OPTN/UNOS Policy Oversight Committee
Meeting Minutes
April 20, 2017
Conference Call

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

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo on April 20, 2017 to review a new committee project from the Vascular Composite Allograft (VCA) Committee and to discuss the upcoming review of the entire committee project portfolio.

1. Committee Projects

The POC has no currently active committee projects.

2. Other Significant Items

- **New Project Review: Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs Public Comment Proposal Review**

  The POC first discussed the primary goal assignment for this project from the VCA Committee. Committee members voted on the primary goal assignment as part of the survey questions they answered prior to the call; their votes were as follows:

  Primary Goal Assignment:
  Goal 4 (Safety) = 8 votes
  Goal 5 (Efficiency) = 5 votes
  Goal 1 (Increase Transplants) = 2 votes
  Goal 2 (Access) = 1 vote

  After discussion and deliberating between goals 4 and 5, the committee voted unanimously to assign the project to goal 4 (safety). They then went on to discuss the merits of the project. The survey results on the project were 12 Yes (to approve), zero No, and 4 Maybe. Their comments included the following:

  - I am unclear as to whether a VCA surgeon will be required to complete a transplant fellowship? The language in the limb example was confusing... pertaining to kidney transplants.
  - Rationalizing and aligning requirements for key personnel of VCA programs at this early stage of field/program development makes sense for VCA programs and for OPTN. It seems fundamental to attempt to align educational requirements for key personnel across programs.
  - The proposal to have the same set of rules for all organs seems reasonable. This may be, in my mind, the strongest rationale for this proposal. Certainly, no arguments are presented to tell us why the rules should NOT be the same. The basis for stating that this change will increase the number of VCAs, increase the safety of VCAs, and increase equity of access to VCAs is presented in a theoretical manner; no data was extended to show how and why the current rules hinder these goals. There are many errors of grammar and syntax in this proposal that detract from its clarity. Having said all

of this, I wish to highlight that this is my first activity related to the POC so, frankly, I may not know of what I am speaking or what I am doing.
- While it does seem to have some surrounding controversy I believe it will benefit from being out for public comment.
- While the committee has placed this project into Goal 4 I believe this really is a Goal 5 project as this is development of bylaws that with collaborative and thoughtful development will allow the MPSC to approve or disapprove applicants for primary positions.
- This is a very important project as more and more VCA programs come in line and the training thought necessary for individuals to act in these primary positions is quite varied often very different from the other solid organs.
- Because of its experimental status, VCA should still be performed according to the strict requirements of the original OPTN Bylaws. Thus, the concerns about the Bylaws being overly restrictive, and dissimilar to other organs is not convincing enough of an argument to reverse the sunset provision. Rather, the most convincing argument is that well-qualified and experienced but not US board eligible VCA surgeons (i.e., foreign surgeons-- many of whom have performed more VCAs than US surgeons) should be permitted to perform the surgery. My concern is with the US-born surgeons who are not US board certified: they should be eligible to perform VCA. That is, because VCA is still so new and experimental (IRBs still need to review protocols), then we need to maintain the most careful provisions for who can perform VCA surgeries, it is premature to change the provisions to enable non-board certified US physicians to perform VCA. In sum, this project should be revised to only permit the foreign (not US board eligible) surgeons to perform VCA.
- This proposal will ensure that VCA programs can continue if a non-US surgeon.
- I'm not clear as to whether the proposed solution is to create a continuing education pathway (and if so, with what time line and applicable to whom?) or to just indefinitely extend the exemption from the required board eligibility / board certification criteria. How many VCA programs currently have non-board certified / non-US board eligible primary transplant surgeons?
- As VCA transplants move into the mainstream this will be an important consideration to make sure developing programs have the quality personnel to protect patient safety. The reason VCA was exempt previously was to not stifle a field which is in such an early stage. It still is in a very early stage. Board certification is not likely to be as meaningful as experience, regardless of whether the experience was in Sweden or the US.

After reviewing the comments and further discussion, the committee voted to recommend approval to the Executive Committee by a vote of 12 Yes, 1 No.

- **Presentation of the Timeline for Existing and New Project Review May 2017**

The POC liaison gave a brief presentation to the committee to provide an overview of the upcoming committee project review of all existing projects and one new project as follows:

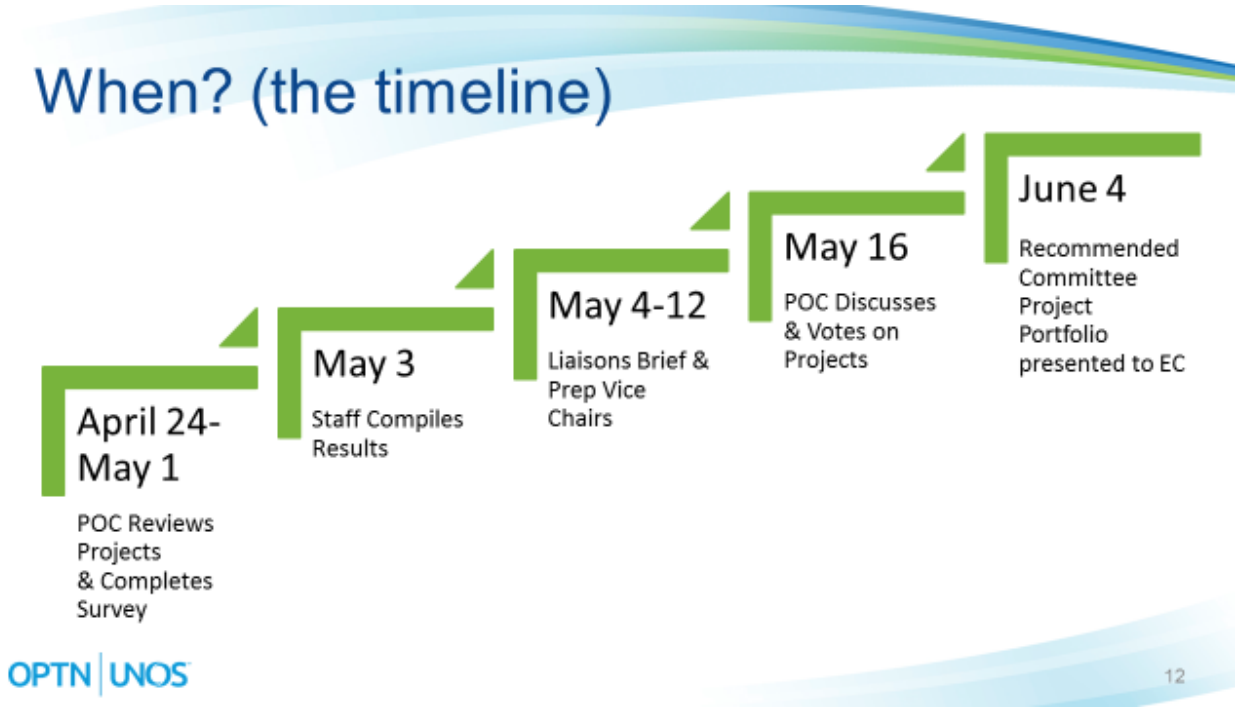
23 Existing Projects

  - Split into 2 review groups (~ 12 projects for each POC member to review)

1 New Project (from Histocompatibility Committee)

  - All POC members review

She provided the following timeline:



In addition, the committee briefly discusses the upcoming in-person meeting in Richmond on May 15-16.

The meeting adjourned at 12:58.

Upcoming Meetings

- Monday, May 15, 2017 – Orientation (New POC members only), Richmond, VA
- Tuesday, May 16, 2017 – Full Committee Meeting, Richmond, VA