

OPTN Heart Transplantation Committee

Meeting Summary

July 2, 2024

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 07/02/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. New member introductions
3. Finalize project form for *Escalation of Status for Time on Left Ventricular Assist Device*
4. Review results of Risk Stratification Data analysis
5. Open Forum
6. Closing remarks

The meeting began with the introduction of the new committee members. During the meeting, the members discussed the proposed changes to the allocation policy for LVAD patients, including time thresholds for advancing patients on the transplant waiting list and the impact on unwell patients with complications. The Committee also discussed the need for feedback and fine-tuning of data collection for risk stratification. The following is a summary of the Committee's discussions.

1. Welcome and agenda review

The Chair welcomed the Committee members and briefly discussed the subject matter that would be discussed during the meeting.

2. New member introductions

The Chair welcomed the new members and their roles on the Committee. Seven new members joined the Committee. One of the new members is a Patient and Donor Affairs Representative and shared their transplant experience with the Committee.

3. Finalize project form for *Escalation of Status for Time on Left Ventricular Assist Device*

There is a proposal to change allocation policy for candidates assigned to adult heart status 4 with dischargeable left ventricular assist devices (LVAD) to improve their prognosis and increase their chances of getting a transplant. The proposal aims to give higher priority to patients who have been on LVADs for longer periods without complications.

Data summary:

Data was presented to determine the appropriate threshold for increasing status for LVAD patients who have been waiting for a long time. The Committee was shown a slide with the distribution of time spent waiting as measured from listing or VAD implant for adult heart-alone candidates waiting as of 04/30/2024. The data indicates there is a long tail of candidates who have been waiting for many years since their LVAD implant. For years since listing, the mean was 2.11 years, the median was 1.52 years,

and the maximum was 10.24 years. For years since implant, the mean was 3.50 years, the median was 3.10 years, and the maximum was 16.83 years. OPTN contractor staff indicated that there may be data quality issues associated with the implant dates of some of the records.

Another slide showing the distribution of years waiting for adult heart-alone VAD candidates waiting on 04/30/2024 was presented to the Committee. The slide provided the number of status 2, 3, and 4 candidates by years waiting since registration on the waiting list and by years waiting since VAD implant. Depicted this way, the data indicate that for those waiting since registration, the largest group of candidates are those who have been waiting less than a year. When considering the data based on waiting since implant, two groups constitute a large proportion of the total, the two groups are those waiting at least one year but less than two years, and those waiting at least two years but less than three years.

The Committee was also provided information about how the number of waiting list candidates by adult heart status would change under the proposed timeframes.

Summary of discussion:

Decision #1: The Committee members agreed with submitting this to the Policy Oversight Committee for project approval.

The Committee's discussion centered around the timeframes for which candidates become eligible for transitioning to status 2 or 3 on the transplant waiting list based on their date of registration on the waiting list or the date their device was implanted. The Committee considered whether to include all time since implant or only time since status 4 activation.

The Chair opened the discussion by reminding the members that during the previous Committee meeting, the consensus was to start with timeframes of five years waiting for status 3 eligibility and seven years waiting for status 2 eligibility. The Chair continued that based on the results of the most recent data analysis, the Committee may want to consider starting with timeframes of six and eight years, instead of five and seven years. It was confirmed that the information used in the analysis came from the status justification forms. For any candidate for whom it was reported either a primary or secondary device was a VAD, then the implant date is associated with that device. It was also confirmed that the VADs represented all dischargeable VADs.

The Committee discussed the impact the proposed changes would have on the number of candidates registered at statuses 2 and 3. The Chair pointed out that the data analysis of the "instantaneous" change in patient volumes shows that using five and seven years as the timeframe, the number of candidates registered at status 3 would increase from 169 to 291 patients if implant date was used. The Chair said that this would result in significantly longer waiting times at status 3, and so OPTN contractor staff were asked to perform an analysis using waiting time of six and eight years for both waiting time after registration and time after implant. The Chair added that there is also an important equity issue for the Committee's deliberation. The Chair stated that there may be patients who have had a LVAD implanted for many years but whose transplant program has not registered them on the waiting list because the program believes the candidate has little realistic chance of transplant at status 4. The Committee needs to consider how the changes in eligibility status and the timeframes being considered impact such patients. Using time registered on the waiting list as a criterion, then those patients who are supported by dischargeable LVADs but not registered on the waiting list receive no benefit for their waiting time. It was mentioned that using time registered at status 4 on the waiting list could systematically exclude patients who wanted to be / deserved to be registered on the transplant waiting

list but were not listed because their transplant program thought getting transplanted at status 4 was futile. There was agreement among the Committee members that time from implant should be used.

The Chair stated that using time from implant does increase the number of patients who will move from status three into status 2. The Chair directed the members to consider the slide documenting the “instantaneous” change in candidate volumes based on the timeframes of five and seven years and six and eight years. The Chair said that using six and eight years results in about 30 candidates being added to status 2, or just over a ten percent increase. The number of candidates being added to status 3 would increase from about seven percent to about ten percent. By comparison, using five and seven year timeframes would result in an increase of candidates listed at status 2 of about 35 percent and would almost double the number of candidates listed at status 3. The Chair continued that as a result, the six to eight year timeframes appear more acceptable than the five to seven year timeframes. The increase in status 2 candidates might cause some deaths because of displacing organs from critical patients in cardiogenic shock. In addition, the increase in status 3 candidates is probably going to lengthen status three waiting times quite a bit for those who are in the hospital, on high dose inotropes with Swan catheters, and other higher medical urgency candidates. A Committee member said that it might be better for the Committee to be somewhat conservative and overestimate the potential number of waitlist additions because; otherwise, having too many candidates transition to statuses 2 and 3 could jeopardize some of those truly medically urgent patients at statuses 2 and 3. The member indicated support for using timeframes of six and eight years.

Another member said that utilizing the six and eight year timeframes may not result in programs being more likely to assign their candidates to status 4. The member added that at their program it is the minority of LVAD candidates who are not accruing some sort of morbidity by six and eight years. The Chair mentioned that the Committee has discussed the possibility of revisiting the timeframes after a certain period of time, but that another important consideration is to not overwhelm the system with the proposed changes.

The Committee also discussed the impact of LVAD priority changes on unwell patients with complications who may now find themselves with less waiting list priority compared to relatively “well” patients who have been waiting for a long time.

Next steps:

The committee expressed general support for moving forward with this initiative.

4. Review results of Risk Stratification Data analysis

The committee discussed the list of currently collected risk stratification data elements and the need for Committee feedback about what is collected and how frequently values are or are not reported, as well as potential fine-tuning of the risk stratification data elements. Concerns were raised about the completeness of data collection, with suggestions to reach out to centers for more accurate and meaningful data. The committee also discussed the possibility of making certain data fields mandatory and the importance of prioritizing key data elements for risk stratification.

Data summary:

The results of an analysis of currently collected risk stratification data was presented/ The analyzed data has been collected since October 2018. The goal at the time was to collect the data elements in order to develop a heart allocation score, similar to the lung allocation score. The completeness of the data varies significantly across different data elements. Some key data, like the results of cardiopulmonary stress tests, are frequently missing. The committee discussed ways to improve data collection and completeness.

Summary of discussion:

Decision #1: The Committee agreed to revisit the risk stratification data elements at a future Committee meeting.

The Committee discussed the information. OPTN contractor staff reminded the members that the results of the risk stratification data (RSD) analysis had been provided to them previously. The RSD elements were added to the status justification forms as part of the changes implemented in October 2018 with the intention that they would be used to develop a heart allocation score. Transplant programs are supposed to update the data fields each time a justification form is submitted on behalf of a candidate. Therefore, while a lot of information is collected, the cadence of when the information is provided depends on how frequently a form (initial, extension, exception) is submitted. For example, policy requires adult status 1 candidates to verify their status much more frequently than status four candidates. However, status 1 candidates are not on the waiting list as long as status 4 candidates. As a result, the amount of time the candidate spends on the waiting list and how often they have to submit initial and/or extension forms means that there is somewhat uneven coverage among the different statuses in terms of how much RSD-related information is reported. The reported RSD values of status 4 candidates are the most reported, accounting for approximately 40% of the data points.

The analysis indicates that median number of data values entered per registration is two. Therefore, there is not a lot of data recorded about most candidates. The data varies widely. There are some candidate with repeated measures of 1,020.

The presentation focused on the level of completeness associated with different sections of the risk stratification data. Considered another way, how much missing data is there? As the Committee develops the continuous distribution allocation framework you should also be considering whether the appropriate data elements are being collected for the identified rating scales, and also looking to the future, are the appropriate data elements being collected to develop a candidate risk score and/or a post-transplant survival score. OPTN contractors staff asked the Committee members to think about whether enough information is being collected that could be used to develop a future score. Additionally, the Committee was asked if they think there are other data elements that should be collected?

Reviewing the risk stratification data by category, some of the categories permit a transplant program to select 'not performed' for the entire category. For some such categories, the level of missingness varies quite a bit. OPTN contractor staff said for example, the data for the cardiopulmonary stress test is over 70% missing, while the data for heart failure severity are around 3% missing. The data in the candidate history category represents a section with some of the least missing data on the form. The category appears first on the justification form so transplant program staff may be more inclined to complete this category than later categories. For the current therapy elements, a lot of the values are highly missing, according to OPTN contractor staff, which makes sense because most candidates not going to be supported by all of the identified data elements. Looking at the VAD data elements, there is a relatively high degree of missingness for elements such as LDH and hemoglobinuria, with about 50% missing values.

The Chair mentioned that when the results of the risk stratification data analysis were previously emailed to the members there was not much feedback in terms of either new data elements that would be needed or modifications to the existing data elements being collected. The Chair suggested sharing the list of risk stratification data elements with the Committee again, along with the results of the data

analysis in order for the Committee to have more discussion during the next few meetings about risk score development.

A Committee member was somewhat surprised by the amount of missingness and recommended sharing some of the analysis results with the transplant programs. The member was surprised by the high level of missingness for reporting of the cardiopulmonary stress test results because that is a common part of a candidate's evaluation and the missingness of the data reported for diuretics. The member added that before adding new data elements, the Committee needs to keep in mind that values are not being reported for data that is already required. If any data elements are going to be added, the Committee needs to also consider removing data elements because if the Committee asks for too much data reporting we will probably end up with less than we want and what is reported might be skewed. Therefore, it might be useful to contact transplant programs letting them know the Committee is working on continuous distribution and the more data you report will help the Committee with developing the risk stratifications. The members had some discussions about whether the "not performed" option is appropriate or whether there are certain data elements that must be reported. A member said that the 'previous history' section is the first for programs to complete and those values are generally well reported; therefore, it could be a human nature thing whereby staff become less inclined to report data as they go through the entire form. So what might be a good solution is to re-organize the risk stratification data collection so that the data the Committee absolutely has to have for listing a patient are the first data elements requested.

SRTR contractor staff said that it appears the data elements associated with the U.S. Candidate Risk Score (USCRS) have generally low rates of missingness, based on the analysis.

Next steps:

OPTN contractor staff will provide the Committee with the risk stratification data elements and analysis results again for the members to review and consider additions or changes. The members also agreed to continue discussions on developing a risk score for allocation at a future meeting.

5. Open Forum

There were no requests to speak during this part of the meeting.

6. Closing remarks

The Chair thanked the members for their participation. The meeting concluded with reminders about regional meeting registration and responsibilities for new regional representatives on the committee. The committee will prepare for upcoming regional meetings where continuous distribution proposals will be presented.

Upcoming Meeting

- ~~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 5, 2025 from 4:00 to 5:00 pm
- February 18, 2025 from 5:00 to 6:00 pm
- March 5, 2025 from 4:00 to 5:00 pm
- March 18, 2025 from 5:00 to 6:00 pm
- April 2, 2025 from 4:00 to 5:00 pm
- April 15, 2025 from 5:00 to 6:00 pm
- May 7, 2025 from 4:00 to 5:00 pm
- May 20, 2025 from 5:00 to 6:00 pm
- June 4, 2025 from 4:00 to 5:00 pm
- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
 - J.D. Menteer
 - Maria Avila
 - Jennifer Cowger
 - Jill Gelow
 - Timothy Gong
 - Eman Hamad
 - Earl Lovell
 - Cindy Martin
 - Mandy Nathan
 - Jason Smith
 - David Sutcliffe
 - Martha Tankersley
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Monica Colvin
 - Grace Lyden
- **UNOS Staff**
 - Cole Fox
 - Kelsi Lindblad
 - Alina Martinez
 - Eric Messick
 - Laura Schmitt
 - Holly Sobczak
 - Sara Rose Wells
- **Other Attendees**
 - None