OPTN/UNOS Policy Oversight Committee Meeting Summary January 21, 2016 Conference Call

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Discussions of the full committee on January 21, 2016 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <u>http://optn.transplant.hrsa.gov/</u>.

Committee Projects

1. None

Committee Projects Pending Implementation

2. Proposal to Increase Committee Terms to Three Years

The proposal was passed at the December 1-2, 2015 Board of Directors meeting on the consent agenda with a vote of 39 in favor, 0 oppose, and 0 abstain. The Committee will need to be a part of the implementation planning for the proposal. The policy language will become 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 will begin to review engagement and participation models in February 2016 and come to consensus on how to evaluate committee member engagement prior to implementation.

Implemented Committee Projects

3. None

Review of Public Comment Proposals

4. POC Review of Public Comment Proposals

The Policy Oversight Committee (POC) met on January 21 to review public comment proposals from the Committees. In reviewing the proposals, the POC focused on whether the proposals were well formulated (i.e., followed our standards for policy development) and supported the Final Rule and Strategic Plan.

POC members completed a survey that asked questions regarding the quality of the problem statement, whether the solution addresses the problem, whether the proposal has evidence to support the problem and solution, and how well the sponsoring Committee collaborated with others. The second purpose (supporting the Final Rule and Strategic Plan), was also reviewed when the Committee proposed the project, and the public comment survey served as a check on those projects that may have evolved since they were first proposed to the POC.

The POC used the results of the survey to make a recommendation to the Executive Committee regarding which proposals should be released for public comment.

The POC unanimously voted (18-yes, 0-No, 0-Abstain) to recommend the following 9 proposals for public comment:

• Improving Post-Transplant Communication of New Donor Information (DTAC)

- The DTAC Vice Chair clarified that the proposal and its proposed requirements apply to both living and deceased donors transplants.
- Adding HLA DQA1 Unacceptable Antigen Equivalences Table (Histocompatibility)
 - Histocompatibility and POC leadership agreed that equivalency table projects still need to follow the defined POC and Executive Committee approval process, even though policy language states that the Histocompatibility Committee review equivalency tables annually. Those projects will now come to the POC and Executive Committee for feedback and approval.
- Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors (OPO)
 - The POC had discussions about which committee should sponsor this proposal. This proposal is a result of actions taken by the Executive Committee, as opposed to the OPO Committee. The OPO Committee also noted that the requirements of this proposal will apply to transplant hospitals as opposed to OPOs and therefore they are asking another committee to sponsor this proposal. The POC recommended that the Disease Transmission Advisory Committee sponsor this proposal.
- Kidney Allocation System (KAS) Clarifications and Clean Up (Kidney)
 - POC members differed in opinions about the concept of informed consent for high KDPI kidneys at the time of listing or prior to transplant in combined organ transplants.
- Simultaneous Liver Kidney (SLK) Allocation (Kidney)
 - The Kidney Committee Vice Chair answered questions about the proposal, including acknowledgement of a typographical error in the proposal, as well as the high cost estimate for implementation.
- List Covered Body Parts Pertaining to Vascularized Composite Allografts (VCA)
 - There was some discussion surrounding the term "body parts" and the perception of that term in the community. The VCA Vice Chair explained that "body parts" is the term used in The Final Rule and federal regulations.
- National Liver Review Board (Liver and Intestinal)
 - POC members asked questions concerning the problem statement of the proposal and if more evidence could be given. The Liver Vice Chair agreed and explained that proof existed throughout the proposal but would be consolidated to better explain the problem to the community.
- Modifications to the Adult Heart Allocation System (Thoracic)
 - Several POC members asked why the Thotacic Committee was moving forward with the proposal without a Heart National Review Board, especially considering the Liver National Review Board proposal. The Thoracic Vice Chair explained that there was not enough data to support a National Heart Review Board, and that increasing the amount of statuses (purpose of the proposal) should reduce the number of exceptions that proceed through the review boards.

- Standardize an Organ Coding System for Tracking of Organs: Requirements for OPO TransNet Use (Operations and Safety)
 - The Operations and Safety Vice Chair, based on earlier POC comments, clarified that the proposal only mandated use of TransNet by OPOs, and the current scope of the proposal did not extend to the transplant hospitals – but that exploratory discussions have begun with transplant hospitals.

Other Significant Items

5. None

Upcoming Meetings

- February 11, 2016, Conference Call, 12-1 p.m. ET
- March 10, 2016, Conference Call, 4-5 p.m. ET
- March 21, 2016, Chicago, IL Meeting, 8:00 a.m. 4:00 p.m. ET