

## **OPTN Heart Transplantation Committee**

### **Meeting Summary**

**July 1, 2025**

**Conference Call**

**J.D. Menteer, MD, Chair**

**Hannah Copeland, MD, Vice Chair**

### **Introduction**

The OPTN Heart Transplantation Committee met via WebEx teleconference on 07/01/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. Outcomes associated with 2-Year Monitoring Report of Amend Status Extension Requirements
3. CD: Discuss research questions needed for OASim
4. Open forum
5. Closing remarks

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

### **1. Welcome, reminders, and agenda review**

The meeting commenced with a brief welcome and overview of the agenda by the Chair. The Chair noted that the session would focus on two primary topics: (1) obtaining confirmation of the Committee's sentiments regarding the results of two-year monitoring report associated with the Amend Status Extension Requirements project, and (2) development of research questions to support the upcoming Organ Allocation Simulation (OASim) for continuous distribution (CD).

### **2. Outcomes associated with 2-Year Monitoring Report of Amend Status Extension Requirements**

The monitoring report results were first shared with the Committee members during their 06/17/2025 meeting. Members were asked to confirm their feedback from the 06/17/2025 meeting. The information will be presented to the OPTN Policy Oversight Committee in the future to indicate whether the proposal succeeded in meeting its objectives.

#### Summary of discussion:

The Committee reaffirmed that the changes were successful in achieving their intended goals.

OPTN contractor staff provided a brief summary of the Committee's prior review of the two-year monitoring report. The policy changes were intended to clarify extension criteria and reduce administrative burden. The Committee reaffirmed that the changes were successful in achieving their intended goals. Key indicators of success included a measurable reduction in the number of extension requests submitted and anecdotal reports of fewer misunderstandings regarding extension criteria. No unintended consequences or limitations were identified. The Committee agreed that no further action was necessary.

#### Next steps:

OPTN contractor staff will present the monitoring results to the Policy Oversight Committee (POC) in late summer or early fall. The POC will issue a formal memo summarizing their feedback, which will be shared with the Heart Committee.

### **3. CD: Discuss research questions needed for OASim**

The Committee focused on identifying key metrics and subgroups to evaluate the impact of CD policies. The SRTR contractor explained the simulation's capabilities and limitations, emphasizing the importance of defining high-level research questions early to ensure accurate modeling. The Committee proposed several metrics and members agreed to collaboratively refine these questions in a shared document ahead of the next meeting.

#### Summary of discussion:

No decisions were made as part of this agenda item.
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The Committee initiated a detailed discussion to identify research questions for the upcoming OASim modeling. SRTR contractor staff provided an overview of the simulation process, emphasizing that the simulation would use historical donor and candidate data to model outcomes under proposed CD policies. The simulation aims to estimate changes in transplant rates, waitlist mortality, post-transplant outcomes, and allocation efficiency.

Key distinctions between OASim and the match run analyses the Committee has been working with were highlighted:

- OASim simulates the full allocation process, including listing, delisting, offer acceptance, and post-transplant outcomes
- The simulation uses real historical donors and candidates but applies new allocation rules to estimate counterfactual outcomes
- Offer acceptance and post-transplant survival are modeled using predictive algorithms trained on historical data

Committee members were encouraged to consider what metrics would be most informative in evaluating the impact of CD. Suggested metrics included:

- Waitlist mortality and transplant rates, stratified by urgency, age, and weight
- Distance traveled for organ offers, particularly in relation to urgency levels
- Sequence number of accepted offers as a proxy for allocation efficiency
- Utilization rates of donor hearts, with attention to potential changes under CD
- Disparities in access to transplant, including pediatric and highly sensitized candidates
- Impact of recipient characteristics such as BMI, predicted heart mass, and weight

The members were also encouraged to consider subgroups within the metrics they would want additional information about, including pediatric subgroups by age, such as birth to two years old, three to 11 years old, and 12 to 18 years old. Other potential sub-groups for consideration included: candidate weight, predicted heart mass, blood type, and sensitization status. Donor characteristics of interest were: DCD versus DBD, and donor-recipient size matching.

The Committee discussed the importance of defining urgency groups using percentage-based thresholds rather than current status labels. There was consensus that stratifying urgency into ranges (e.g., <40%, 40–70%, >70%) would be more meaningful for simulation purposes.

After discussing the metrics and sub-groups for observation, concerns were raised about the potential for CD to unintentionally disadvantage certain populations, such as small or large recipients, or those with unique sensitization profiles. Members emphasized the need to evaluate whether CD policies would exacerbate or mitigate existing disparities.

The Committee also discussed the limitations of modeling hospital days, noting that inpatient status is only indirectly captured through urgency criteria. It was acknowledged that while exact hospitalization duration is not available, proxy measures may be used to estimate inpatient burden.

Members were encouraged to review the Liver Committee's finalized research questions, available on the SharePoint site, as a reference for their own work.

#### Next steps:

OPTN contractor staff will create a shared document and post it the Committee's SharePoint site to collect and refine proposed research questions and subgroup definitions. Committee members will contribute to the document asynchronously prior to the next meeting. At their 07/15/2025 meeting, the Committee will review and finalize the list of research questions to be submitted to the SRTR contractor for simulation modeling. The SRTR contractor will use the finalized questions to develop an analysis plan and validate the simulation model.

#### **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 briefly discussed concerns regarding the future of the CD project in light of recent budgetary developments. While the FY2026 budget did not include cuts to ongoing projects, its implementation is contingent upon approval of a \$48 registration fee increase by the Secretary of Health and Human Services. Previous requests for fee increases have been denied, and HRSA representatives did not commit to supporting the current request. The Chair and others will continue to monitor developments related to the OPTN budget and CD project prioritization and consider contingency planning if necessary.

#### **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
  - Tamas Alexy
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Earl Lovell
  - Cindy Martin
  - Mandy Nathan
  - David Sutcliffe
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Avery Cook
  - Grace Lyden
  - Tim Weaver
  - Nick Wood
- **UNOS Staff**
  - Keighly Bradbrook
  - Matt Cafarella
  - Cole Fox
  - Kelsi Lindblad
  - Eric Messick
  - Laura Schmitt
  - Kaitlin Swanner
- **Other Attendees**
  - Thomas Athey
  - Eli Pivo