

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 25-27, 2016
Chicago, Illinois

Jeffrey Orlowski, Chair
Matthew Cooper, M.D., Vice Chair

Discussions of the full committee on October 25-27, 2016, are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. Updating the OPTN Definition of a Transplant Hospital

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016. The Committee voted in support (37 support, 0 oppose, 0 abstentions) of sending the Bylaws language proposed during public comment for the OPTN/UNOS Board of Directors final consideration at its December 2016 meeting.

2. Consider Primary Transplant Surgeon Requirement- Primary or First Assistant on Transplant Cases

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016. The MPSC voted in support (36 support, 0 oppose, 0 abstentions) of sending the Bylaws language proposed during public comment for the OPTN Board of Directors final consideration at its December 2016 meeting.

3. Updating Primary Kidney Transplant Physician Requirements

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016. In response to public comment feedback, the MPSC made one post-public comment modification to the originally proposed Bylaws changes, and voted (35- support, 1- oppose, 0- abstentions) to send the modified proposal for the OPTN/UNOS Board of Directors consideration during its December 2016 meeting. The post-public comment change is:

- Remove the evaluation of 10 potential living donors requirement from the primary kidney transplant physician “pediatric pathways”- OPTN Bylaws Appendices E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), and E.3.E (Combined Pediatric Nephrology Training and Experience Pathway). The MPSC agreed to make this change in response to public comment feedback that indicated living donor evaluations are outside the scope of pediatric nephrology training and should not be expected for pediatric programs. The Committee discussed the importance of individuals leading kidney programs – including programs that predominantly transplant pediatric patients – being familiar with the living donor process. Although the originally proposed changes to these pediatric pathways are intended to reflect a familiarity and understanding of the process, and not necessarily independently conducted living donor evaluation and determinations, the MPSC appreciates the commenters concerns. The Committee did not want to create a possible unintended consequence where

numerous pediatric nephrologists believed they did not qualify as a primary kidney transplant physician due to the potential living donor evaluation requirement, and thereby possibly creating staffing difficulties for kidney programs that predominantly transplant pediatric patients. The MPSC suggested modifying the living donor evaluation requirement in the pediatric pathways to state that individuals applying through these pathways “should” have this potential living donor evaluation experience, but eventually agreed this was not an ideal approach with respect to the unenforceability of “should” and keeping the key personnel Bylaws focused on absolute requirements. As such, the Committee ultimately agreed to remove the evaluation of 10 potential living donors as a requirement from the primary kidney transplant physician “pediatric pathways” as a post-public comment modification.

4. Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016. In response to public comment feedback, the MPSC made two post-public comment modifications to the originally proposed Bylaws changes, and voted (36- support, 0- oppose, 0- abstentions) to send the modified proposal for the OPTN Board of Directors consideration during its December 2016 meeting.

The two post-public comment changes are:

- Include transplant hepatology board certification as another option for primary liver transplant physicians, in addition to the current gastroenterology board certification requirement. The original proposal recommended replacing the current gastroenterology board certification requirement with a transplant hepatology board certification requirement for primary liver transplant physicians. This modification was a direct response to the primary concern with this proposal, which was raised repeatedly. In reviewing this feedback, the MPSC agreed that this was an appropriate and necessary change to make.
- Similarly, add the advanced heart failure & transplant cardiology subspecialty board certification as another option for primary heart transplant physicians. Changes to the primary heart transplant physician Bylaws were not originally included in this proposal, but the MPSC was motivated to make this change in response to feedback during public comment, in consideration of the amendment for primary liver transplant physicians, in anticipation of similar problems for subspecialty certified transplant cardiologists, and to gain some efficiencies in the policy development process. Although this specific consideration was not included in the original proposal, in anticipation of its public comment feedback review discussions, the MPSC requested that the OPTN/UNOS Thoracic Organ Transplantation Committee (the Thoracic Committee) comment on this possible approach and amendment. The Thoracic Committee supported this possible amendment and did not express any concerns with this approach. This support further encouraged the MPSC to make this post-public comment modification.

5. Transplant Program Performance Measures Review (Outcome Measures)

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016, and unanimously approved implementation of the operational rule for the June 2017 MPSC SRTR outcomes reports (37 support, 0 oppose, 0 abstentions). Although there are no revisions to policy or bylaws, the MPSC is providing an update to the Board of Directors regarding the proposal, the public comment received, and the action taken by the MPSC.

6. Proposed Changes to the OPTN Transplant Program Outcomes Review System

The Committee reviewed the comments received in response to this proposal that was distributed for public comment in August 2016 and did not support sending the proposal to the OPTN/UNOS Board of Directors for approval at its December 2016 meeting (4 support, 33 oppose, 0 abstentions). Although the regions, committees and individual commenters were supportive of the Task Force and MPSC's efforts to make changes to the outcomes review system, the majority of feedback received did not support the specifics of this proposal. Based on the negative feedback received, the MPSC concluded that the proposal did not adequately achieve the goal embodied in the Board's December 2015 resolution. It was clear from the public comment that the quality improvement tiers proposed did not resonate with the community; and therefore, a major overhaul of the proposal would be required to produce a bylaw revision that would be supported by the community. The MPSC is providing an update to the Board of Directors at its December 2016 meeting since the project was originally created in response to a resolution passed by the Board of Directors at its December 2015 meeting.

7. OPTN Bylaws Revisions - Appendix L

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when members fail to comply with OPTN obligations. Appendix L also outlines members' due process rights when the MPSC or Board of Directors is considering taking certain actions. During the October meeting the staff presented proposed revision concepts regarding the Routine Review and Imminent Threat Review pathways to the MPSC. The MPSC was generally supportive of the proposed concepts and will plan to provide additional feedback as necessary in the future.

Committee Projects Pending Implementation

None discussed

Implemented Committee Projects

None discussed

Review of Public Comment Proposals

None discussed

Other Significant Items

8. Pediatric Membership Exception Revisions

The MPSC received an update from members of the joint MPSC/Pediatric Committee work group, which was tasked with drafting recommended improvements to the Pediatric Membership Exception. The Committee provided feedback regarding the work group's approach and suggested solutions and it agreed that the criteria selected made sense.

9. Pancreas Functional Inactivity

The Committee continued its discussion regarding the number of pancreas programs with low volume that the Committee is reviewing for functional inactivity. The Committee raised concerns about not only the low transplant numbers at many of these programs, but also the length of time, often years, that candidates are sitting on the waiting list and the number of organ offers that are declined. The Committee noted that it appears there are too many pancreas programs for the need for pancreas transplant. The Committee also raised the question whether delays are being created in the placement of pancreata due to the number of offers that need to be made by organ procurement organizations to low volume programs that more often than not decline the organs. The Committee has requested that the Pancreas Transplantation Committee provide guidance on how to address this issue and at what volume, does the Pancreas Transplantation Committee believe competency and currency of all pancreas transplantation staff can be maintained.

10. Member Specific Issues

The Committee convened as an expedited threat review committee to conduct a review of a transplant hospital case.

11. 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 1 new transplant hospital
- Fully approve 1 individual member

Existing Members

- Fully approve 2 transplant programs and 1 living donor component
- Fully approve reactivation of 1 transplant program and 2 living donor components
- Fully approve 1 living donor conditional component
- Fully approve 1 living donor component conditional to full status
- 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:

- 59 applications for changes in transplant program and living donor component personnel
- 3 applications for changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 4 transplant programs and 1 living donor components inactivated
- 2 transplant programs and 1 living donor components withdrew from membership
- 3 histocompatibility labs withdrew from membership
- 7 OPO key personnel changes

The Committee issued two notices of uncontested violation to member transplant hospitals that did not notify the OPTN of changes in key personnel within 7 days of departure as required in the bylaws.

12. Living Donor Adverse Events

The Committee reviewed two living liver donor deaths within two years of donation and seven 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.

13. 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 60+ programs at a time is not feasible. Therefore, staff proposed three options for monitoring. The Work Group, and then the full MPSC, will be asked to choose one of these plans or to propose modifications to try to focus the Committee's review.

14. Due Process Proceedings and Informal Discussions

During the meeting, the Committee conducted one hearing, three interviews, and two informal discussions with member transplant hospitals and OPOs.

Upcoming Meetings

- November 7, 2016, Conference call
- February 28-March 2, 2017
- July 11-13, 2017
- October 17-19, 2017