

OPTN Heart Transplantation Committee

Meeting Summary

July 15, 2025

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 07/15/2025 to discuss the following agenda items:

1. Welcome, agenda review, and reminders
2. Other Committee business
3. Next project considerations
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. OPTN contractor staff shared with the members that the target implementation date for the *Amend Adult Heart Status 2 Mechanical Device Requirements* policy changes has been scheduled for mid-September 2025. System notifications will be sent to OPTN members before implementation and the day of implementation. Additionally, the April–June 2025 Heart Review Board report was posted to the Committee's SharePoint site. The report includes data indicating the volume of justification forms submitted, categorized by status, and summary information about how long it took review boards to process exception requests for adult and pediatric candidates. Updates were also provided concerning broader OPTN activities, including HRSA directives and information about the OPTN Board of Directors. The members were reminded of the future Committee meeting dates, and that the next meeting is scheduled for 08/05/2025.

2. Other Committee business

The Committee discussed HRSA's direction to pause work on continuous distribution (CD). Several members expressed deep concerns about the negative impact HRSA's decision might have on adult and pediatric heart candidate safety. The Committee discussed the possibility of drafting a formal letter to the OPTN Board of Directors expressing their concerns and advocating for continued progress in areas uniquely affecting heart candidates.

Summary of discussion:

Decision #1: The members agreed to draft a letter from the Committee to the OPTN Board of Directors expressing their concerns stemming from HRSA's notification that efforts to develop a heart continuous distribution allocation framework are paused until further notice.

The Committee discussed the recent HRSA directive to pause work on CD and identified several key themes and concerns to be included in a formal letter to the OPTN Board. Members expressed deep

concern about the implications of the decision, both for the Committee's ongoing work and for the broader heart transplant community. Members expressed concern over the abrupt halt, citing the significant time and effort invested in CD development and the interdependence of other heart-related policy initiatives on its implementation. Several members emphasized the lack of transparency and communication surrounding HRSA's decision, noting that the current allocation system remains flawed and that CD was intended to address many of its shortcomings. Concerns were raised about the potential loss of institutional knowledge due to normal Committee turnover and the risk of duplicating efforts if CD is resumed in the future. It was noted that the heart transplant population faces distinct challenges compared to other organ groups, particularly in terms of urgency and mortality.

The following points were raised for consideration as part of a Committee letter about the CD pause:

- **Impact on Patients:** Members emphasized that the pause on CD disproportionately affects heart transplant candidates, who face higher urgency and mortality than candidates for other organs. The Committee expressed concern that the delay undermines efforts to improve equity and flexibility in heart allocation.
- **Loss of Progress and Institutional Knowledge:** The Committee noted that years of work and collaboration had gone into developing CD, and that a prolonged pause risks the obsolescence of data, erosion of institutional memory, and duplication of effort if the initiative is resumed in the future.
- **Resource Allocation and Prioritization:** Questions were raised about how resources previously dedicated to CD—particularly those involving MIT and SRTR—would be reallocated. Members requested clarification on whether these resources could be redirected to support alternative projects or whether they were now unavailable.
- **Transparency and Communication:** Several members expressed frustration with the lack of transparency surrounding the decision-making process. Concerns were raised about inconsistent directives, unclear timelines, and the absence of meaningful engagement with the Committee prior to the announcement.
- **Need for Heart-Specific Solutions:** The Committee stressed that policy solutions designed for kidney allocation challenges may not be applicable to heart transplantation. Members urged the Board to recognize the unique clinical and logistical considerations in heart allocation and to avoid one-size-fits-all approaches.
- **Call for Defined Timelines and Shared Accountability:** Members advocated for the establishment of clear expectations and timelines for both Committee work and federal review processes. They emphasized the importance of mutual accountability to ensure that policy development efforts are not indefinitely stalled.
- **Support for High-Priority Populations:** The Committee highlighted the need to address persistent disparities affecting highly sensitized candidates and those with blood type O. Members suggested that these issues be prioritized in future policy development, even in the absence of CD.

Next steps:

Committee leadership indicated that a draft letter would be prepared and shared with the members for feedback.

3. Next project considerations

In light of the CD pause, the Committee reviewed a list of potential projects that had previously been deferred. They also discussed other potential priorities.

Summary of discussion:

No final decisions or actions were made about future projects.

In response to the federal directive pausing work on continuous distribution (CD), the Committee reviewed a list of previously deferred project ideas to identify high-priority initiatives that could be pursued independently of CD. The discussion focused on projects that address pressing clinical and operational challenges, align with HRSA's stated priorities, and could be feasibly implemented within the current policy framework.

The Committee discussed the following project ideas, as well as the advantages, disadvantages, and proposed actions for each:

- **Exception Requests and Review Board Practices:** The Committee identified the growing volume and variability of exception requests—particularly for adult statuses 1 and 2—as a critical issue. Data shared during the meeting indicated that over 60% of adult status 1 and more than 50% of adult status 2 assignments were based on exceptions, with significant variation across transplant programs.
 - Advantages
 - Addresses a major source of allocation inconsistency and potential inequity.
 - Aligns with HRSA's focus on allocation out of sequence (AOOS).
 - Could improve transparency and standardization in exception adjudication.
 - Disadvantages
 - May require significant administrative restructuring.
 - Could face resistance from programs accustomed to current practices.
 - Proposed Actions
 - Explore the creation of a National Heart Review Board for Adults, modeled after the pediatric structure.
 - Consider transitioning from retrospective to prospective review of exception requests.
 - Analyze waitlist mortality among exception vs. non-exception candidates to assess clinical impact.
- **Congenital Heart Disease (CHD) Data Collection:** The Committee emphasized the need for more granular data on CHD patients, particularly those with complex anatomy such as single ventricles, cyanosis, and Fontan physiology. Current data limitations hinder the ability to assess outcomes and develop evidence-based policies for this population.
 - Advantages:
 - Enhances understanding of waitlist and post-transplant outcomes for CHD patients.
 - Supports future policy development tailored to pediatric and adult congenital populations.
 - Disadvantages:
 - Requires updates to data collection infrastructure and forms.
 - May necessitate coordination with other committees and registries.
 - Proposed Actions:

- Initiate a focused data collection project to capture key anatomic and physiologic variables.
 - Collaborate with SRTR and pediatric stakeholders to define data elements.
- **Waitlist Urgency Score Development:** The Committee revisited the concept of developing a model-based urgency score for adult candidates, similar to the MELD score used in liver allocation. SRTR staff confirmed that preliminary work has begun and that HRSA has approved the project for research dissemination.
 - Advantages:
 - Provides a quantitative, objective measure of medical urgency.
 - Could be implemented independently of CD.
 - May reduce reliance on exception requests.
 - Disadvantages:
 - Requires significant statistical modeling and validation.
 - May face scrutiny regarding methodology and clinical applicability.
 - Proposed Actions:
 - Continue collaboration with SRTR to refine the model.
 - Evaluate feasibility of integrating the score into the current classification-based system.
- **Sensitization Policy Enhancements:** Members discussed the limited tools currently available to address sensitization outside of CD. One proposal involved granting additional waiting time to highly sensitized candidates, though concerns were raised about defining sensitization and preventing misuse.
 - Advantages:
 - Could improve access for a historically disadvantaged patient group.
 - May reduce disparities in transplant rates.
 - Disadvantages:
 - Risk of gaming the system without clear, enforceable criteria.
 - Requires redefinition of sensitization thresholds and verification processes.
 - Proposed Actions:
 - Conduct a data analysis of sensitized candidates and outcomes.
 - Develop a standardized method for identifying and verifying sensitization.
- **ABO-Incompatible Transplantation in Adults:** The Committee briefly discussed the potential to expand ABO-incompatible (ABOi) transplantation to adult candidates, building on pediatric experience.
 - Advantages:
 - May increase donor access for select adult candidates.
 - Builds on existing pediatric policy and data.
 - Disadvantages:
 - Limited adult data; potential for increased immunologic risk.
 - Requires careful candidate selection and monitoring.
 - Proposed Actions:
 - Analyze outcomes of pediatric ABOi recipients over age two.
 - Assess feasibility and safety of adult ABOi expansion.
- **Donation After Circulatory Death (DCD) Allocation Practices:** A specific concern was raised regarding DCD donors who progress to brain death. In such cases, the heart is often reallocated via a new match run, potentially disadvantaging the original DCD recipient.
 - Advantages:
 - Promotes fairness and continuity in allocation.

- May reduce logistical disruptions and delays.
- Disadvantages:
 - Requires policy clarification and potential system changes.
 - May raise ethical or procedural concerns.
- Proposed Actions:
 - Evaluate frequency and outcomes of such reallocations.
 - Consider policy language to preserve original DCD allocations when appropriate.
- **Status Time Limits and Reassessment:** The Committee discussed whether candidates assigned to statuses 1 or 2 should be subject to time limits if they do not demonstrate expected mortality risk. This could prevent prolonged high-priority listing for clinically stable patients.
 - Advantages:
 - Encourages appropriate use of high-urgency statuses.
 - May improve access for truly urgent candidates.
 - Disadvantages:
 - Requires clear criteria for reassessment and demotion.
 - May be perceived as punitive or inflexible.
 - Proposed Actions:
 - Analyze duration of status 1 and 2 assignments and associated outcomes.
 - Explore policy options for time-limited assignments with reassessment triggers.

Members agreed that exception requests and review board actions should be prioritized and that the discussions would be continued at the next Committee meeting. There were also questions about how the Committee should approach the next project discussion in light of the directive-related priorities HRSA has identified. It was noted that the Committee should determine the subject matter the members think is most important for future actions.

Next steps:

The Committee agreed to refine this list and prioritize projects based on feasibility, alignment with HRSA directives, and potential impact on patient outcomes. A more developed and narrowed list will be presented at the next meeting. Members were encouraged to submit additional feedback via email.

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 Committee meeting concluded with members reaffirming their commitment to advancing heart transplantation policy despite the current challenges. Committee leadership will circulate a draft sentiment letter to the Committee for review and signature. A refined list of project priorities will be presented at the next meeting. Members were encouraged to submit additional feedback via email.

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
 - Tamas Alexy
 - Maria Avila
 - Jennifer Cowger
 - Kevin Daly
 - Rocky Daly
 - Timothy Gong
 - Eman Hamad
 - Jennifer Hartman
 - Earl Lovell
 - Mandy Nathan
 - Jason Smith
 - David Sutcliffe
 - Dmitry Yaranov
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Yoon Son Ahn
 - Monica Colvin
 - Avery Cook
 - Grace Lyden
- **UNOS Staff**
 - Keighly Bradbrook
 - Matt Cafarella
 - Cole Fox
 - Kelsi Lindblad
 - Eric Messick
 - Laura Schmitt
 - Sara Rose Wells
- **Other Attendees**
 - Shelley Hall
 - John Nigro