OPTN Heart Transplantation Committee
Meeting Summary
May 20, 2025
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 05/20/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. CD: Review next waiting time scenario for match run analysis
3. CD: Incorporating new data collection and revising heart review board processes as part of ongoing CD framework development
4. Pediatric Mechanical Circulatory Support (MCS) Equipment Shortage
5. Open forum
6. Closing remarks

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

1. Welcome, reminders, and agenda review

The Chair welcomed the Committee members and asked the OPTN contractor to provide an overview of the agenda. The contractor stated that there would be two updates related to the Committee's continuous distribution (CD) activities. The first update would address how the Committee might be able to include a match run analysis scenario more closely reflecting the waiting time rating scale the members have been developing than what was submitted for the first scenario. The other update involved revisiting a previous Committee discussion about potential project work associated with CD.

During this part of the meeting, the OPTN contractor informed the members that the OPTN Lung Transplantation Committee's (Lung) two-year monitoring report associated with CD implementation had been recently released. The Chair and contractor provided some of the high-level results from the monitoring report. For example, monitoring results indicate that the transplant rate increased by almost a third when comparing the pre- and post-implementation monitoring periods. In addition, waiting list mortality decreased by slightly more than a third. The monitoring results also suggest no significant change in the probability of patient survival one year after transplant, and also that the utilization rate has increased for both DCD and non-DCD donors. The Chair applauded the success of Lung's CD allocation policy. A meeting participant suggested that some of the growth experienced through lung CD is the result of DCD growth. The Chair agreed that DCD growth is likely a component but also stated that the combination of the four overall findings was a positive outcome.

The members were also told about the Lung Monitoring dashboard. The dashboard provides the public with functionality and tools to make their own comparisons about pre- and post-implementation lung CD changes.

The OPTN contractor also mentioned that members should expect to receive the next round of Committee meeting invitations soon. The invites will be for the July 2025 – June 2026 Committee term.

The contractor also told the members that the OPTN Board of Directors (BOD) was scheduled to meet on 06/09/2025 and 06/10/2025, and that the BOD would be reviewing for approval, the Committee's *Escalation of Status for Time on Left Ventricular Assist Device* proposal.

Next steps:

The Committee members were provided with hyperlinks to the two-year Lung CD monitoring report and the Lung CD dashboard.

2. CD: Review next waiting time scenario for match run analysis

The Chair provided an overview of a waiting time attribute scenario for potential inclusion in the match run analyses being performed by the SRTR contractor. In particular, the approach is intended to address how waiting time and medical priority might interact within CD. This waiting time scenario aligns more closely with the waiting time rating scale the Committee has been developing than the waiting time scenario included in the initial match run analysis.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair identified a few objectives associated with the scenario. For example, a Committee goal has been for very high urgency pediatric candidates to be able to accrue waiting time for a very long time. The proposed rating scale aims to balance fairness and clinical urgency, particularly for pediatric candidates with extended inpatient stays. The scenario attempts to strike that balance by ensuring long-term inpatients accrue 'meaningful' waiting time and preventing lower-acuity patients from overtaking high-urgency patients, in terms of priority.

As part of the initial match run analyses, the weight assigned to medical urgency also ended up accounting for any weight that would have been assigned to an LVAD waiting time attribute. There were concerns that such an approach would result in too much prioritization being given to candidates based on the medical urgency component. For instance, LVAD support duration could end up having greater priority than some of the clinical criteria. The Chair indicated that the waiting time scenario being described in this meeting will lead to a more nuanced, urgency-weighted calculation.

The new scenario intends to index waiting time based on historical medical urgency as well as current medical urgency. In terms of historical medical urgency, each day a candidate spends on the waiting list contributes to their waiting time score. However, the contribution is scaled by the urgency level on that day. For example, a candidate waiting as an outpatient with low urgency accrues fewer points than one hospitalized with high urgency. The total accrued waiting time is then adjusted based on the candidate's current urgency level. If a candidate's urgency decreases from 60% priority to 40%, then their waiting time score is proportionally reduced. However, if their urgency increases again, previously accrued points are partially restored. The Chair described the scenario as rewarding long-term, high urgency waiting while limiting the advantage provided to lower-acuity candidates through waiting time.

The Chair explained why it is so important to develop a waiting time rating scale that allows high urgency candidates to accrue priority points, especially important for pediatric patients who are waiting in the hospital for a year or two at a time. In those cases, even pediatric candidates who are assigned to one of the less medically urgency status 1A criteria are still likely to remain an inpatient until they either get transplanted or are removed from the waitlist as a result of being too sick to transplant or death. According to the Chair, such pediatric candidates must have some hope that they are maintaining and/or

increasing their priority on the waiting list. The Chair added that such candidates should not be de-prioritized on the waiting list because a pediatric patient with an implanted VAD is added to the waitlist, even though the VAD patient has been waiting for less time. To accomplish this, the Chair said there needs to be a mechanism by which candidates can actually move from the less medically urgent status 1A criteria towards what will eventually be the greater amount of priority assigned to the higher end of the status 1A criteria. According to the Chair, without such a mechanism, the potential exists for some status 1A candidates to live for five years as inpatients on inotropes while never getting transplanted because the individual status 1A criteria are separated by too many point variations within the medical urgency rating scale, which would prevent a long-waiting candidate from accruing enough medical urgency points.

Following the overview, Committee members had several questions. A Committee member suggested that there might be an issue involving the transition of candidates if and when the proposed waiting time scenario would be implemented. The member stated that at the time of implementation, status 1B pediatric candidates who have waited a long time would be eligible for a lot of additional waiting time priority points and might overtake existing status 1A candidates, as a result. The Chair responded that the Committee will need to account for potential outcomes like the one suggested when they develop a more detailed assignment of priority for each pediatric and adult criteria. Concerns were expressed that candidates could "store" waiting time points during periods of high urgency and later benefit from them at lower urgency. However, the formula's proportional adjustment mechanism is designed to mitigate this risk. Members suggested running sensitivity analyses to evaluate how the new scenario might impact different patient groups, particularly those who have waited for long periods of time at status 1B. The Committee members emphasized the importance of ensuring that long-waiting, high-urgency patients—especially pediatric candidates—are not disadvantaged by the proposed rating scale. The revised rating scale is intended to provide a path for these patients to move up the list over time, even if they are not at the highest urgency level.

Next steps:

The Committee agreed to submit the new waiting time scenario for inclusion with the next match run analysis performed by the SRTR contractor. The analysis might help determine whether the issues identified with the initial match run analysis were a function of the large weight assigned to medical urgency swamping any effect associated with waiting time, and whether further adjustments are needed.

3. CD: Incorporating new data collection and revising heart review board processes as part of ongoing CD framework development

During the Committee's 05/06/2025 meeting, the Committee considered whether to undertake two new projects associated with CD but to complete and implement the work prior to the implementation of CD. After additional discussion, the Committee rejected the idea of working on the projects outside of CD and instead agreed to incorporate them into the on-going development of the CD allocation framework.

Summary of discussion:

Decision #1: The Committee agreed to undertake this work as part of their on-going CD effort.

One of the projects consisted of collecting additional clinical data to support the components of CD. The identified data collecting more granular information about congenital heart disease, whether a heart

candidate was a prior living donor, whether a pediatric candidate was supported by ECMO therapy, and other variables necessary to accurately calculate a composite allocation score. The other potential project was associated with a MPSC referral regarding the heart review board's authority and processes. Particularly, the MPSC referral questioned the review board's and the Committee's ability to take action in circumstances when a transplant program transplants a candidate at a denied status.

The Committee acknowledged that both the data collection and review board process changes are essential to the success of the CD framework. As such, they will be developed and finalized as part of the broader CD proposal submitted for OPTN Board approval.

Coordination with the MPSC will be pursued to clarify roles and responsibilities related to denied status decisions and potential policy changes.

Importantly, the data reporting components may be implemented ahead of the full CD policy to allow for early adoption and system readiness. The Committee agreed that these data fields must be available in advance of CD implementation to allow transplant programs sufficient time to enter patient information. This pre-implementation data entry period will ensure that CAS calculations are accurate and complete on the go-live date, avoiding any lag or disruption in allocation. This phased approach will help ensure a smooth transition and minimize operational disruptions for transplant centers. This approach mirrors the strategy used during the 2018 overhaul of adult heart allocation policy, where programs were given a preparatory window to input new data elements prior to policy activation.

The Committee identified the following reasons for addressing these efforts as part of CD:

- Avoid delays or rejections from the Policy Oversight Committee in terms of obtaining project approval
- Ensure critical data (e.g., congenital heart disease granularity, prior living donor status) is available at CD implementation
- Allow early data entry by transplant programs to support accurate Composite Allocation Scores at go-live

Next steps:

The Committee will address the topics as they continue developing the CD allocation framework.

4. Pediatric Mechanical Circulatory Support (MCS) Equipment Shortage

The Committee held a focused and urgent discussion regarding a critical shortage of the only durable ventricular assist device (VAD) available to provide pediatric candidates with mechanical circulatory support (MCS).

Summary of discussion:

> Decision #1: The Committee agreed that action is needed to address the access issues faced by certain pediatric heart candidates. The Chair will draft an update to the pediatric guidance document identifying the circumstances under which exception reviewers should consider granting status 1A exception requests. The draft will be shared with the Committee members.

Only one durable VAD is available for treating small pediatric candidates, especially pediatric candidates with dilated cardiomyopathy. For such pediatric candidates who weigh 10 kilograms (kg) or more and who fail inotropic support, the primary therapy is VAD implant. However, a current shortage of the

devices, supplies, and support equipment has limited pediatric candidates' access to the therapy. Moreover, current pediatric heart guidance does not provide a pathway to status 1A by exception for such candidates under shortage circumstances.

The Committee discussed the implications of this shortage on the pediatric patient population. Committee members estimated that between 30 and 50 pediatric candidates need VADs now, while a total of 50 to 100 pediatric patients per year could be affected by the shortage. A Committee member added that this number could rise depending on how transplant programs respond to the shortage and whether exceptions become a more widely used alternative to VAD implantation.

Under current OPTN policy and review board guidance:

- Pediatric patients with dilated cardiomyopathy on high-dose inotropes typically qualify for Status 1B.
- To escalate to Status 1A, these patients must meet additional criteria, such as being on a ventilator, ECMO, or having a VAD in place.
- Exceptions are available for patients under 5 kg or under 10 kg with specific clinical indicators, but for patients above 10 kg, the expectation is that a VAD will be used.

Given the current equipment shortage, many patients who would otherwise receive a VAD cannot do so, potentially delaying or preventing their escalation to Status 1A. This raises significant equity concerns and could lead to increased waitlist mortality among this vulnerable population.

The Committee broadly agreed that immediate action is needed to address this issue. The Chair discussed drafting a guidance update that could address the exception issue. The members added that without uniform guidance for the representatives serving on the National Heart Review Board (NHRB) for Pediatrics to consider, such cases might be reviewed inconsistently resulting in some exception requests being approved while others are denied. The Committee felt strongly that any update should only be available during the shortage and that precautions should be taken, if possible, to avoid unintended consequences.

Next steps:

The Chair will draft a potential update to the pediatric guidance document and share it with the Committee for discussion at the next meeting, which is scheduled for 06/03/2025.

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 Chair thanked the members for attending and reminded them that the next Committee meeting is scheduled for 06/03/2025 starting at 4:00 pm (ET).

Upcoming Meetings

- ~~July 2, 2024 from 4:00 to 5:30 pm~~
- ~~July 16, 2024 from 5:00 to 6:00 pm~~

- ~~August 7, 2024 from 4:00 to 5:00 pm~~
- ~~August 20, 2024 from 5:00 to 6:00 pm~~
- ~~September 4, 2024 from 4:00 to 5:00 pm~~
- ~~September 17, 2024 from 5:00 to 6:00 pm~~
- ~~October 2, 2024 from 4:00 to 5:00 pm~~
- ~~October 9, 2024 from 9:00 am to 4:00 pm (In-person meeting, Detroit, MI)~~
- ~~October 15, 2024 from 5:00 to 6:00 pm~~
- ~~November 6, 2024 from 4:00 to 5:00 pm~~
- ~~November 19, 2024 from 5:00 to 6:00 pm~~
- ~~December 4, 2024 from 4:00 to 5:00 pm~~
- ~~December 17, 2024 from 5:00 to 6:00 pm~~
- ~~January 1, 2025 from 4:00 to 5:00 pm~~
- ~~January 21, 2025 from 5:00 to 6:00 pm~~
- ~~February 4, 2025 from 4:00 to 5:00 pm~~
- ~~February 18, 2025 from 5:00 to 6:00 pm~~
- ~~March 4, 2025 from 4:00 to 5:00 pm~~
- ~~March 18, 2025 from 5:00 to 6:00 pm~~
- ~~April 1, 2025 from 4:00 to 5:00 pm~~
- ~~April 15, 2025 from 5:00 to 6:00 pm – Cancelled~~
- ~~April 18, 2025 from 11:00 am to 4:00 pm~~
- ~~May 6, 2025 from 4:00 to 5:00 pm~~
- ~~May 20, 2025 from 5:00 to 6:00 pm~~
- June 3, 2025 from 4:00 to 5:00 pm
- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
  - J.D. Menteer
  - Hannah Copeland
  - Tamas Alexy
  - Maria Avila
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Eman Hamad
  - Earl Lovell
  - Mandy Nathan
  - John Nigro
  - Jason Smith
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Avery Cook
  - Grace Lyden
  - Nick Wood
- **UNOS Staff**
  - Keighly Bradbrook
  - Cole Fox
  - Kelsi Lindblad
  - Eric Messick
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall