

**OPTN Executive Committee
Meeting Summary
July 11, 2022
Conference Call**

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 07/11/2022 to discuss the following agenda items:

1. OPTN Policy Emergency Actions
2. Modifying Heart Policy to Address Patient Safety Following Recall

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

1. OPTN Policy Emergency Actions

Roger Brown, the Director of the Policy and Community Relations Department, provided a brief overview of the emergency policy action. OPTN *Bylaw 11.7: Emergency Action* allows policy proposals to be implemented for a 12-month period if it meets the requirements and cannot wait for the next Board meeting to be implemented. This proposal is pursuing an emergency action as "a proposal that is required due to an emergency public health issue or patient safety factors."¹

2. Modifying Heart Policy to Address Patient Safety Following Recall

Dr. Shelley Hall, Immediate Past Chair of the OPTN Heart Transplantation Committee, presented the emergency policy action *Modifying Heart Policy to Address Patient Safety Following Recall*. The purpose of this proposal is to provide a pathway for patients with an implanted recalled device to apply for an exception to Status 1, 2, or 3 without requiring hospitalization. These exception requests will follow the existing retrospective review and appeal process through the Regional Review Boards (RRBs).

Summary of discussion:

A member asked for further detail as to why the Heart Committee decided against selecting a specific status for these patients. The Heart Committee felt that there was not adequate data to inform which status would be appropriate. As such, they left this decision to the clinical expertise of the transplant teams and RRB members to decide. A member expressed concerns about potential inconsistency in the application through patients applying for a range of status exceptions, as opposed to being assigned one. The presenter elaborated on the Heart Committee's discussion on this topic and noted that a specific status would be arbitrary without any data to support it at this time. Presently, an overwhelming majority of patients with recalled ventricular assist devices (VADs) are Status 4, which means they are not hospitalized and thus unable to apply for a Status 1, 2, or 3 exception until their condition deteriorates.

A member inquired about the process for device battery changes. The present explained that the batteries tend to last for about 18 hours and patients are taught how to change them before being

¹ OPTN Bylaws, 11.7 Emergency Actions, July 14, 2022.

discharged from the hospital. Patients are instructed to change one battery at a time to ensure connection to the controller, but there is a possibility that both could become disconnected and the controller is not stable enough to guarantee it will restart after being disconnected. A member added that the process for battery exchange and responsibility for the patient is essential to understanding the risk and should be emphasized during public comment.

A member inquired if the U.S. Food and Drug Administration (FDA) was suggesting the recalled devices be replaced. The presenter explained that replacement for VADs requires an open heart surgery that could add undue stress. The medical consensus for VAD patients on the waitlist is to pursue transplant as opposed to VAD replacement to reduce the risk of undue complications for extra surgeries.

There was a motion and a second to call the vote. The Committee unanimously voted in support for the resolution, with 9 members voting in support.

Next steps:

The proposal will be implemented on July 14th. The proposal will undergo a retrospective public comment period from August 3 to September 28, 2022.

Upcoming Meeting

- July 29, 2022
- August 19, 2022
- September 19, 2022
- October 26, 2022

Attendance

- **Committee Members**
 - Brad Kornfeld
 - Dianne LaPointe Rudow
 - Jeff Orłowski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matt Cooper
 - Valinda Jones
- **HRSA Representatives**
 - Chris McLaughlin
 - Frank Holloman
 - Shannon Taitt
- **UNOS Staff**
 - Alex Tulchinsky
 - David Klassen
 - Eric Messick
 - Krissy Laurie
 - Laura Schmitt
 - Liz Robbins Callahan
 - Matt Belton
 - Maureen McBride
 - Roger Brown
 - Sara Rose Wells
 - Susan Tlusty
 - Susie Sprinson
- **Other Attendees**
 - Shelley Hall