OPTN Heart Transplantation Committee
IABP Subcommittee
Meeting Summary
April 13, 2023
Conference Call

Shelley Hall, MD, Chair

Introduction

The IABP Subcommittee, the Subcommittee, met via Citrix GoTo teleconference on 04/06/2023 to discuss the following agenda items:

1. Announcements
2. Review
3. Policy Language Discussion
4. Transitional Candidates Discussion
5. Status 2 Form Discussion

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

1. Announcements

The Chair welcomed the Subcommittee members and reviewed the schedule for upcoming meetings.

Summary of discussion:

The Chair reminded the Subcommittee there they will not be a meeting the following week due to a conference most members are attending. The Chair then informed the members that due to the frequency of the subcommittee meetings staff might not be able to turn around requests between meetings, but members will be informed when materials they have requested are available. The Chair announced that the status 2 proposal will be going to the OPTN Policy Oversight Committee on May 8, 2023; this is a change from the original date of June 12, 2023, but this does not change the timeline of the Subcommittee.

2. Review

The Chair reviewed the work the Subcommittee did in their previous meeting.

Summary of discussion:

During the April 6, 2023, meeting the Subcommittee decided to address IABP status 2 usage by requiring documentation of failure of inotropes prior to use of an IABP. This would allow for patients who need an IABP to stay at status 2, while also reducing congestion of candidates in status 2 and allow more access to organs within status 2. Additionally, this should reduce the number of cases being considered by the review board.

3. Policy Language Discussion

The Chair presented an early draft of the proposed policy language.

Summary of discussion:

The Chair reminded the Subcommittee that the language being presented is only for review purposes, the language is not official of finalized, and the Subcommittee is not voting on the language. The Chair presented the current policy language in *OPTN Policy 6.1.B.v*, followed immediately by the proposed new language that includes verbiage regarding inotropes from status 3 that will be incorporated into status 2.

There was no discussion on this item.

4. Transitional Candidates

The Subcommittee considered and discussed a possible solution for transitional candidates, those who are already at status 2 with an IABP at the time of implementation of this new policy.

Summary of discussion:

An unspecified number of IABP candidates will be at status 2 when this new policy is implemented but will not meet the new criteria. There needs to be a plan in place to address these candidates. The Chair presented a recommended option would be to allow those candidates to stay at status 2 until applying for an extension. If, or when, the program applies to extend the status the new additional fields will display and would be required for an extension. In addition to this all initial forms will have the new additional fields and candidates will be required to meet the criteria. Another option could be that all status 2 candidates with an IABP would have to reapply for status 2.

A member asked for clarification on what would be the in the new additional fields if those would be the hemodynamics and inotropes that will be required for status 2 in the new policy. The Chair confirmed, and stated programs should already be doing this when they apply for an extension but a lot of programs do not.

The Chair asked if anyone is opposed to the recommended plan for transitional candidates. All members were in agreement with the plan.

5. Status 2 Form Discussion

The Chair presented an early draft of the status 2 form transplant centers will use if this policy is implemented.

Summary of discussion:

Using a mockup version of the status 2 form, the Chair was able to show where the new inotrope requirements would go for IABP and how they would need to be entered. The Chair also showed what parts of the form were already in existence and which would be new.

The Chair pointed out that this is currently for IABP only and asked if the Subcommittee wanted to include the same information for percutaneous endovascular circulatory support devices also listed for status 2. A member responded that the requirements should apply to all percutaneous endovascular circulatory support devices. The Chair reminded the committee that while there is a perception of overuse of IABP, one device should not be singled out. Additionally, this would prevent the overuse practice from moving to other devices within status 2. A member agreed that it should apply to all device types. A second member agreed. A third member agreed and pointed out that patients would see the change only to IABP as unfair, making the change applicable to all status 2 devices would be the fairest way to approach the subject.

The Chair highlighted there are other devices in status 2 that perhaps this should not apply to. Those being non-dischargeable surgically implanted non-endovascular left-ventricular assist devices (LVAD), total artificial hearts (TAH), right ventricular assist devices (RVAD), ventricular assist devices (VAD), and

mechanical circulatory support device (MCSD) with malfunction. These could be excluded because medical practices must be followed before these devices are used. The committee agreed.

A staff member asked if there should be a more direct standard for illustrating a failure on inotropes. The Chair pointed out that by requiring inotropes and the submission of hemodynamic information, failure would be illustrated. Staff asked for clarity regarding if the simultaneous use of inotropes and hemodynamics must be shown. The Chair confirmed. A member pointed out that it is possible to wean the candidate off IABP but they would need a two week extension to demonstrate this, and then the candidate would no longer qualify for status 2.

A member asked why IABP was listed in a separate category from other percutaneous devices. The Chair responded that for programming purposes they need to be separated. Another member responded that for tracking purposes it is useful to keep them separated.

Staff asked for clarity that this would also apply to candidates in status 2 during implementation. The Chair responded in the affirmative, when those patients reapply, they would have to submit this information.

Next steps:

Staff will update the status 2 mockup form for the Subcommittee to review.

Upcoming Meetings

- April 27, 2023

Attendance

- **Subcommittee Members**
  - Shelley Hall
  - Richard Daly
  - Glen Kelley
  - Hannah Copeland
  - Jennifer Cowger
- **HRSA Representatives**
  - Arjun Naik
  - Shelley Grant
- **SRTR Staff**
  - Yoon Son Ahn
- **UNOS Staff**
  - Alex Carmack
  - Alina Martinez
  - Eric Messick
  - Holly Sobczak
  - Laura Schmitt