

**OPTN/UNOS Policy Oversight Committee
Meeting Minutes
January 15, 2019
Conference Call**

**Jennifer Milton, BSN, CCTC, MBA, Chair
Alexandra Glazier, JD, MPH, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via teleconference on 01/15/2019 to discuss the following agenda items:

1. Public Comment Proposal Review
2. New Project Review
3. Eliminate the Use of DSA and Region in Kidney and Pancreas Allocation Concept Paper Review

The following is a summary of the POC's discussions.

1. Public Comment Proposal Review

Prior to the meeting, UNOS staff distributed a survey to POC members to review and provide feedback on the following eight public comment proposals:

1. Eliminate the Use of DSAs and Regions in Thoracic Distribution
2. Eliminate the Use of DSAs and Regions in VCA Distribution
3. Expedited Organ Placement
4. Split Liver Variance
5. Modify Hope Act to Include Other Organs
6. Clarifications on Reporting Maintenance Dialysis
7. Ethical Implication of Multi-Organ Transplant
8. Effective Practices for Broader Sharing

The POC reviewed the results of the survey and discussed each proposal in order to validate that they all met the OPTN/UNOS standards for policy development and to make recommendations to the OPTN/UNOS Executive Committee about their readiness for public comment. Seven of the public comment proposals received high survey scores and unanimous support in the pre-meeting survey and were placed on the consent agenda. The survey results of these proposals are provided below:

Proposal	Total Average	Proceed (Y/N)
Clarifications on Reporting Maintenance Dialysis (Living Donor Committee)	4.9	3 Yes; 0 No
Modify HOPE Act Variance to Include Other Organs (Ad Hoc Disease Transmission Advisory Committee)	4.7	3 Yes; 0 No
Ethical Implications of Multi-Organ Transplants (Ethics Committee)	4.2	4 Yes; 0 No

Proposal	Total Average	Proceed (Y/N)
Eliminate the Use of DSAs and Regions in Thoracic Distribution (Thoracic Transplantation Committee)	4.4	5 Yes; 0 No
Region 8 Split Liver Variance (Liver and Intestinal Organ Transplantation Committee)	4.4	5 Yes; 0 No
Eliminate the Use of Regions in VCA Distribution (Vascular Composite Allograft Committee)	4.3	5 Yes; 0 No
Expedited Organ Placement (Organ Procurement Organization Committee)	4.6	4 Yes; 0 No

One proposal, *Effective Practices for Broader Organ Sharing*, did not receive unanimous support and was placed on the discussion agenda. The survey results for this proposal were:

Proposal	Total Average	Proceed (Y/N)
Effective Practices for Broader Organ Sharing (Operations and Safety Committee)	4.4	2 Yes; 1 No

Summary of discussion:

The vice-chair of the POC presented information on the alignment between the current project portfolio and the strategic plan. The vice-chair stated that it is fine that Goal Two (Increase equity in access to transplants) is currently over-allocated, but that it is more concerning that Goal Four (Promote living donor and transplant recipient safety) has no current projects.

The POC did not have any comments on the proposals included on the consent agenda.

A formal vote was taken regarding: Does the POC vote to recommend to the Executive Committee that the seven public comment proposals on the consent agenda be approved for public comment?

Results were as follows: 18 (100%) Yes; 0 (0%) No; 0 (0%) Abstain

The POC then discussed the one proposal on the discussion agenda. The POC member who voted “No” did not feel strongly that the proposal should not proceed to public comment. Rather, he or she wanted the opportunity to say that the document should be more prescriptive than it is currently written. A POC member who helped write the proposal noted that it is difficult for a guidance document to be too prescriptive because it would then require policy change.

The vice-chair stated that this concern should not prevent the document from going out for public comment. The POC member who helped write the document asked if the rest of the POC felt that there was other content that should have been included in the proposal. A POC member agreed that the document could have been more prescriptive. Another POC member felt that the document will serve as a good foundation but it will continue to evolve over time. A

POC member asked if there is a systematic process for reviewing guidance documents. UNOS staff stated that guidance documents are typically reviewed every two to three years, but there is no set schedule.

A formal vote was taken regarding: Does the POC vote to recommend to the Executive Committee that the Effective Practices proposal be released for public comment?

Results were as follows: 18 (100%) Yes; 0 (0%) No; 0 (0%) Abstain

Next steps:

All eight proposals were recommended to go out for public comment by the POC. They will be reviewed by the Executive Committee.

2. New Project Review

Prior to the meeting, POC members reviewed and completed a survey on a new project proposed by the OPTN/UNOS Ethics Committee. The new project is titled, "Eligibility of Intellectually Disabled Individuals for Transplant." It was previously placed on hold, and the Ethics Committee would like to be permitted to resume work on it. The results of the pre-meeting survey are provided below:

Project	Primary Goal	Total Average	Proceed (Y/N)
Eligibility of Intellectually Disabled Individuals for Transplant (Ethics Committee)	Provide equity in access to transplants – 7 Increase the number of transplants - 1	3.7	6 Yes; 0 No; 2 Maybe

Summary of Discussion:

The Ethics Committee chair stated that her committee has been working on this project for approximately one year. The Ethics Committee previously drafted a white paper addressing this topic but wants to update it. Additionally, there has been some attention in the news regarding candidates with intellectual disabilities access to transplant and it is an issue that deserves the transplant community's attention. The vice chair of the Ethics Committee reiterated that this would be an update of an existing document and that her committee is approximately one-half to two-thirds into the project.

The Ethics Committee felt that the goal of the project aligns with providing equity in access to transplants. The POC's survey results agreed with the suggested alignment.

The vice chair of the POC presented the comments submitted by POC members as part of the pre-meeting survey. A POC member stated that the decision to accept or deny a candidate should be left to the individual transplant program, and is not necessarily something that the OPTN/UNOS should dictate. Another POC member felt that the project was still valuable because it is a white paper and not a policy proposal. Another POC member noted that it is difficult to comment on who should be transplanted without considering organ availability.

The Ethics Committee is not trying to create any new listing criteria or dictate to individual programs what they should do, but instead provide clarity about this issue. A number of states have passed or are discussing laws that preclude programs from taking intellectual disability into account when listing a candidate.

The Ethics Committee does not have any other projects in the pipeline and the chair was concerned that if they are not able to continue this project, then committee members may become disengaged.

A formal vote was taken regarding: Does the POC vote to recommend to the Executive Committee that the new project proposal be approved?

Results were as follows: 16 (88%) Yes; 1 (6%) No; 1 (6%) Abstain

Next Steps:

The new project proposal will be reviewed by the Executive Committee.

3. Eliminate the Use of DSA and Region in Kidney and Pancreas Allocation Concept Paper Review

The Kidney and Pancreas Committees are putting out a concept paper titled, “Eliminate the Use of DSA and Region in Kidney and Pancreas Allocation” for public comment. The POC does not need to approve the document because it is a concept paper, but POC members should be aware of it.

Summary of Discussion:

The vice chair of the Kidney Committee gave a high-level overview of the concept paper. The Kidney and Pancreas Committees were charged with removing DSA and region from kidney and pancreas allocation. The original timeline was to have a public comment proposal out in January 2019. The committees requested modelling on two different allocation frameworks:

- Concentric Circles
- Concentric Circles with proximity points, which they refer to as the Hybrid Model

The results of the modelling were received in December 2018. After the modeling was received, the committees realized they needed more data and there was not consensus on which model to put out for public comment. Therefore, the committees decided to put out a concept paper that describes the modeling they received and some of the preferences of the committees. The two committees are also asking feedback on whether or not kidney and pancreas should be allocated separately or together.

Upcoming Meeting

- February 26, 2019 (teleconference)