

OPTN Heart Transplantation Committee

Meeting Summary

July 7, 2022

Conference Call

Rocky Daly, MD, Chair

J.D. Menteer, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 7/7/2022 to discuss the following agenda items:

1. Addressing Patient Safety Following a Device Recall

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

1. Addressing Patient Safety Following a Device Recall

The *OPTN Bylaw 11.7 Emergency Actions* allows for policy proposals to be adopted by the Board of Directors prior to public comment under specific circumstances. The Committee is pursuing the emergency action pathway using the following criterion "a proposal that is required due to an emergent public health issue or patient safety factors."¹ As an emergency policy, this modification will be temporary and not exceed 12 months after the effective date. The policy will also be submitted for a retrospective public comment, if approved.

The proposed change will allow patients whose implanted mechanical circulatory support device is recalled by the Food and Drug Administration (FDA) to apply for a Status 1, 2, or 3 exception request without requiring hospitalization. During the previous discussions about recalled devices, the Committee suggested that these patients should apply for a status exception.² However, the current policy requires patients to be hospitalized to be eligible for Status 1, 2, or 3.

Summary of discussion:

Review and Discuss Proposed Policy Changes

A member inquired about post-implementation monitoring and expressed concern about the potential misuse of FDA warnings. The exception request approval or denial will be subject to the decision of the Heart Regional Review Board (RRB). Furthermore, UNOS staff outlined the documentation that transplant programs will be required to maintain and provide during site surveys to be compliant with this policy. The Committee will also review a post-implementation monitoring report analyzing the first six months and 12 months of data after implementation.

A member suggested that due to the unpredictable nature of the recalled devices the Committee ought to determine a specific status for all patients with recalled devices, as opposed to giving transplant programs the opportunity to apply for a Status 1, 2, or 3 exception. This suggestion would also take the

¹ OPTN Bylaw 11.7, *Emergency Actions*, (July 14, 2022).

² Meeting summary for February 15, 2022 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/i5hjgicx/20220215_heart-committee-meeting-summary_final.pdf.

burden off of the Regional Review Boards (RRB) and Committee level review for these cases. While members thought this was reasonable, it was pointed out that the Committee does not have the waitlist mortality or post-transplant survival data to inform why these patients would meet the criteria for any certain status. Additionally, it was pointed out that the proposed policy language does not restrict the clinical decision-making of the transplant center. The member also suggested providing an indefinite exception duration as opposed to 14 days as the proposal suggests. The 14-day duration is consistent with the existing exception process.

A member clarified that this policy is intended to capture the patients impacted by the Medtronic issues and future patients who could be impacted by additional recalls. Members added that this policy opens the door to collect data and retrospective public comment which will allow the Committee to refine the policy in the future. UNOS staff added that as an emergency policy, it will only be in place for up to 12 months. Staff informed the Committee that any of their questions and concerns can be incorporated into the public comment document as feedback questions. The Committee will have the option to bring the policy to the OPTN Board of Directors to become a permanent component of policy with post-public comment changes made.

A member suggested developing a guidance document outlining the clinical characteristics for patients at each status for the RRB to use but agreed that without data it would be arbitrary recommendations. Members felt that the proposed policy language balances the needs of the patients most at risk without developing a potential avenue for abuse.

A member suggested specifying a 'surgically implanted' device in the policy language to make the distinction between permanent and temporary support devices. A member noted that the language in this proposal needs to match the existing policy language, which in this case is 'mechanical circulatory support device (MCSD).'

Committee Vote

The Committee took two votes. There was a motion and a second to call the initial vote. The Committee was asked *do you vote to approve the proposed policy changes addressing patient safety concerns following a heart device recall?* The Committee conducted a voice vote and there was unanimous support for the proposal with 15 members voting in favor.

There was a second motion and a second to call the next vote. The Committee was asked *do you vote to recommend that the Executive Committee approve the proposed policy changes addressing patient safety concerns following a heart device recall as an emergency action?* The Committee conducted a voice vote and there was unanimous support for recommending approval to the Executive Committee with 15 members voting in favor.

Next Steps Towards Approval and Implementation

The Executive Committee will review the proposal on Monday, July 11th and vote whether or not to approve the emergency policy. If approved as an emergency action, implementation is scheduled for Thursday, July 14th. System notices will be emailed to heart transplant program administrators and heart review board members, among others. The proposal will go out for retrospective public comment review on August 3rd.

Upcoming Meetings

- July 19, 2022
- August 16, 2022

Attendance

- **Committee Members**
 - Adam Schneider
 - Cristy Smith
 - Earl Lovell
 - Glen Kelley
 - Hannah Copeland
 - Kelly Newlin
 - J.D. Mentee
 - Jennifer Carpellucci
 - Jennifer Cowger
 - John Nigro
 - Jonah Odum
 - Jose Garcia
 - Martha Tankersley
 - Nader Moazami
 - Rocky Daly
 - Shelley Hall
 - Timothy Gong
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Matt Belton
 - Eric Messick
 - Janis Rosenberg
 - Krissy Laurie
 - Kristin Cuff
 - Rebecca Murdock
 - Roger Brown
 - Susan Tlusty
 - Susie Sprinson