OPTN Pediatric Transplantation Committee
Meeting Summary
March 6, 2025
Conference Call
Rachel Engen, MD, Chair
Neha Bansal, MD, Vice Chair

Introduction

The Pediatric Transplantation Committee (the Committee) met via WebEx teleconference on 3/6/2025 to discuss the following agenda items:

1. Public Comment Item: *Establish Comprehensive Multi-Organ Allocation Policy*
2. Allocation Out of Sequence: The pediatric perspective
3. Public Comment Item: *Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS*
4. Project Update: *Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care*
5. Open Forum

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

1. Public Comment Item: Establish Comprehensive Multi-Organ Allocation Policy

Establish Comprehensive Multi-Organ Allocation Policy is available for OPTN public comment from January 23, 2025 to March 19, 2025. The Committee began discussing their feedback on the proposal during their February 27, 2025 meeting.

Summary of discussion:

> The Pediatric Committee strongly advocated for pediatric kidney-alone candidates to be sequenced before pancreas and kidney/pancreas (K/P) classifications in the proposed allocation orders for DBD donors aged 11-17 with Kidney Donor Profile Index (KDPI) 0-34% and DBD donors aged <11 with KDPI 35-85%.
>
> Regarding the allocation table for DBD donors aged <11 with KDPI 35-85%, the Pediatric Committee supports the inclusion of pediatric candidates in Classification 13 and 14.

The Committee reviewed the pediatric donor tables included in the request for feedback (RFF).

The Pediatric Committee strongly advocated for pediatric kidney-alone candidates to be sequenced before pancreas and kidney/pancreas (K/P) classifications in the proposed allocation orders for DBD donors aged 11-17 with Kidney Donor Profile Index (KDPI) 0-34% and DBD donors aged <11 with KDPI 35-85%.

There were concerns that prioritizing pancreas and K/P candidates would further limit the donor pool for pediatric candidates. The Pediatric Committee emphasized that pediatric kidney-alone candidates often have limited access to appropriate organs, given that pediatric candidates typically are not offered kidneys with a KDPI >35%. Some members felt prioritizing K/P candidates over pediatric kidney-alone candidates represents risk for missed transplant opportunities for pediatric patients, particularly given

the frequency of late declines among K/P recipients. A member from an OPO stated that they see late pancreas decline a considerable amount which in turn disadvantages candidates sequenced after K/P on the match run. These declines can result in pediatric-appropriate kidneys being allocated to lower-priority candidates instead of pediatric kidney candidates in need.

Regarding the allocation table for DBD donors aged <11 with KDPI 35-85%, the Pediatric Committee supports the inclusion of pediatric candidates in Classification 13 and 14. The Committee maintains that pediatric kidney candidates should be prioritized for pediatric donor organs over K/P candidates. A member noted that that Hepatitis C status will no longer be captured in the KDPI calculation, so the pool of donors may shift favorably for pediatrics.

Additionally, the Pediatric Committee highlighted the need to factor medical urgency and sensitization needs into kidney classifications for pediatric candidates. A member commented that they have a medically urgent pediatric candidate waiting for a small kidney that has been listed for over a year with no offers. Another member commented that it's likely because pediatric candidates don't get any extra benefit for being both pediatric and medically urgent.

Highly sensitized pediatric candidates have much lower access to transplant opportunities. Due to their increased sensitization and decreased donor compatibility, these candidates may face significantly prolonged wait times.

The Committee briefly reviewed the table for DCD donors aged 18+ with KDPI 0-35%. Contractor staff explained this table is still under development. There was a question about why this table has fewer lines compared to other allocation tables. Staff noted, one reason is that national shares are being broached by Liver Class 13.

Next steps:

The Committee's feedback will be posted on the OPTN website for review by OPTN Multi-Organ Transplantation Committee.

2. Allocation Out of Sequence: The pediatric perspective

On February 21, 2025, the Health Resources and Services Administration (HRSA) provided the OPTN with a response to a critical comment regarding organ allocation out of sequence (AOOS).

Summary of discussion:

No decisions were made.

The Chair provided an overview of the timeline of OPTN discussions and work related to AOOS, spanning from 2023 to-date (see Appendix A). The Committee reviewed key aspects of the HRSA directive letter provided to the OPTN on February 21, 2025:

"[*This] letter directs the OPTN to complete the following actions by March 31, 2025:*

1. *Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions. …*
2. *Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs. …*
3. *(C) Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants. …*

4. *Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS*."

The Committee discussed their feedback on aspects of the directive letter and AOOS.

Out-of-Sequence Offers and OPO Behavior

- **Continued concern over lack of regulation:** Committee members expressed alarm that OPOs can allocate organs out of sequence without standardized national rules, and practices vary widely across regions.
- **Bypass without center visibility:** Members reported concerns that OPOs are bypassing centers even when they meet match criteria and filters, undermining transparency.
- **Need for guardrails:** The Committee called for clear OPTN rules governing when and how out-of-sequence allocation can occur, particularly for low KDPI (high-quality) kidneys.
- **Pediatric relevance:** Out-of-sequence allocation may impact pediatric access to organs, even if less common, and requires oversight.

Equity vs. Efficiency Tradeoffs

- **Competing incentives:** The Committee highlighted the misalignment between hospital and OPO priorities, with hospitals driven by CMS metrics (e.g., graft survival) and OPOs by organ utilization targets.
- **Ethical implications:** There is concern that a focus on minimizing non-use rates may come at the cost of equity, justice, and pediatric access, especially if lower-risk pediatric candidates are bypassed for perceived expedience.

Compliance and Oversight

- **Discussion around reviews of AOOS events**: A member from an OPO spoke to their experience with submitting to the OPTN documentation to explain why an organ was allocated OOS. It was noted that with such high volumes of AOOS, it may be difficult to keep up with quality reviews.
- **Form-letter justifications:** A member noted that they have heard some OPOs submit boilerplate responses to the OPTN, raising doubts about the meaningfulness of current oversight.

Granular Refusal Codes

- **Support for increased specificity**: The Committee emphasized the need for more granular tracking of refusal codes, especially to differentiate between various clinical factors (e.g., donor biopsy findings, transport time).
- **Current limitations**: They noted the overuse of generic or "other specified" codes, which hinders transparency and tracking.
- **Suggestions for improvement**:
    - Include structured, numeric refusal codes (e.g., specifying ranges of sclerosis on biopsy).
    - Allow multiple refusal codes to reflect complex decisions.
    - Reduce reliance on free-text fields to enable systematic analysis.

Communication Outside the OPTN System

- **Transparency concerns:** Committee members criticized the use of informal communications (e.g., cell phone calls) between OPOs and surgeons or centers, which sidestep the OPTN Computer System and reduce traceability.
- **Legal and ethical questions:** Members questioned the legality and fairness of these off-system communications, particularly in relation to equity and government oversight.

Committee Recommendations and Considerations

- Clarify the distinction between:

    - OPO behaviors (e.g., out-of-sequence allocation, bypassing).
    - Transplant center decisions (e.g., individual refusals).
- Develop OPTN-wide standards for when and how out-of-sequence offers are made.
- Increase public and patient transparency about when patients are excluded from offers.
- Track and report pediatric-specific out-of-sequence activity, even if low.

The Committee was informed that an AOOS Workgroup, sponsored by the Operations and Safety Committee (OSC), will be formed to address items A) #3-5 of the HRSA directive. There was a call for self-nominations to represent the pediatric perspective on the AOOS Workgroup.

Next steps:

A Committee member will serve as the pediatric representative on the OSC-sponsored AOOS Workgroup.

3. Public Comment Item: Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS is available for OPTN public comment from January 23, 2025 to March 19, 2025.

Summary of discussion:

There was support for the addition of contrast-enhanced ultrasound (CEUS) as an optional imaging option to provide a pathway to automatic standard HCC exception approval.

The Committee considered the following feedback questions posed by the OPTN Liver and Intestinal Transplantation Committee:

- Do you agree with the addition of contrast-enhanced ultrasound (CEUS) as an optional imaging option to provide a pathway to automatic standard HCC exception approval in Policy 9.5.I?
- Do pediatric practitioners incorporate LIRADS-5 criteria into case management? If not, what system or categories should be used to classify pediatric HCC?

There was support for the addition of contrast-enhanced ultrasound (CEUS) as an optional imaging option to provide a pathway to automatic standard HCC exception approval. Two members with expertise in liver transplant indicated that LIRADS-5 criteria are not typically used in pediatric case management. No specific concerns were raised regarding the incorporation of LIRADS-5 criteria, or otherwise.

Next steps:

The Committee's feedback will be posted on the OPTN website for review by OPTN Liver and Intestinal Transplantation Committee.

4. Project Update: Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care

On September 17, 2024, the Committee decided to move forward with a project related to recipient loss to follow-up. During the October and November 2024 meetings, the Committee refined the project idea and scope before submitting a proposal for review by Policy Oversight Committee (POC) and the Executive Committee.

Project information

Below is a timeline from idea origin to review for project approval:

- Winter 2023-2024 – Project idea originated during guest presentation to Committee
- Spring to Fall 2024 - Idea development & refinement
- Winter 2025 – Project brought forth for review
    - February 10, 2025 – Endorsed by Data Advisory Committee (DAC)
    - February 13, 2025 – Recommended for approval by POC
- March 6th, 2025 – Executive Committee approved the project

Project purpose as presented to POC and Executive Committee:

- Standardize reporting of recipient loss to follow-up (LTFU) and transfers of care
    - Clarify transplant program responsibility for reporting LTFU & transfers of care to create consistency in this data collection
    - Add to policy definition/reporting criteria for LTFU & transfers of care
- Better understand factors contributing to LTFU designation in OPTN Data System
    - LTFU designation stops the generation of transplant recipient follow-up forms, in turn, there is loss of critical data
    - Improve understanding of barriers to accessing post-transplant follow-up care
    - Age at transfer to adult care is of particular interest for pediatric recipients

Summary of discussion:

The Committee recommended a formal data request to inform project development.

The Committee Vice Chair informed members that *Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care* was approved by the Executive Committee. The Vice Chair stated that the Executive Committee suggested exploring language as a barrier to obtaining follow-up care. The Committee reviewed feedback provided during DAC check in on February 10, 2025 (see Appendix B).

The Committee recommended a formal data request to inform project development. There was interest in examining:

- LTFU reporting by organ type, region, and across age groups
- Time from transplant to when the recipient is marked “Lost”
- How often someone is “lost” then returns to care
- Sociodemographic information for those marked lost, such as insurance coverage

The Chair informed Committee members that a Workgroup would be formed to develop a proposal, and progress would be brought to the full Committee as needed.

Next steps:

The Committee will request volunteers from the Pediatric Committee, DAC, Transplant Administrators Committee and Transplant Coordinators Committee to join a Workgroup. The Workgroup will meet in early April 2025 and discuss a formal data request for the project.

5. Open Forum

There were no open forum speakers.

Upcoming Meeting

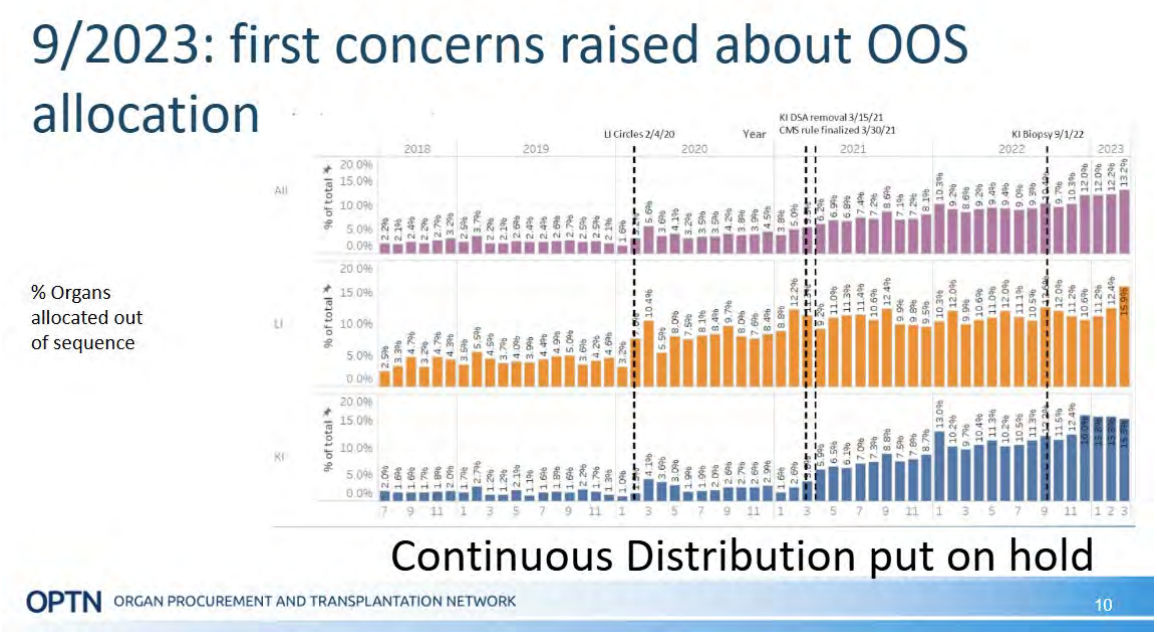
- March 27, 2025, teleconference, 4-5 PM ET

Attendance

- **Committee Members**
  - Rachel Engen
  - Neha Bansal
  - Aaron Wightman
  - Meelie Debroy
  - Shawn West
  - Katrina Fields
  - Namrata Jain
  - Reem Rafaat
  - Ryan Fischer
  - JoAnn Morey
  - Carol Wittlieb-Weber
  - Woodlhey Ambroise
  - Sonya Kirmani
  - Jennifer Vittorio
  - Jill McCardel
- **HRSA Representatives**
  - None
- **SRTR Representatives**
  - Avery Cook
  - Jodi Smith
  - Simon Horslen
- **UNOS Staff**
  - Leah Nunez
  - Matt Cafarella
  - Dzhuliyana Handarova
  - Niyati Upadhyay
  - Sarah Roache
  - Meghan McDermott
- **Other attendees**
  - Joseph DiNorcia (guest presenter)

Appendices

Appendix A: Timeline of AOOS discourse within OPTN and transplant community.



9/2023: OPTN Expeditious Task Force formed

Prioritized objectives

- Reduce organ non-use
- Increase organ acceptance rates
- Rapidly increase the number of transplants
- Define thresholds for 'difficult to match' organs, after which allocation out of sequence is allowable

Pediatric Committee voiced importance of offering kidneys to pediatric and highly sensitized prior to OOS allocation and excluding KDPI <35% kidneys from protocols.

Proposal 1: Trial protocol for accelerated placement of KDPI 75-100 kidneys in 5 OPOs after offering the organ to 'high priority classifications'

- Concerns raised during Public Comment about the inequity of having a trial of 5 OPOs; HRSA halted plan

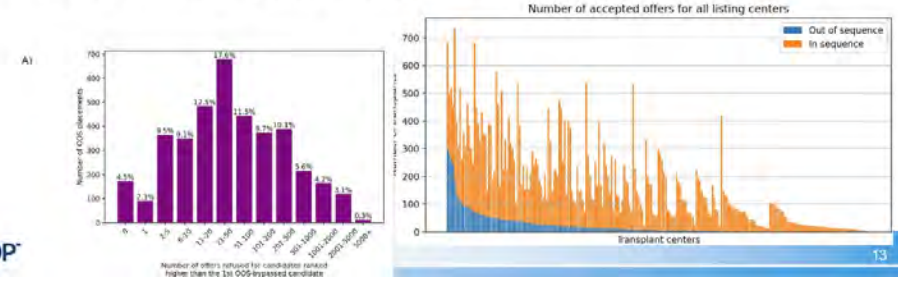
Expeditious Task force last posted updates 3/2024

5/15/24: Pediatric Committee Open Forum

- Community member presents a de-identified case to Pediatric Committee regarding a highly sensitized pediatric candidate
  - Patient was match for organs that were initially allocated to kidney-pancreas (KP) candidate
  - KP team declined after procurement; OPO allocated kidney out-of-sequence locally without offering it to pediatric patient
- Committee thanked Community member for presenting, briefly discussed issue of out of sequence allocation and pediatric priority relative to multiorgan transplantation. This was also presented to the MOT committee.

2/2025: AJT article, Liyanage et al

- 20% of kidneys placed OOS
- 4.5% of kidneys offered OOS without being offered to anyone in sequence
- 33% of OOS kidneys had been declined for >100 candidates
- 4 OPOs accounted for 29% of all OOS placements



Appendix B: DAC feedback & next steps for DAC check-ins re *Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care.*

2/10 Data Advisory Committee Feedback

- Data Advisory Committee holds an initial check-in for new projects including data collection changes to provide feedback and endorsement
- 2/10 Feedback:
  - DAC endorsed the project
  - Supported including adult transplant recipients in addition to pediatric recipients
  - Suggested considering patient perspective & differences across organs
  - Suggested exploring utilization of "Not seen" option on TRF
- Next Steps:
  - If project is approved, the Pediatric Committee and DAC will schedule a second check-in to review a more detailed description of the proposed changes to OPTN data prior to public comment release