

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
February 2, 2016
Conference Call

Jonathan M. Chen, M.D., Chair
Jeffrey Orlowski, Vice Chair

Discussions of the full committee on February 2, 2016, are 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. Transplant Hospital Definition Consensus Building

The MPSC Vice Chair updated the Committee on the Transplant Hospital Definition Work Group's progress on updating the definition of a transplant hospital in OPTN/UNOS Policy and Bylaws. The Work Group has finalized concepts that it is comfortable with, and that the MPSC showed its support for at its October 2015 meeting. The Vice Chair reviewed these concepts with the Committee, and they are as follows:

A transplant hospital:

- Must meet current requirements in OPTN Bylaws Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)
- Can only have one transplant program for each respective organ
 - Each transplant program may include multiple ORs, ICUs, post-operative care units, for transplant patient care

All transplant facilities **must**:

- Be within a single DSA
- Have common executive leadership and shared governance, demonstrated to satisfaction of MPSC
- Be preemptively documented with the OPTN

Geographical Considerations:

- All of the hospital's transplant facilities are **either**:
 - Within a "contiguous campus"
 - Within a one-mile walking distance
 - Other scenarios outside of these criteria, *as approved at the discretion of the MPSC*
- Only one transplant hospital can be approved for any given hospital campus, unless the proposed transplant hospital within that same campus is a children's or Veteran Affairs hospital.

In between now and the summer 2016 public comment proposal release, the work group thought it would be beneficial to build consensus around these concepts. The Vice Chair presented a plan to engage CMS through HRSA, attendees at the 2016 Transplant Management Forum, and a number of OPTN/UNOS Committees (Transplant Administrators, Operations and Safety, Pediatric Transplantation, and POC). The MPSC responded in support of these consensus building efforts, and did not have any suggestions on other groups that should be explicitly engaged at this time.

2. Task Force to Reduce Disincentives to Transplantation

The MPSC Vice Chair informed the Committee about the Task Force to Reduce Disincentives to Transplantation (the Task Force) that has been formed to address the clinical thresholds for transplant program outcome reviews project. The MPSC Vice Chair proceeded to review the resolution adopted by the OPTN/UNOS Board of Directors (the Board) that prompted this project:

RESOLVED, that the MPSC is tasked over a period of 6 months to provide the Board with a proposal for an improved program specific reporting system that identifies substantive clinical differences in patient and graft outcomes.

FURTHER RESOLVED, that the President will appoint a working group consisting of 10 members; 3 from the UNOS/OPTN Board, 3 from the societies of the AAAU, and 3 from the MPSC, and 1 ad hoc member from CMS - this working group will, over a three month period, identify objective measures that define clinically relevant outcome differences - this work group will then submit their findings to the MPSC for approval, and by the June 2016 board meeting, present that proposal to the Board for action.

Additionally, the MPSC reviewed the Task Force roster and its schedule of upcoming calls. The Task Force had met twice prior to this MPSC teleconference. These preliminary calls primarily focused on data requests to help investigate this topic and reviewing some of those data that had been compiled. To conclude this update, the Vice Chair reviewed a table that summarized each respective quality improvement effort that the OPTN and the MPSC are currently engaged. This table had been created to help delineate what each group has been charged to address, and to prevent an unnecessary overlap and duplication of efforts.

Committee Projects Pending Implementation

None

Implemented Committee Projects

None

Review of Public Comment Proposals

None

Other Significant Items

3. Update from the Policy Oversight Committee

The MPSC Vice Chair updated the Committee on recent decisions made by the OPTN/UNOS Policy Oversight Committee (the POC) regarding new and on-hold MPSC projects that had been submitted for its consideration during a recent teleconference that focused on the approval of “new” committee projects. The POC recommended moving forward with all five of the MPSC’s projects submitted for consideration during this meeting. Those five projects are:

- Approved Transplant Fellowship Training Programs
- Updating Bylaws’ Primary Kidney Transplant Physician Requirements
- Consider Primary Surgeon Qualifications – Primary or First Assistant on Transplant Cases
- Primary Physician Specialty/Subspecialty Board Certifications
- Clinical Thresholds for Transplant Program Outcome Reviews

The first four projects listed above were addressed by a Joint Societies Work Group formed to review a number of transplant program key personnel Bylaws. The MPSC intended to distribute proposals addressing each of these topics for public comment in August 2015; however, these projects had been placed on hold in June 2015, resulting from an organizational-wide effort to align all committee work with the new strategic plan adopted by the Board at its June 2015 meeting.

The last project listed above- Clinical Thresholds for Transplant Program Outcome Reviews- is a new project prompted by a resolution adopted by the Board at its December 2015 meeting, and corresponds to the Task Force to Reduce Disincentives to Transplantation that is mentioned above.

Ultimately, the Executive Committee will make the final determination regarding what efforts should be pursued. The MPSC Vice Chair alerted the committee that the Executive Committee is slated to meet in February 2016, and during this meeting, it will be discussing and acting on the POC's new committee project recommendations.

4. Membership Standards for Organ Perfusion Companies

UNOS Staff presented this topic to the MPSC at its December 2015 meeting but time constraints limited any committee discussion. At that time, MPSC leadership asked the Committee to continue to think about the topic of membership standards for organ perfusion companies, and plan to discuss this matter during its next meeting. During the February 2, 2016, MPSC meeting, UNOS staff presented a truncated version of the presentation reviewed in December 2015 to remind the Committee about this topic and prompt its discussion.

The Committee began by stating that this topic should be an area of MPSC focus. Organ perfusion of lungs, livers, and hearts is an expanding and emerging technology. The MPSC suggested that the OPTN should think about this technology and its potential impact now in hopes of avoiding problems, instead of reacting to problems as they arise. The MPSC thought that these efforts align very well with the OPTN Strategic Plan goal of increasing the number of organ transplants. Committee members noted that organ perfusion technology has the potential to be a critical component to increase the number of organs transplanted from donation after cardiac death (DCD) donors.

Other Committee members echoed support for the MPSC reviewing and addressing this topic citing patient safety concerns. It is critical that organ perfusion companies are held to the same standard as OPOs. Repackaging and labeling organs after perfusion are patient safety issues that need to be monitored.

MPSC members also noted concerns about allocation confusion that may arise with increasing usage of this technology. UNOS staff reminded the MPSC that organ allocation impacts are a separate topic and it is important for the MPSC to stay focused on the membership component- should there be membership requirements in the OPTN Bylaws that pertain to companies that are involved with organ perfusion? Should the OPTN have some oversight role with these companies? UNOS Staff reminded the committee that the organ perfusion companies membership questions came from OPTN/UNOS Thoracic Organ Transplantation Committee (the Thoracic Committee) lung allocation discussions. The Thoracic Committee ultimately agreed that no allocation changes are necessary at this time, and that all lungs should be allocated following a match run. The MPSC chair responded that although the MPSC should stay focused

specifically on the membership question, as these discussions and this technology evolve, it will be important to recognize potential organ allocation issues and then share these with the organ-specific committees to evaluate further.

Committee members stated that this discussion reminded them of when islet transplants began to become more prominent. Lessons can be learned from that experience, and there must be an appropriate balance between establishing oversight parameters to protect patient safety and allowing exciting innovation to occur. The Committee opined that it may be helpful if the OPTN led this oversight so innovation can thrive in pursuit of more organs being transplanted, while simultaneously putting necessary safe guards in place to protect patient safety. The MPSC Chair agreed with this sentiment, referencing a more recent example of the OPTN's involvement with vascularized composite allografts (VCA). Although VCA transplantation is still a new and growing field, VCA practitioners sought the OPTN's oversight and structure to help this field grow. Commending the VCA community in its proactive approach, it seems the transplantation community would benefit from the OPTN's early engagement with new organ perfusion technology that is on the horizon.

Committee members raised questions if the OPTN's involvement with organ perfusion oversight may prompt FDA concerns as it is responsible for medical device oversight. To avoid this possibility, call participants advised that the OPTN focus on process and procedure that occur around the device, avoiding any guidance that relates to how the organ perfusion technology operates.

The Committee suggested a work group be formed to begin addressing this topic. The Chair requested volunteers to email him and UNOS staff if interested in volunteering for this work group.

To conclude this discussion, the OPTN Vice Chair recommended that the work group consider focusing on minimal standards and guidance for all groups- OPOs, transplant hospitals, private companies, etc- involved with organ perfusion. What are the patient safety issues that warrant the OPTN's establishment of specific universal standards? Proposed Bylaws could concentrate on mitigating the occurrence of these potential patient safety issues, factoring in the appropriate balance between oversight and continued innovation.

5. Living Donor Follow Up Reporting

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, 2013 and December 31, 2013. The Committee reviewed the specific elements required by the policy and the upcoming increase in the minimum reporting thresholds. The Committee will be reviewing new cohorts of data once a year at each July meeting, to monitor members' progress.

The Committee received an update on members not meeting the thresholds for submission of one year follow-up forms for 2013 donors. All of the programs submitted the requested corrective action plans, and the Committee will have an additional process discussion in March before the new set of forms are available for the July meeting.

6. Member Related Actions

Live Donor Adverse Events Reporting

The Committee reviewed two reported living kidney redirected organ reports. The Committee is not recommending any further action to the Board at this time for any of the issues.

7. Ethics - Requesting Feedback for a Report on Ethical Considerations of Imminent Death Donation

The committee reviewed the Ethics Committee's memorandum dated December 8, 2015 requesting feedback for a report on ethical considerations of imminent death donation (IDD). The Committee raised several concerns, including:

1. The need for detailed, explicit policies. For example, the Committee felt IDD policies should clearly prohibit donation from causing death. Policy should also include safeguards to ensure free and informed consent, particularly for donors with psychosocial issues. Policy should also clearly state whether OPOs or transplant programs are responsible for completing and documenting the donor workup. If transplant programs complete the work up, must the program have an approved and active living donor kidney or living donor liver component?
2. The potential benefits to donor families. The Committee believes some families that have a strong desire to donate, but are unable to because the patient progresses to death in a way that precludes transplantation.
3. The contents of the recently published paper in American Journal of Transplantation regarding donation after physician-assisted suicide.
4. Feedback from the general public, particularly regarding the potential effect of IDD on the public's trust in the transplant system. The Committee feels it is necessary to obtain broad support from the public and transplant community before permitting IDD.

Educational efforts. The Committee believes IDD is a significant paradigm shift that will likely require dedication of significant time and educational resources not only to obtain sufficient support for IDD but also to ensure members involved in IDD are able to understand and comply with policy requirements. The Committee supports further consideration of IDD and plans to further discuss the implications at its in-person meeting in March 2016.

The Committee sent a memorandum back to the Ethics Committee summarizing its discussion and stating that it continues continued, broader discussion of IDD.

Upcoming Meetings

- March 15-17, 2016, Chicago
- April 18, 2016, Conference Call
- May 24, 2016 Conference Call
- June 28, 2016, Conference Call
- July 12-14, 2016, Chicago
- October 25-27, 2016, Chicago