OPTN Thoracic Committee
Heart Subcommittee - Meeting Summary
January 9, 2020
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Heart Subcommittee of the Thoracic Committee met via Citrix GoTo teleconference on 01/09/2020 to discuss the following agenda items:

1. The Adult Heart Exceptions Project
2. Updates of Other Subcommittee Activities

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

1. Adult Heart Exceptions Project

The Committee reviewed the information they had previously considered and their previous actions regarding the project. These included: potential contraindications to durable VADs that could lead to an exception request for a Status 2 candidate on an IABP, development of a template identifying potentially useful information to have when submitting a request or considering such an exception, and ways to let the Heart community know the Subcommittee is addressing the use of exceptions.

It was reiterated that when submitting either an initial exception request or an extension exception request, the program does not need to provide any specific criteria. Instead, the exception requests only require that programs submit a narrative describing why a candidate should be listed at the identified statues. Based on the information provided in the narrative, the Regional Review Board (RRB) members must determine if the exception request is justified. Subcommittee members agreed that under the circumstances, it may be difficult for programs to know what information to submit with the request, and RRB members may find it difficult to make decisions on the information being provided.

The Subcommittee discussed that the intention of using IABPs, as a temporary support, was to get the candidate out of cardiogenic shock and in to a better clinical situation. At the time, the thinking was that in such cases, the likely outcome is that a candidate would get a LVAD; however, it did not exclude the potential for transplant. The status and criteria were not intended to serve as a bridge to transplant, but that appears to be what is happening, according to a Subcommittee member. A Subcommittee concern is that exception requests for Status 2 candidates on IABP are being used as a long term mechanism to get a candidate transplanted and to avoid the use of a LVAD.

The Subcommittee considered the list of contraindications that had been previously discussed. Specifically, the Subcommittee members discussed the level of detail they wanted to incorporate in the list of contraindications. The Subcommittee members stated intention was to balance specificity and generality for the guidance document without telling the programs how to practice. At least one member commented that the list was reasonable, but cautioned that a guidance document should not be so prescriptive as to become policy requirements. The goal should be to provide the regional review board members with enough information to make consistent decisions around the difference exceptions. At the same time, the Subcommittee should not require a level of detail that is going to be difficult for a program to provide. Another member agreed with those statements and added that

requiring too much information can also reduce the flexibility of the regional review board members to make decisions. For example, providing value ranges for the programs submitting requests to consider, could be looked upon as restrictions. Therefore, where possible, the Subcommittee may want to consider identifying factors to be mentioned, but not provide any values or ranges of values. Another Subcommittee member said the values included in the guidance template were intended to provide the regional review board members with at least an expected range for certain factors, based on known information.

The following factors were considered to be important:

- Need for multi-organ transplant – considered as a straight-forward contraindication to a VAD
- Blood dyscrasias
- Inability to take or contraindications to Warfarin
- Active stroke

A member suggested that the group might want to consider recurrent VT for inclusion. It is still burdensome for the patient.

Another member recommended having a program identify whether the candidate had a Swan-Ganz (right heart) catheter. If the answer is yes, the recommendation was for the program to identify the hemodynamics, and then indicate why a candidate cannot be weaned. The Subcommittee members talked about which hemodynamics to include on the guidance template.

The Subcommittee members had some discussions around what happens when a candidate's extension exception request is denied, and what happens to a candidate's status. For example, is a candidate is at Status 2 by exception for an IABP, but the program discontinues the IABP and then re-starts its use in two weeks, what happens to the candidate's previous status? The answer is that the candidate would maintain their time at a higher status, and then start adding to it after their higher status was renewed. Suppose for example, a candidate is at Status 2 for 28 days, and then goes to Status 3 for five days. After the five days, the candidate is re-listed at Status 2. The candidate would then be starting his or her 29th day at Status 2.

The Subcommittee then discussed whether to include language in the guidance document addressing patient preference and that it should not be considered as a reason to stay at Status 2. The members acknowledged that including such language may not be well received by the Thoracic community. However, after discussing the matter, they decided to proceed with something like adding a note at the end of the template and/or guidance document stating "patient preference is not considered an acceptable reason for placement of a durable VAD." The members wanted it made clear that this only applied where the use of patient preference was done in isolation of other considerations. One member said that if there is some other medical reason provided in addition to patient preference, then this clause should not apply.

There were no other suggestions for inclusion on the list.

Summary of discussion:

The Subcommittee reviewed and largely finalized the list of factors they want included in a guidance document addressing the use of exceptions for Status 2 candidates on IABP.

Next steps:

The Subcommittee asked that the draft list be revised and edited one more time. Following that, they asked that staff start building out the guidance document. The members also asked if it is possible to

include an example of examples of a well-written exception request or some patient vignettes. Internal staff agreed to start making the identified changes.

2. Updates of Other Subcommittee Activities

The Subcommittee heard a discussion about the drafting of a notification that would be emailed to all Thoracic programs and regional review board members. The objective of the notification is to inform members about the guidance document being developed, and the reasons for its development. It was mentioned that PCR staff are working with Communications to finalize the message. The objective is to send the notifications to programs and review board members on a monthly basis.

The Subcommittee also discussed the upcoming regional meeting schedule, and who was presenting. The discussion included an overview of the National Heart Review Board for Pediatrics public comment proposal. The overview included information about how the requests will be routed, how the reviewers will be chosen and appointed, among other things.

The Subcommittee was reminded that the leadership of the Thoracic Committee had submitted a response to the Cogswell, et al article about the heart allocation system. The Subcommittee members were told that HRSA was still reviewing the document. The HRSA representative asked that a copy of the response be forwarded to him and that he would try to get a response expedited.

The Subcommittee was also informed that the policy for implementing the Eliminating the Use of DSA in Thoracic Distribution went live earlier in the day. There were no known issues as of the meeting.

Upcoming Meetings

- January 23
- February 27
- March 26
- April 17, in-person meeting