**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**
**Meeting Summary**
**March 15-17, 2016**
**Chicago, Illinois**

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

*Discussions of the full committee on [Month, Day, Year] are summarized below. All committee meeting summaries are available at http://optn.transplant.hrsa.gov/.*

## Committee Projects

### 1. Transplant Hospital Definition

The MPSC Vice Chair provided an update on the Committee's project to better define an OPTN transplant hospital member. A number of discussions have been arranged with different groups to present the Committee's current concepts for updating the transplant hospital definition. These discussions are intended to build consensus around and obtain feedback on these concepts, prior to their formal public comment distribution. The Transplant Hospital Definition Work Group will be meeting after these consensus building discussions to review the feedback and to adjust the concepts, as necessary. The feedback received and the Work Group's recommendations will be presented for the full Committee's consideration during its May 2016 teleconference. These concepts will also be presented during a breakout session at the June 2016 OPTN/UNOS Board of Directors meeting. Feedback from that discussion will be reviewed a few weeks later with the full Committee during its June 2016 teleconference. During this teleconference, and at the conclusion of these discussions, the MPSC will be asked to vote on the final Bylaws language to be included in the public comment proposal that will be distributed in August. In preparation for these future discussions and this final vote, UNOS staff stressed the importance of the MPSC's review of the draft Bylaws language. To refresh the Committee on these concepts, the Vice Chair reviewed the information that will be presented to each group during the upcoming consensus building discussions.

### 2. Transplant Program Performance Measures Review (Outcome Measures)

The Committee received an update on refinements made to a concept developed by the work group and presented to the Committee on its December conference call. The concept was presented at OPTN regional meetings and a concept document was included in the spring public comment on the OPTN website. Within the presentation and concept document, the Committee requested feedback on the concept to be used in the development of a proposal. The public comment period had not ended at the time of the meeting. However, UNOS staff provided a summary of the feedback received prior to the meeting. Following consideration of the feedback, the Committee plans to release a proposal for public comment in summer 2016 and forward it to the Board of Directors in December 2016.

### 3. OPO Metrics

The OPO Metrics Focus Group provided an update to the Committee. Currently, the Committee excludes pancreas yield from OPO performance reviews. The Committee had requested that the Focus Group review this decision one year after implementation of the new pancreas allocation system. The Focus Group reviewed data on the number

of pancreata recovered for transplant, discarded and transplanted. Based on a finding that the number of pancreas transplants has continued to decline since the implementation of the new pancreas allocation system, the Focus Group recommended that the Committee continue to exclude pancreas yield for the Committee's review of OPO performance. The Committee approved this recommendation. The Focus Group also recommended that the Committee approve a request to the OPO Committee to form a joint work group to evaluate the current yield model and provide feedback to the SRTR for use in its evaluation of the model in late 2016. The Committee approved this recommendation.

**4. Task Force to Reduce Disincentives to Transplantation**

The Committee Vice Chair, and member of the Task Force to Reduce Disincentives to Transplantation (the Task Force), provided a status update. This update included a review of the Board of Directors resolution that prompted the formation of the Task Force and the expected timeline of events for bringing the results of these efforts back to the Board of Directors at its June 2016 meeting. To make sure that the Committee was aware of the time restraints for accommodating this resolution, the Vice Chair stressed that the MPSC will receive the Task Force's recommendations for Board consideration during an MPSC teleconference that is scheduled thirty minutes after the conclusion of the last scheduled Task Force teleconference.

Task Force discussions thus far yielded the following general ideas to address the resolution adopted by the Board of Directors in December 2015:

- Update the current Bayes model to "raise" the flagging space
- Establish a "warning" threshold tier
- Add a second requirement that also evaluates the outcomes of a more recent cohort
- Combine the patient and graft survival metric

To supplement the Task Force status update, the Scientific Registry of Transplant Recipients (SRTR) reviewed some of the results of analyses it provided the Task Force during its discussions and the consideration of these concepts.

After presentation of this information, a committee member noted that relatively small adjustments had been suggested - will this have a large enough impact to promote the desired behavior changes? SRTR responded that this is a challenging question to answer because the current system is arranged such that a program's probability of flagging decreases as the program performs more transplants and takes on transplants with greater risk factors.

As a possible approach for leveraging the desired behavioral changes, numerous Committee members noted the critical need for the incorporation of pre-transplant metrics reviews. A hypothetical program with a transplant rate twice the average with outcomes that are slightly below expected is saving more lives than a program with average volume that has outcomes that are marginally better than expected. Patients are dying on the waitlist, and to obtain a more complete picture of transplant programs' outcomes, the outcomes of patients waiting for an organ must be considered.

The MPSC also noted the incremental nature of the presented recommendations, and that they hoped bolder, more significant changes would be proposed. The transplant community does not have confidence in the risk adjustment modeling performed for kidney transplant recipients, and trying to tweak the current system will not yield the changes that are hoped for. Members suggested that the OPTN needs to move away

from observed versus expected outcomes reviews, or do a better job of capturing the risks that shape expected outcomes.

Another MPSC member echoed that tweaks are not going to yield much changed. More complicated transplants incur a greater expense, and the possibility of higher reimbursement for more complicated transplants, including those involving donor organs with greater risk factors, may yield a greater impact.

Committee members also questioned the impact these changes may have considering the perspective that CMS reviews and insurance companies' centers of excellence assessments are the larger concern for transplant hospitals. The OPTN making changes to its outcomes review system in isolation may not have a profound impact.

The MPSC did express support for the concept of looking at more recent results in addition to the outcomes of larger cohorts. It is common for programs to respond to and fix issues that they have noted on their own, prior to MPSC involvement. The MPSC's impact in these types of situations is likely minor, and this approach may help filter these scenarios from further review.

The OPTN Vice President responded to the Committee's discussion stating that two things are accomplished by the current OPTN flagging system- programs that are in real trouble with their outcomes are identified and the MPSC uses its tools (peer review, interviews, etc.) to work with these identified programs to promote change. Secondly, it prods programs' self-assessment to explore opportunities for improvement. Both of these considerations come with a stigma of being flagged. These considerations are what prompted the idea of creating a "warning tier" to nudge programs to improve without the stigma that is associated with it. In an effort to avoid the "flagging stigma," the OPTN should explore establishing a process that looks at all programs periodically. Regarding payer structures, it seems unlikely at this time that the OPTN can significantly impact the decisions made by those groups.

The MPSC Chair alluded to the discussions and work the Committee had performed over the previous two days, and stated that whatever changes are pursued, patient safety must remain a focus. The MPSC has had legitimate concerns with a number of programs it has engaged, and a new monitoring system should not create an environment that significantly relaxes the overall concern for patient system. He also echoed the opinion that pre-transplant metrics are critical.

Regarding the operational aspect of the Board's December 2015 resolution, the Chair indicated he is not totally convinced that there will be a complete product to present to the Board by June. The OPTN Vice President responded that all that can be expected is that the MPSC do its best to continue moving these discussions, and this process, forward.

To conclude the discussion of this topic, a committee member stated that the current outcomes review system has yielded a situation where the community is now an enemy of its own success. Continuing to push the bar higher for what is considered a successful program does not necessarily help all patients- particularly extremely sick patients that entail more complex transplants.

**5. Membership Standards for Organ Perfusion Companies**

UNOS staff informed the Committee about those members who had volunteered to participate on the MPSC's Organ Perfusion Membership Standards Work Group. Additional work group members from the 2016-2017 MPSC roster will also be asked to

join these efforts upon the rotation of committee members on July 1, 2016. This work group's first meeting is scheduled for March 24.

**6. Joint Society Work Group Prijects Report**

Earlier in the year, the MPSC resubmitted for project approval four of its projects addressed by a Joint Societies Working Group (JSWG) that the OPTN/UNOS Executive Committee placed on hold in June 2015. These four projects - Elimination of OPTN/UNOS Bylaws Regarding Approved Transplant Fellowship Programs; Aligning OPTN Bylaws' Primary Kidney Transplant Physician Pathways with Transplant Nephrology Fellowship Requirements; Modify Primary Transplant Surgeon Qualifications: Primary or First Assistant on Transplants and Procurements; and, Primary Transplant Physician Subspecialty Board Certifications – are the four JSWG projects that proposals had already been drafted for submission during the summer 2015 public comment cycle, but do not include all of the JSWG projects that the Executive Committee placed on hold. UNOS staff informed the MPSC that the Executive Committee approved moving forward to public comment with these projects, with the exception of Modify Primary Transplant Surgeon Qualifications: Primary or First Assistant on Transplants and Procurements. The OPTN/UNOS Vice Chair explained that the Executive Committee opted to leave this project on hold due to its alignment with goal 4 (Promote living donor and transplant recipient safety), and the disproportionate number of goal 4 projects in the OPTN project portfolio relative to the OPTN strategic plan. He continued that the Executive Committee will be reviewing the entire project portfolio again this spring, and that this particular project will be reconsidered at that time to accommodate the possibility that a public comment proposal could be distributed during the next public comment cycle in August.

Committee members commented about the JSWG process, suggesting that the process "shuts down" the community's discussion of these topics. The Committee noted that feedback provided in response to any JSWG project usually receives a response along the lines of, 'This is what is the JSWG came up with, and because of that process, there isn't much flexibility with regards to what is being proposed.' A Committee member commented from the perspective of an AST member, most have no idea that a JSWG has been formed and what those groups are discussing. Then, seemingly all of a sudden, policy and Bylaws changes that stem from this process are made by the OPTN. Another Committee member referenced the original intent of creating this process - consensus building prior to public comment- and responded that the concerns raised about this process is likely an unintended consequence of developing potential policy and bylaws changes in this manner. OPTN/UNOS Vice President stated that it would be reasonable for the effectiveness and efficiency of this process to be reviewed by OPTN leadership, to include feedback from OPTN members and the three other organizations that are involved in the JSWG process- American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), and the Organization for Transplant Professionals (NATCO).

The Committee also raised questions about the specifics of two of the MPSC's JSWG proposals:

Approved fellowship training programs: The Committee indicated it believed that it is important that transplant program key personnel can still qualify through the respective fellowship pathways in the OPTN Bylaws. UNOS Staff reassured the Committee that these pathways will remain a viable option, and that this proposal solely focuses on

eliminating the OPTN approval process of fellowship programs that could be cited for the purpose of qualifying as key personnel through the fellowship pathways.

Primary surgeon qualifications: primary, co-surgeon, or first assistant on transplant cases: An MPSC member raised questions about inclusion of the term "co-surgeon" in this proposal. UNOS staff reminded the Committee that this specific term was included as a direct response to feedback provided by the MPSC during its March 2015 meeting when the Committee discussed this proposal as it prepared for the proposal's distribution during the fall 2015 public comment cycle. If there are significant questions or concerns about this particular term, or any of the language included in any of these proposals, then it is the MPSC's responsibility to discuss and update each proposal as necessary so that it is proposing Bylaws changes that reflect what the MPSC believes is necessary to update. UNOS staff reiterated that it is critical that the MPSC review these draft proposals for this purpose because, if the Board of Directors ultimately adopts the Bylaws changes included in these proposals, all OPTN members will be held responsible to the expectations established by the modified Bylaws language.

**7. Local Backup Work Group Report**

The MPSC Vice Chair alerted the Committee of recent decisions reached by Committee and OPTN leadership to pause the current local backup work group efforts. The work group's discussion have revealed that this topic has more layers than establishing a consistent definition for "local back up," including a number of questions raised about the entire allocation review process. UNOS has embarked on several projects to evaluate its monitoring practices. Analyzing the entire allocation monitoring process is a part of these efforts, including the use of "local back up," to identify allocation monitoring improvement opportunities. Ultimately, the purpose of an entire review of UNOS monitoring practices is to optimize the value added through allocation monitoring. The Local Backup Work Group's efforts are being paused to allow staff the time to conduct these analyses. Progress and final results of these efforts will be reported back to the full committee.

**8. 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 and December 31, 2013, and these thresholds increase by 10% for 2014 and 2015 donors. The Committee will be reviewing new cohorts of data once a year at each July meeting, to monitor members' progress.

The Committee continued its discussion of the process for reviewing these members. The Committee believes that the purpose of the policy was to encourage follow-up, increase the available data on living donors, and make sure that the donation process was safe. However, at its upcoming July meeting, the Committee needs to find a way to stratify member compliance, since the Committee will be reviewing the 2013 two year follow-up forms, the 2014 six month forms, and the 2014 one year forms. Overall, data submission compliance has improved, and the Committee is interested in monitoring member progress. If a member continues not to meet the thresholds, but has increased its level of follow-up, the Committee will consider that in its review. In addition, the Committee is planning to consider how the program's ability to meet the thresholds may be impacted by the number of donors with expected data. The UNOS Research Department will be creating reports for the Committee to use in its review of programs, to try to show compliance and progress.

The Committee also suggested trying to work with members of the Living Donor Committee, to determine whether they are getting the information they need from this policy, and whether the policy requirements are still appropriate.

**Implemented Committee Projects**

None discussed

**Review of Public Comment Proposals**

**9. Improving Post Transplant Communication of New Donor Information (DTAC)**

The Committee reviewed this proposal at its March meeting and offered the following comments:

- The Committee supports a requirement for OPOs to perform toxoplasmosis testing on all deceased donors. This will allow for more efficient communication of positive results to all of the transplant programs receiving organs from a donor since the results are likely to be returned after organ recovery. If policy allows a transplant program to perform toxoplasmosis testing, then Policy 15.5.A (Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy) needs to specify a timeframe for the transplant program to report the test result back to the host OPO – preferably within 24 hours after receiving the result.
- The proposal needs to address timeframes for OPOs to obtain test results. Results cannot be communicated until they are received, so delays in obtaining test results can be just as harmful as delays in communicating received results.
- The list of pathogens of special interest needs to be located somewhere that is easy for members to find. UNOS needs to communicate changes to the list like policy changes, with formal notice to all members in advance of the effective date, so that members can educate their staff and remain compliant with reporting requirements.
- OPTN policy should not address tissue donors, tissue donation, or communication between OPOs and tissue banks. The tissue donation process is heavily regulated by the FDA, so redundant oversight by the OPTN is unnecessary.
- Table 15-1 in Policy 15.4.A (Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions) requires the host OPO to report positive cultures from tissue specimens. The policy needs to specify whether these are tissue specimens taken during organ recovery, tissue recovery, or both. OPO representatives on the committee are not supportive of including tissue specimens taken during tissue recovery.
- Table 15-1 contains contradictory language between the header, which says, “The host OPO must report all of the following positive results”, and the 8th row, which says “Any histopathology results (including negative results) reported post-procurement.” If the requirement to report negative results is intentional, it may be overlooked in a table addressing reporting of positive results.
- The policy requires both the transplant program and the host OPO to report the same event through the patient safety portal when a suspected donor-derived

transmission occurs in a transplant recipient. This redundancy may be intentional, but it seems inefficient for the OPO to have to report something already reported by the transplant program.

The MPSC also encourages the DTAC to continue identifying improvements to disease transmission reporting processes. OPO representatives on the committee described difficulties reaching designated patient safety contacts at transplant programs and the need to hire additional staff just to communicate necessary donor information. Transplant program representatives described inconsistent methods of communication from OPOs ranging from faxes and emails to phone calls and text messages. The committee is supportive of efforts to leverage technology in order to standardize the communication process and associated documentation and make communication more efficient.

[Brief statement of comments provided to the proposal's sponsoring committee. Formatting in this section is more condensed to save space.]

**Other Significant Items**

**10. 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 3 individual members
- Fully approve 2 public organizations
- Fully approve 3 medical/scientific organization

Existing Members

- Fully approve 4 transplant programs
- Fully approve reactivation of 1 transplant program
- Fully approve 1 conditional program and 1 living donor component
- Fully approve 2 transplant program and 1 living donor component conditional to full program status changes
- Fully approve 1 conditional program extension and 1 conditional living donor component extension

The Committee also reviewed and approved the following actions:

- 81 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:

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

**11. Living Donor Adverse Events**

The Committee reviewed two reported living kidney donor deaths within two years of donation, and one recovery procedure 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.

**12. Due Process Proceedings and Informal Discussions**

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

**13. Ethics Committee Referral: Requesting Feedback for a Report on Ethical Considerations of Imminent Death Donation (IDD):**

The Committee initially discussed the memo from the Ethics Committee on a teleconference in February, but agreed that there was value to discussing this concept again in person, given its controversial nature. The MPSC's discussion at the in-person meeting revolved around the following points.

The MPSC members believed this decision is outside the scope of the MPSC and impacts more than just the OPTN/UNOS. There was discussion about whether it was a conflict of interest for the transplant community to lead the effort to expand beyond the dead donor rule, or whether the OPTN needs to step in and be a leader to affect change. Federal and state laws may come into play, and it is unclear whether this would fall under the Uniform Anatomical Gift Act or informed consent laws (two things that OPOs would prefer to keep distinct).

MPSC members pointed out that it is difficult to determine whether this practice would necessarily increase the total number of transplants. There are clearly some patients that would be able to donate as IDD who are currently unable to donate, but at this point it is unknown what impacts this change could have on overall public perception of organ donation. The last time this topic was discussed, members of the Board of Directors received a large number of emails from members of the disabled and Catholic communities who were strongly opposed to the idea. The MPSC raised concerns that IDD could prompt a greater number of authorization declines for potential deceased donors, thereby creating an unintended consequence of an overall negative impact on the number of organs transplanted. There was also discussion that approaching families with the option of IDD or DCD may result in less organs donated if a patient would progress to donation after cardiac death (DCD), but the family chose IDD instead.

The Committee agreed that it is relatively straightforward to explain the concept that when a person has experienced cardiac or brain death, then he is dead, and if a person is alive and making the decision for himself to accept the additional risk of being a living donor, then that person is informed. However, it would be more difficult to explain to the general public that it is not crossing a line if someone in the family is allowed to make the organ donation decision for someone who is in the hospital and is not going to experience cardiac death or brain death. Currently, OPOs still get push back in some environments from people over whether the families' wishes or the patients' stated wishes are more binding.

The MPSC members discussed whether IDD was more like living donation, not causing harm to the patient or something different because the patient is not otherwise healthy like a typical living donor. One member mentioned that it might be a good subject for a

pilot for kidney donation by patients with specific neurological states. Another member suggested that perhaps first person consent should be required.

The Committee members stated that IDD would require a major paradigm shift, and were uncertain whether the United States is ready for that shift. Although it may work in other countries, their cultural and political circumstances are different from those in the United States. Acknowledging this, other Committee members responded that these types of paradigm shifts are likely necessary if the goal is to make significant impacts on organ availability.

The Committee was still concerned with ensuring that there are clear boundaries between the transplant hospital role and the OPO role in these cases. It was also interested in narrowing down how quickly a donor would need to progress to death in order to be "imminent" and determining if this would require a new membership type for which the MPSC would have to review applications.

**Upcoming Meeting(s)** ***(delete the parynthesis and/or the 's' if necessary)***

- April 18, 2016, 3:30-5:30 pm Call
- May 24, 2016, 3:00 – 5:00 pm Call
- June 28, 2016, 3:30 - 5:30 pm Call
- July 12-14, 2016, Chicago
- October 25-27, 2016, Chicago