

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
December 10-11, 2014
Chicago, IL

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Work of the full committee on December 10-11, 2014, is summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.

Committee Projects

1. Summary of Committee Projects

UNOS staff updated the Committee on the status of all the MPSC's projects related to OPTN Policy and Bylaws development. To summarize:

- Proposals submitted to the OPTN/UNOS Board of Directors for consideration at its November 2014 meeting were approved, and will be implemented on February 1, 2015.
 - Requests for Exceptions Based on Geographic Isolation
 - Proposal to Clarify Data Submission and Documentation Requirements
- Feedback in response to proposals distributed during the fall 2014 public comment cycle will be reviewed by the Committee during an early 2015 meeting, the date of which is to be determined. All three of these proposals received substantial and varying feedback, running the gamut from complete support to complete opposition. When the MPSC reviews the public comment feedback it will determine the next course of action for these proposals, which could include submitting this for the Board of Directors' consideration as is, or with minor modifications, or substantial changes may be considered that would require additional consideration through public comment.
 - Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations
 - Proposal to Define a Transplant Hospital
 - Proposal to Implement Pre-Transplant Performance Review by the Membership and Professional Standards Committee
- UNOS staff provided an update on the progress made thus far by the Joint Society Working Group (JSWG) that is focusing on a number of topics related to key personnel requirements in the Bylaws. The JSWG has reached agreement on recommendations that pertain to the following topics:
 - *Foreign Board Certification*
 - Delete all references to "foreign equivalent"
 - Include certification by the Royal College of Physicians and Surgeons of Canada in the list of acceptable certifications
 - Require all reported case experience to be performed at OPTN-approved transplant hospitals

- Create additional pathway for primary surgeons/physicians who are not American board certified
- In lieu of American board certification:
 - Must meet all other key personnel requirements through clinical experience pathway
 - Provide two letters of attestation from program directors not affiliated with applying hospital
 - Obtain continuing medical education credits with self-assessment comparable to American board maintenance of certification
 - Subject to OPTN review
- *“Primary or First Assistant” on transplant cases*
 - *Fellowship pathways*
 - *Require submission of ASTS surgical log*
 - *Case is acceptable if accepted by ASTS*
 - *Similar recommendation likely for cardiothoracic, but JSWG still needs to discuss*
 - *Clinical experience pathways*
 - *Require 50% of reported cases performed as primary surgeon*
 - *Apply consistently across pathways for all abdominal organs*
 - *Keep current thresholds for primary heart surgeon (75%) and primary lung surgeon (66%)*

MPSC members expressed some concern with these recommendations, fearing they may be too restrictive, thereby limiting the ability of talented and otherwise qualified individuals – particularly those at smaller centers – to serve in a key personnel role. This feedback will be provided to the JSWG for further discussion.

2. Organ Perfusion Work Group Report

The Committee received an update from the Chair of the Organ Perfusion Membership Standards Working Group. This group had its first call in November 2014. The call focused on potential patient safety issues that could arise from the use of third-party, non-OPTN member, perfusion companies. The working group opined that the lack of oversight of these third-party companies to monitor and promote improvement, relative to the potential impact of these patient safety concerns, is problematic. The Working Group then proceeded to discuss potential strategies for addressing this matter, with the two main themes being a centralized monitoring system established through OPTN membership and decentralized monitoring of third-party perfusion companies through formal affiliations with current OPTN-members. A straw poll of working group members revealed that six supported a centralized approach, three supported a decentralized approach, and one was undecided at the time. The work group will meet again in early 2015 to continue its discussion about creating a framework to accommodate a centralized monitoring system.

3. Multi-organ outcomes work group update

At the Committee’s December meeting, the SRTR presented a summary of the data analysis provided to the work group that is reviewing the options for including multi-organ transplant outcomes in the Committee’s performance reviews. The Committee provided some guidance to the work group and supported focusing on those multi-organ transplants that are more common, such as simultaneous liver and kidney. The data presented included all multi-organ liver transplants. They also supported looking at the outcome for both organs, for example looking at both liver outcomes and kidney outcomes for simultaneous liver kidney transplants. Finally, the Committee felt that more

evaluation of whether the review would be based on a combined multi-organ and single organ model or a separate multi-organ model. The work group will continue to examine the unique issues and challenges related to an effort to incorporate multi-organ transplants in the Committee's outcomes monitoring.

Other Committee Actions:

4. Living Donor Liver - Domino Transplants:

The Committee Chair received a question from an approved liver transplant program, which is not currently approved to perform liver recoveries from living donors, regarding whether it was necessary to have an approved living donor liver recovery program in order to perform a domino liver transplant. Current policy seems to indicate that domino donors need to be treated as living donors with all of the included evaluation, although the transplant procedure is different. In addition, the Liver Committee and the Living Donor Committee have been discussing this issue, to clarify which aspects of living donor evaluation will need to be followed for a domino donor, and to exclude domino donors from any living donor follow-up requirements. The Living Donor Committee is working on an upcoming policy change to better define domino donors. The Committee heard an update on the proposed policy changes, including an addition to clarify requirements for programs where domino donor recoveries can take place. The Committee agreed that the Living Donor Committee proposal will help clarify policy, but stated that the language may need further revision. The proposal will go out for public comment in a future session.

5. Pancreas Committee Proposal: Define Pancreas Graft Failure

The Pancreas Transplantation Committee's public comment proposal to define pancreas graft failure was presented to the Committee for comment. The Committee offered the following comments:

- Several members of the Committee expressed concerns that the section defining a recipient's insulin use greater than or equal to 0.5 units/kg/day for a consecutive 90 days as pancreas graft failure is somewhat arbitrary and not data driven.
- Concern was expressed that some patients whose pancreas is functioning but develop insulin resistance post-transplant would be captured as a graft failure.
- Concern was also expressed that this section of the definition may drive program behavior and result in a delay in returning recipients to insulin use when it is clinically appropriate.
- One member suggested that the section regarding insulin usage should include a goal such as "insulin use greater than or equal to 0.5 units/kg/day to achieve a Hemoglobin A1c of xx for a consecutive 90 days."
- Two members were concerned that an unintended consequence of this new definition is that it will result in additional graft failures that may be used by third party payers to exclude pancreas programs.
- Other members of the Committee noted that the proposed definition is an improvement over the current definition and a reasonable step forward in the effort to define pancreas graft failure.
- A member encouraged the Pancreas Transplantation Committee to work with the pancreas islet community to develop a consistent definition of graft failure.

6. Histocompatibility: Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

The Committee reviewed the Histocompatibility Committee's public comment proposal to amend the bylaws governing histocompatibility laboratories and agreed to support the proposal as written.

7. Operations and Safety Committee: Proposal to Allow Collective Patient and Wait Time Transfers

The Committee reviewed the OSC proposal to amend the Bylaws and Policies to create a process to transfer patients collectively. It supported more than one 90-day post-transfer report since it may take longer than 90 days to transition a large group of candidates to another transplant hospital. It suggested having a second 90-day report at 180 days.

The Committee also considered the requirement for the accepting transplant program to develop and implement a plan that includes a procedure for the immediate review and designation of appropriate candidates on the waiting list upon completion of the collective transfer. A Committee member suggested that while the accepting hospital is responsible for designating appropriate candidate waiting list status after transfer, the transferring hospital should inform patients that their waiting list status/candidacy could change based on the accepting hospital's review of medical records, patient evaluation, and/or the accepting hospital's selection criteria. The transferring hospital should be responsible for communicating/previewing the potential (risk) for such waitlist status changes at the accepting center. This forewarns patients, helps set system expectations, and shares burden of communicating this information, rather than the receiving hospital alone being solely responsible.

Other questions included the following:

- Is there a mechanism to exclude any regulatory deficiencies that transferred with the candidate? In other words if the accepting hospital undergoes an audit in the future and the listing letter was then written by the original transferring hospital, would the receiving hospital be held accountable if there was deficiency with the original letter?
- Does the accepting hospital assume responsibility for waitlist mortality if a candidate is transferred, but has not yet been evaluated and reactivated on the waitlist?
- Can this same protocol be used in a natural disaster situation that temporarily results in a transplant hospital not being able to transplant?

8. Policy Oversight Committee: Proposal to Clarify Definition of Organ Transplant & Transplant Date

The Committee reviewed the Policy Oversight Committee's public comment proposal to amend the bylaws to clarify the definition of the start and end of a transplant. The Committee supported the proposal as written.

9. Improving the OPTN Policy Development Process

The Committee offered the following comments on the Executive Committee's public comment proposal to amend the policies to improve the responsiveness of OPTN policy to a changing environment:

- If the proposal process is streamlined, will the policy implementation process be able to keep up?

- There needs to be a strategy for dealing with the time needed to complete the OMB approval process when changes to the data collection tools are needed.
- Public education regarding the changes to the process will be needed.
- There will need to be a process for presenting the proposals, such as a webinar, when the proposals cannot be presented during a regular regional meeting.

10. Policy Oversight Committee: Policy Rewrite Parking Lot - "Quick Fixes"

The Committee considered the Policy Oversight Committee's public comment proposal to amend the policies to address easy, non-controversial changes. A Committee member was concerned that backup offers can currently bypass OPOs and asked if this Policy 5.4.E "Backup Organ Offers" could be pulled out as one that should be looked at more substantively.

11. Vascularized Composite Allograft (VCA) - Revised Membership Requirements Proposal

The Committee reviewed the draft VCA membership requirements and suggested the following changes to the proposed language:

- Require all VCA programs to be co-located with another solid organ transplant program.
- Add the American Board of Surgery to the list of acceptable board certifications for head and neck transplant programs.
- Add kidney and pancreas surgeons (in addition to liver) to the list of eligible primary surgeons for an abdominal wall program.

While it did not suggest specific changes the Committee also asked if training programs for head and neck include the necessary microvascular experience for the primary surgeon and suggested stating this experience more prominently. The Committee also suggested that the proposal or briefing paper narrative include further explanation of some of the finer points of the requirements.

12. Pediatric Program Requirements - Preliminary Proposal Review

The Committee considered the OPTN/UNOS Pediatric Transplantation Committee (the Pediatric Committee), proposal to add specific requirements to the bylaws for the designation and approval of pediatric components at programs. The MPSC will co-sponsor the proposal with the Pediatric Committee.

There was considerable discussion following the presentation but a number of committee members supported the proposal. Ultimately, the Committee recognized that the only way to obtain broad input from the community about their concerns is to move the proposal out to public comment. The Committee approved a motion for the proposal to be distributed for public comment.

13. Outcomes Measures Discussion (proposal for increasing transplants)

The OPTN President, Dr. Carl Berg, provided a summary of recent discussions on prioritization of strategic plan goals at Regional meetings and the Board meeting. The goal of increasing the number of transplants was overwhelmingly endorsed as the number one priority during these discussions. Dr. Berg also provided information on discussions by a work group of representatives from OPTN leadership, AST, ASTS and AOPO about ways to adjust our outcomes metrics to support this goal of increasing the number of transplants. The work group would like to engage with members of the Committee as support of the Committee for any adjustments to the outcomes metrics would be important to its success. Dr. Berg requested that the Committee chair appoint

an MPSC work group to meet with the AST/ASTS/AOPO work group to hear their ideas and work on a proposal. Currently, the AST/ASTS/AOPO work group have been focusing on one organ, kidney, initially. The Committee was supportive of the concept and suggested parallel simultaneous consideration of the options for multiple organs rather than focusing on one organ. Dr. Berg indicated that he would discuss the idea of parallel consideration of options for different organs with the OPTN leadership and respond back to the MPSC chair.

Summary of Peer Review Actions:

14. Member Related Actions and Personnel Changes

The Committee is charged with determining that 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 and unanimously approved the consent agenda.

The Committee took the actions reported below during its meeting and will ask the Board of Directors to approve the following recommendations during the June 1-2, 2015, meeting:

- New Members
 - Approve 1 new transplant hospital
- Existing Members
 - Fully approve 5 transplant programs
 - Conditionally approve 1 new transplant program for 24 months
 - Conditionally approve 2 new living donor components for 12 months
 - Approve 4 transplant programs and 1 living donor component reactivations
- Program-Related Actions and Personnel Changes
 - The Committee reviewed and approved the following:
 - 95 applications for changes in transplant program personnel
 - 5 applications for changes in histocompatibility lab personnel
- The Committee also received notice of the following membership changes:
 - 1 living donor component withdrew from membership
 - 1 lab withdrew
 - 7 OPO key personnel changes

15. Late Notification of Key Personnel Change

The Committee discussed one transplant hospital that did not meet the notification requirements in the Bylaws. The Committee issued a Notice of Uncontested Violation to the member.

16. Live Donor Adverse Events Reporting

The Committee reviewed two mandatory reported cases: two living donor deaths and one non-utilized organ. The Committee was also informed of a voluntary report of a living donor death after two years and unrelated to donation. The Committee is not recommending any further action to the Board at this time for any of the issues.

17. Due Process Proceedings and Informal Discussions

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

Next Scheduled Meetings

- February 4, 2015, Call, 3:00pm – 5:00pm EDT
- March 24-26, 2015, Chicago
- April 14, 2015, Call, 2:00pm - 3:30pm EDT
- July 14-16, 2015, Chicago
- October 27-29, 2015, Chicago