

OPTN Pediatric Transplantation Committee

Meeting Summary

June 16, 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 6/16/2021 to discuss the following agenda items:

1. Recognition of Committee Members Rolling Off in July
2. Review of Vice Chair Selection Process
3. Board of Directors Meeting Update
4. Current Progress of Abstracts/Presentations and Active Collaborations
5. Next Steps: Letter to OPTN Blood Draw Policy
6. PELD/Status 1B Project Update
7. Heart ABO-incompatible (ABOi) Project Update
8. Ethical Principles of Pediatric Organ Allocation

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

1. Recognition of Committee Members Rolling Off in July

The Chair recognized members whose terms end in July and expressed appreciation for their participation and contribution to the Committee.

Summary of discussion:

There was no discussion.

2. Review of Vice Chair Selection Process

The Committee reviewed the Vice Chair selection process to prepare for when the Committee needs to start this process.

VC Selection Process

- Call for nominations in October
 - Consider Committee needs (specialty, expertise, diversity)
 - Sent to current committee members and members who served in the last 5 years
- Survey with candidate information sent to committee
- Top 4 candidates are interviewed by current chair and/or vice chair
- Primary and secondary candidates are recommended to the OPTN President-Elect for consideration and final appointment

Summary of discussion:

The Chair inquired if the 5 year interval was chosen for a reason as opposed to anything longer. Staff explained that someone who had served on the Committee in the last 5 years would still be familiar with the projects that are being worked on and mentioned that would be important when transitioning into the role of vice chair.

3. Board of Directors Meeting Update

The Committee reviewed that the OPTN Board of Directors approved all of the following projects:

- 2021-2024 Strategic Plan
- Updating National Liver Review Board Guidance & Policy Clarification
- Calculate Median MELD at Transplant (MMaT) around the Donor Hospital & Update Sorting within Liver Allocation
- Clarify Multi-Organ Transplant Allocation
- Revise General Consideration in Assessment for Transplant Candidacy White Paper
- Refusal Codes
- Deceased Donor Registration (DDR) Updates

Summary of discussion:

A member stated that, from a pediatric standpoint, these projects being approved were good for the Committee; however, this policy cycle was weak in terms of the quantity of policies that affected pediatrics. The member emphasized that multi-organ transplant is where the Committee should stay focused.

The Chair mentioned that there's an emphasis on efficiency of work, but it's important to maintain the goal of trying to do the right thing for every patient. For example, multi-organ transplant allocation may cause organ procurement organizations (OPOs) to place as many organs as possible, but that may get in the way of pediatric priority or disadvantage those candidates waiting for a single organ.

A member noted that there's a theme of not waiting for continuous distribution to make changes – it's better to get it into the policy process now than wait for continuous distribution.

4. Current Progress of Abstracts/Presentations and Active Collaborations

The Committee reviewed the progress of the following abstracts and presentations that members are collaborating on:

- Effect of Multi-Organ Allocation Priority on Pediatric Kidney Candidates (Pediatric Academic Societies)
 - Presentation was viewed on 5/2/2021
- Pediatric National Liver Review Board: What Happens to Waitlist Registrations With Denied Exception Forms (American Transplant Congress)
 - Presentation was recorded and will be a rapid fire oral presentation on 6/7/2021
- Four Years of KAS: A Pediatric Specific Report (American Transplant Congress)
 - Presented in 2020

The Committee also reviewed the workgroups that Committee members are participating in.

Summary of discussion:

The Chair inquired if staff could explain the OPTN resources available and what the priorities are for disseminating research that has been done within committee work. Staff stated that members can

always bring forward projects that the Committee would like to create manuscripts on, but the resources and priorities need to be double checked with UNOS leadership in the Research department.

The Chair inquired if there's an interest in disseminating this information or should this be something that is included in committee minutes, since it's hard to get this information published if there aren't resources available. Staff explained that there is interest in getting these manuscripts published.

5. Next Steps: Letter to OPTN Blood Draw Policy

The Committee received the following update on the PHS Blood Draw Policy Workgroup:

- Workgroup to review relevant literature and current data
 - Potential solutions may include education, guidance, and policy
- First meeting will be on 6/22

Summary of discussion:

The Chair expressed concern about the formalized approach for this workgroup and mentioned that there just needs to be data that shows there's very few infections in small children and that the blood volume is too much.

The Vice Chair agreed and mentioned that data was shared showing 1 infection in thousands of transplants, and the infection was a living donor.

The Chair mentioned they are happy to represent the Committee on that call and advocate for a more efficient process to solve this problem.

A member stated they started pulling together some data for the workgroup call and mentioned that, if this policy is applied to adults, then the workgroup could delineate the cutoff when not to apply this policy for small children.

6. PELD/Status 1B Project Update

The Committee received an update on the PELD/Status 1B Workgroup. The PELD/Status 1B Workgroup received the results of the statistical modeling request for adolescents from Scientific Registry of Transplant Recipients (SRTR) and will have the following Status 1B discussions:

- Sorting in Status 1B
- Specific subpopulations to consider
 - Metabolic disease
 - Tumor
 - Chronic liver disease
- MELD/PELD 25 threshold for chronic liver disease

Summary of discussion:

The Chair inquired when the workgroup will be recommending changes to the OPTN Liver and Intestine Committee. Staff explained that the goal is to going to public comment in January 2022, so these changes will need to be finalized and voted on by the OPTN Liver and Intestine Committee in November 2021.

7. Heart ABO-incompatible (ABOi) Project Update

The Committee was updated that the Pediatric Heart ABOi Workgroup had their first meeting on 6/11 and discussed some potential choices and barriers. The following were considerations discussed during the first workgroup meeting:

- Making titer threshold in policy instead of age – ABOi patients with low titer are equivalent to ABO-compatible non-identical patients
- ABOi re-transplantation
- Questions for next meeting
 - What would the titer cut-off be?
 - Would we place high titer candidates in the secondary blood group designation or at end of match run?
 - Whether or not to have an age cut-off – U.S. research studies on have data on patients under age 2?

Summary of discussion:

The Vice Chair inquired if the workgroup is anticipating recommending concrete thresholds that apply to everyone for what offers they receive or put something into place that gives centers an option to opt-in or opt-out of getting ABOi hearts for a patient. A member stated that they think it should be along those lines – at each candidate registration there should be the opportunity to declare whether the candidate would accept an ABOi offer, but behind the scenes there also needs to be a titer that defines a low-risk, incompatible situation.

The member emphasized that if a program chooses to opt-in for the higher risk, higher titer ABOi transplant, then that candidate shouldn't disadvantage conventional candidates at an equivalent level of waiting time or urgency status.

The Vice Chair stated that the workgroup should keep in mind that the change in policy isn't allocating the heart to the candidate, it's just opening the offer to these candidates if they want to accept an ABOi heart.

8. Ethical Principles of Pediatric Organ Allocation

The Committee discussed the ethical principles of pediatric prioritization and proposed the following questions to lead discussion:

- How are the principles currently applied in organ-specific pediatric priority?
- Can we identify ways in which priority is not ideal for specific organs?

It was emphasized that identifying these gaps is important, especially as organ-specific committees begin working on continuous distribution.

Summary of discussion:

A member stated that distributing the ethics white paper would be very helpful and inquired if it is possible to write an editorial that highlights where the Committee stands at the moment, regarding how well the policies match up with the ethical principles in the white paper. The Chair stated that it's been hard to independently write an editorial and suggested it may be easier if members of the Committee from each organ field can identify where the gaps are, such as split liver transplant in liver. The Chair suggested looking at the Kidney Allocation System (KAS) and multi-organ policy to identify whether pediatric candidates are being appropriately prioritized and how prioritization can be done better.

A member inquired if the white paper expresses that children should be prioritized. The Chair stated that the white paper does suggest children should be prioritized and it also lays out ethical principles that support this idea; however, it doesn't say how children should be prioritized.

A member mentioned that their biggest concern is kidney and pancreas allocation because pancreas and kidneys are seen as life-enhancing organs unlike hearts and livers, which are considered life-saving

organs. The member doesn't believe pancreas allocation, relative to pediatric transplantation, is currently embodying these principles.

The Chair suggested doing pre-work for specific organs before the Committee meets in person and write up that work after the discussion. Members agreed that that would be a good way to start. The Chair stated the Committee should identify members who can review this data, determine where the gaps are in pediatric prioritization for specific organs, and suggest potential paths forward.

The Chair inquired, for thoracic organs, if there's any primary gaps for priority for children or if pediatric status is less relevant than the size of the heart. A member mentioned that the current adult allocation scheme is reasonably favorable to pediatrics and it was just revised with the status change in adult heart allocation in 2018. The member noted that pediatric patients who are listed at the highest pediatric urgency status are actually in pretty good standing for receiving organs from adult donors, as long as there's no other candidate who can take that organ due to size.

A member mentioned that there are some gaps in kidney allocation, similar to the issues with liver, due to the scoring systems not being as applicable to the pediatric population as they are to the adult population (i.e., Kidney Donor Profile Index). The member stated that this would be a worthwhile project and suggests that the Committee pursues it.

A member agreed with the idea and emphasized that it is critical for this Committee to really know what the key issues for children in all organ allocation systems. The member pointed out that the Committee should know what organ allocation systems are doing well and which allocation systems can work on pediatric prioritization.

Upcoming Meetings

- July 21, 2021 (Teleconference)

Attendance

- **Committee Members**
 - Evelyn Hsu
 - Emily Perito
 - Abigail Martin
 - Brian Feingold
 - Caitlin Shearer
 - George Mazariegos
 - Jennifer Lau
 - Kara Ventura
 - Rachel Engen
 - Regino Gonzalez-Peralta
 - William Dreyer
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Chris Folken
 - Jodi Smith
- **UNOS Staff**
 - Matt Cafarella
 - Betsy Gans
 - Katrina Gaunt
 - Leah Slife
 - Matt Prentice
- **Other Attendees**
 - Joseph Hillenburg
 - Sharon Bartosh