

**OPTN Heart Transplantation Committee
Meeting Summary
November 6, 2024
Conference Call**

**J.D. Menteer, MD, Chair
Hannah Copeland, MD, Vice Chair**

Introduction

The Committee met via WebEx teleconference on 11/06/2024 to discuss the following agenda items:

1. Welcome, introductions, and agenda review
2. Ensure final policy proposal language for *Escalation of Status* project
3. Continue Committee’s discussion of hearts and xenotransplantation
4. Open Forum
5. Closing remarks

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

1. Welcome, introductions, and agenda review

The Chair welcomed the members and provided an overview of the agenda. Members calling in by phone only were reminded to tell OPTN contractor staff their names for attendance purposes. Non-committee members and those without business before the Committee were reminded that they should follow the proceedings using vimeo.com/optn.

2. Ensure final policy proposal language for *Escalation of Status* project

OPTN contractor staff presented the proposed policy language for *Escalation of Status* project for the Committee’s consideration and a vote to submit the language as part of the public comment document.

Data summary:

During the Committee’s 10/09/2024 meeting, the members had expressed support for referring to the types of devices addressed by the proposed policy as “qualifying dischargeable VAD which supports systemic circulation”. Subsequent to 10/09 meeting, Committee leadership reviewed the new reference and found it to be inconsistent with device references in existing OPTN policy. Leadership cited the following as potential issues with moving forward with the new reference language:

- Inconsistency would breed confusion
- Confusion would increase use of exception requests
- Making existing references consistent with 10/09 suggestion overly expands project scope

Leadership recommends maintaining consistency with how covered devices are currently referenced.

Summary of discussion:

Decision 1: The Committee voted to submit the proposed policy language for the *Escalation of Status for Time on Ventricular Assist Device* project for public comment as part of the January 2025 cycle.

Vote: 17 yes, 0 no, 0 abstain

A Committee member inquired whether a recommendation would be made regarding the step-down process. OPTN contractor staff explained that the Committee had discussed allowing an 18-month window following implementation of the 6- and 8-year timeframes before stepping down to the 5- and 7-year timeframes. The 18-month window will allow the Committee to review monitoring results from the initial changes while still enabling progress towards those timeframes. The Chair raised a question about the public comment document, specifically whether it would include the 5- and 7-year timeframes. OPTN contractor staff confirmed that those timeframes would be addressed. The Chair indicated that the Committee would need at least one year of data by the 6-month mark, but it was uncertain whether an analysis of that data could be completed within an 18-month period. OPTN contractor staff stated that monitoring results should be available approximately 8 to 9 months after implementation of the 6- and 8-year timeframes, depending on what the Committee would like to track. The Chair suggested that the Committee focus on several key metrics: the number of patients elevated to statuses 2 and 3, the number of patients transplanted at the impacted statuses, and any changes in waitlist mortality.

Next steps:

OPTN public comment will occur starting in January 2025. The Committee’s regional representatives will be asked to present the proposal at their regional meeting. OPTN contractor staff will work with the regional representatives to prepare for the meetings.

3. Continue Committee’s discussion of hearts and xenotransplantation

The Chair shared ideas about heart allocation policy and xenotransplantation for the Committee’s consideration and feedback.

Summary of discussion:

The Heart Committee did not make any decisions.

The Committee had initiated discussion of heart allocation policy and xenotransplantation during their 10/09/2024 meeting, but had not finished. OPTN leadership shared with the Committee members the OPTN Ethics Committee’s early efforts to publish a white paper about the ethical considerations associated with organ allocation and xenotransplantation. Some of the ethical considerations the Ethics Committee expects to address include how xenotransplantation may interface with the human allograft allocation system. Because xenotransplantation is a rapidly evolving field regarding heart candidates, the Chair wants the Committee to be ahead of the curve when it comes to considering how xenotransplantation might fit in the allocation system.

One committee member suggested that the Committee should consider this as another type of heart device. Another member raised the issue of whether transplant programs will consider listing recipients of xenotransplants for heart transplants, emphasizing the implications for waitlist mortality and post-transplant survival rates. The same member recommended that heart transplant programs might seek a variance to exclude xenotransplant data from the standard transplant program risk models. Another member pointed out that a major challenge to incorporating xenotransplant in heart allocation policy is the lack of large-scale data regarding the risk profiles of xenografts, making it difficult to assign priority status.

Next steps:

The Committee agreed to continue the discussion as part of a future meeting.

4. Open Forum

There were no requests to speak during this part of the meeting.

5. Closing remarks

The Chair thanked the members for attending and advised that the December 4th meeting is cancelled.

Upcoming Meetings

- ~~July 2, 2024 from 4:00 to 5:30 pm~~
- ~~July 16, 2024 from 5:00 to 6:00 pm~~
- ~~August 7, 2024 from 4:00 to 5:00 pm~~
- ~~August 20, 2024 from 5:00 to 6:00 pm~~
- ~~September 4, 2024 from 4:00 to 5:00 pm~~
- ~~September 17, 2024 from 5:00 to 6:00 pm~~
- ~~October 2, 2024 from 4:00 to 5:00 pm~~
- ~~October 9, 2024 from 9:00 am to 4:00 pm (In-person meeting, Detroit, MI)~~
- ~~October 15, 2024 from 5:00 to 6:00 pm~~
- ~~November 6, 2024 from 4:00 to 5:00 pm~~
- November 19, 2024 from 5:00 to 6:00 pm
- ~~December 4, 2024 from 4:00 to 5:00 pm – Cancelled~~
- December 17, 2024 from 5:00 to 6:00 pm
- January 21, 2025 from 5:00 to 6:00 pm
- February 18, 2025 from 5:00 to 6:00 pm
- March 18, 2025 from 5:00 to 6:00 pm
- April 15, 2025 from 5:00 to 6:00 pm
- May 20, 2025 from 5:00 to 6:00 pm
- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
 - J.D. Menteer
 - Hannah Copeland
 - Denise Abbey
 - Tamas Alexy
 - Maria Avila
 - Kim Baltierra
 - Jennifer Cowger
 - Kevin Daly
 - Rocky Daly
 - Jill Gelow
 - Timothy Gong
 - Jennifer Hartman
 - Earl Lovell
 - Cindy Martin
 - Mandy Nathan
 - Jason Smith
 - David Sutcliffe
 - Martha Tankersley
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Monica Colvin
 - Grace Lyden
- **UNOS Staff**
 - Viktoria Filatova
 - Cole Fox
 - Katrina Gauntt
 - Kelsi Lindblad
 - Eric Messick
 - Holly Sobczak
 - Kaitlin Swanner
 - Sara Rose Wells
- **Other Attendees**
 - None