

**OPTN Thoracic Committee
Heart Subcommittee
Meeting Summary
January 23, 2020
Conference Call**

Shelley Hall, MD, Subcommittee Chair

Introduction

The Thoracic Committee's Heart Subcommittee met via Citrix GoTo teleconference on 01/23/2020 to discuss the following agenda items:

1. The Adult Heart Exceptions Project
2. Notification to Thoracic Community about Subcommittee Activities
3. Updates of Other Subcommittee Activities

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

1. The Adult Heart Exceptions Project

During a previous Heart Subcommittee meeting on January 9, 2020, Subcommittee members drafted a template outlining clinical information that should be considered when preparing an exception request for a status 2 heart transplant candidate on an Intra-Aortic Balloon Pump (IABP).

Summary of discussion:

The Subcommittee Chair led a review of the template. The Chair asked whether the template should require transplant programs to indicate if cardiac index was measured via thermodilution or Fick, noting that the distinction should be excluded if the method of measurement would not influence their interpretation of the results. The members agreed to exclude this distinction.

The second section of the template asks programs to describe why the candidate was not weaned from IABP. The members agreed to add clarifying language to indicate that the list of clinical criteria in this section should serve as evidence that the candidate remained in persistent cardiogenic shock. The intent of this revision was to indicate to transplant programs that they should be submitting clinical measurements (numbers) in this section and not just indicating the presence or absence of a condition.

The third section of the template asks programs to describe the candidate's contraindications to Ventricular Assist Device (VAD) insertion. The members agreed to remove a note stating that submission of this information is not required. The members also agreed to add refractory ventricular arrhythmia to the list of contraindications.

The Subcommittee discussed whether or not to remove a note from the template recommending that requesting programs not rely solely on patient preference when submitting an extension exception request to maintain a candidate at status 2. Members noted that the intent of the proposed guidance is to ensure that the exception is available for patients who need to stay on the IABP and cannot transition to a VAD, and to prevent patients from choosing a temporary device over a durable device without other clinical justification. Members agreed that including this note will serve as a useful reminder for the regional review boards and the transplant centers listing candidates. Members also agreed that there is an important patient education component regarding the decision to stay on IABP versus

transitioning to VAD that should be addressed in the forthcoming guidance. In particular, members noted that after a couple weeks on an IABP, the candidate moves down to status 3. Additionally, if a candidate's status 2 extension exception request is denied, the candidate moves to status 3. While status 3 is a relatively high status for candidates with a VAD, candidates that stay on IABP face higher complication risks.

Next steps:

The Subcommittee Chair emphasized the importance of sharing the proposed guidance with transplant community members to get initial feedback prior to posting the guidance for public comment in the fall. The Chair noted that the International Society for Heart and Lung Transplantation (ISHLT) conference on April 22-25 and the American Transplant Congress (ATC) from May 30 to June 3 would be good opportunities to gather feedback from colleagues. The Chair asked UNOS staff to draft the guidance to share with the Subcommittee for review.

2. Notification to Thoracic Community about Subcommittee Activities

UNOS staff presented a draft letter to notify members of the thoracic community about the ongoing work of the Subcommittee. The letter explains that this will be the first in a series of communications as the Subcommittee reviews the use of Status 2 exceptions for candidates on IABP, and reminds community members of existing guidance documents.

Summary of discussion:

Members stated that communications should be kept short, and affirmed that these notifications should be sent to community members before the guidance document is published to let the community know that the OPTN is listening to their feedback, is working to address concerns, and will share more information as it becomes available. A member stated that she did not think the email said enough about the Subcommittee is doing to address the issue. Others thought a sentence could be added to the email notification pointing out that the matter is being actively reviewed.

One member expressed concern that this notification would prompt some transplant programs to rush to submit their candidates for consideration. The Chair noted that the Subcommittee saw similar patterns over the past year in response to the new heart allocation process, but that this is the first opportunity the Subcommittee has to start sharing more detailed information with the community about guidance changes. UNOS staff noted that participants in the ongoing regional meetings are also receiving updates on both the Status 2 exception work and updates on the heart allocation system.

Members expressed support for using patient vignettes, with appropriate redactions, to share the issues that the Subcommittee is seeing with exception requests with the rest of the community.

Next steps:

UNOS staff will continue working on the notification to the thoracic community. The Subcommittee Chair asked all members to draft a case example with the right way and the wrong way to submit an exception so that the Subcommittee can start reviewing these examples to share as part of the notifications.

3. Updates of Other Subcommittee Activities

UNOS staff notified Subcommittee members that the Board of Directors will be considering the Subcommittee's recommendation to create separate OPTN Heart and Lung Committees at the March 2020 meeting. There is a potential cost increase associated with the proposal but it would benefit each

committee by providing expanded support and representation within the regions and on the Board. If approved, implementation is projected for July 2020.

UNOS staff also reviewed future meeting dates and topics for the Heart Subcommittee, the Pediatric Heart Workgroup, and the full Thoracic Committee meeting on April 17. The Chair noted that April 23rd will not work as a Heart Subcommittee meeting date since it will be during the ISHLT conference.

UNOS staff notified Subcommittee members that the response to the Cogswell et al article about the heart allocation system had been submitted for publishing and would be shared with the Subcommittee members following the call.

Upcoming Meetings

- February 27, 2020
- March 26, 2020
- April 17, 2020, in-person meeting