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This report reflects the work of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) Committee between October 2014 and April 2015.

Action Items

1. Membership Status Changes and Application Issues
   Public Comment: N/A
   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 2 new transplant hospitals
   - Fully approve 1 individual member
   - Fully approve 2 public organizations
   - Fully approve 2 medical/scientific organizations
   
   Existing Members
   - Fully approve 8 transplant programs
   - Conditionally approve 1 new transplant program for 24 months
   - Conditionally approve 3 new living donor component for 12 months
   - Fully approve reactivation of 5 transplant programs and 1 living donor component

2. Quality Assessment and Process Improvement Requirements (QAPI)
   Public Comment: September – December, 2014
   The Committee developed a proposal (Exhibit A) to require members to develop, implement, and maintain a quality assessment and performance improvement (QAPI) plan. The Committee has noted that members having difficulty with compliance or performance often do not have well-developed QAPI programs. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and remain in compliance with OPTN obligations.

   The Committee considered feedback from public comment on the proposal and revised the proposal to remove the requirement that the QAPI plan contain certain specified components. The Committee approved the revision to the proposed language by a vote of 29 For, 0 Against, and 1 Abstention.

   RESOLVED, that Bylaws Appendix B and Appendix D are modified as set forth in Exhibit A, effective September 1, 2015.
Committee Projects

3. Projects Referred to the Joint Society Working Group

Public Comment: August 2015, January 2016

At its December 2014 meeting, UNOS staff provided an update on the progress made by the Joint Society Working Group (JSWG) that is focusing on a number of topics related to key personnel requirements in the Bylaws. MPSC members expressed some concern with some aspects of the preliminary 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. To conclude this discussion, UNOS staff agreed to provide the MPSC’s feedback to the JSWG for further discussion.

At its March 2015 meeting, the JSWG Chair presented the JSWG’s recommendations for the MPSC’s consideration. The following provides the recommendations presented for the MPSC’s consideration, and the feedback provided by the MPSC in response:

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/UNOS 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
  - Make the transplant hospital and non-American board certified applicant responsible for maintaining documentation of adherence to this continuing education requirement
  - Documentation of adherence to the continuing medical education credits requirement will be 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/UNOS 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/UNOS Bylaws.
- Add a 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 Committee then proceeded to vote in support of these recommendations: 31-yes, 0-no, 1-abstentions.

### Approved Transplant Fellowship Training Programs

Regarding approved transplant fellowship training program Bylaws, the JSWG recommended that the Board eliminate all OPTN/UNOS Bylaws that reference and define approved fellowship programs. The JSWG believes that proceeding with this recommendation will establish consistency across all organs.

The Committee 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 made the following recommendations:

- Modify OPTN/UNOS Bylaws to require that a primary transplant kidney physician must have evaluated:
  - 25 potential kidney recipients
  - 10 potential living donor
- 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.”
OPTN/UNOS Membership and Professional Standards Committee

- Proposed modifications will allow individuals who did not complete their fellowship in 12 months (i.e., physicians who completed their fellowship through the Transplant Nephrology Fellowship Training Accreditation Program’s alternative pathway) to qualify as a program’s primary kidney transplant physician through the transplant nephrology fellowship pathway outlined in OPTN/UNOS Bylaws Appendix E.3.A.

- In addition to deleting language that requires the fellowship was completed in 12 months, the JSWG recommends increasing the case volume requirements for those who did not complete their fellowship in 12 months to reflect similar expectations of those who complete their fellowship through the Transplant Nephrology Fellowship Training Accreditation Program’s alternative pathway.

After little discussion, the Committee 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/UNOS 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.
- The procurement requirements must include the organ of the transplant program that they are applying to be the primary physician of (OPTN/UNOS 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 Committee voted in support of these recommendations: 29-yes, 0-no, 0-abstentions.

Multi-organ Procurement Requirement

The JSWG recommends that the Board delete multiple organ procurement requirements from OPTN Bylaws. Specifically, multiple organ procurement requirements should be deleted from all primary kidney surgeon pathways and all the primary physician pathways for each organ.

After minimal discussion, the Committee 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 in the OPTN/UNOS 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 Committee voted in support of these recommendations: 32-yes, 0-no, 0-abstentions.
Primary Transplant Surgeon Procurements Including Donor Selection and Management

The JSWG recommends that the Board delete the donor management and donor selection procurement requirement from the primary liver surgeon pathways in the OPTN/UNOS Bylaws.

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

Fellowship Pathway Log Signatures

The JSWG recommends that the Board modify the OPTN/UNOS 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 are not 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.

During the MPSC’s April 2015 meeting, UNOS staff reminded the Committee that moving forward with these modifications is also contingent upon the Joint Societies Policy Steering Committee’s endorsement of the recommendations. Hopeful for this endorsement and in anticipation of the fall 2015 public comment cycle, the Committee worked on preliminary draft Bylaws that incorporated the changes recommended by the JSWG and supported by the Committee at its March 2015 meeting. Committee members provided guidance on particular questions raised by UNOS, while also noting other areas of concern.

4. Transplant Hospital Definition

Public Comment: September – December, 2014

Board Consideration: TBD

The Committee continued its discussion of the proposal to clarify the definition of a transplant hospital in the bylaws. The proposal was distributed for public comment from September 29 to December 5, 2014, but received mixed reviews. The Committee decided during its February 4 conference call to continue to discuss the proposal and not to forward it to the Board of Directors in June.

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:

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

Questions they considered included

- What are we trying to monitor?
- Are outcomes influenced by the facility?
- Instead of redefining a hospital, does there need to be a higher-level membership category?
- Could we take an approach similar to CMS, where the member decides how it will apply?

The Committee discussed these concepts and agreed there had to be some limitations, such as facilities must be within the same region and DSA and have the same reporting structure.

They supported the concept of conducting a survey of the transplant programs to identify current geographic and organizations models and well as the potential fiscal impacts or applying the currently proposed definition. They did have some concerns about whether members would complete a voluntary survey; even if it is collecting information that would inform their recommendations.

The Committee also considered that there are potential ramifications to changing the way we presently monitor members, and that it would mean that combined hospitals would “live and die together”. Additionally, they had concerns about bait and switch practices, which could mask bad outcomes or potential patient safety issues.

The Committee discussed following a process similar to CMS – that is, the hospitals must all be in the same DSA, limited geographic distance, same reporting structure, and allow members to make the case that they meet the guidelines. HRSA pointed out that the Committee should not let the current IT system dictate its response.

One of the comments heard during the public comment period was the worry that the original proposal might have a fiscal ramification because of duplication of services and required paperwork, if current members needed to separate into multiple hospitals. The Committee considered ways this could be mitigated, for example, when a hospital and/or program relocated to a new facility. Currently, the new location must complete an application, but the Committee suggested that this burden could be lessened if all the staff are the same.

Next Steps: The work group will hold another conference call in the coming weeks and will work on developing the questions for the survey. One of the Committee members suggested seeking input from the Transplant Administrator’s Committee and the AST Community of Practice Transplant Administrators on the survey questions.

5. Outcomes Measures (Proposal for Increasing Transplants)

At the December 2014 Committee meeting, 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 in November. The goal of increasing the number of transplants was
OPTN/UNOS Membership and Professional Standards Committee

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/UNOS 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 a MPSC work group to meet with the AST/ASTS/AOPO work group to hear their ideas and work on a proposal.

A MPSC 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 chair of this work group, Dr. David Cronin, presented an update to the Committee.

At the first meeting on February 6, the work group met with the members of the ASTS/AST/AOPO/UNOS (AAAU) leadership group. Kevin O’Connor presented a summary of this group’s discussions and ideas. The presentation by Mr. O’Connor on behalf of the AAAU group focused on opportunities to decrease the number of discarded organs. The core concepts of the AAAU group suggestions involve the creation of a secondary allocation pathway and an outcome measuring system that will incentivize programs to perform “non-ideal” transplants. A secondary allocation pathway would match up organs that were at high risk for discard with programs willing to accept these organs for its candidates. In addition, the group suggested an alternative outcome metric be created for review of transplants involving those non-ideal organs. Mr. O’Connor noted that there is a perception in the community that for those transplants where a less than ideal donor organ is used in a recipient with substantial risk factors, the risk factors are not fully adjusted for in the expected outcomes.

At the second meeting on February 26, the SRTR provided a presentation previously given to the AAAU group on risk adjustment for kidney transplants. The SRTR provided the group with information regarding the factors included in the old and the new kidney graft failure model. Data regarding the effectiveness of the new risk adjustment model to account for high risk donor factors and for combined donor and recipient risk was reviewed. The data indicates that the model effectively adjusts for risk in donors and recipients for those data points currently collected by the OPTN. Work group members noted that there might be factors that affect the acceptance of organs that are not currently factored into the risk adjustment.

The work group plans to investigate further the characteristics of discarded organs in an effort to determine common characteristics that lead to discard that may not currently be captured in the risk adjustment. The SRTR has been asked to determine adjusted outcomes for donors where kidneys were transplanted that had similar risk to those donors where kidneys were recovered but not transplanted. Additionally, the SRTR has been asked to assess the impact of utilization of these organs on centers’ risk adjusted performance metrics and show the demographic distribution for these discarded organs as well as the matched transplanted organs. In addition, the work group requested that UNOS staff gather literature on the characteristics of discarded organs. The work group also requested that the SRTR repeat the analysis of evaluation of the kidney model risk adjustment for varying levels of donor and recipient risk profiles for liver transplants and heart transplants. Finally, the work group concluded that there appears to be a need for education on the effectiveness of risk adjustment.
6. Multi-organ Outcomes Work Group Update

Prompted by discussions at the March 2014 meeting, a work group was formed to review options for inclusion of multi-organ transplant outcomes in the Committee’s performance reviews. Currently, multi-organ transplants are excluded from the Scientific Registry of Transplant Recipients’ (SRTR) patient and graft survival models and are not monitored separately. Previously, the work group reviewed data from the SRTR on the options available for review of multi-organ transplants using data from the spring 2014 Program Specific report (PSR) cohort. The decisions required of the work group and ultimately the MPSC include:

- Which multi-organ transplants they would like to evaluate?
- Which program will be held accountable?
- Whether to evaluate multi-organ recipients separately from single-organ recipients?

The work group has been focusing on multi-organ transplants involving a liver. These are the most numerous multi-organ transplants. Following review of the SRTR analysis of all multi-organ transplants involving a liver in November, the work group’s thoughts were to initially review simultaneous liver/kidney which are the most numerous multi-organ transplants and to evaluate multi-organ recipient outcomes separately from single organ recipients. In order to evaluate the issue, the work group requested that the SRTR provide an analysis of SLKs at the next work group meeting.

At the March Committee meeting, the chair of the work group, Dr. Sudan, provided an update on its meeting by conference call on March 6, 2015. The SRTR presented its data analysis of liver multi-organ transplants using the fall 2014 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.

In addition, at its March 6 work group conference call, the policy liaison to the SLK Working Group presented an update on the work of that group.

7. Composite Pre-Transplant Metrics (CPM)

Public Comment: September 26 – December 5, 2014

Board Consideration: TBD

The purpose of this proposal is to provide the MPSC with a tool, the Composite Pre-transplant Metric (CPM), for identifying kidney and liver programs that may be in need of review based on outlying performance in accepting deceased donor organ offers, transplanting waitlisted patients, and/or mitigating waitlist mortality. The CPM is an aggregate, pre-transplant performance metric that combines programs’ acceptance rate, geography-adjusted transplant rate, and waitlist mortality rate observed-to-expected (O/E) ratios into a single number for prioritizing programs for potential review.

The proposal was distributed for public comment from September 29 to December 5, 2014. The Committee reviewed the responses to public comment during its February call. The Committee noted the concerns raised by many of the commenters about some of the component models and the inability to adequately evaluate the proposal without access to their own program’s metrics. In response, the Committee formed a work group to determine
if the metrics can be fine-tuned or need significant revision, and to develop a plan for
distribution of the metrics prior to implementation. The work group will meet on May 29 and
provide a report to the Committee at its July 2015 meeting.

Committee Projects Pending Implementation

None

Implemented Committee Projects

8. Requests for Exceptions Based on Geographic Isolation

Public Comment: March 14 – June 13, 2014

Board Approval: November 2014

Implementation Date: February 1, 2015

The new Bylaws established a mechanism for the MPSC to recommend that the Board of
Directors consider approving designated transplant programs located in Alaska, Hawaii, or
Puerto Rico that do not meet all of the key personnel requirements in the Bylaws because of
their geographic isolation. The Committee can only make this recommendation if they
conclude that the geographically-isolated applicant’s key personnel have a satisfactory level
of transplant experience. The applicant must also have an established history of transplant
success for the specific organ type indicated in their application. Similarly, the Board will
now be able to approve a geographically isolated transplant program upon recommendation
from the MPSC. The Board will be considering a request for program approval under this
bylaw during the June meeting.

9. Proposal to Clarify Data Submission and Documentation Requirements

Public Comment: March 14 – June 13, 2014

Board Approval: November 2014

Implementation Date: February 1, 2015

The revised policy explicitly states that members are obligated to submit accurate data and
provide documentation to support the accuracy of their data, if the MPSC requests it. Since
the proposal has been implemented, the MPSC has not received any similar arguments
from members that have been cited for submitting inaccurate information.

Review of Public Comment Proposals

The Committee reviewed seven of the 18 proposals released for public comment from
September to December 2014, and 5 of the 10 proposals released for comment between
January and March 2015.

10. Define Pancreas Graft Failure (Pancreas Committee)

The Pancreas Transplantation Committee’s public comment proposal to define pancreas
graft failure was presented to the Committee for comment during the December meeting.
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.

11. Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II) (Histocompatibility Committee)

During the December meeting, 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.

12. Proposal to Allow Collective Patient and Wait Time Transfers (Operations and Safety Committee)

During the December meeting, the Committee reviewed the Operations and Safety Committee (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 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 natural disaster situation that temporarily results in a transplant hospital not being able to transplant?
13. Proposal to Clarify Definition of Organ Transplant and Transplant Date (Policy Oversight Committee)

During the December meeting, 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.

14. Improving the OPTN Policy Development Process (Executive Committee)

During the December meeting, the Committee reviewed the Executive Committee’s public comment proposal to amend the policies to improve the responsiveness of OPTN policy to a changing environment. The Committee offered the following comments:

- 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.

15. Policy Rewrite Parking Lot - “Quick Fixes” (Policy Oversight Committee)

During the December meeting, the Committee considered the Policy Oversight Committee’s (POC) public comment proposal to amend the policies to address easy, non-controversial changes. The following comments were made during the discussion of this proposal:

- 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.
- A Committee member asked if the POC or another work group could review the policy to address the allocation for multi-organ transplants.
  - When is an OPO required to give a kidney with an extra renal organ (and multi-organ transplants)?
  - Look at donor to determine which ones are potentially multi-organ, what is the hierarchy (i.e. does the kidney go with the heart or the kidney go with the liver).

The Committee was informed that the POC was also considering multi-organ allocation and it will either address it or direct another committee to do so. A subcommittee of the Ethics Committee is also considering this topic.

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

During the December meeting, Sue McDiarmid, M.D., and Rich Luskin, chair and vice chair respectively of the Vascularized Composite Allograft (VCA) Committee, presented the draft VCA membership requirements to the MPSC. The Committee 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 that this experience should be stated more prominently.

The Committee also discussed the following elements of the proposal and suggested that the proposal or briefing paper narrative include an explanation of the following issues:

- The importance of the primary surgeon for each VCA type observing the multi-organ procurement process and if both abdominal and cardiothoracic organs must be recovered during these two cases. Dr. McDiarmid indicated that the VCA Committee had tried not to be overly prescriptive about these guidelines and if both types must be included in the multi-organ cases. The Committee suggested that the proposal narrative could further elaborate on this requirement and the reason for its inclusion.

- Clarification that an individual patient can be counted in more than one category of procedures found in Table J.1 (Minimum Procedures for Upper Limb Primary Transplant Surgeons) and Table J.2: (Minimum Procedures for Head and Neck Primary Transplant Surgeons).

- Several committee members pointed out the need for a close coordination with the OPO during these recoveries. While the current version of Appendix J.1 reiterates the need for a written agreement with the OPO, it is not in the current draft. Since similar language exists in Appendix B.3.A and Appendix D.3.B the requirement to document the arrangement is still in the bylaws, but it was thought that the need for close coordination could be emphasized in the proposal or briefing paper narrative.

Dr. McDiarmid presented the final VCA membership requirements proposal to the MPSC during its March meeting. The MPSC 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.

Dr. McDiarmid also provided an overview of 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.

17. Address Requirements outlined in the HIV Organ Policy Equity Act Planning (OPO Committee)

Dr. Daniel Kaul presented this proposal to the MPSC. The Committee was supportive of this OPO Committee sponsored proposal, but offered the following comments/concerns:

- 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 UNet™ 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 informing the OPTN 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 these 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.

18. Modify or Eliminate Internal Vessel Label (Operations & Safety Committee)

The Committee reviewed the Operations & Safety Committee sponsored proposal that seeks to modify the requirements for the sterile internal vessels label. The amount of information required on this label will be reduced. The Committee supports this proposal to modify the sterile internal vessels label, because it simplifies labeling process while providing critical information.

19. Clarify Requirements for Blood Type Verification and Align with CMS Regulation Where Possible (Operations & Safety Committee)

This proposal sponsored by the Operations & Safety Committee, will amend the policies to clarify requirements related to ABO blood type determination, reporting, and verification for donors and candidates; strengthen current key system safety components; and align OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) blood type requirements more closely. The MPSC reviewed this proposal 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 at times there may 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. Not having two samples may create a situation where donors are considered high risk solely for that reason.

20. Proposal to Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients (Thoracic Organ Transplantation Committee)

The Committee offered the following comments regarding this Thoracic Organ Transplantation Committee proposal.

- 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.

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

The Committee supported this proposal, which was sponsored by the Living Donor Committee. 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 a new ID was issued that the donor’s history would not be available to the hospital that ultimately performed the donation surgery.

Other Committee Work

22. Education & Communication: Effective Practices & Process Improvement:

During the December meeting, the Committee members recommended reviewing possible educational efforts regarding USPHS Increased Risk and Living Donation Informed Consent requirements based on the patient safety concerns associated with these policy violations, the complexity of the requirements and the number of violations reviewed by the Committee. The Committee also recommended educating members on best practices for corrective action plans to ensure members are able to thoroughly and proactively address their compliance issues and to facilitate the MPSC’s review of potential policy violations.

When it met in March the Committee suggested the following as items for possible educational efforts:
OPTN/UNOS Membership and Professional Standards Committee

- Classifying donors as USPHS Increased Risk and communicating a donor's increased risk status to transplant programs
- Primary physicians’ and primary surgeons’ responsibilities under the Bylaws
- The need for OPOs to use two unique identifiers
- Guidelines regarding when to weigh donors

The Committee suggested that UNOS consider modifying assigned donor identification numbers to exclude numbers and letters that can easily be confused with each other and contribute to labeling errors. The Committee also noted that the community might benefit from guidelines, suggestions, and/or templates regarding what members should include in submissions to the MPSC.

23. Organ Perfusion Membership Standards Working Group Update

At its December 2014 meeting, 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/UNOS 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/UNOS 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.

At its March 2015 meeting, the Committee was informed that this group continues to meet and discuss these issues.

In early April, UNOS staff distributed a document to the Organ Perfusion Membership Standards Working group that listed the working group’s recommendations, questions raised in response to those recommendations, and other possible alternatives that might be considered. The purpose of this document is to determine the pros and cons of each approach to assist OPTN/UNOS leadership when it considers whether to approve this topic as a formal project for the MPSC to continue working on, and if so, to help determine the approach that should be pursued. Working group members were asked to review this document and provide feedback in preparation for these future project review discussions.

24. Primary Heart Transplant Surgeon - VAD Training and Experience Requirements

A Committee member suggested that the primary heart transplant surgeon Bylaws should include requirements that pertain to training and experience with ventricular assist devices (VADs). During the March meeting, the Committee reviewed a brief presentation that demonstrated the increasing prevalence of VADs in heart transplantation, and arguments why heart transplant procedures involving VADs are more complicated such that additional considerations in the Bylaws directed at this experience would be appropriate.

The Committee 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 committee 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. UNOS staff
also reminded the Committee that any potential Bylaws changes would need to go through the normal OPTN/UNOS policy/bylaws development process, including the need for project approval by the Executive Committee.

25. Criteria for Intestine Surgeons and Physicians (Liver and Intestinal Organ Transplantation Committee)

During the October meeting, Dr. Beau Kelley, a member of the Liver and Intestinal Organ Transplantation Committee, presented the proposed membership and personnel requirements for intestine transplant program to the MPSC for its input prior to the formal public comment period. The Committee considered the modifications that had been made to the proposal in response to comments received during the spring 2014 public comment period and made several suggestions that would improve the proposal.

26. Pediatric Program Requirements (Pediatric Transplantation Committee)

During its December meeting, prior to the formal public comment period, 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.

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.

27. Infectious Disease Verification Process to Enhance Patient Safety - Pre-Proposal Review

The Committee was updated on this project, which was referred to Operations & Safety Committee (OSC) in part from the MPSC, because infectious disease cases were reported where results were available that would affect the transplant, but the results had not been reviewed. This resulted in near misses or disease transmission. The Committee was informed that the OSC is gathering input and plans to have a proposal ready to release for public comment in August. For more information, see the Operations and Safety Committee’s June 2015 Report to the Board of Directors.

28. Data Advisory Committee (DAC) Presentation – Pre-Proposal Review

The Committee heard a presentation from the Data Advisory Committee liaison regarding the Committee’s efforts to seek broad input in developing a long term, innovative vision for the OPTN/SRTR data set. Specific areas addressed were the data release policy, the evaluation of current and new data elements for OPTN database, and improvements to the OPO metrics & measures.

The MPSC was supportive of this effort by the DAC. Committee members specifically noted the importance of collecting data that will help us better understand the donor population and how the organs are being utilized. For more information, see the Data Advisory Committee’s June 2015 Report to the Board of Directors.

29. Proposal to Increase Committee Terms to Three Years – Pre-Proposal Review

The Committee provided feedback to the Policy Compliance 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.

The Committee also reviewed the general comments that were submitted to the POC from the MPSC members who participated in an earlier on-line survey. The primary reason that members favored a 3-year term was that it took them so long to come up to speed on the committee. Committee members were asked for ideas on for improving the orientation and training program, and whether or not they thought a mentor program would be helpful. The Committee support the mentor concept. Members offered the following suggestions:

- Balance mentorship with perspective of new members
- Two-tier training program with orientation in July and ongoing topics presented in a 1-2 hour session prior to each MPSC meeting.
- More training on the Committee Management System (regarding how to view case discussions) and the Dashboard navigation
- Advice on how to best organize their time and committee expectations
- How to conduct an interview (hearing, informal discussion)
- Include practical work, such as case studies during orientation
- Give new members actual past cases to review and talk through with staff/mentor during orientation
- Organize cases on Committee Management by type to improve time allocation

For more information about the proposal, see the Policy Oversight Committee’s June 2015 Report to the Board of Directors.

30. 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 thresholds will increase for donors who donated in 2014 and again for donors who donate in 2015.

During the December meeting, the Committee reviewed the specific elements required by the policy and reports of 59 living donor programs not meeting at least one of the required thresholds for the 2013 donors six month follow-up forms. The Committee discussed recommendations for addressing the current violations. The Committee also discussed its plan for its continued review of non-compliance, including the upcoming increase in the minimum reporting thresholds and the upcoming availability of one year and two-year follow up forms. Based on its discussions, the Committee requested that noncompliant members submit corrective action plans. The Committee decided to provide links to various educational and compliance tools to noncompliant members.

During the March meeting, the Committee reviewed the programs’ responses. The Committee discussed common themes in the program responses and recommendations for addressing the current violations. The Committee continued its discussions regarding the best methods for reviewing non-compliance with this policy. The Committee determined that additional work is needed to refine the review process. The Committee will continue to monitor non-compliant programs as it refines its review process. The Committee also decided to provide the themes from the corrective action plans to the Living Donor Committee.

31. Member and Applicant Related Report of Committee Actions

The Committee reviewed and approved the following actions:
• 150 applications for changes in transplant program personnel
• 11 applications for changes in histocompatibility lab personnel
• The Committee also received notice of the following membership changes:
  • 4 transplant programs inactivated
  • 1 histocompatibility lab inactivated
  • 4 transplant programs withdrew from membership
  • 3 living donor components withdrew from membership
  • 12 OPO key personnel changes

The Committee discussed three transplant hospital members that had not met the key personnel notification requirements in the Bylaws and issued all three members a Notice of Uncontested Violation.

The Committee discussed several other unique applications and made recommendations on each.

32. Living Donor Adverse Events Reporting

As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) and Policy 12.8.5 (Reporting of Non-utilized Living Donor Organs), 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. Transplant programs also must report instances when a recovered live donor organ is transplanted into a recipient other than the intended recipient within 72 hours.

During the December meeting, the Committee reviewed three 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 discussed a potential need for a policy change clarifying which member is required to report non-utilized organs in a kidney exchange, and is not recommending any further action to the Board at this time for any of the issues.

During the March meeting, 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.

33. OPO Metrics

The Committee reviewed eight organ procurement organizations (OPOs) for lower than expected organ yields when it met in December. Following its review, the Committee recommended that six OPOs be released from monitoring and two OPOs continue in monitoring by the Committee. During the March meeting, the Committee reviewed three organ procurement organizations (OPOs) for lower than expected organ yields. Following its review, the Committee recommended that one OPO be released from monitoring, one OPO continue in monitoring by the Committee and one OPO be sent an initial inquiry by a vote of 30 For, 0 Against, 0 Abstentions.

The focus group also continued to examine ways to decrease the burden on OPOs responding to MPSC inquiries. Specifically, the group has been revising the initial questionnaire and reviewing ways to decrease the number of donors on which the OPOs will be requested to report. The focus group has decreased the number of questions and revised some of the questions on the initial survey to provide more guidance on the information requested. In addition, when an OPO is under review, the MPSC requests that the OPO provide certain information on all donors where at least one organ was
transplanted but the organ for which the OPO is identified was not. For OPOs identified based on lower than expected kidney yield, the list of donors can be quite long. The focus group explored two options to decrease the number of donors that an OPO would need to address in its response. The first option was to develop certain criteria, such as KDPI over 85%, positive HBC or HCV serologies, PHS high risk or offers in the extreme tail of the OPO's distribution, to eliminate donors. The focus group reviewed this data and noted that not all of these variables were associated with lower organ yield. The second option was to rank the donors based on the difference between the expected and observed yield and determine a cutoff to create a list of donors the OPO would need to address. The expected is derived from the organ yield models as provided in the SRTR’s OPO Specific Reports (OSRs). The focus group reviewed these two options and data regarding the number of donors each option would produce for four example OPOs.

The OPO Metrics Focus Group recommended and the Committee approved the following:

- Use of the revised initial survey
- Provide a list of kidney donors for the OPO under review to address based on the ranking between the expected and observed yield using two cutoffs.
  - Donors with a gap greater than 1.2 between expected and observed kidney yield
  - An additional 25% of donors with a gap between 1.2 and 0.7 between expected and observed kidney yield
- Use new survey and new method of identifying kidney donors during the next three MPSC cycles. Focus group will meet in late 2015 or early 2016 to evaluate the new survey and donor identification method and to evaluate whether to begin to review OPOs identified for lower than expected pancreas yield.

The Committee approved the recommendations of the OPO Metrics Focus Group by a vote of 30 For, 0 Against, 0 Abstentions

34. Due Process Proceedings and Informal Discussions

During the December and March meetings, the Committee conducted 5 interviews and 2 informal discussions with member transplant hospitals and organ procurement organizations. The interviews and informal discussion were convened as provided for in Appendix L (Reviews, Actions, and Due Process) of the Bylaws.

35. Approval of Committee Actions

During the meetings held on October 7 and December 9-11, 2014; and February 4, March 24-26, and April 14, 2015, the Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

Meeting Summaries

The Committee held meetings on the following dates:

- October 7, 2014
- December 9-11, 2014
- February 4, 2015
- March 24-26, 2015
- April 14, 2015

Meetings summaries for this Committee are available on the OPTN website at: http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=8.