

OPTN Pediatric Transplantation Committee

Meeting Summary

February 9, 2022

Conference Call

Evelyn Hsu, MD, Chair

Emily Perito, MD, Vice Chair

Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 2/9/2022 to discuss the following agenda items:

1. Public Comment Presentation: Redesign Map of OPTN Regions
2. Public Comment Discussion: Modify Living Donor Exclusion Criteria
3. Public Comment Discussion: Pediatric Candidate Pre-Transplant HIV, HBV and HCV Testing
4. Wrap-Up & Next Steps

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

1. Public Comment Presentation: Redesign Map of OPTN Regions

The Committee reviewed the Organ Procurement and Transplantation Network (OPTN) Executive Committee's Redesign Map of OPTN Regions concept paper. The OPTN Executive Committee hopes to gather feedback on the options for updating the map of OPTN Regions.

Summary of discussion:

A member inquired if these updated regions will be used for both allocation and governance purposes. Staff explained that the use of these regional options is two-fold – (1) a structure that determine how members will convene at regional meetings and (2) Board of Directors (BOD) and Committee representation.

A member inquired if these regional options will affect allocation. Staff explained that, ideally, allocation is shifting towards continuous distribution and will not include regions anymore.

A member inquired about the distribution of pediatric transplant centers in the regional options, since there are typically less pediatric centers in a region compared to adult centers. The member explained it would be helpful to see the distribution of pediatric transplant centers by organ or transplant type in each regional option to ensure that the voices from the pediatric community are not diluted.

A member inquired if regional representation on the BOD would remain one individual per region regardless of region size or if regional representation would increase. The member further explained that fewer regions would dilute input if there's only one representative on the BOD or committees. Staff explained that this is currently being discussed and has been brought up by other committees. A member emphasized that there should also be some guidance for larger regions in regards to sub-regional division and distribution of representatives.

A member noted that one could argue that fewer number of regions would potentially allow for a more obvious pediatric presence than a large number of regions. A member noted, however, that there are vast geographic areas in the west where there aren't many pediatric transplant centers.

Staff inquired if there was a specific number of regions that the Committee thinks would be better or worse. Members agreed in general that they didn't want to dilute the pediatric perspective in various areas, but it was hard to agree on an appropriate number of regions without knowing the plan to ensure adequate pediatric distribution within those really big regions. A member noted that, if the structure changed to four regions, then they would want more than four regional representatives on the BOD and committees. By maintaining eleven regions, the structure is preserving the number of representatives currently involved.

A member mentioned that they liked the eleven region structure; however, they noticed most of the regional options created a huge region that spanned from Minnesota to Washington. The member noted that the difference in time zones and large geographic area can cause complications in regards to attendance at regional meetings. Another member mentioned that, for the large geographic areas, there will need to be an emphasis on encouraging interactions at a regional level.

A member also expressed concern about the six to eight hour window pediatric representatives would have to voice their perspectives at a larger regional meeting since there are typically more adult providers than there are pediatric providers.

Staff questioned whether the Committee thought it would be a good idea to use one regional map to plan regional meetings and another map for BOD and committee governance. A member thought that having two regional maps would be too complicated; however, if one of the maps was a sub-structure of the other and they were related then that may work. A member also highlighted that those regional sub-structures may naturally create themselves once the regions have been redesigned for some time.

A member from Region 6 agreed with all the concerns mentioned above, especially time zones since they work with representatives from Hawaii. The member also mentioned that they would be concerned with the opinions of the northwest pocket being lost if they only had one representative within a larger region.

The Committee agreed that they would like to see the distribution of pediatric transplant centers stratified by the following to ensure there is no underrepresentation:

- Number of centers by organ
- Number of transplants by organ

There was no further discussion.

2. Public Comment Discussion: Modify Living Donor Exclusion Criteria

The Committee reviewed the OPTN Living Donor Committee's Modify Living Donor Exclusion Criteria proposal.

The Committee was tasked with providing feedback on the relevancy of the following exclusion criterion regarding age, which was reaffirmed by the OPTN Living Donor Committee:

- "Is both less than 18 years of age and mentally incapable of making an informed decision."

Summary of discussion:

A member emphasized that the notion that being 18 years old characterizes an individual as an adult is arbitrary – someone who is 18 years old does not have different capabilities than someone who is 17 years and 9 months old. The member mentioned that living donor coercion is not unique to those under 18 years old and there are systems in place to handle coercion, so it shouldn't be a reason to not use a minor as a living donor. The member stated that there are older siblings who are interested in donating to their younger siblings and suggested that this criterion be made even broader.

A member inquired if the member would suggest changing the policy language to express encouragement of minors as living donors. The member stated that they think the current language is already broad and that it would be difficult to include language that encouraged minors to consider being living donors.

A member suggested, in regards to the emotional maturity consideration, that the criterion could state 'children under the age of 18 with exceptional maturity may be considered' instead of being a hard exclusion.

A member mentioned that the American Academy of Pediatrics (AAP) has an ethics paper on donation by minors which argues that living donation by minors should be limited to those cases where there's no other option for donation for the individual. The member stated that, from their experience, it is difficult to know if a 16-17 year old is fully understanding and consenting to what's going on. The member stated that they believe the current criterion language is appropriate – it leaves ambiguity for those exceptional cases and doesn't put teenagers in a rough spot with their families.

A member inquired if there's any distinction in the policy language between a 17 year old emancipated minor versus a 17 year old whose parents still consent for them. Staff mentioned that the OPTN Living Donor Committee did discuss emancipated minors and found no distinction in policy. The requirements to be an emancipated minor vary between states and the OPTN Living Donor Committee decided to maintain the age of 18 years old, which is standard in policy. Staff also noted that the OPTN Living Donor Committee reviewed data to assess the utilization of this criterion and found that, in 2014, there had been eleven living donors under the age of 18 and they were all domino donors who are not subject to exclusion criteria.

A member inquired if there is specific policy language requiring teenagers to give assent, even if they don't give consent. For example, there's a situation where a teenager is expressing 'no' to donating but their parents are saying 'yes'. Staff stated that there are other exclusion criteria in living donor policy and one is suspicion of donor coercion.

A member inquired if concerns, such as coercion, would come up and be addressed in the psychological exam for living donation. A member mentioned that that is correct and emphasized that this proposal does not change the requirement for every donor to go through a psychosocial evaluation and informed consent process.

A member mentioned that the psychosocial evaluation is not always a full psychological evaluation done by a psychologist or psychiatrist – at some centers it might be a social worker doing the best they can. The member emphasized that, in these cases, the psychosocial evaluation is not a full evaluation about understanding and mental capacity. A member agreed and mentioned that the psychosocial evaluation is not meant to decide legal capacity.

A member stated that the other modifications to the exclusion criteria in this proposal are actually meant to give programs more flexibility when considering whether a specific living donor is appropriate in a specific situation. The member also noted that the exclusion criterion related to age does not seem to be utilized even though there is flexibility in the criterion language.

The Committee encouraged the OPTN Living Donor Committee to discuss specifics about when it might be appropriate to consider a minor as a living donor and to reference the ethics paper from AAP. The Committee also agreed that, in cases where minors might be considered living donors, it's important that age-appropriate informed consent processes and psychosocial evaluations were followed.

There was no further discussion.

3. Public Comment Discussion: Pediatric Candidate Pre-Transplant HIV, HBV and HCV Testing

The Committee reviewed the proposal that they co-sponsored with the OPTN Ad hoc Disease Transmission Advisory Committee (DTAC).

The proposal modifies policy so that all candidates younger than 11 years of age are not required to receive human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) testing during hospital admission for transplant. Instead, they can receive testing at any time between when they are waitlisted and transplantation.

Summary of discussion:

Staff mentioned that the federal government has begun their public comment process, which includes amending the Public Health Service (PHS) guidelines, and it's open until March 7th. Staff noted that there will be a formal comment submitted on behalf of the OPTN, but members are encouraged to submit their own individual comments.

A member stated that they are very satisfied with this proposal. The member mentioned that it has been interesting looking at the comments it has received, most of which question the age threshold or question why the proposal doesn't use a weight threshold instead. A member explained that those are the questions that the initial discussions of the DTAC-Pediatric Workgroup aimed to address. The member emphasized that the DTAC-Pediatric Workgroup settled on age 11 because of data from the Centers for Disease Control (CDC) that showed incidence of HIV, HBV, and HCV infections in children under the age of 11 near zero.

The Chair stated that she has heard comments that the amount of blood needed for post-transplant infectious disease testing is a risk, so there may be commentary from the pediatric community in regards to that as well.

There was no further discussion.

4. Wrap-Up & Next Steps

The Committee's feedback on the public comment items will be summarized and posted to the OPTN website.

The meeting was adjourned.

Upcoming Meetings.

- March 3, 2022 (Virtual)

Attendance

- **Committee Members**
 - Evelyn Hsu
 - Emily Perito
 - Abigail Martin
 - Brian Feingold
 - Caitlin Shearer
 - Douglas Mogul
 - Jennifer Lau
 - Rachel Engen
 - Warren Zuckerman
 - William Dreyer
- **HRSA Representatives**
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Christian Folken
 - Jodi Smith
- **UNOS Staff**
 - Rebecca Brookman
 - Matt Cafarella
 - Betsy Gans
 - Katrina Gauntt
 - Kelley Poff
 - Leah Slife
 - Lindsay Larkin
 - Meghan McDermott
 - Samantha Weiss
 - Susan Tlusty
- **Other Attendees**
 - Melissa McQueen