OPTN/UNOS Policy Oversight Committee Meeting Summary January 18, 2017 Conference Call

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Discussions of the full committee on January 18, 2017 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. None

Committee Projects Pending Implementation

2. None

Implemented Committee Projects

3. None

Other Significant Items

4. New Project Review

The POC reviewed two new proposed committee projects at this call:

- 1. Expediting Organ Placement (OPO Committee)
- 2. Tracking Pediatric Transplant Outcomes Following Transition to Adult Transplant Programs (Pediatric Committee)

For the 2 new projects presented to the POC, POC members completed a survey that asked questions regarding the quality of the problem statement, whether the proposal has evidence to support the problem, need for collaboration, development of project timeline, and primary strategic goal alignment.

The POC provided all comments about these projects that were entered as part of the survey to the sponsoring Committee and the Executive Committee for their consideration at their January 19, 2017 conference call.

The POC used the results of the survey to make a recommendation to the Executive Committee regarding whether the 2 new projects should be approved to be part of the committee portfolio. The POC, after review of the projects, voted to make these recommendations to the Executive Committee:

Expediting Organ Placement (OPO Committee)

The POC voted unanimously to recommend approval of this project after discussion. Comments from committee members were as follows:

- One main hesitation was the cost noted and can they tell us how the system can
 assess whether or not candidates listed at "non aggressive" centers are truly being
 bypassed by this change if it is implemented
- Acknowledge the need for expedited placement but I'm concerned about the room for well-meaning but unfair practices that could occur.
- This will be very difficult to implement.
- Follow-up on who is receiving these organs and outcomes needs to be implemented.
- The problem statement would benefit from further development. It would be helpful to add more granular information about results of the monitoring via "out of sequence" allocations (perhaps in the last 5 years or so). The information would provide a framework of the problem and the proposes solution.
- The reasons for increased discard of organs are multifactorial and promoting a system of expedited placement to "aggressive centers" would not solve these many problems, but would instead create a second-tier allocation system that would potentially undermine the current, publically vetted systems that exist in Policy.
- This is an important issue that should be investigated.
- This is an important project that will likely take longer than expected since there are significant regional and transplant center practices regarding usage of marginal organs. It will be important to include each organ group committee to determine best practices for expedited placement in collaboration with the OPO's that meets the majority of transplant candidate's needs.
- This continues to be a thorny issue in organ allocation. Despite the large impact for programming, it's time that attention and policy guidance be given to OPOs for expedited placement. This is a first step to broader changes with multi-organ allocation.
- This is an important project to do several things decrease organ wastage, provide full transparency to the community at large that 'not all programs are created equal' and patients should be afforded a true opportunity to make an informed decision about their choice of programs. There has also been a great deal of concern on the part of the MPSC as how to monitor this moving forward in terms of what is considered an appropriate 'effort' (if one is necessary at all) on the part of an OPO before moving to an expedited placement. OPOs currently are routinely identified for out of sequence allocation as there is nothing in policy currently when OPOs want to see an organ transplanted and know that without rapidly changing direction and allocating to an 'aggressive' center will wastage be prevented. Having said that, this is going to be an enormous undertaking with just about every UNOS committee needing to collaborate. Liver is probably a good place to start and the committee is going to have to be comfortable that there will be a large amount of opposition from various directions but ultimately is going to have to serve the greater good.

Tracking Pediatric Transplant Outcomes Following Transition to Adult Transplant Programs (Pediatric Committee)

The POC voted unanimously to approve this project after discussion. Committee members provided these comments about the project:

With regard to the primary strategic goal of the proposal, is it really improving the
outcomes of these patients or simply insuring that there is a more efficient means of
reporting on these patients as they transition from pediatric to other providers? In

- other words, are these patients not receiving care or is it that appropriate care givers are not taking responsibility for reporting their follow-up data to UNOS?
- The group lays out the problem very well, however, 3 queries, 1) Needed clarification- currently is the transplant center who performed the transplant responsible for giving updates for life of the graft? 2) Is there currently a box that can be checked that patient transitioned successfully or are the only options either giving the data requested vs out of compliance vs lost to follow up? 3) Would appreciate a little more discussion on the suggested solution.... is the education piece to both the Transplant center AND the recipient/recipient family? Does there need to be an educational target of adult nephrologists/cardiologists/hepatologists etc. who are not part of OPTN to recognize the importance of giving follow up back to the center.
- While it is important to track long term outcomes it is a lot of work for centers to gather data from outside their institution and this often falls behind as the coordinators are dealing with the issues of the patients in front of them.
- The data obtained through this proposal would help support a bigger focus which is
 pediatric transitioning to adult transplant centers. This process is fragmented at best
 and having this data could be the seed for other attempts at looking at transition
 programs and improving patient outcomes.
- This topic is very important. The Committee should propose some solutions for the added costs/resources (or developing IT - TIEDI tracking systems is promising) required of transplant centers to track and follow up with pediatric recipients after transitioning. This issue is going to be a major concern.
- This is an area that we need to focus on if we intend to impact graft survival and retransplantation rates. This project may include smaller numbers of patients but is worthwhile.
- Proposal is better developed than in last iteration.
- Not certain that the committee can provide OPTN members who perform pediatric transplants information that they don't already know - follow-up is important and they should make every effort to assure when adolescents transition to adults (both chronologically and emotionally) that they should continue to have regular follow-up and report data to the program that completed their transplant.

5. Public Comment Proposal Review

The Committee reviewed seven public comment proposals and four new projects from the Committees.

POC members completed a survey for each proposal and project; the results of the survey were provided to the Executive Committee along with the individual comments entered by POC members.

The POC used the results of the surveys to make the following recommendations to the Executive Committee regarding which proposals should be released for public comment beginning January 23, 2017.

The POC voted to recommend the following 6 proposals for public comment:

- 1. White Paper Addressing Financial Incentives for Organ Donation (Ethics Committee)
- 2. Histocompatibility Laboratory Bylaws and Policies Guidance Document (Histocompatibility Committee)

- 3. Improving Allocation of En Bloc Kidneys (Kidney Committee)
- 4. Liver Review Board Guidance Documents (Liver Committee)
- 5. National Liver Review Board (Liver Committee)
- 6. Rewrite of Bylaws Article II: Board of Directors (Executive Committee)

The POC's vote on the 7th public comment proposal, Infectious Disease Verification to Enhance Patient Safety (Operations and Safety Committee), was split, with six *YES* votes and six *NO* votes.

Primary comments and concerns from POC members included:

- Need to get AST and ASTS input before this goes out for public comment. Concern that these important stakeholders weren't involved in the development of the proposal.
- This is a lot of work for LD transplant centers and we are already very highly regulated.
- Remember this is not the only proposal; we have to be mindful of what we're asking our committees and members to do. Is this really necessary? A lot of work.

The POC Chair reported these recommendations to the Executive Committee at their conference call on January 19, 2017.

The conference call ended at 3:06 pm EST.

Upcoming Meetings

- February 16, 2017 12:00 PM EST conference call
- March 16, 2017, 12:00 PM EST, conference call
- April 20, 2017, 12:00 PM EST, conference call
- Monday, May 15, 2017 Orientation (New POC members only), Richmond, VA
- Tuesday, May 16, 2017 Full Committee Meeting, Richmond, VA