OPTN/UNOS Board of Directors Executive Committee
Meeting Minutes
August 1, 2018
Conference Call

Sue Dunn, RN, B.S.N., M.B.A., Chair
Maryl R. Johnson, M.D. FACC, Vice Chair

Introduction

The Executive Committee (EC) met via Citrix GoToTraining teleconference on 08/01/2018, to discuss the following agenda items:

1. Welcome and Overview of Executive Committee Work
2. Letter from HRSA
3. Recommendations from the POC - Public Comment Proposals
4. Recommendations from the POC - Proposed New Projects
5. OPTN Closed Session

The following is a summary of the Committee's discussions.

1. Welcome and Overview of Executive Committee Work

An Executive Committee orientation was presented since this is the first meeting for many members.

Data summary:

The bylaws dictate membership of the Executive Committee and require 50% transplant MDs; minimum 25% candidates, recipients, donors, and family members; minimum 1 member of the general public; OPTN Executive Director and HRSA member. Selection is by category or class voting with a 1-year term. Board officers are EC members plus a minority transplant professional representative. Five additional members are elected to include required perspectives.

Membership for 2018-2019: Sue Dunn, President; Maryl Johnson, Vice President; Yolanda Becker, Immediate Past President; Deanna Santana, Vice President of Patient and Donor Affairs; Theresa Daily, Secretary; and David Reich, Treasurer.

New members were welcomed: Akinlolu Ojo, Minority Transplant Professional Rep; Danyel Gooch, Transplant Coordinator; John Schmitz, Histocompatibility Lab Rep; Willie Oler, Patient and Donor Affairs Rep; Macey Henderson, Patient and Donor Affairs Rep; and Christopher Anderson, At-Large MD.

Other returning members include Brian Shepard, OPTN Executive Director; Frank Holloman and Christopher McLaughlin, HRSA members.

The Committee meets monthly, more frequently as smaller groups. In-person meetings are in the spring in addition to the December Board Meeting. EC will consider issues that will require expedited action in between meetings of the Board of Directors and provide strategic oversight and direction to the Committee. Types of actions and issues considered are approvals (clarify changes to policy, expedited or emergency changes, committee proposals for public comment, reviewing overall committee project portfolio), acting on urgent member issues, endorsing official OPTN positions on federal issues, and providing strategic direction to other committees on budget, member and policy issues.

The EC plays a role in the OPTN Policy Development Process, namely in the committee projects. A committee project must first be approved by the Policy Oversight Committee (POC), and then recommended for approval as a project to the EC. The EC will also review projects that are recommended to go out to the fall public comment cycle.

There are four types of projects that must go out for public review: changes to OPTN policies and bylaws, new data entry requirements, changes to member requirements, and OPTN guidance documents.

There are two layers of review in the policy development process. The POC has two or three questions that they review primarily when it comes to approving projects. The EC focuses on ensuring alignment with Final Rule and benchmarks within the OPTN strategic plan; analyzing whether the OPTN has adequate resources to work on and implement projects; and discussing whether timing is appropriate on a given project to expend resources.

2. Letter from HRSA

Highlights from the letter received from HRSA administrator on July 31, 2018, were presented by Brian Shepard, OPTN Executive Director.

Data summary:

The administrator having reviewed critical comments of OPTN policies, concluded that DSAs and regions are not appropriate tools for determining the distribution of organs. While proximity is an appropriate element of allocation policies when it is for specific reasons that are set out in the final rule, such as reducing ischemic damage and wastage promoting utilization or promoting efficient use of resources, the DSAs are not consistent enough in any way (size or population) to be a good proxy for the definition of what is a local transplant.

The Administrator directed EC work on revisions so that they employ consistent and Final Rule-compliant rationales for any time that organs are kept near the donor or geography distribution is restricted. He calls on OPTN to complete the path laid out by the EC in the letter of June 25th addressing liver issues. The Liver Committee was directed to begin working on revisions to that policy and propose changes to the Board for adoption after the December Board of Directors' Meeting.

The Liver Committee is currently modeling different approaches from SRTR, fundamentally circle-based approaches. One model has an emphasis on the most urgent patients and cost and efficiency for patients with less urgent medical acuity. The other model begins with most urgent candidate that then progressively gets further away, and then moves to the next level of urgency. Different sizes of circles are being considered in both models. Operational details such as exceptions using Median Meld of Transplant in DSA as baseline for establishing exception scores are also being considered. The proposal will be discussed at the in-person December Board Meeting, as well as October/November special public comment.

The EC will develop a timetable for revisions to the policies for all organs so that DSAs and regions are not part of the allocation policies. This will not affect the recovery process or assignment of OPOs to geographic areas. EC has begun talking to other committee leaderships about the lawsuit and the need for modeling in the next month to have ready for public comment in the spring and to bring before the Board next June.

Summary of discussion:

One Committee member asked if the deadline meshes with the Geography Committee's work and potential of other allocation systems down the road. The Geography Committee is proposing for public comment three different frameworks with a goal of having a single fundamental concept. The liver policy from last December now being revised is some ways

using a softer circle where the circle created a points preference. A little closer meant a little more advantage, but someone who was significant more medically urgent outside the circle could still come before someone less urgent inside. The second concept uses a mathematically-optimized area that could be districts, neighborhoods or a population-based circle. The third is an algorithmic model which gives people a score based on how far away they are, mainly how much it costs to get to them. It is unlikely that the Geography Committee will come up with one model that everyone must adopt immediately.

One Committee member highlighted a couple of key points. In the letter, the Department continues to rely on OPTN for expertise in policy development. It also says DSAs and regions cannot be justified in allocation policies, but that does not mean there cannot be a form of geographic area. Rather, it means there needs to be good data, evidence, and rationale to back up particular boundaries that are being set. With the policies going forward, there needs to be rationale on how the policies are consistent with the Final Rule. The Committee Chair agreed.

Next Steps:

A draft of the plan response will be sent out to the Committee via email by next week, with a conference call for approval of the draft following. Then it can be given to HRSA before the August 13th deadline.

3. Recommendations from the POC - Public Comment Proposals

Data summary:

Six proposals were presented for review:

- Frameworks for organ distribution (Ad Hoc Geography)
- Changes to islet bylaws (Pancreas)
- Pancreas program functional inactivity (Pancreas)
- Addressing HLA typing errors (Histocompatibility)
- Change to hospital-based OPO voting privileges (MPSC)
- Tracking pediatric transplant outcomes following transition to adult care (Pediatric)

A chart of the current strategic plan alignment was then presented, which demonstrated strategic goals in the strategic plan. The height of each column represented current allocation to projects in those strategic goals. Benchmarks have shifted with the new 2018 strategic plan and are applied to the overall portfolio. POC is currently reviewing problems in the portfolio. Projects that are going out for public comment were represented in goals 3, 4, and 5, related to outcomes in efficient management of OPTN. The graph indicated the size of the projects in terms of staff and resource hours involved in development and implementation.

The POC recommended unanimously that all six proposals move forward to public comment. Most of the feedback from POC was on the pediatric proposal in terms of confusion about whether or not these are new rules for members.

Summary of discussion:

After a motion was made and seconded, the Executive Committee approved the six proposals to move forward to public comment.

4. Recommendations from the POC - Proposed New Projects

Summary of discussion:

Data summary:

Proposed new projects were presented:

- Eliminate the use of DSAs and regions in kidney and pancreas distribution
- Eliminate the use of DSAs and regions in thoracic organs in distribution
- Eliminate the use of DSAs and regions in liver distribution
- Eliminate the use of DSAs and regions in VCA distribution

POC recommended that the projects move forward to the Executive Committee. There was some concern by some people about the rapid timeline of the proposal development. There certainly could be plans to include additional persons in the project development for those committees. There was no pushback on the need to develop proposals or make changes in policy.

Regarding alignment of the new projects, over the last 3 years EC has been moving into closer alignment with the strategic plan as new projects are approved. This is not a requirement and the important work should take precedence over benchmarks. The projects are grouped by shared IT systems for policies. The first three will receive SRTR modeling. The liver and intestine proposal is headed to the Board in December with the other projects going to public comment in the spring of next year.

Summary of discussion:

One member asked if the projects should stay in a separate grouping or be put in a strategic plan. If it is directed from HRSA, it will have to be done. The practice in the past has been that projects come from the Board according to one of the strategic goals. The Chair felt this is the best way to capture the Committee's activity versus having another list somewhere else; however, it does skew the workload under goal #2--increase equity in access to transplants--quite a bit. It is not just about alignment, but about getting the right projects.

After a motion was made and seconded, the Executive Committee approved the four new committee projects.

5. OPTN Closed Session

The meeting then moved to OPTN closed session to vote on approval of a new transplant hospital.

Data summary:

Typically the approval of a program is a joint effort between membership staff and the MPSC. The bylaws require that the Board approves recommendations, and so they typically go to the Board in a consent agenda on a long list of a lot of membership actions that the Committee has approved. The need to vote on this transplant hospital is because in this particular case, one of the patients has an insurance carrier who will not cover the child's transplant care unless the center has full approval. This member received interim approval in April of 2018, MPSC approval in July 2018, and now comes to the Executive Committee for expedited approval on behalf of the Board, rather than wait until the December Board meeting.

Summary of discussion:

After a motion was made and seconded, the Executive Committee approved the new transplant hospital. Committee members with conflicts abstained.

Upcoming Meeting

- August 9, 2018
- September 27, 2018

Attendance

- **Committee Members**
  - Ms. Sue Dunn
  - Dr. Christopher Anderson
  - Ms. Danyel Gooch
  - Dr. David Reich
  - Deanna Santana
  - Dr. John Schmitz
  - Dr. Macey Henderson
  - Mr. Willie Oler
  - Ms. Theresa Daly
  - Dr. Yolanda Becker
  - Dr. Maryl Johnson
  - Mr. Frank Holloman (HRSA)
  - Mr. Chris McLaughlin (HRSA)
  - Mr. Brian Shepard (OPTN Executive Director)