OPTN Heart Transplantation Committee
Meeting Summary
April 18, 2025
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 04/18/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. Committee work: Review public comment analysis document and consider policy changes regarding *Escalation of Status for Time on Left Ventricular Assist Device* project
3. CD: Continue review and discussion of match run analysis results from 04/01/2025 Committee meeting
4. Committee work: Final vote on proposed policy language for *Escalation of Status for Time on Left Ventricular Assist Device* project
5. Status Update: Comprehensive Multi-Organ Allocation Policy
6. Presentation of 12-month monitoring results associated with *Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates*
7. Presentation of 12-month monitoring report associated with *Report Primary Graft Dysfunction in Heart Transplant Recipients*
8. Discuss email to Committee about Fontan recipients
9. Open forum
10. Closing remarks

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

1. Welcome, reminders, and agenda review

The Chair began the meeting by welcoming the members and providing an overview of the day's agenda. The Chair emphasized the importance of the topics to be discussed and encouraged active participation from all members. The agenda included discussions on public comments, continuous distribution (CD) match run analysis, updates on multi-organ allocation policies, and monitoring reports.

2. Committee work: Review public comment analysis document and consider policy changes regarding *Escalation of Status for Time on Left Ventricular Assist Device* project

The Committee reviewed final public comments on the escalation of status for LVAD patients.

Summary of discussion:

No decisions were made as part of this agenda item.

The discussion emphasized the importance of timely access to transplants for LVAD patients to improve their quality of life and post-transplant outcomes. The Committee considered public feedback, which suggested shorter eligibility time frames based on clinical realities and increased risk of complications. The goal is to ensure equitable and timely access to transplants for LVAD patients.

The Committee reviewed the public comments received for the *Escalation of Status for Time on LVAD* project. The project aims to address the concern about status 4 candidates with implanted dischargeable LVADs not getting transplanted. The heart community has been concerned about such candidates because analyses indicate that survival rates on the waiting list decrease the longer a device remains implanted. The proposed solution is to provide additional priority to candidates with dischargeable LVADs based on having a device implanted for six or eight years.

A total of 172 comments were received, including feedback from regional meetings, OPTN committees, and various stakeholders. The Committee discussed the public comments received. The general sentiment was supportive of the proposal, with suggestions for shorter eligibility time frames. Concerns were raised about the impact on waitlist mortality for status two and status three candidates. The Committee discussed the suggestions for shorter eligibility timeframes and decided to keep the eight- and six-year timeframes that had been proposed.

OPTN contractor staff highlighted the general themes from public comments and shared graphics indicating the levels of support and opposition to the proposal. The goal was to determine whether the themes warranted making changes or whether enough support existed to submit the proposal as written to the OPTN Board. Contractor staff stressed the need to ensure that the community could reasonably anticipate the final policy and that any changes should be a logical outgrowth of the proposed policy. If they make change that the community could not have expected, then such a change would likely need another round of public comment.

The following are examples of the members' feedback. A member expressed satisfaction with the overall support for the policy and noted that the explanation provided to the public about the potential impact on waitlist mortality seemed to address most concerns. The importance of balancing the needs of LVAD patients with those of other high-urgency patients was emphasized. Another member indicated they had been initially skeptical of the proposal and thought the community would express greater concern than they did. However, the member cited the favorable trend of the community's response.

Next steps:

The Committee was told that vote on approving the policy language would be held later in the meeting.

3. CD: Continue review and discussion of match run analysis results from 04/01/2025 Committee meeting

The Committee revisited the match run analysis results, focusing on attribute weights and rating scales, and discussed options for future iterations of the analysis.

Data summary:

SRTR contractor staff reviewed the match run analysis results that were initially shared during the 04/01/2025 Committee meeting. The review focused on how the proposed continuous distribution score prioritized different groups of candidates compared to the current policy. The analysis aimed to provide insight into how attributes interacted and influenced the prioritization of candidates.

The match run analysis involved reordering real match runs under the proposed continuous distribution attributes, their weights and rating scores to evaluate effectiveness. The primary goals included

prioritizing ECMO candidates, pediatric candidates, dischargeable LVAD patients, and blood type O and B candidates. SRTR contractor staff highlighted several key findings:

1. **Adult Status 1 Candidates**: Both the current policy and the simplified continuous distribution scenario (referred to as scenario one) gave adult status 1 candidates the highest priority across medical urgency categories. The median sequence number for adult status 1 candidates under the current policy was around 22, while under scenario one, it was significantly higher at around 6. This indicated that adult status 1 candidates received even more priority under the scenario one, likely due to the inclusion of candidates who were farther away from the donor hospital.
2. **Pediatric Candidates**: The analysis showed that pediatric candidates received more priority under scenario one compared to the current policy. For all donors, pediatric candidates had a median sequence number of around 113 under the current policy, which improved to around 45 under scenario one. The gains were more pronounced for adult donors, with pediatric candidates appearing significantly higher on adult donor match runs under scenario one.
3. **Dischargeable LVAD Candidates**: The prioritization of LVAD candidates was substantially higher under scenario one compared to the current policy. Long-term LVAD candidates, who typically appeared around sequence number 300 under the current policy, were prioritized much higher under scenario one, with a median sequence number of 23. This was comparable to adult status 1 under the current policy, indicating that LVAD candidates received a significant boost in priority under scenario one due to both medical urgency points and waiting time points.
4. **Blood Type O and B Candidates**: The analysis examined the proportion of blood type O and B candidates within the top 50 sequence numbers, where heart transplants are most likely to be accepted. Scenario one showed a higher proportion of blood type O and B candidates in the top 50 sequence numbers compared to the current policy. This suggested that these candidates received more priority under scenario one, potentially leading to more equal transplant rates across blood types.
5. **Distance**: The committee aimed to see an increase in distance as candidates moved down the match run. Scenario one achieved this goal, with distance increasing at each sequence number. The analysis showed that the distance was substantially farther at every sequence number under scenario one compared to the current policy. Additionally, the proportion of offers going out over 500 nautical miles was higher under scenario one, indicating that candidates farther away received more priority.

Summary of discussion:

Decision #1: The Committee identified several new scenarios for SRTR to perform match run analyses.

The Committee revisited the match run analysis results, focusing on attribute weights and rating scales. The analysis aimed to refine the continuous distribution model, considering feedback and data from previous match runs. The discussion included the prioritization of pediatric candidates and the impact of distance on transplant allocation. The Committee also considered the effects of blood type and sensitization on transplant allocation, aiming to ensure fair access for highly sensitized patients.

The Committee discussed the results of the CD match run analysis. Key findings included:

- **Prioritization**: ECMO candidates, pediatric candidates, and dischargeable LVAD patients were prioritized.
- **Blood Type Priority**: Blood type O and B candidates received higher priority.

- **Distance**: The distance between donor hospital and transplant program increased for candidates farther down the match run.

The Committee members discussed several additional scenarios (beyond scenario one) for further analysis, including increasing the proximity efficiency weight from 20% to 30% and adjusting blood type priority points. Additional considerations included stratifying analysis by recipient size and combinations of blood type and CPRA groups, and addressing concerns about distance and sensitization priority.

The Chair emphasized that the attribute weights were starting points and not final. The medical urgency attribute was slightly higher weighted due to the inclusion of LVAD waiting time. Additionally, blood type O received a 50% advantage for blood type access points. The waiting time attribute applied equally to all members, regardless of urgency, which was recognized as a potential weakness.

The Committee discussed the prioritization of pediatric donors to pediatric recipients and the potential for donor modifiers to enhance this prioritization. Concerns were raised about the double points given to LVAD patients for both waiting time and medical urgency. The Committee discussed both eliminating the waiting time formula and incorporating a weighted waiting time attribute to address this issue in the next iteration of the match run analysis.

The goal of the weighted waiting time attribute would be to index the waiting time formula so that candidates with high medical urgency would accumulate waiting time points more quickly, while those with low urgency would accumulate points more slowly. This approach aims to ensure that candidates with greater medical need receive higher priority.

The discussion also touched on the impact of distance on match runs. The Committee aimed to see an increase in distance as candidates moved down the match run, with the goal of offering hearts to candidates closer to the donor hospital first and then moving farther away. The proposed scenario achieved this goal, with distance increasing at each sequence number. However, the Committee agreed to keep an eye on this aspect to ensure that it did not disadvantage centers that were farther away from major metropolitan areas.

Next steps:

The Committee will submit the new match run analysis scenarios to the SRTR contractor to perform another match run analysis.

4. Committee work: Final vote on proposed policy language for *Escalation of Status for Time on Left Ventricular Assist Device* project

The Committee conducted a final vote on the proposed policy language for the LVAD project.

Summary of discussion:

Decision #1: The Committee approved submitting the proposed policy language to the OPTN Board of Directors for approval.

Following a scheduled break in the meeting proceedings, the Committee held a vote on the proposed policy language. A motion was made to call the vote and seconded. The Chair then directed the members to indicate in the Webex chat function whether they support or oppose the proposal, or if they chose to abstain from voting. At the time, there were 15 members participating on the call, enough to meet quorum. The vote was conducted and the result was 14 yes (in this case, “support”); zero no;

and zero abstained. The proposed policy language was approved for submission to the OPTN Board of Directors for their June 2025 meeting.

Next steps:

The proposed policy changes will be submitted for OPTN Board approval as part of the Board's June 2025 meeting.

5. Status Update: Comprehensive Multi-Organ Allocation Policy

An update was provided about the development of standardized tables for multi-organ allocation.

Summary of discussion:

Decision #1: The members agreed that a suggestion should be offered to the OPTN Multi-Organ Transplantation (MOT) Committee to consider reviewing their proposed allocation tables to ensure heart candidates are being assigned the appropriate amount of priority given their waitlist mortality rates and other factors when compared to non-heart candidates.

In February 2025, the Committee received a presentation from the MOT Committee describing the MOT Committee's efforts to develop multi-organ allocation tables. In the weeks leading up to the Heart Committee's 04/18/2025 meeting, the MOT Committee had refined the allocation tables presented during the February meeting. A Committee member who also serves on the MOT workgroup addressing the multi-organ allocation tables provided an update about the development of the standardized tables for multi-organ allocation. The Committee reviewed the proposed allocation tables, which aim to ensure equity and efficiency in transplant prioritization. Concerns were raised about heart-liver and heart-kidney patients not covered by current tables. A proposal was made to include additional heart classifications in the allocation table, with specific concern for Fontan patients needing heart-liver transplants. The Committee discussed the importance of modeling and refining the policy based on data and the need for exception points for certain patient groups.

Next steps:

The Committee member serving on the MOT workgroup will present the Heart Committee's suggestion to the MOT workgroup and then report the results to the Committee.

6. Presentation of 12-month monitoring results associated with *Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates*

The Committee reviewed the 12-month monitoring results associated with the changes modifying heart policy to allow ABOi (intended incompatible blood type) offers to pediatric candidates. The project was implemented in two stages to address the needs of pediatric heart transplant candidates who could benefit from receiving ABOi transplants.

Summary of discussion:

No decisions were made as part of this agenda item.

Committee members were reminded that the changes were initially adopted using the emergency policy change process on 03/16/2023. The changes allowed heart, heart-lung, or lung candidates listed before age 18 with appropriate titers to receive ABOi transplants. On 11/29/2023, additional provisions were

implemented that had not been included with the 03/16 implementation, specifically, eligibility was expanded to pediatric heart status two candidates. The different implementations resulted in three monitoring periods for the results: a pre-implementation period (03/16/22 – 03/15/2023), a transition period (03/16/2023-11/29/2023), and a post-implementation period (11/30/2023-11/29/2024). The key findings included: no significant changes in willingness to accept ABOi hearts, a small decrease in heart utilization, and similar survival outcomes pre- and post-implementation.

The presentation of the monitoring report results covered the willingness to accept ABOi hearts, ABOi heart transplants, utilization of hearts, and pediatric waiting list mortality. The findings indicated no significant changes in the willingness to accept ABOi hearts or the percentage of ABOi heart transplants across the different monitoring periods. It was noted that there was a slight decrease in heart utilization, especially among donors less than one year old.

The 12-month monitoring results indicated that the policy changes to allow ABOi offers to pediatric candidates did not result in significant changes in willingness to accept ABOi hearts, transplant rates, or survival outcomes. The willingness to accept ABOi hearts was highest among candidates less than one year old, with a slight decrease in the post-implementation period. Candidates aged one to two years showed an increase in willingness to accept ABOi hearts in the post-implementation period. In terms of transplant rates, the majority of ABOi transplants were performed on candidates less than one year old, with a slight decrease in the post-implementation period. Candidates aged one to two years showed consistent rates of ABOi transplants across all periods. Older age groups had a few ABOi transplants following the policy change, with two transplants performed on candidates aged eleven to seventeen years. Considering survival outcomes by ABOi compatibility, the one-year survival probability for ABOi heart recipients was slightly lower than for ABO-compatible recipients, but the difference was not statistically significant. Survival rates remained consistent pre- and post-implementation.

The monitoring results also indicated a decrease in waiting list mortality for pediatric heart candidates in the transition and post-implementation periods, although the decrease was not statistically significant. Additionally, Status 1A candidates willing to accept ABOi hearts waited significantly longer for transplants compared to those who were not willing. Status two candidates willing to accept ABOi hearts in the post-implementation period waited about 210 days for transplants. The utilization rate of donor hearts less than one year old decreased significantly in the post-implementation period. Utilization rates for other donor age groups increased slightly.

The policy changes provided additional opportunities for older pediatric candidates to receive ABOi transplants, with a few transplants performed in previously ineligible age groups.

Next steps:

The Committee will receive another monitoring report in the future. The Committee noted the importance of continuous monitoring and refinement of the policy to ensure equitable access to transplants for all pediatric candidates.

7. Presentation of 12-month monitoring report associated with *Report Primary Graft Dysfunction in Heart Transplant Recipients*

The committee reviewed the 12-month monitoring results for the project aimed at reporting primary graft dysfunction (PGD) in heart transplant recipients. This project was initiated to address the lack of standardized data collection on PGD, a leading cause of early mortality in heart transplant recipients. The goal was to collect comprehensive data on PGD to better understand its incidence, contributing factors, and outcomes.

Summary of discussion:

No decisions were made as part of this agenda item.

The Committee members were reminded that the data collection requirements were implemented on 09/14/2023, and the monitoring period covered data from 09/14/2023, to 09/14/2024. New data elements were added to the Transplant Recipient Registration (TRR) form to capture detailed information on PGD at 24 and 72 hours post-transplant. These elements included: Presence of PGD (as determined by the transplant program); left ventricular dysfunction; right ventricular dysfunction; use of mechanical circulatory support device; hemodynamic measurements; and other relevant clinical data.

The report highlighted the incidence of PGD at 24- and 72-hours post-transplant. The overall incidence was 12.4% at 24 hours and 8.5% at 72 hours for heart-alone transplants. The report noted a high percentage of missing values for left and right ventricular dysfunction data elements. The six-month overall patient survival was similar for recipients with PGD at 24 and 72 hours.

Certain challenges were identified and potential solutions were recommended. For instance, the high percentage of unknown values for left and right ventricular dysfunction indicates a need for clearer definitions and improved data entry practices. Furthermore, the variability in PGD reporting by transplant programs suggests a need for standardized definitions and training to ensure consistent data collection.

The 12-month monitoring results provided valuable insights into the incidence and impact of PGD in heart transplant recipients. The data highlighted the variability in PGD reporting and the need for standardized definitions and improved data collection practices. The Committee recognized the importance of addressing these challenges to ensure accurate and reliable data for future analysis and policy development. The Committee concluded that the initial implementation of the PGD data collection policy was successful in capturing important information, but further refinement and standardization are needed.

Next steps:

The next steps will involve addressing the identified challenges, improving data consistency, and using the collected data to inform policy decisions and enhance clinical practices.

8. Discuss email to Committee about Fontan recipients

The Committee discussed an email Heart Committee leadership received from a Liver Committee member raising concerns about the challenges faced by Fontan recipients with heart failure. The email highlighted the increasing number of individuals living longer with Fontan procedures and the complexities involved in their heart transplantation.

Summary of discussion:

Decision #1: The Committee agreed to explore opportunities to collect data regarding congenital heart disease factors.

Concerns were raised about post-Fontan heart failure and transplant outcomes. The email Committee leadership received identified the following challenges in heart transplantation for Fontan recipients: increasing population; experiences and outcomes; and regulatory risks.

A proposal was made to allow pediatric heart transplant programs to transplant adults with congenital heart disease or exempt adult programs from regulatory penalties for these patients. The Committee discussed the need for better data capture and risk adjustment for congenital heart disease patients.

The Committee agreed on the importance of addressing the challenges faced by Fontan recipients and exploring policy changes to ensure equitable access to transplants. The following steps were proposed:

- Data Collection and Analysis: Improve data collection on Fontan patients, including detailed clinical information and outcomes, to inform policy decisions.
- Policy Refinement: Explore the possibility of allowing pediatric heart transplant programs to transplant adults with congenital heart disease and consider regulatory exemptions for adult programs.
- Exception Points: Encourage liver centers to apply for exception points for MELD and PELD scores for Fontan patients, ensuring they receive the necessary organ support.
- Modeling and Simulation: Use modeling and simulation to understand the impact of policy changes and refine the allocation tables to better support Fontan patients.

Next steps:

The Committee emphasized the need for continuous monitoring and refinement of policies to address the unique challenges faced by Fontan recipients and ensure equitable access to transplants for all patients.

9. Open forum

No requests from the public were received prior to the meeting asking to address the Committee during open forum.

10. Closing remarks

The meeting concluded with an acknowledgment of the progress made and a commitment to addressing the identified issues. The Committee aims to ensure that policy changes lead to improved outcomes for transplant patients while maintaining fairness and efficiency in the allocation process. The discussions highlighted the complexity of transplant allocation and the need for ongoing data collection and analysis to support informed decision-making.

The Committee emphasized the importance of continuous refinement of policies to ensure equity and efficiency in transplant prioritization. Future work will focus on clarifying definitions, improving data collection, and addressing specific patient populations' needs.

Upcoming Meeting(s)

- ~~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
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Eman Hamad
  - Earl Lovell
  - Cindy Martin
  - Mandy Nathan
  - Jason Smith
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Avery Cook
  - Grace Lyden
- **UNOS Staff**
  - Keighly Bradbrook
  - Matt Cafarella
  - Cole Fox
  - Kelsi Lindblad
  - Eric Messick
  - Laura Schmitt
  - Holly Sobczak
  - Kaitlin Swanner
  - Sara Rose Wells
- **Other Attendees**
  - None