

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
December 15, 2016
Conference Call**

**Sue Dunn, RN, BSN, MBA, Chair
Jennifer Milton, BSN, CCTC, MBA, Vice Chair**

Discussions of the full committee on December 15, 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 <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. Education To Reduce Unnecessary Discard of Kidneys with Small RCC Found Pre-Transplant - Disease Transmission Advisory Committee (DTAC)
2. Assessment of Transplant Programs Conducting A2/A2B Deceased Donor Kidney Transplants to Blood Type B Recipients - Minority Affairs Committee (MAC)

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 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:

Education To Reduce Unnecessary Discard of Kidneys with Small RCC Found Pre-Transplant – The POC voted unanimously to recommend approval of this project after discussion. Comments from committee members were as follows:

- This is a really small project but similar to previous project, seems reasonable to pursue given resources are minimal and gains, no matter how small, are real in terms of potential benefit to patients.
- Guidance document seems appropriate to ensure that centers are making decisions based on what is currently known about the risks. Obviously, the targeted population (i.e. donors with small RCC) is very small and will provide only a small increase in the number of kidney donors, but a guidance document represents a relatively limited commitment by the committee.
- Should these kidneys be considered for everyone? Will there be a change in KDPI??
- One recommendation was to clarify what the proposed solution is. The wording under proposed instructional solution states " this project will be followed for specific instructional needs during the development of the project plan." Could this be clarified to specify more exactly what the anticipated goals of the project are? Because of the relatively small numbers, my other recommendation would be to have reassurance that once data from 2008-2011 is obtained, that the numbers will be sufficient to achieve more certainty that these kidneys could be used. Is the follow-up time enough to document the safety of using these kidneys?
- The project form is not very well developed and it's difficult to know the real impact if this policy were moved forward.
- While preliminary data (on small samples) were obtained and reported, more data are needed before policy can be approved on: a) What is the prevalence of the contralateral kidney developing renal cell cancer? b) What is the risk of organs re-developing RCC in the excised kidney (did the cancer return?). c) What is the risk of transmission of disease to recipients? These donor organs should be classified similar to the 'increased risk donor' organ status for informed consent purposes. There is concern about the informed consent process that has been utilized for recipients of these organs.
- Uncertain this is a big problem that needs to be addressed.
- Our community must find ways to utilize every organ possible and opportunities to reduce kidney discards must be pursued.

Assessment of Transplant Programs Conducting A2/A2B Deceased Donor Kidney Transplants to Blood Type B Recipients – The POC voted unanimously to approve this project after discussion. Committee members provided these comments about the project:

- It's concerning that the survey only had a 21% response rate. Still, this is a straightforward project and I think should help.
- The development of the guidance document would be helpful. The response rate of the survey seems low.
- Previous work has identified the need for a guidance document, which the workgroup is therefore proceeding with. There appears to be ample evidence that the option to list B recipients for A2/A2B donors and obtain titers is underutilized and that education might assist with this.
- Appears to be a desire to move forward with an educational webinar and guidance document to assist with letting centers know more concretely how to conduct A2/A2B into Blood Type B recipients. This seems like the appropriate plan to respond to the results from a survey the MAC previously performed
- The suggested project goals of webinar or guidance documents seem reasonable and strategic. Since O blood type kidney candidates wait almost as long as B

candidates, a minor point of clarification that would be helpful for the non kidney reviewers would be to include a brief statement on the relative proportion of A2 kidneys that are used for O recipients and how that process is affected by this proposal.

- This is proven science and should be better understood by transplant centers across the country. ABO-B recipients will definitely have better access if this education takes place.
- A committee member supports the proposals but thinks that there may be a significant financial impact to the center even if their lab performs the test. Our center has experienced issues with insurance covering the cost on non-Medicare patients.
- This is an important project that should continue to be supported. Here are some questions for clarification: 1) For proposed solutions: who is the webinar's audience? Transplant center staff or transplant candidates? 2) One barrier may be transplant candidates and their conceptions and concerns about organ matching. 3) There seems to be a disconnection between the proposed solutions and the anticipated costs. That is, the solution is to develop the webinar and guidance document. But the costs reflect the fees associated not with developing these educational materials, but with doing laboratory titer testing. 4) Consider drawing upon established theories of behavior change e.g., Diffusion of Innovations, in order to optimally implement this variance in other transplant centers. The committee member is happy to provide some guidance in this process. 5) Why have some committees not collaborated with or have backed out of collaborating with MAC, e.g., Histo? What is at stake for those other committees?
- This is an easy win for the OPTN. The element was put in KAS to increase minority transplants and it is not being fully utilized. Personal experience can confirm this works in increasing minority, blood type B recipients.
- I believe that transplant centers are put off by the perceived barriers to implementing A2/A2B transplants. When you weigh the system/compliance requirements against the small number of transplants they are likely to perform each year in this category it is difficult to make the case to proceed. With limited resources we have to choose among competing projects. Anything that can be done to make this easier for centers to implement is critical in moving this forward. Centers need consents, policy and protocol examples that they can easily adopt in order to pave the way for more centers to start doing these transplants.

5. Preview of January Conference Call and Upcoming Public Comment Proposal Review –

POC Chair, Sue Dunn, gave a brief overview of the work required in preparation for the January 18 2017 conference call where committee members will review public comment proposals and new projects to make recommendations to the Executive Committee at their January call.

Ms. Dunn reported that the POC will review 8 public comment proposals and 2-3 new projects. She showed the detailed timeline of when the survey and proposals or forms for the review would be distributed and the due date for the reviews.

The conference call ended at 12:51 pm EST.

Upcoming Meetings

- January 18, 2017, 2:00 PM EST conference call
- February 16, 2017 12:00 PM EST conference call
- March 16, 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