OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK Meeting Summary

OPTN Pediatric Transplantation Committee
Meeting Summary
September 15, 2025
Conference Call

Rachel Engen, MD, Chair
Neha Bansal, MD, Vice Chair

Introduction

The Pediatric Transplantation Committee (the Committee) met via WebEx teleconference on 9/15/2025 to discuss the following agenda items:

1. OPTN Updates
2. Public Comment Presentation: *Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage*
3. Public Comment Presentation: *Require Patient Notification for Waitlist Status Changes*
4. Public Comment Presentation: *Establish a Comprehensive Multi-Organ Allocation Policy 2025*
5. Project Check-in: *Standardize Reporting & Enhance Data Collection on Lost to Follow-up and Transfers of Care*
6. Open Forum

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

1. OPTN Updates

The meeting opened with updates on current OPTN activities, including HRSA directives. Committee members were reminded to attend regional meetings for direct updates from HRSA and the OPTN.

Summary of discussion:

Committee members discussed maintaining pediatric representation and influence within OPTN governance. Members felt that pediatric representation on the Board is strong, including multiple pediatric physicians and surgeons.

2. Public Comment Presentation: *Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage*

The OPTN Heart Transplantation Committee Chair presented the emergency guidance update addressing shortages of durable pediatric mechanical circulatory support (MCS) devices. The guidance allows certain pediatric candidates with dilated cardiomyopathy who cannot access MCS devices to qualify for Status 1A by exception under defined clinical criteria.

Summary of discussion:

Committee members expressed support for the intent of the guidance, recognizing the critical need to ensure equitable access for pediatric candidates who cannot obtain MCS devices. Several members emphasized that the guidance appropriately clarifies circumstances under which Status 1A exceptions may be granted, but they raised concerns about potential misinterpretation within the transplant community. Specifically, members noted that some providers may mistakenly believe the update automatically elevates all inotrope-dependent patients to Status 1A, which is not the case. The Committee stressed the importance of education for transplant programs and the National Heart Review Board (NHRB) to reinforce that exception requests must include documentation of clinical deterioration and inability to access MCS equipment. Members also discussed monitoring trends in exception requests to assess whether the guidance leads to an influx of Status 1A candidates, which could affect wait times for other high-acuity patients. There was debate about how to determine when the shortage ends; suggestions included relying on FDA declarations or tracking exception volumes.

Next steps:

The Committee's feedback will be posted to the OPTN website and provided to the OPTN Heart Transplantation Committee.

3. Public Comment Presentation: ***Require Patient Notification for Waitlist Status Changes***

The OPTN Transplant Coordinator Committee Chair presented a proposal to require written notification to patients of any waitlist status change. The goal is to improve transparency and empower patients to maintain accurate status.

Summary of discussion:

Committee members broadly supported the proposal, citing its alignment with principles of transparency and patient empowerment. Many noted that their programs already provide such notifications, but they acknowledged variability across centers and agreed that standardization would benefit patients.

Discussion focused on operational challenges, particularly for patients who frequently move between active and inactive status due to short-term issues such as minor illnesses or vacations. Members expressed concern that written notifications for brief changes could create unnecessary administrative burden and confusion for families. Several suggested allowing documented phone calls as an alternative to written letters, noting that phone communication often provides better clarity and an opportunity for families to ask questions. Others proposed developing standardized templates that explain inactive status, reasons for the change, and steps for reactivation to reduce patient anxiety and minimize panicked calls. The Committee also highlighted the long-term need for a centralized patient portal to provide real-time status updates, which would reduce reliance on manual notifications and improve patient engagement. While members agreed that written notification remains important for compliance and documentation, they recommended flexibility in implementation and dual modalities where feasible.

Next steps:

The Committee's feedback will be posted to the OPTN website and provided to the OPTN Transplant Coordinator Committee.

4. Public Comment Presentation: *Establish a Comprehensive Multi-Organ Allocation Policy 2025*

The OPTN Multi-Organ Transplantation Committee Vice Chair presented the proposed multi-organ allocation policy aimed at standardizing allocation processes across organ systems.

<u>Summary of discussion:</u>

Committee members acknowledged the importance of creating a transparent, consistent framework for multi-organ allocation and expressed general support for the policy's objectives. However, discussion revealed persistent concerns about pediatric kidney candidates being disadvantaged relative to kidney-pancreas candidates, particularly for adult donors. Members noted that while the proposal introduces modest improvements, such as prioritizing highly sensitized kidney-alone candidates, it does not fully address the issue of pediatric candidates losing access to optimal kidneys because of multi-organ prioritization. Several members argued that pediatric kidney-alone candidates should be placed ahead of kidney-pancreas candidates in allocation tables, citing data showing that the number of pediatric candidates is small and that such a change would have minimal impact on pancreas utilization. Others acknowledged the pancreas community's concerns about organ non-use risk but questioned whether those concerns outweigh pediatric access needs.

Members also observed that changes for younger pediatric donors (under age 11) offer limited benefit, as these kidneys are rarely used for pediatric recipients. The committee agreed that post-implementation monitoring must include pediatric access metrics and evaluation of whether the policy improves equity without compromising organ utilization. While supporting the overall framework, members reiterated the need for stronger pediatric prioritization and suggested that future revisions revisit the placement of pediatric kidney candidates relative to kidney-pancreas classifications.

<u>Next steps:</u>

The Committee's feedback will be posted to the OPTN website and provided to the OPTN Multi-Organ Transplantation Committee.

5. Project Check-in: *Standardize Reporting & Enhance Data Collection on Lost to Follow-up and Transfers of Care*

The meeting concluded with updates on the Committee's ongoing Lost to Follow-Up and Transfers of Care project, which aims to standardize transplant recipient loss to follow-up reporting and improve data collection on lost recipients and pediatric recipient transfers to adult care. A proposal is in development and is anticipated for public comment in 2026.

<u>Summary of discussion:</u>

A committee member questioned how often transplant hospital staff reporting loss to follow-up would know the reason the recipient was lost and could reliably report that reason, especially in scenarios where hospital staff cannot contact the recipient.

Regarding the draft list of reasons for lost to follow-up, a member questioned how useful it would be to include "language barriers" as a distinct option as it may be less frequently reported. A member from a transplant hospital in Florida noted that they face this frequently as a larger portion of their patient population is Spanish-speaking. Another member discussed a case in which their patient spoke an extremely rare language; they noted it may be helpful to know how often this occurs, so that transplant hospitals have data to support improvements at the transplant hospital-level.

Next steps:

The Committee's feedback will be shared with the Lost to Follow-up and Transfers of Care Workgroup to consider as they continue project development.

6. Open Forum

There were no open forum speakers.

Upcoming Meeting

- TBD

Attendance

- **Committee Members**
    - Rachel Engen
    - Neha Bansal
    - Emily Perito
    - Aaron Wightman
    - Jennifer Vittorio
    - JoAnn Morey
    - Sonya Kirmani
    - Daniel Ranch
    - Shawn West
    - Katrina Fields
    - Jill McCardel
    - Reem Raafat Qbeiwi
    - Carol Wittlieb-Weber
    - Woodlhey Ambroise
    - Melissa McQueen
    - Ryan Fischer
    - Namrata Jain
- **HRSA Representatives**
    - N/A
- **SRTR Representatives**
    - Avery Cook
- **UNOS Staff**
    - Leah Nunez
    - Matt Cafarella
    - Dzhuliyana Handarova
    - Jamie Panko
    - Eric Messick
    - Sarah Roache
- **Guest attendees**
    - Jondavid Menteer
    - Christine Brenner
    - Christopher Sonnenday