

**OPTN Membership and Professional Standards Committee (MPSC)
Meeting Minutes
July 17-18, 2019
Chicago, IL**

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Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois on July 17-18, 2019, to discuss the following agenda items:

1. Appendix L Implementation Review
2. Educational Referrals
3. OPTN Contract Tasks
4. MPSC Project Work

Additionally, the Committee met in closed session and discussed member specific issues.

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

1. Appendix L Implementation Review

The Committee sponsored a proposal to revise Appendix L of the OPTN Bylaws that went through public comment January 22-March 23, 2018. Appendix L of the OPTN Bylaws details actions that the OPTN, through the MPSC and Board of Directors, may take when OPTN members fail to comply with OPTN Obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The Committee intended the change to improve the OPTN review process and describe the process in a way that is more detailed and easier for members to understand. The Board of Directors approved the proposal on June 13, 2018.

To evaluate whether the changes were successful, the Committee stated that it would monitor whether the changes yield unanticipated consequences, and review data on types of member interactions with the Committee. At the meeting, staff provided the first post-implementation update for the MPSC. So far, the Committee has seen an increase in informal discussions with members and a decrease in interviews and hearings. This change in member interactions is what the Committee expected to see based on the Bylaw changes. In addition, the MPSC continues to review and evaluate patient safety risks, and has quickly reacted to issues with members by asking them to perform specific actions to mitigate potential risk.

Staff is continuing to collect data on the post-implementation consequences, and is gathering information from members and the Committee on the process and benefit of the informal discussions, interviews, and hearings. The Committee will receive another update on the implementation when more data is available.

2. Educational Referrals

Staff presented an overview of recently completed educational efforts including the following presentations:

- MPSC Overview and Performance Review Process at Cigna LifeSource Conference

- MPSC Partner in Performance Improvement and Important Parts of Measuring Quality at the Transplant Management Forum
- MPSC & OPO Collaboration and Improvement at the AOPO Annual Meeting

Staff also provided an overview of various efforts to help share Member Quality and MPSC related information with the community, including:

- Taking educational topics from the MPSC to multi-department meeting of UNOS staff to refer topics as appropriate
- Providing routine reports to the Operations and Safety Committee which provide an overview of information submitted through the UNet Improving Patient Safety Portal
- Presenting aggregate data and transplant conferences

Staff are currently assessing ways to help members share lessons learned from their events.

Staff then summarized educational topics that had already been identified:

- ABO discrepancies
- Reports of frozen kidneys
- Heart/lung and other multi-organ allocation issues
- Thymoglobulin reactions in living donor recoveries
- Turning off a transplant program's waitlist when surgeons are unavailable
- Making sure final match run dispositions match the candidate to whom the organ was allocated, not the candidate who ultimately received the transplant
- Data entry errors due to APIs overwriting information in DonorNet

In addition, MPSC members requested that the following items be added to the list of possible educational topics:

- Educating living donor kidney components that participate in a non-OPTN kidney paired donation program that they continue to be obligated to comply with OPTN obligations are responsible for ensuring the paired donation program's process does not contradict or exclude those requirements
- Reminding the living donor components that they must add candidates to the waitlist prior to receiving a living donor organ, even if the program has no intention of evaluating or accepting deceased donor organ offers for that candidate.
- In addition to the heart/lung allocation issues, the MPSC noted the need for clarification in other multi-organ combinations, including which combinations get priority if there is more than one from a single donor
- Reminding OPOs to run a match before exporting organs
- Providing OPOs with guidance on effective practices regarding consent and authorization when a donor transitions from DCD to brain death
- Effective practices from OPOs that expedite placement

After the meeting, an MPSC member asked that staff consider hosting a seminar at UNOS for relatively new to transplant surgeons and physicians to introduce them to the OPTN and concepts like organ stewardship.

All these ideas will be discussed at an August meeting with staff from many UNOS departments including Communications, Professional Education, Policy & Community Relations, and the Organ Center to determine next steps.

3. OPTN Contract Tasks

Staff presented information on two OPTN contract tasks that require input from the Committee.

Encouraging Self-Reporting of Potential Patient Safety Issues

Under the new OPTN contract, UNOS “shall develop a plan, with the input of the OPTN MPSC to encourage OPTN member self-reporting of potential patient safety issues, provide incentives to report issues by assisting members in identifying root causes of issues and developing appropriate corrective actions.” After reviewing the contract task requirements, staff reviewed the current state of member self-reporting, including data on the volume and types of reports. Staff noted that the number of total events reported (approximately 150 events for 2018) is low given the number of transplants that occur each year. A review of reporting data by region showed that more than half of OPTN members in one region were not involved in any reports submitted through the UNet Improving Patient Safety Portal. Staff also noted that many of the problems members mention are not reported through the UNet Improving Patient Safety Portal. Staff noted that the number of self-reports has only been tracked since 2017, but went down between 2017 and 2018. This suggests that there is significant opportunity to better engage members in reporting safety data. The goal of this project is to increase reporting so that the OPTN can better identify trends and patterns and promote member improvement, whether through general awareness, formal education, guidance or policy requirements.

A Committee member asked whether Member Quality staff are prepared for an influx of self-reports if incentivize reporting. For example, what if a member reported to the OPTN that the member had six late deliveries of Prograf on the unit. Staff responded that we had thought about this issue, but recognize that clarifying what exactly members should report is an important aspect of this project that will require further discussion. The type of issues that should be reported should support the stated objectives of developing education, policy change, etc.

Staff then asked the Committee to consider the following questions in small groups:

- What do you think encourages members to report patient safety issues?
- What do you think is discouraging members from reporting?
- What educational activities can the Committee do to encourage members to report data?
- What process changes can the MPSC implement to encourage members to report?
- Provide feedback on staff produced internal ideas.

The smaller groups reported their thoughts to the full Committee. The main themes from the small groups include:

- Things that discourage reporting:
 - Worry and fear that self-reporting will spotlight a program and lead to additional audits and investigations
 - People are not aware of how to use the portal
 - Increased work by the member with an uncertain return
 - Lack of clarity on who should be reporting and what should be reported
 - No easy anonymous reporting
 - MPSC still viewed by many as bad and not helpful

- Encouraging reporting/process changes:
 - Receive feedback in real time
 - Provide dashboard on patient safety events reported by the member/program as well as a national dashboard
 - Look at how other entities have done this to not reinvent the wheel
 - Develop a system to collate data to analyze what is highest priority and lowest priority
 - Self-reporting system that goes to another entity, like Operations and Safety, rather than MPSC, if it does not involve a policy violation or something required to be reported
 - Leniency for self-reporting
 - Members report areas that they are benchmarking through their own quality programs to identify common issues that members are experiencing
 - Mediation services through UNOS or MPSC that could help members decide if issue should be reported
 - Better ways to truly report anonymously. One group suggested providing the ability to create an account that the reporter could log onto rather than email coming back to the individual's organization email.
 - Survey after an interaction with specific questions to get feedback on process
 - Rebrand self-reporting using language that has less of a negative connotation
 - Consider no action or interaction when a member proactively identifies a problem and internally fixes the problem.
 - Use a grading scale for adverse events, as in research, with least severe requiring no action and more serious events , such as living donor death in OR, always requires an action.
- Education:
 - Education on where to find and how to use the safety portal and what should be reported
 - Education on lessons learned from MPSC delivered to the community in an engaging way with a short timeline; share actual cases to make education more engaging
 - Demonstrate that much of what comes to MPSC does not end in punitive action for member
 - Offer CME for education activities as a way to incentivize participation in education. UNOS education underutilized by members.
 - Monthly or quarterly newsletter highlighting reported events and the fact that reporting can save lives and help avoid future events
 - Education on and sharing of data about the outcomes in self-reported events versus those found through complaints or monitoring.
 - Face to Face education incentivizing self-reporting better than through written documentation – informal discussions, peer visits, conferences, regional meetings
 - Emphasize importance of self-reporting and how the process can be collaborative rather than a retribution.
 - More messaging – the more the community understands that the MPSC is mostly process improvement and not punitive, people will be more inclined to report

Measures of Effectiveness of MPSC Monitoring

Staff led two sessions for the MPSC aimed at familiarizing committee members with a new contract task regarding measuring the effectiveness of the MPSC's monitoring and collecting their input on the topic. The contract task requires the development of "objective metrics to monitor the

effectiveness of the processes used to monitor members, identify compliance problems, encourage performance improvement and determine sanctions.”

During the first session, which took place on Wednesday afternoon, July 17, the committee members were asked to brainstorm and discuss the answers to four key questions amongst their roundtable groups and then report out their top three answers to the entire group. The questions that were discussed are as follows:

- What about the monitoring that the MPSC does is important?
- What is the MPSC trying to accomplish with its monitoring?
- What specific outcome of MPSC monitoring do we consider a success?
- What are appropriate measures to track our success?

The MPSC members actively participated and as a result of the feedback received during the brainstorming session, identified six primary themes: member interactions, OPO metrics, policy/education, self-reporting, “graduation” rates, which generally refers to once a member is released from monitoring, are they successful in preventing reoccurrence, and “catch and release,” which generally refers to how long a member is monitored for an identified/flagged issue.

Based on the identified themes, staff helped facilitate an interactive session, during which the MPSC members were oriented to some of the measures of monitoring effectiveness that staff have already come up with, which include using relevant survey items from both the annual UNOS Member Survey, the UNOS Member Quality Touchpoint Survey that is sent to members following any touchpoint, and tracking the outcomes of certain monitoring (i.e. Informal Discussions). The committee members were then asked to contribute their own specific ideas and were given time to write down specific metrics and clarifying statements that corresponded to any of the six themes, which were written on flip charts around the room. Approximately 110 pieces of feedback were received from MPSC members during the meeting, which have been analyzed by UNOS staff; the staff will continue to share the progress of the project as the draft metrics are prepared for submission on September 29, 2019.

4. MPSC Project Work

Staff provided an overview of the OPTN policy development process and provided updates on the status of projects in the various phases of that process. Two performance monitoring projects are currently on hold, pre-transplant metrics (previously composite pre-transplant metric (CPM)) and post-transplant performance review of multi-organ transplants. Staff recommended that these two projects remain on hold until the Committee received guidance on how to proceed in response to the Ad Hoc System Performance Committee’s report. The Committee considered a significant number of project ideas in a separate project prioritization discussion described below.

Staff provided an update on four projects that are in the pending implementation phase of the policy development process. One MPSC project, define transplant hospital, has a target implementation date of December 2019. Staff and the Committee are currently reviewing and evaluating information submitted by all transplant hospital members. The Committee’s recommendations on each of these submissions will go to the OPTN Board of Directors in December 2019 for approval. The bylaw will become effective at that time or very soon after dependent on completion of the transfer of all patients for merging hospitals. Three additional projects sponsored by policy development committees are pending implementation:

Pediatric training and experience requirements: The Pediatric Transplantation Committee proposed pediatric training and experience requirements that were approved by the OPTN Board of Directors in

December 2015. The Pediatric Transplantation Committee's implementation plan included a three-year delay to allow programs to prepare for the implementation. Staff will provide an update to the Committee once the implementation plan is finalized, but it is expected that applications will be sent out in early fall with an expected effective date that coincides with the review of the applications by the OPTN Board of Directors in December 2020.

- VCA membership requirements: The Vascularized Composite Allograft Transplantation (VCA) Committee proposed VCA membership requirements through multiple proposals approved by the OPTN Board of Directors from December 2016 through June 2018. Implementation of these bylaws is pending approval of membership application forms.
- Islet transplant program requirements: The Pancreas Transplantation Committee upon request by the MPSC developed new islet transplant program requirements that were approved by the OPTN Board of Directors in December 2018. Implementation of these bylaws is pending approval of membership application forms.

The Committee also has three projects that are in the post-implementation review phase of the policy development process:

- Kidney outcomes operational rule: The Committee implemented the kidney outcomes operational rule in June 2017. Under the operational rule, programs that are identified for lower than expected one-year post-transplant survival based on all transplants in the cohort will have a second evaluation with the higher risk transplants removed. A program will receive an initial inquiry only if the program is identified under both evaluations. UNOS and SRTR staff provided initial data to the Committee at its October 2018 meeting and expect to provide a second year report in October 2019. A full evaluation of the effect of the operational rule is planned for three years post-implementation in October 2020. The Committee will then decide whether to continue to apply the operational rule.
- Appendix L revisions: Staff provided an update on the effect of the Appendix L revisions implemented in June 2018 earlier in the meeting.
- Hospital-based OPO voting privileges: Five of the seven hospital-based OPOs have requested and received voting privileges. Staff have not received any concerns regarding these OPOs' participation in regional meeting voting or in the OPTN officers and regional councilor elections.

The Committee participated in a project prioritization exercise. Staff provided summaries of existing project ideas including:

- Voting privileges for hospital-based histocompatibility labs requested by American Society of Histocompatibility and Immunogenetics (ASHI)
- Pediatric functional inactivity requirements requested by the MPSC
- Process for periodic reassessment of membership status, which is an OPTN contract requirement
- Membership requirement revisions, which includes multiple project ideas requested by the MPSC
- Stratification of key personnel requirements based on previous primary experience, which is a staff idea based on concerns raised by members
- Additions to the transplant pharmacist bylaw requested by American Society of Transplantation (AST)

- Kidney Paired Donation (KPD) participation by programs without a living donor component, which is a staff identified interpretation issue
- Clarify conditional approval requirements for intestine programs, which is a staff identified interpretation issue
- Transplant program inactivity, withdrawal and termination (Appendix K), which is a staff identified interpretation issue
- Relocation or transfer of designated transplant programs, which is a staff identified interpretation issue.

Staff asked the Committee to identify additional project ideas and any ideas that should not be pursued. Individual committee members then voted using dots on whether they agreed or disagreed on the addition or removal of a project idea. Additional project ideas included new performance metrics for transplant program and OPOs, multi-organ transplant reviews and incorporating D.O. training more comprehensively into the key personnel membership requirements. Some additional feedback included consideration of a policy regarding National Kidney Registry and revision of policies related to allocation priority for multi-organ. One group suggested that the clarifications of the conditional approval requirements for intestine programs be referred to the Liver and Intestinal Organ Transplantation Committee. At least one of the groups requested an updated CMS/OPTN crosswalk, electronic tracking of physician logs with OPO validation and a mediation process when more than one member is involved in an event or complaint.

The Committee did not unanimously support eliminating any of the project ideas. The additions to the transplant pharmacist bylaw had the most votes to not pursue. Staff described the request from AST in more detail to the Committee. A few Committee members familiar with the background of this request provided context. The request is based on a concern that in current practice, OPTN bylaws and recently revised CMS conditions of participation allow programs to identify anyone as their pharmacotherapy expert. Programs can identify non-pharmacists, for example, a physician or an advanced practice practitioner. The AST asserts that this presents a patient safety issue since pharmacists bring a special skill set to the care of a transplant patient beyond dosing of immunosuppressants, such as drug interactions and renal and hepatic effects. Committee members noted that inclusion of a requirement of a transplant pharmacist with certain training or experience is a patient safety issue and will provide programs with a basis to advocate for transplant pharmacist FTEs. Although all of the Committee members who spoke acknowledged the patient safety aspect, some expressed concern about the availability of sufficient numbers of qualified transplant pharmacists for all the programs in the United States. Committee members noted that the Board of Pharmaceutical Specialties has needs assessment data and the American Society of Health System Pharmacy just released a publication that includes data on outcome reports and the impact of pharmacy. Another Committee member questioned where the line would be drawn on requirements for other staff associated with the program noting that each new requirement creates additional burden on members. Following this discussion, the Committee voted to consider a revision to the transplant pharmacist bylaw by a vote of 23 For and 12 Against.

The Committee also discussed and voted on whether the multiple membership project ideas, including the membership status reassessment contract task, should be

1. Prioritized and considered separately
2. Combined into one project but keep current form and format of the membership requirements
3. Review and rewrite content of membership requirements with a goal of simplification and accommodation of the periodic reassessment of membership status.

The Committee supported a rewrite of the membership requirements to simplify and accommodate the periodic reassessment of membership status by a vote of 7 -1-28. MPSC members that participated in focus group calls during late May and June also supported the third option by a vote of 0-6-13.

Following these discussions, staff asked the Committee to prioritize project types as high, medium or low priority, taking into account impact on patient safety, whether it would change member behavior with patients, urgency, community support, impact on members and patients, and innovation. The Committee prioritized four projects:

1. Performance monitoring with 27 votes of high or medium priority (25 high, 2 medium, 0 low)
2. Membership requirements with 26 votes of high or medium priority (16 high, 10 medium, 0 low)
3. Pediatric functional inactivity with 21 votes of high or medium priority (7 high, 14 medium, 7 low)
4. Voting privileges for histocompatibility laboratories with 2 votes of high or medium priority (2 high, 0 medium, 25 low).

The Committee prioritized performance monitoring as the first priority but will delay work on this project until guidance is received based on the Ad Hoc System Performance Committee's report to avoid using committee resources on work that may be contrary to guidance from the OPTN Board of Directors. The Committee prioritized membership requirements as a second priority. Based on this vote and the need to begin work on the contract task to develop a plan for reassessment of membership status, staff solicited volunteers for a subcommittee that would focus on this project. Twenty-two Committee members volunteered. The Committee chair will review the volunteers and appoint subcommittee members. In addition, staff requested initial ideas on data or additional information the Committee may need to begin to analyze the problem and develop a problem statement. Several Committee members requested that the subcommittee consider making the process more automated, simplify the requirements, and define the roles in line with contemporary practice. A Committee member requested data on the time for a member to complete an application under the current membership requirements and the time for staff to process the application.

Upcoming Meetings

- August 12, 2019, Conference Call, 1-3pm
- September 27, 2019, Conference Call, 12-2pm ET
- November 5-7, 2019, Chicago, IL
- 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