

**OPTN Thoracic Organ Transplantation Committee
Heart Subcommittee
Meeting Summary
March 26, 2020
Conference Call**

Shelley Hall, MD, Subcommittee Chair

Introduction

The Thoracic Committee's Heart Subcommittee met via Citrix GoTo teleconference on 03/26/2020 to discuss the following agenda items:

1. Creating Separate OPTN Heart and Lung Committees
2. Review Draft of Guidance Document Addressing the Use of Status 2 Exceptions
3. Other Committee Business

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

1. Creating Separate OPTN Heart and Lung Committees

UNOS staff notified the Subcommittee that the Board of Directors approved the creation of separate heart and lung committees with an implementation date of July 1, 2020. The Chair noted that regions will be selecting their members mid-April, and thanked members who have agreed to stay on for an additional year to support the new Heart Committee. UNOS staff noted that the deadline to apply for a committee position ended on March 25, but in light of the pandemic, UNOS staff invited Subcommittee members to encourage anyone else who was interested to submit their application on March 26.

2. Review Draft of Guidance Document Addressing the Use of Status 2 Exceptions

The Chair and UNOS staff led the Subcommittee in a review of the draft guidance document.

Summary of discussion:

The Chair said that the background information in the document clearly lays out the history of the issue and why the guidance document is being provided. The Chair asked the Subcommittee for feedback as to whether the recommendations are clearly expressed in the guidance. In particular, UNOS staff asked the Subcommittee for feedback on a line stating, "if the transplant program cannot provide the information identified below, then most candidates are appropriately categorized in Status 3." The Chair thought this was a good reminder that candidates who are not approved for Status 2 are placed at Status 3, which is a relatively high status; they are not dropped to Status 6. A member suggested softening this language to say, "Each transplant program is strongly encouraged to provide the information identified below. If not, then most candidates may appropriately be categorized as Status 3." The Subcommittee agreed with this language.

The Subcommittee discussed a section of the draft that said, "It is the Committee's intention that the list of clinical criteria in this section should serve as evidence that the candidate remained in persistent cardiogenic shock." The Subcommittee noted that a lot of centers have trouble with the term "persistent cardiogenic shock" because centers treat patients to stabilize their condition which makes it difficult to prove persistent cardiogenic shock. The Subcommittee decided to change this phrase to "persistent hemodynamic instability."

The Subcommittee agreed to insert a header titled, "Proposed Template" above the recommended clinical criteria to highlight to transplant programs that they can copy the template into their exception requests and fill in the information. The Subcommittee changed the title of the first section of the template to "Characterization of the Patient" rather than "Description of Type of Heart Failure." The Subcommittee changed the name of the second section of the template from "Description of Why Program Did Not Attempt to Wean Candidate" to "Inability to Wean." The Subcommittee changed the name of the third section of the template from "Contraindications to Ventricular Assist Devices (VAD)" to "Contraindications to LVAD." The Chair asked UNOS staff to call more attention to information in the background section regarding exception request volume.

Next steps:

UNOS staff requested that Subcommittee members recommend people familiar with exception requests who may be able to review the guidance document and provide feedback. UNOS staff also requested that the Subcommittee provide an example of a well-written clinical narrative that could be provided in the background section of the guidance document and separately as a notification to the community. The Subcommittee will continue to review the document and provide feedback within two weeks so that the Subcommittee can review an updated draft during the virtual meeting on April 17.

A member requested that UNOS provide the Subcommittee with the number of Status 2 candidates, candidates on intra-aortic balloon pump, and Status 2 exceptions during the COVID-19 pandemic as the member expected that transplant programs are demonstrating better adherence to candidate status definitions at this time. The Chair supported this request. UNOS staff recommended waiting to pull this data until more information is available.

3. Other Committee Business

COVID-19 Emergency Response Actions

The Chair discussed potential COVID-19 emergency actions that had been raised during the Policy Oversight Committee (POC) call on March 26. POC considered whether the requirement for patients to be hospitalized to achieve certain waiting list statuses should be waived to allow these patients to be discharged from the hospital while remaining at the same status. The Chair had explained that for heart candidates, most of the candidates at higher statuses have devices inserted and cannot be discharged, except for some Status 3 candidates. The Chair had commented that she did not think this requirement should be waived out of concerns that centers would game the system. The Chair said that for candidates at Status 3, centers need to be monitoring hemodynamic information to keep their patients stable, and sending those patients home would indicate that they are stable enough that the hemodynamic information is not required. A member agreed, noting that if someone is stable enough to go home, then the risk outweighs the benefit of transplant in that scenario. The Subcommittee agreed that patients need to stay hospitalized to retain Status 3.

The Chair shared that POC discussed using a separate site either for listed patients or for transplant if a hospital was overrun. The Chair noted that there will not be a policy change but the Membership and Professional Standards Committee (MPSC) is drafting language about what would be deemed acceptable in that scenario so that transplant teams and patients can relocate to avoid COVID-19 exposure.

Notices to the Thoracic Community

UNOS staff drafted a second notice regarding the guidance document to send to the thoracic community. The notification highlights that the one-year monitoring report for changes to heart allocation policy is available on the OPTN website and shares key findings. The Chair asked UNOS staff to add a note that the monitoring report showed that almost all exception requests were approved. UNOS

staff will send the draft notification to the Subcommittee for their review. The Chair requested any documents a week prior to review as members are increasingly busy with COVID-19 response.

Upcoming Meetings

- April 17, 2020 Thoracic Committee in-person meeting (virtual)
- April 23, 2020