OPTN Heart Committee
Meeting Summary
March 6, 2024
Conference Call

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

Introduction

The Heart Committee (Committee) met via WebEx teleconference on 03/06/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. CD of Hearts Request for Feedback update
3. Other Committee business
4. Open Forum

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

1. Welcome and agenda review

Members were encouraged to complete the Values Prioritization Exercise (VPE) associated with the Request for Feedback (RFF) document, both of which are currently available for public comment. The deadline for completing the VPE is March 19, 2024. The Committee Chair informed the members that an article recently published in the Journal of the American Medical Association (JAMA) presents an alternative way to consider adult heart medical urgency than the Committee is currently proposing for continuous distribution. The Chair said the Committee should review the option proposed in the article. Members were reminded about the upcoming in-person meeting scheduled for March 29th in Houston, Texas. They were encouraged to complete all travel plans as soon as possible. OPTN Contractor staff stated that the meeting is also being streamed online at Vimeo.com/OPTN.

2. CD of Hearts Request for Feedback update

The OPTN Contractor provided an overview of the comments received regarding the Committee's Request for Feedback document. Comments have been provided from various sources, including individuals and groups submitting feedback to the OPTN website, other OPTN committees, and comments captured during the OPTN regional meetings. To date, some of the general themes from the comments have been around the attributes of proximity efficiency, post-transplant survival, and recently at an OPTN regional meeting, priority for living donors.

Summary of discussion:

OPTN Contract staff told the members that a .pdf file containing all of the comments submitted through March 5th is available for their review on the Committee's SharePoint site.

For the most part, the comments received have been supportive of the Committee's proposed attributes and rating scales. Starting with the priority for prior living donor attribute, an attendee at the recent OPTN Region 9 meeting asked what it is about being a prior living donor that warrants additional priority in the allocation system? The individual continued that while this is an altruistic act, it is really

worthy of increasing the potential for such individuals to get transplanted, more so than any other altruistic act that might help the waiting list population? Shortly after this individual spoke, another regional meeting attendee who identified themselves as a living donor spoke about how important giving prior living donors greater priority is in order to encourage others to also become living donors. The individual said that they are part of a larger group of living donors who met recently and who also felt strongly that there should be an attribute giving priority to prior living donors. OPTN Contractor staff wanted to make sure the Committee is aware that the community is interested in this attribute. A Committee member said that they previously worked for some time in their center's kidney transplant program and that living donors were just woven into the day-to-day operations, so it is interesting to hear comments pushing back against priority for prior living donors. The member agreed that how this will be weighted will be important, especially with the understanding that it's not going to be something that happens every day.

With regard to post-transplant survival, those who are actively involved with heart transplantation appear to agree with the Committee's approach to hold-off on trying to create a post-transplant survival attribute and implement it with the first iteration of continuous distribution of hearts. Comments from those not associated with heart transplantation appear to be more inclined to ask why such an attribute is being excluded with the first iteration. Overall, this likely reflects the fact that heart does not have an adequate option at the moment, as opposed to the way the OPTN Lung Transplantation Committee could rely on the post-transplant survival calculation in the Lung Allocation Score when developing its continuous distribution allocation framework.

The proximity efficiency attribute has received multiple comments and might be something the Committee wishes to re-visit in the future in order to ensure the members are comfortable with where that ended up in terms of the rating scale. During the OPTN Transplant Administrators Committee (TAC) meeting, some concerns were raised about the additional costs of new systems being introduced to care for donor organs after procurement. It was mentioned that such systems might be a strain on transplant programs without a lot of resources. Additionally, it was asked whether other programs, who can afford such systems, might have greater access to organs as a result? The Committee members were reminded about how they set up the rating scale for proximity efficiency in an effort make sure donor hearts are not traveling super far, while also making sure that there is some ability to travel and get an organ. Another TAC member asked to what extent driving had been factored into the committee's proposed proximity efficiency rating scale. It was acknowledged that Committee members have previously said they are more likely to fly by plane or helicopter to procure an organ than they are to drive.

Other themes appearing in the public comments include ensuring pediatric candidates are not disadvantaged by any changes and for the Committee to be thinking about potential unintended consequences for pediatric candidates based on changes. There also appears to be support among the comments for the Committee's proposed method of giving additional priority within the medical urgency attribute for time on a VAD.

Committee members who have presented at a regional meeting were asked if they would like to share their experiences. A Committee member commented on the proximity efficiency part by saying that at their regional meeting last week, they perceived a kind of anxiety and attention on the costs associated with pump support for ex-vivo perfusion, as well as with the travel that has come with the most recent adjustments to the allocation system. The member said that from the Committee's perspective the primary objective is making sure that as many hearts are allocated as possible and not have potential donor organs go unused because such organs cannot be allocated to high urgency patients. At the same time, the Committee wants to encourage closer distribution when possible. The member further commented that they think the Committee's approach does that. The rating scale continues sharing out

to five hundred nautical miles, and then priority decreases after that and on the scale. The important thing that will keep travel from being all over the country will be how much weight is assigned to the attribute. Still, given all the discussions that have occurred at the regional meetings, it would be interesting to have that discussion or revisit the previous decisions during the Committee's next in-person meeting.

Another member said that they've also heard about the costs associated with travel, it's not just the organ being on the pump, but there is also anxiety from the OPO standpoint because as we share organs more nationally, then the OPO coordinators are not as familiar with the procedures and testing requests of individual centers that they usually that they usually work with. So, there is a lot more communication, a lot more testing delays, and that sort of thing because it's harder for an OPO to anticipate and address the delays that might occur because of a distant transplant center's requests.

Another member also discussed the proximity efficiency attribute. The member said that they encouraged everyone at their center to complete the VPE, and then everyone who completed it met and shared their perspectives. A couple of comments acknowledged that with the organ devices permitting organs to travel farther it creates advantages for centers with more resources. The commenters said that they gave less weight to the proximity efficiency attribute, and they preferred priority for a candidate who is physically closer to the donor hospital. The Committee member said they did not entirely agree completely with the sentiment of the others at their transplant program, but it was interesting to hear the issue come up in that way.

The Chair talked about using the weighting of the attribute to help reduce the very long distance traveling. The Committee can look at the data the Lung Transplantation Committee has regarding the impact of proximity efficiency. If the proximity efficiency attribute is weighted to heavily it could inadvertently give undo weight to low urgency patients who are considered local compared with patients who are at slightly longer distances but who are at higher urgency. That's probably something the Committee wants to avoid. The modeling activities should help the Committee better understand the impacts.

The Chair indicated that there are at least two topics the Committee needs to spend additional time considering. The first is returning to the medical urgency attribute and rating scale. The Committee discussed and planned moving the statuses onto a continuous curve and then possibly breaking up the various criteria within a status. An alternative to this approach would be something like a risk score as described in the JAMA article. (It was said that the OPTN Contractor previously emailed the article to the members, but if anyone still needed it to let the contractor know.) Members were asked to review the article ahead of the in-person meeting, in order to start thinking about some kind of risk score for predicting mortality on the waiting list. This is a different approach from the current statuses that are basically centered on the type of mechanical support that patients are receiving. The Chair said that a concern with the proposed risk score is that a lot of it is based on physiologic variables that are all normalized with time on mechanical support. As a result, the score ends with trying to predict risk of being on a particular device over time and that really is what the Committee is already doing in terms of transitioning the current statuses to a continuous scale.

The second topic for consideration the Chair raised involves how to incorporate waiting time in a continuous distribution of hearts allocation framework. So far, the Committee has not listed it as an attribute. The Committee may want to discuss it as an attribute for patient access in some way so that waiting time receives some additional priority. The Committee may end up not giving it a lot of weight. Nonetheless, the community is so used to waiting time being part of the allocation process, that not addressing it in continuous distribution may end up confusing people. The Committee can consider how it might be used as a tie breaker.

The Vice Chair commented that waiting time is an important factor for pediatric candidates and should be addressed as an attribute, but it may not be as important for adult candidates. For pediatrics waiting time almost has to be a relatively major factor in the allocation system because as pediatric patients become hospitalized and wait for six months, nine months, twelve months, or fifteen months on the waiting list as an inpatient, if there is no hope that such candidates are gaining priority on the waiting list, that can cause a lot of despair to the families and create even more uncertainty. The Vice Chair said that the pediatric community is going to cry very loudly for waiting time to be included. The concept of using it as a tiebreaker does not work very well for pediatrics.

Still, even if a fairly large amount of priority is associated with waiting time for access or whatever, it does not necessarily translate that such patients are going to get all of the potential priority available. The pediatric waiting time algorithm the Workgroup has been developing is geared towards giving priority to patients only after they have been waiting for a very long time at very high urgency.

As a result, the Committee may want to also consider applying it to adult candidates. For example, an adult patient who has been in the hospital on ECMO for one or two weeks would not get any additional waiting time priority. Similarly, an adult patient who has been waiting at status two or status three for a couple of weeks would not get much priority either. So, applying the pediatric approach to waiting time that the Workgroup has developed that to the adult system, it could become a tie breaker in the way that has been described, even if there is a lot of priority provided to those at high urgency for a long period of time.

The OPTN Contractor provided an update on the number of individuals who have completed the Values Prioritization Exercise. As of March 5th, a total of 394 exercises have been completed. Several emails have been sent to the community at-large, and some sub-groups have gotten extra updates asking them to add their opinions. A breakdown of who has completed the exercise by OPTN member type and other groups was provided. Committee members were encouraged to complete the exercise if they have not already done so. Individuals associating themselves with transplant programs account for the largest number of completions, and 44 individuals who identified themselves as having an OPO association have also completed the exercise.

Next steps:

Members were told that there are three more regional meetings to go as well as upcoming presentations to the OPTN Living Donor Committee and the OPTN Ethics Committee. A more detailed analysis of the public comment feedback associated with the Request for Feedback document will be provided to the Committee. Additionally, the Committee should expect to receive a more detailed analysis of the VPE results in May. All of the information will be presented will be used to help the Committee make decisions about weighting the attributes and whether to consider changes to existing rating scales. Time for further discussion of waiting time will be part of the in-person meeting.

3. Other Committee business

Summary of discussion:

Members were reminded that public comment ends on March 19th, and that will be the last day to complete the VPE as well. They were also told about the upcoming changes to access the Committee's SharePoint site. More information was provided about the Committee's March 29th in-person meeting in Houston and the Committee dinner the night before the meeting.

Next steps:

The Committee will meet again on March 19th and March 29th.

4. Open Forum

There were no speakers for the open forum discussion period.

Upcoming Meetings

- March 19, 2024
- March 29, 2024 – In-Person Meeting, Houston, TX
- April 3, 2024
- April 16, 2024
- May 1, 2024
- May 21, 2024
- June 5, 2024
- June 18, 2024

Attendance

- **Committee Members**
  - Rocky Daly
  - JD Menteer
  - Tamas Alexy
  - Amrut Ambardekar
  - Jennifer Carapellucci
  - Eman Hamad
  - Glen Kelley
  - Cindy Martin
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - James Alcorn
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Sarah Roache
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall