OPTN Heart Transplantation Committee
IABP Subcommittee
Meeting Summary
May 11, 2023
Conference Call

Shelley Hall, MD, Chair

Introduction

The IABP Subcommittee, the Subcommittee, met via Citrix GoTo teleconference on 05/11/2023 to discuss the following agenda items:

1. Progress Update
2. Status 2 Policy Review and Vote
3. Ventricular Assist Device (VAD) Discussion

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

1. Progress Update

The Subcommittee Chair shared an update on the progress of the Subcommittee and explained the potential for future meetings.

Summary of Presentation:

This is the fifth, and potentially final, meeting of the Subcommittee. The status 2 policy the subcommittee has been working will be presented to the full OPTN Heart Transplantation Committee on May 16, 2023. If the full committee approves the policy language the Subcommittee will dissolve. However, if the full committee requests major changes to the policy, then the Subcommittee will reconvene to discuss and address those requests.

The OPTN Policy Oversight Committee (POC) approved the status 2 policy project on May 8, 2023. The POC was very supportive of the policy and found the data that was presented compelling and clearly demonstrated the issue.

Summary of discussion:

There was no discussion on this item.

2. Status 2 Policy

The Chair reviewed the status 2 policy the Subcommittee is proposing. The Subcommittee voted to send the policy to the full OPTN Heart Committee.

Summary of Presentation:

The purpose of the status 2 policy proposal is to address the congestion within status 2 heart transplantation. The use of intra-aortic balloon pumps (IABPs) has been identified as the biggest contributor to this congestion. Many programs seem to be using IABPs as a way to list candidates in status 2, when a more appropriate listing would be in a higher and less urgent status. The policy change the Subcommittee is proposing would require programs to submit inotropic and hemodynamic information for candidates with an IABP when applying to list or extend a candidate in status 2.

Summary of discussion:

A member asked for clarification on the inotrope measurements that are going to be required. The Chair responded that the inotrope levels in the proposed policy are the same as the inotrope levels found in the heart status 3 policy. The Chair reminded the Subcommittee that if the full committee notices a change that needs to be made within the policy there would still be enough time to address the concerns and make the necessary changes.

The Subcommittee voted unanimously to send the policy to the full committee.

3. Ventricular Assist Device (VAD) Discussion

The Subcommittee discussed a potential project regarding time on VAD. Data that had been referenced by members was presented and a possible solution was discussed.

Summary of Presentation:

The Chair informed the committee of a potential opening for POC review on June 12, 2023, is available for this project, and the hope is to send the project to public comment in January of 2024.

Data from a recent study of VAD patients was shown. The current VAD survival rates, by year, from one external source is 82% after one year, 61% after three years, and 43% after five years. The Chair pointed out some literature does exist that certain devices have a five-year survival rate over 50%. Survival percentage while after three years on VAD decreases regardless of age group, and mortality associated events increase every year after one year on VAD. Risk of device complication also increases with time on VAD, once a device complication occurs the likelihood of survival decreases.

The Chair reviewed a potential timeline solution that would increase the status priority of a candidate while on VAD. For 30 days after a VAD is implanted a candidate could be listed at status 3, because mortality risks are extremely high immediately following a VAD implant. After the initial 30 days is over, the candidate would be listed at status 4 for one year, in year 2 the candidate would move into status 3, and after three years the candidate would move into status 2. All dates are based on the time of implant.

Summary of discussion:

A member asked if, under the timeline being discussed, if a candidate with a dryline infection but is only 2 years post VAD implant be eligible for status 2 or 3. The member pointed out that the infection could make the candidate eligible for status 2, but their time on VAD would be status 3. The Chair responded that the candidate would qualify for the highest status, so in that scenario the candidate would qualify for status 2.

Another member asked if the data used in the presentation was Heartmate III data or INTERMACS data. Staff answered that the data was from INTERMACS from a seven-year period. The member expressed serious concerns over that data being used, believing it was collected for that study to draw a specific conclusion. The member continued that they are also concerned the potential timeline would cause congestion in status 2 by placing VAD candidates in status 2. The member pointed out that some of the candidates with a VAD after three years could be stable but would automatically get into status 2 because of their time on a VAD. This would increase the wait times for non-VAD status 2 candidates. The member stated they understand and agree that something needs to be done, but asked for caution while considering solutions. Another member responded that infections and serious issues are the same regardless of which study is used and suggested the data is trustworthy.

The Chair stated examining other data from other studies would be helpful, but that no matter what the committee ultimately decides to do there will be a surge initially because there are many VAD candidates in status 4 who would move into a different status. A member agreed and elaborated that although it might be difficult initially, something must be done because the system is not working for VAD candidates. The Chair agree and said the system is not working because of what is happening with temporary support devices, and the other work that is happening with devices may encourage more VAD usage. The member responded that it is seems nearly impossible to transplant a VAD patient, but the Chair disagreed stating it is more difficult in some regions but there are VAD transplant happening.

A member suggested examining the mortality rates of status four candidates with an LVAD. The Chair agreed.

Another member said it might be helpful to have a detailed transition plan to prevent a massive influx of VAD candidates from becoming status 2 all at once. The member did not have a concrete solution in mind, but a regional or center by center solution might work. The member also pointed out that the changes to status 2 the Subcommittee has been working could help this issue work itself out.

Another member cautioned against moving all candidates into status 2. The member stated that a candidate who has been on a Heartmate III with no complications is more stable than other status 2 candidates. The purpose of the status 2 candidates is for hearts to be allocated to the candidates most in need on the waitlist, not all candidates on VAD would fit into that description.

Another member stated their hesitancy is from not knowing how big of transition would be involved for a plan like this, or how long the transition would take. The Chair reminded the Subcommittee that every proposal must have a transition plan.

The Chair asked staff how granular the proposal must be when it is presented to POC. Staff responded that it is not encouraged to present a policy to POC that is not fleshed out, with some level of detail, and a clear plan in place to address the problem. Staff continued that it is possible to present more of a general idea to POC and if they approve then the project would have to be presented to POC again once there is more detail. The Chair stated that part of the data they would need to present would be the number of candidates on VAD that are one year, two years, three years, and five years post implementation. Another member responded that there are also VAD patients who are not currently listed so the number of people impacted by a change like this could be much higher than way the data would suggest.

The Chair asked the Subcommittee if there is a desire to create a solution, even if it is a stop-gap solution before continuous distribution is implemented. One member responded that not creating one would be a disservice. Another member responded that although they might not agree on the potential solution that was presented today, they do support the general idea.

A member stated they were under the impression they had a long time to discuss a solution to this issue. The Chair responded that is true for incorporating the solution into continuous distribution, but this conversation is for a stop-gap solution to be in place prior to the implementation of continuous distribution.

A member suggested considering a solution that would place VAD candidates into appropriate statuses based on morbidities or complications rather than time. The Chair responded that some of that data is already publicly available and could be discussed. The Chair continued stating that a solution may be appropriate to incorporate into continuous distribution rather than a stop gap solution. The Chair asked staff if POC approves a project based on time on VAD, but the committee changes their mind and

decides to focus on device complication instead would the project have to go back to POC for consideration. Staff responded that the project would have to go back to POC for an update.

The Chair asked the question, again, if the group feels this issue is important enough that a stop gap solution is necessary or should it be addressed in continuous distribution first after the implementation of the subcommittee's current status 2 project is implemented. A member responded that a stop gap solution should be considered because there is a certain level of demand for it from the heart community. Another member stated this issue is important enough to address now rather than waiting for it to be addressed by continuous distribution. The Chair responded in agreement, even though heart is moving much faster in the continuous distribution framework building than the other organs it still not slated to be implemented until January 2027. Two other members agreed that something needs to be done sooner rather than later. One member said that even a conservative solution would be better than no solution.

A staff member mentioned that the status 2 project received a fairly low benefit score from POC, despite having broad support from POC members. The staff member attributed this to the fact the project form did not have enough information in it to build a case on its own. Ensuring that does not happen with the VAD project will be important, and so any information on VADs that committee members are willing to share with staff would be appreciated. A member asked who are the members of POC? Staff responded the membership is made of Vice Chairs from all OPTN Committees.

Next steps:

Subcommittee members will send staff articles to help inform either the next meeting or if a new subcommittee needs to be formed to address this issue.

Upcoming Meetings

- No upcoming meetings scheduled.

Attendance

- **Subcommittee Members**
  - Shelley Hall
  - Amrut Ambardekar
  - Richard Daly
  - Glen Kelley
  - Hannah Copeland
  - Jen Cowger
  - Nader Moazami
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Grace Lyden
  - Yoon Son Ahn
  - Katherine Audette
- **UNOS Staff**
  - Alex Carmack
  - Alina Martinez
  - Eric Messick
  - Holly Sobczak
  - Laura Schmitt
  - Sara Rose Wells