

## **OPTN Membership and Professional Standards Committee**

### **Meeting Summary**

**April 23, 2024**

**Conference Call**

**Zoe Stewart Lewis, M.D., Chair**

**Scott Lindberg, M.D., Vice Chair**

### **Introduction**

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on April 23, 2024, to discuss the following agenda items:

1. Membership Requirements Revisions
2. Potential Performance Monitoring Next Steps to Support Expeditious Initiatives
3. Special Public Comment: Whistleblower & Code of Conduct
4. Compliance Issues
5. Membership Issues
6. Investigative Activities

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

#### **1. Membership Requirements Revisions**

The Committee did not discuss this project due to time constraints.

#### **2. Potential Performance Monitoring Next Steps to Support Expeditious Initiatives**

The Committee evaluated potential changes to post-transplant outcomes and offer acceptance flagging criteria, as well as other potential options to support the Expeditious Task Force Bold Aim of 60,000 deceased donor transplants in 2026.

OPTN Contractor staff provided a timeline of work to date. At its January 19 conference call, the Committee considered a potential moratorium on post-transplant outcomes monitoring. The Committee communicated to the Task Force that they did not support a complete suspension of review of all post-transplant outcomes but suggested consideration of changes to the thresholds for review, risk adjustment model improvement, and additional education efforts. At its March 25 meeting, the Executive Committee passed a resolution requesting that the MPSC consider revising the post-transplant outcomes criteria to capture fewer programs to remove barriers to increased transplants and increase the offer acceptance criteria to create a stronger incentive for transplant programs to accept organs.

OPTN Contractor staff presented data regarding the number of programs flagged for post-transplant outcomes review during the initial July 2022 cycle of review using the new criteria and the actions in those reviews taken (e.g., continue to monitor, released, informal discussion, peer visit) for each subsequent MPSC review cycle from October 2022 – March 2024. Data were also presented on the number of offer acceptance flags during the July 2023 and January 2024 PSR cycles. An update was provided on the status of offer filters. Lung offer filters were launched in January 2024 and liver and heart offer filters will be launched this summer followed by the implementation of the optimize kidney filters project.

SRTR Contractor staff provided information on the effect of threshold changes on the number and characteristics of programs identified and no longer identified, including details regarding the process of setting flag boundaries and the effect of specific changes to the current MPSC flagging criteria for the two post-transplant graft failure metrics and the offer acceptance metric.

Data were presented regarding the number of programs that were flagged in the January 2024 cycle for both post-transplant outcomes and offer acceptance, compared to the number of programs that would be flagged using alternate flagging boundaries, movement of the graft failure boundary from 1.75 to 2.0 and the offer acceptance boundary from .30 to .35. The number of programs flagged for both post-transplant graft failure metrics would decrease by about half, while the number of programs flagged for offer acceptance would increase by a little more than one-third. Utilizing the alternate post-transplant boundary would result in 67 total flags for adult programs across all metrics (including pre-transplant mortality with no changes), compared to 78 using current flagging boundaries.

#### Summary of Discussion:

**Decision #1:** The Committee supported consideration of adjustments to both the post-transplant outcomes criteria and the offer acceptance criteria for adult candidates and transplants only.

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Committee members suggested that it might be too soon to make adjustments to the offer acceptance criteria since this metric was just implemented last July. Committee members asked whether there is data that supports the hypothesis that raising thresholds will increase transplant programs' tolerance for riskier organs and lead to meaningful change. Committee members requested that a literature review be done to determine if any evidence of a correlation between transplant program behavior change based on less restrictive MPSC monitoring. The Chair stated that it is difficult to predict the impact and the Committee will need to experiment noting that the MPSC has been criticized for using a high bar that results in risk-averse behavior by programs despite explanations regarding risk adjustment methodology. A Committee member commented on the need to monitor the effectiveness of any changes.

Committee members discussed applying any change to the metric criteria only to adult candidates and transplants and not pediatric since pediatric volumes are low and there are many additional considerations regarding use of marginal organs in children.

The Committee participated in a vote to determine the next steps. The vote was split with nine members supporting consideration of adjustments to both post-transplant outcomes and offer acceptance criteria, six supporting consideration of adjustments to post-transplant outcomes criteria only, none supporting consideration of adjustments to offer acceptance criteria only and nine supporting the need for more time to collect data to evaluate whether the criteria should be changed.

#### Next steps

The Committee will review additional data and relevant literature to determine changes that could be considered to adult post-transplant outcomes and offer acceptance criteria at the upcoming meeting on May 21, 2024.

### **3. Special Public Comment: Whistleblower and Code of Conduct**

OPTN Contractor Staff informed the MPSC of the OPTN Executive Committee's proposal to *Establish Code of Conduct and Whistleblower Protection Bylaws*. This proposal is out for special public comment from April 17 to May 17. Members are encouraged to attend a webinar on the proposal on April 25 at 1:00 pm ET and submit their feedback on the OPTN website. Members did not have any feedback or questions.

### **4. Compliance Issues**

The Committee reviewed a consent agenda consisting of 10 routine OPO allocation monitoring reports; they closed all 10 reviews with no action. The Committee also reviewed allocation errors for two transplant programs and issued two Notices of Noncompliance. The Committee voted to approve the consent agenda by a vote of 24 Yes, 0 No, and 1 Abstention. The Committee also reviewed four discussion items.

### **5. Membership Issues**

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 22 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 2024 meeting as listed below:

- Approve 1 Program Change from Full Approval to Conditional Approval
- Approve 1 Program Change from Conditional Approval to Full Approval
- Approve 1 Conditional Extension
- Approve 2 New Programs
- Approve 1 Program Reapplication
- Approve 3 Program Reactivation
- Approve 2 Business Membership Renewals
- Approve 2 Medical Scientific Membership Renewals
- Approve 1 Public Organization Membership Renewal
- Approve 2 New Individual Members

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

- 42 applications for changes in key personnel in Transplant Programs or Components
- 4 applications for new key personnel in Histocompatibility Laboratories

The Committee received notice of member and program withdrawals OPO key personnel .

### **6. Investigative Activities**

OPTN Contractor staff supplied a summary of investigative activity from March 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 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, lack of patient safety issue or policy noncompliance.

#### **Upcoming Meetings**

- May 21, 2024, 2-5pm, ET, Conference Call
- May 29, 2024, 4-6pm, ET, Conference Call
- June 28, 2024, 2-5pm, ET, Conference Call
- July 23-25, 2024, Detroit

## Attendance

- **Committee Members**
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker
  - Hannah Copeland
  - Chad Ezzell
  - Robert Fontana
  - Roshan George
  - Darla Granger
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Catherine Kling
  - Peter Lalli
  - Raymond Lee
  - Scott Lindberg
  - Maricar Malinis
  - Deborah McRann
  - Nancy Metzler
  - Cliff Miles
  - Saeed Mohammad
  - Regina Palke
  - Martha Pavlakis
  - Deidre Sawinski
  - Malay Shah
  - Zoe Stewart Lewis
  - J. David Vega
  - Mark Wakefield
  - James Yun
- **HRSA Representatives**
  - Arjun Naik
  - Kala Rochelle
- **SRTR Staff**
  - Ryo Hirose
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Anne Ailor
  - Stephanie Anderson
  - Sally Aungier
  - Matt Belton
  - Tameka Bland
  - Nadine Cahalan

- Elinor Carmona
- Tommie Dawson
- Laureen Edwards
- Katie Favaro
- Liz Friddell
- Jasmine Gaines
- Rebecca Goff
- Shavon Goodwyn
- Asia Harden
- Houlder Hudgins
- Elias Khalil
- Lee Ann Kontos
- Krissy Laurie
- Jon McCue
- Amy Minkler
- Heather Neil
- Delaney Nilles
- Jacqui O'Keefe
- Rob Patterson
- Liz Robbins Callahan
- Melissa Santos
- Sharon Shepherd
- Sarah Stevenson
- Juanita Street
- Stephon Thelwell
- Melissa Tisdale
- Marta Waris
- Betsy Warnick
- Trevi Wilson
- Hobie Wood
- Karen Wooten
- Amanda Young
- **Other Attendees**
  - None

