

OPTN Heart Transplantation Committee

Meeting Summary

June 21, 2022

Conference Call

Shelley Hall, MD, Chair

Rocky Daly, MD, Vice Chair

Introduction

The Heart Committee met via Citrix GoToMeeting teleconference on 06/21/2022 to discuss the following agenda items:

1. Welcome, Information, and Reminders
2. Alert: August 30 Implementation of “Data Lock”
3. Committee Work
4. Farewells to Departing Members

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

1. Welcome, Information, and Reminders

All returning and new committee members are reminded to complete their onboarding and continuing education requirements. The call for Board and Committee Nominations is now open for terms beginning on July 1, 2023. Members are encouraged to share the call for nomination will colleagues and update their Volunteer Forms for continued Committee service.

2. Alert: August 30 Implementation of “Data Lock”

On August 30, 2022 the Modify Data Submission Policies, commonly referred to as ‘Data Lock,’ will be implemented.¹ Training materials will be available on UNOS Connect closer to the implementation date.

3. Committee Work

First, the Committee considered developing a formal process for reviewing existing heart guidance materials. The purpose of this review would be to ensure consistency with clinical best practices and ensuring relevance in the community.

Second, the Committee briefly discussed the project to revise Status 2. The goal of this project is to rectify some of the issues that the community is experiencing, especially with regard to status exceptions for this status. This project will be implemented simultaneously with the heart continuous distribution framework.

Lastly, the Committee considered potential topics for the Heart Committee emails. These emails are formal communications sent out on behalf of the Heart Committee to heart transplant programs and providers. The purpose of these emails is to be an informative and timely form of communication.

¹ OPTN Data Advisory Committee, “Modify Data Submission Policies,” December 2019, accessed June 21, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-data-submission-policies/>.

Summary of discussion:

Members were supportive of reviewing the existing guidance documents. Members volunteered for the guidance documents that they would like to review. These reviews will occur in smaller groups and be brought to the full Committee for discussion and approval.

The Chair suggested developing a Request for Feedback paper for public comment to get a better understanding of how the community feels about revising Status 2. Committee members agreed that it would be helpful to better understand how the community believes the current issues should be resolved. Developing a request for feedback will also build community support for the policy change. Committee leadership supported early and often education for continuous distribution and the analytic hierarchy process (AHP).

In terms of education emails, a member suggested providing an update on multi-organ distribution pending Board approval for the simultaneous heart-kidney proposal from the Ad Hoc Multi-Organ Transplantation Committee.² The Chair responded that this correspondence will come directly from the OPTN and is not the prerogative of the Heart Committee.

A member suggested providing additional guidance and clarification on when the 14 days on an Intraortic Balloon Pump (IABP) and proving that the patient is not a candidate for a Ventricular Assist Device (VAD). Members discussed the ethical challenge of allowing patients to opt-out of receiving a VAD which has implications for their access and the access of other patients. By opting out of a VAD, a patient is maintaining their urgency for a transplant compared to patients who are medically ineligible to receive a VAD and their only treatment option is transplant.

The Chair proposed developing a formal process that occurs when a program transplants a patient at a denied status. In the preceding months, the Committee has noted the issue of centers that transplant their patients while awaiting an exception request and are subsequently denied. Currently, the Committee level review board will consider these cases but often times these denials, when upheld by the Committee review board, are not escalated to the Membership and Professional Standards Committee (MPSC). Multiple members agreed with this suggestion, in alignment with the ongoing sentiment shared by the Committee.

The Chair suggested a prospective review board process to mitigate patients receiving the requested status pending the review board decision. Support staff noted that when the Committee revised the heart allocation system in 2018 the Committee elected to proceed with a retrospective review. Moving forward with continuous distribution the Committee will have the opportunity to make changes to the review board process, but until then there likely will not be any substantive policy changes.

4. Farwells to Departing Members

Committee support staff and Committee leadership acknowledged the members and thanked them for their contributions, who are rolling off the Committee on June 30, 2022.

² OPTN Ad Hoc Multi-Organ Transplantation Committee, "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," January 2022, accessed June 6, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/>.

Upcoming Meeting

- July 19, 2022

Attendance

- **Committee Members**
 - Adam Schneider
 - Amrut Ambardekar
 - Cindy Martin
 - Fawwaz Shaw
 - Jennifer Carapellucci
 - Jonah Odim
 - Michael Kwan
 - Nader Moazami
 - Rocky Daly
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Grace Lyden
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Keighly Bradbrook
 - Kristin Cuff
 - Laura Schmitt
 - Sara Rose Wells
 - Susan Tlusty
- **Other Attendees**
 - Glen Kelley
 - Jennifer Cowger
 - John Nigro
 - Martha Tankersly
 - Timothy Gong