OPTN Heart Committee
Meeting Summary
April 16, 2024
Conference Call

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

Introduction

The Heart Transplant Committee ("Committee") met via Webex teleconference on 04/16/2024 to discuss the following agenda items:

1. Continuous Distribution of Hearts
2. Public Comment Analysis Document
3. Committee Business: Quarterly Review Board and Heart Offer Filters

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

1. Continuous Distribution of Hearts

It was decided that OPTN Contractor staff would email the members the list of risk stratification data elements, and the members would share feedback, questions, and concerns with staff. In addition, the results of the OPTN Contractor staff's data analysis of the risk stratification data will be presented during one of the Committee's June meetings.

Summary of Presentation:

Slides were presented reflecting the Committee's approach to a medical urgency attribute is to transition existing adult and pediatric statuses and criteria to a continuous rating scale. As part of the transition, what is currently considered adult heart status 1 will receive 100 percent of the prioritization, and what is currently considered to be adult heart status 6 will receive zero percent of the prioritization.

Summary of discussion:

The Chair started the discussion by reminding the members that following the presentation of the U.S. CRS during the March 29th meeting, there was strong consensus that CD of hearts is not quite ready to develop and implement a CRS. The Chair pointed out how the Committee plans to transition the statuses to a continuous scale. The Chair said that an advantage of this approach is that the community would understand the change. CD of hearts will be confusing when first implemented, and keeping some consistency in how medical urgency is determined between now and CD in the future could help with the transition. They also acknowledged that there is community-wide desire for progress around better defining medical urgency and moving forward with CD of hearts. It was also pointed out that results from public comment documented the community's frustration that heart allocation continues to rely on the statuses, which are built around devices and inotropic supports. Furthermore, the Committee still needs to determine whether candidates waiting with left ventricular assist devices will be permitted to receive as much priority as candidates considered to be the most urgent under the current allocation framework.

There was concern about the effectiveness and applicability of the candidate risk score that was presented as part of the Committee's March 29th meeting. The Chair said that the authors of the U.S. CRS journal article identified a group of lower medically urgent patients, and a subset of those patients had poor outcomes. The poor outcomes indicate the patients actually had higher medical urgency and as a result should have been assigned to a higher status. The thinking is that the subset of patients may have had more heart failure or enough heart failure based on lab studies than the transplant programs realized. According to the Chair, a potential issue with the journal article's finding is that the use of mechanical support treats the heart failure and corrects all the lab data. The authors' results especially highlighted patients supported by or who had ever been supported by a durable LVAD as being disadvantaged, and the Committee and community are acutely aware of the issues facing this group of patients.

Another member said that a variety of candidate risk score calculations have been considered by the community in the past and all come up a little short. The member added that the data currently available may not be adequate for moving forward with a CRS at this point. Therefore, developing a CRS now should not be a priority of the Committee.

The Chair asked if members wanted to consider a hybrid approach applying to status 6 patients, those patients who are at home, not on a device, not on inotropes, but on heart failure medications. The Chair pointed out that developing a CRS requires resources and time and would impact getting a CD of hearts policy approved and implemented. It also means that it will be harder in the future to identify the reasons why some aspects of CD might be working while others are not. For the medical urgency attribute, the members were asked to indicate their preference for pursuing the current approach of transitioning the statuses and criteria to a continuous rating scale or pursuing a candidate risk score, at least as a hybrid approach for candidates assigned to lower statuses. Approximately, six members were interested in learning more about a candidate risk score.

A member reminded the Committee that during the March 29th meeting, there was discussion and some agreement that it was a good idea to pursue a hybrid approach to developing and including a CRS in the initial version of CD of hearts. The member continued that if not addressed now, then it will be years before a CRS is added to CD of hearts. The member stated if the Committee does not try to include it now, at least to a small degree through a hybrid approach involving the lower risk candidates, then the Committee is committing to not developing and implementing a CRS for years to come. A Committee member agreed and pointed to the amount of time it will take to get the status 2 changes implemented for balloon pumps and percutaneous mechanical circulatory devices and the Committee voted on those six months ago. A meeting attendee agreed that a change like this would add time to getting to a final policy proposal, However, this is also an opportunity to consider a CRS which is something the community has been requesting for a long time. The attendee went on to say that if the Committee is transparent about planning for and developing a CRS, then the community may accept the additional time. A Committee member suggested that an actual timeline identifying milestones could be beneficial. For example, describing that the Committee will collect certain data elements for two years, at which time a CRS will be instituted.

A meeting attendee said the Committee should clearly state why they chose not to begin developing a candidate risk score for inclusion with this version of CD of hearts. The attendee said that there was a lot of discussion of a candidate risk score at the International Society of Heart and Lung Transplantation (ISHLT) conference earlier in April. As a result, the attendee said that the Committee should explain its decision-making around these topics to educate the community. A member agreed that it needs to clearly be communicated to the heart community that the Committee does not think there is a good

patient predictor model right now, and the Committee agrees that the next step is to work towards a risk model, but more information needs to be collected.

The Committee discussed that as part of the allocation changes implemented in October 2018, the OPTN began collecting data believed to be associated with medical urgency and post-transplant survival. There is now approximately five-year's worth of risk stratification data available. The members were interested in learning more about the data to determine if it can be used in developing a candidate risk score. For example, a member mentioned that the data elements being discussed can be captured electronically, and it seems odd for the Committee to be unable to develop some type of score when the data are available. Some members expressed concern about the quality and standardization of the data.

OPTN Contractor staff told the Committee that the risk stratification data are being reviewed with the intention of providing the results to the Committee in September. However, that analysis could be presented sooner if that is the Committee's desire. OPTN Contractor staff also asked the Committee if there are any particular data elements that they would like the analysis to focus on or are there specific questions the members want to explore? For example, what information does the Committee think is important for a risk score but which the OPTN is not currently collecting? A group of members indicated they are interested in sharing their ideas and questions.

Returning to the concept of a timeline, a meeting attendee said the Committee could tell the community the five-years' worth of risk stratification data are being analyzed now to determine the quality, availability, what can be interpreted from it, can the data be used to develop a score? If the answer is yes, then the Committee could attempt to include it in the first version of CD of hearts, but if the data does not lend itself to that or additional information is needed, then the Committee will work towards including something in the next version.

The Committee briefly covered previous conversations on approaches to waiting time, including additional priority for pediatric patients with extended waiting times, as well as adults with extended waiting times.

Next steps:

OTN Contractor staff will email the current risk stratification data elements to the members for review. Members are asked to send staff any feedback or concerns about the data elements. Results of the data analysis currently being performed will be shared with the Committee at a future meeting.

OPTN Contractor staff informed the Committee that the OPTN Policy Oversight Committee (POC) has a formal process for committees to summarize whether policy changes or data collection efforts were successful, whether there were unintended consequences, and/or any other information a committee wants to share. Because the 5-year monitoring report is the final report about the modifications to adult heart policy that were implemented in October 2018, OPTN Contractor staff will work with the Committee on drafting the summary response for POC. Committee members will be asked in the future to provide their feedback.

2. Public Comment Analysis Document

No decisions were made.

Summary of Presentation:

OPTN Contractor staff shared information about the Values Prioritization Exercise (VPE) with the Committee. A graphic identifying the volume of responses received categorized by OPTN stakeholder

group was shared. A graphic identifying the weights associated with each attribute based on the Committee members' responses was also shared.

Summary of discussion:

OPTN Contractor staff told the Committee that a total of 702 individuals completed the VPE. Individuals associating themselves with transplant programs accounted for the majority of responses. However, individuals identifying as patients, donors, or affiliated with patients and donors accounted for the second most number of responses. A member highlighted the importance of patient responses in this public comment analysis. This member also expressed the importance of pediatric candidate weighting getting a high response. OPTN Contractor staff provided a brief summary of the attribute weights based on the Committee's responses. Based on the responses of the 13 Committee members who completed the VPE, the "high medically urgent candidate" attribute received the greatest weight (39.0%), and "a pediatric candidate" received the second highest weighting (26.2%). The priority for "prior living donor" attribute received the third highest weighting (13.7%), more than "a biologically difficult to match candidate," "a candidate with good post-transplant outcomes," "a candidate who waited a long time," or "a very nearby candidate." OPTN Contractor staff added that the full VPE results will be provided during the Committee's May 21st meeting.

Next steps:

The VPE results will be shared with the Committee during the May 21, 2024 meeting.

3. Committee Business: Quarterly Review Board and Heart Offer Filters

No decisions were made.

Summary of Presentation:

OPTN Contractor staff provided brief updates about the latest quarterly review board report and the upcoming implementation of heart offer filters.

Summary of discussion:

OPTN Contractor staff said that the most recent quarterly review board report is available on the Committee's SharePoint site. The report provides information about regional review board decisions during the last three months, and includes information about adult and pediatric exception requests, and the process times associated with the regional review board decisions. In addition, OPTN Contractor staff informed the members that implementation of the heart organ offer filters is likely to occur in mid-May, and that members will be asked in the future to share their experiences on how the filters are being used.

Next steps:

None

Upcoming Meeting(s)

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

Attendance

- **Committee Members**
  - Richard Daly
  - J.D. Menteer
  - Amrut Ambardekar
  - Jennifer Carapellucci
  - Jennifer Cowger
  - Tim Gong
  - Eman Hamad
  - Jennifer Hartman
  - Earl Lovell
  - John Nigro
  - Martha Tankersley
  - Dmitry Yaranov
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Grace Lyden
  - Katie Audette
  - Monica Colvin
- **UNOS Staff**
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Sarah Roche
  - Holly Sobczak
  - Sara Rose Wells
- **Others**
  - Shelley Hall