

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
March 21, 2016
Chicago, IL**

**Sue Dunn, RN, BSN, MBA, Chair
Jennifer Milton, BSN, CCTC, MBA, Vice Chair**

Discussions of the full committee on March 21, 2016 are summarized below. All committee meeting summaries are available at <http://optn.transplant.hrsa.gov/>.

Committee Projects

1. None

Committee Projects Pending Implementation

2. None

Implemented Committee Projects

3. **Proposal to Increase Committee Terms to Three Years**

The policy language became effective March 1, 2016, but will not impact current committee member terms. The policy language will be effective for new committee member terms beginning in July 2016.

The Committee planned on discussing the committee participation indicators for the implementation plan during the in-person meeting, but did not get to that agenda item. It was agreed that the participation indicators discussion be moved to the April 14, 2016 full committee teleconference.

Review of Public Comment Proposals

4. None

Other Significant Items

5. **Committee Project Portfolio Work Plan**

Projects follow a relatively linear path before they are presented to the POC for project review. Staff collect project ideas from multiple sources: Committee members, Board members, HRSA, the public, etc. Ideas are assigned to a policy analyst to discuss with the leadership of the potential sponsoring committee. They discuss whether the idea is worth pursuing and the general priority of the idea. Some ideas won't progress past this point. If committee leadership are supportive of the idea, and there are staff resources available, then staff and the committee will begin analyzing the problem; often times this requires the UNOS Research Department to review data in the OPTN data system. Once the committee understands the problem, has a concept for the solution, and agrees that it is worthy of resources, then the committee will prepare a project proposal for POC consideration.

Staff resources are not guaranteed for projects until the POC recommends approval of the project. After that point, the project is sent to the Executive Committee for approval and is prioritized for resources across the company. At this point, the project moves from

analyzing the problem to evidence gathering. Generally speaking, proposals are also not permitted to proceed to public comment unless the POC and Executive Committee have approved the project.

Once a year, usually at the spring in-person meeting, the POC reviews the entire committee project portfolio work plan, including ongoing projects and any new proposed projects. On March 21st, POC members reviewed projects in the following categories:

- Ongoing projects already part of the committee portfolio work plan
- New projects that were sent back to POC by the Executive Committee for further evaluation
- New projects that the POC were reviewing for the first time

For new projects, POC members completed a survey that asked questions regarding the quality of the problem statement, whether the proposal has evidence to support the problem, need for collaboration, development of project timeline, and primary strategic goal alignment.

For ongoing projects, POC members completed a survey that asked questions regarding whether the project was on track with proposed timeline, still fit the originally approved primary strategic goal, and whether the project should continue.

The POC provided all comments about these projects that were entered as part of the survey to the sponsoring Committee for their consideration.

The POC uses the results of the survey to make a recommendation to the Executive Committee regarding which 28 new and ongoing projects should be approved to be part of the committee portfolio.

6. Ongoing Projects Already Part of the Committee Portfolio Work Plan

POC recommends approval of all ongoing projects that were out during the spring 2016 public comment cycle, due to their progress. The 9 most recent public comment proposals are not included in the work plan below.

The POC recommends approval of the following ongoing projects:

Goal 1 – Increasing the number of transplants

- Guidance on Explaining Risk for Increased Risk Donor Organs When Considering Organ Offers – DTAC (20-Yes, 0-No, 0-Abstain)
- Improving Allocation of Double and En Bloc Kidneys – Kidney (20-Yes, 0-No, 0-Abstain)
- Removing Disincentives for Candidates to Consider Living Donation – Living Donor (20-Yes, 0-No, 0-Abstain)
- Transplant Program Performance Measures Review – MPSC (20-Yes, 0-No, 0-Abstain)
- Clinical Thresholds for Transplant Program Outcome Reviews – MPSC (20-Yes, 0-No, 0-Abstain)
- System Optimizations to Expedite Organ Allocation and Increase Utilization – OPO (20-Yes, 0-No, 0-Abstain)
- Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types – Pancreas (20-Yes, 0-No, 0-Abstain)
- Define Exhausting the Match Run – International Relations (20-Yes, 0-No, 0-Abstain)

- POC recommends approval with December 2016 deadline for completion (no further resource allocation after December 2016).
- Ethical Considerations of Imminent Death Donation – Ethics (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval with project resource allocation ending with final white paper action item to Board in June 2016.

Goal 2 – Promote equity in access to transplants

- Liver Distribution Redesign Modeling (Redistricting) – Liver (20-Yes, 0-No, 0-Abstain)
- Changes to HCC Criteria for Auto Approval – Liver (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval because of its need to accompany National Liver Review Board project. HCC is a key component to the success of those projects.

Goal 4 – Promote living donor and transplant recipient safety

- Histocompatibility Testing Guidance Document – Histocompatibility (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval with guidance document going to Board in June 2016.
- Define Transplant Hospital – MPSC (20-Yes, 0-No, 0-Abstain)
- Infectious Disease Verification Process – Ops and Safety (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval with praise for the OSC in delaying public comment until after ABO Verification implementation in June 2016.
- Review Existing White Papers for Accuracy and Relevancy – Ethics (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval since two white papers (Presumed Consent and Split Liver) will go to the Board in June 2016. The POC wants a detailed timeline for the rest of the white papers before the next POC review.

Goal 5 – Promote the efficient management of the OPTN

- Approved Transplant Fellowship Training Programs – MPSC (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on Joint Society Work Group (JSWG) completion and December 2016 Board timeline.
- Updating Bylaws' Primary Kidney Transplant Physician Requirements – MPSC (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on JSWG completion and December 2016 Board timeline.
- Primary Physician Specialty/Subspecialty Board Certifications – MPSC (20-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on JSWG completion and December 2016 Board timeline. POC also changed the primary strategic goal from Goal 4 to Goal 5 to better align with other MPSC projects.

7. New Projects That Were Sent Back to POC by the Executive Committee for Further Evaluation

The POC recommends approval of the following new projects that were sent back to POC by the Executive Committee for further evaluation:

Goal 2 – Promote equity in access to transplants

- Ethical Implications of Multi-Organ Transplants – Ethics (17-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on importance to multi-organ as a whole and low level of effort; it also corresponds to direct initiative in the strategic plan.
- Broader Sharing of Adult Donor Lungs – Thoracic (13-Yes, 4-No, 0-Abstain)
 - POC recommends approval if some EVLP aspects are incorporated, and due to its connection to the Exhausting Match Run project.

Goal 5 – Promote the efficient management of the OPTN

- OPTN Data Vision Statement – Data Advisory (17-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on HRSA request, no public comment, draft already sent to HRSA, June 2016 Board date, and low level of effort.
- Consider Primary Surgeon Qualifications – MPSC (17-Yes, 0-No, 0-Abstain)
 - POC recommends approval based on JSWG completion and December 2016 Board timeline. POC also changed the primary strategic goal from Goal 4 to Goal 5 to better align with other MPSC projects.
- Clarify Multi-Organ Allocation Policy – OPO (16-Yes, 1-No, 0-Abstain)
 - POC recommends approval based on importance to clarify existing policy language and plan substantive changes to multi-organ project timeline; IT also changed level of effort from large to small.

8. New Projects That the POC Were Reviewing for the First Time

The POC does not recommend approval of the Changes to KAS: CPRA and priority for patients undergoing desensitization project proposed by the Histocompatibility Committee. This new project was originally voted down 0-Yes, 16-No, 2-Abstain but histocompatibility expertise was not clarified – POC will re-evaluate this new project when Histocompatibility expertise can be given at the next POC meeting.

The POC recommends approval of the following new projects that the POC were reviewing for the first time:

Goal 1 – Increase the number of transplants

- Guidance on Increasing Pancreas After Kidney (PAK) Transplants – Pancreas (11-Yes, 6-No, 1-Abstain)
 - POC recommends approval with a close vote. Pancreas Committee will finish with a data analysis soon to make final decision on problem analysis.

Goal 3 – Improve waitlisted patient, living donor, and transplant recipient outcomes

- Modification of Existing and Potential New Requirements for the Informed Consent of Potential Living Donors – Living Donor (17-Yes, 0-No, 1-Abstain)
 - POC recommends approval and placed it in Goal 3 (Outcomes) instead of Goal 4 (Safety) due to the outcome related informed consent risks that are the focus of the project.

- Review HLA Tables (2016) – Histocompatibility (18-Yes, 0-No, 0-Abstain)
 - POC recommends approval and decided any of the HLA Table Review projects in the future should also be categorized in Goal 3.

Goal 5 – Promote the efficient management of the OPTN

- Modify Data Submission Policies – Data Advisory (18-Yes, 0-No, 0-Abstain)
 - POC recommends approval due to its importance to data integrity, future data reports and projects, and possibly an impact on member burden of submission.

9. Fiscal Impact Discussion

Emily Ward, policy analyst, used POC members as a focus group to gather feedback on a newly developed fiscal impact process. This initiative is an effort to allow the Board of Directors to consider high level direct financial implications to member organizations. A process for gathering fiscal information and a template for reporting it will be based on member and staff input. A draft proposal will be presented at the June 2016 Board Directors meeting. OPTN members would like the Board of Directors to review the potential financial impact of proposed projects to their organizations during the policy development process. Currently, only UNOS potential financial impact is estimated on the Resource Assessment Impact Summary (RAIS) for each project, presented at Board meetings.

The Committee also reviewed fiscal impact survey questions and process. POC members asked questions about who from the external members would fill out the fiscal impact survey, and how those organizations get chosen. Emily answered that organizations, chosen by volume and target audience of project, choose who the best person is to fill out the survey, and that organizations will be chosen on rotating basis so no hospital, OPO, or lab is targeted for every project.

POC members were worried about the time commitment for organizations to complete the fiscal impact survey, but were overall supportive of the process, and agreed that there was a need for external fiscal impact analysis for policy proposals.

10. Transplant Hospital Definition Discussion

Jeff Orłowski, Vice Chair to the Membership and Professional Standards Committee (MPSC), presented new progress of the transplant hospital definition project. The MPSC is currently engaged in an effort to modify the definition of a transplant hospital. This may seem like a pretty straight forward issue, but for the MPSC’s purposes, it has become a sticky wicket. The transplant hospital definition in policy/bylaws has not been touched since it was originally adopted by the Board in 1986. Recent membership applications and corresponding discussions have revealed that the current definitions is too simplistic as it relates to the evolving structure of medical systems and hospitals, and is prone to varying interpretations. A proposal to update these definitions was submitted for public comment the latter part of 2014, but the feedback was not very favorable. So, the MPSC went back to the drawing board to develop a different approach to address this matter.

After Jeff presented, the POC members asked questions regarding the impact of the new definition to several scenarios that were specific to their programs. The POC was supportive of the progress made on the project and supportive of the new version of the transplant hospital definition. The transplant hospital definition project will most likely go to public comment in August 2016, so POC will review it again to recommend whether it meets all requirements for community input.

Upcoming Meetings

- April 14, 2016, Conference Call, 12-1 p.m. ET
- May 12, 2016, Conference Call, 4-5 p.m. ET
- June 9, 2016, Conference Call, 12-1 p.m. ET