

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
April 14, 2016
Conference Call**

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

Discussions of the full committee on April 14, 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 discussed the difference between the committee participation indicators and the committee member job descriptions. There was confusion, thinking that both documents were the same deliverable. UNOS staff explained that the committee participation indicators were to be used as discussion tools for UNOS staff, committee leadership, and committee members. With committee terms being three years, there was wide agreement that some way to discuss engagement and participation of committee members was needed. The committee member job descriptions were not part of this project. That is a deliverable being worked on by Board of Directors Leadership and being reviewed by the Corporate Affairs Committee.

Committee members expressed that clarity and definition of purpose was needed to introduce the committee participation indicators to committee members. Some committee members were against any participation indicators, citing volunteer status and busyness of schedules. UNOS staff and other committee members proposed that different types of engagement be included, not just attendance, such as e-mail engagement, case or project reviews, subcommittee work, etc.

The Vice Chair of the Membership and Professional Standards Committee (MPSC) advocated for the use of some sort of participation indicator, referencing its use in the MPSC and its positive effects of engagement and meeting deadlines.

The project lead will take the feedback and draft an updated version of the committee participation/engagement indicators to use when the three terms project becomes effective for new members in July 2016.

Review of Public Comment Proposals

4. None

Other Significant Items

5. Recap of POC Recommendations to Executive Committee

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

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.

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

POC recommended 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 were also recommended to proceed.

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

The POC recommended 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)
- Broader Sharing of Adult Donor Lungs – Thoracic (13-Yes, 4-No, 0-Abstain)

Goal 5 – Promote the efficient management of the OPTN

- OPTN Data Vision Statement – Data Advisory (17-Yes, 0-No, 0-Abstain)
- Consider Primary Surgeon Qualifications – MPSC (17-Yes, 0-No, 0-Abstain)
- Clarify Multi-Organ Allocation Policy – OPO (16-Yes, 1-No, 0-Abstain)

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

The POC did 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 re-evaluated this new project when Histocompatibility expertise was given at the April 14 POC meeting.

The POC recommended 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)

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)
- Review HLA Tables (2016) – Histocompatibility (18-Yes, 0-No, 0-Abstain)

Goal 5 – Promote the efficient management of the OPTN

- Modify Data Submission Policies – Data Advisory (18-Yes, 0-No, 0-Abstain)

6. Executive Committee Decisions based on POC Recommendations

The Executive Committee met on April 11, and made decisions on the Committee Portfolio Work Plan using POC recommendations and their own discretion. The decisions were presented to the POC during its April 14 meeting.

- **Approved Projects**
 - All ongoing projects
 - OPTN Data Vision Statement (Goal 5)
 - Consider Primary Surgeon Qualifications (Goal 5)
 - 2016 Review HLA Tables (Goal 3)
 - Guidance on Increasing Pancreas after Kidney Transplants (Goal 1)
 - Modification of Existing and Potential New Requirements for the Informed Consent of Potential Living Donors (Goal 3)
- **Non-approved Projects**
 - Ethical Implications of Multi-Organ Transplants (Goal 2)
 - Clarify Multi-Organ Allocation Policy (Goal 5)
 - Broader Sharing of Adult Donor Lungs (Goal 2)
 - Modify Data Submission Requirements (Goal 5)

Betsy Walsh, President of UNOS Board of Directors, joined the April 14 meeting to help explain the Executive Committee decisions and answer any questions. She explained that the Executive Committee is committed and consistent in its message that the strategic alignment benchmarks are meaningful and the OPTN needs to be in closer alignment. This meant that several Goal 2 (equity in access) and Goal 5 (efficient management of OPTN) projects were not approved, as Goal 1 (increase transplants) and Goal 3 (outcomes) are vastly underallocated. Her and POC Leadership encouraged POC members to bring Goal 1 and Goal 3 projects for POC review.

One POC member asked if the Board is planning on re-evaluating the benchmarks of the strategic plan. The answer was that the Board may re-evaluate the benchmarks but it would not be until the strategic plan needed to be reviewed. Currently, the OPTN Strategic Plan is 2015-2018.

7. Review/Revisit New Histocompatibility Project

The new project *Changes to KAS: CPRA priority for patients undergoing desensitization* was reviewed by POC at its in-person March 21 meeting. Unfortunately, there was no histocompatibility expertise at the meeting to present the project. The project was

recommended not to move forward to the Executive Committee with a 0-Yes, 16-No, 2-Abstain vote.

UNOS staff and POC leadership decided to allow re-review of the project when histocompatibility expertise was available. The Vice Chair of the Histocompatibility Committee presented the project again with responses to previous comments, a newly defined smaller scope, and reasons why the project could be considered part of Goal 3 (outcomes).

After discussion, the POC moved to vote on the strategic alignment of the project. The Committee voted that the project should now be considered a Goal 3 primary project (13-Yes, 0-No, 1-Abstain).

The Committee then voted to recommend approval of the project to the Executive Committee in its new goal and smaller scope (13-Yes, 1-No, 0-Abstain).

POC will review more new projects during its May 12 meeting, and will present all new project recommendations to the Executive Committee during its June meeting.

Upcoming Meetings

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