OPTN/UNOS Policy Oversight Committee (POC)
Meeting Summary
June 15, 2015
11 am EST, Conference Call

Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair

Discussions of the full committee on June 15, 2015 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 http://optn.transplant.hrsa.gov.

1. Review of Committee Projects

The POC changed the scope of its review based on input from the Executive Committee at its May 31 meeting in Atlanta. Projects that have been Board approved and are pending implementation were considered to be "safe" and will be implemented. All other projects were eligible to be put on hold; this includes projects that are scheduled for fall 2015 public comment. This allowed the POC to prioritize the most important projects within the portfolio, regardless of where they are in the process.

On June 5th a new survey was distributed and completed by POC members. This survey:

- Asked for project's impact on each of the strategic goal with ***+2 = Significant positive impact*** to ***-2 = Significant negative impact***
- Also explicitly asked "Should this project be put on hold?"

The POC used the data collected from this survey to evaluate the project portfolio, looking closely at:

1. POC members' answers to the "should this project be placed on hold?" question from the survey
2. The recommendation in the straw man portfolio reported to the Executive Committee on May 31
3. The "primary strategic goal" identified in the POC's survey

This resulted in a POC agenda that included proposed ON HOLD, CONTINUE, or DISCUSS items based on how numbers one and two above were in agreement.

The POC Chair presented the agenda with the proposed ON HOLD, CONTINUE, or DISCUSS items.

<u>Recommendations</u>
The POC, after much deliberation and consideration, voted unanimously to recommend to the Executive Committee to put these 9 projects ON HOLD (these nine projects combined free up 3,329 hours of resources in the project portfolio):

Project Name	Committee
1. New Requirements for the Transport of Living Donor Organs	Living Donor; Operations and Safety
2. Consider if living donor recovery hospitals should be responsible for providing care for post-operative complications	Ethics
3. Enhancing Priority for DR Matching in Kidney Allocation	Histocompatibility
4. Approved Transplant Fellowship Training Programs	Membership & Professional Standards)
5. Consider primary surgeon qualification - primary or first assistant on transplant cases	Membership & Professional Standards
6. Primary Physician specialty - sub-specialty board certifications	Membership & Professional Standards
7. Consider requirement for primary physician observation of procurements	Membership & Professional Standards
8. Define working knowledge For primary physician qualification pathways	Membership & Professional Standards
9. Reassess currency requirements for primary surgeons and primary physicians	Membership & Professional Standards

These three projects were discussed as projects that could “maybe” be put on hold but the Committee could come to no consensus during its call (these three projects combined free up 7,699 hours of resources):

Project Name	Project Hours	Committee
Changes to KAS CPRA and priority for kidney candidates undergoing desensitization	5399	Histocompatibility
Composite Pre-transplant Metrics	1500	Membership & Professional Standards
Proposal to Notify Patients Having an	800	Transplant Coordinators

Project Name	Project Hours	Committee
Extended Inactive Status		

Committee members offered these specific comments about these projects included:

- **Changes to KAS CPRA and priority for kidney candidates undergoing desensitization (Histocompatibility):**

The Minority Affairs and Kidney Committees are collaborating on this project. It is yet unclear the number of patients this will impact. A survey is ready to go out to that will help the Committee decide if this project will continue. Allowing the project to continue would enable the Committee to release the survey to collect the data it needs.

A POC member also noted that this is a project that has clearly been impacted by another project already in the works (KAS). The preliminary KAS data is adding complexities. Some POC members asked if putting this on hold could actually improve the project as KAS data comes in and we have a clearer understanding of what we have.

The Histocompatibility Vice Chair commented that although this is true, there clearly is a subgroup of the 99% and 100% CPRA patients who are not getting offers.

- **Composite Pre-transplant Metrics (MPSC)**

Some POC members argued that this could also increase transplants, since you're making centers accountable for their waitlist management in terms of making sure they're accepting organs, what their transplant rates are, putting in refusal codes, etc. And we (OPTN) have not yet looked at this as far as quality measures and it's a huge deal as far as making sure patients get transplants.

- **Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators Committee):**

One POC member added that there are many reasons people are placed on inactive status and he was not sure how big an impact there will be to notify people this. Some POC members agreed that there would be a lot of costs associated with this project and the impact is uncertain.

The TCC Vice Chair stated that this project is meant to capture those who are truly likely to be reactivated; it's giving equity in access to patients we already have on the list. We're making sure they're not forgotten about. Currently there is no requirement to notify patients.

In addition, the POC Chair received an email from the TCC liaison (after the call). Comments are summarized here:

> *Based on public comment received for this project, at this time, the goal is **not** to move forward with policy but to provide education to the community which is what was recommended during the public comment period. Committee members will continue to review the data they currently have and conduct the interviews with some assistance from the liaisons and Communications department to draft articles summarizing the*

interviews. There is no IT involvement and is a relatively small project as indicated on the project form.

It seems as though POC members are still stuck on the burden issue that was identified during public comment. However, the project is no longer focused on creating policy requiring centers to provide their inactive patients written notification of their inactive status. The focus now is to increase patient education and awareness of their status; thereby increasing the number of patients able to receive a transplant if their status is changed to active.

These projects were voted unanimously by the POC to recommend for continuation:

Project Name	Committee
1. Ethical Considerations of Imminent Death Donation	Ethics
2. Define Biologically Incompatible for KPD	Kidney Paired Donation
3. Facilitated placement reduced discards	Liver and Intestines
4. Modifications to How New Donor Information Received Post-Transplant is Reported to Recipient Centers	Ad Hoc Disease Transmission Advisory)
5. Consider multi-organ procurement requirement for primary surgeon criteria	Membership & Professional Standards
6. Proposal to Increase Committee Terms to Three Years	Policy Oversight
7. Simultaneous Liver Kidney (SLK) Allocation	Kidney
8. Develop materials to educate RRB members promote consistent review of exceptions	Liver and Intestines
9. Primary Surgeon Procurement Requirement	Membership & Professional Standards
10. Pancreas Underutilization	Pancreas
11. Limit Paper Documentation Required to be included with Organ Packaging	Organ Procurement Organization
12. Modification of the Heart Allocation System	Thoracic

Project Name	Committee
13. Histocompatibility Testing Guidance Document	Histocompatibility
14. Kidney Allocation System (KAS) Clarifications and Clean Up	Kidney
15. Revising KPD Priority Points	Kidney Paired Donation
16. Foreign Board Certification	Membership & Professional Standards
17. Post-transplant performance review of multi-organ transplants	Membership & Professional Standards
18. Standardize an organ coding system for tracking of organs	Operations & Safety
19. Pediatric Lung Allocation Policy Review	Thoracic
20. Review Existing White Papers for Accuracy and Relevancy	Ethics
21. Liver Distribution Redesign Modeling (Redistricting of Regions)	Liver
22. National Liver Review Board	Liver and Intestines
23. Clarify Status of Domino Donors	Living Donor
24. Update 'What Every Patient Needs to Know' Brochure	Patient Affairs
25. Define Exhausting the Match Run	Ad Hoc International Relations
26. Infectious Disease Verification Process to Enhance Patient Safety	Operations & Safety
27. Guidance on Informed Consent for Living Donors Representing Vulnerable High Risk Populations	Minority Affairs
28. Pediatric Transplantation Training and Experience Considerations in the Bylaws	Pediatric

Project Name	Committee
29. Define Transplant Hospital	Membership & Professional Standards

Upcoming Meetings:

- June 24, 2015 Conference Call, 12:00 PM EST
- Jul 14, 2015 Conference Call, 3:00 PM EST
- August 10, 2015 Conference Call, 3:00 PM EST