

**OPTN Executive Committee
Meeting Summary
August 29, 2024
Webex**

Richard Formica, MD, Chair

Introduction

The OPTN Executive Committee met via Webex teleconference on 08/29/2024 to discuss the following agenda item:

1. Welcome & Announcements
2. New Projects from the Policy Oversight Committee (POC)*
3. POC Review of MPSC Proposal: Update Criteria for Post-Transplant Graft Survival Metrics*
4. OPO Merger

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

1. Welcome & Announcements

Richard Formica, Chair of the Executive Committee, welcomed the committee to their meeting and presented the agenda for the meeting.

2. New Projects from the Policy Oversight Committee (POC)*

Erika Lease, Vice Chair of the Policy Oversight Committee (POC) presented a new project from the Heart Transplantation Committee on Escalation of Status for Time on Left Ventricular Assist Device and a new project from the Minority Affairs Committee (MAC) to Monitor Ongoing eGFR Modification Policy.

Dr. Lease shared that the purpose of the project from the Heart Transplantation Committee on Escalation of Status for Time on Left Ventricular Assist Device was to provide a pathway to higher medical urgency for adult heart status 4 candidates supported by dischargeable left ventricular assist device (LVAD). Dr. Lease explained that research suggests that while dischargeable LVAD patients are often stable, the longer they are supported by the device, the greater their risk of complications, such as stroke, infection, and bleeding. Dr. Lease shared the key metrics of the project, alignment to the strategic plan goals and metrics, the project's rationale, the anticipated timeline, resource estimates for the project, and the benefit score assigned to the project by the POC. Dr. Lease shared key points from the discussion held by the POC and their recommendation to approve the project.

Dr. Lease then shared the background and purpose of the new project from the MAC to Monitor Ongoing eGFR Modification Policy. Dr. Lease shared that the project was referred to the MAC by the Membership and Professional Standards Committee (MPSC), requesting that the OPTN review the waiting time modification policy to include even more specific requirements to transplant programs regarding *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations Reporting Requirements*. Dr. Lease shared that the proposal would require every kidney transplant program to maintain a written protocol that outlines the process for completing eGFR calculations, and to check if new candidates on the OPTN Waiting List qualify for waiting time modifications. This project will enhance the ongoing policy requirements and compliance monitoring of *OPTN Policy 3.7.D*. Dr. Lease shared the key metrics of the project, including alignment to the strategic

plan, goals and metrics, the rationale for the project, anticipated timeline, resource estimates, and the project benefit score assigned by the POC. Dr. Lease shared the discussion held by the POC and their recommendation to approve the project.

Summary of Discussion:

Committee members asked clarifying questions on each new project proposal. When discussing the project proposal from the Heart Transplantation Committee, a committee member asked what impact the project could have on Heart Continuous Distribution. Dr. Menteer, Chair of the Heart Transplantation Committee, explained that the committee predicts that this project will aid the committee when they implement heart into a continuous distribution format as they will have more data available at that time due to this project.

A committee member asked if moving forward there could be additional information provided to the committee on other projects expected to come to the Executive Committee for review, so the committee can ensure they are prioritizing resources and have a more holistic approach when considering new projects.

When discussing the new project from the MAC, the committee discussed the role of the MPSC in recommending the project to the MAC. A committee member commented that it may be more difficult to operationalize the policy as more time passes. The committee discussed how they could address this moving forward to ensure that modifications are being made in the most efficient manner. The committee discussed how this project interacts with the other two eGFR policies and a committee member suggested that this information continue to be audited when site visits are completed.

Vote:

The Executive Committee approved the initiation of the projects from the Policy Oversight Committee (POC):

- Escalation of Status for Time on Left Ventricular Assist Device (Heart)
- Monitor Ongoing eGFR Modification Policy (Minority Affairs)

3. POC Review of MPSC Proposal: Update Criteria for Post-Transplant Graft Survival Metrics*

Erika Lease, Vice Chair of the Policy Oversight Committee (POC) presented the POC's review of a proposal from the Membership and Professional Standards Committee (MPSC) to Update Criteria for Post-Transplant Graft Survival Metrics. Dr. Lease shared that the POC reviewed the project for a special public comment period.

Dr. Lease presented that the proposal to Update Criteria for Post-Transplant Graft Survival Metrics comes from the MPSC's recommendation to raise the flagging threshold for 90-day graft survival and 1-year conditional on 90-day graft survival. Dr. Lease explained that the policy would continue to identify programs with the greatest need for improvement, and she noted that a majority of serious patient safety issues are not identified through these metrics. Dr. Lease shared the expected timeline for the special public comment period, and shared how the project aligns with the strategic plan.

Dr. Lease shared the POC's feedback on the special public comment proposal, the associated resource estimates, and she shared that the POC unanimously voted to recommend the project to the Executive Committee for their approval for special public comment.

Summary of Discussion:

Dr. Formica shared that the project was created based on a suggestion by the Expeditious Task Force. He shared that that Task Force suggested that the metric be modified so more high complexity organs are

utilized, as there is concern throughout the community about the potential effect of these organs on outcome metrics. The committee discussed how changing the metric could affect the reporting of data to the SRTR and commercial payers. The MPSC Chair explained that by changing the metric, it may allow the MPSC to address other opportunities throughout the community. A committee member commented that the language used in the proposal, specifically around modifying the metric, needs to be carefully considered.

Vote:

The Executive Committee approved the release of the proposal to Update Criteria for Post-Transplant Graft Survival Metrics for Special Public Comment.

4. OPO Merger

Contractor staff presented on an upcoming merger between two OPOs, noting that the committee must decide how to classify members that are currently in Region 10 but are affected by a cross-regional merger of the two OPOs. Kentucky Organ Donor Affiliates (KYDA) and LifeCenter Organ Donor Network (OHOV) will become one OPO, and go by the name Network for Hope. Contractor staff presented two potential options for the committee to consider. Contractor staff explained that as a related item, the committee will also consider a proposal to remove granular definitions of regions in OPTN Policies and Bylaws to avoid additional modifications of Policies and Bylaws if future mergers affect regional boundaries.

Contractor staff presented background information to the committee on the two OPOs that are merging, and the implications of the merger. Contractor staff explained that due to the merger and the new OPO (KYDA) being located in Region 11 and 4 members (currently part of OHOV) being located in Region 10, the committee must decide how to clarify these member's regional classifications.

Contractor staff reminded the committee of key definitions relating to the merger. Donation Service Areas (DSA) is a geographic unit used by the Centers for Medicare and Medicaid Services (CMS), and OPTN Regions are geographic units used by the OPTN for administrative purposes. Contractor staff shared the role of each within organ donation and transplantation, and how they differ from one another.

Contractor staff presented the two potential options for the committee's consideration:

- Option 1: Extend Region 11 to include the areas of Indiana and Ohio served by the new KYDA OPO, thereby changing the regional affiliation for the 3 Ohio transplant hospitals and 1 histocompatibility lab from Region 10 to Region 11.
- Option 2: Allow the members in Ohio affected by the merger to remain in Region 10, while also being part of a DSA served by a Region 11 OPO.

Contractor staff shared the benefits and drawbacks associated with each option and the cost estimates for each option. The committee discussed the two options and ultimately voted to recommend the option to extend Region 11 to include the areas served by the new OPO and change the regional affiliation of the 4 members from Region 10 to Region 11.

Summary of Discussion:

A committee member asked if patients will be affected by the merger. Contractor staff shared that patients will not be affected, and that the main impact from the merger is from a data and administrative standpoint. The committee discussed the precedence that their decision on this merger could potentially set for mergers in the future.

The committee discussed the impact the merger could have on regional review board members and whether they would be able to complete their terms if they moved from Region 10 to Region 11. Contractor staff explained that there would be a transition period for these review board members, so they would be able to complete their terms.

Vote:

RESOLVED, that the OPTN Region 11 boundary is revised to include all the geographic areas that will be served by the KYDA OPO as of October 1, 2024, inclusive of all OPTN members therein.

Next Steps:

Contractor staff shared that CMS is reviewing the proposed merger. The OPTN will notify the community of the Executive Committee's decision. Contractor staff shared that other policy language changes will be discussed with the committee at a future meeting. They shared that these policy language changes will help remove granular details about regional affiliation within policy.

Upcoming Meetings:

- September 26, 2024
- October 24, 2024
- November 14, 2024
- December 12, 2024

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Emily Blumberg
 - Erika Demars
 - George Surratt
 - Jen Lau
 - Jennifer Muriett
 - Richard Formica
 - Silas Norman
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
- **UNOS Staff**
 - Anna Messmer
 - Cole Fox
 - Darby Harris
 - Eric Messick
 - James Alcorn
 - Kelley Poff
 - Kieran McMahon
 - Krissy Laurie
 - Lindsay Larkin
 - Liz Robbins Callahan
 - Maureen McBride
 - Roger Brown
 - Sara Langham
 - Sharon Shepherd
 - Susan Tlusty
 - Susie Sprinson
 - Viktoria Filatova
- **Other Attendees**
 - Cliff Miles
 - Erika Lease
 - JD Menteer
 - Steven Gonzalez