

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 26-29, 2015
Chicago, Illinois

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

Discussions of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) committee on October 26-29, 2015 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. Key Personnel Procurement Requirements

Public Comment: [August 14 – October 14, 2015](#)

Some transplant program key personnel requirements in OPTN/UNOS Bylaws involving organ procurement experience need to be updated. Specifically, certain Bylaws have been recognized as unnecessary due to the evolution of transplantation, unenforceable as currently written, inconsistent across the different transplant programs, or including periods to obtain necessary procurement experience that have been restrictive and problematic for some members. This Committee developed and distributed a public comment proposal recommending Bylaws changes that address these issues and update transplant program key personnel procurement requirements. Proposed changes stemmed from recommendations provided by a Joint Societies Working Group, and include: deleting multi-organ procurement requirements for all key personnel; requiring that all primary transplant physicians must (as compared to “should”) observe three procurements of the organ that corresponds to the transplant program they are applying to be the primary physician of; removing “selection and management of the donor” requirements from the primary liver transplant surgeon pathways; and extending the time period for performing the requisite number of procurements in each primary transplant surgeon training pathway. Clarifying and updating these Bylaws primarily supports the OPTN strategic plan key goal of promoting the efficient management of the OPTN.

During its October 2015 meeting, the MPSC reviewed and considered all the public comment feedback provided in response to this proposal. After making changes to address the public comment feedback provided, the MPSC voted in support (29 For, 0 Against, 0 Abstentions) of sending these proposed changes to the OPTN/UNOS Board of Directors for consideration during its December 2015 meeting.

2. Delete “Foreign Equivalent” from Bylaws

Public Comment: [August 14 – October 14, 2015](#)

OPTN/UNOS Bylaws’ transplant program key personnel requirements use the term “foreign equivalent.” Specifically, transplant program key personnel are required to have current American board certification or the “foreign equivalent,” and cited experience must have been obtained at a designated transplant program or the “foreign equivalent.” This term is

unclear for members when assessing if certain staff are qualified to serve as transplant program key personnel and for the Committee when evaluating membership applications and determining if a board certification or case experience performed outside the United States should be considered equivalent. To address this problem, and after consideration by a Joint Societies Working Group, the MPSC proposes deleting the term “foreign equivalent” from the Bylaws (except for vascularized composite allograft (VCA) program key personnel); permitting board certification by the Royal College of Physicians and Surgeons of Canada in addition to American board certification; and establishing a new process for those individuals who are not American or Canadian board certified to qualify as transplant program key personnel. These proposed changes are anticipated to advance the OPTN Strategic Plan key goals of promoting living donor and transplant recipient safety and the efficient management of the OPTN. Changing the Bylaws to better reflect the training and experience expected of transplant program key personnel should contribute positively to increased transplant recipient safety. Additionally, removing the ambiguous term “foreign equivalent” and providing a detailed option to qualify as key personnel for those who do not possess American board certification should help promote the efficient management of the OPTN.

During its October 2015 meeting, the MPSC reviewed and considered all the public comment feedback provided in response to this proposal. After making changes to address some of the public comment feedback provided, the MPSC voted in support (29 For, 0 Against, 0 Abstentions) of sending these proposed changes to the OPTN/UNOS Board of Directors for consideration during its December 2015 meeting.

3. Remove Reference to Time Frames from Bylaws regarding Inactivation after Conditional Approval

Public Comment: N/A

The Committee is proposing a non-substantive change to the Bylaws regarding inactivation of a program after a period of conditional approval because the current bylaws are misleading. There are two main things contributing to this.

- The Bylaws stating that the program must inactivate after a fixed length of time are counter to the Bylaws stating that the approval period may vary depending on whether or not the conditional approval is extended at the discretion of the MPSC. The periods of time vary by program type.
- The paragraph in each section that explains extension of a conditional approval is after the paragraph that requires the transplant program to inactivate if they do not receive full approval at the end of their conditional approval period. It is in neither chronological nor logical order.

Changing the language to make it consistent provides more transparency about what may happen if a conditionally approved transplant program is unable to meet the full requirements for program approval by the end of its conditional approval period. It also provides clear guidance for the actions of the OPTN regarding decisions about conditionally approved transplant programs and living donor components.

During its October meeting, the Committee reviewed the proposed bylaw language and unanimously approved the language for consideration by the Board of Directors (29 For, 0 Against, 0 Abstentions).

4. Transplant Hospital Definition

The Committee received an update on the Working Group September's teleconference. First, the MPSC reviewed the transplant hospital definition elements that had been agreed to thus far:

- All transplant hospitals must continue to meet current requirements outlined in Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)
- Additionally, all of a member's transplant facilities
 - Must have common executive leadership and shared governance structure demonstrated to satisfaction of the MPSC
 - Must all be within a single DSA
- Transplant hospital includes either:
 - Facilities within a "contiguous campus"
 - Facilities within a specific distance
 - Other scenarios outside of these criteria may be reviewed and approved at the discretion of the MPSC; two locations not approved as a single member would need separate OPTN memberships
- The transplant hospital may include multiple ORs, ICUs, post-op care units, for transplant patient care
 - The operating room locations must be preemptively documented with the OPTN
 - Transplant hospital must assure that appropriate infrastructure to care for transplant patients is in place at each location

Prompted by feedback provided during the MPSC's August meeting, the Work Group presented other considerations for the full committee's review:

- *Expand on what defines a "continuous campus"*- The Work Group agreed to the following definition to define a "continuous campus:"

"The physical area within a boundary line drawn on a map that exclusively encompasses land and buildings owned by the hospital. The exclusion of separate commercial or residential property adjacent to hospital property dictates the placement of this boundary line."

- *Radial distance from main hospital if transplant facilities on a noncontiguous campus*- After discussing numerous options, and the pros/cons of each, the Work Group agreed to one mile walking distance. Acknowledging the arbitrary nature of any decision to this point, the Work Group agreed that this suggestion would be a reasonable recommendation to present and continue discussing. In considering this definition, it is important to note that a more restrictive radius would likely increase the frequency of cases that fall outside of the standard criteria and that would be presented for the MPSC's review. The amount of new MPSC work created by this proposal will need to be monitored upon implementation of these Bylaws. UNOS staff also noted that it appears the approval of transplant hospital facilities not included on a contiguous campus will heavily depend on the member demonstrating common governance and leadership. As such, the OPTN and MPSC will need clear documentation to validate this, and it will be important to know what resources could be used for this purpose.

- *Key personnel at more than one transplant hospital-* Previously, the work group agreed that key personnel should only be allowed to serve in this role for one transplant hospital. Committee members expressed concern with this approach. The Work Group discussed this further during its September teleconference, and agreed that a proposal to update the transplant hospital definition should not include changes to the current key personnel Bylaws. Although there are still concerns about individuals' ability to uphold all key personnel responsibilities at multiple transplant hospitals, in addition to other issues related to coverage plans at multiple transplant hospitals, the Work Group made this suggestion considering the potential that addressing key personnel in this proposal may incite additional controversy and distract discussion from the main focus of the proposal. If the MPSC believes that additional key personnel restrictions are necessary, then this issue can be explored separately from the transplant hospital definition discussions.
- Work Group discussion of key personnel segued into discussions about assuring that each transplant hospital only had one designated transplant program for each organ. The Work Group agreed this should be the case, and that the proposed Bylaws should incorporate considerations that only one transplant hospital can be approved for any particular hospital campus (as defined by one of the three options to be proposed; contiguous campus, within a one mile walking radius, or as approved per the discretion of the MPSC). This perspective prompted questions about how to handle pediatric hospitals that share a campus with another hospital, and that may want to retain (or obtain) a separate OPTN membership. The Work Group replied that it would seem necessary for proposed Bylaws to accommodate these situations. Accordingly, the Work Group modified its previous recommendation and stated that only one transplant hospital could be approved for any given campus area, unless the second proposed transplant hospital within that same area is a children's hospital.

In response to this recommendation, UNOS staff asked the work group how it envisioned operationalizing this distinction. The MPSC Vice Chair referred to the CMS conditions of participation for pediatric transplants to help the OPTN address this matter. Specifically, an approved pediatric program must perform 50% or more of its transplants in pediatric patients over a 12-month period. The work group thought a similar requirement would be appropriate to distinguish pediatric transplant hospitals for the purpose of allowing two discrete transplant hospitals within the same general campus area. The 50% or greater threshold should capture all hospitals that would traditionally be thought of as children's hospitals, while still allowing sufficient flexibility for the member to care for adult transplant candidates as is deemed necessary (e.g., congenital heart patients who are older than 18 years of age). The "children's transplant hospital" would be regularly monitored to assure that it is above this 50% threshold, and OPTN membership would be in jeopardy if this threshold is not sustained.

- *Multi-organ transplant considerations-* a final consideration raised by the MPSC pertained to multi-organ transplants, and whether the transplant hospital definition needed additional considerations to assure these more challenging procedures are approached safely. The Work Group considered this topic, and opined that the current construct of requiring individual program approval for each organ involved in a potential multi-organ transplant is effective.

The MPSC expressed its gratitude for the Work Group's efforts and indicated that it generally supported the concepts presented. Members noted that questions will likely be

raised about the “one-mile walking distance” parameter, and that the MPSC should continue to build its arguments for explaining this decision. Understanding that every transplant hospital may not fit into the contiguous campus or one mile walking distance definitions, the third option of allowing a transplant hospital to present their case before the MPSC seems to be a critical component that will bolster support for this proposal. The MPSC also raised questions about Veteran Affairs (VA) hospitals, and how this definition will accommodate those groups. The Working Group had not explicitly discussed VA hospitals, but indicated it would do so during its next teleconference. Additionally, the Work Group will also begin creating draft Bylaws that incorporate these concepts. These draft Bylaws will be presented for the full Committee’s consideration after the Work Group has sufficiently reviewed and refined the language. The Committee also suggested that it should reach out to interested stakeholders to build consensus around its proposed solution prior to distributing a public comment proposal.

5. Transplant Program Performance Measures Review (Outcome Measures)

The charge of the work group is to evaluate ways to decrease the perceived disincentives to transplant created by the current system for reviewing post-transplant outcomes. The ultimate goal of this evaluation is to discover ways to increase transplants. Since the last Committee meeting, the MPSC work group, joined by representatives from ASTS, AST, APO and UNOS leadership, met on August 4, September 18, and October 20. The work group has focused initially on modifying the methodology for post-transplant outcomes review for kidneys.

The work group has reviewed data on characteristics of discarded kidneys as well as the outcomes associated with similar kidneys that were transplanted to determine the appropriate criteria for those transplants that would be excluded from post-transplant outcomes reports. The work group has also reviewed literature on the characteristics of discarded organs. In addition, the Scientific Registry of Transplant Recipients (SRTR) has provided data on the effect of decreased discard rates on program evaluations and on a SRTR suggestion to reweight low and high risk transplants, thereby putting less emphasis on the higher risk transplants rather than excluding them from the model altogether. The work group developed a draft proposal that was presented to the Committee at its October 2015 meeting.

The draft proposal provides that the Committee would only make an inquiry to a kidney transplant program if the program falls outside the threshold for review of kidney graft or patient survival using all kidneys currently included in the analysis, and if they fall outside the threshold for review when kidneys from donors with Kidney Profile Donor Index (KDPI) greater than 85% or age greater than 65 are excluded from the analysis. The work group considered whether the criteria should include recipient characteristics but concluded that there was not enough data available to determine appropriate characteristics. In addition, the work group decided that the criteria should be kept simple; noting that the more complicated the criteria, the less likely it would affect change in behavior. There was significant discussion of the possibility of initially excluding programs that are currently under review for post-transplant outcomes. After discussion, the work group concluded that all kidney programs would be evaluated initially using the proposed operational rule. One outstanding issue was put before the Committee when the proposal was presented in October 2015. Should minimum survival criteria for these high-risk kidney transplants be established? If a program fell below a minimum survival requirement, the program would no longer be eligible to have these high-risk kidneys excluded from the MPSC post-transplant outcomes reports. The Committee did not make a decision on this issue.

Following discussion at the October 2015 meeting, the Committee did not approve the release of the proposal for feedback during the next spring public comment period. Questions were raised during the discussion about whether the workgroup's decision not to include recipient characteristics in the criteria was wise, and several suggested that EPTS scores could be used to identify appropriate candidates for high-risk kidneys. There was also considerable discussion about the proposed evaluation plan for the proposal. The Committee requested that the work group review additional data and conduct additional investigation of other options to fulfill the goal of the work group and report back to the Committee at its March 2016 meeting.

6. OPO Metrics

At its October meeting, the Committee received an update from the OPO Metrics Focus Group. The focus group met on October 12, to discuss whether it was an appropriate time for the group to review and evaluate the current yield model produced by the Scientific Registry of Transplant Recipients (SRTR). The SRTR plans to evaluate the model in late 2016. The focus group plans to review what is currently included in the model and the data currently collected in UNet and develop a list of additional data that should be considered for inclusion in the model. The group will also consider whether there is additional data that should be collected by the OPTN for inclusion in the model. Following this review, a memo will be sent to the OPO Committee providing its findings and suggesting a joint work group to evaluate the yield model and provide feedback to the SRTR. In addition, if the focus group determines that additional data should be collected, a memo will be sent to the Data Advisory Committee (DAC) requesting that the DAC consider the inclusion of this data in data collection.

Implemented Committee Projects

None discussed

Review of Public Comment Proposals

7. Establish Pediatric Training and Experience Requirements in the Bylaws

During its meeting in October the Committee was updated on the status of this proposal and the post-public comment amendments being considered by the Pediatric Committee. As the Committee did not have specific language to review, the Chair asked the Committee if it had any preliminary response to the general concepts that may be included as amendments, including: an exception clause for programs that do not have a designated pediatric component, removal of pediatric transplant lung surgeon and physician requirements, and reducing the transplant patient age that would necessitate a transplant program to have a pediatric component. The Committee briefly discussed these considerations, indicating that changes of this nature would be substantive and suggesting that an amended proposal should be redistributed for public comment.

Other Significant Items

8. 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 5 individual members
- Fully approve 2 public organizations
- Fully approve 1 medical/scientific organization
- Fully approve 2 business members

Existing Members

- Fully approve 12 transplant programs
- Fully approve 7 transplant program components
- Fully approve reactivation of 8 transplant programs and 1 living donor component
- Fully approve the reclassification of a laboratory from independent to hospital based
- Fully approve 1 conditional program and 2 conditional living donor components

The Committee also reviewed and approved the following actions:

- 157 applications for changes in transplant program personnel
- 12 applications for changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

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

9. Due Process Proceedings and Informal Discussions

During the meeting, the Committee conducted eleven interviews and one hearing with member transplant hospitals and OPOs.

Upcoming Meetings

- December 8, 2015, Conference Call
- February 2, 2016, Conference Call
- March 15-17, 2016, Chicago
- July 12-14, 2016, Chicago
- October 25-27, 2016, Chicago