

OPTN Heart Transplantation Committee

Meeting Summary

August 19, 2025

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee (Committee) met via WebEx teleconference on 08/19/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. Other Committee business
3. Next project consideration: Developing a Heart waitlist mortality score and Committee discussion
4. Open forum
5. Closing remarks

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

1. Welcome, agenda review, and announcements

The meeting commenced with a review of the agenda and confirmation of attendance.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair welcomed the members and the meeting commenced with confirmation of attendance and a review of the agenda.

Next steps:

Members were reminded about the schedule of future Committee meetings.

2. Other Committee business

The OPTN contractor provided information about the OPTN public comment cycle and OPTN regional meeting schedule.

Summary of discussion:

No decisions were made as part of this agenda item.

Members were informed about the upcoming OPTN public comment period, scheduled to begin on 08/27/2025 and to conclude on 10/01/2025. The Committee was also briefed on current OPTN directives from the Health Resources and Services Administration (HRSA).

Next steps:

OPTN contractor staff stated that they will keep the Committee updated regarding public comments received for the Committee's pediatric guidance update.

3. Next project consideration: Developing a Heart waitlist mortality score and Committee discussion

The primary focus of the meeting was a presentation and discussion regarding the development of a heart waitlist mortality score and its potential for improving the existing heart allocation framework.

Summary of discussion:

No decisions were made as part of this agenda item.

The Committee received a presentation from SRTR contractor staff regarding the development of a new heart waitlist mortality risk score, referred to as the United States Candidate Risk Score (U.S. CRS 2.0).

The risk score was made possible by the availability of new clinical lab data following the heart allocation changes implemented in October 2018. The SRTR contractor's presentation detailed the evolution from the original candidate risk score to a revised model incorporating a broader cohort and a composite outcome of death or removal for deteriorated condition within six weeks. The updated model leverages time-varying data, including laboratory values and heart support device variables, with biweekly updates to reflect changes in clinical status. Device variables, such as durable ventricular assist devices (VAD), extracorporeal mechanical oxygenation ECMO), Impellas, and intra-aortic balloon pump (IABP), were defined with specific criteria for inclusion in the model.

The analysis identified several heart support devices as significant predictors of waitlist mortality. The duration of device support was also found to influence survival probability, with longer support correlating with increased risk of death or removal from the waitlist over time. Interactions between device use and laboratory values revealed that certain lab values have distinct prognostic implications depending on device status.

The SRTR contractor shared that validation of the waitlist risk model included assessments of how well the model performed under different scenarios and how well calibrated it was when evaluated both overall and by status. The U.S. CRS 2.0 consistently outperformed the OPTN's existing six-status heart allocation framework in risk discrimination and provided accurate predictions for most candidate groups. Calibration analysis revealed some discrepancies, particularly for candidates qualifying by exception under status two, suggesting areas for further refinement.

The Committee members discussed potential for diagnosis-specific adjustments and the inclusion of subpopulations, such as congenital heart disease patients and hypertrophic cardiomyopathy patients. The possibility of integrating the proposed model as a component of a standard heart exception system was also discussed. Concerns were raised about the impact of the model's use of informative censoring, particularly for candidates receiving transplants at higher urgency statuses. SRTR contractor staff discussed the use of inverse probability of censoring weights as a methodological approach to address this issue.

The presenter illustrated how the proposed risk score could be operationalized within allocation policy. The analysis demonstrated that a risk score-based system would more effectively prioritize medically

urgent candidates, with minimal impact on organ travel distance. The Committee was encouraged to reflect on the approach and prepare for further discussion at the next meeting.

Next steps:

The Committee members agreed to continue evaluating the risk score model and to consider further refinement. Members were encouraged to reflect on the approach and share feedback at an upcoming meeting.

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 Chair concluded the meeting by thanking the Committee and the SRTR contractor staff for their presentation.

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
 - Timothy Gong
 - Earl Lovell
 - Cindy Martin
 - Mandy Nathan
 - David Sutcliffe
 - Dmitry Yaranov
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Monica Colvin
 - Avery Cook
 - Grace Lyden
 - Molly White
- **UNOS Staff**
 - Tory Boffo
 - Matt Cafarella
 - Cole Fox
 - Eric Messick
 - Kelsi Lindblad
 - Sara Rose Wells
- **Other Attendees**
 - Sommer Gentry
 - Shelley Hall
 - Will Parker