OPTN Pediatric Transplantation Committee
Meeting Summary
January 16, 2024
Conference Call

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

Introduction

The OPTN Pediatric Transplantation Committee (The Committee) met via WebEx teleconference on 1/16/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Public Comment: *Expedited Placement Variance*

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

1. Welcome and Announcements

The Chair extended a warm welcome to the Committee as the meeting commenced. The OPTN contractor staff then provided a reminder to Committee members about their upcoming in-person meeting scheduled for February 2nd in Houston, Texas. He emphasized that booking for the in-person meeting was currently available.

Summary of discussion:

The Committee did not make any decisions.

2. Public Comment: *Expedited Placement Variance*

OPTN contractor staff introduced the special public comment item that focuses on expedited placement variance.

Presentation summary:

The *Expedited Placement Variance*, originating from the Expeditious Task Force and sponsored by the Executive Committee, is currently open for public comment. The purpose of the proposal is to create a variance to test expedited placement protocols.

Structure of Pilot:

- Structure as a variance
  - Board/ExCom approves an open variance
  - Special public comment
  - Time limited study
  - Members opt in
- Protocols
  - Collect protocols from community
  - Task force will develop framework to select protocols to test
  - The protocols would live outside of policy but be accessible to the community

- Test protocols to assess most effective protocols
    - Evaluation plan with objective criteria to measure the variance's success
    - Members submit information required by variance

Requirements for Protocols:

- Each protocol must include criteria for organs eligible for expedited placement, criteria for candidates eligible to receive expedited placement offer, conditions for the use of expedited placement, and OPO and transplant hospital responsibilities
- Protocols must comply with NOTA and the OPTN Final Rule

Proposed Changes to Variance Governance:

- Clarification regarding the creation of variances
- Remove requirement to solicit agreement prior to public comment
- Change frequency of reporting requirements. Important for short, iterative variances.

Summary of discussion:

The Committee did not make any decisions.

The Chair highlighted that the proposal was intentionally crafted with a broad scope to allow for flexibility in implementing innovations. However, she emphasized the need for the Pediatric Committee to carefully consider the potential ramifications of this variance, particularly in terms of safeguarding the interests of children and other vulnerable populations.

Echoing these concerns, another member expressed reservations about the proposed variance, suggesting that it represented a regression from previous years. She voiced unease over the way the Executive Committee was handling the proposal, perceiving it as potentially detrimental to patient outcomes. In her view, there was a risk that the variance mechanism could be exploited to prioritize transplanting more patients without adequate consideration for long-term graft survival or the specific needs of pediatric recipients. To address these concerns, she proposed excluding kidneys with a Kidney Donor Profile Index (KDPI) of 0-20% from the variance, citing the utility of these offers for pediatric patients. She stated that while the Committee supports the goal of increasing organ utilization and reducing discard rates, they remain committed to ensuring that these efforts do not compromise patient outcomes, particularly for pediatric recipients.

A committee member expressed concern that the proposal seemed to prioritize quantity over quality, focusing on increasing organ utilization rather than ensuring favorable outcomes. He questioned whether the conditions outlined in the requirements for protocols would truly assess whether the expedited pathway would lead to better results or if it simply aimed to boost organ usage regardless of longevity. In response, a member involved in the proposal confirmed that the primary goal was indeed to increase the number of organs available to serve more people, acknowledging the member's valid concerns.

The member continued to inquire if there were any provisions in the proposal specifically addressing outcomes through the expedited pathway. However, it was clarified that currently, there were no such provisions in place. Emphasizing the importance of prioritizing patient outcomes over sheer quantity, the original member stressed that decisions should be based on the quality of organs.

Another member highlighted that while the task force aimed for a one-year outcome, it was imperative to recognize that this timeframe might not adequately reflect the success of the expedited pathway,

especially for pediatric patients. The Chair concurred, underlining the necessity of ensuring robust safeguards for long-term outcomes, particularly for vulnerable groups.

A member commented and said that in general, he thinks this is a great idea as efforts to increase utilization is a positive step. However, he questioned how these interventions are powered to show any difference in terms of whether they work. From the pediatric perspective, he said that the Committee needs to ensure that, at a minimum, kids and other vulnerable populations will not be worse off because of these protocols. Acknowledging the challenge of assessing outcomes over short periods, he suggested including a provision for extended monitoring tailored to vulnerable populations. Furthermore, he proposed that if monitoring revealed negative impacts on these groups, protocols should be promptly halted.

The Chair expressed agreement, voicing concern over the adequacy of sample sizes to discern differences in outcomes for pediatric patients within the span of one year. Another member echoed this sentiment, emphasizing the need to power variances not only to assess primary outcomes but also to evaluate the impact on small, vulnerable populations. However, she cautioned against unnecessarily prolonging protocols, advocating for a minimum duration required to demonstrate primary outcomes. Instead, she suggested incorporating language into the variance specifically targeting difficult-to-place organs. This proposed language would limit protocols to focusing on kidney allocation with a documented history of being more challenging than average. As a result, kidneys with a KDPI less than 35%, which typically have low rates of non-utilization, would be excluded from this provision.

A member expressed appreciation for the OPTN's attention to the matter, acknowledging the importance of ensuring efficient organ allocation. She highlighted that the proposal may also be beneficial as delays in organ acceptance by transplant centers could result in organs being allocated out of sequence, potentially impacting pediatric patients' access to those quality organs. She suggested implementing rules to limit instances of out-of-sequence allocation, emphasizing the need to prioritize pediatric patients in the allocation process. Specifically, she proposed a carve-out provision to prioritize pediatric patients for kidneys with a KDPI of 35% or less. This approach, she believed, would help mitigate the risk of pediatric patients being bypassed in the allocation process while ensuring that organ quality remains a central consideration.

A member inquired whether the proposal applied to all organs or was specifically targeting kidneys. Expressing confusion, he questioned why the focus seemed broad when kidneys appeared to be the primary concern. The Chair confirmed that the policy indeed encompassed all organs. Another member explained that the decision to include all organs had been extensively debated within the Executive Committee. The rationale behind this approach was to ensure inclusivity and avoid neglecting other organ types, with a particular emphasis on addressing issues within the adult population.

During discussions about the review process, participants emphasized the significance of the task force providing recommendations to the Executive Committee. Given the small size of the Executive Committee, ensuring balance and accountability through the involvement of the task force was deemed crucial. A member stressed the importance of explicitly including this aspect of task force recommendations and involvement in the protocol process within the policy, as it was not currently stated. The Chair concurred, acknowledging the importance of this comment in ensuring pediatric representation through the task force. Without such provisions in policy, there would be no guarantee of involvement or protection of the pediatric community from unintended complications. This highlighted the need to formalize mechanisms for task force involvement and recommendations within the policy framework.

The Chair encouraged all participants on the call to share their feedback regarding the special public comment item. This invitation underscored the importance of gathering diverse perspectives and insights from the group, ensuring that all voices are heard and considered in the decision-making process.

Next Steps:

OPTN contractor staff will compile the Committee's comments and will submit a public comment for this proposal that reflects the sentiments of the group. The Committee will review the comment during the next meeting.

Upcoming Meeting

- February 2, 2024; Houston, Texas

Attendance

- **Committee Members**
  - Emily Perito
  - Rachel Engen
  - Neha Bansal
  - Joe Brownlee
  - Dan Carratturo
  - Meelie DebRoy
  - Namrata Jain
  - Melissa McQueen
  - Caitlin Peterson
  - Reem Raafat
  - Aaron Wightman
  - Simon Horslen
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Staff**
  - Avery Cook
  - Jodi Smith
- **UNOS Staff**
  - Alex Carmack
  - Kaitlin Swanner
  - Betsy Gans
  - Dzhuliyana Handarova