

OPTN Heart Transplantation Committee

Meeting Summary

August 20, 2024

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 08/20/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Escalation of Status for Time on LVAD: Confirm timeframes for transitioning to statuses 2 and 3
3. CD of Hearts: Proximity efficiency attribute and costs associated with travel and/or perfusion technology
4. Open forum
5. Closing remarks

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

1. Welcome and agenda review

The members were welcomed to the meeting. An overview of the agenda items was provided. Members were reminded that if they only call in to the meeting by phone, they will need to state their name to OPTN contractor staff. Non-Committee members and those without business before the Committee were reminded they should follow the proceedings using vimeo.com/optn.

2. Escalation of Status for Time on LVAD: Confirm timeframes for transitioning to statuses 2 and 3

The Committee members were informed that on 08/08, the OPTN Policy Oversight Committee (POC) approved the project plan and recommended that the project form be submitted for review by the OPTN Executive Committee (ExCom). The ExCom meeting is scheduled for 08/29. The members confirmed the use of "device implant date" should be used when determining time waiting. The members also discussed whether to incorporate a gradual decrease in the years waiting as part of the initial proposal or to wait until they can review monitoring results before modifying policy again to reduce the number of years waiting for eligibility.

Summary of discussion:

Decision #1: The Committee agreed that the initial draft proposal should use "date of device implant," rather than "date of registration on the waiting list at status 4 with a LVAD" when determining time waiting with a LVAD for transitioning to statuses 2 or 3.

Decision #2: The Committee agreed that the initial draft should propose that candidates assigned to status 4 through the LVAD criterion are eligible to transition to status 3 after six years of waiting following device implant, and to status 2 after eight years of waiting following device implant.

Decision #3: The Committee agreed that the initial draft proposal should incorporate a gradual decrease in the number of years waiting after device implant for candidates to be eligible for

transition to statuses 2 or 3. The members agreed that 18 months after implementation of the proposed changes, the number of years waiting required to transition from status 4 to status 3, should be decreased from six to five, and the years waiting required to transition from status 4 to status 2 should decrease from eight to seven.

OPTN contractor staff shared that the Committee Chair had presented the project to the POC and that POC had voted to approve the project (Yes = 15, No = 0, Abstain = 0) for review by the ExCom at its 08/29/2024 meeting. If ExCom approves, then the project will move forward towards submitting a public comment proposal in January 2025 and going to the OPTN Board in June 2025.

Contractor staff told the Committee that POC members asked how the Committee determined that a 6- and 8-year window was the appropriate timeframe and how pediatric candidates might be impacted. In responding to the questions, the Chair described the data the Committee reviewed regarding the instantaneous change in active adult heart waiting list under possible LVAD priority policies. The Heart Committee members were shown the graphic they reviewed when initially deciding upon 6- and 8-year timeframe. The graphic showed instantaneous changes and impacts on different candidate groups associated with the timeframes. It also compared the impact of using the date of waitlist registration versus the date of device implant. Committee members confirmed that the timeframe should start at the date of device implant, not date of listing.

The Committee discussed the potential impact of changing timeframes associated with the Escalation of Status. They discussed whether to include a step down to shorter time frames (five and seven years) automatically after a year or two. They also considered the impact of changing the timeframes on patient care and practice, and whether it will induce a practice change. Members talked about the feasibility of implementing a graded approach versus a one-step approach. The Committee members agreed that the policy proposal should include transition steps for a gradual decrease in the number of eligibility years from the initial 6- to 8-year window to a 5- to 7-year window, and that the transition should occur at about 18 months following implementation of the policy changes.

OPTN contractor staff noted that the Committee had previously discussed using a 6- and 8-year timeframe, then shortening it to a 5- and 7-year timeframe. This transition was referred to as a 'step-down' approach. The Committee members discussed the advantages and disadvantages associated with the 'step-down' timeframe. In terms of advantages, it was noted that including a step-down in the proposal addresses the needs of the targeted population more quickly. For example, anecdotal evidence suggests that LVAD candidates are developing complications well before six or eight years. Additionally, using six and eight years of waiting times may be too long to incentivize programs and candidates to utilize LVADs. In terms of disadvantages associated with a 'step-down' timeframe, OPTN contractor staff noted that data indicates use of the 6- and 8-year timeframe after implant results in a more manageable population size. Reducing the timeframe to 5- and 7-years makes the population less manageable. In addition, some studies suggest comparable survival rates between HeartMate 3 recipients and heart transplant recipients (Kirschner, et), so the step-down may be less necessary. Moreover, requiring a step-down timeframe prevents the Committee from analyzing the effectiveness of initial changes before moving to the next step. Finally, the proximity of implementing Heart CD following implementation of the status 4 changes may make a step-down timeframe unnecessary.

The members were asked if the proposal should only include a 6- and 8-year timeframe. A member noted that a rationale for the proposal was to incentivize the use of LVADs. The member continued that they support gradually moving to shorter timeframes because: 1) at six and eight years many patients will be experiencing complications and thus be eligible for Status 3; and 2) this approach would help avoid an influx of patients at higher statuses. Another member agreed that the 6- and 8-year timeframe

would lead to manageable number of patients at implementation but questioned whether it is too long to encourage programs to implant more dischargeable LVADs?

A member asked whether the step-down approach would impact timeline for implementation? They noted that the step-down approach is in the spirit of what the Committee had planned. It was stated that the Committee should clarify if the proposal is to start with a 6- and 8-year timeframe and then decide whether to include a step-down in the proposal. The Chair pointed out the complexity and long periods of time associated with policy development and implementation. It was suggested that the step-down language should be included with the policy proposal, and that adjustments could be made later, if necessary.

OPTN contractor staff noted that 1 year after implementation, the Committee will have access to the six-month monitoring report, which would likely show any significant changes. It was noted that at this stage, there will still likely be the bolus of candidates at higher statuses. Contractor staff asked the Committee to determine the appropriate interval between implementation and the step-down. SRTR staff noted that simulations likely would not be available to inform this decision. A member suggested the step-down occur 12-18 months after implementation, as long as data does not indicate any issues resulting from the policy change. After discussion, the Committee agreed to move forward with the step-down approach occurring 18 months after implementation, and including a review of the monitoring results at 12 and 18 months post-implementation.

Next steps:

The OPTN Executive Committee is scheduled to review the project plan on 08/29/2024. If approved, the Heart Committee will continue working on the draft proposal as part of the 10/09/2024 in-person meeting. In addition, the Committee will continue working on the policy proposal.

3. CD of Hearts: Proximity efficiency attribute and costs associated with travel and/or perfusion technology

The Committee submitted the *Continuous Distribution of Hearts Update, Summer 2024* for public comment. Some of the public comments received have addressed the proximity efficiency attribute. Respondents have expressed concerns that transplant programs are being negatively impacted by the increasing costs associated with organ procurement, especially the rise in perfusion device usage. Commenters have raised equity concerns that transplant programs who cannot afford the rising costs and/or perfusion devices will not be able to travel for donor organs, resulting in an access disadvantage for their candidates.

Summary of discussion:

Decision #1: The Committee agreed to continue using the current rating scale for the proximity efficiency attribute.

OPTN contractor staff reminded the members that the public comment document, Continuous Distribution of Hearts Update, includes a question asking respondents if they agree with the relatively low priority associated with the proximity efficiency attribute in the Values Prioritization Exercise (VPE). Contractor staff provided an update about some of the initial public comment feedback addressing proximity efficiency. For example, those submitting individual comments about the proposal as well as those commenting at the regional meetings are sharing concerns about the increasing costs associated with traveling to procure a donor heart and the high costs associated with perfusion technology devices. Contractor staff asked the Committee members to consider the following concepts:

- To what extent might costs associated with traveling and/or costs of perfusion technology cause transplant programs to forego donor opportunities?
- When thinking about the goal of promoting the efficient management of the organ placement system, how can heart CD account for potential behavioral changes resulting from increased costs?
- Should the Committee consider additional opportunities to promote efficiency?
 - E.g. Ensuring standardization of donor information (recommended based on lung transition to CD)
 - E.g. Defining a 'hard to place' donor heart and establishing incentives for their use (Liver Committee considering similar approach)?

Staff also reviewed the Final Rule requirements for considering geographic proximity as a factor in organ allocation.

The Committee members reviewed the rating scale they previously created. The scale provides 100 percent of the priority points when the donor and candidate hospital are within 500 nautical miles (NM) or less of each other. After 500 NM, the priority points decrease linearly to zero priority points at 1,500 NM. The priority points remain at zero beyond 1,500 NM. When developing the proximity efficiency rating scale, the Committee members concurred that 500 NM was an appropriate inflection point because it captured most travel distances based on results provided in the five-year monitoring report. The members were also comfortable with decreasing the priority beyond that distance. A member said that when developing the rating scale, the Committee considered using a shorter distance appropriate for driving, but it was acknowledged that driving is uncommon for hearts. The Committee also wanted to discourage unnecessary flying across the country, so settled on 1,500 NM for priority cutoff.

Contractor staff added that when the Committee develop the rating scale, heart perfusion technologies were just starting to become available. The Committee's decision at that time was not to address perfusion technology because it was not universally available/adopted and costs were unknown.

The members discussed how the overall weighting given to the proximity efficiency attribute in the composite allocation score may need to be greater than the Committee was initially considering in order to ensure a sustainable network. Without the appropriate weighting, offers will come from all over the country, potentially leading to people accepting offers that are too far away. Therefore, if the Committee wants to reduce travel of donor organs, then it can increase the attribute's weight within the composite allocation score. Additionally, the allocation of efficiency points should be carefully considered to avoid bias against remote centers. Shorter distances should be looked at to consider the effect of efficiency, but trade-offs in equity need to be considered. Cost is also a concern, but some believe that highly urgent patients should be able to receive long distance hearts if the outcomes are good. If organs are procured and travel long distances, then there may be a need for centers to disclose certain elements of their donor selection process to patients, such as whether they take long distance donors or high-risk donors.

At least seven Committee members participating in the meeting indicated support for keeping the proximity efficiency rating scale as it is currently configured. No Committee members indicated that they oppose the current rating scale. A member asked if the Committee could request optimization and/or modeling of multiple scenarios involving distance and efficiency. OPTN contractor staff responded that the optimization effort is well-designed to provide such information in a timely manner for the Committee's consideration. Members largely agreed that the attribute should receive a relatively large weighting within the composite allocation score. They thought this would be appropriate to ensure donor organs do not travel too far.

Next steps:

The Committee will continue reviewing the attributes and rating scales for appropriateness. For the proximity efficiency rating scale, the Committee can use the optimization tool to consider different inflection points associated with how much priority to provide. The expectation is that sometime in the near future the Committee will begin considering attribute weights within the composite allocation score.

4. Open forum

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

5. Closing remarks

The Chair thanked the members for attending the meeting.

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 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
 - Tamas Alexy
 - Kim Baltierra
 - Jennifer Cowger
 - Kevin Daly
 - Rocky Daly
 - Timothy Gong
 - Eman Hamad
 - Earl Lovell
 - Cindy Martin
 - Mandy Nathan
 - John Nigro
 - David Sutcliffe
 - Martha Tankersley
 - Dmitry Yaranov
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Yoon Son Ahn
 - Monica Colvin
 - Grace Lyden
- **UNOS Staff**
 - Cole Fox
 - Kelsi Lindblad
 - Alina Martinex
 - Eric Messick
 - Sarah Roache
 - Holly Sobczak
- **Other Attendees**
 - Shelley Hall
 - Glen Kelley