OPTN Heart Transplantation Committee
Meeting Summary
September 2, 2025
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 09/02/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. OPTN Operations and Safety Committee project update, *Re-Evaluation of Deceased Donor Testing Requirements* and changes to the troponin data element
3. OPTN Multi-Organ Transplantation (MOT) Committee public comment presentation, *Establish Comprehensive Multi-Organ Allocation*
4. Revisiting 09/19 discussion of U.S. CRS and waitlist mortality models
5. Open forum
6. Closing remarks

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

1. Welcome, agenda review, and announcements

The Chair welcomed the members and reminded them that the meeting had been extended by 30 minutes in order to accommodate the work the Committee needs to get through. Members were informed that the meeting was being recorded and there was a review of the agenda items and the time allocated for each discussion. The meeting agenda was reviewed. Announcements included the start of the public comment period on 08/27/2025, with regional meetings scheduled through 10/01/2025. Members were reminded of the importance of letting the Chair know if they had joined by phone.

2. OPTN Operations and Safety Committee project update, *Re-Evaluation of Deceased Donor Testing Requirements* and changes to the troponin data element

The Committee received a presentation from the OPTN Operations and Safety Committee (OSC) regarding the OSC's project addressing the ongoing reevaluation of deceased donor testing requirements, focusing on OPTN *Policy 2.11.C: Required Information for Deceased Heart Donors*. The presentation was given by a Heart Committee member who has volunteered to be part of the OSC workgroup pursuing the project.

Summary of discussion:

Decision #1: The Committee agreed to recommend to the OPTN Operations and Safety Committee that arterial blood gas results and ventilator settings should become system requirements, but remain as policy requirements, to avoid unnecessary delays in match runs.

Decision #2: The Committee agreed to recommend to the OPTN Operations and Safety Committee that with regards to troponin data collection, a mandatory dropdown menu for units (nanograms per milliliter or nanograms per liter) should be created, including a "high sensitivity" label for clarity.

It was stated that the OSC project has identified persistent challenges faced by Organ Procurement Organizations (OPOs) in obtaining required testing data for all deceased donor heart offers. The presenter pointed out that this is pertinent when it comes to heart angiogram troponin. The presenter added that heart transplant programs frequently need to request additional testing information from the OPOs, resulting in lengthy discussions between both sides concerning which tests are acceptable and can be performed. The challenges often result in delays and extended negotiations between OPOs and transplant centers regarding acceptable testing protocols. The project is focused on several areas. An area of review is the assessment of current risk evaluation policies, infectious disease testing, and donor-specific testing requirements. Another area the OSC workgroup is addressing is the finalization of modifications to policy language and OPTN Computer System requirements. It was said that the workgroup is likely to produce recommendations for updates to guidance documents and data collection practices.

The Workgroup has identified multiple recommendations that they wanted shared with the Committee. These include removal of outdated policy language regarding additional testing. They also include elimination of the twelve-lead specification from the electrocardiogram (ECG) requirement. This would be replaced by a mandate to upload actual ECG imaging for all deceased donor heart offers to the OPTN Donor Data and Matching System (also referred to DonorNet®), ensuring accessibility for all transplant centers. The Workgroup is also recommending the introduction of explicit requirements for reporting troponin values, including the upper normal limit for each test, to address variability in cutoff values across procurement sites. The presenter said that individual OPOs and procurement sites use different troponin cut-off values and that it is very difficult for the transplant program to understand the values without knowing what is the cut-off value. For potential deceased donors aged 35 or older, a coronary angiogram with right heart catheterization is recommended, with complete hemodynamic data provided when available. This includes central venous pressure, pulmonary artery pressures, wedge pressure, cardiac output, and cardiac index. Additionally, serial troponin measurements and relevant cardiac enzyme panels (CPK, CKMB) should be uploaded when available. The presenter said that the coronary angiogram recommendation might not be as useful to the heart community because most hearts are imaged in high resolution or the angiograms are done at standard resolution.

The Committee members discussed whether arterial blood gas (ABG) and ventilator settings should be a OPTN system requirement for heart donors, as the settings are for lung donors. OPTN contractor staff stated that if this became a system requirement, then the information would need to be document in the system before an electronic notification of the match run could be sent. The consensus was that, while useful, these data should remain a policy requirement rather than a system requirement, to avoid unnecessary delays in match runs. OPTN contractor staff confirmed the OSC Workgroup will recommend not including it as a system requirement and that it will remain as a policy requirement.

There was also agreement among the Committee members that the workgroup should recommend maintaining current practices, allowing transplant centers to request additional information as needed. The discussion also addressed the need for standardized units in troponin reporting, with a proposal to implement a mandatory dropdown menu for units (nanograms per milliliter or nanograms per liter), including a "high sensitivity" label for clarity.

OPTN contractor staff supporting the project said that OSC's next steps involve outreach to and further review from other OPTN committees, with the goal of finalizing policy language for public comment in

January 2026. The Chair thanked the Heart Committee member and OPTN contractor staff for the presentation and the discussion.

Next steps:

The Committee will look towards release of the proposed policy and data collection changes as part of the January 2026 public comment cycle.

3. OPTN Multi-Organ Transplantation (MOT) Committee public comment presentation, *Establish Comprehensive Multi-Organ Allocation*

The Vice Chair of the OPTN Multi-Organ Transplantation Committee (MOT) presented the public comment proposal, *Establish Comprehensive Multi-Organ Allocation*. The Committee members indicated their support of the proposal, but agreed to recommend in their formal response that adult heart status 4 candidates should be included in the proposed allocation tables.

Summary of discussion:

> Decision #1: The Committee's formal response concerning the proposal will recommend that adult status 4 heart candidates be referenced in the proposed multi-organ allocation tables, even if such candidates are identified near the end of the tables.

The Committee received a detailed presentation on the MOT Committee's public comment proposal to establish a comprehensive multi-organ allocation policy. The proposal aims to standardize the allocation order for multiple organs from a single donor. Primary goals of the proposal include improving equity, consistency, and transparency in multi-organ transplantation.

According to the MOT Vice Chair, the proposed policy would direct allocation across multiple match runs using standardized tables based on medical urgency and unique recipient populations. The proposed changes would also remove certain priorities for kidney multi-organ candidates to ensure high-priority single-organ candidates retain access. The changes would also clarify which organs follow others in multi-organ offers, including the implementation of with binary "must" or "must not" allocation rules replacing current "permissible" practices. The proposal relies on IT support to generate multi-organ allocation plans for OPOs, dictating the order of offers and eligibility criteria.

The presentation included analysis of historic data, indicating that the proposed tables would cover approximately 80% of deceased donor match runs and multi-organ recipients. Seven donor types were identified, collectively accounting for nearly all multi-organ transplants. The MOT Committee acknowledged limitations in modeling the impact of these changes and acknowledged the importance that post-implementation monitoring will have in identifying successes and challenges.

A Heart Committee member who assisted with development of the MOT allocation tables said that a lot of effort had gone into comparing the medical urgency of the organs and reflecting those urgencies in the prioritization. The member said that one concern for consideration is whether an adult status 4 candidate who also needs a liver, would have a legitimate chance at receiving a liver under the proposed allocation tables. This might be especially true to the single ventricle heart candidates who need a heart-liver. A Committee member said that such candidates are already face challenges because their liver disease is very different. In addition, some sub-populations of heart candidates will have to start waiting in the hospital.

Committee discussion focused on several implications that could potentially result from implementation of the proposal. The members raised questions about the impact for heart-liver and heart-kidney

candidates as they appear on the proposed allocation tables. The potential for requiring certain adult heart status 4 candidates to transition from out-patient to in-patient and also experience increased waiting times as in-patients was another concern expressed by the members. They said that such a change would require an increased need to monitor the specific subgroups most impacted. In light of the acknowledged limitations, Heart Committee members emphasized the need for post-implementation monitoring, particularly for vulnerable populations such as single ventricle patients, such as Fontan patients, and those with amyloidosis.

There was consensus that status 4 heart candidates should be included in allocation tables, at least at the lowest priority, to ensure transparency and equity. The Committee recognized that further data analysis may be required, and that changes to the tables could impact the policy timeline. The public comment period was noted to end on 10/01/2025, which limits additional opportunities for the Committee to discuss the public comment proposal before their formal feedback response must be submitted.

Next steps:

OPTN Contractor staff stated that they would draft an initial Committee response and share it with Committee leadership. Leadership can then share a revised version with the Committee for consideration during the next meeting. Because of the short turnaround time, the Chair asked the members to submit any additional comments or concerns about the MOT proposal as soon as possible.

4. Revisiting 09/19 discussion of U.S. CRS and waitlist mortality models

The Committee discussed the advantages and disadvantages they see associated with developing and incorporating the waitlist risk score in current heart allocation policy.

Summary of discussion:

Decision #1: The Committee decided to continue exploring opportunities to learn more about how the U.S. CRS 2.0 could be used in the future as a tool to improve allocation policy.

The Committee revisited prior discussions on the U.S. CRS and waitlist mortality models. The Chair introduced the topic by stating that at question is whether the U.S. CRS is sufficiently developed for incorporating into existing heart allocation policy or is it still an ill-fit with the current policy priorities and should be tabled until after continuous distribution or another policy cycle?

The Committee members discussed a range of topics associated with heart allocation policy, the U.S. CRS and waitlist mortality models generally, and the pause on the Committee's development of a continuous distribution allocation framework that started in July 2025. A primary point of discussion involved the concerns the Committee and the heart community have regarding the impact that status exception requests continue to have on the heart allocation system. It was mentioned that the complexity of the current status-based system has a role in generating exception requests. There is the potential utility of the CRS in assessing exception requests and informing review board decisions. Members and other meeting attendees also discussed the possibility of piloting CRS calculations using existing data systems, with iterative feedback and education for clinicians. Finally, the need to balance exception mitigation with broader allocation system reforms was also discussed.

The Chair stated that a real challenge will be developing the U.S. CRS, or any waitlist risk score, into a more comprehensive and actional allocation scheme, that incorporates distance, blood type, sensitization, and access to care without it looking too much like continuous distribution. If the

Committee produces a project that looks too much like CD, the Chair stated, that could lead to pushback from the Policy Oversight Committee and/or the Executive Committee. Some members indicated that the Committee's efforts would be better prioritized addressing the use of exception requests and review board practices. A Committee member made the argument that applying the waitlist risk model in the context of exception requests would give the heart community some sense of how the model performs or underperforms. SRTR contractor staff talked about how liver allocation policy employs a risk score to groups of candidates, which them allows rank ordering to occur within those groups based on attributes like waiting time. And that would still be fully like a classification-based system. It was also mentioned that the issues with heart exceptions are the result of the current allocation system's use of statuses and being too complex.

There was general support for embedding the CRS into exception mitigation strategies and review board processes, with a gradual approach to broader implementation. The Committee agreed to continue exploring the integration of CRS into regular practice and to address exception issues in parallel. Suggestions included calculating CRS for all listed patients, monitoring outcomes, and considering the use of CRS in national review board processes. The Committee expressed enthusiasm for making CRS a regular part of practice, while acknowledging the need for further data analysis and stakeholder education.

Next steps:

The Committee will discuss opportunities to incorporate the U.S. CRS 2.0 into the exception process to potentially assist reviewers with their decision-making.

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

The meeting concluded with reminders of upcoming meetings and acknowledgment of productive discussion. The Committee expressed its intent to continue work on the identified projects, with attention to policy development timelines and stakeholder feedback.

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
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Eman Hamad
  - Earl Lovell
  - Cindy Martin
  - Mandy Nathan
  - Jason Smith
  - David Sutcliffe
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Avery Cook
  - Grace Lyden
  - Molly White
- **UNOS Staff**
  - Matt Cafarella
  - Cole Fox
  - Kelsi Lindblad
  - Eric Messick
  - Sarah Roache
  - Kaitlin Swanner
  - Stryker-Ann Vosteen
  - Sara Rose Wells
  - Joann White
- **Other Attendees**
  - Shelley Hall
  - Will Parker
  - Chris Sonnenday