OPTN Heart Transplantation Committee
IABP Subcommittee
Meeting Summary
April 6, 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. Regular Meeting Announcement
2. Objective
3. Possible IABP Options

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

1. Regular Meeting Announcement

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

Summary of discussion:

The Subcommittee will meet on Thursday at 5 pm ET. The Subcommittee has five regular meetings scheduled beginning next week and is scheduled to dissolve on May 31, 2023. The Subcommittee will not meet on April 20, 2023, because of a conference where most will be in attendance. There are two meetings scheduled, for May 18 and 25, 2023, that will only be used if needed. The plan is to have a proposal completed by the Subcommittee to present to the OPTN Heart Transplantation Committee on May 16, 2023. The proposal will then go to the OPTN Policy Oversight Committee for their consideration on June 12, 2023.

Next steps:

Staff will send calendar invites to the Subcommittee reflecting the new meeting dates and time.

2. Objective

The Chair reviewed the objective and purpose of the Subcommittee.

Summary of discussion:

The purpose of the Subcommittee is to develop a policy proposal that addresses the use of Intra-Aortic Balloon Pumps (IABP) and the placement of candidates with an IABP as status 2. This is causing allocation congestion among status 2 candidates. Heart allocation currently uses statuses for candidates based on mortality rates, and the mortality rates of candidates with IABP is more aligned with status 3 than status 2. The objective is to formulate a simple and accurate solution for a policy proposal to present to the OPTN Policy Oversight Committee in June. However, if a simple solution is not possible the Subcommittee could ask for an extension in existence in order to address the issue. The OPTN Heart Transplantation Committee wants to address this issue prior to the implementation of continuous distribution of heart so it can be built into the initial version.

The Chair continued, the goal for this meeting is to select an option to pursue and discuss what information is available to support that decision. During informal discussions among committee members two possible solutions have started to gain some support, the Subcommittee will discuss these two options and see if there are other options that could work to address the issue.

3. Possible IABP Options

The Chair reviewed two possible options before opening the floor for discussion.

Summary of discussion:

The first option would be to be to move all candidates who receive an IABP into status 3, this would properly align the mortality rates of these patients. The second option would be to add medical requirements and documented failures of inotropes seven days prior to an IABP being used. The second option would leave IABP candidates in status 2.

The Chair asked the Subcommittee members if there was a third option that should be considered. No Subcommittee members responded.

The Chair then asked, between these two options which is preferred and why. A member responded that they support the seven-day medical requirements over moving IABP candidates to status 3, because there are some patients with lower access and other medical issues who should be status 2, moving them to status 3 would disadvantage them. The member continued by saying the seven-day medical requirements shows the candidate is very sick and justifies the use of the IABP device. Another member agreed, stating there are still some candidates with an IABP that need to be status 2; it is a good support mechanism for many candidates because it's cheaper, it is easier for surgeons to put in, and has utility. The member continued by explaining the seven-day medical requirement makes the process of achieving status 2 more merit based, and this would ensure medical therapy is used in order to get status 2.

A member pointed out that it is possible for a candidate to get better once receiving the IABP, and asked if there was a way to show a need for the continued use of a balloon pump. The Chair said the need for continued use of the IABP is documented on the extension request forms, noting the bulk of status 2 candidates are done within two weeks. The Chair reiterated that exception forms do require some documentation that candidates are not tolerating being weaned off their temporary devices.

The Chair reviewed the current forms required for IABP. They notated the required measurements for hemodynamics, but if the hemodynamics were not obtained there must be a documented sign of shock within 24 hours which includes CPR and/or blood pressure less than 70, among others. The Chair continued that, as the number one exception for IABP these are not always present, or at least weak. The Chair then showed the inotropes support category form for status 3. The proposal would take this selection criterion and create a drop-down option that documents the possible medication that would need to be used, or attempted to use, prior to an IABP. The new form for IABP status 2 would require both the existing hemodynamics documentation and the inotropes documentation. Doing so would demonstrate failure in status 3 which would then necessitate a temporary device like an IABP. This would be the logistical side of the Subcommittee's proposal.

A member voiced support for this logistical component, stating they believe it to be fair and prevents overuse of IABP. The member asked if there would be a tutorial video posted online to demonstrate this change later in the process, the Chair confirmed there would be a video explaining these changes.

The Chair noted that review boards are starting to see more denials, and that is causing some frustration. This would curb some of the workload for the review board and could possibly result in fewer denials.

Staff asked the Subcommittee if they could foresee any pushback from the community in making this change. The Chair responded that there could be push back from some physicians because the policy would require the use of medicines before devices, and that could be seen as dictating treatment. The Chair continued by saying the bulk of the community is going to be in favor of this change.

A member asked if there would be changes to arrhythmias or if centers will still have to apply for exceptions. The Chair responded they would still apply for exceptions. The member responded they support this because it allows for better tracking of treatments being used.

The Chair shared they feel this will be an effective stop gap as the full OPTN Heart Committee develops a continuous distribution framework.

Staff asked a member if they could speak to what the response from the patient community might be. The member responded that this may be a little bit too far into the weeds for many patients, but a values statement on the proposal explaining the reason for the change will be very helpful to patients. The change is logical, and the patient population trusts that the Subcommittee is considering the greater community. The Chair asked the member to help in the writing of the values statement for the proposal.

Staff asked the Subcommittee to clarify if failure of inotropes should be included on any other criteria for status 2. The Subcommittee Chair responded they believe it should be included on all status 2 criterion, elaborating that a mechanical device should be used when medicines fail, or the patient is in the middle of a code as that is their intended purpose. The Subcommittee Chair did note that durable ventricular assist devices (VADs) provide a different type of support and should not be included. The Heart Committee Chair shared that it is currently possible for a patient to get a right heart catheter on Friday, meeting the criteria for an IABP but get sent home, that patient could come back the next week and electively get an IABP and qualify for status 2 without failing any other medical therapy.

Staff asked if this disadvantages any populations. The Subcommittee Chair noted that with the medical therapy it is applicable to everyone regardless of weight or gender, and so this tactic should not disadvantage anyone. These medical therapies are also available at every hospital that uses IABP, so geographically this should not be an issue.

A member asked if there could be guidance to the review board members on what is and is not appropriate. The Chair responded that language was added to guidance regarding the appropriate dialogue and data to submit, but it did not have an impact on the number of exceptions that were submitted. The Chair continued that though there are restrictions on what guidance can be provided by detailing what a review board can accept and deny, it is ultimately left up to discretion of the review board members. A member stated they don't want the exceptions to be a pathway to inappropriate listings, and they are concerned that people submitting the exceptions are not appropriately educated on how to do so. The Chair responded that new members of the review boards should be better educated. Another member also commented that a lot of the exceptions that are submitted do not provide the necessary information to give a proper judgement. A member asked if an analysis of the exceptions submitted is possible. The Chair responded that there is some data on this already, but because the exceptions are narrative in form, they have to be categorized manually which becomes difficult and extremely tedious. This means the granular information is labor intensive and difficult to achieve.

Staff asked if the proposed seven-day timeline would need to go into other portions of policy. The Chair responded that the same language would need to be in status two and three, and a line would need to be removed due to redundancy. Another member agreed.

The Chair summarized the next steps on the IABP project. The drafting of the policy proposal will begin soon, and the technological component will also need to be finalized before going to POC. Staff noted that policy language will also be drafted soon, with the goal of sending the proposal to the full committee's meeting in May 2023. The Chair responded that although this process is moving faster than normal, the public comment cycle will remain the same. Staff asked the Subcommittee if there is any other data that is needed, as those requests need to be submitted quickly. The Chair responded that the data they have now should suffice, but if other members think of something they should reach out to staff.

Next steps:

Staff will send published articles they have collected to Subcommittee members. Technology estimation will be performed by staff. Staff will also begin drafting policy language for the proposed changes.

Upcoming Meetings

- April 13, 2023
- April 27, 2023

Attendance

- **Subcommittee Members**
  - Shelley Hall
  - Richard Daly
  - Glen Kelley
  - Hannah Copeland
  - Jennifer Cowger
  - Nader Mozami
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Grace Lyden
  - Katherine Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Alex Carmack
  - Alina Martinez
  - Eric Messick
  - Kelsi Lindblad
- **Other Attendees**
  - First Name Last Name