

OPTN Membership and Professional Standards Committee (MPSC)

**Meeting Summary
November 5-7, 2019
Chicago, Illinois**

**Lisa Stocks, RN, MSN, FNP, Chair
Heung Bae Kim, M.D., Vice Chair**

Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois and via Citrix GoToTraining on 11/5 – 11/7/2019 to discuss the following agenda items:

1. Membership Requirements Revision Project
2. Plan to Encourage Self Reporting
3. Educational Referrals
4. Report of the Systems Performance Improvement Subcommittee

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

1. Membership Requirements Revision Project

The Committee reviewed and endorsed the problem statement for this project. The Policy Oversight Committee will review the project at its December 2019 meeting. The Committee then participated in small group work to review questions and suggested revisions to the membership requirements in the following appendices in the OPTN Bylaws:

- Appendix A: *Membership Application and Review*
- Appendix B: *Membership Requirements for Organ Procurement Organizations (OPOs)*
- Appendix C: *Membership Requirements for Histocompatibility Laboratories*
- Appendix D: *Membership Requirements for Transplant Hospitals and Transplant Programs*

Committee small groups responded to inserted comments, questions and suggested revisions for review based on the contract task for reassessment of membership status, the parking lot from the previous plain language bylaws rewrite, and project ideas from the committee and staff. Each work group was encouraged to provide any additional ideas or suggestions for improvement. The work groups were asked to refrain from language drafting or wordsmithing at this time.

The Histocompatibility Committee will review the comments and MPSC feedback during its teleconference meeting on December 10.

The MPSC Membership Requirements Revision Subcommittee will meet by conference call on December 6, 2019, to address outstanding questions in Appendix A and B. Following this review, staff and the subcommittee will begin drafting language for Appendix A. The Committee will request review of Appendix B *Membership Requirements for Organ Procurement Organizations (OPOs)* by the OPO Committee in January or February 2020.

The Committee also provided feedback on the current transplant program key personnel requirements and made suggestions for changes using surveys made available to Committee members through Survey Monkey. The survey included the following specific questions for each current requirement:

- What is the purpose of the requirement?
- Should this be a minimum requirement in order to have an OPTN approved program?
- Program must document the primary meets this requirement [check all that apply]
 - For all proposed primaries regardless of previous experience
 - During reassessment of qualification of primaries
 - If the proposed primary has not previously/recently served as primary for that program type?
 - Does not need to be a requirement
- Is there other data/documentation that could be collected that would serve the same purpose as this requirement but is less burdensome on the member?

The survey also included additional questions to gather suggested alternative requirements and other things the committee members want the subcommittee to consider when developing new transplant program key personnel requirements. The subcommittee will use the results of this survey to begin work on a new format for transplant program key personnel requirements.

2. Plan to Encourage Self-Reporting

The MPSC continued discussions from its July 2019 meeting about the OPTN Contract Task 3.6.7 to encourage OPTN members to self-report potential patient safety issues to the OPTN Contractor.

First, staff summarized the following key concepts that the MPSC identified during its previous discussions at its July in-person meeting:

- Consider significant changes to the UNetsm Improving Patient Safety Portal for ease of use and reporting
- Create an online anonymous reporting mechanism that enables communication with the reporter
- Clearly define the kinds of patient safety events or data that members should report
- Think of ways members can receive information or benefit from patient safety reports, such as dashboards, data reports, benchmarking activities
- Consider changing MPSC processes to streamline the nature and volume of cases sent to the committee for review

The MPSC then further discussed potential changes to its processes. Options the committee suggested at its July meeting included:

- Stratifying policies into levels or tiers based on patient safety implications
- Only reviewing cases that meet certain triggers or criteria
- Consider closing cases sent to the MPSC for review, if certain criteria are met.

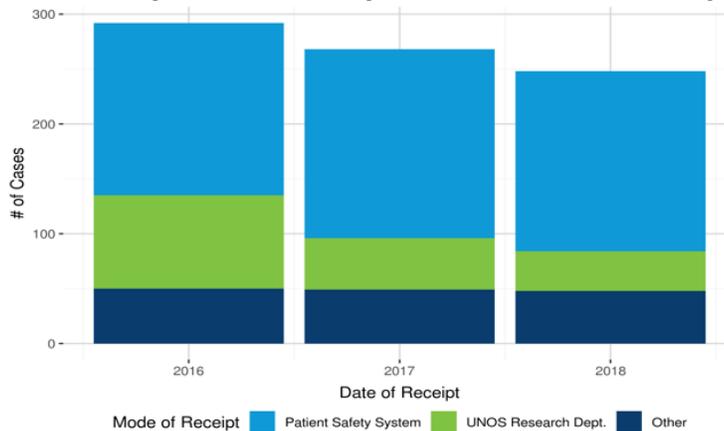
The MPSC discussed each of these issues in detail. Regarding policy stratification, staff expressed concerns that the process for creating and maintaining a stratification would be very burdensome, and that a classification system would likely not capture all possible scenarios the MPSC may come across in the future. The Committee agreed that such a framework is not ideal and should not be further considered.

A committee member asked staff to clarify how many issues are currently reported through the Improving Patient Safety Portal each year. Staff responded that in 2018, staff investigated approximately 150 patient safety reports. Staff noted that the number of total reports received is much larger, and that the total number of reports has been increasing as well. In response to a follow up question from another MPSC member, staff also explained that of the approximate 150 investigations conducted, over half (n = 87) were not sent to the MPSC because the investigation did not identify any potential policy noncompliance.

Another committee member asked staff to clarify what is meant by a patient safety investigation. Staff clarified that a patient safety investigation refers to reports received through the Improving Patient Safety Portal, the Member Reporting Phone Line, mail, fax, email, etc. Patient Safety investigations are separate from routine monitoring activities associated with other reports the MPSC may receive for review, such as routine site survey reports and routine allocation monitoring reports. Staff shared the following graphic with the MPSC as well to highlight the number and types of patient safety reports received:

Figure 1: Patient Safety Events by Mode of Receipt

Patient Safety Events by Mode of Receipt



A committee member asked staff whether there were any existing “filters” that resulted in certain cases not being sent to the MPSC. Staff noted that the MPSC currently has some “operational rules” such as the first time non-compliance rule for failing to register a living donor candidate on the waitlist prior to living donation. Staff explained that the purpose of operational rules, however, was never to encourage self-reporting but instead was to manage the volume of MPSC cases needing review. A limitation on the effectiveness of operational rules is that they have traditionally been created in response to a very well defined scenario that occurs frequently enough for staff and the MPSC to implement an operational rule in response. Operational rules in their current form have not had a significant enough impact to likely encourage members to self-report more potential events or to significantly impact the volume of cases requiring MPSC review.

A committee member asked if staff would continue to record and make available as needed reports that are received and investigated but not sent to the MPSC for review. Staff will continue to receive, evaluate, document and report to the MPSC all available information about a member as requested,

even if a single or multiple investigative reports are not sent to the MPSC for individual review and adjudication.

A committee member also asked if staff could provide a report of the most common noncompliance issues identified. Staff noted that we could easily report the top violations identified during site survey reviews, since they review the same policy requirements during each visit. Staff noted that for patient safety investigations, the top violations vary by year. More importantly though, staff explained that part of the need for improved reporting is because our attempt to categorize top issues is limited by the small data set we have. For example, the top violation one year may only have included three or four instances. Alternatively, while the same policy requirement may be cited a few times, the reasons behind that noncompliance may vary significantly, so two seemingly similar issues may in fact be very different.

A committee member suggested that the MPSC needs to find ways to incentivize self-reporting and educate the community that the MPSC is considering self-reporting as a mitigating factor when it is determining an appropriate action.

Staff elaborated on ways in which the MPSC could consider changing its processes to encourage member self-reporting. In addition to the operational rules and policy stratification approaches already discussed, staff noted that a compliance “balanced scorecard” approach could be implemented. This scorecard approach could require the Committee to periodically review all members’ compliance activity, including site survey, allocations, self-reports and other reports, and the members’ response to each. Alternatively, the Committee could default to not reviewing any member unless certain triggers or thresholds are met over a period.

Another committee member suggested that OPTN site surveys incorporate a review of quality processes similar to the Centers for Medicare and Medicaid Services (CMS) focused Quality Assurance and Performance Improvement (QAPI) survey. Staff noted that doing so would significantly change the survey process and require a lot of planning, but agreed it was an idea worth evaluating. An MPSC member also suggested that staff and the Committee should focus on evaluating whether quality improvement practices such as root cause analyses and corrective action plans were completed as stated, rather than the details surrounding the initial error, as this would likely encourage more reporting.

Staff then presented a series of polls to obtain feedback from the MPSC about the types of cases and information that should be sent to the MPSC for review and the action the Committee should take for self-reported issues.

- Poll 1: Staff reminded the MPSC that the current process is for the MPSC to receive a report for almost every confirmed noncompliance, regardless of the type of noncompliance or other factors.

In response to the statement, “The MPSC should review each individual noncompliance identified through the Patient Safety Portal” the MPSC responded as follows:

- Strongly Agree – 3
- Agree – 6
- Neutral – 1
- Disagree – 13
- Strongly Disagree – 8

- Poll 2: Staff noted that the MPSC currently receives individual reports of confirmed noncompliances and determines an appropriate action for each case. However, staff does not currently provide the MPSC with an aggregate report or analysis of all noncompliance's reported through the Improving Patient Safety Portal, though something similar is currently created for the OPTN Operations and Safety Committee. A committee member asked whether such a report is dependent on the types of cases the MPSC determines it should still review and take an action on. Staff explained that this aggregate report would be independent from any other decisions the MPSC makes about individual case reviews or actions.

In response to the statement, "The MPSC should review an aggregate report of all noncompliances identified through the Patient Safety Portal" the MPSC responded as follows:

- Strongly Agree – 9
- Agree – 14
- Neutral – 3
- Disagree – 7
- Strongly Disagree – 0

- Poll 3: In response to the statement, "The MPSC should only review individual reports of noncompliance identified through the Patient Safety Portal if certain criteria are meet" the MPSC responded as follows:

- Strongly Agree – 13
- Agree – 14
- Neutral – 1
- Disagree – 2
- Strongly Disagree – 1

The MPSC acknowledged that while this approach is theoretically supported, significant work would be needed in order to determine the applicable criteria.

- Poll 4: Staff reminded the MPSC that the most common and historical action (the suggested action to be consistent with previous MPSC decisions in similar cases) is to issue a Notice of Noncompliance for confirmed noncompliance with no apparent patient safety issues or other concerns.

In response to the statement, "The MPSC should continue to issue members Notices of Noncompliance for confirmed policy violations" the MPSC responded as follows:

- Strongly Agree – 7
- Agree – 12
- Neutral – 1
- Disagree – 7
- Strongly Disagree – 2

- Poll 5: In response to the statement, "The MPSC should document and close cases with no action if there are no concerns about a likelihood of recurrence, patient safety, etc." the MPSC responded as follows:

- Strongly Agree – 11

- Agree – 12
- Neutral – 2
- Disagree – 4
- Strongly Disagree – 1

The MPSC discussed the discrepancy between responses to polls 4 and 5 above. A committee member explained that she would answer the questions differently for only self-reported cases, because self-reported cases would give her a greater confidence in the institution’s ability to identify and address quality processes. The MPSC agreed that, particularly if the purpose of the task is to encourage member self-reporting, that the MPSC would be willing to close with no action if members self-report the issue and there are no concerns about a likelihood of recurrence, etc. However, the MPSC suggested that it should continue to issue Notices of Noncompliance for members that do not self-report the noncompliance issues. Staff created a poll to reflect that option and re-poll the Committee.

- Poll 6: In response to the statement, “The MPSC should close self-reported cases with no action if there are no concerns about a likelihood of recurrence, patient safety, etc.” the MPSC responded as follows:
 - Strongly Agree – 17
 - Agree – 10
 - Neutral – 3
 - Disagree – 0
 - Strongly Disagree – 0

The MPSC noted that it was important to not only incentivize self-reporting by only closing noncompliances that have been self-reported, but also to educate the community on this approach. The MPSC also requested that staff clearly note in a member’s compliance history whether every issue was self-reported.

A committee member asked whether changes to the possible actions outlined in Appendix L should be made to better reflect closing self-reported actions. Staff explained that such a change would require a public comment proposal; however, the Bylaws already indicate that the MPSC can and should consider whether the member appropriately identified and self-reported the issue when deciding which action to take. However, staff noted they could update resource documents to better reflect the MPSC’s focus on closing appropriately addressed and self-reported issues, as well include this practice in widespread education to the MPSC.

A committee member asked whether staff have evaluated the harm of each issue and noted that the MPSC would likely close an issue that was a noncompliance but where no harm occurred. Staff noted that whether direct and immediate harm occurred would be an important factor in evaluating all cases, and any cases with an indication of ongoing, direct immediate harm are escalated for MPSC review.

Lastly, staff requested volunteers from the MPSC who would be willing to work with staff on this project between meetings.

3. Educational Efforts

Staff updated the MPSC on educational activities related to the MPSC that took place since the last MPSC meeting or are planned for the coming months, including:

- A presentation about how to prepare for an effective informal discussion and peer visit at the Transplant Quality Institute in October 2019

- A presentation by a member about their positive experience with the MPSC at the Transplant Management Forum, planned for April 2020

Staff also announced a plan to perform two cases analysis projects, one for living donor events and one for ABO typing errors. The projects will focus on reviewing and sharing details of certain case types and lessons learned. The projects are a first attempt at better sharing information and educating the community, but must not violate any peer review protections. Staff and the MPSC will work closely with UNOS General Counsel. If the initial projects are successful, staff hope that these kinds of activities can become a routine function of the MPSC's work.

Staff asked the MPSC if there were any topics they would like staff to develop into educational efforts. The MPSC did not have any recommendations at this time.

4. Report of the Systems Performance Improvement Subcommittee

A Committee member, who co-chaired the Ad Hoc Systems Performance Committee, presented an overview of the work of that committee. He described the composition of the Ad Hoc Systems Performance Committee and the process used to develop recommendations; and provided a high-level description of the recommendations placing emphasis on the OPO and transplant program enhanced performance monitoring scorecard recommendations. Information on this content can be found in the Ad Hoc Systems Performance Committee Report to the OPTN Board of Directors available on the Ad Hoc Systems Performance Committee sub site on the OPTN website.

Upcoming Meetings

- December 17, 2019, Conference Call, 3-5pm ET
- January 21, 2020, Conference Call, 2-4pm, ET
- Feb 25-27, 2020, Chicago, IL
- April 14, 2020, Conference Call, 2-4pm, ET
- May 21, 2020, Conference Call, 2-4pm, ET
- June 29, 2020, Conference Call, 2-4pm, ET
- July 21-23, 2020, Chicago, IL

Attendance

- **Committee Members**
 - Sanjeev Akkina
 - Errol Bush
 - Kenneth Chavin
 - Matthew Cooper
 - Maryjane Farr
 - Richard Formica
 - Adam Frank
 - Jonathan Fridell
 - Michael Gautreaux
 - PJ Geraghty
 - David Gerber
 - Patrick Healey
 - Kelley Hitchman
 - Edward Hollinger
 - Patricia Jones
 - Heung Bae Kim
 - Jon Kobashigawa
 - Scott Lindberg
 - Didier Mandelbrot
 - Christine McGarry
 - Clifford Miles
 - Saeed Mohammad
 - David Mulligan
 - Nikole Neidlinger
 - Matthew O'Connor
 - Jeffrey Orłowski
 - Hamang Patel
 - Nicole Pilch
 - Jennifer Prinz
 - Kirti Shetty
 - Scott Silvestry
 - Zoe Stewart Lewis
 - Lisa Stocks
 - Rajat Walia
 - Keith Wille
 - Heidi Yeh

- **HRSA Representatives**
 - Marilyn Levi
 - Raelene Skerda

- **SRTR Staff**
 - Jon Snyder

- **UNOS Staff**
 - Sally Aungier
 - Matt Belton

- Ronnie Brown
 - Michelle Furjes
 - David Klassen
 - MiYoung Kwon
 - Kaylin Lagana
 - Trung Le
 - Ann-Marie Leary
 - Jason Livingston
 - Maureen McBride
 - Anne McPherson
 - Sandy Miller
 - Amy Minkler
 - Jacqui O'Keefe
 - Elizabeth Robbins
 - Sharon Shepherd
 - Roger Vacovsky
 - Gabe Vece
 - Nevada Wagner
 - Betsy Warnick
 - Karen Wooten
- **Other Attendees**
 - None