OPTN Heart Transplantation Committee
IABP Subcommittee
Meeting Summary
April 27, 2023
Conference Call

Shelley Hall, MD, Chair

Introduction

The IABP Subcommittee, the Subcommittee, met via Citrix GoTo teleconference on 04/27/2023 to discuss the following agenda items:

1. Review
2. Policy Language Update
3. Potential Barriers

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

1. Review

The Chair welcomed the Subcommittee members and reviewed the schedule for upcoming meetings, the Subcommittee's objective, and reviewed work that has already been done.

Summary of Presentation:

The Chair reminded the Subcommittee there are only two additional meetings before presenting the proposal to the full OPTN Heart Transplantation Committee on May 11, 2023. The Chair reviewed the work that had been done so far including adding medicine intervention in the status 2 policy for both Intra-aortic balloon pumps (IABP) and percutaneous endovascular mechanical circulatory support devices. The proposal's project form has been submitted to the OPTN Policy Oversight Committee, which will review the project on May 8, 2023. The Subcommittee also approved a plan for transitioning candidates who will be impacted by the change when implementation occurs. Candidates assigned to adult heart status 2 under either the IABP criterion or the percutaneous endovascular MCSD criterion will be allowed to continue at status 2 through the duration of their existing assignment. Subsequent to that assignment, such candidates will be required to submit the new information upon filing an extension request.

Summary of discussion:

There was no discussion.

2. Policy Language Updates

The Chair reviewed the policy language and led a discussion with the Subcommittee members.

Summary of Presentation:

The Chair presented the change in policy language and compared that to the current policy language in *OPTN Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP)*. Additional recommended changes that have been suggested by Subcommittee members were then presented. The additional recommended changes

provide more clarity regarding the use of inotropes. The Chair also reviewed new language regarding extension requests.

Summary of discussion:

A Subcommittee member asked whether the policy proposal appropriately identifies the amount of time a candidate needs to be treated with inotropes in order to qualify? For example, is the expectation that a candidate has to be on inotropes for the full seven days, or just at any point within the seven days in order to qualify for the status? The members acknowledged the importance of the timing. Purely as an extreme example, a member said a transplant program could provide inotropic treatment to a patient for 10 minutes without any resulting positive improvement, and decide to implant an IABP. As a result, it important for the proposal to be clear about the intent of the change, as well as the letter of the change. Another member asked if there is any data or information that would support including a specific or general timeframe for receiving inotropic support? A member said a reasonable timeframe might be 24 hours of continuous support unless the transplant program can provide evidence of deterioration in the candidate's clinical condition; as long as there is a recognition that if a patient's hemodynamics are truly crashing, then the program needs to be able to respond immediately. The Chair suggested that the Subcommittee could consider creating two separate qualifying criteria. The first qualifying criteria would be a combination of the new language related to inotrope use coupled with the hemodynamic criteria indicating cardiogenic shock. The second set of criteria by which a candidate could qualify would consist of the elements, such as receiving CPR, when hemodynamic measures could not be obtained regardless of inotrope therapy. Under this option, candidate could qualify by way of criteria A *or* criteria B. A member pointed out that the criteria for when hemodynamic measures could not be obtained will likely indicate a clinical condition where the patient is too sick to receive an IABP, and would instead be treated with peripheral ECMO possible. Other Subcommittee members concurred with this idea.

Another member pointed out that within the qualifying criteria demonstrating cardiogenic shock, the reference to a cardiac index "less than 1.8 L/min/m2 if the candidate is not supported by inotropes" should be removed because the previous section of the draft policy requires inotropic use. The Subcommittee members agreed.

A member asked if the lactate requirement was necessary. The Chair pointed out that this is in current policy and removing it would be too significant of a change.

A member asked if arrhythmias should be included in policy language. The Chair responded that doing so would require a strict definition of arrhythmias for status 2, and arrhythmias are covered in other portions of policy. The member agreed and said there could be some exceptions filed that would include that information in their narrative.

A member asked why durable ventricular assist devices (VAD) cannot be included in this policy. The Chair responded that including VADs would require a larger proposal and timeframe, but IABPs can be addressed quickly and efficiently in a much shorter timeframe.

3. Potential Barriers

The Chair led a discussion on potential barriers to this policy.

Summary of presentation:

The Chair noted the importance of discussing potential barriers early in the policy process. Identifying those barriers allows the Subcommittee to address them within the proposal and increases the likelihood of building broad support in the transplant community.

Summary of discussion:

The Chair started the discussion by suggesting one barrier, or counterpoint, to the policy proposal could be the perception that the policy dictates treatments physicians must provide. However, the Chair noted that other policies do this. Moreover, the problem this policy is trying to address is the use of a treatment that goes against the intent of current policy; what the Subcommittee is proposing is more of a clarification of current policy.

A member pointed out that there is support within the community that the current use of IABPs to obtain status 2 assignment is an issue that needs to be addressed. The member added that the proposed changes are not such a major change that they should upset the community.

Another member said they have received positive feedback that the policy the Subcommittee is proposing is reasonable.

A member asked if there could be more detailed guidance on how to write and present exception requests to the Regional Review Boards, and whether the guidance requirements could be included with the new policy? Staff responded that there is a difference between policy and guidance. Still, there are references to guidance within policy, and so there could be something in the new policy that directs people to the guidance document currently found on the OPTN website.

The Chair also stressed the need for education on this topic, so the public is educated on both the problem and the benefits of what the Subcommittee has proposed.

A member stated they do not believe the community will be opposed to the policy, but there may be some comments about specific parameters in the proposal that may receive some recommended changes.

Upcoming Meetings

- May 4, 2023

Attendance

- **Subcommittee Members**
  - Shelley Hall
  - Richard Daly
  - Hannah Copeland
  - Jennifer Cowger
  - Glen Kelley
  - Nader Moazami
- **HRSA Representatives**
  - Shelley Grant
  - Marilyn Levi
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - Alex Carmack
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Laura Schmitt
  - Sara Rose Wells