

OPTN/UNOS Membership and Professional Standards Committee
Meeting Summary
March 25-26, 2015
Chicago, Illinois

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Discussions of the full committee on March 25-26, 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. Quality Assessment and Process Improvement Requirements (QAPI)

At its March meeting, the Committee approved one slight adjustment to the proposed language approved at the February conference call. In addition, the Committee reviewed the draft briefing paper and had no further revisions.

The Committee approved the revision to the proposed language by a vote of 30 For, 0 Against, 1 Abstention.

2. Joint Society Working Group Projects

During the Committee's March meeting, The Joint Societies Working Group (JSWG) Chair presented the JSWG's recommendations for the MPSC's consideration.

- "Foreign Equivalents"- the JSWG made the following recommendations on this topic:
 - Include certification by the Royal College of Physicians and Surgeons of Canada in the list of acceptable certifications
 - Delete all references to "foreign equivalent" in the OPTN Bylaws
 - Create additional, organ-specific pathways for proposed key personnel who are not American or Canadian board certified, that require the individual to:
 - Meet all other key personnel requirements included in the respective clinical experience pathway
 - Provide two letters of attestation from program directors not affiliated with the applying hospital
 - Obtain continuing medical education credits with self-assessment, comparable to what is expected of American board maintenance of certification for that respective field
 - Transplant Hospital and non-American board certified applicant responsible for maintaining documentation of adherence to this continuing education requirement
 - Subject to review by the MPSC/OPTN, upon request.

The MPSC suggested that the continuing medical education credits with self-assessment requirement should be extended over multiple years, empathizing with situations where unforeseen circumstances may prohibit individuals from obtaining the necessary credits in a given year. Instead of 20 continuing medical education credits with self-assessment per year, it was recommended that the requirement be 40

continuing medical education credits with self-assessment over the course of two years. The JSWG Chair agreed that was a reasonable modification.

The MPSC then proceeded to vote in support of these recommendations; 31-yes, 1-no, 0-abstentions.

- Primary Surgeon Qualification – Primary or First Assistant on Transplant Cases- The JSWG made the following recommendations:
 - Fellowship pathways- the application should include surgical training logs that have been submitted to the American Society of Transplant Surgeons or the American Board of Cardiothoracic Surgery during one’s training. The rationale is that if a case is accepted by these organizations for training purposes, then those cases should also apply towards OPTN primary surgeon requirements.
 - Clinical experience pathways- at least 50% of required cases must be performed as the primary surgeon. The JSWG recommends applying this only to the primary surgeon requirements in the clinical experience pathways for kidney, liver, and pancreas programs since the primary heart transplant surgeon and primary lung transplant surgeon clinical experience pathways already require a set number of cases as the primary surgeon.

An MPSC member asked how co-surgeons would be viewed with regards to these requirements. The JSWG Chair stated that he would envision co-surgeons counting towards the number of procedures that must have been performed as the primary surgeon. The MPSC did not object to this assessment, nor the general recommendations on this topic, and proceeded to vote in support of these recommendations: 31-yes, 0-no, 0-abstentions.

- Primary Physician Subspecialty Board Certifications- The JSWG made the following recommendations:
 - Remove the gastroenterology board certification requirement for primary liver transplant physicians from OPTN Bylaws
 - Replace with requirement that the applicant must possess current board certification in transplant hepatology or a current pediatric transplant hepatology certification of added qualification
 - Continue to monitor the prevalence of the Advanced Heart Failure and Transplant Cardiology certification subspecialty. Considering the relative newness of this certification, the JSWG did not think now was the appropriate time to make this change; however, a similar modification to the primary heart transplant physician certification requirements would seem prudent at an appropriate time in the future.

The MPSC then proceeded to vote in support of these recommendations: 31-yes, 0-no, 1-abstentions.

- Approved Transplant Fellowship Training Programs- The JSWG made the following recommendation regarding approved transplant fellowship training program Bylaws:
 - Eliminate all OPTN Bylaws that reference and define approved fellowship programs. Proceeding with this recommendation will establish consistency across all organs.

The MPSC voted in support of these recommendations: 29-yes, 0-no, 0-abstentions.

- Aligning Primary Kidney Transplant Physician Pathways with Transplant Nephrology Fellowship Requirements- The JSWG recommends:
 - Modify OPTN Bylaws to require that a primary transplant kidney physician must have evaluated:
 - 25 potential kidney recipients.
 - 10 potential living donors.
 - Modify Appendix E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway) to accommodate physicians that opt to complete their transplant nephrology fellowship through the Transplant Nephrology Fellowship Training Accreditation Program’s “alternative pathway.”
 - Allows for a fellowship period that extends longer than 12 months
 - Expands upon the case volume requirements for those who did not complete their fellowship in 12 months.

After little discussion, the MPSC voted in support of these recommendations: 31-yes, 0-no, 0-abstentions.

- Primary Physician Observation of Procurements Requirement- The JSWG made the following recommendations:
 - Modify OPTN Bylaws, for each organ type and each primary physician pathway, to require that each primary physician must have observed at least three organ procurements and three organ transplants.
 - Must include the organ of the transplant program that they are applying to be the primary physician of (OPTN Bylaws currently only require this for transplant observations, not procurements).
 - E.g., a primary liver physician must have observed three liver procurements and three liver transplants.
 - For primary transplant physicians at kidney programs, at least one of the observed procurements must be from a living donor and at least one must be from a deceased donor.

After minimal discussion, the MPSC voted in support of these recommendations: 29-yes, 0-no, 0-abstentions.

- Multi-organ Procurement Requirement- The JSWG made the following recommendation:
 - Delete multiple organ procurement requirements from OPTN Bylaws
 - Primary kidney surgeon pathways
 - All primary physician pathways

After minimal discussion, the MPSC voted in support of these recommendations: 29-yes, 0-no, 1-abstentions.

- Primary Surgeon Fellowship Pathway Procurement Period- The JSWG made the following recommendations:
 - Modify primary surgeon fellowship pathways OPTN Bylaws for each organ type to allow procurements performed during the two years immediately following the completion of one’s fellowship training to count towards the procurement requirements.

- This extended time period to meet the procurement requirements in the primary surgeon fellowship pathways should not be extended to any other fellowship pathway requirement.

After minimal discussion, the MPSC voted in support of these recommendations- 32-yes, 0-no, 0-abstentions.

- Primary Transplant Surgeon Procurements Including Donor Selection and Management- The JSWG made the following recommendation:
 - Delete the donor management and donor selection procurement requirement from the primary liver surgeon pathways in the OPTN Bylaws.

After minimal discussion, the MPSC voted in support of these recommendations- 28-yes, 1-no, 0-abstentions.

- Fellowship Pathway Log Signatures- The JSWG recommended:
 - Modifying the OPTN Bylaws for each organ so that every log required in the primary transplant surgeon fellowship pathways must be signed by the training program director.

The MPSC expressed some concerns with this recommendation. Committee members explained it is sometimes challenging to obtain the required signatures that correspond to fellowship experience when proposing key personnel through the fellowship pathways. Other committee members underscored these concerns, noting that they completed their fellowship over 20 years ago and that it would be extremely difficult, if not impossible, to obtain signatures from the training program director of their fellowship. UNOS staff replied to the MPSC that these recommendations intended to address the inconsistency with regard to this requirement across organ types, and that these signatures are already often supplied, even though they aren't required. As these signatures are not a new requirement for most of the required procurement logs provided through the fellowship pathway, failing to act on the JSWG's recommendations will not address the concerns raised by the Committee. Nevertheless, the MPSC was hesitant to adopt this recommendation without additional considerations to address its concerns. The MPSC ultimately supported a motion to oppose this particular recommendation- 27- yes, 4- no, 1- abstention.

The JSWG Chair empathized with the concerns raised by the MPSC, and stated that he would bring this feedback back to the group for further discussion during their next scheduled teleconference.

3. Multi-organ Transplant Performance Review

The chair of the Multi-organ Transplant Performance Review Work Group provided an update to the Committee at its March 2015 meeting.

The work group met on March 6 by conference call. On that call, the policy liaison to the Kidney Transplantation Committee's SLK Working Group presented an update on the work of that group. In addition, the SRTR presented its data analysis of liver multi-organ transplants using the fall 2014 program specific reports (PSRs). After reviewing the additional data analysis provided by the SRTR, the work group concluded that multi-organ transplant outcomes should be reviewed separately from single organ transplant outcomes, the MPSC should initially review simultaneous liver/kidney transplant outcomes and separate models should be utilized for the SLK transplants and the single organ transplants. Before recommending the implementation of any review process, the work group would like to develop and execute a SLK pilot evaluation. The next task for

the work group is to develop recommendations for the MPSC on how to execute the pilot.

4. Organ Perfusion Membership Standards Working Group Update

At its March 2015 meeting, the Committee received an update that this group continues to meet to work on these matters.

5. Transplant Hospital Definition

The Committee continued its discussion of the proposal to clarify the definition of a transplant hospital in the bylaws. The proposal was posted for public comment from September 29 to December 5, 2014, and received mixed reviews. The Committee decided during its February 4 conference call to continue to improve the proposal and to withhold forwarding it to the board of directors in June. During its March 25-26, meeting, the Committee listened to the feedback from the work group, which met on March 6. It considered the request to broaden the definition to incorporate multiple hospitals under a single membership, without regard to geographic limitations such as shared walls, same state, same DSA, or maximum distances between facilities. It identified three tasks that to work on during the next quarter:

- Investigate impact on allocation policies & waitlist, which may need to be re-engineered if a new definition is substantially different than the present one.
- Develop & conduct survey to evaluate the business models.
- Propose a revised transplant hospital member definition in the OPTN bylaws

6. Outcomes Measures Discussion (proposal for increasing transplants)

Following a presentation by the OPTN President at the December 2014 meeting, a work group was formed in mid-January and held meetings on February 6 and February 26. 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. The work group has reviewed data and information from members of the ASTS/AST/AOPO/UNOS (AAAU) leadership group and the Scientific Registry of Transplant Recipients (SRTR). The chair of this work group presented an update to the Committee at its March 2015 meeting.

Review of Public Comment Proposals and Preliminary Proposals

7. Proposal to Increase Committee Terms to Three Years

During its March meeting the Committee provided feedback to the Policy Oversight Committee (POC) on a pre-proposal idea to extend all committee terms to 3 years. They discussed the options and the nuances that might be involved with a change in the term of the regional representatives and their ascension to the board. They also talked about the workload of the committee and the susceptibility of burn out towards the end of the third year. The Committee voted to support extending the MPSC terms to 3 years with the exception of the chair and vice chair. The vote was 23 For, 8 No, and 0 Abstentions.

8. HIV Organ Policy Equity Act Planning

The OPO Committee's public comment proposal to define pancreas graft failure was presented to the Committee. The MPSC was generally supportive of this proposal but offered the following comments:

- Measures were introduced to safely transplant HIV positive recipients with good outcomes. One member expressed a concern for reinfection with a large viral load of a different species and a different drug sensitivity or resistance at a time when the immunosuppression is at its highest during induction.
- Can the recommended changes be programmed in UNetsm by November 2015, when the HOPE Act is implemented?
- If an HIV positive donor is positive by NAT testing, is there enough time to do viral loads on these donors and is there enough time to do drug sensitivity?
- Concern that many donor hospitals may have trouble finding staff to be involved with large blood exposure with known HIV positive donor.
- What will be the process for the OPTN learning that a hospital's IRB has been approved?
- The Committee also suggested that the Policy 16.7.B *Vessel Recovery, Transplant, and Storage* be reviewed because the first sentence appears to preclude storage and the second appears to allow it as long as the OPTN contractor is notified.

Living donor related comments:

The Committee understands that this proposal currently only applies to transplanting livers and kidneys from HIV positive donors and does not address living donors. The Committee did offer comments related to living donors since it is presumed that they will be part of the final research protocol.

- Need to consider opening up to living donor because there are so few brain dead HIV positive donors.
- Concern about extending an experiment that has no data yet for living donors that may be HIV positive. What is their risk of renal failure in the future?

The Committee was informed that the NIH would be soliciting comments on this issue.

9. Modify or Eliminate Internal Vessel Label

The MPSC supports this proposal from the Operations & Safety Committee, to modify the sterile internal vessels label, because it simplifies labeling process while providing critical information.

10. Clarify Requirements for Blood Type Verification and Align with CMS Regulation Where Possible

The MPSC reviewed this proposal from the Operations & Safety Committee and was generally in support. It suggested that the language could be amended to provide additional clarification in the following sections:

- Section 2.15.B Organ Procurement: Pre-Recovery Verification: There were questions about the verification process in the OR by the recovery surgeon. It is intended that each different recovery surgeon (team) perform a quick verification or time out. There was discussion about "time-out" having multiple interpretations, but it was pointed out that the term is not used in the proposed policy. The OPO develops their own protocol and process to confirm the required information. The Committee noted that the verification of recipient information by the recovery surgeon has been removed from the proposal.
- Section 2.6.B – Deceased Donor Blood Subtype Determination: A committee member suggested that the language might need to be clarified. It is not clear whether the subtyping policy requiring pre-red blood cell (RBC) transfusion specimens be used to determine subtype applies only to donors receiving RBC

products during the current hospitalization or if it includes a specific period prior to the current hospitalization as well. The 2011 guidance document on subtyping explains that any red blood cell products given within the past 4 months could potentially affect results, but the committee suggested that it needed to be clarified in the Policy itself.

- The Committee also asked that the Guidance document on TransplantPro be updated.

In addition, the Committee observed that there may at times be limited samples of pre-transfusion blood as needed for the two lab tests. It may be difficult to obtain two samples that have the same basic hemodilution status, and not having two samples may create a situation where donors are considered to be high risk solely for that reason.

11. Proposal to Collect Ex Vivo Lung Perfusion (EVLV) Data for Transplant Recipients

The Committee reviewed the Thoracic Organ Transplantation Committee's proposal to collect ex vivo lung perfusion data for transplant recipients and offered the following comments:

- How would a program indicate "where were the lungs pumped" that lungs were recovered and put on the pump in the Donor Hospital then transported on the pump to the transplant hospital and continued pumping?
- How does the Committee plan on identifying "marginal" lungs and their outcomes since marginal lungs are not defined in policy.
- Will forms capture if a commercial entity or the transplant hospital is perfusing the lungs? While the "Other" field can be used, the preferred choice is for "3rd party perfusion company" to be an option rather than a free text field.
- This is a good first step but there is not enough granularity in the system for determining if one EVLP technique leads to better outcomes or has fewer patient safety risks than another has.

In summary, the Committee was concerned that if the additional essential data elements are not added during this review period that it will be difficult to add them later. Additional data elements are needed in order to collect the data needed for statistical analysis in the future.

12. Improve UNet Reporting of Aborted Procedures and Non Transplanted Organs (Living Donor Committee)

The MPSC supported this proposal. The Committee asked what happens if a donor surgery is aborted then restarted on another day. For example, if the donor had an adverse reaction to the initial anesthesia and the surgery was aborted and rescheduled after additional evaluation, how would the donor ID be assigned? Would a new donor ID be issued or could the original one still be used? There was some concern that if new ID was issued and the donor's history would not be available to the hospital that ultimately performed the donation surgery.

13. Membership Requirements for Vascularized Composite Allograft Transplant Programs (Vascularized Composite Allograft (VCA) Committee)

The Membership and Professional Standards Committee reviewed the proposal and offered the following comments:

- This proposal is silent on living VCA donation. It is not clear what transplant programs would need to do in order to perform living donor VCA transplants.
- At a minimum, the proposal should have specified that living donor recovery could only occur at a transplant program that has another approved living donor program that would provide some minimum level of expertise.
- The proposal does not have any requirements for the living donor VCA recovery surgeon and/or physician.

The Committee also reviewed the Guidance Document for Living VCA Donations. The Committee understands that the guidance document may address some of these issues in the short term but it was concerned that these elements need to reside in the bylaws as requirements, since guidelines do not carry the same force as policy.

Other Significant Items

14. Primary Heart Transplant Surgeon- VAD training & experience requirements

At its March 2015 meeting, an MPSC member suggested that the primary heart transplant surgeon Bylaws should include requirements that pertain to training and experience with ventricular assist devices (VADs). The MPSC agreed that it would be reasonable to continue discussing the need for primary heart transplant surgeon requirements that focused on VADs. The Committee stated that a small working group should be formed with members of the Thoracic Committee, and that group's conclusions should be presented to the MPSC for final consideration. Three MPSC members volunteered to represent the MPSC on this working group, and UNOS staff said it would communicate with the Thoracic Committee's support staff to make it aware of this discussion and in pursuit of additional working group participants.

15. Member Related Actions and Personnel Changes:

During the March meeting, the Committee reviewed and approved applications from new and existing members. The Committee will ask the Board of Directors to approve recommendations for approval during its June 1-2, 2015, meeting:

- New Member
 - Approve 1 new transplant hospital
- Existing Members
 - Fully approve 3 transplant programs
 - Conditionally approve 1 new living donor component for 12 months
 - Approve 1 transplant program reactivation

The Committee also reviewed and approved the following:

- Program-Related Actions and Personnel Changes:
 - 55 applications for changes in transplant program personnel
 - 6 applications for changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 4 transplant programs withdrew from membership
- 2 living donor component withdrew from membership
- 4 transplant programs and 1 histocompatibility lab inactivated
- 5 OPO key personnel changes

16. Late Notification of Key Personnel Change

The Committee discussed two transplant hospital members that had not met the notification requirements in the Bylaws.

17. Live Donor Adverse Events Reporting

As required in Policy 18.5.C (Submission of Living Donor Death and Organ Failure), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed three mandatory reported cases, all living donor deaths. The Committee is not recommending any further action to the Board at this time for any of the issues.

18. Due Process Proceedings and Informal Discussions

During the meeting, the Committee conducted four interviews with member transplant hospitals and OPOs. The Committee is not recommending any further action to the Board for any of these issues.

Upcoming Meetings

- April 14, 2015 (conference call)
- July 14-16 , 2015
- October 27-29, 2015