

OPTN Pediatric Transplantation Committee

Meeting Summary

April 17, 2024

Conference Call

Emily Perito, MD, Chair

Rachel Engen, MD, Vice Chair

Introduction

The Pediatric Transplantation Committee (Committee) met via WebEx teleconference on 04/17/2024 to discuss the following agenda items:

1. Expeditious task force & Expedited placement variance update
2. Pediatric Bylaws 3-year Monitoring Report
3. Open Forum

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

1. Expeditious task force & Expedited placement variance update

OPTN Policy 5.4.G: *Open Variance for Expedited Placement*¹ was implemented on April 2, 2024. Though protocols may be proposed by anyone, the Expeditious task force (Task force) formed the Rescue Pathways Workgroup to support this variance by designing and reviewing rescue pathway variance protocols for proposal to the OPTN Executive Committee. This presentation covered: protocol safeguards to protect vulnerable populations from unintended consequences, the protocol approval process and information about monitoring.

Summary of discussion:

No decisions were made.

The Committee discussed recommendations for the assessment of proposed protocols. Members felt there should be an explicit focus on organs at risk for non-use, such as kidneys with high KDPI or organ offers with a late turndown. Furthermore, a member stated that the Task force and the Executive Committee should not move forward protocols that would expedite kidneys with KDPI less than 35% ahead of offers to pediatric candidates, as these organs are unlikely to be declined. A member commented that pediatric donor organs are also at low risk for non-use, therefore, should not be eligible for expedited placement. It was discussed that protocols must state when expedited placement may begin; the Vice Chair commented that if used properly, this requirement could protect pediatric candidates from being negatively impacted.

While appreciative that some pediatric safeguards are outlined in Policy 5.4.G, members expressed concerns about the monitoring plans for future expedited placement protocols. Due to small samples sizes in pediatric transplantation, rules for protocol expiration will only apply to kidney and liver transplants. It was clarified that although other pediatric transplant types are not listed in policy, there

¹ OPTN Policy 5.4.G, *Open Variance for Expedited Placement*, (April 2, 2024).

are plans to monitor for unintended consequences to these populations. If approved, each proposed protocol will include extensive monitoring beyond what is listed in policy. The Chair asked to review the more detailed monitoring plans. It was explained that they are not yet developed as there are currently no proposed protocols under review.

There were concerns that only OPTN members participating, which will consist primarily of organ procurement organizations (OPO), in each protocol will be monitored for unintended consequences, as non-participants (i.e. transplant programs) may be impacted. Since pediatric candidates often rely on regional or national organ sharing, there was a suggestion to monitor lost opportunities for offers to pediatric candidates if the organs went through expedited placement pathways. The Chair proposed the idea of recommending to the Task force pediatric-specific metrics to include in all monitoring plans.

To improve transparency surrounding these protocols, a member recommended directly notifying transplant programs that are likely to be impacted by approved protocols. Increasing awareness of potential impacts may prompt transplant programs to provide feedback on any unintended consequences of the protocol. Additionally, there was a suggestion to send e-mail communication with information about the protocol, intended timeline, list of participating OPOs and other relevant information.

Next steps:

Feedback collected during this meeting will be communicated to the Task force for consideration.

2. Pediatric Bylaws 3-year Monitoring Report

In December 2020, *Establish pediatric training and experience*² updated OPTN Bylaws to establish requirements for pediatric components of the following transplant program types: kidney, liver, pancreas, heart, lung. The 3-year monitoring report³ for this bylaw implementation was presented.

Data summary:

Data analysis compared the pre-implementation period (December 14, 2017-December 14, 2020) to the post-implementation period (December 15, 2020-December 15, 2023).

Pediatric transplant volume:

- Total number of pediatric transplants decreased by 8
- Pediatric heart and kidney transplant volume increased slightly
- Pediatric liver and pancreas transplant volume decreased slightly
- Number of pediatric lung transplants decreased from 119 to 70

The Committee was unable to complete this data review due to time constraints.

Summary of discussion:

No decisions were made.

² *Establish pediatric training and experience*, OPTN Pediatric Transplantation Committee, December 2020, https://optn.transplant.hrsa.gov/media/2074/policynote_20151201_pediatric_training_experience.pdf (accessed May 13, 2024).

³ OPTN Descriptive Data Request. "Pediatric Bylaw Change 3 Year Monitoring Report." Prepared for OPTN Pediatric Transplantation Committee Conference Call, April 17, 2024.

The Chair requested feedback on the decrease in pediatric lung transplants from Committee members in the lung transplant community. Members discussed that this is likely related to a development in pediatric cystic fibrosis treatment, which decreased the need for transplant, rather than an issue with pediatric lung transplant program availability.

A member raised concerns about the decrease in pediatric liver transplants from 1,621 transplants pre-implementation to 1,562 post-implementation. Members discussed possible explanations for this decrease, including the impact of recent treatment innovations and the COVID-19 pandemic. Members concluded that the decrease in pediatric liver transplant volume may be attributable to innovation, the pandemic, as well as issues with program availability, though it is difficult to discern. The importance of reviewing metrics related to quality and recipient outcomes was discussed.

Next steps:

The Committee will continue to review this monitoring report at their next meeting.

3. Open Forum

There were no open forum speakers.

Upcoming Meetings

- May 15, 2024, 4 PM ET, conference call
- June 26, 2024, 4 PM ET, conference call

Attendance

- **Committee Members**
 - Emily Perito
 - Rachel Engen
 - Neha Bansal
 - Aaron Wightman
 - Caitlin Peterson
 - Dan Carratturo
 - Geoff Kurland
 - Joseph Brownlee
 - JoAnn Morey
 - Jodi Smith
 - Sonya Kirmani
 - Meelie DebRoy
 - Melissa McQueen
 - Reem Raafat
 - Ryan Fischer
 - Carol Wittlieb-Weber
- **HRSA Representatives**
 - James Bowman
 - Marilyn Levi
 -
- **UNOS Staff**
 - Leah Nunez
 - Kaitlin Swanner
 - Susan Tlusty
 - James Alcorn
 - Katrina Fields
 - Keighly Bradbrook
 - Robert Hunter
 - Betsy Gans
 - Laura Schmitt