OPTN Heart Transplantation Committee
Meeting Summary
October 15, 2024
Conference Call

J.D. Menteer, MD, Chair
Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 10/15/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Summarize decisions made during 10/09/2024 in-person Committee meeting
3. Continue introduction to xenotransplantation and hearts
4. Open Forum
5. Closing remarks

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

1. Welcome and agenda review

The Chair welcomed the members and provided an overview of the agenda. Members calling in by phone only were reminded to tell OPTN contractor staff their names for attendance purposes. Non-committee members and those without business before the Committee were reminded that they should follow the proceedings using vimeo.com/optn.

2. Summarize decisions made during 10/09/2024 in-person Committee meeting

The Chair of and OPTN contractor staff summarized the Committee's decisions from the 10/09/2024 in-person meeting. Key topics discussed were identifying and prioritizing options for enhancing the No pediatric exception and review board process, and identifying optimization metrics of success for CD attributes.

Summary of discussion:

> Decision 1: The Committee agreed to pursue an optimization metric of success for sensitization that considers minimizing the variance in transplant rate across three PRA groupings: patients with PRAs from zero to 50, PRAs from greater than 50 to 80, and PRAs greater than 80.

The Chair discussed the options the Committee considered during the 10/09/2024 meeting related to pediatric heart exceptions use and the National Heart Review Board (NHRB) for Pediatrics. During the 10/09 meeting, the primary option the Committee agreed to pursue was creation of a Chair position for the NHRB for Pediatrics. The position would be modeled after similar positions on the Lung Review Board and the National Liver Review Board. The position will function as a liaison and educational resource between the NHRB for Pediatrics reviewers and the heart community. Creating the position requires changes to the operational guidelines and OPTN contractor staff are working to determine whether changing the guidelines requires OPTN public comment.

A member mentioned that during the Committee's in-person meeting, they discussed issues related to adult exceptions and wanted to know what actions the Committee would take regarding these matters. The Chair responded that they used the Pediatric Committee as an example in an effort to improve the Committee's performance. This decision was influenced by public perception of the system, while also recognizing that the adult system has its own challenges. The Chair suggested that we should wait to see how difficult it is to change the operational guidelines, as this may make it easier to address the adult exceptions.

A question was asked about when implementation will occur for the policy changes associated with the *Amend Adult Heart Status 2 Mechanical Device Requirements* project? The policy changes established additional eligibility criteria for assignment at adult heart status 2 using the intra-aortic balloon pump (IABP) criterion and the percutaneous endovascular mechanical circulatory support device criterion. The OPTN Board approved the policy changes in December 2023. OPTN contractor staff explained that the *Amend Adult Heart Status 2* project was one of six OPTN Board approved projects that HRSA delayed from starting the OMB review process under the federal Paperwork Reduction Act. HRSA delayed submission of those projects with the intention of combining them with the data collection changes that would be associated with the HHS Data Collection Directive (Directive). The Directive was issued in April 2024. As of the 10/15/2024 Committee meeting, the six projects had not been submitted for starting the OMB review process.

The members then discussed the sensitization attribute, rating scale, and the associated optimization metric of success. Specifically, they discussed the best optimization metric to use with the rating scale. One option discussed was whether the optimization metric should address minimizing the difference in transplant rate for those with CPRA values of less than 50% compared to those with CPRA values of equal to or greater than 50%. The Chair said that during the Committee's 10/09 meeting, they had discussed minimizing the difference and trying to make patients with higher PRAs have waiting times that are the most similar, within the realm of possibility, to those patients with PRAs that are less than 50%.

Another option was that the goal could be to minimize the variance in transplant rate instead of just minimizing the difference between the groups. The could consider minimizing the variance in the transplant rate across three groups, those with PRAs from zero to 50, those with PRAs of 50 to 80, and those with PRAs of 80 and greater. SRTR contractor staff said that is a reasonable approach for optimization, but added that the groupings are also dependent on the number of candidates in the cohort who will be in each grouping. For example, there probably are not a lot of candidates in the 80 and greater grouping. If it turns out there are only two candidates in the grouping, then it doesn't make sense to optimize the transplant rate for two candidates. The members agreed to pursue this option, at least initially.

Some members raised concerns about the accuracy and appropriateness of the data being used. The concern is that the currently reported information does not necessarily reflect the actual CPRA in the population. How the Committee decides CPRA will be reported could lead to behavioral changes at the transplant program level. The Chair explained that the Committee is developing the sensitization attribute so that a candidate receives greater prioritization based on the number of unacceptable antigens reported by the transplant program. The more unacceptable antigens reported, the greater the prioritization within the attribute. Regarding comparisons with other organs and CPRA values within those populations, OPTN contractor staff noted that the heart distribution of CPRA appears similar to the other organs, with a little bit less in the highly sensitized range. Contractor staff added that there is data available if the Committee wants to make such comparisons in the future. They acknowledged that data from other organ populations could be beneficial but may have certain limitations.

Regarding the priority for pediatric waiting time attribute, the Committee had previously identified the optimization metric as 'time on the waiting list.' A member asked if it would be more appropriate to specify 'active time' on the waiting list. It was pointed out that the other committees developing CD allocation frameworks have used just active waiting time because inactive time is something that policy cannot impact. For example, policy cannot give a transplant to someone who is inactive on the waiting list. Therefore, it is not something than can be optimized of change behavior as the policy is changed. This is similar to transplant rates. Transplant rate is calculated as the number of transplants divided by active years, where we are dividing by the active years because that is what the policy can impact. A Committee member asked whether the Committee should consider a size-related attribute that provides additional priority to very small candidates, especially when they are very small pediatric candidates. A member said the Committee will need to be wary that pediatric priority points might significantly increase access for teenagers and larger pediatric recipients while doing nothing to change the transplant rates for smaller pediatric candidates. Another member acknowledged the possibility but also reminded the others that the primary issue for babies, toddlers, and less than school aged kids is the lack of donors.

The Committee also discussed the waiting time attribute and what an appropriate optimization metric might be for measuring whether it has been successfully optimized. During the 10/09 meeting, the plain language purpose of the attribute was identified as 'time on the waiting list.' The Chair explained that the attribute is trying to account for both medical urgency and time on the waiting list so that candidates accrue waiting time points or prioritization more quickly if they have a higher medical urgency. Candidates with lower medical urgency get fewer waiting time points. The Chair stated that candidates who are equivalent to status 6 in the current allocation system would receive zero waiting time points because they have zero urgency based on the Committee's previous decision to assign zero medical urgency points to that category. The Chair further clarified that when considering the waiting time attribute, the Committee does not want to sacrifice waiting list mortality for candidates with the greatest medical urgency. If a candidate has a high medical urgency, the Committee does not want another candidate to be prioritized ahead of the first candidate based solely on the second candidate's waiting time. At the same time, the Committee wants to provide patients with medical urgency and a non-zero waiting list mortality to have some hope that if they wait long enough their priority will rise to the point that they will have a reasonable chance of getting a transplant. The Chair offered the following clarification of the waiting time attribute's purpose 'it is twofold, in that it allows access for moderate urgency candidates to be offered grafts without impacting the transplant rate for the highest medical urgency candidates. The Chair also offered that maybe the attribute or rating scale should operate in a way that does not impact the waiting list mortality of the most medically urgent candidates, and its impact is somehow restricted to candidates considered to have moderate medical urgency; for example the current status 2, 3, and 4 candidates.

SRTR contractor staff said that the Committee might want to consider an optimization metric like a transplant rate that is stratified by waiting time at the time the simulation is started. When performing the simulation, a specific date is chosen as its starting point. Based on that date, the candidates and their historical information, have a defined waiting time. The analysis could then focus on transplant rates stratified by waiting and somehow adjust for medical urgency of the candidates. Under those circumstances, the metric of success the Committee would want to see is in the groups who have been waiting a longer time, that they have a faster rate of transplant after the differences in medical urgency have been accounted for.

Next steps:

OPTN Contractor staff will continue seeking feedback regarding whether public comment is required for revising the NHRB for Pediatrics Operational Guidelines. Support staff will continue exploring opportunities to enhance or improve the identified optimization metrics of success. Such opportunities will be shared with the Committee. The current functionality of the waiting time rating scale will be explored more closely with MIT staff.

3. Continue introduction to xenotransplantation and hearts

The xenotransplantation and hearts discussion was tabled and will be discussed during a future meeting.

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 and reminded them that the next Committee meeting is on November 6, 2024.

Upcoming Meetings (ET)

- ~~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~~ – Cancelled
- ~~October 9, 2024 from 8:00 am to 3:00 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
  - Denise Abbey
  - Maria Avila
  - Jennifer Cowger
  - Kevin Daly
  - Jill Gelow
  - Tim Gong
  - Eman Hamad
  - Earl Lovell
  - Mandy Nathan
  - John Nigro
  - Jason Smith
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - Keighly Bradbrook
  - Viktoria Filatova
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Laura Schmitt
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall
  - Ted Papalexopoulos