OPTN Executive Committee
Meeting Summary
January 13, 2021
Conference Call

David Mulligan, MD, FACS, Chair
Matthew Cooper, M.D., Vice Chair

Introduction

The Executive Committee (EC) met via teleconference on January 13, 2021, to discuss the following agenda items:

1. Welcome & Roll Call
2. COVID Policies Data Review
3. New Committee Projects Recommended for Approval
4. Projects Recommended for Winter 2021 Public Comment Cycle
5. Other Significant Items

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

1. Welcome & Roll Call

The Committee Chair welcomed all attendees to the teleconference. The agenda was reviewed. Congratulations and appreciation was expressed for the amount of work the Committee and the transplant community during the pandemic this past year.

2. COVID Policies Data Review

The UNOS Research Analyst presented an update on the COVID-19-related actions. During the December Board of Directors' meeting, the four emergency actions were made permanent, with the first three actions awaiting a decision from the EC on the right time to repeal them. All Committee members have access to the monthly monitoring report with more details regarding the presentation today.

- Action #1: Updating candidate data during COVID-19 Emergency

  The highest usage for this action is in adult liver, which has been consistent over the last several months at about 1%. This usage is lower than initially expected.

- Action #2: Relax data submission requirements for follow-up forms

  Recipient follow-up forms expected by week up through 1/9/21 shows use of the emergency action is at around 25%. Form use shows a large variation in number and percent of forms in amnesty status across transplant centers across the country. The updated data report of forms under amnesty now includes forms expected through 11/30/20. Compared to the last status report showing forms expected through 10/31/20, percent of Living Donor Follow-up Forms (LDF) dropped from 21.6% to 16.8%, Post-Transplant Malignancy Form (PTM) from 8.7% to 7.7%, and for Transplant Recipient Follow-up Forms (TRF) from 20.7% to 17.1%. Median number of forms went from 59.5% to 34%; maximum number of forms in amnesty at a single outlier center was 3,024 to 2,360; median percent of forms from 14% to 9%; and patient and graft

status in first three years post-transplant, forms in amnesty went from 20.1% to 17.1%. Of note, prior to the pandemic, 8% of forms had reported patients as “not seen” in 2019, compared to 22% of forms “not seen” and in amnesty.

As of 12/2/20, center-specific data compared to across the U.S. are being sent to program leadership weekly, encouraging submission of these data. In response to questions and requests for resources, additional details are now provided in the report in the Data Services Portal and this week the language of the email was changed to provide better direction on accessing forms and how to enter data into the system. The communication efforts seem to be working, as after sending out the first communication, more than 3,500 TRF forms in amnesty have been validated (as of 1/3/21).

The Chair asked if Committee members have seen reactions from the community or any impact from the weekly emails and communications. One member noted his center put together a work plan and has since seen a slow weekly decrease in forms in amnesty. Another has noted a significant amount of discussion amongst at her center regarding the reports due to the pressure being put on the team to enter the data. The language in the reports demonstrates a value to obtain the data, recognizing the circumstances as they are. However, based on feedback, it may be worthwhile to consider helping transplant administrators with passing on the communication to their data teams in a positive way or looking at other modes of communication by OPTN to the teams, such as on Listserv. Any input from the Committee regarding language used in the communications is welcome.

Unfortunately, the pandemic is ongoing with the death rate surging even higher in the past 14 days. With many parts of the country still struggling with the effects of COVID-19, it is difficult to predict a good expiration date for the emergency actions. Feedback from the Committee related to the expiration of the amnesty policy was requested at this time. There was back and forth discussion regarding two opposing recommendations, which are that the EC should start looking at a time to pull back on the amnesty status policy versus continued weekly communication to the centers and reviewing the data again in one month.

One view is that the pandemic may go on for long periods of time, while the amnesty forms are starting to impact the ability to do meaningful statistical analyses of performance and creating a bigger backlog for transplant centers to catch up. A percentage of the data will be lost forever without some kind of a deadline. The systems are up and running and a target date to look forward to going back to normal operations will incentivize those procrastinating centers to get caught up. At least a stronger message that amnesty is going to end at some point, whether it be six months to a year from now, will be important. There is a difference between being punitive and setting some goals. The Committee should be discussing exactly what in the current pandemic conditions are barriers to completing each of the forms.

The alternate view is that a positive response to the weekly communications and the data presented today show improvement in numbers, so it does not seem as though there will be a cumulative backlog that will prevent SRTR from doing outcomes calculations. Transplant programs have only adjusted to the new normal, but are not back to normal. In addition, different parts of the country are being affected differently and the effects of the pandemic over the next several months are still unknown. Some centers are having to divert resources to filling out forms versus doing things to get the transplants done. The Committee should wait to see a major downturn in COVID cases before setting a target expiration date.

The EC Chair concluded that the majority of the forms in amnesty are from a handful of centers. Having the research team or MPSC reach out to those centers to figure out what barriers they are facing that are causing the problem so that they can move forward, might be useful. They could also evaluate whether the centers that are behind are those centers that were traditionally behind prior to the pandemic. Then the Committee can start to make goals as to expiration and what the new normal will be. There was agreement. The UNOS research team will add those metrics to the next data report.

- Action #3: Modify wait time initiation for non-kidney dialysis candidates

  Number of candidate wait time modifications submitted to UNOS related to this action was 81 or 93% in December 2020.

- Action #4: Incorporate COVID-19 Infectious Disease Testing into DonorNet

  The Board approved making the requirement of collection of COVID-19 testing results permanent. This will be implemented 1/27/21. At that time, it will not be possible to send out electronic offer notifications without providing a response of yes/no/unknown to the initial question of whether COVID testing was done. A "yes" answer is not required, but the question must be answered.

3. New Committee Projects Recommended for Approval

The Policy Oversight Committee (POC) reviewed four new projects proposals and the POC Chair presented them today.

<u>Data summary:</u>

a) Review of Extension Requirements in Adult Heart Allocation Policy - Heart Transplantation Committee

   A number of questions from the community have come up that need to be clarified, but it is important for this work to take place before and in preparation of the shift to continuous distribution. Transplant Coordinators Committee will be collaborating. The Heart Committee currently has a project going on, but this project will be shorter in duration.

b) Improving the MELD Calculation - Liver and Intestinal Organ Transplantation Committee

   The goal of the project is to better predict waitlist mortality to reduce sex-based disparity in liver allocation focused on females and small-stature adults. The Liver Committee felt it important to address this issue prior to the shift to continuous distribution. It aligns with the strategic goal of equity. Liver currently has a full workload, but confirmed to the POC they felt they had the ability to take this on. The project will fit within Liver's work of reducing pediatric liver waitlist mortality, as well as commencing the work on continuous distribution, which will not start until 2022.

c) Establish Membership Requirements for Genitourinary Organ Transplant Programs - Vascularized Composite Allograft (VCA) Transplantation Committee

   This project focuses specifically on membership requirements for genitourinary VCA. With specifically uterus being one of the highest volume VCAs at this point, it is important that the VCA start this work so that the membership requirements can be established specific to these types of VCAs. MPSC and Living Donor Committees will collaborate. VCA has the resources to complete the work.

d) Ethical Considerations of Continuous Distribution in Organ Allocation - Ethics Committee

This project will consider continuous distribution in organ allocation. It is not designed to evaluate the continuous distribution framework itself compared to other frameworks, but to help guide other committees in the work of continuous distribution with some consistent application of ethical principles. Several committees are noted to be collaborating on this project. The Ethics Committee has bandwidth to take on this work and agree that this is a priority for continuous distribution reform. The project falls under Promote Efficient Management of the OPTN in the Strategic Plan.

There is over-alignment in the Increase Equity in Access to Transplants in the Strategic Plan, but there are some sequencing considerations with the Heart and Liver projects, as this work needs to be completed in advance of the continuous distribution work. Resource requirements for these projects are not large. The Heart, Liver, and Ethics projects align with the Continuous Distribution Strategic Policy Priorities.

Summary of discussion:

The EC Chair felt the biggest takeaway from the Strategic Plan Alignment is that the Committee should focus on prioritizing proposals to continue to increase the number of transplants.

A motion was made and seconded for the Executive Committee to approve the four projects as presented and as recommended by the Policy Oversight Committee.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

4. Projects Recommended for Winter 2021 Public Comment Cycle

The POC Chair presented ten public comment items that were discussed at their 1/8/21 meeting.

Data summary:

The POC put into place a pre-review of public comment in order to give feedback to the committees. Based on feedback from 11/5/20, the Minority Affairs Committee decided not to pursue second round of public comment on the Data Collection to Assess Socioeconomic & Access to Transplants project. The POC also had concerns with the Liver and Intestinal Committee project on Updating Median MELD at Transplant Calculation and Sorting Within Liver Allocation Classifications, but after discussion, but after discussion, voted to move it forward for public comment.

The POC discussion on the 10 items for Winter 2021 public comment was limited to the substance of the proposal and whether or not the proposal and document looked prepared and ready to be sent. The POC voted to recommend all 10 move to public comment. The 10 items were not discussed in detail at this meeting, but the materials are all provided to the Executive Committee members to individually review. Of note, there was discussion raised by HRSA about the work from the Ethics Committee, Revise General Considerations in Assessment for Transplant Candidacy. The HRSA representative confirmed there are recommendations regarding the language within the document, but there is no concern with it going out for public comment.

Summary of discussion:

There were no questions or comments from the EC regarding the above 10 items.

A motion was made and seconded for the Executive Committee to approve the ten items as presented for Winter 2021 Public Comment.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

5. Other Significant Items

The OPTN Executive Director updated the Committee on the critical comment briefly mentioned at the last meeting. The law firm that submitted the critical comment has submitted what they refer to as a supplemental critical comment. The OPTN staff and legal staff reviewed it and feel there no additional issues raised in the new letter that are not already in the previous letter. In addition, HRSA has not yet requested a response from OPTN and the Executive Committee and OPTN.

Upcoming Meeting

- March 1, 2021 at 3 p.m. ET
- April 26, 2021 at 1-5 p.m. ET in Chicago, IL
- June 13, 2021, TBD in Richmond, VA

Attendance

- **Committee Members**
  - David Mulligan
  - Matthew Cooper
  - Valinda Jones
  - Atsi Yoshida
  - Maryl Johnson
  - Robert Goodman
  - Lisa Stocks
  - Jeff Orlowski
  - Tim Snyder
  - Medhat Askar
  - Christopher McLaughlin (HRSA)
  - Brian Shepard, OPTN Executive Director
- **UNOS Staff**
  - Sarah Taranto
  - Chelsea Haynes
  - Susie Sprinson
- **Other Attendees**
  - Alexandra Glazier, POC Chair