OPTN/UNOS Policy Oversight Committee Meeting Minutes February 26, 2019 Conference Call

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Introduction

The Policy Oversight Committee (POC) met via teleconference on 02/26/2019 to discuss the following agenda items:

- 1. Committee Projects Review
- 2. Overview of Feedback to Date on Public Comment Proposals
- 3. Follow-up on POC Work
- 4. Ideas for Vice Chair Training Professional Education

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

1. Committee Projects Review

Prior to the meeting, POC members reviewed and completed a survey on two new projects:

- 1. Considerations in ABO Testing Operations and Safety Committee
- 2. Update to VCA Transplant Outcomes Data Collection Vascularized Composite Allograft (VCA) Committee

The results of the pre-meeting survey are provided below:

Project	Primary Goal	Total Average	Proceed (Y/N)
Considerations in ABO Testing	 Promote living donor and transplant recipient safety – 14 Improve waitlisted patient, living donor, and transplant recipient outcomes – 1 Promote efficiency in donation and transplantation - 1 	3.9	12 Yes; 0 No; 4 Maybe
Update to VCA Transplant Outcomes Data Collection	 Improve waitlisted patient, living donor, and transplant recipient outcomes – 12 Provide equity in access to transplants - 1 	4.4	12 Yes; 0 No; 1 Maybe

Summary of discussion:

The goal of "Considerations in ABO Testing" is to determine if there should be guidance, education, or policy to deal with the situation where a donor receives multiple blood transfusions, leading to conflicting blood typing results on the donor. The Operations & Safety

Committee (OSC) intends to convene a workgroup to examine what the project should entail. It will most likely involve education, but could also involve new ABO testing techniques.

The POC Chair was concerned that the proposed project was still in the pre-project phase, as it was not clear what the project would ultimately entail. The Chair asked if the OSC would consider doing more pre-work. The OSC Vice Chair stated that the OSC has reached out to multiple blood banks and has started a literature review, but until the OSC does more investigating, the OSC is still unclear on whether the project will end up being education, policy or guidance.

UNOS staff added that the OSC would be able to work on the topic without it being an approved project, and it may be best for the OSC to continue analyzing the problem before approving the project. The OSC does not need POC approval to create an educational resource.

A POC member stated that there are many different types of notifications in DonorNetSM and UNet[®] but none that relate to ABO testing. The POC member suggested that the OSC consider this in their future work.

The OSC Vice Chair noted that OPTN policy states that in the event that there are contradictory ABO results, the OPO must have a process in place to determine the correct ABO. The OSC Vice Chair suggested that this should also apply if one of the ABO results is indeterminate.

The POC Chair and UNOS staff reiterated their recommendation that the OSC do more problem analysis before approving the project. UNOS staff also recommended that the OSC consider the size of the project and the resources that will be needed.

A formal vote was taken regarding: Are any members opposed to sending the project back to the OSC for further analysis?

Results were as follows: 0 (0%) Yes; 15 (100%) No; 0 (0%) Abstain

The POC then discussed the second project, "Update to VCA Transplant Outcomes Data Collection." The VCA Committee Vice Chair stated that the initial VCA data collection protocol went into effect in 2014. Since then, some programs have been non-compliant in their data submission because they don't collect particular outcomes. Additionally, some VCA transplants that are currently being done were not included in the initial protocol. The VCA Committee decided that it would be best to work with the VCA transplant community to modify the data collection forms to create more meaningful outcomes data.

The POC did not have any questions or comments.

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: 15 (100%) Yes; 0 (0%) No; 0 (0%) Abstain

Next steps:

The OSC will continue to analyze the problem for "Considerations in ABO Testing." "Update to VCA Transplant Outcomes Data Collection" will be reviewed by the Executive Committee.

2. Overview of Feedback to Date on Public Comment Proposals

There are 10 proposals out for public comment. UNOS staff provided an update on each proposal.

Summary of Discussion:

• Ethical Implications of Multi-Organ Transplants (MOT)

 This proposal was supported by all of the regions that have had meetings thus far. There has been general support for the notion that MOT policy should be updated. There have been a few questions about how removing donation service area (DSA) and region will effect MOT policy. There have been some questions on how this overlaps with simultaneous liver-kidney policy. There has also been concern about the impact of MOT on the pediatric population and whether or not kidney-pancreas transplants should be included in the discussion.

• Expedited Organ Placement

 This proposal was supported by five regions and was not supported by one. OPOs have generally not supported the proposal. Other results have been mixed. Comments have included concern that the 20 minutes to respond to the expedited offer is too short; that every program will opt in; that programs should be held accountable for late turn-downs; and that some areas already have efficient ways to place expedited organs.

• Split Liver Variance

• This proposal has received mixed support. Some themes include concerns about the variance benefitting either pediatric or adult programs; discussion about limiting the variance to certain types of split livers; concerns about the effect on programs that are not participating in the variance; concern that the requirement to share the second segment will reduce the incentive to split; and questions about how OPOs will keep track of which programs are participating in the variance.

• Eliminate the Use of DSAs in Thoracic Distribution

 Feedback has been mixed, but trending in support of the proposal. Some comments include concern about the impact on pediatric candidates and programs in less-populated areas and concern about removing policy for highlysensitized candidates.

• Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution

 This concept paper was put out to receive feedback from the community to inform a policy proposal that will go out for public comment in the fall. Some of the feedback includes support for the hybrid framework; mixed support on the size of circles and number of points; support for separate frameworks for kidney and pancreas allocation; concern about the effect on transplant rate, transplant count, waiting time, and cold ischemic times; concern about increased transportation; concern about impact on socioeconomic disparities; and suggestions on the next round of modelling.

• Eliminate the Use of Regions in VCA Distribution

- Current sentiment shows support for 750 nautical mile (NM) distribution. Some comments have noted a preference for a 500NM circle.
- Clarifications on Reporting Maintenance Dialysis
 - This proposal is a language clarification and has been on the consent agenda at regional meetings. It has been supported at all regional meetings.

• Modify HOPE Act Variance to Include Other Organs

- This proposal is on the consent agenda and has been supported at all regional meetings.
- Effective Practices in Broader Organ Sharing
 - The guidance document has been approved at all regional meeting thus far. The main concern deals with the finance and billing section of the document.

• MELD Exception Scores during NLRB Transition

 There has been mixed support for this proposal. Some themes include the preference to maintain a three-month implementation period between the National Liver Review Board (NLRB) and Acuity Circles implementation; support for simultaneous implementation; suggestion to use MMaT for transplant center; recommendation to convert scores or have NLRB review all scores prior to Acuity Circles implementation. This will go to the Executive Committee in March.

Next Steps:

No next steps were identified.

3. Follow-Up on POC Work

Summary of Discussion:

At the December 2018 OPTN Board of Directors (Board) meeting, the Board approved the continuous distribution framework. During a previous POC meeting, UNOS staff stated that a subcommittee of the POC would serve in an oversight role to guide the implementation of continuous distribution across organ systems. However, it will not be a subcommittee but the entire POC that serves in this oversight role.

The Thoracic Committee will be the first group to move towards continuous distribution with lung. To do this, the Thoracic Committee will identify the different factors in lung distribution and weigh those factors against each other. Each factor will need to be converted into points. Then, a framework will be built based on these factors, modelling will be completed, and the proposal will go out for public comment. Finally, the proposal will go to the Board. Each organ-specific committee will go through this process.

The POC Chair then presented information on which Committees are listed as collaborating Committees for each approved project. UNOS staff will distribute a full list of this information to the POC.

Next Steps:

UNOS staff will distribute information on collaborating Committees.

4. Ideas for Vice Chair Training Professional Education

At the in-person meeting, there will be professional training that is relevant in both the OPTN role and outside professional roles. The POC Chair asked POC members to think about what kind of training they would find useful.

Next Steps:

POC members will think about professional education topics they might find useful

Upcoming Meetings

- March 26, 2019 (Teleconference)
- April 23, 2019 (Teleconference)
- May 9-10, 2019 (In-person)