OPTN Heart Transplantation Committee
Meeting Summary
September 16, 2025
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 09/16/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. Request for approval of data request associated with Allocation Out of Sequence and hearts
3. Consideration of Heart Committee project proposals
4. Open forum
5. Closing remarks

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

1. Welcome, agenda review, and announcements

The Chair welcomed the members and provided a brief overview of the agenda items.

Summary of discussion:

No decisions were made as part of this agenda item.

The Committee convened to review implementation updates, discuss allocation practices occurring out of sequence, refine priorities for near-term policy projects, and consider data collection enhancements to support future policy development.

OPTN contractor staff described the Committee Vice Chair's presentation to the OPTN Policy Oversight Committee (POC) regarding the final post-implementation monitoring results associated with the *Amend Status Extension Requirements* project. The project was implemented in October 2022 and the results presented to POC represented two-years' worth of monitoring results. The results had initially been presented to the Heart Committee earlier in 2025. POC members appeared to agree with the Vice Chair that the policy changes had successfully achieved the Heart Committee's objectives.

Contractor staff said also shared with the Committee that a draft public comment response was shared with Committee leadership regarding the OPTN Multi-Organ Transplantation (MOT) Committee's proposal "Establish Comprehensive Multi-Organ Allocation Policy." When the MOT proposal was previously presented, the Committee members mostly agreed with the proposed allocation tables. At the time, some members brought up concerns related to how certain heart patients would be addressed through the allocation tables, specifically Fontan, amyloidosis, and single ventricle candidates. The draft public comment response includes a request to MOT that they consider adding adult heart status 4 patients to the proposed allocation tables. Leadership have the chance to review and comment on the draft, after which it will be posted on the OPTN website.

An update was provided about public comment feedback received to date concerning the Committee's "Modify Guidance for Pediatric Heart Exception Requests to Address Temporary MCS Equipment Shortage." Because the guidance update was implemented in June 2025, the feedback is retrospective. Nine responses had been received, all of which were mostly supportive of the change. Consistent with the Board resolution approved in June 2025, the Committee submitted a report to the OPTN Board in September 10, 2025 indicating the device shortage remains recognized on relevant federal lists and recommended maintaining the update, with re-evaluation by December 10, 2025.

Lastly, the Committee was reminded that on September 17, 2025, the changes associated with their "Amend Adult Heart Status 2 Mechanical Device Requirements" would be implemented. The changes were approved by the OPTN Board of Directors in December 2023 but delays in federal review and approval of the data collection changes prevented implementation from occurring sooner. The changes add eligibility requirements to the status 2 criteria for percutaneous endovascular MCSD and IABP by requiring demonstrated failure of inotropic therapy to stabilize cardiogenic shock before device implantation. For extensions, candidates must fail weaning from the device while receiving inotropes. Members reviewed practical questions raised by transplant programs leading up to implementation and clarified that extension decisions must meet the new criteria, even when initial qualification occurred under previous rules. The Committee anticipates an initial increase in exception requests as transplant programs adapt to the new requirements, but it is expected that ultimately the changes will positively impact the use of status 2 exception requests moving forward. Some members noted that initial temporary mechanical support not meeting Status 2 cardiogenic shock criteria does not currently have a direct, non-exception Status 3 pathway. Until policy is updated, programs may need to use exception requests to assign Status 3 in such scenarios.

Next steps:

Members will be kept up=to-date about public comments addressing the Pediatric Heart Guidance update. In the future, monitoring results associated with implementation of the "Amend Adult Heart Status 2 Mechanical Device Requirements" will be shared with the Committee.

2. Request for approval of data request associated with Allocation Out of Sequence and hearts

Because the OPTN's concerns about Allocation Out of Sequence (AOOS) was the major reason for pausing development of continuous distribution (CD) allocation frameworks, the Committee was interested in learning more about the impact AOOS may have on heart allocation.

Summary of discussion:

Decision #1: The Committee decided to pursue an OPTN data request addressing Allocation Out of Sequence (AOOS) and hearts.

The Committee discussed a targeted data request to characterize frequency, context, and outcomes of hearts allocated out of sequence. Preliminary metrics identified by the members for inclusion were: (1) occurrence by year, (2) sequence number at which AOOS begins and classification, and (3) post-transplant survival comparisons for in-sequence versus out-of-sequence placements. Members proposed additional dimensions, such as the feasibility of measuring time from first offer to transplant to identify time-pressure drivers, and anonymized distribution across organ procurement organizations (OPO), including rates relative to total allocations per organization. Other considerations included: multi-organ combinations to identify whether multi-organ logistics correlate with AOOS events and brain death vs. DCD (including NRP considerations) to detect systematic differences.

During the discussion, the Committee was reminded that CD work remains paused to prioritize AOOS issues. The Chair shared that the pause is intended to be measured in months (up to roughly a year), rather than an indefinite delay. Members expressed concern about losing momentum and institutional knowledge if the pause extends.

Next steps:

OPTN contractor staff will draft the data request and share it with Committee leadership for approval before submitting it to HRSA for review.

3. Consideration of Heart Committee project proposals

In light of the OPTN Board of Director's pausing development of continuous distribution allocation frameworks in July 2025, the Committee considered other potential project ideas.

Summary of discussion:

> Decision #1: The Committee identified two project ideas they wish to pursue: (a) Exception policy reform and review board process modernization and (b) Candidate data collection improvements for specific heart diagnoses and populations.

The Committee affirmed two project directions: Exception policy reform and review board process modernization, as well as Candidate data collection improvements for specific cohorts.

Exception policy reform and review board process modernization: The Committee's discussion focused on both the substantive content of exception policies and the operational framework through which exception requests are evaluated and adjudicated. Members acknowledged persistent challenges with the current exception process, including ambiguity in guidance documents, variability in the quality and completeness of the information submitted as part of exception requests, and high rates of approval of such requests by regional review boards.

A central theme of the discussion was the potential transition from regional review boards to a National Heart Review Board (NHRB) for Adults structure. The Committee discussed modeling a NHRB for Adults after the existing National Heart Review Board for Pediatrics. Members noted that the pediatric framework offers enhanced transparency, allowing reviewers to access the full adjudication history of cases and facilitating more consistent decision-making, attributes that are limited or unavailable under the current regional review board model.

The Committee considered the operational implications of such a transition, including the anticipated increase in review volume and the need to ensure timely turnaround of decisions. Data presented indicated that review boards currently process between 800 and 3,900 forms per month. The forms encompass both exception and standard status assignment requests; however, the vast majority of forms are associated with exception requests. Members emphasized that any move to a national model must be accompanied by careful workload management strategies.

The Committee discussed the merits of codifying key guidance elements into OPTN policy. Specifically, the members discussed establishing standards for the level of clinical detail required with each exception request and the timeliness of the clinical details, as well as the criteria for demonstrating medical urgency or similarity to higher-status candidates. Members debated whether certain types of requests should bypass review boards entirely, particularly in cases where eligibility criteria are straightforward and well-defined.

The Committee focused heavily on the idea of implementing a structure using prospective review rather retrospective review for exceptions requests, or some type of hybrid approach. A challenge of the current use of retrospective review is that it can result in candidates being transplanted at a status while awaiting a review board decision, only for that decision to deny the exception request. The Committee considered whether policy changes could mitigate such occurrences by clarifying eligibility and review pathways. There was consensus that moving critical guidance into policy would reduce ambiguity, improve consistency, and empower reviewers to make more definitive determinations.

Members highlighted the importance of understanding the volume and complexity of exception requests to inform the design of the new review board process. The Committee requested detailed data on the number and types of requests, turnaround times, and regional disparities in workload. This information will be used to model the resource requirements for a national review board and to anticipate potential bottlenecks.

Candidate data collection improvements for specific heart diagnoses and populations: The Committee also discussed the potential of enhancing candidate data collection, with particular emphasis on cohorts characterized by complex clinical profiles. The discussion was motivated by recognition that current data elements may not sufficiently capture the clinical details necessary to appropriately assign priority when compared with existing status criteria. Members indicated this is especially the case among patients with congenital heart disease, single-ventricle physiology, and other specialized subgroups. The lack of more granular data about these populations limits the OPTN's ability to monitor their outcomes.

The Committee emphasized that the primary objective is to collect data that directly informs allocation decisions, rather than expanding data collection for research purposes. Members proposed a systematic review of current OPTN data collection instruments to identify areas where additional fields or modifications are warranted. Examples of suggested data elements included:

- Detailed anatomical and physiological descriptors for congenital heart disease (e.g., type of defect, prior surgical interventions, ventricular function metrics)
- Specific markers for single-ventricle patients (e.g., stage of palliation, oxygen saturation levels, history of Fontan procedure)
- Clinical indicators relevant to multi-organ transplantation candidacy (e.g., renal or hepatic function, comorbidities)
- Pediatric-specific metrics, such as growth parameters, echocardiographic findings, and sensitization status

The Committee outlined a multi-step process for advancing data collection improvements. First, members were encouraged to identify and submit discrete data elements that would enhance allocation accuracy for the targeted cohorts. Input from clinicians with direct experience managing these populations was considered especially valuable. OPTN contractor staff would conduct a detailed mapping of collection instruments to determine where new data elements can be integrated, which fields require modification, and which obsolete data elements may be removed. As part of the project, the Committee would solicit feedback from transplant programs, and pediatric and adult cardiology experts to ensure proposed changes are clinically relevant and operationally feasible. The members also recognized that changes to data collection will require review and endorsement from the OPTN Data Advisory Committee and may trigger federal Office of Management and Budget review and approval.

Next steps:

The Committee will pursue the project ideas.

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

Committee leadership shared the upcoming meeting dates with the members and stated that an additional extended October meeting may be scheduled to address the matters of project scoping and AOOS analytics.

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~~
- ~~September 2, 2025 from 4:00 to 5:00 pm~~
- ~~September 16, 2025 from 5:00 to 6:00 pm~~
- October 7, 2025 from 4:00 to 5:00 pm
- October 21, 2025 from 5:00 to 6:00 pm
- November 4, 2025 from 4:00 to 5:00 pm
- November 18, 2025 from 5:00 to 6:00 pm
- December 2, 2025 from 4:00 to 5:00 pm
- December 16, 2025 from 5:00 to 6:00 pm
- January 6, 2026 from 4:00 to 5:00 pm
- January 20, 2026 from 5:00 to 6:00 pm
- February 3, 2026 from 4:00 to 5:00 pm
- February 17, 2026 from 5:00 to 6:00 pm
- March 3, 2026 from 4:00 to 5:00 pm
- March 17, 2026 from 5:00 to 6:00 pm
- April 7, 2026 from 4:00 to 5:00 pm
- April 21, 2026 from 5:00 to 6:00 pm
- May 5, 2026 from 4:00 to 5:00 pm
- May 19, 2026 from 5:00 to 6:00 pm
- June 2, 2026 from 4:00 to 5:00 pm
- June 16, 2026 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
  - J.D. Menteer
  - Hannah Copeland
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Tim Gong
  - Eman Hamad
  - Earl Lovell
  - Cindy Martin
  - Mandy Nathan
  - Jason Smith
  - David Sutcliffe
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Monica Colvin
  - Avery Cook
  - Grace Lyden
- **UNOS Staff**
  - Matt Cafarella
  - Cole Fox
  - Kelsi Lindblad
  - Eric Messick
- **Other Attendees**
  - Shelley Hall