

OPTN Membership and Professional Standards Committee`

Meeting Summary

December 13, 2024

Virtual

Cliff Miles, M.D., Chair

Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met virtually in both open and closed sessions on December 13, 2024, via Webex teleconference, to discuss the following agenda items:

1. Performance Improvement (Yellow Zone) Boundaries
2. Required Reporting of Patient Safety Events, 6 Month Monitoring Report
3. Membership Issues
4. Other Significant Items

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

1. Performance Improvement (Yellow Zone) Boundaries

The MPSC's proposal to Update Criteria for Transplant Program Metrics was passed by the OPTN Board of Directors at its December meeting. Because that proposal changes the thresholds for MPSC review of adult post-transplant graft survival, the Committee determined at its November meeting that it would need to discuss changes to the current performance improvement (yellow) zone. Contractor staff provided information on the background of the yellow zone, the number of programs that would fall within the yellow zone under various thresholds, the number of programs in the yellow zone that later require MPSC interaction, and the level of effort to follow the current process for members. With post-transplant outcomes, the data that will result in the program being identified for review may already exist by the time the program falls in the yellow zone. However, receiving the notice may alert the members to begin evaluating their processes and initiate corrective action plans.

For the last Program Specific Report (PSR) data, 49 programs received memos notifying them that their data fell in the performance improvement zone and providing a link to resources on the OPTN website. If the MPSC did not move the lower threshold from 1.5 despite changing the upper threshold to 2.25, an estimated 87 programs would be in the yellow zone. The contractor staff also presented information about the manual process for creating and sending the memos to members and the feedback from previous processes. Feedback has been mixed, with some members confused about whether they need to respond.

Summary of Discussion:

Decision #1: The Committee voted to update the performance improvement thresholds to programs with a 50% probability that their hazard ratio is greater than 1.75 but less than 2.25 by a vote of 25 For, 0 Against, 0 Abstentions.

Decision:

The Committee asked about the level of effort and the ways that members find out about the performance improvement zone. Contractor staff acknowledged that the current level of effort is fairly high. SRTR staff confirmed that their private summary reports for each PSR, available on the members' secure sites, include information on both the MPSC review zone and the performance improvement zone. However, since this discussion was happening as they were programming their updates to the PSR data, they removed that performance improvement information from the report for the January 2025 PSR. SRTR staff and Contractor staff will work together to propose some alternative ways to provide information for the July 2025 PSR.

A committee member asked whether there was any statistical validation indicating that the performance improvement thresholds may be based on patient safety risks. The intention of the yellow zone is to provide resources for members who are not identified but may be trending in that direction. SRTR staff responded that programs taking on additional riskier donors would not end up with a higher hazard ratio due to risk adjustment. The Committee also asked whether there were alternatives that might be more meaningful, such as limiting the cohort for the yellow zone to newer data or using the CUSUM reports that show newer information to determine members that may need resources. The Committee may discuss future improvements at later meetings, but for now determined only to change the current threshold.

There is no firm science where the right place to draw the threshold is, the zone is really based on how many programs the MPSC would like to review or to provide information. The previous threshold was just based on being 0.25 below the current threshold. Moving the threshold to 2.0 would only include a very small number of programs. Therefore, in order to help additional programs, the Committee determined to move the threshold to a 50 percent probability that the hazard ratio is greater than 1.75.

2. Required Reporting of Patient Safety Events, 6 Month Monitoring Report

Contractor staff provided a 6-month post-implementation monitoring report for Policy 18.5 (*Required Reporting of Patient Safety Events*).

The changes in the policy went into effect on January 10, 2024, and better aligned the OPTN members' patient safety reporting requirements with the OPTN Contractor's requirements to report certain patient safety events to MPSC leadership and HRSA. Additionally, the proposal consolidated patient safety reporting requirements into a centralized location in policy. As a part of the post-implementation monitoring the MPSC will be provided with the volumes of patient safety events every six months for up to two years.

The following list represents the number and types of reports that were received between January 10, 2024, and July 10, 2024:

- 1 - A donor organ is identified as incorrect during pre-transplant processes conducted according to Policy 5.8.A or 5.8.B
- 2 - An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt or Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt
- 12 - A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.
- 1 - A living donor dies within 2 years after organ donation
- 1 - A living kidney donor begins regularly administered dialysis as an ESRD patient within 2 years after donation

- 4 - A living donor organ is recovered and transplanted into someone other than the intended recipient
- 3 - An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype, and after the OPO has executed a match run

Discussion Summary

The Committee discussed the findings and the format of the report and suggested including the denominator in order to best interpret trends. For example, provide the number of living donor transplants and specify kidney or liver.

The Committee asked that the next six-month report also include this set of data for comparison.

3. Membership Issues

Application Related Topics: The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda. The Committee reviewed and approved the consent agenda by a vote of 27 For, 0 Against, and 0 Abstentions.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during the June 2025 meeting.

- Approve 1 New Hospital
- Approve 3 New Program/Component
- Approve 4 Program/Component Reactivation
- Approve 2 Program/Component – Conditional to Full
- Approve 2 Program - Conditional
- Approve 1 Program - Reapplication
- Approve 1 Business membership renewals

The Committee also reviewed and approved the following program related actions and personnel changes.

- 50 applications for changes in key personnel in Transplant Programs or Components
- 10 applications for changes in key personnel in Histocompatibility Laboratories
- 2 applications for Program Inactivation Extension

The Committee also received notice of inactivations and OPO key personnel changes and discussed one change in key personnel, which was approved.

4. Other Significant Items

- Board of Directors Meeting Feedback
The Chair briefly informed the Committee that he had presented the highlights of its written report during the December 2-3, 2024, OPTN Board of Directors meeting. He shared that the Board members had expressed support for the hard work on the MPSC and had questions or comments about the following topics.
 - MPSC status on multi organ performance monitoring
 - Allocation out of sequence and the nature of the cases

- Third party membership for organizations that participate in donor recovery.
- Pre-Transplant mortality flagging and understanding risk adjustment.

- Report of Investigative Activities
OPTN Contractor staff supplied a summary of investigative activity from November 2024. The report included the number of reports staff received, modes of receipt, reporting and subject, member type, general classification of the issue, and how many cases staff referred to the MPSC, closed without sending them to the MPSC, or are still actively investigating. Most of the report focused on reports that staff did not refer to the full MPSC for review, and the reasons why. Reasons for non-referral included an inability to substantiate the claim, no demonstrated patient safety issue, or policy noncompliance.

Upcoming Meetings

- January 24, 2025, 1-4pm ET
- February 21, 2025, 1-4pm, ET
- March 4-6, 2025, TBD – virtual or in person
- March 28, 2025, 1-4pm, ET
- April 25, 2025, 11am-2pm, ET
- May 22, 2025, 11am – 1pm, ET
- June 27, 2025, 11am-2pm, ET

Attendance

- **Committee Members**
 - Kamyar Afshar
 - Mitzi Barker
 - Megan Bell
 - Kristine Browning
 - Christopher Curran
 - Chadrick Denlinger
 - Amishi Desai
 - Nahel Elias
 - Sander Florman
 - Roshan George
 - Shelley Hall
 - Richard Hasz
 - Nicole Hayde
 - Kyle Herber
 - Michelle James
 - Christy Keahey
 - Lindsay King
 - Kevin Korenblat
 - Peter Lalli
 - Raymond Lee
 - Scott Lindberg
 - Maricar Malinis
 - Deborah Maurer
 - Luis Mayen
 - Deborah McRann
 - Clifford Miles
 - Deirdre Sawinski
 - Malay Shah
 - Nirmal Sharma
 - Zoe Stewart Lewis
 - Carrie Thiessen
 - Mark Wakefield
 - James Yun
- **HRSA Representatives**
 - Marilyn Levi
 - Raymond Lynch
 - Arjun Naik
- **SRTR Staff**
 - Jonathan Miller
 - Jon Snyder
 - David Zaun
- **UNOS Staff**
 - Robert Albertson
 - Sally Aungier
 - Matt Belton

- Torry Boffo
- Jadia Bruckner
- Linwood Butler
- Tameka Butler
- Robyn DiSalvo
- Nadine Drumn
- Laureen Edwards
- Katie Favaro
- Liz Friddell
- Jasmine Gaines
- Caroline Hales
- Stuart Henley
- Houlder Hudgins
- Elias Khalil
- Andy Klein
- Lee Ann Kontos
- Jessie Kunnamann
- Krissy Laurie
- Jon McCue
- Amy Minkler
- Heather Neil
- Emily Powell
- Melissa Santos
- Laura Schmitt
- Erin Schnellinger
- Sharon Shepherd
- Courtney Skeen
- Betsy Warnick
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Hobie Wood
- Hollie Woodcock
- **Other Attendees**
 - None