

OPTN Heart Committee

Meeting Summary

May 21, 2024

Conference Call

Rocky Daly, MD, Chair

J.D. Menteer, MD, Vice Chair

Introduction

The Heart Committee (Committee) met via WebEx teleconference on 05/21/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. OPO Committee requests feedback related to Machine Perfusion Data Collection project
3. Results of Values Prioritization Exercise (VPE) – Part 1
4. Committee discussion of VPE results
5. Update regarding Escalation of Status for Time on Ventricular Assist Device
6. Open forum
7. 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.

2. OPO Committee requests feedback related to Machine Perfusion Data Collection project

The OPO Committee is in the process of gathering information before initiating a data collection project addressing machine perfusion practices. The OPO Committee addressed the Committee in order to determine if there are heart-specific data elements that should be considered for data collection.

Data summary

The OPO Committee is seeking input regarding machine perfusion practices from other OPTN committees. The OPO Committee is in the process of developing a data collection project to gather more information about machine perfusion. The presenter said the OPO Committee needs to better understand the impacts of machine perfusion on allocation, proximity efficiency, and the evaluation of organ offers. Currently, not enough information is collected to look at normo-thermic perfusion (NRP) cases across the United States. Additionally, current OPTN data collection efforts do not allow for the collection of necessary organ-specific and/or pump-specific data. The OPO Committee determined there is a need for machine perfusion data collection as part of their previous project addressing deceased donor registration and based on a review of donor information collected in the OPTN Computer System.

Summary of discussion:

Decision #1: A current Committee member and an in-coming Committee member expressed interest in joining an OPO-sponsored workgroup that is being formed to initiate a machine perfusion data collection project.

The presenter asked the Committee members to consider what heart-specific data related to machine perfusion and NRP should be collected. Committee members were also asked to consider whether such information needs to be at a detailed level or if high-level information is sufficient for the identified purposes? The presenter said that the OPO's project would likely create policy establishing the data collection and reporting requirements. As such, the members were asked to consider which OPTN entity or entities should be responsible for reporting the identified data elements from the various OPTN Computer Systems? The presenter added that the OPO Committee is creating an OPO-sponsored workgroup to assist with the project and asked for volunteers.

The Committee Vice Chair suggested to the presenter that the OPO Committee might want to consider contacting transplant programs directly in an attempt to collect more specific information for the project. The Chair asked whether members whose terms are ending on June 30, 2024 could participate on the workgroup and report back to the Heart Committee? Two individuals expressed interest in joining.

Next steps:

OPTN Contractor staff supporting the OPO Committee will follow-up regarding potential volunteers to join the Machine Perfusion workgroup.

3. Results of Values Prioritization Exercise (VPE) – Part 1

The Chair started the discussion by updating the members about a conversion Committee leadership had with the OPTN President and Vice President about the status of the continuous distribution (CD) of hearts activities. Following that, OPTN contractor staff shared the results of the values prioritization exercise (VPE).

Data summary:

OPTN contractor staff shared the quantitative VPE results. These included the number of individuals who completed the exercise, the groups the individuals identified themselves belonging to, and the attribute weightings.

A total of 702 individuals completed the exercise. Of the 702 participants, 396 (56%) identified themselves as associated with a transplant program, 138 (20%) as a patient or caregiver, 90 (30%) with an OPO, 66 (9%) as part of the general public, and 12 (2%) identified with a histocompatibility lab.

The attribute weightings were presented in multiple ways. The weightings were shown based on all 702 responses, unadjusted and adjusted for the demographic entities previously described, as well as by the Committee members who participated. The overall weights when adjusted for respondent type are shown on the table at the beginning of the next page. As the table indicates, all of the participants and the Committee members prioritized the attributes in the same rank order with slight differences in the individual weights. The weightings based on the group type reflected the same prioritization, also with slight differences in the individual weights. Committee members assigned greater weights to a highly medically urgent candidate and a pediatric candidate than the other groups did.

Attribute / Factor Used in Comparison	Weighting: All Participants (N=702)	Weighting: Committee Members (N=13)
A highly medical urgent candidate	37.3%	39.0%
A pediatric candidate	24.3%	26.2%
A prior living donor	13.9%	13.7%
A biologically difficult to match candidate (Understood to mean a candidate whose blood type and/or sensitization make it challenging to receive organ offers)	10.6%	9.5%
A candidate with good post-transplant survival outcomes	6.2%	5.5%
A candidate who has waited a long time	4.7%	3.8%
A very nearby candidate (Understood to mean, a candidate whose transplant hospital is very close in nautical miles to the donor hospital)	3.0%	2.4%

4. Committee discussion of VPE results

Summary of discussion:

No decisions were made concerning the agenda item.

The Chair began the discussion by updating the members on Committee leadership’s discussion with the OPTN President and Vice President. The discussion occurred on May 13, 2024 and was requested by the OPTN President and Vice President as an opportunity to provide a status update on the CD of hearts effort. OPTN leadership said that all of the CD efforts remain an OPTN priority. Committee leadership provided a status update about the Committee’s decisions to date and future activities. Both sides discussed the topic of allocation efficiency. According to OPTN leadership, allocation efficiency may be specific to each organ. Committee leadership described that the Committee is addressing efficiency concerns through the development of a proximity efficiency attribute designed to reduce unnecessary travel to procure a donor heart. They said that the implementation of heart offer filters will also promote efficiencies in heart allocation.

Turning to the VPE results, the Chair said it was exciting to have the information, and reminded members that the Committee is ultimately responsible for determining the weights within the requirements of the National Organ and Procurement Act (NOTA) and the OPTN Final Rule. The Chair continued that the VPE results aligned with Committee expectations prior to the exercise being made available to the public, and provide support for the Committee’s decisions to date. Committee members indicated that they had not expected the prior living donor attribute to be weighted as much as it was, nor had they expected the post-transplant outcome attribute to be weighted as low as it was. A member said that the efficiency attribute seems to be a lower priority among the public than it may be for the OPTN strategically, but that some participants may have had difficulty understanding the intent of the attribute. Regarding the post-transplant outcome attribute, a member said that the low prioritization might reflect that the public realizes that post-transplant outcomes cannot be predicted well as this time. The Chair added that the low weighting supports the Committee’s previous decision to exclude post-transplant outcomes as an attribute in the first iteration of CD of hearts. A member said that the Committee will need to make a strong and compelling case to the public, especially the patient, donor, and family community, as to the reasons the Committee chose to exclude it.

Next steps:

The Chair stated that the Committee will continue working to determine the attribute weights and will eventually provide information to MIT staff for them to perform the mathematical optimization. Based on those results and additional Committee considerations, a request for SRTR staff to simulate potential policy options will be submitted in the future.

5. Update regarding Escalation of Status for Time on Ventricular Assist Device

The Committee discussed developing the *Escalation of Status for Time on Ventricular Assist Device* project form for submission to the OPTN Policy Oversight Committee.

Summary of discussion:

Decision #2: The Committee agreed to submit a project form to the Policy Oversight Committee for approval to move forward with a project that will make candidates with implanted dischargeable LVADs eligible for status 3 or status 2 based on long waiting times at status 4. The Committee is taking this step to incentivize the use of dischargeable LVAD support by increasing the opportunity for such status 4 candidate to be transplanted.

Decision #3: The Committee agreed to extend their June 12 and July 2 meetings by 30 minutes in order to develop and submit the project form in time for consideration during the OPTN Policy Oversight Committee's August 8 meeting.

A member stated that the Committee had previously considered this as a project topic in 2023 when developing the *Amend Adult Heart Status 2 Mechanical Device Requirements* project as they tried to address the high volume of assignments to adult heart status 2 based on the use of intra-aortic balloon pumps (IABP) and the simultaneous reduction in assignments to adult heart status 4 using the dischargeable left ventricular assist device (LVAD) criteria following the implementation of allocation changes in October 2018. The Committee is undertaking this action now because the timeline for submitting a CD policy proposal and implementation of such changes might be farther in the future than previously thought.

The member outlined a potential approach that includes patient access to higher medical urgency statuses if they have been waiting for a substantial period of time at status 4. It is believed that a large number of status 4 candidates would benefit immediately from such a change. As a result, the Committee must also consider the appropriate way to address the situation that does not result in a very large surge of candidates into adult heart status 2 and status 3.

OPTN contractor staff informed the Committee that the Policy Oversight Committee needs to review the project proposal and determine whether the project can move forward. Members discussed whether the proposal should permit transplant programs to assign at least one status 4 candidate who meets the eligibility criteria to status 2 at any time. Some responded that this would likely be viewed as arbitrary and not receive public support. The Committee also discussed how transitioning candidates to higher medical urgency statuses based on waiting time could result in relatively 'stable' patients (such as patients who are not admitted to a hospital) obtaining higher medical urgency status than candidates who are considered clinically sicker and are admitted to their transplant hospital. The Committee agreed to begin developing the project form as part of the next Committee meeting with the intention of submitting it for consideration at the August 8, 2024 POC meeting.

Next steps:

The Committee will develop a project form for review at POC's August 8, 2024 meeting. The members agreed to extend their June 12 and July 2, 2024 meetings by 30 minutes to work on the project form. OPTN Contractor staff supporting the OPO Committee will follow-up regarding potential volunteers to join the Machine Perfusion workgroup.

6. Open forum

No members of the public requested to speak during the open forum period.

7. Closing remarks

The Chair thanked the members for their work related to the agenda items.

Upcoming Meetings

- June 12, 2024
- June 18, 2024

Attendance

- **Committee Members**
 - Rocky Daly
 - J.D. Menteer
 - Tamas Alexy
 - Amrut Ambardekar
 - Kim Baltierra
 - Jennifer Cowger
 - Timothy Gong
 - Eman Hamad
 - Glen Kelley
 - Earl Lovell
 - Cindy Martin
 - Cristy Smith
 - Martha Tankersley
 - Dmitry Yaranov
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Yoon Son Ahn
 - Monica Colvin
 - Grace Lyden
- **UNOS Staff**
 - Cole Fox
 - Robert Hunter
 - Kelsi Lindblad
 - Alina Martinez
 - Eric Messick
 - Sarah Roache
 - Sara Rose Wells
- **Other Attendees**
 - Shelley Hall
 - Mandy Nathan
 - Jason Smith
 - David Sutcliffe