

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
March 1-2, 2017
Chicago, Illinois**

**Jeffrey Orlowski, MS, CPTC, Chair
Matthew Cooper, M.D., Vice Chair**

Discussions of the full committee on March 1-2, 2017, are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. MPSC Project Prioritization

During its January 2017 meeting, the Membership and Professional Standards Committee (MPSC) requested that UNOS staff distribute a survey to help prioritize which topics the Committee should focus on next. At its March 2017 meeting, the MPSC Chair presented the survey results and led the Committee's discussion about which efforts it would like to focus on next.

The Committee recognized the following projects as its highest priorities:

- Pancreas Program Functional Inactivity
- Changes to the OPTN Transplant Program Outcomes Review System
- Post-transplant Performance Review of Multi-organ Transplants
- Revise OPTN Bylaws Appendix L

The Chair alerted the MPSC that earlier in the week the Executive Committee approved the Pancreas Transplantation Committee (the Pancreas Committee) continuing to work on the pancreas program functional inactivity project. The Pancreas Committee will sponsor this project, but MPSC engagement and feedback will be critical to its success. The Committee supported moving forward in this manner, agreeing to work with the Pancreas Committee in its efforts to address this topic.

The Committee proceeded to discuss the importance of continuing to evaluate ways to improve the OPTN transplant program outcomes review system. This is an extension of the Task Force effort that the MPSC pursued in 2016, but that received significant criticism during public comment. Changing the transplant program outcomes review system will be simultaneously pursued along with the Collaborative Innovation and Improvement Network (COIIN) project and the new operational rule that the MPSC adopted in October 2016 (exclude from outcomes review transplants that involve recipients with an Estimated Post-Transplant Survival (EPTS) score greater than 80 or a donor with a Kidney Donor Profile Index (KDPI) of 85 or greater). The Committee agreed that performance reviews of multi-organ transplants is important, but focus on this topic should follow updates to the current outcomes review process. This will allow for a clearer framework when considering how to evaluate outcomes of multi-organ transplants.

The MPSC also acknowledged that its efforts to update OPTN Bylaws Appendix L is a critical project, and one that the MPSC must continue to pursue.

The MPSC Chair informed the Committee that besides the pancreas program functional inactivity project, MPSC members will be engaged in a few other committees' projects as MPSC representatives. This includes an expedited placement workgroup being led by the OPO Committee and an infectious disease verification process workgroup that will be sponsored by the Operations and Safety Committee and also include members of the Ad Hoc Disease Transmission Advisory Committee.

2. Modifications to OPTN Bylaws Regarding the Approval of Transplant Fellowship Programs

UNOS staff continues to work with representatives from the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) to address OPTN Bylaws regarding the "approval" of transplant fellowship programs for the purpose of key personnel applicants who apply through one of the Bylaws' fellowship pathways. Staff noted that the plan is to distribute this proposal for public comment in the summer, and at an upcoming meeting the Committee will need to discuss the proposal's contents and vote on the final Bylaws language to be proposed. Staff directed the MPSC to the meeting materials where the draft proposal is located, and requested that the MPSC review this document and provide any feedback in preparation for public comment.

3. OPTN Bylaws Revisions - Appendix L

The Bylaws state that the MPSC may ask members to inactivate; however, the Bylaws do not explicitly outline this process. During the March meeting, UNOS staff proposed concepts for revising Appendix L to better define and detail the member inactivation process, and asked the MPSC for its feedback. Specifically, the MPSC discussed the following:

- The MPSC may ask members to inactivate at any point during its review of a potential noncompliance with OPTN Obligations— after multiple cycles of review, after an informal discussion, etc. Members may not fully understand this and may be surprised to hear that the MPSC is asking them to inactivate. Staff proposed that the MPSC must indicate to the member in writing that the MPSC is considering asking the member to inactivate to lessen members' surprise and confusion. In this written correspondence, the MPSC will also specify the concerns that the member must address to avoid the inactivation request.

The MPSC concurred that these considerations are appropriate to include in Appendix L.

- Members have limited time after receiving the MPSC's request to inactivate to decide whether it will voluntarily inactivate. The member has no opportunity to interact with the MPSC prior to making its decision. To address this concern, the proposed written notice to inform members that the MPSC is considering asking the member to inactivate should also offer the member an opportunity for an informal discussion. During the informal discussion, the member can address the MPSC's concerns and provide any information it believes is relevant to the MPSC's decision making. If the MPSC continues to have concerns after the informal discussion it can formally ask the member to inactivate.

The MPSC agreed that members should have an opportunity to engage with the committee before actions and determinations are made. The MPSC stated that the

informal discussion should be held with the member and an assigned MPSC subcommittee. Considering scheduling logistics and the challenges of a full-committee teleconference, the MPSC indicated that it is not necessary to convene the full committee to conduct an informal interview.

- Members often respond to inactivation requests by the specified deadline and say they will agree to inactivate, but request additional time before they formally inactivate the program. Staff suggested that a member address when it would be able to inactivate during its informal discussion. After the informal discussion, if the MPSC formally requests inactivation, it will give the member a date by which they must complete the inactivation process.

The MPSC responded that ambiguity during this process, particularly with timelines, does not help members fix their deficiencies in a timely manner. Additionally, sometimes the “shock value” of a near term inactivation request is necessary to attract hospital administrators’ attention. The Committee suggested that it establish a consistent timeframe to guide member’s that are asked to voluntarily inactivate. A set timeframe will avoid future questions and concerns about why one member received more time to inactivate, and this would be one less subjective decision for the MPSC to make. Although the Committee understands how members may be challenged by this, the MPSC does not reach the point of requesting inactivation without reason to do so. Furthermore, a strict inactivation timeline may incentivize members to be more careful in their ongoing transplant activities to avoid this possibility. If the standard amount of time currently offered has proven to be problematic, then it would be worth readdressing the amount of time, but setting this in the Bylaws seems necessary.

- Because members are not currently offered an opportunity to speak to the MPSC prior to the MPSC’s inactivation request, the MPSC offers the member an interview regardless of whether they inactivate. This has led to significant confusion about the reason for the interview and the member and MPSC’s options after the interview. Offering members an informal discussion prior to the MPSC’s request to inactivate and requiring an informal discussion prior to the reactivation is also intended to alleviate confusion regarding the purpose of the interview. Additionally, staff also proposed that members who voluntarily inactivate by the requested deadline would be entitled to an interview to dispute the MPSC’s request and request reactivation. If the MPSC does not rescind its request, the member would have the right to a hearing. If the member fails to inactivate by the specified deadline, the MPSC would be asked to consider whether it wishes to take a separate action (up to and including considering Member Not in Good Standing) for the member’s failure to inactivate. The member would then also have the right to an interview, both to dispute the MPSC’s request and to discuss the MPSC’s consideration of an adverse action.

The MPSC also provided its general support for this approach. The Committee stated that the member should still be entitled to a hearing after the interview only if an adverse action is still being considered. If an adverse action is not being considered, the Committee did not think a member would likely change the MPSC’s perspectives from the interview, and therefore thought the hearing to be unnecessary. Additionally, in those instances where the member refuses to inactivate, the Committee believed that the urgency by which the MPSC addresses a member’s failure to inactivate should be determined by the MPSC Chair’s at their discretion. The Committee supported Chair discretion in this circumstance

recognizing not all inactivation requests carry the same level of urgency (e.g., outcome issues versus program functional inactivity). Instead of treating all instances where a member fails to inactivate as a potential risk to patient health and public safety (as is done currently), the Bylaws should allow for MPSC Chair discretion to accommodate and appropriately respond to the varying urgency of matters that prompt a request for the member to inactivate voluntarily.

- Currently, the interview offer letter states that the MPSC will consider an action up to and including Member Not in Good Standing if members do not inactivate by a set date. It is not clear how the MPSC should engage members that inactivate, but do so later in the process and after the set deadline. Staff presented a possible solution of clarifying in the Bylaws that a members' failure to inactivate by the specified deadline may result in the MPSC taking any action, including member not in good standing.

A MPSC member responded additional action is not needed, noting that this behavior would likely be considered during the member's reactivation discussion. Other committee members agreed with that this would be considered during any reactivation discussion, but believed the Bylaws needed additional tools to engage programs and to support deadlines that the MPSC may set. Ultimately, the Committee agreed that reviewing and addressing a members' failure to inactivate as a separate potential non-compliance, and the urgency that this occurs, should also be left to the Chair's discretion.

This also prompted a discussion about members that address the concerns that initially led the MPSC to request the inactivation during the interview or hearing process. The MPSC agreed that it may rescind its inactivation request and the member will be allowed to resume transplant activity immediately (though the MPSC/PAIS may continue to monitor the member) if the member addresses what prompted the initial concerns. In these circumstances, and similar to what the MPSC suggested for members that inactivate after the set deadline, the MPSC may still proceed with its consideration of an action for the members' failure to inactivate by the stated deadline.

Committee Projects Pending Implementation

Transplant Program Performance Measures: The MPSC operational rule will be implemented in the Spring 2017 Scientific Registry of Transplant Recipients (SRTR) MPSC Outcomes reports. The operational rule includes a two-step analysis to identify kidney programs for lower than expected graft or patient survival. The Committee will review all kidney transplants to determine if the program meets the established criteria. If so, the program's kidney transplants excluding higher risk transplants will be analyzed to determine if the program still meets the criteria. Higher risk kidney transplants are defined as a transplant involving a recipient with an Estimated Post-Transplant Survival (EPTS) score greater than 80 using a kidney from a donor with a Kidney Donor Profile Index (KDPI) that is 85 or greater. Only those kidney programs that meet the MPSC criteria in Bylaws, Appendix D.11.A. in both analyses will received an inquiry from the Committee.

Review of Public Comment Proposals

4. Improving Allocation of En Bloc Kidneys

The Committee received a presentation on the Improving Allocation of En Bloc Kidneys proposal and offered the following recommendations to the Kidney Transplantation Committee (Kidney Committee):

- The MPSC agreed that there should be a size threshold below which kidneys must be allocated en bloc. The majority of the MPSC agreed with the proposed donor weight threshold of less than 15 kg.
- The proposed language that gives OPOs the option to allocate kidneys from donors between 15 and 25 kg either singly or en bloc should be removed because the language is confusing and unnecessary.
- The Kidney Committee should discuss and provide clear guidance to the OPO community on ways to efficiently place the released (second) kidney, in the event that kidneys allocated en bloc are split by the accepting hospital. The MPSC was concerned about the risk of extended cold ischemic time or discard of the second kidney, which may detract from the intended goal of the proposal.

Other Significant Items

5. OPO Performance:

The Committee approved sending initial inquiries to two OPOs newly identified for lower than expected organ yield and offered informal discussions to two additional OPOs. In addition, the Committee approved the following recommendations from the OPO Metrics Focus Group:

- Continue to defer the review of pancreas organ yield and reconsider when and if there is a 20% increase in the pancreas transplants nationally.
- Adopt a guideline to request an informal discussion if an OPO has been identified for review for 4 consecutive cohorts. The guideline would not prohibit a request for an informal discussion or peer visit sooner if warranted.

6. Collaborative Innovation Improvement Network (COIIN) Update

UNOS staff provided an update to the Committee regarding the ongoing work of the COIIN.

From October – December 2016, UNOS staff visited all nineteen participant hospitals for coaching visits. In January 2017, UNOS staff invited three participants from each hospital to attend a two-day kick-off meeting and learning session in Richmond, VA. At the event, participants networked, collaborated, and learned more about the project's change package, a living document comprised of effective practices leading to increased utilization of moderate-to-high kidneys with favorable outcomes. At the session, UNOS staff declared the overall project aim of increasing transplants by 150 additional transplants from January 2017 to January 2018 based on the center-specific aims and data from participant hospitals.

UNOS staff has developed a high-level performance dashboard, measuring engagement, outcome, and process measures. This high-level dashboard assists UNOS staff in determining the level of intervention needed to coach and assist teams in their progress. Teams also assessed themselves using an IHI-based progress scale measuring where they are in terms of their particular quality improvement journey.

The next steps for the project are to continue the monthly deliverables, continue participant engagement, prepare an evaluation plan, and begin recruitment for the next cohort. UNOS staff will be providing updates to the COIIN Advisory Council in April, June, and September 2017.

Following the presentation, the floor was open for questions and comments. The Committee discussed their ongoing support with the work, and asked about the application process for the following cohort. UNOS staff will not require previous applicants to re-submit documentation, but may request an addendum for information that has changed since the last application period in August 2016.

Member Specific Issues

7. Member Related Actions and Personnel Changes

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. The Committee reviewed the applications and status changes listed below and recommend that the Board of Directors take the following actions:

New Members

- Fully approve 2 new transplant hospitals

Existing Members

- Fully approve 2 transplant programs and 1 living donor component
- Fully approve reactivation of 5 transplant programs
- Fully approve 1 living donor component for a 12-month conditional extension
- Fully approve 1 transplant program extension of inactive program status

The Committee also reviewed and approved the following actions:

- 50 changes in transplant program and living donor component personnel
- 7 changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 3 transplant programs and 3 living donor component inactivated
- 2 transplant programs and 2 living donor component withdrew from membership
- 3 OPO key personnel changes

The Committee issued a notice of uncontested violation to a member histocompatibility laboratory that did not notify the OPTN of an adverse action by a regulatory agency within 10 business days as required in the Bylaws, Appendix C.6(B) *Histocompatibility Laboratory Policies and Procedures*.

8. Living Donor Adverse Events

The Committee reviewed three living liver donor deaths within two years of donation and 12 recovery procedures canceled after the patient received anesthesia. The Committee is not recommending any further action to the Board at this time for any of the issues.

9. Living Donor Follow-up Case Reviews

Policy 18.5.A (Reporting Requirements after Living Kidney Donation) requires that hospitals report accurate complete and timely follow-up donor status and clinical information for at least 60% of living kidney donors and report laboratory data for at least

50% of living kidney donors who donated between February 1 and December 31, 2013, and these thresholds increase by 10% for 2014 and 2015 donors. The Committee continued its review of its process for reviewing members that do not meet the thresholds.

Since at this time over half of the existing living donor recovery programs were below the policy threshold for at least one of the form groups reviewed, the Committee discussed the best way to stratify member compliance, in order to focus on the members that may need the most help to come into compliance. The Committee leadership met with the Living Donor Committee leadership, to discuss the impact of this policy, determine whether they are getting the information they need, and whether the policy requirements are still appropriate.

The MPSC leadership acknowledged to the Living Donor Committee leadership that the policies are intended to increase the safety and knowledge of living donors. However, the MPSC does not have the capacity to review all cases with a high level of interaction. The Living Donor Committee leadership acknowledged that there are different levels of compliance with the policy, and seemed supportive of some type of tiered response to program review. The Living Donor Committee leadership stated that they would keep looking at the aggregate data and the individual elements, but were not sure whether any changes would result.

At this time, planning for the Committee to conduct in-depth reviews of more than 60 programs at a time is not feasible. Therefore, staff proposed three options for monitoring. The Work Group, and the full MPSC, were asked to choose one of these plans or to propose modifications to try to focus the Committee's review. The MPSC approved converting some of the monitoring of these thresholds to the site survey process, while carving out the programs having the most trouble complying for a special MPSC review process. The group will continue to refine the methods and information needed with a new group of forms for the July meeting.

10. Due Process Proceedings and Informal Discussions

During the meeting, the Committee held an informal discussion and two interviews with member organizations.

Upcoming Meetings

- July 11-13, 2017
- October 17-19, 2017