OPTN Heart Transplantation Committee
Meeting Summary
June 12, 2024
Conference Call

Rocky Daly, MD, Chair
J.D. Menteer, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via WebEx teleconference on 06/12/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Review results of Values Prioritization Exercise (VPE) and Committee Discussion – Part 2
3. Project form development for E*scalation of Status for Time on Ventricular Assist Device*
4. Open Forum
5. Review results of Heart risk stratification data analysis and Committee discussion
6. Closing remarks

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. OPTN contractor staff mentioned that heart offer filters were scheduled to give on June 13, 2024. The new and returning members were reminded that they must complete the education modules in the OPTN Computer System and sign the conflict of interest and confidentiality agreement. The upcoming regional meeting dates were shared with the Committee and members were told they may need to present an update of heart continuous distribution at their regional meetings.

2. Review results of Values Prioritization Exercise (VPE) and Committee Discussion – Part 2

Shared with the Committee were the results of analysis of the written comments submitted as part of the VPE. The members discussed the main themes identified based on the public's written feedback. The Chair reminded the members that community input about the Heart CD work is valuable and will serve as a reference as the Committee moves forward.

<u>Data summary:</u>

OPTN contractor staff provided a brief overview of the comments included in the analysis. There was a total of 1,298 written comments submitted by those completing the values prioritization exercise. Of these, 453 comments were removed from the analysis because they reiterated the individual's rating or had no analyzable content. A total of 845 comments were coded for analysis to identify themes. In addition to the information provided in the presentation, a written summary was also provided to the Committee members and posted to the Committee's SharePoint site.

The following were identified as major themes:

- Biologically difficult to match candidates receive very few offers and often become medically urgent due to lack of offers

- Predicting good post-transplant outcomes is difficult
- Improvements and advances in technology are nullifying concerns regarding distance and will continue to improve
- Pediatrics have less options and face challenges similar to biologically difficult to match candidates; ped hearts should be prioritized for peds
- Mixed response about living donor status in thoracic allocation

When reviewing the pairwise comparisons, the following sentiments were identified among the comments (meaning the comment or a sentiment similar to it was expressed multiple times):

- A highly medically urgent candidate vs. a pediatric candidate:
    - Depends on age of medically urgent candidate; young adults should receive more priority than older adults
    - Pediatric candidates have access to fewer donors
    - Pediatric candidates should receive priority for pediatric donor hearts
    - Life years benefit for pediatric candidates
- A highly medically urgent candidate vs. a prior living donor (PLD)
    - PLD should not matter for heart allocation
    - PLD is for altruistic reasons and risks of donation are known
    - PLDs should be prioritized to honor donation and encourage donation
- A highly medically urgent candidate vs. a biologically difficult to match candidate
    - Biologically difficult to match get few offers whereas medically urgent will likely get another offer soon
    - Biologically difficult often become urgent due to lack of offers
- A highly medically urgent candidate vs. a candidate with good post-transplant outcomes
    - Predicting outcomes is difficult
    - Concerns about transplanting patients with expected survival of <1 year
- A highly medically urgent candidate vs. a candidate waiting a long time
    - Main goal should be to save lives
    - Medically urgent cannot wait
    - Special considerations for those with left ventricular assist devices (LVADs) and artificial hearts
- A highly medically urgent candidate vs. a nearby candidate
    - Advances in technology nullify concerns about hearts traveling longer distances
    - Prioritize closer candidate to maximize outcomes

Summary of discussion:

Decision #1: The Committee agreed not to include a post-transplant survival attribute as part of the first version of continuous distribution of hearts.

Decision #2: The Committee also agreed to put-off future discussions of the topic until new or more information is available to move the conversation forward, or until after the first iteration of the policy has been finalized.

The Chair reminded the Committee that the community's input on CD is valuable, but not binding on the Committee's decision-making. The members began by discussing the 'very nearby candidate' (which was used to represent the proximity efficiency factor). The Vice Chair mentioned the comments regarding technology nullifying the concerns regarding distance. The Vice Chair noted that this seems somewhat at odds with the OPTN Borad of Director's directive to improve efficiency in the allocation process. The

Vice Chair added that it is important to weigh the consideration of using 'long distance donors' against the fact that there is a fixed heart donor pool and that may not increase the number of transplants. The Chair added that when thinking about proximity efficiency, the Committee should also consider the costs and access to such technologies that each transplant program faces and how they are different depending on the program. A Committee member agreed that the costs of technology and the costs of transportation over longer distances must be considered. The Chair reminded the members that the way they constructed the proximity efficiency rating scale means the more weight they give the attribute should help reducing flying organs back and forth across the country and make it more efficient to accept organs that are closed to the transplant hospital. Another member asked if the future modeling activities can provide more insights into the question about how new technologies will impact distance traveled? The member also asked if the modeling can identify where efficiencies can be gained with little cost? OPTN contractor staff stated that a benefit of mathematical optimization is that the Committee can suggest multiple weighting scenarios and also quickly iterate on the results. A member of the SRTR contractor staff explained that there is limited transportation cost data and also limited data about the presence and/or lack of technologies across transplant centers. The SRTR contractor staff said that offer acceptance can be modeled across transplant centers, but it is difficult to model transplant center trade-offs for costs and urgency.

The Chair said that all blood groups should have equal access to transplant, and that the Committee can learn from the experience with lung continuous distribution. It was mentioned that small-sized candidates face a limited donor pool, and wondered how this might be addressed in terms of prioritization of pediatric candidates?

The Committee then discussed the results of the VPE weighting related to post-transplant survival and the comment submitted by the participants. The Committee has discussed several times whether post-transplant survival should be included as an attribute in the first iteration of heart CD, the Chair stated and following each discussion, the Committee has decided that it should not be included in the first iteration. The Chair continued that post-transplant survival is the primary consideration heart transplant professionals think about in all transplant matching. All programs are held accountable for 1-year survival. Accountability is so stringent that it may decrease access as a program may decide not to add a patient to the waiting list because the program believes the candidate will not do well after transplant. Additionally, there is no validated model to assess post-transplant survival for heart recipients. For these reasons, the Committee decided not to include this attribute in the first iteration, noting that it could be included in future iterations.

Based on the reasons provided, the Chair asked the Committee members if they agreed that post-transplant survival should not be addressed as part of the first iteration of heart CD and also if they agree the matter does not need to be re-adjudicated in the near future? The members concurred with not including it as an attribute in the first iteration for the reasons mentioned, especially because there is insufficient data from which to build a model at this time. At the same time, several members stressed that this is a very important issues and the Committee needs to consider how it will work towards such a model moving forward.

Next steps:

The Committee agreed not to include a post-transplant survival attribute as part of the first version of continuous distribution of hearts. They also agreed to put off future discussions of the topic until new or more information is available to move the conversation forward, or until after the first iteration of the policy has been finalized.

3. Project form development for E*scalation of Status for Time on Ventricular Assist Device*

The members agreed they want to pursue a policy project to give additional medical urgency priority to adult heart status 4 candidates with dischargeable left ventricular assist devices (LVADs) who have been on the waitlist for a long time. The Committee spent the rest of the meeting reviewing waitlist mortality information of such candidates and discussing potential solutions to include in the project form.

Data summary:

The Committee was presented information from the five-year monitoring report associated with the modifications to adult heart allocation policy that was implemented in October 2018. The information included the numbers of candidates and registrations added to the waiting list, waitlist mortality rates, and median days to transplant, among other information, comparing adult heart status 4 candidates with other statuses. In some cases, the information was specific to status 4 candidates listed using the dischargeable LVAD criteria.

Summary of discussion:

> Decision #1: The Committee agreed to move forward with a project form proposing transitioning status 4 candidates with dischargeable LVADs to status 3 after such candidates have been waiting for five years, and status 2 after they have been waiting seven years (Option 1).

The Chair opened the discussion by thanking one of the Committee members for leading the discussion. The Chair reminded the Committee that they had initially agreed to not take up the question now and instead address it through continuous distribution. However, because it now may take longer to develop the heart CD policy proposal and have it implemented, it seems appropriate to work on developing an interim solution that can be implemented prior to heart CD.

A member reviewed with the Committee the proposed timeline for completing the project form and submitting it for consideration by the OPTN Policy Oversight Committee (POC). The Committee has dedicated time during today's meeting and the July 2, 2024, meeting to developing the project form and reaching agreement on a potential solution. The form will be submitted for review at POC's August 8, 2024, meeting.

A potential solution previously considered in May, 2023 was presented as a starting point for discussion. The potential solution included transitioning candidates assigned to status 4 with a dischargeable LVAD to status 3 after a candidate had been on the waiting list for 365 days. On day 366 at status 4, a candidate would be transitioned to status 3. In addition, a candidate waiting 730 days would be transitioned to status 2. The Committee members described an issue with this approach is that it would result in a large increase in the number of patients assigned to statuses 2 and 3. The member asked how the Committee might phase in such changes to avoid an over-assignment of status 2 and 3 candidates?

The Committee reviewed and discussed the following information from the Five-Year Monitoring Report of Heart Allocation: Proposal to Modify the Heart Allocation System. The Committee cited the following as important to the potential project:

- Deaths per 100 active-patient years waiting by criteria within medical urgency status
- Median days to transplant by criteria within medical urgency status post-implementation
- Adult heart waitlist additions by criteria within medical urgency status at listing post-implementation

In addition, information about survival rates for patients supported by continuous flow (CF) LVADs was also presented to the members. The information suggests that survival rates have increased for patients who have received a durable LVAD.

A member stated that if the Committee is going to assign a high status to patients who are waiting while being supported by a durable LVAD, then it is important for that time on LVAD to somewhat match that medical urgency. The member added that the Committee has to make some important designs about the time frame and the urgency because there are not a lot of data analyses available that answer these questions. Additionally, the Committee needs to consider how the number of years waiting will impact the volume of potential waitlist additions to statuses 2 and 3 if a policy proposal moves ahead. Furthermore, the Committee needs to think about how policy changes might be able to incentivize transplant programs to rely more heavily on durable LVADs to support their patients as opposed to merely extending patients' time at the higher statuses. The member suggested that to prevent a large number of patients from accumulating at statuses 2 and 3, the Committee may need to rely on timeframes that are somewhat lengthier than might initially be expected, at least in the short-term. For example, the Committee may want to initially propose that a candidate must wait five years while supported by a durable LVAD before being eligible for status 3, and the waiting time for status 2 eligibility might be appropriate at seven years. Because the initial waiting times might be considered too long, the member suggested the Committee might consider whether a 'phase-in' period could be used. For example, if initial timeframes are five and seven years, then perhaps after a pre-defined interval, the Committee analyzes the data from the time after implementation and decides to decrease the waiting time to four years and six years.

Three options were presented for initial consideration. Candidates assigned to status 4 on the waitlist list using the dischargeable LVAD criteria would be transitioned to statuses 3 or 2 based on having waited the following number of years, respectively:

- A candidate would be transitioned from status 4 to status 3 after 5 years and to status 2 after 7 years (Option 1)
- A candidate would be transitioned from status 4 to status 3 after 4 years and to status 2 after 6 years (Option 2)
- A candidate would be transitioned from status 4 to status 3 after 3 years and to status 2 after 5 years (Option 3)

The Committee agreed that the transitions should be phased in over time but did not determine what such a timeframe would be.

A member supported the suggested timeframes and the phase-in approach. The member also stated that how the change is communicated to the heart transplantation community is very important. A member favored starting with the five- and seven-year approach described by Option 1. There was also discussion that five- and seven-years might be too long because while durable LVAD patients are generally stable, their clinical situation deteriorates quickly after they start experiencing complications or other issues associated with the device.

It was asked how many current LVAD patients have been waiting for five, six, and seven years? The response was that it would be very challenging to identify the number of impacted patients because it would require mering two different sources of data, one of which is not OPTN data. This led to a discussion about whether it is appropriate for otherwise healthy LVAD patients to get priority ahead of other medically urgency patients. For example, a candidate with a durable LVADs who is experiencing a pump issue is eligible for status 3; however, what is being suggested would allow healthy status 4 LVAD patients access to status 2 after seven years. Is that appropriate?

The Committee agreed to move forward with submitting a project form to the Policy Oversight Committee. They also agreed to consider five and seven years as the first eligibility criteria with the understanding that they will revisit the criteria during future discussions.

Next steps:

The Committee agreed to move forward with proposing Option 1 in the project form. They were reminded that they will also have opportunities to discuss the subject as part of their June 18 and July 2, 2024 meetings. OPTN contractor staff said they would provide the Committee with an updated version of the project form before the next meeting.

4. Open Forum

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

5. Review results of Heart risk stratification data analysis and Committee discussion

The meeting time was spent discussing the values prioritization exercise results and the Escalation of Status project form. The Committee did not discuss the results of the risk stratification data analysis. The meetings agreed to re-schedule the discussion for a future meeting.

6. Closing remarks

The Chair thanked the members for their participation.

Upcoming Meeting

- June 18, 2024
- July 2, 2024
- July 16, 2024

Attendance

- **Committee Members**
  - Rocky Daly
  - J.D. Menteer
  - Tamas Alexy
  - Kim Baltierra
  - Jennifer Cowger
  - Timothy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Glen Kelley
  - Earl Lovell
  - Cindy Martin
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - Brendon Cummiskey
  - Cole Fox
  - Alina Martinez
  - Eric Messick
  - Sarah Roache
  - Laura Schmitt
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - Maria Avila
  - Kevin Daly
  - Jill Gelow
  - Shelley Hall
  - Amanda Nathan
  - David Sutcliffe