

## **OPTN Executive Committee**

### **Meeting Minutes**

**July 30, 2020**

**Conference Call**

**David Mulligan, MD, Chair**

**Matthew Cooper, MD, Vice Chair**

## **Introduction**

The Executive Committee (EC) met via teleconference 07/30/2020 to discuss the following agenda items:

1. Welcome
2. Emergency COVID-19 Actions
3. OPTN Projects Recommended for Public Comment
4. New OPTN Project Recommended for Approval
5. OPTN Executive Committee Elections Bylaw Amendment

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

### **1. Welcome**

The Committee Chair welcomed all attendees to the meeting. The agenda was reviewed. Seven new members were introduced and welcomed to the Committee. A brief overview of upcoming projects and upcoming meeting dates was given. December's meeting is tentatively scheduled as an in-person meeting in Dallas, but is subject to change.

### **2. Emergency COVID-19 Actions**

The OPTN Executive Director presented the emergency policy for COVID-19, which was adopted by the EC. The emergency policy has not gone through public comment, but will be reviewed at each EC meeting. The Committee will have the option to repeal the policy, keep the deadlines in place and allow the actions to expire, or extend deadlines into the future.

#### Data summary:

Review of the number of deceased donor and living donor transplants shows a healthy recovery in May 2020 from the decreased numbers in March and April. Number of transplants at this up to this point in the year 2020 is actually ahead of the number of deceased donor transplants through the same stage of 2019, which is not the case in other areas around the world.

Waitlist additions or registrations are financial indicators, as the bulk of the OPTN revenue comes from member registration fees, as well as an indication of behavior for the transplant community. That number has nearly fully recovered. Number of registrations inactivated due to COVID-19 reasons spiked in March and April, but has decreased. Many lessons were learned during the COVID-19 experience in the Northeast. There is no longer an across-the-board overwhelming hospital census beyond ventilator capacity. OPOs are now managing a little better and the community has been able to continue doing transplants.

The EC is authorized to act on the Board's behalf and adopt emergency policies when necessary, but must have a repeal date no more than 12 months from the policy effective date. The policy will go out for public comment to gain feedback on whether the policy was appropriate.

A summary of the emergency actions was reviewed. The first action allowed centers to use the most recent lab value so to minimize the number of patients needing to return in person to renew labs. Actions from April 3rd added COVID-19 fields to DonorNet, changed the process for kidney waiting time, and relaxed data submission requirements to minimize in-person visits.

The monitoring report was previously distributed to EC members. UNOS Research staff highlighted the emergency policy data and IT modifications. Lab data for adult livers shows a drop to 1% to 2% of candidate values week over week. Adult and adult heart numbers were also in the report. Requests submitted to the organ centers related to COVID-19 has increased, so candidates are definitely taking advantage of getting waiting times reinstated for the months that they were unable to get labs drawn. The proportion of TRF forms in Amnesty status has been increasing as more data is accumulated. Status of forms reflects the limited staff due to COVID-19.

The organ offer refusals show a continued decrease in COVID-19-related refusals. "OPO or transplant hospital operational issues" was the most common refusal reason. There have been two reports of COVID-19-positive donors. One was determined to be an inactive infection passed from mother to child during pregnancy. The other is still being investigated as a probable false positive.

Summarizing the data, carry-forward values remain very small, the percent of additions qualifying for waiting times remains stable, the percent of TRF and LDF forms in Amnesty status continues to increase, COVID-19-related waiting list and post-transplant deaths were mostly attributable to kidney candidates and recipients, and all donors are reporting receiving COVID-19 testing prior to transplantation.

#### Summary of discussion:

One Committee Member inquired whether there was any known instance of a COVID-19-positive organ being used for transplant. His concern was that there has not been any good outcome for any COVID-19-positive patient undergoing surgery across the board, much less transplant patients. According to the OPTN database, it does not appear that any positive donors have been transplanted. The two previously-mentioned positive donors are the only two recorded.

The emergency policy was written for candidate labs that were required to maintain waiting list status. Kidney candidate lab values were not part of the data evaluation since lab values are not necessarily required for kidney candidates to stay active.

The Committee discussed the different options moving forward based on the data review. One member expressed support for extending the expiration date of the emergency policy through December 31, 2020, which would allow the Board to review the policy. There was agreement that there is still uncertainty as to whether the COVID-19 situation will get better or get worse again and extending the expiration as long as possible will only protect patients and be beneficial to patients, as well as the transplant centers and OPOs. The extended timeline will also allow for collection of public comment. Additionally, the MPSC is also extending their monitoring adjustments due to COVID-19 through the end of December, so there is consistency across the organization.

A motion was made and seconded for the Executive Committee to extend the expiration date of the Emergency Policy Actions for further consideration, including by the full Board of Directors.

Results were as follows: 100% yes; 0% no; 0% abstained.

### 3. OPTN Projects Recommended for Public Comment

The Chair of the Policy Oversight Committee (POC) presented the projects recommended by the POC for fall 2020 public comment.

#### Data summary:

The POC did an earlier review of nine of the projects at their May 20th meeting. A final review of the 10 public comment documents was then conducted at the July 29th meeting, including the updated Public Health Service guidelines, which were not released yet at the time of the May 20th meeting. The POC recommends all 10 proposals move forward to public comment.

- The Lung Committee's first proposal is the Update to the Continuous Distribution of Organs, which is really a part two building on the 2019 concept paper. It identifies attributes discussed by the Lung Committee, how it aligns with the Final Rule requirements, and eventually its utilization in conversion of all allocation policies to a continuous distribution framework. It is not a policy proposal, but asks for specific feedback.
- The Lung Committee's second proposal is the Lung Allocation Score (LAS) public comment document. The values used for LAS calculation includes a cohort that ended in 2008. The proposal is to update the cohort to 2018.
- The Executive Committee's COVID-19 Emergency Policies and Data Collection proposal, as reviewed earlier, will need feedback for the Board to make its decision in December.
- The Heart Committee's first proposal is Guidance and Policy Clarifications on Addressing Adult Heart Allocation Policy, which includes changes to policy, as well as clarification and guidance. It includes updated policy language to clarify timing of when hemodynamic data need to be reported, as well as types and amounts of information needed for the Regional Heart Review Board to evaluate exception requests.
- The Heart Committee's second proposal is Guidance Addressing the Use of Pediatric Heart Exceptions, which is for the National Heart Review Board to try to standardize some of the decision-making for certain diagnoses relevant to the pediatric candidate population.
- The Ad Hoc Disease Transmission Advisory Committee's (DTAC) proposal is to Align OPTN Policy with the U.S. Public Health Service Guideline. The public comment document includes updates that will make the OPTN policy consistent with this new guidance, including areas of informed consent, specimen storage, universal testing post-transplant, documentation of vaccination, and the use of certain terminology.
- The Liver Committee's proposal is Further Enhancements to the National Liver Review Board. This is the second round of enhancements proposed from the Liver Committee, including components for policy related to exception criteria, operational guidelines related to the repeats process, and updated guidance related to recommendations on polycystic liver disease and MELD calculations.
- The Living Donor Committee's proposal is to Modify Living Donor Policy to Include Living Vascularized Composite Allograft (VCA) Donors, as the general policy on living donors had previously specifically excluded VCA living donors. Numbers of VCA donors are still overall small, but there has been a significant increase since 2016.
- The VCA Transplantation Committee's first proposal is to Modify Data Collection on VCA Living Donors. Programs are currently voluntarily submitting limited data on VCA donors.

The proposal would add requirements for data submission consistent with other existing living donor policies, as well as add new data elements relevant to VCA.

- The VCA Transplantation Committee's second proposal is Programming VCA Allocation in UNet. Programming at this time is a manual process due to small numbers, but as numbers are increasing, programming VCA allocation and data collection into UNet needs to be done.

Summary of discussion:

One Committee member asked how the publishing of the PHS guideline updates might impact surveys, since they're not currently aligned with the OPTN policies, and whether hospitals would need to be compliant with OPTN policies or PHS guidelines as published. The DTAC representative clarified that the OPTN notice released regarding this was that the OPTN policy according to the 2013 guidelines should be followed until the 2020 proposal is implemented. It is a Final Rule requirement that OPTN policies are consistent with PHS recommendations. Additional feedback from the community on this issue will be obtained with public comment.

A motion was made and seconded for the Executive Committee to approve distributing all 10 proposal papers for the Fall 2020 public comment period, as recommended by the POC.

Results were as follows: 100% yes; 0% no; 0% abstained.

**4. New OPTN Project Recommended for Approval**

The POC Chair presented one new project proposal to the EC.

Data summary:

The new project proposal from the Data Advisory Committee (DAC) is a combination of two related project ideas to update refusal codes and to look at capturing data related to late turndowns. The goal for the project is to provide better, more granular data into acceptance and refusal practices and to allow for anticipated additional project work that needs the data collection in order to identify where changes might be made to drive efficiencies and ultimately transplant more organs. The POC felt it vital that this project move forward. The POC did recommend back to the DAC that they collaborate with the Operations and Safety Committee (OSC), as they felt projects would be tasked to OSC coming out of this work, as well as to ensure pediatric representation on the work.

The POC continues to look to place new project proposals in the context of the larger OPTN Strategic Plan Alignment to deliver value to the community and drive larger strategic policy initiatives/strategic goals of the OPTN. The DAC's new proposal fits within the increasing the number of transplants, as well as with promoting efficient management. It will require resources because it involves programming. The work is ongoing in the three strategic policy priorities. This would be an active project affiliated with the efficient donor/recipient matching to increase utilization priority.

DAC identified the collaborating committees as the Transplant Administrators Committee, the Membership and Professional Standards Committee, the Organ Procurement Organizations Committee, the Transplant Coordinators Committee, and as previously mentioned, POC added the Operations and Safety Committee should be included. The DAC is currently not working other active projects where they are the sponsor even though they are the collaborating committee on a lot of work, so the POC felt the DAC will be able to handle this project.

The POC expects this work to move forward rapidly, as other projects will be dependent on this data collection. The project timeline allows for the proposal to be ready for public comment in the next cycle in January 2021.

### Summary of discussion:

One Committee Member commented that this issue has been in constant discussion for quite some time in a number of different committees and this proposal is a good step forward.

A motion was made and seconded for the Executive Committee to approve the Refusal Codes/Late Turndown project proposal, as recommended by the POC.

Results were as follows: 100% yes; 0% no; 0% abstained.

### **5. OPTN Executive Committee Elections Bylaw Amendment**

#### Data summary:

Due to time constraints, UNOS staff provided a brief overview of the potential amendment to the bylaws regarding EC elections, which was introduced at the June 7th Executive Committee call. The issue came up when a Board Member asked why voting for at large EC members by categories takes place, such as M.D. Board of Directors members only vote for M.D. Board of Directors members on the Executive Committee. The answer is that it is required in the bylaws. The Final Rule does stipulate composition of the EC, but not categorical election. Therefore, the EC at the June meeting recommended that this practice be reviewed. The EC composition breakdown was given, indicating there are three at-large seats that are voted on depending on make up of the rest of the committee.

The options moving forward would be to maintain status quo or make a strike to the language of the bylaws in Section 4.3 to broaden voting to the entire board for the three at-large seats that come up annually.

#### Next Steps:

Committee Members may share any comments with UNOS staff by email. The next step will be for the EC to recommend this bylaws change to the Board and will vote on this during their September meeting.

#### **Upcoming Meetings**

- September 18, 2020 at 1 pm ET
- October 20, 2020 at 1 pm ET
- December 6, 2020 in Dallas, Texas

## Attendance

- **Committee Members**
  - David Mulligan, Chair
  - Atsi Yoshida
  - Denise Alveranga
  - Jeff Orlovski
  - Lisa Stocks
  - Maryl Johnson
  - Mindy Dison
  - Matthew Cooper
  - Medhat Askar
  - Robert Goodman
  - Tim Snyder
  - Valinda Jones
  - Brian Shepard, OPTN Executive Director
  - Christopher McLaughlin (HRSA)
  - Shannon Dunne (HRSA)
  - Shannon Taitt (HRSA)
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Chelsea Haynes
  - Susie Sprinson
  - Craig Connors
  - Jason Livingston
  - Maureen McBride
  - Henri Haskell
  - Amber Wilk
- **Other Attendees**
  - Alexandra Glazier, POC Chair