OPTN Heart Transplantation Committee
Meeting Summary
March 4, 2025
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 03/04/2025 to discuss the following agenda items:

1. Welcome, introductions, and agenda review
2. Review information regarding MOT Committee's presentation on 02/04
3. Escalation of Status public comment update
4. Other Committee business
5. Open Forum
6. Closing remarks

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

1. Welcome, introductions, and agenda review

The meeting commenced with a welcome and an overview of the agenda. The primary focus was on reviewing the information presented on 02/04/2025 about the OPTN Multi-Organ Transplantation (MOT) Committee's proposal. The purpose of reviewing the information was to develop the Committee's formal public comment response. The meeting also focused on discussing the public comments regarding the Escalation of Status for Time on Left Ventricular Assist Devices (LVADs). Additional updates on committee business and upcoming meetings were also covered.

2. Review information regarding MOT Committee's presentation on 02/04

The Committee members generally concurred with the MOT Committee's proposed allocation classifications but emphasized the need for more data to ensure informed decision-making. The Committee also highlighted the importance of continuous distribution efforts to address sensitization and other factors in the heart allocation process, and how such information might suggest changes in future MOT allocation classifications.

Summary of discussion:

Decision 1: The Committee agreed with the overall prioritization the MOT Committee proposed assigning to the donor classification tables.

Decision 2: The Committee agreed that they did not want to recommend any additional criteria by which another organ could pull a heart. Likewise, the Committee agreed they did not want to recommend any criteria describing the conditions when a heart must pull any other organ.

During the Committee's 02/04/2025 meeting, the MOT Committee co-Chair presented a policy proposal aimed at balancing the allocation of organs between single and multi-organ recipients. The policy

proposal seeks to ensure equity in the allocation process, addressing concerns about medical urgency and access, particularly for sensitized kidney patients and pancreas allocation. The presentation provided an overview of the multi-organ allocation tables developed by the MOT Committee. The tables are tailored to specific donor types. The tables include classifications for adults with Kidney Donor Profile Index (KDPI) ranging from 80% to 35%, pediatric donors, higher KDPI donors, and Donation after Circulatory Death (DCD) donors with low KDPI. In developing the allocation tables, the MOT Committee members placed a lot of emphasis on the extent to which patients had access to life-sustaining therapies or supports while such patients waited for a transplant. The MOT Committee members agreed that the highest priority liver candidates have practically no life-sustaining therapy available to them the way heart candidates have access to mechanical circulatory support and kidney candidates have access to dialysis. As a result, multi-organ candidates who are primarily liver candidates assigned to status 1A are considered to have the greatest priority among all multi-organ candidates.

The Committee members reviewed the appropriateness of the proposed classification rows, in light of the heart classifications, and the order of priority for organ allocation. The members were reminded that the MOT Committee's tables prioritize medical urgency, followed by access considerations, particularly for sensitized kidney patients. The Committee generally agreed with the proposed classifications but raised concerns about the potential impact on heart candidates, particularly those who are highly sensitized. It was noted that current heart allocation policy does not address candidate sensitization as a factor; therefore, an entirely new heart allocation framework would need to be developed before sensitization could be addressed in the MOT proposal.

An important discussion topic for the Committee was whether they should propose any restrictions to the MOT Committee about the circumstances under which another organ can pull a donor heart. The MOT proposal indicates that hearts, livers, and lungs can pull all other organs. The Committee discussed whether there should be minimum requirements for hearts to be pulled by other organs, particularly in cases involving highly sensitized heart candidates. Concerns were raised about the potential for liver patients with high Model for End-Stage Liver Disease (MELD) scores to pull hearts, and whether exceptions should be made for combined heart-liver patients with high liver status.

The MOT Committee's tables prioritize medical urgency, with liver status 1A patients being able to pull hearts before status 1 heart patients. It was noted that liver status 1A patients are expected to die within seven days without mechanical support. The Committee members discussed the implications of this prioritization, noting that while both liver and heart patients have higher medical urgency, heart patients have access to mechanical support options that liver patients do not. The members generally concurred with the MOT Committee’s thinking on this topic, although some members noted that heart candidates supported by ECMO also have very problematic waitlist mortality rates. The Committee emphasized that when considering future changes to the multi-organ classification tables, the MOT Committee should prioritize capturing more data on waitlist mortality and post-transplant survival in a way that is comparable across organ types to make better informed decisions.

Next steps:

Committee members were encouraged to email any additional feedback to leadership and OPTN contractor staff. OPTN contractor staff will draft a response to the MOT Committee's request for feedback, incorporating the Committee's discussions and concerns. The draft will be presented to Committee leadership for approval and eventual posting on the OPTN website.

3. Escalation of Status public comment update

The committee received an update on the public comments regarding the proposal to escalate the status of patients with Left Ventricular Assist Devices (LVADs) based on the duration of device implantation. The Committee reviewed the public comments received to date and discussed the potential implications of the proposed policy. They acknowledged the strong support for the proposal and the suggestions for shortening the timeframes.

Summary of discussion:

No decisions were made as part of this discussion.

As of 03/03/2025, a total of 99 public comments had been received, with the majority expressing support for the proposal. The comments were categorized into several key themes, including support for the proposal, suggestions for shortening the proposed timeframes, and concerns about the potential impact on other patient groups.

Many commenters, including those who identified themselves as patients, individuals associated with transplant hospitals, and members of the general public, expressed strong support for the proposal. They highlighted the importance of addressing the long waiting times faced by patients who are supported by dischargeable LVADs and the associated decrease in survival rates while on the waiting list. Commenters appreciated the Committee's efforts to prioritize these patients and acknowledged the potential benefits of the proposed policy in improving access to transplantation for this group.

Several commenters suggested that the proposed timeframes for escalating the status of patients with LVADs should be shortened. The current proposal includes timeframes of six and eight years for eligibility for adult heart status 3 and status 2, respectively. Commenters argued that shorter timeframes would better address the urgency of the situation and provide more timely access to transplantation for patients with LVADs. Some suggested reducing the timeframes to five and seven years or even shorter durations.

Some commenters raised concerns about the potential impact of the proposed policy on other patient groups, particularly those in adult heart status 2. They noted that increasing the number of patients eligible for status 2 could lead to longer waiting times and potentially higher mortality rates for existing status 2 patients. The Committee acknowledged these concerns and discussed the need to balance the priorities of different patient groups. They emphasized the importance of carefully monitoring the impact of the proposed policy and making adjustments as needed to ensure equitable access to transplantation.

Next steps:

The next steps include finalizing the proposal based on the public comments and presenting it to the OPTN Board of Directors for approval. OPTN contractor staff will continue to gather and analyze the public comments received about the *Escalation of Status* proposal and share the information with the Committee members.

4. Other Committee business

OPTN contractor staff told the Committee that the OPTN Operations and Safety Committee is seeking a volunteer to assist with directive-related work from HRSA about addressing allocation out of sequence (AOOS). In addition, members were encouraged to maintain their availability for the upcoming virtual in-person meeting, despite the change in format.

5. Open Forum

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

6. Closing remarks

The Committee was informed about the schedule for upcoming meetings, including the expectation of receiving data on continuous distribution in April. The April 15th meeting was canceled in favor of the virtual in-person meeting on April 18th.

The meeting concluded with a reminder for members to provide any additional comments or feedback on the MOT proposal and the LVAD escalation proposal. The importance of active participation in the upcoming meetings was reiterated.

Next steps:

Committee members were asked to send any additional comments to leadership or OPTN contractor staff.

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 – In-person meeting
- 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
  - Hannah Copeland
  - Tamas Alexy
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timithy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Mandy Nathan
  - Jason Smith
  - Martha Tankersley
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Avery Cook
  - Grace Lyden
- **UNOS Staff**
  - Keighly Bradbrook
  - Matt Cafarella
  - Cole Fox
  - Shaina Kian
  - Kelsi Lindblad
  - Eric Messick
  - Kaitlin Swanner
  - Sara Rose Wells
- **Other Attendees**
  - None