

**OPTN Pediatric Transplantation Committee
Meeting Summary
December 21, 2022
Conference Call**

**Emily Perito, MD, Chair
Rachel Engen, MD, Vice Chair**

Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference, on 12/21/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: OPTN December Board Meeting
3. National Academies of Science, Engineering, and Medicine (NASEM) Report Survey Results
4. Discussion of New Projects
5. Project Slate: January Public Comment
6. Reminders and Closing Remarks

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

1. Welcome and Announcements

Committee leadership welcomed the Committee and gave a few announcements.

2. Recap: OPTN December Board Meeting

The Chair recapped agenda items and decision points from the OPTN December Board meeting.

Presentation Summary:

The Chair first explained agenda items that were approved from the consent agenda, then the items approved after Board discussion. The Chair noted some particular projects with pediatric relevance, such as the OPTN Ethics Committee's Transparency in Program Selection White Paper.

The Chair noted the discussion surrounding transportation in organ transplantation.

Summary of Discussion:

A member stated that they thought that the Board meeting was a good show of the increased accountability of the transplant system in general to the community and a good reminder of how important it is to advocate for children. A visiting Board member echoed this and emphasized that pediatric representation is a priority for the Board. The Chair encouraged members to apply for a Board position if they are interested in a deeper commitment to the OPTN.

A member described a recent experience with a kidney transplant with transportation difficulties and emphasized the importance of efficiency and timeliness in pediatric transplant. The Chair explained that this is certainly a priority of the Committee and told members that leadership is in collaboration with the OPTN Kidney Transplantation Committee to further discuss transportation and the recent modeling for continuous distribution and their impact on the pediatric population. A member stated that it is

important for the Committee to identify and provide specific recommendations to improve pediatric access to other OPTN Committees.

3. National Academies of Science, Engineering, and Medicine Report (NASEM) Survey Results

The Committee received the results of the NASEM survey sent out after the last Committee meeting.

Presentation Summary:

The Chair gave an overview of the NASEM report and explained that the OPTN Policy Oversight Committee (POC) had charged each of the OPTN Committees to identify projects and priorities aligning with the recommendations in the report. At a prior Committee meeting, members worked to identify possible project ideas and priorities. This was then formulated into a survey allowing members to rank the policy priorities they see as most important moving forward.

Most survey respondents selected “increase and improve pediatric representation throughout the entire policy development process” as their first choice. The Chair explained that because other OPTN Committees may not have dedicated pediatric representatives, the pediatric community is a vulnerable and sometimes disadvantaged population. The NASEM report identified the importance of giving these vulnerable populations a seat at the table, and the Committee will think about specific recommendations to help achieve this. Respondents also selected focusing on including the social determinants of health (SDoH) in the transplant process and increasing pediatric specific metrics in monitoring and reporting as first choices.

Top second choices included including SDoH and a greater focus on equity in the transplant process, increasing pediatric-specific metrics in reporting, and increasing transparency of the transplant system for patients and their families. The Chair briefly explained each of these and their importance to the pediatric community.

As a result of this survey, the Committee will bring the following two priorities to the POC along with the Committee’s initial ideas about how to achieve these.

- Increase and improve pediatric representation throughout the entire policy development process
- Include SDoH and allow for greater focus on equity throughout the transplant process

These priorities clearly align with the NASEM report and will be brought to the POC to highlight the importance of equity and representation for the pediatric population.

The Committee also discussed a desire to increase pediatric-specific metrics in post-implementation reporting. The Committee can work on this as a Committee driven idea and does not need to bring this to the POC as a NASEM recommendation. Initial work on this project is planned for the January in-person meeting, where the Committee can look at the data collected in prior OPTN monitoring reports and decide what is missing or what would be helpful additions in evaluating pediatric impact.

The Chair explained the monitoring reports project idea. All implemented policy projects are monitored through OPTN monitoring reports, but the data collection and metrics reported are not standardized. There may be more helpful or additional metrics for evaluating the impact on pediatric candidates that are not currently included in monitoring reports. The goal of this project would be to create an internal reference document for research staff to include or not include certain metrics on monitoring reports moving forward. Next steps include reviewing the monitoring reports (planned for the in-person meeting in January), deciding on what is helpful and not helpful in evaluating pediatric impact, and then working towards the reference document.

The Chair thanked the Committee for completing the survey.

Summary of Discussion:

Staff asked members if the proposed policy priorities aligned with NASEM to bring to the POC sounded reasonable as recommendations to focus on in policy for the future. Several members stated the priorities looked good.

The Chair asked the Vice Chair, who serves on the POC, for any additional information about what the POC is looking for. The Vice Chair and staff explained that the POC will review these recommendations at their in-person meeting in March, and that other Committees are still reviewing the NASEM report. The Chair stated that if members have any additional ideas or additions to the priorities to send them along to leadership or to staff before March.

4. Discussion of New Projects

The Committee discussed two new project ideas.

Presentation Summary:

Staff first gave an overview of the project approval and policy development process and noted that the ideas introduced in this meeting are in the idea phase. The Committee will bring their ideas through the project approval process, which involves the POC reviewing ideas to ensure strategic alignment, resource alignment, and due diligence.

The Chair introduced a request from the OPTN Membership and Professional Standards Committee (MPSC) for the Committee to review and explore alternatives to the pediatric emergency exception pathway. The emergency exception pathway was created to account for a situation where a pediatric patient presents at a hospital without an approved pediatric program but it is not medically advisable to transfer the patient to a hospital with an approved pediatric transplant program. Very specific criteria are included in bylaws to describe when this pathway can be used, however, most of the cases that used the pediatric exception pathway did not meet the criteria in policy and so were sent to the MPSC for review. From December 2020 to August 2022, one heart candidate met the emergency exception criteria. In this period, five other pediatric candidates were listed where the exception criteria was not met.

Pediatric emergency exception bylaws cannot include all situations where the patient should be kept at the admitting hospital without an approved pediatric transplant component. A possible solution to this would be to create a pediatric review board. Next steps for this project include Committee leadership meeting with MPSC leadership to discuss the project.

The Chair then introduced a possible project to modify Heart Status 1A as the OPTN Heart Transplantation Committee transitions to continuous distribution. Currently, policy outlines how candidates may meet Status 1A, which is meant for the sickest pediatric heart candidates. Centers can apply for exceptions to have their candidates listed as Status 1A, which are then reviewed retrospectively by the National Heart Review Board (NHRB). Interest was shown to investigate whether Status 1A is too broad and encompasses candidates who may not need the status and to review common exception requests for trends that could point to clinical situations that may warrant incorporation into policy.

The goal of this project would be to collaborate with the OPTN Heart Transplantation Committee to incorporate any recommendations within heart continuous distribution. In the in-person meeting in January, the Committee will hear more details about heart continuous distribution and areas for policy improvement and modification in line with this project idea.

Summary of Discussion:

Members first discussed the emergency exception pathway project. One member asked what problem the Committee was trying to solve with this project, as it seemed to them like the MPSC review was an adequate way to deter inappropriate use of the pathway and maintain accountability. The Chair explained that the MPSC review is retrospective, and that the MPSC asked the Committee to investigate a possible more productive, prospective way to review the cases. A member stated that they agreed with the project in theory but given that this has only affected a handful of patients, more information is needed about why the candidates were listed. This member explained that if the data reveals that the listings happened with good intent and followed the spirit of the policy, this would be helpful feedback for the MPSC. The Chair stated that the MPSC is asking the Committee to explore a possible better way to handle these cases, and as part of that, the individual cases will be reviewed in more detail. Staff clarified that the MPSC did not take action against any centers that listed candidates outside of the emergency exception criteria.

A member asked about the pediatric representation on the MPSC. Staff answered that they would need to get back to the Committee about exact numbers, but that pediatric experience was represented. Staff also explained that the MPSC was concerned about policy being inadequate to accurately capture all cases where an emergency exception is warranted, so a review board framework may make sense.

A member asked if the proposed review board would be an existing review board or a new one. The Chair answered that this would be one of the things the Committee would weigh in on.

One member suggested reviewing the criteria in OPTN bylaws and determining which criteria the candidates did not meet would be helpful in deciding any tweaks to the existing bylaws. The Chair explained that this is a good opportunity for the Committee to weigh in on how best to account for pediatric patients in the system. A member suggested including an emergency exception pathway for pediatric lung candidates as something to consider within this project.

A member stated that the project sounded reasonable, but that it may be an inordinate use of time for the Committee when there are so many other pressing issues facing more candidates. The Chair agreed and stated that the project should be limited in scope. The Chair asked if any members would be interested in reviewing the data, and several members volunteered to help review. Staff clarified that because resources are not unlimited, focusing on this project may push the timeline for other projects back. The Chair stated there isn't really a better suited group to review this, so it would be worthwhile for the Committee to review but cautioned members that it would be limited in scope and time.

A member suggested giving the cases to the preexisting organ-specific review boards, such as the National Liver Review Board. The Chair concluded discussion by stating that having specific requirements for pediatric centers was a big victory for the pediatric population and that this project would not be the only thing that the Committee would be working on moving forward.

The Committee then discussed the Heart Status 1A project. A member shared that they attended a recent OPTN Heart Transplantation Committee meeting where the one year monitoring report for the Pediatric National Heart Review Board was presented and shared their initial impressions from the data. This member also shared that the Heart Committee has a Pediatric Medical Urgency Workgroup that met for the first time recently. This Workgroup seemed to share the opinion that heart Status 1A may need modification. This member described that they were hopeful for the collaboration with the OPTN Heart Transplantation Committee to incorporate changes within continuous distribution.

A member asked to be included in the discussions and the Workgroup, and stated that a concern with Status 1A is that the intention is for the candidates to be hospitalized. This member suggested reviewing the narratives of the exception requests.

Next Steps:

Staff will follow up with Committee members interested in further work or cross-Committee collaboration for the projects mentioned above.

5. Project Slate: January Public Comment

Presentation Summary:

The Chair showed the list of projects going out for January Public Comment and asked members to review the list and identify any projects that they'd like a presentation for in the January in-person meeting. The Chair also reminded members of the upcoming Regional Meetings schedule.

6. Reminders and Closing Remarks

Presentation Summary:

Staff briefly reminded members of the in-person meeting on January 30th and travel details. The Chair and staff thanked the Committee for their time and participation.

Upcoming Meeting

- January 30th, 2023 (in-person in Chicago)

Attendance

- **Committee Members**
 - Abigail Martin
 - Neha Bansal
 - Danny Ranch
 - Emily Perito
 - Evelyn Hsu
 - Gonzalo Wallis
 - Jennifer Lau
 - Johanna Mishra
 - Katherine Audette
 - Meelie Debroy
 - Kara Ventura
 - Namrata Jain
 - Rachel Engen
 - Reem Raafat
 - Shellie Mason
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Simon Horslen
 - Jodi Smith
- **UNOS Staff**
 - Austin Chapple
 - Matt Cafarella
 - Kieran McMahon
 - Dzhuliyana Handarova
 - Krissy Laurie
 - Samantha Weiss
 - Susan Tlusty
- **Other Attendees**
 - Melissa McQueen