

**OPTN Policy Oversight Committee
Meeting Summary
August 8, 2024
Teleconference
Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair**

Introduction

The OPTN Policy Oversight Committee (POC) met via teleconference on 08/08/2024 to discuss the following agenda items:

1. Post Implementation Monitoring Review: Modify the Adult Heart Allocation System
2. New Project: Escalation of Status for Time on Left Ventricular Assist Device
3. New Project: Monitor Ongoing eGFR Modification Policy Requirements

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

1. Post Implementation Monitoring Review: Modify the Adult Heart Allocation System

The Committee reviewed a summary of the Heart Committee's assessment of the post-implementation monitoring report for the *Modify the Adult Heart Allocation System* project.

Presentation Summary:

The changes to the allocation system were largely successful in achieving their primary goals of improving urgency-based allocation and increasing access to transplants. The new tiered system seems to be more nuanced in categorizing patient urgency, which likely contributes to the improved outcomes. However, the unexpected outcomes highlight areas that may need further attention. The increased use of specific status 2 criteria and exception requests could indicate that healthcare providers are adapting to the new system in ways that weren't anticipated. This may require further investigation to ensure that these practices align with the overall goals of the system and don't lead to further unintended consequences in the long term.

Summary of Discussion:

The Vice Chair asked if the Heart Committee compared waitlist mortality for patients who would have been Status 1 in the old system to their mortality in the new system. A member of the Heart Committee advised that while that specific data wasn't available, current data suggests that combining mortality rates for new Status 1, 2, and 3 and comparing them to old Status 1A showed improvement in the new era. Members raised concerns about increased organ travel distances and potential effects on organ viability. It was noted that while average travel distance increased, it remained within acceptable ranges for transplant professionals (up to four hours of cold ischemic time). Very short-distance transport decreased, but overall cold ischemic time didn't change significantly.

Data on Primary Graft Dysfunction is still being gathered, as it was only added as a metric two years ago. Complete graft failure leading to patient death is uncommon in heart transplantation. Overall median time to transplant for all statuses and overall decreased from 200 days to 59 days for the entire cohort. This improvement was seen across all statuses, raising questions about better allocation or changes in

listing practices. It was noted that the number of patients listed for transplant did not decrease, and utilization rates remained stable.

Next Steps:

The POC's comments will be summarized in a memo for the Heart Committee's consideration.

2. New Project: Escalation of Status for Time on Left Ventricular Assist Device

The Committee reviewed the following project: *Escalation of Status for Time on Left Ventricular Assist Device*

Presentation Summary:

This project aims to address the potential unintended consequence of the 2018 allocation changes, which may have disadvantaged stable LVAD patients. By providing a pathway to higher urgency status based on LVAD support duration, the project seeks to balance the needs of these patients with those of other critically ill candidates.

Summary of Discussion:

A member asked based on the data since 2018, how many patients are included in the scope of this project. The presenter answered that question by advising that they had looked at the number of currently waitlisted patients who have been on durable LVADS for different periods of time at status 4. However, they did not know the exact number of patients up front. They were looking for numbers that were not a large fraction of the number of patients who were at status 3 or 2. A member commented on this discussion highlights the careful balance the committee is trying to strike between addressing the needs of long-term LVAD patients and maintaining the integrity of the current urgency-based system. It also shows how they are using this as an opportunity to gather data and insights for future policy development, particularly for the transition to a continuous distribution model.

Vote:

Does the Committee recommend approval of new project to Executive Committee?

15 yes, 0 no, 0 abstention

Next Steps:

The project will be reviewed by the Executive Committee for approval.

3. New Project: New Project: Monitor Ongoing eGFR Modification Policy Requirements

The Committee reviewed the following project: *Monitor Ongoing eGFR Modification Policy Requirements*

Presentation Summary:

This project aims to address potential disparities in kidney allocation that may have resulted from the use of race-inclusive eGFR calculations. By requiring written protocols, it seeks to standardize and clarify the process across all transplant programs, aiming to reduce errors and ensuring more equitable application of waiting time modifications. The focus on reducing Membership and Professional Standards Committee case reviews suggests that there may have been inconsistencies in how transplant programs have been implementing this policy.

Summary of Discussion:

Members emphasized that addressing the gap identified by the MPSC should be a priority. It is suggested that compliance with OPTN policies, especially considering the January 2024 update, be clarified. The lack of a specified deadline for transplant programs to comply with the new policy was noted, and it is recommended that a compliance deadline be communicated as part of the policy rollout to allow sufficient time for adjustments. Scheduling follow-up audits and compliance checks after the deadline was suggested.

The presenter reported that every kidney program in the country has at least started the process of addressing previously disadvantaged patients. It was explained that the lack of specific deadlines is intentional to avoid undue burden on programs, considering the significant time investment required (e.g., hundreds of coordinator hours). The emphasis is on having a process in place to give patients the waiting time they deserve. It is expected that most of the work will be upfront, with the policy being effective as new patients are listed. This is considered a critical project.

Members commented these perspectives highlight the importance of the project while also acknowledging the challenges in implementation. Members further commented that while the project is necessary and valuable, it must be implemented with consideration for the practical difficulties faced by transplant centers. The lack of strict deadlines seems to be a deliberate choice to allow centers flexibility, but there was a suggestion that some form of timeline and follow-up audits could be beneficial.

Vote:

Does the Committee recommend approval of new project to Executive Committee?

13 yes, 0 no, 0 abstention

Next Steps:

The project will be reviewed by the Executive Committee for approval.

Upcoming Meeting(s)

- August 21, 2024 Teleconference

Attendance

- **Committee Members**
 - Erika Lease
 - Lorrinda Gray-Davis
 - Aneesha Shetty
 - Arpita Basu
 - Dennis Lyu
 - Cynthia Foreland
 - Heather Bastardi
 - Jason Huff
 - Kelley Hitchman
 - Lisa McElroy
 - Lori Markham
 - Neha Bansal
 - Oscar Serrano
 - Paige Porrett
 - Rachel Miller
 - Sanjay Kulkarni
 - Shimul Shah
 - Scott Lindberg
 - Macey Levan
- **HRSA Representatives**
 - Shannon Dunne
 - Steven Keenan
- **SRTR Staff**
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Lindsay Larkin
 - Viktoria Filatova
 - Cole Fox
 - Kaitlin Swanner
 - Kimberly Uccellini
 - Darby Harris
 - Eric Messick
 - Kelley Poff
 - Rebecca Goff
 - Roger Brown
 - Susan Tlusty
- **Guests**
 - Jondavid Menteer