

OPTN Heart Transplantation Committee

Meeting Summary

June 17, 2025

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee (the Committee) met via WebEx teleconference on 06/17/2025 to discuss the following agenda items:

1. Welcome, introductions, and agenda review
2. Review of OPTN Board of Directors approvals and next steps for pediatric guidance
3. Presentation of 24-month monitoring results associated with the *Amend Status Extension Requirements in Adult Heart Allocation Policy*
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

Committee leadership thanked members for their service and commitment. Members whose terms are expiring at the end of the month were acknowledged for their significant contributions to the OPTN over multiple projects and initiatives.

2. Review of OPTN Board of Directors approvals and next steps for pediatric guidance

The OPTN Board of Directors met on 06/09/2025 and approved two of the Committee's recent projects.

Summary of discussion:

No decisions were made as part of this agenda item.

Two Heart Committee projects were approved during the OPTN Board of Directors meeting held on 06/09/2025. First, the proposal *Escalation of Status for Time on Left Ventricular Assist Device (LVAD)* was approved and will be implemented at a future date, pending notification to the community. The proposal, which had previously undergone public comment, was developed to address concerns regarding adult heart candidates with long-term, dischargeable LVADs who face limited access to transplantation. The policy introduces time-based criteria to escalate such candidates to higher statuses (statuses 2 or 3) based on the number of years since device implantation. The Board approved the proposal, and while an exact implementation date has not yet been determined, it is expected to occur in the near future.

Second, the Board approved an update to the *Guidance for Pediatric Heart Exception Requests* document. The Board approved the update as an emergency action and the guidance update was

implemented on 06/12/2025. The guidance update will expire by 06/11/2026, following the requirements associated with an emergency action, unless action is taken to sunset the update sooner. The guidance update was developed rapidly following the Committee's 05/20/2025 meeting, during which they discussed the shortage of mechanical circulatory support (MCS) devices, supplies, and support components that serve as the primary support therapy for pediatric candidates with dilated cardiomyopathy (DCM) who weigh 10 or more kilograms. Prior to the update becoming effective, pediatric exception guidance addressed candidates who weigh less than 10 kilograms, but not those weighing 10 or more kilograms. As a result, access to treatment can be limited when the devices, supplies, and/or support equipment are in limited supply. During and following the 05/20/2025 meeting, the Committee drafted updated guidance language, reached consensus, and submitted the update to the Board, which approved it as an emergency action. The guidance became effective on 06/12/2025 and is set to expire no later than 06/11/2026. The Committee will revisit the need for continuation or revision of the guidance during its August 2025 meetings. The *Guidance for Pediatric Heart Exception Requests* update will be submitted for retrospective public comment as part of the 08/08/2025 to 10/07/2025 cycle. The Committee will review community feedback and further discuss whether there is a need to keep the guidance update effective beyond 06/11/2026.

The Committee discussed other proposals set to be included in the upcoming OPTN public comment period. A member provided an overview of the OPTN Ad Hoc Multi-Organ Transplantation Committee's upcoming proposal, *Establish Comprehensive Multi-Organ Allocation Policy*. The member mentioned a small concern with the priority provided to liver candidates with certain diagnoses but indicated that overall heart candidates are fairly treated in the proposed allocation tables. The member suggested that the Committee receive a presentation during public comment on this proposal. OPTN contractor staff informed the members that the OPTN regional meetings would start on 08/20/2025 and run through 09/26/2025. Members were encouraged to participate in public comment by reviewing the materials on the OPTN Website and submitting comments and participating in regional meetings.

A member, who also serves on the OPTN Board of Directors, shared an update with the Committee regarding recent Board discussions about the OPTN's budget and the ongoing continuous distribution (CD) projects. The member stated that during the Board meeting, several cost-saving measures were proposed including a resolution to pause all new CD work for Q4 2025 (July, August, and September). The resolution was ultimately rejected by the Board, but concerns remain that CD work may be paused in federal fiscal year 2026 (October 2025 – September 2026). The member added that they voiced their opposition to such a pause and urged Committee members to share any concerns with current Board members. It was noted that it appears much priority is currently being placed on resolving issues related to out-of-sequence allocation across all organs, particularly in light of increased out-of-sequence events following the implementation of lung CD. This shift in focus was cited as a rationale for the proposed Board resolution deprioritizing CD work in the short term. Several Committee members emphasized that halting progress could lead to a loss of institutional knowledge and momentum, particularly given the natural turnover of OPTN committee membership. Others noted that CD offers a flexible framework capable of addressing known inequities in the current allocation system—such as disparities related to blood type and sensitization—that cannot be addressed through traditional policy structures. A member also cited the importance of CD in addressing allocation inequities. The Committee members conducted a straw poll, and 13 of the 14 members in attendance supported conveying to the Board that the Heart Committee believes it is important to continue CD work.

Next steps:

During their August 2025 meetings, the Committee will review whether there is still a shortage of MCS devices, supplies, and other equipment necessitating the need to keep the guidance update in place.

They will also monitor the public comment feedback and consider whether the guidance update should be set to expire before 06/11/2026 or if it should remain effective until then.

3. Presentation of 24-month monitoring results associated with the *Amend Status Extension Requirements in Adult Heart Allocation Policy*

The Committee reviewed the results of the two-year monitoring report associated with the project *Amend Status Extension Requirements in Adult Heart Allocation Policy*.

Data summary:

- The number of extensions under the criteria of interest decreased by nearly 50% post-implementation
- The number and time spent waiting under consecutive extensions decreased for the criteria of interest post-implementation, but total time spent waiting under extensions rose
- The criterion with the greatest number of extension forms post-implementation was “MCSD with device infection – Erythema,” but the proportion of extension forms submitted for this criterion decreased post-implementation
- The new criterion “MCSD with device infection – Recurrent debridement” saw moderate use post-implementation
- The new criterion “MCSD with life-threatening ventricular arrhythmia” saw no use post-implementation

Summary of discussion:

Committee members concluded that the policy was successful as a result of the observed decreases in the use of extensions. They also agreed that there were no unintended consequences associated with the changes.

The policy changes associated with the project were implemented on 10/27/2022. OPTN contractor staff provided a detailed analysis of the policy’s impact over a two-year period, comparing data from the pre-implementation phase (October 2020–October 2022) to the post-implementation phase (October 2022–October 2024).

The Heart Committee developed the policy changes in response to concerns about inconsistencies in how adult heart status extensions—particularly at statuses 1 and 3—were being applied and interpreted by transplant programs. Prior to the policy change, there was significant variability in the duration of extensions and the criteria used to justify them, especially for patients with mechanical circulatory support (MCS) devices such as durable Left Ventricular Assist Devices (LVADs). The revised policy aimed to accomplish the following:

- Clarify eligibility criteria for initial status assignments and extensions
- Standardize the duration of extensions
- Reduce ambiguity in clinical definitions (such as infection and pump thrombosis)
- Introduce two new status 3 criteria to address gaps in the existing framework

The OPTN contractor shared key finding from the monitoring report and let members know the report was available on their SharePoint site. The presentation focused on three primary metrics: waiting list additions, extension form submissions, and time spent at each status. It also provided more detailed information about the metrics as they applied to status 1 and status 3 assignments.

Among the identified trends associated with status 1 criteria, there was a modest increase in waiting list additions observed across each criterion. The most notable increase occurred in the ECMO without hemodynamic values category. Most submissions were initial forms, with relatively few extensions. The results associated with status 3 assignments suggested a general decline in usage across most status 3 criteria. The most significant decrease occurred in the MCSD with pump thrombosis category. Two new criteria were introduced as part of the policy changes. This included a criterion for MCSD with device infection requiring recurrent debridement, which witnessed moderate usage. The other new criterion was MCSD with life-threatening ventricular arrhythmia after seven days, which saw no use.

In terms of the submission patterns associated with the justification forms, status 1 forms were predominantly initial submissions. Status 3 forms showed a shift away from the use of extensions, with a nearly 50% reduction in extension forms submitted post-implementation.

Time spent at each status had been a concern when the Committee first developed the policy changes. The monitoring results suggest that median wait times for status 1 criteria remained short (3–4 days). For status 3 criteria, median wait times generally declined.

Committee members expressed strong support for the policy's effectiveness, noting the changes successfully addressed prior inconsistencies and improved clarity. They agreed that no significant unintended consequences were identified. The reduction in extensions was viewed as a positive development. It was pointed out that changes in heart device technology may have contributed to the decline in pump thrombosis cases. A member reminded the others that the purpose of this project was to clarify the circumstances and requirements around the extension language, which they believed the changes had achieved without having unintended consequences. Another member agreed. A member noted that the decline in the number of extensions under the criteria is positive because it means that candidates are receiving transplants thus limiting the number of extensions. The member added that the other benefit is less burden on the system itself in terms of forms needing completion.

The Committee agreed that the policy had achieved its intended goals and did not recommend any immediate revisions. The feedback will be compiled and presented to the Policy Oversight Committee (POC) as part of the formal post-implementation review process.

Next steps:

The two-year monitoring report is the final scheduled evaluation and no further are planned for this policy. The data analyses and Committee feedback will be shared with the POC for post-implementation evaluation.

4. Other Committee business

The Committee discussed other projects in their portfolio.

Summary of discussion:

The Committee expressed strong support that the continuous distribution of hearts project should continue in its development. They also supported the OPTN Board member's offer to share with other Board members the Committee's strong support for continuing their CD efforts.

Committee members raised concerns regarding the prolonged timelines associated with the implementation of previously approved policies. These concerns were particularly focused on the *Amend Adult Heart Status 2 Mechanical Device Requirements* project, which was OPTN Board approved

in December 2023 but is still not implemented. It was noted that the *Amend Adult Heart Status 2* project required OMB approval of the data collection elements, which is the primary reason it is not implemented. OPTN contractor staff provided an update indicating that the *Amend Adult Heart Status 2* policy changes are currently expected to be implemented in early fall 2025, aligning with the end of the federal fiscal year. This places the anticipated implementation nearly two years after the policy's approval.

Several Committee members expressed disappointment and frustration with the extended delay. They noted that such prolonged timelines can undermine the perceived impact of the Committee's work, discourage member engagement and participation, and create uncertainty about whether policy changes will be implemented in a timely or meaningful way. Their discussion emphasized the need for greater transparency and accountability with the heart transplantation community in the implementation process. They also emphasized the importance of communicating realistic timelines to the transplant community and ensuring that approved policies are prioritized for timely execution.

The Committee revisited the discussion regarding the prioritization of the CD projects. A member stated that any potential pause to the project would be difficult to reengage the community once it was restarted. The member emphasized that it is imperative to continue to develop the CD project to address current inequities in the system. The member sought to ensure that the OPTN Board of Directors understood the impact of any decision that may result in a pause of the work.

The Committee reached consensus to share with the OPTN Board of Directors their strong support that the continuous distribution of hearts project should continue in its development.

Next steps:

The Committee's support for continuous distribution will be relayed to the OPTN Board of Directors as part of their next meeting.

5. Open forum

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

6. Closing remarks

Committee leadership thanked members for their engagement. The meeting adjourned with a reminder of the next scheduled session in two weeks.

Upcoming Meetings

- July 1, 2025 from 4:00 to 5:30 pm
- July 15, 2025 from 5:00 to 6:00 pm
- August 5, 2025 from 4:00 to 5:00 pm
- August 19, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
 - Tamas Alexy
 - Maria Avila
 - Kim Baltierra
 - Rocky Daly
 - Jill Gelow
 - Timothy Gong
 - Eman Hamad
 - Jennifer Hartman
 - Earl Lovell
 - Cindy Martin
 - Mandy Nathan
 - Jason Smith
 - David Sutcliffe
 - Martha Tankersley
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Matt Cafarella
 - Cole Fox
 - Kelsi Lindblad
 - Eric Messick
 - Laura Schmitt
 - Sara Rose Wells
- **Other Attendees**
 - None