

OPTN Pediatric Transplantation Committee

Meeting Summary

March 17, 2021

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 3/17/2021 to discuss the following agenda items:

1. Public Comment Presentation: OPTN Executive Committee 2021-2024 Strategic Plan
2. Public Comment Presentation: OPTN Organ Procurement Organization Committee Clarify Multi-Organ Allocation Policy
3. MELD/PELD Workgroup Update
4. Heart ABOi Project Update
5. Active Collaborations

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

1. Public Comment Presentation: OPTN Executive Committee 2021-2024 Strategic Plan

The Committee received a presentation on the OPTN Executive Committee's 2021-2024 Strategic Plan proposal. Members were asked to provide feedback.

Summary of discussion:

The Chair inquired, with regards to previous strategic plans, how the OPTN followed metrics and assessed how that strategy improved each of the goals. Staff stated that the OPTN has continued to evolve the way in which they measure the success of the strategic plan. For example, there was a pre and post comparison between the 2018-2021 strategic plan and the current strategic plan that was part of the conversation when creating the current plan.

The Vice Chair noted that the strategic plan is a major focus during Policy Oversight Committee (POC) meetings. The Vice Chair emphasized that it's important to think ahead about how the Committee's projects fit into this balance of priorities.

A member mentioned that pediatric initiatives have usually fallen under goal 2 and goal 4 although there's some overlap with increasing the number of transplants overall. The member stated that they believe these priorities work well for pediatric initiatives in general, although they would want to see more concentration on outcomes overall.

A member suggested that, in order to see an increase of focus on outcomes, the weight of goal 4 could be increased by increasing the percentage. A member explained that having more detail on what those projects in goal 4 look like would be helpful for the Committee to make better recommendations.

A member explained that this alignment may be an acknowledgement of recently good wait list and recipient outcomes and the current strategic plan is trying to prioritize increasing the number of transplants and equity in order to get to these good outcomes.

The Chair inquired about how the OPTN will increase equity in access to transplants – is the OPTN looking at health equity or equal opportunity for good outcomes. The Chair stated it would be nice to have more details about what is meant by this and what metrics the OPTN will use to measure the improvement in equity.

2. Public Comment Presentation; OPTN Organ Procurement Organization (OPO) Committee Clarify Multi-Organ Allocation Policy

The Committee reviewed the OPO Committee’s public comment proposal and provided feedback.

Summary of discussion:

The Chair noted that one of the main concerns of the Committee is the impact on children who have been listed for single kidneys when those kidneys are allocated with the heart, liver or lung and inquired if there is a plan in place to look at this. The Chair stated that the pediatric community has data that shows that kidney-pancreas (KP) listings are taking a fair amount of single kidneys away from children on the list. The presenter stated that this is some of the feedback that the OPO Committee has received and plans to ensure that the pediatric population is still taken care of. It is a small number in the total scheme of all the multi-organ transplants; however, there is a commitment to monitor to see if kidney alone candidates are being disadvantaged due to this policy change.

A member pointed out that pediatric heart candidates (Status 1A and 1B) are specifically addressed in this policy proposal, but the lung allocation scores (LAS) that must draw the second organ are only used for candidates 12 and older, meaning there is no LAS-mandatory sharing threshold for candidates under 12. The presenter stated, again, that this will be monitored with the opportunity to continue to address the problem since this is a multi-phase project. The presenter mentioned that a workgroup is already being assembled to begin looking at phase 2 of this project, which could establish eligibility requirements around kidney functionality for example.

A member explained that the inclusion of Status 1A and 1B should cover almost all of the pediatric candidates that would need a heart-kidney or, rarely, a heart-liver. The member continued by stating that some pediatric candidates may be listed as Status 2 for a re-transplant or a failed Fontan who would need a heart-kidney or heart-liver, however, they would not be included. The member mentioned that they thought Status 1A and 1B is appropriate and, in a rare case where a Status 2 candidate is listed at home who also needs heart-kidney, it could be a reasonable request for a Status 1B exception.

A member inquired about how many pediatric heart-kidney transplants had been performed. The presenter informed members that there were a total of 219 heart-kidney transplants over the 5 year span and, of those, 3 transplants were Status 1A, 1 was Status 1B, and 1 was Status 2.

The Vice Chair suggested that, because Status 2 heart-kidney transplants is a small number, pediatric heart Status 2 should be included in the multi-organ allocation criteria. The Vice Chair emphasized that there may be centers that don’t know they can apply for a Status 1B exception or don’t know how to do it, so then that patient will be disadvantaged.

Members agreed with including pediatric heart Status 2 in the allocation criteria and emphasized that it wouldn’t be a big change, could potentially be very important for an individual patient in that situation, and would eliminate any variability, by OPO discretion or Status 1B exception, in whether the Status 2 patient gets offered the kidney.

Members agreed that 500 nautical miles seemed appropriate for the heart statuses in this policy proposal.

3. Heart ABOi Project Update

The Committee was updated on the Heart ABOi project, which aims to update policy in order to reflect current science that demonstrates ABO-incompatible heart transplants are safe and reliable for infants.

Summary of discussion:

A member noted that they had had a conversation with the University of Alberta team, although they're not a part of the OPTN, but they have done a lot of the key research on this topic and would enjoy the opportunity to communicate with this workgroup on the work they have done.

A member inquired about next steps for this project and if this project is going to be sponsored by the Committee. Staff explained that this project will be sponsored by the OPTN Heart Transplantation Committee and that next steps will be to form the workgroup for this project, meet once or twice in order to finalize the purpose of this project, including evidence necessitating this change, before going to the POC for approval, and then aiming for this project to go through January 2022 public comment cycle.

The Chair inquired when this would need to go to Board of Directors for approval. Staff explained that, with this timeline, the project would be going to the Board of Directors in June 2022.

Members were encouraged to volunteer to participate on this workgroup if interested.

4. MELD/PELD Workgroup Update

The Committee was provided with the following updates on the PELD/Status 1B Criteria Workgroup:

- Workgroup continuing to review factors that predict pediatric waitlist mortality
- SRTR completing statistical modeling of updated PELD score
 - PELD eGFR vs. PELD Creatinine
 - Delta PELD
 - Age adjusted mortality
- Once updated PELD options are finalized, workgroup will move forward with liver simulated allocation model (LSAM) modeling
 - Liver Committee recently started a project to update MELD score and modeling requests will be submitted together

Summary of discussion:

There was no discussion.

5. Active Collaboration

The Committee reviewed the following projects that members are currently participating on:

- Continuous Distribution
 - Use of age at the time of registration for pediatric definition in continuous distribution
- Kidney-Pancreas Continuous Distribution
- Liver PELD/Status 1B Criteria Workgroup
- Heart ABOi Workgroup

Summary of discussion:

A member stated that, for kidneys, it's difficult to determine the definition of pediatrics because the Kidney Allocation System (KAS) starts waiting time at the time of dialysis start in order to get more equitable allocation and wait listing. So, with the definition of pediatrics as age at time of registration,

pediatric patients could be disadvantaged if they were registered after age 18, but started dialysis before age 18. The member emphasized that this would be out of alignment with what KAS is meant to be doing.

The Vice Chair wondered if this could be considered as a caveat in the definition of pediatrics for continuous distribution. The Vice Chair mentioned that this is different for kidneys because there is a perfect definition for disease onset, but is harder for other organs.

The Chair emphasized that what the Committee wanted to avoid, when making the decision on the definition, was age at the time of the match because then a candidate could lose their pediatric priority if they don't get transplanted before turning 18.

A member noted that with the KAS there's a significant number of children that receive preemptive transplants as opposed to after they've started renal replacement therapy, so there might need to be a dual definition of pediatrics in the kidney world. The member suggested it should be either registration before age 18 or time of start of dialysis.

Upcoming Meetings

- March 30, 2021 (Virtual In-Person)
- April 21, 2021 (Teleconference)

Attendance

- **Committee Members**
 - Evelyn Hsu
 - Emily Perito
 - George Mazariegos
 - Abigail Martin
 - Brian Feingold
 - Caitlin Shearer
 - Jennifer Lau
 - Johanna Mishra
 - Kara Ventura
 - Shellie Mason
 - Walter Andrews
 - Warren Zuckerman
 - William Dreyer
 - Regino Gonzalez-Peralta
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Chris Folken
 - Jodi Smith
- **UNOS Staff**
 - Rebecca Brookman
 - Matt Cafarella
 - Betsy Gans
 - Julia Foutz
 - Leah Slife
 - Lloyd Board
 - Matthew Prentice
 - Robert Hunter
- **Other Attendees**
 - Arundhati Kale
 - Diane Brockmeier
 - Joseph Hillenburg
 - Rachel Engen