OPTN Heart Transplantation Committee
Meeting Summary
May 6, 2025
Conference Call

J.D. Menteer, MD, Chair
Hannah Copeland, MD, Vice Chair

Introduction

The Committee met via WebEx teleconference on 05/06/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. CD: Review next set of scenarios for match run analysis
3. Considering new project activity associated with CD
4. Open forum
5. Closing remarks

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

1. Welcome, reminders, and agenda review

The Chair welcomed the members and provided an overview of the agenda items. The agenda items included a review of previously discussed continuous distribution (CD) match run scenarios and evaluating potential refinements to the attribute weightings. The Committee would also consider two new project proposals. The meeting focused on refining pediatric prioritization strategies, sensitization scoring, and proximity efficiency. The meeting also discussed future data collection and exception review processes.

2. CD: Review next set of scenarios for match run analysis

The Committee reviewed and refined the next set of match run scenarios for CD analysis that will be submitted to the SRTR contractor. The discussion built upon the Committee's 04/18/2025 discussion and focused on confirming the parameters for upcoming SRTR modeling, with particular attention to attribute weighting, rating scales, and subgroup prioritization.

Summary of discussion:

> Decision #1: The Committee decided to submit several new match run analysis scenarios to the SRTR Contractor to assist the Committee with developing a CD allocation framework.

The following scenarios were previewed and discussed by the Committee members.

Two distinct **blood type prioritization scenarios** were reviewed:

- **Scenario A:** Full priority was assigned exclusively to blood type O candidates, with zero priority allocated to types A, B, and AB. This approach was designed to test the impact of maximizing support for the most disadvantaged blood group.

- **Scenario B:** A proportional model was introduced, distributing priority based on the relative frequency of incompatible donors. In this model:
    - Type O candidates received 100% of the 7.5-point allocation
    - Type B candidates received approximately 47% of the allocation, or approximately 3.5 points
    - Type A candidates received 5%, or approximately 0.4 points
    - Type AB candidates received no additional priority

This proportional model was intended to reflect a more nuanced approach to blood type compatibility while still emphasizing the disadvantage faced by type O candidates.

Two **proximity efficiency scenarios** were proposed:

- **Scenario A:** Increase the attribute weight for proximity efficiency to 30%, which would require recalibration of other attribute weights to maintain a total of 100%.
- **Scenario B:** Maintain the current 20% weight but reduce the initial distance threshold from 500 to 250 nautical miles (NM). This change aims to evaluate the impact of tighter geographic constraints on allocation efficiency and equity.

The Committee agreed that comparing the 250 NM and 500 NM thresholds would provide valuable insights into the trade-offs between broader sharing and logistical feasibility.

A **waiting time scenario** was introduced to test the effect of removing the waiting time attribute entirely from the match run by setting its weight to 0%. All other attribute weights would remain unchanged. This scenario is intended to assess whether waiting time contributes meaningfully to allocation outcomes or if it introduces unintended bias.

The Committee discussed two **sensitization scenarios**:

- **Scenario One (Baseline):** Points are assigned linearly between CPRA 50% and 80%, with full points awarded at 80% and above. Candidates below 50% CPRA receive no sensitization points.
- **New Scenario:** The linear scale would begin with CPRA values of 50 and extend it to values of 90. Candidates with CPRA values of 50 to 90 would receive between 1% and 99% of the rating scale points. Candidates whose CPRA value is 90 or greater would receive 100% of the prioritization points. This approach aims to better support highly sensitized candidates, for example, those with a CPRA value equal to or greater than 98. who face significant barriers to transplantation. A Committee member said they are most interested in providing transplant programs with an incentive to list patients with high CPRAs at higher prioritization rather than incentivizing programs to implant a left ventricular assist device (LVAD) and sending the patient home. The member said the new scenario addresses that concern.

There was consensus that while the numerical impact of this change may be modest, it could provide important incentives for listing highly sensitized patients rather than defaulting to durable LVAD support.

A member added that the Committee might want to reconsider the amount of priority provided LVAD candidates who have been waiting at least seven years with an implanted device. The member said they thought 60% of the priority points is too much given that candidates with IABPs are getting 50% of the points in light of the new restrictions in terms of priority being put on IABP as a therapy.

The Committee revisited the weighting of medical urgency, specifically a **scenario focusing on pediatric status 1A candidates**. The members were reminded that Committee decided to use relatively simple scenarios when they submitted the initial match run analysis request. As part of the initial match run analysis, the Committee agreed that pediatric status 1A candidates would receive 60% of the points assigned to the medical urgency attribute. The Committee also understood that there would be plenty of opportunities to iterate on the scenarios submitted as part of the initial match run analysis. With this in mind, Committee members discussed potential changes to how much priority should be assigned to pediatric status 1A candidates. Currently, status 1A consists of five criteria. During the meeting, concerns were raised that 60% of the priority may not sufficiently prioritize the sickest pediatric patients, particularly those on ECMO or inpatient mechanical support.

- Members discussed whether to increase the amount of prioritization for pediatric status 1A candidates to 70% or 80%, but concerns were expressed about disrupting the intended separation between high-acuity pediatric and adult candidates
- SRTR contractor staff confirmed that while adult status justification forms were developed to capture the individual criteria within each status, that is not the case with the pediatric status justification forms. As a result, while adult ECMO patients can be easily identified using justification form information, that is not the case for pediatric ECMO candidates. Instead, surrogate markers will be needed to identify pediatric ECMO candidates and other pediatric subgroups when performing the match run. For example, transplant programs are required to report any implanted support devices at the time of waiting list registration. So, that information is captured on the Transplant Candidate Registration (TCR) form. Transplant programs are also required to report on all the devices a candidates has ever had implanted and or explanted, when the candidate is removed from the waiting list. Therefore, the potential exists to use those sources of information to help inform the proportion of pediatric candidates who are supported by specific devices.
- A working plan was proposed to collaborate with the SRTR contractor to define and extract granular pediatric subgroups, including:
    - ECMO-supported patients
    - Inpatient VAD recipients
    - Inotrope-dependent patients
    - Patients with congenital heart disease or Fontan complications

The Committee acknowledged that while retrospective analysis has limitations, early subgroup separation could lead to more accurate future simulations and policy development.

Next steps:

The review of match run scenarios reflects the Committee's ongoing commitment to refining the CD framework through iterative analysis, stakeholder input, and data-driven decision-making. Further match run analyses and results will inform whether additional scenario iterations are needed before transitioning to full simulation modeling.

3. Considering new project activity associated with CD

The Committee also discussed two potential new project initiatives that could be pursued in parallel with the ongoing development of the CD framework. These proposals emerged from recent discussions

and were presented to help the Committee determine where to focus its limited bandwidth in the coming year.

Summary of discussion:

No decisions were made as part of this agenda item.

Project Proposal 1: New Data Collection to Support CD Implementation

The objective of this project would be to initiate the collection of more granular clinical data—particularly for pediatric candidates and congenital heart disease (CHD) candidates—to better inform medical urgency prioritization. The Committee acknowledged the following as key data elements that would be useful with CD**:**

- Pediatric ECMO status
- Pediatric VAD status (including dischargeability and inpatient/outpatient status)
- Detailed congenital heart disease classifications. For example, more granular data needs to be captured about Fontan physiology, and the same could apply to single ventricle anatomy.

Rationale and Benefits:

The members discussed how these data elements are currently underrepresented in the existing dataset but are critical for accurately modeling medical urgency and post-transplant outcomes. Beginning to collect the information now could support more precise attribute weighting and subgroup prioritization in future CD iterations. Early collection would also allow for integration into future simulation modeling and policy evaluation, particularly as the adult CHD population (including Fontan patients) continues to grow.

Challenges and Limitations:

In terms of challenges, the timeline for implementing new data collection is lengthy, requiring public comment, OPTN Board approval, and Office of Management and Budget (OMB) approval. Based on past experience, the process can take months to years. Even if approved, the data would not be available in time to influence the initial CD implementation. There is also concern that the effort may not yield actionable insights before CD goes live, potentially delaying progress without immediate benefit.

Committee Discussion Highlights:

- Some members emphasized the long-term value of collecting CHD data, especially given the increasing complexity of adult congenital cases.
- Others cautioned that the timeline and resource demands may not justify the effort unless CD implementation is delayed—which is not currently planned.
- A suggestion was made to integrate this data collection into the broader CD policy package rather than pursue it as a standalone project.

Project Proposal 2: MPSC Referral – Review of Exception Request Practices

In the case of the MPSC referral, the objective would be to respond to the request specifics while also exploring opportunities to better align the review bord processes and operational components with how exceptions will be administered and managed as part of CD. MPSC's request calls for an evaluation of the current retrospective review process for heart transplant exception requests, particularly for adult candidates.

The referral identified the following issues regarding heart exception requests:

- High approval rates for exception requests, raising concerns about consistency and rigor
- Instances of patients being transplanted at a status that was later denied upon retrospective review
- Lack of clear consequences or accountability for centers that proceed with transplants under denied exceptions

The members pointed out that the Committee and the heart community have been aware of the issues.

Potential Areas of Focus:

- Assessing whether the current retrospective model is effective or if a prospective review process should be implemented
- Exploring the feasibility of a national heart review board for adults, similar to the pediatric model
- Evaluating whether structural changes to the review board system are needed ahead of CD implementation

Rationale and Benefits:

- Addressing inequities and inconsistencies in exception handling could improve fairness and transparency in the allocation system
- A prospective review model may align better with the CD framework, where exception points will directly affect composite allocation scores

Challenges and Considerations:

- The scope of the problem is not yet fully defined; more data is needed to determine how often transplants occur under denied exceptions and whether this is a systemic issue
- Implementing a prospective review system would require rapid turnaround times, which may strain existing infrastructure and delay urgent transplants
- There is concern about whether the community would support such a shift, given past resistance to prospective review

Committee Discussion Highlights:

- Some members supported exploring prospective review as a necessary evolution under CD, especially given the direct impact of exception points on allocation
- Others emphasized the need for a clearer problem statement before committing to a structural overhaul
- A suggestion was made to engage the MPSC in further dialogue to clarify expectations and explore collaborative solutions

<u>Next steps:</u>

Committee members were asked to reflect on both proposals and come prepared to make a decision at the next meeting on 05/20/2025. OPTN Contractor staff will support further exploration of both options, including gathering additional data on exception request outcomes and feasibility of pediatric data

collection. The Committee acknowledged that while both projects are important, resource constraints may necessitate prioritizing one initiative in the near term.

4. Open forum

No requests from the public were received prior to the meeting asking to address the Committee during open forum.

5. Closing remarks

The meeting concluded with a reminder that the Committee's next meeting is scheduled for 05/20/2025 starting at 5:00 PM (ET). Members were encouraged to reflect on the project proposals and be prepared to make a decision at that time.

Upcoming Meetings

- ~~July 2, 2024 from 4:00 to 5:30 pm~~
- ~~July 16, 2024 from 5:00 to 6:00 pm~~
- ~~August 7, 2024 from 4:00 to 5:00 pm~~
- ~~August 20, 2024 from 5:00 to 6:00 pm~~
- ~~September 4, 2024 from 4:00 to 5:00 pm~~
- ~~September 17, 2024 from 5:00 to 6:00 pm~~
- ~~October 2, 2024 from 4:00 to 5:00 pm~~
- ~~October 9, 2024 from 9:00 am to 4:00 pm (In-person meeting, Detroit, MI)~~
- ~~October 15, 2024 from 5:00 to 6:00 pm~~
- ~~November 6, 2024 from 4:00 to 5:00 pm~~
- ~~November 19, 2024 from 5:00 to 6:00 pm~~
- ~~December 4, 2024 from 4:00 to 5:00 pm~~
- ~~December 17, 2024 from 5:00 to 6:00 pm~~
- ~~January 1, 2025 from 4:00 to 5:00 pm~~
- ~~January 21, 2025 from 5:00 to 6:00 pm~~
- ~~February 4, 2025 from 4:00 to 5:00 pm~~
- ~~February 18, 2025 from 5:00 to 6:00 pm~~
- ~~March 4, 2025 from 4:00 to 5:00 pm~~
- ~~March 18, 2025 from 5:00 to 6:00 pm~~
- ~~April 1, 2025 from 4:00 to 5:00 pm~~
- ~~April 15, 2025 from 5:00 to 6:00 pm – Cancelled~~
- ~~April 18, 2025 from 11:00 am to 4:00 pm~~
- ~~May 6, 2025 from 4:00 to 5:00 pm~~
- May 20, 2025 from 5:00 to 6:00 pm
- June 3, 2025 from 4:00 to 5:00 pm
- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
  - J.D. Menteer
  - Tamas Alexy
  - Maria Avila
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Earl Lovell
  - Mandy Nathan
  - Jason Smith
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Avery Cook
  - Grace Lyden
  - Nick Wood
- **UNOS Staff**
  - Keighly Bradbrook
  - Matt Cafarella
  - Cole Fox
  - Shelby Jones
  - Kelsi Lindblad
  - Eric Messick
  - Laura Schmitt
  - Holly Sobczak
  - Kaitlin Swanner
  - Sara Rose Wells
- **Other Attendees**
  - None