

OPTN Membership and Professional Standards Committee

Meeting Summary

February 16, 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 February 16, 2024, to discuss the following agenda items:

1. Follow-up to Project Overview and Prioritization
2. Key Personnel Requirements: Virtual Experience Discussion
3. Estimated Glomerular Filtration Rate (eGFR) Update
4. Investigative Activities
5. Membership Issues

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

1. Follow-up to Project Overview and Prioritization

OPTN staff provided an overview of the MPSC project portfolio and requested Committee feedback on the prioritization of this work. Summaries of that status and next steps for each project were reviewed. This was a continuation of a topic that was first presented at the January 19, 2024, meeting. However, there was not sufficient time for discussion at that meeting.

- Membership Requirements Revision
 - This project is in the evidence gathering stage. HRSA has approved resuming work on this project.
 - A draft proposal was developed in 2020 for comprehensive revisions to the requirements for application and review, OPO membership requirements, and transplant hospital and general transplant program membership requirements. This proposal was the first phase of a project to comprehensively review and revise all membership requirements to address inconsistencies and simplify the OPTN membership requirements, as well as make revisions needed to implement an OPTN contract requirement of a process for periodic reassessment of members' membership status.
 - This proposal could be ready, with minimal revisions, for summer 2024 public comment.
 - Additionally, a Request for Feedback on a framework for revisions to the organ-specific transplant program and key personnel requirements was released for public comment in Winter 2021 and revisions need to be made based on public comment.
- Enhanced OPO Performance Monitoring
 - Postponed release of concept paper for public comment
 - The Workgroup has been working on response to the HRSA request for input on upcoming HHS Secretarial Directive. Likely, there will be additional work in response to the Directive. Feedback was provided to HRSA at the end of January.
- Enhanced Transplant Program Performance Monitoring

- Implementation stage
- The last metric, pre-transplant mortality, will be implemented on the last day of the July 2024 MPSC meeting. A program review process, tools, and guidance for the review of programs identified for higher-than-expected pre-transplant mortality will need to be developed over the coming months. OPTN staff have already done some work by conducting key informant interviews with high performing transplant programs to gather feedback on best practices. A thematic analysis of the feedback gathered has been completed and an effective practice document is included in the meeting packet for the Committee's review.
- Require Reporting of Patient Safety Events
 - Implementation stage
 - The proposal was implemented on January 10, 2024
- Allocation Review
 - Operational project
 - The Committee has reviewed but not reached a consensus on donor characteristics for kidneys likely to be allocated out of sequence and a definition for kidney late turndown. The Committee has expressed concerns about accuracy and availability of data to define late turndown, and the Committee potentially wants more input from subject matter experts when developing the definition.
 - The work on this project will be intermittent when new ideas or issues arise. The Expeditious Task Force work on potential expedited placement variances and the proposal of a non-use study could affect the Committee's future work on this project and help inform future Committee allocation review. The Committee will discuss in the future whether it is appropriate to refer this issue to another committee such as the OPO committee that can collaborate with the Kidney committee to establish a definition.
 - OPTN Staff also highlighted additional staff driven work, including collaboration with IT to enhance the match run bypass code data entry that could reduce the need to inquire with some OPOs, decrease the burden on OPOs for responding to inquiries on allocation deviations, and increase the accuracy of information by gathering it in real time rather than an inquiry months later. There have also been improvements to allocation case packets.

OPTN staff also shared feedback given by the OPTN Board of Directors at its December 2023 meeting on the current projects.

- Allocation Review:

This project may be affected by the initiatives of the Expeditious Taskforce and the OPTN Variance proposal that is currently out for public comment.
- Membership Requirements Revision:

There is a need to continue work on language to address required reports removed from the required reporting proposal, specifically pertaining to the reporting of sanctions against transplant professionals and attempts to deceive the OPTN and/or HHS. The Board requested that work continue on bylaw revisions for primary physician and primary surgeon requirements, voicing specific concerns about limited currency requirements.
- Transplant Program Performance Monitoring:

The Board discussed possible changes to the review of post-transplant outcomes to align with Expeditious Task Force goals and pilot projects. At the January 19 meeting, the MPSC discussed a

potential moratorium on post-transplant outcomes review and provided feedback to be shared with the Board. The Committee's feedback has been provided to the Expeditious Task Force and OPTN leadership. The Committee will be informed as updates on this topic are available.

Summary of discussion:

A Committee member noted they had received several questions at their regional meeting on the upcoming implementation of the pre-transplant mortality metric. A regional meeting attendee expressed concern about the effect of very sick liver candidates that have a high risk of dying on the waiting list on the program's pre-transplant mortality metric. Additionally, a regional meeting attendee noted that most of the candidates on the kidney waiting list are not in the care of the transplant program prior to transplant. Finally, concern was also expressed over the inclusion of patients that are removed from the waiting list. OPTN staff provided some of the historical context on the new metrics relevant to the community concerns. The liver transplant was addressed by explaining that the new metric is risk adjusted, so based on the characteristics of patients, the level of expectation of mortality would be adjusted. SRTR Staff added that the liver pretransplant mortality model adjusts for MELD score when the patient was listed as well as other components. In addition, the MPSC heard similar concerns from kidney transplant programs during public comment, and after consideration decided to move forward with this metric. They noted that for kidney programs, there is not a whole lot of variation in pre-transplant mortality, meaning not many, if any, kidney programs are outliers. Currently, only one program is identified.

Another member commented that when the Committee started reviewing cases for offer acceptance rate, there was not sufficient guidance provided to the MPSC on how to think about those cases since it was a new metric. They asked if there was a plan to provide guidance to the MPSC when they start reviewing the new metric in July. OPTN Staff responded that the subcommittee would create guidance as part of the development of the review process.

A Committee member asked a question about when the data collection described in the HRSA Data Directive will start. OPTN Staff answered that HRSA has indicated during regional meeting updates that the expectation is the data would start to be collected in September 2024, but that is pending OMB approval.

Several Committee members noted that continued evaluation of a definition for late decline is needed and commented on the Expeditious Task Force work regarding expedited placement variances and non-use study.

With regard to the Membership Requirements Revision project, a committee member noted that a significant amount of work had already been done and contains a significant decrease in redundancies and inconsistencies, as well as simplifying the requirements.

The Committee supported resuming work on the Membership Requirements Revision project.

2. Key Personnel Requirements: Virtual Experience Discussion

During the MPSC meeting on January 29, 2024, following review of a membership application, the committee expressed interest in discussing the use of experience gained virtually as opposed to in person and if virtual experience should be allowed to fulfill OPTN bylaw requirements for key personnel. Staff gathered relevant information and historical decisions and presented them to the committee during the February meeting.

In 2020, because of restricted access to hospitals and operating rooms during the COVID 19 pandemic, OPTN transplant hospital members proposed the utilization of experience gained virtually to fulfill the

OPTN key personnel bylaw requirement for transplant and procurement observations. OPTN bylaw language does not specify if the experience must be obtained in person or can be performed virtually. In May 2020, the MPSC voted to allow virtual observations to fulfill bylaw observation requirements for the next six months and then reassess, taking the state of the pandemic and the success or failure of the virtual experience into consideration. In January 2021, the committee revisited the topic and reviewed positive feedback from one member that had utilized the virtual observation option. The MPSC debated the issue, but eventually agreed that there was not enough clarity or data to apply supportive or exclusionary bylaw interpretation. The committee put the issue to a vote which resulted in the allowance of virtual observations until further notice. All committee discussions and decisions to this point only considered virtual transplant and procurement observations and did not include virtual patient care.

In January 2024, the MPSC reviewed and approved an application for a primary transplant physician, which included one instance of virtual post-transplant follow up care. This care, performed within the last two years, was included on the physician's log to demonstrate a current working knowledge of transplant in accordance with OPTN bylaws. This application prompted a follow-up discussion regarding virtual experience.

Staff explained they currently escalate any applications that knowingly utilize any virtual experience, either observations or patient care, for review by a subcommittee of the MPSC. The subcommittee applies clinical expertise to determine appropriateness and if OPTN bylaw requirements are fulfilled. The subcommittee can request the application be reviewed and discussed by the entire committee. Staff asked the committee if this application process was sufficient, if the topic of virtual experience could be addressed during the upcoming membership bylaw revision project, and if the MPSC would like to vote to allow or reject virtual experience moving forward.

A member pointed out that staff may not always be aware that experience was gained virtually if the applicant does not clearly notate it somewhere on their logs or the application. Another member added that a lot of care is now provided virtually and is embedded in medical practice. They mentioned that the applications may need to be updated to indicate when experience was gained virtually. They also proposed allowing a certain percentage of care performed virtually be acceptable. Another member affirmed that this should be part of the membership bylaw revision project, but until then the committee needs to know if experience was gained virtually and suggested an update to the application.

Staff informed the committee that application forms must go through OMB approval, so it is a longer process to update those. For an immediate action, staff will now ask if any of the experience provided in an application has been performed virtually and if so, escalate the application for subcommittee review. The committee determined this operational update was sufficient until the topic could be addressed during the membership bylaw revision project and did not require a formal vote.

3. Estimated Glomerular Filtration Rate (eGFR) Update & Case Review

Staff provided a very brief update on the Committee's review of eGFR implementation during closed session. The MPSC sent inquiries to programs that submitted waiting time modifications for fewer than 20 percent of their candidates registered on the waiting list as Black or African American. The program responses. The Committee will review all responses and determine any appropriate next steps at its late March meeting.

4. Report of Investigative Activities

OPTN Contractor staff supplied a summary of investigative activity from January 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.

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 during closed session. The Committee reviewed and approved the consent agenda by a vote of 25 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 16-18, 2024, meeting as listed below.

- Approve 9 New Programs
- Approve 2 New Components
- Approve 1 Program Change from Full Approval to Conditional Approval
- Approve 2 Program Reactivations
- Approve 1 Medical Scientific Membership Renewal
- Approve 3 Public Organization Membership Renewals

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

- 2 Program Inactivation Extensions
- 1 Component Inactivation Extension
- 37 applications for changes in key personnel in Transplant Programs or Components

The Committee also received notices of inactivations and OPO personnel changes.

Upcoming Meetings

- March 5-7, 2024, Detroit
- March 29, 2024, 2-4pm,ET, Conference Call
- Apr 23, 2024, 3-5pm, ET, Conference Call
- May 21, 2024, 2-4pm, ET, Conference Call
- June 28, 2024, 2-4pm, ET, Conference Call
- July 23-25, 2024, Detroit

Attendance

- **Committee Members**
 - Alan Betensley
 - Kristine Browning
 - Robert Fontana
 - Roshan George
 - Darla Granger
 - Rich Hasz
 - Kyle Herber
 - Victoria Hunter
 - Catherine Kling
 - Peter Lalli
 - Carolyn Light
 - Scott Lindberg
 - Maricar Malinis
 - Amit Mathur
 - Deborah McRann
 - Saeed Mohammad
 - Regina Palke
 - Martha Pavlakis
 - Deidre Sawinski
 - Zoe Stewart Lewis
 - J. David Vega
 - Candy Wells
 - James Yun
- **HRSA Representatives**
 - Shannon Dunne
 - Marilyn Levi
 - Arjun Naik
- **SRTR Staff**
 - Ryo Hirose
 - Jonathan Miller
 - Jon Snyder
 - Bryn Thompson
- **UNOS Staff**
 - Robert Albertson
 - Stephanie Anderson
 - Sally Aungier
 - Matt Belton
 - Linwood Butler
 - Nadine Cahalan
 - Elinor Carmona
 - Laureen Edwards
 - Liz Friddell
 - Jasmine Gaines
 - Rebecca Goff
 - Caroline Hales

- Elias Khalil
 - Lee Ann Kontos
 - Krissy Laurie
 - Amy Minkler
 - Heather Neil
 - Rob Patterson
 - Liz Robbins Callahan
 - Melissa Santos
 - Laura Schmitt
 - Sharon Shepherd
 - Courtney Skeen
 - Sarah Stevenson
 - Juanita Street
 - Marta Waris
 - Betsy Warnick
 - Trevi Wilson
 - Claudia Woisard
 - Hobie Wood
- **Other Attendees**
 - None