OPTN/UNOS Policy Oversight Committee
Meeting Minutes
September 15, 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 September 15, 2017 to discuss the remaining multi-organ projects and to review a new project proposed by the Pancreas 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

Multi-organ Projects: Discussion and Recommendation to the Executive Committee

To kick off the discussion, the POC chair presented the complete history of the multi-organ project to the committee as follows:

- 2015: Included as specific initiative in OPTN strategic plan;
  Board approved POC proposal to clarify certain elements of multi-organ.
- 2016:
  - Jan: POC reviewed and approved substantive multi-organ project (Primary Goal = #5 efficiency)
  - Assigned to OPO Committee
  - Jan/Feb: Executive Committee did not approve project
- 2017: Board leadership requested updated plan for multi-organ; SLK implemented August 10, 2017.

The Chair also offered the current data on multi-organ transplants to help frame the discussion and to help prioritize the remaining multi-organ discussion.

Type of Multi-Organ	#	Policy?
All Multiple Organs	1433	
Liver-Kidney	730	Yes
Kidney-Pancreas	437	Yes
Heart-Kidney	140	No
Liver-Intestine-Pancreas	58	No
Liver-Heart	18	No
Heart-Lung	18	Yes
Liver-Lung	9	No
Intestine-Pancreas	8	No

Type of Multi-Organ	#	Policy?
Kidney-Intestine	5	No
Kidney-Lung	4	No
Liver-Pancreas	3	No
Liver-Intestine	2	Yes
Liver-Kidney-Heart	1	No
Liver-Pancreas-Lung	0	No

This data was further summarized as follows:

- Multi-organ transplants made up 5.2% of all deceased donor transplants (27,628) in 2016
- Liver-kidney transplants made up 51% of multi-organ transplants
- Kidney-pancreas transplants made up 30% of multi-organ transplants
- 83% of multi-organ transplants are currently addressed by policy
- .9% (253) of all transplants were multi-organ combinations not covered in policy. (If we address heart-kidney the % would drop to .409%)

The Chair went on to explain that the multi-organ projects are needed to address several problems including the lack of medical criteria and assessment of medical need for a multi-organ transplant in our current Policies. Also, there is currently no tie-breakers for several situations (For example, heart-liver and lung-liver combinations), and this leads to inconsistent behavior among members. Requirements do exist at the DSA allocation level but not beyond the DSA (region and nation), and this also leads to inconsistent behavior. Finally, the SLK proposal raised the ethical issue of who should receive multiple organs and when they should get priority over single-organ recipients.

The policy director reported to the Committee its prior recommendation to the Executive Committee, in 2016. He reported that this recommendation included the following:

1. Clarify current multi-organ policies to match prevalent interpretation
2. Ethics Committee guidance around Principles of Allocation and multi-organ candidates
3. Allow organ specific committees to finalize recommendations with regard to medical criteria and medical need projects into one comprehensive proposal
4. Rewrite broad multi-organ policy

The Committee discussed this previous recommendation and agreed that the current recommendation should be the same, and that items number 1 and 2 could occur simultaneously. The Ethics Committee already has completed work on their guidance/white paper on the principles of multi-organ allocation, so that is not a project that will require a lot of resources.

The Committee agreed that this is an important issue and that resources should be allocated to complete these projects. The Committee voted to recommend the following to the Executive Committee:

Project	Committee	Phase	Cost	Notes
1. Clarify current multi-organ policies to match prevalent interpretation	OPO	1	No IT	• Projects 1 and 2 can run parallel but need to finish before projects 3 and 4 can begin. I estimate 12-18 months for phase 1. • POC floated the idea of a consensus conference after the conclusion of phase 1. • This is a Goal 5 project that aims to lessen confusion without changing monitoring or enforcement. • This will be more staff driven than a typical policy project since the goal is to clearly communicate how staff and the MPSC have interpreted the multi-organ policies. • Project form available
2. Guidance around Principles of Allocation and multi-organ candidates	Ethics	1	No IT	• This would be an addition to the principles of allocation and be released for PC and approved by the Board. • This is a Goal 2 project, as are the rest of the projects.
3. Allow organ specific committees to finalize recommendations with regard to medical criteria and medical	Organ specific	2	Heavy IT	• These would be prioritized by the frequency of the specific multi-organ combination. • These would be sponsored by an organ specific committee. (Similar to SLK) • We will not consider or create specific rules for every type of combinations. (Ex. There will be no VCA-Heart rule.) • These can run parallel or subsequent to project 4.
4. Rewrite broad multi-organ policy	OPO	2	IT possible	• This would review and update the overall multi-organ policy. • Similar to SLK, a large workgroup under the OPO committee would work on this. Somebody floated the idea of a new *ad hoc* committee that could focus on this.

Review of Pancreas Committee New Project

The Committee's next task for the call was their review of the Pancreas Committee's new proposed project, *Review Pancreas Primary Physician and Surgeon Bylaws*. Previous to the call, the Committee reviewed the project form and completed a survey about the project. The following summary was presented to the Committee:

Goal Assignment	**Total Average Score (out of 5)**	**Vote**
#4 (LD and recipient safety) = 14 #3 (Improve outcomes) = 1 #1 (Increase transplants) = 1	4.1	14 YES; 2 NO; 1 MAYBE

The Committee made the following comments and suggestions about this project:

- Additional discussion with the Liver-Intestine Committee to get input regarding adult multi-visceral transplant activity and to clarify the section on multi-visceral transplants either through an experienced working group or through Committee is needed before Executive Committee.
- Given that pancreas transplant is performed at a significantly lower volume than other solid organs, it is reasonable to add flexibility to the procurement requirement. The recommendations outlined by the pancreas committee supports the strategic goal of ensuring patient safety while acknowledging that a combination clinical experience pathway will likely allow a more reasonable duration of time (2-5 years) in order to gain sufficient training as well as fulfilling the required procurement requirements. Modifying the requirements for islet cell personal to include specific islet cell experience will help to ensure that these providers are also adequately trained for this specific procedure including the core elements of islet cell transfers such as infusion supervision. I answered no for now as Goal 4 is currently over allocated by 6%, with most projects 'dark green' and 2 only very recently approved (in other words, it will be over allocated for some time) This projected is evaluated to be a 'medium' project size with an estimated 610 hours required... if approved now, before any other projects mature, it will likely result in Goal 4 being 15-20% over allocated for a substantial period of time.
    1) If this is not 'urgent' (as in: patients or programs are currently impacted,) should this be deferred until resources are free.
    2) Is the June 2015 modification referencing foreign equivalencies in keeping with all of the more recent approvals for other key personnel requirement bylaws
    3) Under cost impacts, the committee states this will impact all pancreas programs, but will it in fact only impact new program applications, and/or changes in key staff at existing programs should they occur. With other personnel changes, grandfathering occurred for existing key roles.
- I am not sure how living donation fits into this (islets?). I am also not clear on how islet procurement proficiency is determined?

- I think this is a needed project to clean up some loose ends in UNOS policy. I think the committee should be encouraged to wrap up many of these issues and align the policy with existing resources.
- Typo under "Transplant Hospital Impact": last line states "(pancreas primary surgeon or primary surgeon; islet primary surgeon or primary physician)". I believe that is meant is "pancreas primary surgeon or primary physician, islet primary..."I only see a few passing references to the issue of multivisceral transplants and pancreata, but since that issue seems to be primarily a pediatric transplant center concern, does the Pediatric Committee need to be a stakeholder and weigh in on those elements of the project?
- Goal 4 is under-allocated; this project fits that category. It is a project that had been worked on a lot but was never completed. The result is that islet programs are difficult to establish due to requirements for islet surgeons that are likely excessive and should have been modified long ago. It is time to pick up this (close-to-being done) project and complete it.

The Committee voted unanimously (16-0) to recommend approval of this project to the Executive Committee. The Chair will report the Committee's recommendation to the Executive Committee at its next conference call on September 18, 2017.

The meeting adjourned at 3:51 pm.

Upcoming Meetings

- Friday, November 17, 3:00 PM ET, conference call
- Wednesday, December 20, 3:30 PM ET, conference call