

OPTN Pediatric Transplantation Committee

Meeting Summary

June 21, 2023

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 06/21/2023 to discuss the following agenda items:

1. Welcome and Recognition of Outgoing Members
2. Finalize Monitoring Report Reference Document Project
3. Update on Use of Pediatric Emergency Exception Pathway
4. Quick Brainstorm: New Projects

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

1. Welcome

Committee leadership welcomed the Committee members to the meeting. Outgoing members were recognized for their dedication to the Committee.

2. Finalize Monitoring Report Reference Document Project

The Chair summarized the previous Committee discussions on this project and the Committee voted to put the document in practice.

Presentation Summary:

All implemented policy projects are monitored through OPTN monitoring reports, but the metrics reported are not standardized. The OPTN Contractor's research team develops outcome metrics in conjunction with sponsoring committees for each project. There may be more helpful or additional metrics for evaluating the impact of policies on pediatric candidates that are not currently included on monitoring reports. The goal of this project create an internal reference document for UNOS research staff to include or not include certain specific metrics on monitoring reports moving forward.

The Committee has been working on this document since January 2023. It is the product of combined input from Committee members and the organ-specific research teams. The goal for today's discussion is finalize the document so that it can be added to the research department's resources and used immediately in creation of monitoring reports. The Committee can revisit and update the document at regular intervals to ensure it remains useful and current and can also comment on monitoring plans included in proposals as a renewed focus.

The Committee reviewed the updated document.

Summary of Discussion:

Decision 1: The Committee approved the monitoring report reference document project and it will be used by research staff in the creation of monitoring reports moving forward. The Committee opted to update the document every 6-8 months.

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After reviewing the document, two members stated that it makes sense to put the document into practice. Regarding the interval at which the Committee would review the document and make updates, members explained that the interval should be long enough to encompass the publication of multiple monitoring reports and implementations. The Committee agreed on an interval of 6-8 months.

The Committee took a snap poll and unanimously approved the document.

Next steps:

This document will be used in the development of future monitoring reports and updated at an interval of 6-8 months.

3. Update on Use of Pediatric Emergency Exception Pathway

The Chair presented updated information about the use of the pediatric emergency exception pathway in the OPTN Bylaws and the Committee discussed.

Presentation summary:

The OPTN Bylaws were updated to require specific pediatric training and experience for pediatric transplant programs in December 2020. The Bylaws also outline a Pediatric Emergency Exception Pathway to account for situations where a pediatric patient presents at a hospital without an approved pediatric program but it is not medically advisable to transfer the patient to hospital with an approved pediatric transplant program. Very specific criteria are included in the Bylaws that outline when this pathway can be used for heart and liver candidates.¹ The Chair briefly reviewed these criteria.

The Chair then recapped prior Committee discussion on this topic. A concern was brought to the Committee that the majority of cases that used the pediatric emergency exception pathway did not meet the criteria and so were sent to the OPTN Membership and Professional Standards Committee (MPSC) for review. The pediatric emergency exception bylaws cannot include all situations where the pediatric patient should be kept at the admitting hospital without an approved pediatric transplant component.

Upon review, the MPSC was concerned that there may be a better way to adjudicate these cases that leverages more pediatric expertise, so it was brought forward as a potential Pediatric Committee project. The MPSC is looking for pediatric expertise to help review cases, perhaps as some form of review board prior to MPSC investigation.

The Committee received a presentation on the use of the pathway in December 2022 and continued to discuss in January 2023. From the use data presented (further detailed below) the Committee concluded that the majority of cases occurred within the first six months of implementation, citing COVID-19 and a

¹ OPTN Bylaws: *Appendix F.7.E* and *Appendix H.4.E*

lack of familiarity with the Bylaw as possible factors. The Committee concluded that Bylaws will never be able to account for every situation where it's medically advisable to keep a pediatric candidate at an adult program. But, the number of cases is very small still and decreasing with time. Upon review of the cases, the Committee decided that they did not seem to represent nefarious use of the bylaws or intention to game the system. In January, the Committee opted to receive another report on usage of the pathways in six months, which is why an updated presentation was presented during this call. In January, other options were discussed, such as creating a Committee project to create a review board or modify the Bylaws, however, at that time, members concluded that the best use of Committee resources was ongoing monitoring before deciding on a concrete plan.

The Chair asked the Committee if members wanted to proceed with a Committee project on this topic, ongoing monitoring, or had any other ideas.

Data Summary:

Figure 1: Use of Pediatric Emergency Exceptions Pathway Where Candidate Did Not Meet Criteria, December 2020-December 2022

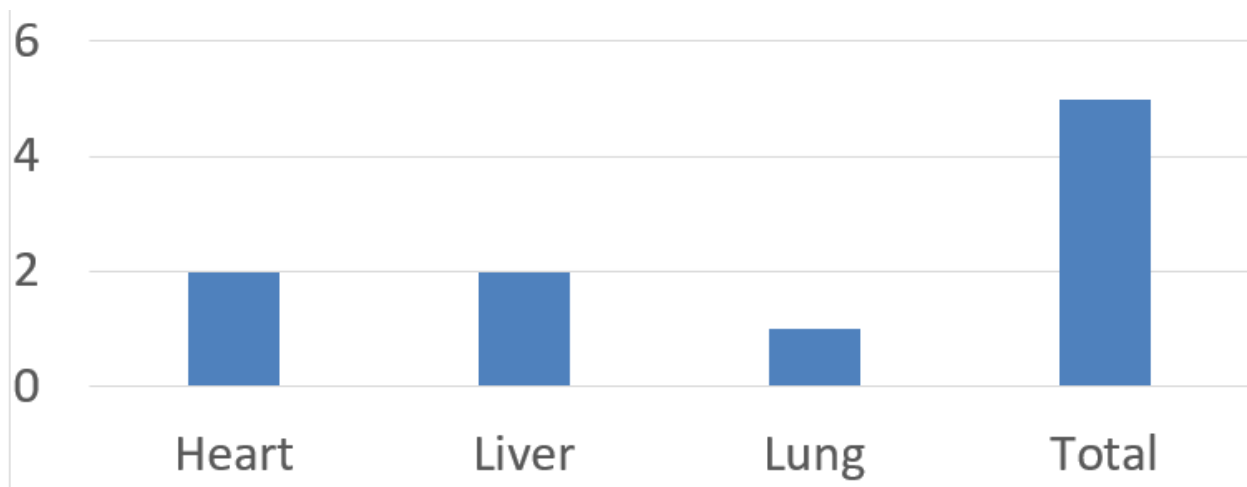
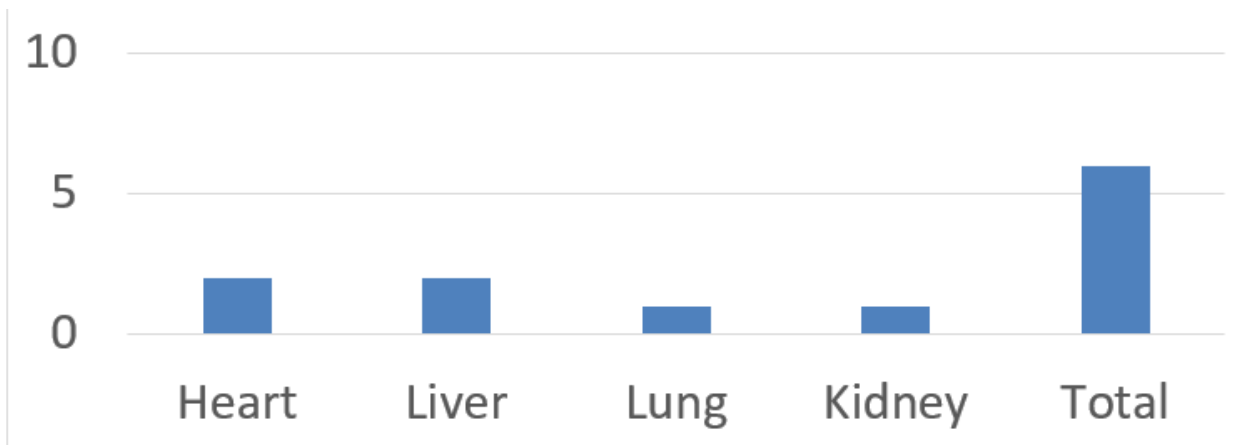


Figure 2: Use of Pediatric Emergency Exceptions Pathway Where Candidate Did Not Meet Criteria, December 2020-May 2023



A total of 2 heart candidates met the criteria between December 2020 and December 2022, with no additional candidates meeting the criteria from December 2022 to May 2023. Between December 2022

and May 2023, there was one additional kidney case where the candidate did not meet the criteria. It is important to note that the Bylaws only outline criteria for heart and liver candidates.

Summary of discussion:

Decision 1: The Committee requested a three-year monitoring report for the Bylaw.

Decision 2: The Committee opted for ongoing monitoring instead of taking this up as a Committee project at this time.

A member stated that the cases seem to represent good faith efforts even if they are outside the letter of the Bylaws and recommended ongoing monitoring of case volume. Several members agreed. The Chair said it was encouraging to see how rarely this pathway is used because it points to pediatric candidates receiving the appropriate care. A member asked how many cases would represent a number of concern for the Committee and would point to the need for a project. The Vice-Chair stated that if the data suggests that the pathway is being used 3-5 times per year, this would be concerning and would warrant a new process to review the cases. A member asked if under the Bylaws, it would be a possibility that an infant could be transplanted by an adult center. The Chair and a member answered that while this would technically be allowed if the adult program accepted the infant and a pediatric transplant program signed off on it, in their professional opinions, adult surgeons do not typically operate on infants and this is not a large area of concern for use of this pathway.

A member asked if there was a way to tell how many pediatric patients were transplanted at adult centers before this Bylaw went into effect. The Vice-Chair answered that because there were no criteria defining a pediatric versus adult center, this is hard to get at, however, that the number of centers who did not apply to become a pediatric center (because they did not meet the criteria) is known. The Chair noted that it was not a large number of centers who were doing pediatric transplants that did *not* apply to become approved pediatric programs.

Decision 1: The Committee requested a three-year monitoring report for the Bylaw.

The Committee requested a three-year monitoring report on this Bylaw. The Chair suggested including information about the impact of this Bylaw on pediatric listings in monitoring, to assess for potential impacts on pediatric patients who might be getting listed later on due to lack of access to an approved pediatric center. The Vice-Chair suggested including distance to transplant center and any increases seen as a result of this Bylaw in the monitoring.

Decision 2: The Committee opted for ongoing monitoring instead of taking this up as a Committee project at this time.

The Chair explained that the Committee is happy to provide a member to assist the MPSC in their review of the cases if they feel it is appropriate. The Committee opted for ongoing monitoring instead of taking this up as a Committee project at this time.

4. Quick Brainstorm: New Projects

The Committee held a brief brainstorming session to discuss new project ideas.

Presentation Summary:

The Chair gave a brief recap of the OPTN Policy Development Process and the OPTN Strategic Plan Goals to guide discussion. The Chair explained that some recent Committee ideas have included identifying improvements to the National Heart Review Board (NHRB) processes and investigating and potentially

modifying the functional status variables collected for candidates and recipients to make them more useful in evaluating outcomes.

Summary of Discussion:

A member asked for an update on internal discussions regarding the NHRB improvement ideas. Staff answered that conversations are being held with the OPTN Heart Committee support staff and leadership to determine where these improvement ideas fit in to the current Committee work and that internal conversations with information technology (IT) specialists and organ placement staff are also occurring to identify any system improvements that may not necessitate a full Committee project. The Chair requested an update on this in the July Committee call.

An incoming Committee member suggested adding an assessment of life participation for pediatric recipients as a way to assess the impact of transplantation on children. This member suggested that the Committee look into international research being conducted on a measure of life participation and kidney transplants. The Vice-Chair added that the idea of looking into the functional status variables is to determine if the current variables collected are the correct ones, and ensure consistency in use and reporting across programs. The Chair agreed, and added that a concern is whether or not the data is being used by the community. The Chair suggested that the aim of a possible project on this subject would be to look at the utility of the variables being collected for functional status, and then the possibility of replacing them with something else.

A Committee member suggested a project looking into candidates listed for heart-liver transplants and the specifics of which listing is driving their status, especially for specific heart congenital defects. Specifically, there is concern that if a candidate is extremely sick in their liver but not as sick in their heart, the multi-organ allocation is not always pulling the heart along with the liver that is allocated to the candidate, and some programs have been petitioning for exceptions on this. This member explained that the conversations they have heard have mostly been in adult contexts, but wondered if it is appropriate to look into this for pediatrics. The Vice-Chair answered that a good place to start would be to examine the current policy language, because multi-organ allocation is complex, and suggested bringing this up to the OPTN Ad Hoc Multi Organ Transplantation Committee.

Another member suggested looking into mortality for specific subgroups of populations, such as Fontans heart patients, and the impact on transplant. This member explained that because the mortality rate is typically high for these patients, some programs may not consider them for transplant because they have an eye on outcome success measures, even though they may benefit from transplantation.

Next steps:

The Committee will continue this discussion in their next call.

Upcoming Meeting

- July 12, 2023 (Teleconference)

Attendance

- **Committee Members**
 - Emily Perito
 - Rachel Engen
 - Caitlin Peterson
 - Caitlin Shearer
 - Daniel Ranch
 - Neha Bansal
 - Gonzalo Wallis
 - Johanna Mishra
 - Namrata Jain
 - Melissa McQueen
 - Meelie Debroy
 - Geoffrey Kurland
 - Shantavia Edmonds
 - Reem Raafat
 - Simon Horslen
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **SRTR Staff**
 - Simon Horslen
- **UNOS Staff**
 - Kieran McMahon
 - Besty Gans
 - Laura Schmitt
 - Dzhuliyana Handarova
 - Susan Tlusty
- **Other Attendees**
 - JoAnn Morey
 - Sonya Kirmani
 - Aaron Wightman
 - Carol Wittlieb-Weber
 - Ryan Fischer
 - Katrina Fields