

**OPTN/UNOS Policy Oversight Committee  
Meeting Minutes  
July 26, 2017  
Conference Call**

**Jennifer Milton, BSN, CCTC, MBA, Chair  
Elizabeth Pomfret, MD, PhD, Vice Chair**

**Introduction**

The Policy Oversight Committee (POC) met via Citrix GoTo on August 26, 2017 to discuss Committee projects and public comment proposals. The Committee also looked at updated resources estimates for the Enhancing Liver Distribution proposal from the Liver and Intestinal Organs Transplantation Committee. The following is a summary of the Committee's discussions.

**1. Committee Projects**

The POC has no currently active committee projects.

**2. Other Significant Items**

Project and Proposal Review Metrics

The POC first discussed the workload and survey completion tasks when they reviewed their public comment proposals. Each committee member was assigned six or seven public comment proposals to review and then had to complete the survey monkey survey about each one. The committee members reviewed all of the three new committee projects in addition to their assigned public comment proposals. They were provided 5 days to complete these reviews.

Most of the Committee members said they spent between 45 mins to 2 hours on each of the proposals so the review burden was larger than expected. They also wanted to have a better tool so that when they started a review and went back to complete, the survey would know where they had left off. There was some optimism that they would get a little bit faster at the process as they did it more frequently, but in general felt that the time commitment would not decrease that much and that the number of proposals each member was expected to review should be decreased.

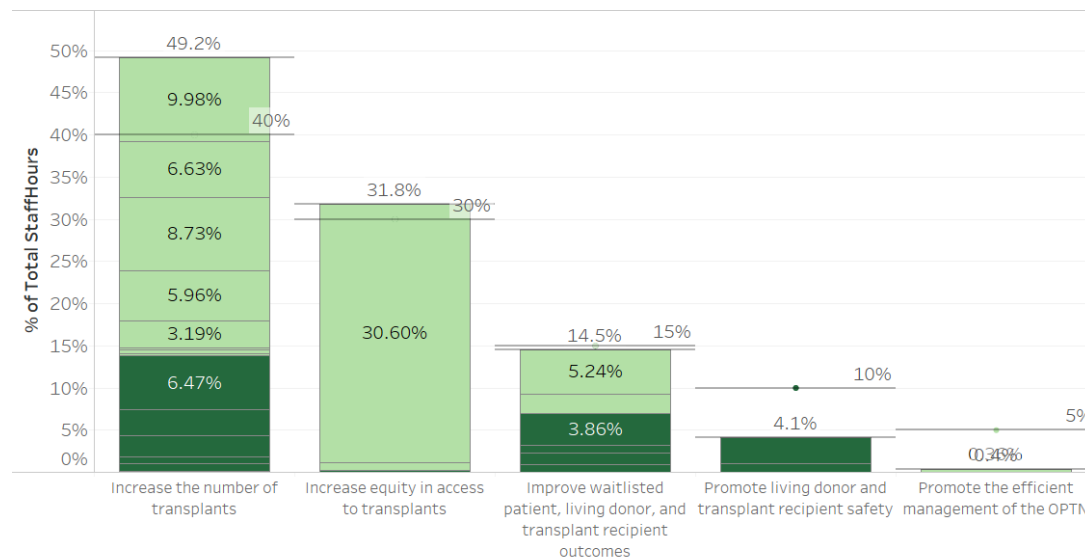
Enhancing Liver Distribution Proposal – Review of Updated Resource Estimate

As part of their ongoing review of Committee projects, a new process has been put into place that will require the POC to review a project again if the resource estimates change drastically from the original estimates when the project was approved. The original Liver Redistribution proposal (now entitled Enhancing Liver Distribution) from the Liver and Intestinal Organs Transplantation Committee is the first one to undergo this project since it recently had a significant increase in its resource estimates as follows:

- ORIGINAL: 1750 / Very Large
- UPDATE: 9000 / Enterprise (range: 5850 – 13500)

Both estimates and range can be refined based on additional information/feedback from Public Comment. The reason for this increase is tied mostly to the addition of liver allocation functionality to the original request for just redistribution. When compared to other large projects such as KAS, match allocation was 8241.75 hours compared to 7250 for liver allocation and 1750 for liver redistribution (9000 total).

As part of the review the Committee was provided the updated project portfolio alignment as follows:



The Committee briefly acknowledged that while it is important that they are informed when project resource estimates change drastically, in this case there is really no option but to continue the work on this project and release it for public comment. This project is a high profile and priority project for HRSA and the Board has requested that the project go back out for public comment this cycle.

#### Public Comment Proposal Review – 13 proposals

The Committee next took on its review and discussion of the 13 Committee Public Comment Proposals with the goal to make a recommendation to the Executive Committee about the proposals' readiness for public comment scheduled to begin on July 31, 2017. The POC liaison reminded the group that the goal of the review is to validate whether the proposal meet the OPTN/UNOS standards for policy development so that a recommendation can be made to the Executive Committee about the proposals' readiness for public comment. The review is not about whether the POC member likes the proposal or thinks it's a good idea. To prepare for the discussion, POC members reviewed and completed the survey for these 13 proposals ahead of the call:

1. Addressing Approved Transplant Fellowship Training Programs Bylaws - Membership & Professional Standards Committee
2. Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types - Pancreas Committee
3. Revise White Paper Addressing Financial Incentives for Organ Donation - Ethics Committee
4. Guidance on the Benefits of Pancreas After Kidney (PAK) Transplantation - Pancreas Committee
5. Implementation of A2\_A2B to Blood Group B Deceased Donor Kidney Transplant Allocation Guidance - Minority Affairs Committee
6. Improving Allocation of Dual Kidneys - Kidney Committee
7. Improving Allocation of En Bloc Kidneys - Kidney Committee
8. System Optimizations to Expedite Organ Allocation and Increase Utilization - OPO Committee
9. Enhancing Liver Distribution - Liver Committee

10. Living organ donation by persons with certain fatal diseases who meet the criteria to be living organ donors - Living Donor Committee
11. Congenital Heart Disease Exception Request Guidance for Review Boards - Thoracic Committee
12. Review of HLA Tables (2016) - Histocompatibility Committee
13. Revisions to Pediatric Emergency Membership Exception - Pediatric Committee

There was also a concept paper from the Kidney committee: *Allowing Deceased Donor Initiated Kidney Paired Donation (KPD) Chains*. The goal of a concept paper is to put the idea out there and solicit input about specific aspects of the project or to ask specific questions of the community. The POC historically has not reviewed concept papers or made a recommendation to the Executive Committee.

Based on the Committee members review and survey results, 10 of the proposals were put on the consent agenda. These proposals received high survey scores and had no “NO” votes for the survey question “*Should this proposal proceed to public comment?*” These were the proposals on the POC’s consent agenda, along with a summary of the survey results:

PUBLIC COMMENT PROPOSAL	Total Average	Proceed?
Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types - Pancreas Committee	4.4	7 YES; 0 NO; 1 MAYBE
Improving Allocation of En Bloc Kidneys - Kidney Committee	4.1	6 YES; 0 NO; 0 MAYBE
Guidance on the Benefits of Pancreas After Kidney (PAK) Transplantation - Pancreas Committee	4.2	7 YES; 0 NO; 0 MAYBE
Implementation of A2_A2B to Blood Group B Deceased Donor Kidney Transplant Allocation Guidance - Minority Affairs Committee	4.5	7 YES; 0 NO; 0 MAYBE
Improving Allocation of Dual Kidneys - Kidney Committee	4.4	6 YES; 0 NO; 1 MAYBE
Revise White Paper Addressing Financial Incentives for Organ Donation - Ethics Committee	4.2	8 YES; 0 NO; 0 MAYBE
Congenital Heart Disease Exception Request Guidance for Review Boards - Thoracic Committee	4.7	5 YES; 0 NO; 1 MAYBE
Living organ donation by persons with certain fatal diseases who meet the criteria to be living organ donors - Living Donor Committee	4.5	7 YES; 0 NO; 0 MAYBE
Review of HLA Tables (2016) - Histocompatibility Committee	4.6	6 YES; 0 NO; 0 MAYBE

<b>PUBLIC COMMENT PROPOSAL</b>	<b>Total Average</b>	<b>Proceed?</b>
Revisions to Pediatric Emergency Membership Exception - Pediatric Committee	4.4	5 YES; 0 NO; 0 MAYBE

None of the Committee members wanted to discuss any of these items, so the Committee subsequently voted unanimously to make the recommendation to the Executive Committee that all ten of these proposals be approved for public comment.

Based on the survey results and comments received, these three proposals were placed on the POC's discussion agenda:

<b>PUBLIC COMMENT PROPOSAL</b>	<b>Total Average</b>	<b>Proceed?</b>
Liver Distribution Redesign Modeling - Liver Committee	4.3	5 YES; 1 NO; 0 MAYBE
Addressing Approved Transplant Fellowship Training Programs Bylaws - Membership & Professional Standards Committee	4.6	7 YES; 1 NO; 0 MAYBE
System Optimizations to Expedite Organ Allocation and Increase Utilization - OPO Committee	4.0	5 YES; 0 NO; 3 MAYBE

The POC discussed each of these proposals before voting on them separately. The Addressing Approved Transplant Fellowship Training Programs Bylaws proposal and the Systems Optimizations to Expedite Organ Allocation proposal were discussed by the POC based on receiving a NO vote and three MAYBE votes, respectively, during the survey, but after a brief discussion that focused mainly on goal alignment the POC ultimately voted unanimously to recommend that they go out for public comment.

The Committee spent the bulk of their time discussing the Enhancing Liver Allocation proposal. The major comments received were as follows:

- Several POC members asked why we are sending this out for public comment without modeling or proper data analysis?
- Specifically they wanted to know if this is part of the normal process, to send something out for public comment without modelling? Has that been done this way before? Did we do it with other large projects, such as KAS?
- Several expressed concern that the lack of supportive modelling will negatively impact a very good proposal and provide ammunition to those who don't support it.
- However, several thought that this was the best proposal to come out of the (Liver) Committee thus far.

Many members ultimately expressed support for the proposal saying that it was the best one yet but that they worried that the lack of modelling would ultimately hurt the proposal's chance to get passed. Following the discussion, the committee voted to recommend approval for public comment narrowly by a vote of 9 YES, 7 NO.

The Committee Chair noted that she would bring all of these concerns along with the other recommendations to the Executive Committee on Friday July 28 during their conference call to approve public comment items.

#### New Project Review – 3 Projects

The Committee then moved on to their review of three new committee projects. The goal was to make a recommendation to the Executive Committee at the same conference call as the public comment proposal review recommendations on Friday, July 28. The POC reviewed and completed a survey for these three proposed new Committee projects:

Project	Goal	Total Ave Score (5 max)	Vote
Update Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB (Operations and Safety)	#4 (LD and recipient Safety)	4.4	13 YES; 0 NO; 0 MAYBE
Extra vessels: Reducing reporting burdens and clarifying policies (Operations and Safety)	#4 (LD and recipient safety)	4.4	10 YES; 0 NO; 2 MAYBE
Informed Consent Clarification (DTAC)	#5 (efficient management)	4.5	10 YES, 0 NO, 2 MAYBE

Because the projects received zero “NO” votes and committee members expressed very little concern about the projects, the committee voted unanimously to recommend approval of all three projects, 15 YES, 0 NO. These projects will now be in Evidence Gathering status and the sponsoring Committee can begin work on them.

The meeting agenda had two additional items, SRTR Visiting Committee Update and August Call Prep, that the Committee did not complete since they ran out of time. The SRTR Update will be moved to the August call and the POC liaison informed the Committee that she would send out materials for the August call prep early the following week.

The meeting adjourned at 3:40 pm.

#### **Upcoming Meetings**

- Friday, September 15, 2017, 3:00 PM ET, conference call
- **Friday, October 6, 2017, 8:30 AM – 3:30 PM CENTRAL, In-person, CHICAGO, IL**
- Wednesday, October 18, 3:30 PM ET, conference call
- Friday, November 17, 3:00 PM ET, conference call
- Wednesday, December 20, 3:30 PM ET, conference call