells
 - Susie Sprinson
- **Other Attendees**
 - Crosby Marketing
 - Madeline Beck
 - Nicole Bandy
 - Marie Budev
 - Heather Hunt