

OPTN Heart Transplantation Committee

Meeting Summary

March 29, 2024

Houston, Texas

Rocky Daly, MD, Chair

J.D. Menteer, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met in Houston, Texas on 03/29/2024 to discuss the following agenda items:

1. Agenda review and meeting logistics
2. Introductions and ice breaker
3. Continuous Distribution (CD) of Hearts Request for Feedback document: Review of final comments and general themes
4. Results of 5-year monitoring report associated with adult heart allocation modifications implemented in October 2018
5. Committee Work: CD – Consideration of medical urgency and a potential risk score
6. Call to purpose: Introduction of Glen Kelley’s donor family
7. Committee Work: CD – Consideration of Waiting Time
8. Committee Work: Prepare project form for Escalation of Status for Time on Ventricular Assist Device
9. Heart Regional Review Boards: Update regarding exception usage and opportunities for improvement
10. Public forum
11. Open discussion and closing remarks

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

1. Agenda review and meeting logistics

The meeting agenda was reviewed and other meeting information was shared.

Summary of discussion:

Decision #1: Not applicable.

An overview of the agenda items and the timing of the discussions was provided.

Next steps:

Not applicable.

2. Introductions and ice breaker

The Chair welcomed the Committee members and other attendees. Everyone was given the opportunity to introduce themselves.

Summary of discussion:

Decision #1: Not applicable.

Following the introductions, there were no questions or comments and the Committee proceeded to discussing the agenda items.

Next steps:

Not applicable.

3. Continuous Distribution (CD) of Hearts Request for Feedback document: Review of final comments and general themes

The discussion focused on reviewing and addressing the public feedback received on the Request for Feedback document, with particular emphasis on medical urgency, waiting time, and placement efficiency considerations as the committee continues its work on the Continuous Distribution of Hearts.

Summary of discussion:

Decision #1: The Committee agreed again not to pursue a post-transplant survival attribute for inclusion in the first iteration of CD of Hearts.

The committee then reviewed the public comments received on the Request for Feedback document. Key themes included support for giving additional priority based on waiting time, suggestions for improving the proposed medical urgency rating scale, concerns about unintended consequences from the placement efficiency attribute, and agreement not to include post-transplant survival in the initial version.

Detailed comments were discussed, including feedback on the escalation of status for time on durable VADs, the medical urgency attribute and rating scale, the impact of exceptions, post-transplant survival, placement efficiency, and other considerations such as disparities and sensitization.

The committee acknowledged the importance of addressing medical urgency, waiting time, and potential risk scores in the CD framework. They also recognized the need to carefully consider placement efficiency and the impact on smaller programs, travel distances, and organ care systems.

While the committee agreed to defer including post-transplant survival in the initial version, they acknowledged the importance of initiating efforts to develop that metric for future versions.

A member asked how the 75 public comment responses received for the Request for Feedback compares with other public comment proposals? OPTN Contractor staff said that this was probably the most comments received for a Heart-related public comment document in the last five years.

The Chair mentioned that there has recently been the release of some additional data regarding disparities in transplant. The Chair said that because the Heart Committee is focused on allocation, it is not the appropriate body for addressing disparities in access to transplant. The Chair's recommendation is that the OPTN should establish a working group consisting of all the organ systems to address the issue of disparities to access. That the issue is too complex for a single OPTN Committee to try and resolve by way of an attribute in continuous distribution. This is a topic that needs a lot of expertise from a wide array of sources to be appropriately addressed. Having said that, the Committee plans to invite the primary author of an article concerning disparities in heart transplant to an upcoming

Committee meeting. The article was published in the Journal of the American Medical Association (JAMA) in the last few weeks.

A member commented on the community's feedback related to complications around LVADs and time on VAD. The member reminded the others that the policy changes the Committee worked on and the Board approved in December have not been implemented. When those changes are implemented requiring candidates to fail inotropic therapy before they can be listed at status 2, then we should see more status 3 candidates getting transplanted which should help address some of the issues with VADs and VAD complications we're seeing in allocation.

A member pointed out that it is important for the Committee to consider the sentiment among the public comments that candidates who have been supported by a VAD for a long period of time without a complication still deserve the same opportunity to transplant as those who experience complications. The member said that the public comment appears to support the idea of transplanting people who are in better condition before they get sick.

Another member discussed the placement efficiency attribute and the comments related to it. The member said that while it has not worked on very much, the Committee really needs to get it right before rolling out continuous distribution. The Chair added that an important factor in making sure the Committee gets placement efficiency correct, is the weighting assigned to it. Fortunately, the Committee will have opportunities with the modeling to get the appropriate weighting. The Committee can also take advantage of what the Lung Committee has learned with regard to placement efficiency. The Vice Chair brought up that, with regard to broader sharing, there is sentiment at the regional level and from OPOs about the difficulties that the OPOs have regarding timely distribution and allocation of the organs when required to share so broadly as is now the case. Part of the challenge is that OPOs have to work with transplant hospitals that are far away, and with whom an OPO is not familiar. The Vice Chair added that hopefully the modelling results will identify a sweet spot of how much efficiency is appropriate while also reducing a lot of unnecessary travel.

A member indicated they were pleased with the feedback received related to the Committee's position regarding a post-transplant survival attribute. It was helpful to get comments that acknowledged the importance of post-transplant survival but also that the public realizes that the data may not exist to incorporate such an attribute now. The Chair echoed the importance of the public comment received about post-transplant survival and outcomes. The Chair also said that the Committee should keep those comments in mind as they continue working on continuous distribution, and especially when considering the VPE results, which might over-emphasize the importance of post-transplant survival.

Next steps:

OPTN Contractor staff will provide the comment with a public comment analysis document. The document will provide more details about the general themes and comments received. As part of a future meeting, the Committee will receive a presentation regarding disparities in heart transplantation.

4. Results of 5-year monitoring report associated with adult heart allocation modifications implemented in October 2018

The Committee received a presentation of the results of the 5-year monitoring report for the modifications to the adult heart allocation system that were implemented in October 2018. The 5-year monitoring report represents the final version that the Committee will receive.

Summary of discussion:

Decision #1: The Committee identified information in the report for additional follow-up and analysis

The meeting continued with a presentation of the results of the 5-year monitoring report for the modifications to the adult heart allocation system that were implemented in October 2018. The key findings included:

- An increase in transplants traveling longer distances post-implementation
- Reduced median time spent waiting for a transplant
- Increased transplant rates across most regions
- Higher waitlist mortality for higher medical urgency statuses (2, 3, 4) compared to lower statuses (5, 6)
- A steady increase in the number of justification forms submitted to regional review boards for exception requests

There was discussion around the monitoring data not fully capturing current realities, such as significantly increased wait times for status 2 candidates in some regions. Concerns were raised about patients occupying hospital beds for extended periods, increased costs, and potential waitlist mortality not reflected in the data.

The Committee discussed the information related to median days to transplant. According to the analysis, candidates are being transplanted much more quickly following the October 2018 implementation than they were prior. Several members indicated that the results in the monitoring report did not align with their experiences at their institutions. They indicated that waiting times are increasing at their programs and in their regions. A member stated that the reported median days to transplant seemed short compared to their patients and their region. Members asked for additional analyses related to time on the waiting list and time to transplant. For example, a member asked if the median waiting time / time to transplant categorized by each heart transplant program can be provided? Another member asked for more data specific to the adult status 4 candidates that could better describe the waiting times such candidates are experiencing.

A member pointed out that the monitoring report results indicate large changes by region in the number of transplants before and after the policy changes. For instance, there were large increases in regions 1 and 5, but the number of transplants in region 4 was almost identical in the post and pre-implementation timeframes. Another member mentioned that the increases could reflect the fact that the three largest DCD centers are located in two of the regions with the largest increases. A member said that the changes in the number of transplants could also be considered a proxy for how the distance between the donor and transplant hospitals come into play with allocation, and suggested that the Committee remember these differences when considering the proximity efficiency attribute in continuous distribution. Another member mentioned that the waiting time results suggest a change in program and clinician behavior. For example, six years ago no clinician would have let a candidate wait 45 days at status 2 with an implanted mechanical circulatory support device. The program would have implanted a durable ventricular assist device (VAD) before then.

Next steps:

OPTN Contractor staff will work on gathering the additional information the Committee requested, such as a closer inspection of the median days to transplant.

5. Committee Work: CD – Consideration of medical urgency and a potential risk score

The Committee received a presentation about another way of determining medical urgency. Then the Committee discussed the differences between their current approach to medical urgency in continuous distribution, which transitions the current statuses and criteria onto a continuum, the candidate risk score described in the presentation, and other options.

Summary of discussion:

Decision #1: The Committee members agreed to continue moving forward with their previously accepted approach to medical urgency, which involves transitioning the existing status to a continuous score.

Decision #2: The Committee members also agreed to pursue further modeling and data collection for potential inclusion in the next iteration, while also exploring the potential of including a “hybrid” version of the U.S. CRS as part of the medical urgency attribute, with the hybrid focusing on status 4, 5, and 6 candidates.

The Committee received a presentation describing an alternative approach to determining medical urgency different than the Committee’s chosen approach up to this point in time. The presentation was given by one of the authors of the article, *Development and Validation of a Risk Score Predicting Death Without Transplant in Adult Heart Transplant Candidates*.¹ The presentation described the development of a multi-variable, objective medical urgency risk score for adult heart candidates based on physiologic variables rather than the current status criteria. A key message of the author was that the proposed U.S. Candidate Risk Score (U.S. CRS) outperformed the current adult six-tier status system in terms of accurately identifying medical urgency. The author also discussed how the approach aims to align with the OPTN Final Rule’s guidance on prioritizing urgency based on measurable criteria like laboratory values.

The author said that their study adapted the French risk score model to U.S. data, using lab data values collected following implementation of the adult heart policy changes in October 2018. The authors developed the U.S. CRS as a potential continuous medical urgency score intended for use with the upcoming continuous distribution allocation framework. The U.S. CRS is a risk-based scoring model to assess medical urgency for adult heart transplant candidates, rather than the current status-based system. It should be noted that the applicability of the U.S. CRS to pediatric heart candidates was not discussed by the Committee or the author.

The presenter shared details on the development and performance of a multi-variable model that incorporates lab values like sodium, bilirubin, and albumin to predict waitlist mortality. In addition to the lab values, the model also includes two variables related to the use of mechanical circulatory support devices. One of the two variables captures whether the candidate is currently supported by or was previously supported by a temporary mechanical circulatory support device. The other of the two

¹ Zhang KC, Narang N, Jasseron C, et al. Development and Validation of a Risk Score Predicting Death Without Transplant in Adult Heart Transplant Candidates. *JAMA : the journal of the American Medical Association*. 2024;331(6):500-509. doi:10.1001/jama.2023.27029.

variables captures whether the candidate is currently supported by a durable LVAD. The author stated that model was shown to outperform the current status system, particularly for identifying higher risk patients who are currently categorized at lower status levels. The author stated that most of the benefit is identifying medically urgent candidates who are currently designated as statuses 3, 4, 5, and 6 but who should actually be assigned to higher statuses based on their clinical lab values.

The author said that a next step for their research team is to add another year's worth of OPTN data to the model and find out if the model still performs the same way. The author also said that it would be beneficial for SRTR or OPTN Contractor staff to verify the published results. OPTN Contractor staff indicated they would be interested in validating the U.S. CRS on the Committee's behalf.

The Chair asked if the research compared the predicted medical urgency of the status 4, 5, and 6 patients to confirm that such patients actually had a high waitlist mortality? The author said the model had not been calibrated by status and that is definitely worth reviewing.

Another member asked whether the analysis considered the combination of the variables and the treatment. The member pointed out that certain clinical values will indicate the degree to which a patient is sick; however, if the patient has those values and is on low dose inotropes, for example, that person is likely sicker, and someone with the same clinical values who is on temporary MCS is even sicker. The author responded that for the interaction effects the member described, the model performed relatively the same as a more complicated model they also tested, so the authors think the proposed U.S. CRS does account for such interactions.

The Vice Chair stated that the major benefit of the proposed U.S. CRS is how it could be used to address the patients who are assigned to statuses 4, 5, and 6. The Vice Chair mentioned that such candidates have very long wait times and the Committee and community have struggled to identify ways to increase their medical urgency. Perhaps the Committee should revisit using some of these objective markers to elevate urgency scores for patients that are at the bottom of the priority list. The Vice Chair expressed some concern that adopting an urgency model that places too much emphasis on abnormal lab values because it could result in a system that favors patients who are actually under-supported at the time of waitlist registration.

Following the presentation, the Committee discussed the potential advantages and disadvantages of pursuing the development and implementation of a candidate risk score as part of the first iteration of continuous distribution of hearts.

While some committee members expressed support for this objective risk score approach, others raised concerns about potential limitations, unpredictable behavioral changes by the heart transplant programs, and the complexities of implementing it for the initial continuous distribution model. Concerns were also raised about the model's ability to accurately capture the risks for patients on temporary mechanical circulatory support devices, as the lab values may not fully reflect their medical urgency. The Committee Chair acknowledged the uncertainties but wanted the committee to consider this alternative approach.

The committee discussed several options for incorporating this type of risk-based scoring approach:

1. Adopt it for the initial iteration of continuous distribution, with the understanding that it has limitations and may disadvantage some high-risk patients
2. Postpone implementation to the next iteration, but start collecting the necessary data in the meantime
3. Use a hybrid approach, applying the risk score only to lower status patients initially, while maintaining the current status-based system for higher urgency patients.

Overall, the committee was receptive to the potential value of a risk-based scoring model, but felt it was not ready for full implementation in the first iteration of continuous distribution given the remaining uncertainties and operational challenges. The general consensus was to pursue further modeling and data collection for potential inclusion in the next iteration.

Next steps:

The Committee will explore opportunities to have the U.S. CRS validated by OPTN Contractor staff and the potential of developing a “hybrid” approach that uses the U.S. CRS to identify the medical urgencies associated with adult status 4, 5, and 6 patients.

6. Call to purpose: Introduction of Glen Kelley’s donor family

A Committee member who received a donor heart introduced the donor’s mother to the members. The mother described her son to the Committee and shared with them her experiences with the donation journey. Everyone in attendance thanked her for sharing her son’s story, and her story as well.

Decision #1: Not applicable.

7. Committee Work: CD – Consideration of Waiting Time

The Committee next discussed the proposed waiting time attribute for potential inclusion in the first iteration of Continuous Distribution of Hearts.

Summary of discussion:

Decision #1: The Committee agreed with the proposed approach to providing additional priority to pediatric candidates who have been registered on the waiting list for a long time.

The Committee discussed the proposal to incorporate waiting time into the continuous distribution heart allocation policy, particularly for pediatric candidates. The current policy uses waiting time as a tie-breaker within a given medical urgency classification. The Committee is exploring whether waiting time should be a more significant factor in the continuous distribution allocation framework.

The Committee reviewed how the OPTN liver, kidney, and pancreas committees are considering waiting time as part of their development of continuous distribution allocation frameworks. For example, the kidney and pancreas committees have each developed potential waiting time attributes for inclusion in their continuous distribution allocation frameworks because of the important role waiting time plays in their current allocation frameworks. On the other hand, the OPTN Liver Committee has chosen not to include waiting time as a separate attribute in its continuous distribution framework.

The Committee then discussed the specific proposal developed by a subgroup that included members of the pediatric heart transplant community. The key aspects of this proposal are:

- Waiting time points would be awarded based on a formula that multiplies the candidate’s medical urgency points by the number of days at that urgency level. This would give more weight to waiting time for the sickest candidates.
- There would be a cap on the maximum number of waiting time points that could be accrued (e.g. ~30 points over 1.5 years of high urgency).
- The waiting time points would either be added to the medical urgency score or incorporated into a patient access category, as waiting time is fundamentally an access to care issue.

- The committee discussed whether to apply this waiting time approach to both pediatric and adult candidates, or just pediatrics. There was general agreement that it could be beneficial for adults as well, recognizing that adult waiting times are typically shorter than pediatric waiting times.

The Committee acknowledged the importance of balancing medical urgency and waiting time, as the goal is to ensure the sickest patients are transplanted while also providing hope and a sense of progression for those who have been waiting the longest. The Committee agreed to model the impact of this waiting time proposal, both for pediatric and adult populations, before making a final decision. Careful consideration will be given to the appropriate weighting of waiting time points relative to medical urgency.

Overall, the Committee demonstrated a thoughtful, collaborative approach to addressing the complex issue of how to incorporate waiting time into the continuous distribution allocation framework in a way that best serves heart transplant candidates.

Next steps:

OPTN Contractor staff will find out more information about how both mathematical optimization and modeling can best be used to identify the most efficient and effective ways to address waiting time in the continuous distribution allocation framework. In addition, the Committee will determine whether to proceed with a waiting time attribute specifically addressing pediatric candidates, or whether to address both pediatric and adult candidates.

8. Committee Work: Prepare project form for Escalation of Status for Time on Ventricular Assist Device

The Committee continued the discussion of waiting time and also discussed the escalation of priority for time on VAD.

Summary of discussion:

Decision #1: The Committee agreed to form a group to explore the topic as a separate project.

The discussion focused on potential changes to the heart allocation policy, specifically around providing additional priority to candidates who have a lot of time on the waitlist with durable VADs.

For VAD patients, the group recognized the need to incentivize this therapy as a bridge to transplant, rather than it being a "bridge to nowhere" as it is currently perceived. They discussed potentially providing a defined timeline (e.g. 1-2 years) where VAD patients would be prioritized for transplant, to give them a realistic chance of being transplanted.

The group acknowledged this would likely create a "glut" of status 2 candidates initially, so they suggested a phased implementation approach to avoid this issue. They requested data on the current waitlist composition to help model the potential impact.

Additionally, the group discussed the rising number of cases being reviewed by the regional review boards, and the concerning high rate of decisions made without a majority vote. They recognized this as a problem that needs to be addressed, though did not have immediate solutions.

Overall, the discussion centered around finding an interim solution to better prioritize pediatric and VAD candidates, while acknowledging the need to coordinate this with the upcoming transition to continuous distribution. Volunteers were requested to participate in developing a potential solution and project to

further explore ways to provide candidates with durable LVADs additional priority based on the longer they spend on the waitlist.

Next steps:

Those who volunteered will be contacted about developing a project form.

9. Heart Regional Review Boards: Update regarding exception usage and opportunities for improvement

The Committee received a presentation about the use of exception requests and concluded their meeting.

Summary of discussion:

Decision #1: No decisions were made.

The committee discussed the significant increase in the volume of exception requests being submitted, particularly for status 2 candidates. This has led to challenges with the current manual review process, including delays, lack of consistency, and high rates of requests being approved without a clear majority.

There was extensive discussion around potential solutions, including:

- Creating a small, dedicated, trained group of reviewers to review exception requests, rather than relying on the current regional review boards approach, which involves a large number of members
- Implementing more structured data requirements and a pre-screening process to ensure complete information is provided by transplant programs requesting exceptions
- Considering incorporating more regular in-person or virtual meetings of the review committees to discuss controversial exception request cases
- Providing programmatic feedback and reports to regional review board chairs and/or individual reviewers regarding exception request approval rates in order to increase accountability

The Committee acknowledged the need to potentially prioritize certain types of exception requests, such as status 2, while potentially deferring lower priority status 3 and 4 requests. There was also discussion around updating the operational guidelines for exception requests, including the possibility that any changes to the guidelines would require public comment and OPTN Board approval before such changes could be implemented. Concerns were raised about the lack of clear criteria and definitions being used to evaluate exception requests, as well as the inherent incentive for programs to submit requests in order to get patients listed at a higher status.

Finally, the committee touched on the idea of better integrating and coordinating between the various national transplant committees and patient groups to reduce siloes and improve collaboration.

Overall, the discussion focused on identifying ways to improve the efficiency, transparency, and accountability of the exception request review process.

Next steps:

OPTN Contractor staff will share the Committee members suggestions with others and explore the opportunities for implementation.

10. Public forum

No one had requested to speak during the public forum.

Decision #1: Not applicable.

11. Open discussion and closing remarks

The Chair asked members if there were any additional topics they wanted to discuss. A member recommended that OPTN Contractor staff consider revisions to how information is collected for the data field Troponin, and suggested improvements. Another member discussed the need to bring together the many heart-specific organizations, both medical and patient-centric, to create more functional responses to issues facing the entire heart community.

Summary of discussion:

Decision #1: The Committee asked that the reportable values for Troponin be clarified.

As part of the open discussion, a Committee member recommended changing the Troponin field from high sensitivity to Troponin. There was agreement with the recommendation. The member said that the values being provided are off by the thousands and this is creating a lot of confusion. The member pointed out that they made the same recommendation at their first Committee meeting almost three years ago. OPTN Contractor staff replied that they would share the request and seek a resolution.

Another Committee member shared a concern that while there is a large number of “upper level” heart-specific and/or transplant-specific groups, these groups are largely siloed. For example, there is HFSA, ISHLT, AST, and the OPTN Heart Transplantation Committee, but these entities do not engage each other in a way to find out what the others are doing and to share current activities and concerns. The member suggested that creating a forum for such information sharing among the heart-specific entities could identify unique issues or partnered agendas and problems as a way to better integrate the heart community. Several members agreed with the idea that there needs to be more coordination and information sharing among the groups.

The Committee Chair and Vice Chair thanked everyone for their time.

Next steps:

OPTN Contractor staff will follow-up on the recommended improvements to the Troponin data field and report back to Committee leadership and the member who suggested the changes.

Upcoming Meetings

- April 16, 2024
- May 1, 2024
- May 21, 2024
- June 5, 2024
- June 18, 2024

Attendance

- **Committee Members**
 - Rocky Daly, Chair
 - J.D. Mentee, Vice Chair
 - Tamas Alexy
 - Amrut Ambardekar
 - Jennifer Carapellucci
 - Jennifer Cowger – Virtual
 - Timothy Gong
 - Eman Hamad – Virtual
 - Jennifer Hartman
 - Glen Kelley
 - Earl Lovell
 - Cindy Martin
 - Cristy Smith
 - Martha Tankersley – Virtual
 - Dmitry Yaranov – Virtual
- **HRSA Representatives**
 - Jim Bowman – Virtual
 - Marilyn Levi – Virtual
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette – Virtual
 - Monica Colvin – Virtual
 - Grace Lyden
- **UNOS Staff**
 - James Alcorn – Virtual
 - Cole Fox – Virtual
 - Kelsi Lindblad
 - Alina Martinez
 - Eric Messick
 - Jamie Panko – Virtual
 - Sarah Roache
 - Laura Schmitt – Virtual
 - Kimberly Uccellini – Virtual
 - Sara Rose Wells – Virtual
- **Other Attendees**
 - William Parker – Virtual
 - David Sutcliffe – Virtual