

## **OPTN Executive Committee**

### **Meeting Minutes**

**October 20, 2020**

### **Conference Call**

**David Mulligan, MD, Chair**

**Matthew Cooper, MD, Vice Chair**

## **Introduction**

The Executive Committee (EC) met via teleconference 10/20/2020 to discuss the following agenda items:

1. Welcome and Roll Call
2. Projects Recommended by the Policy Oversight Committee (POC) for Approval
3. COVID Emergency Actions Review and Recommendations to the Board
4. OPTN Strategic Plan Discussion and Next Steps
5. Adjourn

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

### **1. Welcome and Roll Call**

The Committee Chair welcomed all attendees to the meeting. The agenda was reviewed.

### **2. Projects Recommended by the Policy Oversight Committee (POC) for Approval**

Alex Glazier, Chair of the POC, provided an update on the Efficient Matching Workgroups. The three Efficient Matching Workgroups are: Provisional Yes, Local Recovery, and Biopsy. Each workgroup is comprised of members from various committees tasked with addressing specific pain points of system efficiency and making recommendations on a pathway forward, which might later be developed into project work or policy proposals. The POC prioritized the recommendations by assessing value and impact. Additionally, they discussed how to sequence the portfolio of work to deliver the intended maximum value, which is to increase the efficiency of the matching process and increase the number of transplants. Some recommendations may not result in a policy project, but are focused on system design components.

The projects that the POC felt were of the highest priority and could deliver the most value and impact included three from the Provisional Yes Workgroup, one from the Local Recovery Workgroup, and three from the Biopsy Workgroup. The first two Provisional Yes Workgroup recommendations are: Increase Offer Filters and Dynamic Match Run. The Increase Offer Filters recommendation is designed to reduce the volume of offers highly likely to be declined, and the Dynamic Match Run is designed to reduce inefficiency of late turn downs by automating match runs when a donor condition changes that would trigger a turn down. POC leaders are in the process of developing a work plan for these recommendations.

Ms. Glazier then presented three projects from the POC:

**Kidney Pediatric Project (Kidney Transplantation):** This project was previously approved, but was then put on hold. This project would add additional priority to pediatric candidates in a Sequence C. The POC felt this project would fit well within the continuous distribution work. It would also be more efficient in

terms of OPTN resources in the shift to continuous distribution, instead of addressing it as a standalone project and then having to do re-work. Therefore, the POC recommends that this work be incorporated in to the continuous distribution project instead of addressing it as a separate project.

**Modifications and Education in Organ Packaging Policies (Operations and Safety):** This project focuses on standardizing differences in practices and inefficiencies that currently exist in organ packaging, specifically in regard to some reports through the MPSC of kidneys that were partially or fully frozen upon arrival. It is important to note there have only been eight instances identified in the past, but it is possible that this number was underreported. The POC felt the better pathway, rather than a policy pathway, would be to refer the project to the Collaborative Improvement Team. In addition, the OPTN Operations and Safety Committee is about to receive a number of significant high-priority projects under the efficient matching strategic policy priority.

**Required Reporting on HLA Typing Changes (Histocompatibility):** This project requires reporting on HLA typing changes, specifically: notifications to members, OPOs, and transplant hospitals when there is a change in donor HLA typing. The POC considered other work of the sponsoring committee, the collaborating committees for the project, where it falls within strategic alignment, and overall resources. The POC felt the project was appropriate to pursue this project at this time.

A motion was made and seconded for the Executive Committee to approve the Required Reporting on HLA Typing Changes project proposal, as recommended by the POC.

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

### **3. COVID Emergency Actions Review and Recommendations to the Board**

The OPTN Executive Director presented the four emergency action proposals in response to COVID-19, which had been previously approved by the Executive Committee.

The COVID-19 emergency action proposals all fall under the emergency bylaw clause and have an expiration date of no more than 12 months. The emergency actions were adopted in March and April 2020. They continue to be reviewed at every meeting and will be reviewed at the December Board of Directors' meeting. Currently, one action will expire in March of 2021 and the other three will expire at the end of 2020. All the actions went out for public comment and the EC will decide today whether to recommend to the Board to repeal or keep the expiration dates of each emergency action.

Craig Connors, UNOS Director of Policy and Community Relations, provided a summary of the public comment. Overall, there was broad support for the emergency actions. When considering the expiration of the actions, several public comments suggested extending the emergency actions with some future repeal, instead of selecting a set date. Comments did not contain any explicit suggestions to end the emergency actions.

**Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency:** There was broad support for continued utilization. The OPTN Heart Committee does not see the need to extend Action 1 (candidate data submission) specifically for heart candidates. The usage of the policy continues to be fairly low when looking at overall listing percentages. Adult lung has been less than 5%, liver has been about 1%, and adult heart has had almost no usage. There was support in public comment to continue past March 2021.

The Committee did not feel Action 1 should be repealed immediately or that the expiration date should be changed at this time. The EC recommended that they should retain discretion to end Action 1 when it appears appropriate, but will provide ongoing updates to the Board. The impact of the pandemic on programs is still unknown.

A motion was made and seconded that the recommendation to the Board be that Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency have no fixed end date and that the end be determined by Executive Committee or Board resolution in the future. This recommendation also includes regular updates to the Board.

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

Action 2: Relaxing Data Submission Requirements for Follow Up Forms: The public comment generally was positive for the policy changes and the action itself, as the COVID-19 pandemic is evolving. However, several entities, including the Data Advisory Committee (DAC), suggested this policy should expire due to the continued data loss when forms go into amnesty. There was differing feedback on whether centers would need to retrospectively complete the data entry that was not submitted during amnesty. There were some comments that retrospective data entry should not be required, and that the data should become truly lost data in response to the pandemic, and that recovering the retrospective data would be a burden on the centers. Other comments supported retrospective data entry, noting a complete data set is important for understanding outcomes and future modeling, as it is difficult to draw conclusions based on an incomplete data set, but that the process and the deadlines for submission should be made clear. The DAC recommended a due date of 90 days after amnesty ends. There was one suggestion to allow for partial data entry.

For the week preceding October 5th, the number of TRFs in amnesty status passed 30% and the LDFs have been hovering around 30% for a few months. As of October 1st, 51,600 TRF forms, 2,879 LDF forms, and 464 PTM forms are in amnesty status. Of all forms due since March 13, 2020, 67,815 TRF forms were ever in amnesty status and about 20% were subsequently validated, but 80% are still in amnesty.

One additional factor affecting retrospective data entry on the LDF is Policy 18.2, which does have a 60-day timeline post testing to submit data, and this was not altered with the emergency action. If the recommendation is retrospective data entry, this policy would need to be addressed. There is also an additional potential complication due to the fact that the LDF forms are Office of Management and Budget (OMB) approved forms. HRSA is still trying to assess whether a decision by the Board to let the data go into amnesty forever would have to be followed on by an action related to the OMB status of these forms.

The UNOS Research Department put together three options for the EC regarding the retrospective data collection. Option 1 is to have no retrospective data collection, Option 2 is to require retrospective data only where expected patient data is available, and Option 3 is to have all forms need to be retrospectively submitted.

Dr. Mulligan asked for feedback from the committee, and one member commented that they were in favor of option 2, because they are in favor of having as much data as possible without jeopardizing anyone's health. Another committee member also voiced support for option 2. One member of the committee noted that the timing of data collection will be important, as different regions of the country are facing different COVID-19 rates. Another member of the committee noted that option 2 provides the most flexibility. The OPTN Executive Director clarified that 70% of the data has been collected, but since some patients did not come into the transplant centers during COVID-19, 100% of the data does not exist. The conversation is around how to collect more than 70% of the data, but still less than 100%. All options require communication to the community of the importance of entering data that are available. Mr. Shepard noted that it is important to consider under what circumstances a program would come before MPSC for not providing the data. One committee member noted that the MPSC could approach the amnesty forms from a process improvement perspective.

Jon Snyder provided the SRTR perspective, noting program-specific reporting is on hold indefinitely, pending further analysis. The two main outcomes are patient deaths and graft failures, so the SRTR's main concern is status reporting of graft loss. It was also noted that data collection is important to evaluate the impact of COVID-19 on the transplant system.

Action 2 is currently allowed to expire December 31, 2020. The Committee did not feel it should be repealed on December 31st. One committee member asked if it was possible to identify programs that have a significant number of forms in amnesty, and UNOS staff confirmed that this would be possible. UNOS staff requested specific recommendations regarding retrospective data submission whenever the EC resolves to end the amnesty policy. The EC supported adding Option 2 to the recommendation to the Board, providing some discretion to the programs as to what is safely available given the COVID-19 pandemic. Obtaining data "safely" would refer to both the patient experience and program resources.

A motion was made and seconded that the recommendation to the Board be Action 2: Relaxing Data Submission Requirements for Follow Up Forms has no fixed end date. The Executive Committee will continue to monitor the status of the pandemic and give regular reports to the Board in order to determine when amnesty status should end, with the additional note that the Executive Committee also recommends Option 2, requiring retrospective data as much as possible.

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

Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

There were no specific comments on this action. The Kidney Committee leadership supported the continuation of the action until the pandemic has minimal national impact with no travel restrictions.

Action 3 is currently scheduled to expire December 31, 2020. The suggestion was to make a recommendation similar to that made for Action 1.

A motion was made and seconded that the recommendation to the Board be that Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates have no fixed end date, with Executive Committee discretion to terminate when appropriate, and with ongoing reports to the Board.

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

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

There was strong support, especially from OPOs, noting that this was helpful in facilitating organ placement and allocation. There were many comments in favor of keeping the infectious disease testing field as a requirement long-term or permanently. Currently the field is in DonorNet, but is not required. The UNOS Research Department validated that 100% of donors who have had organs transplanted have been tested for COVID-19, with the overall the average use of the field being 80% since April 2020. Currently, use of the field is at ~96%.

Action 4 is currently allowed to expire December 31, 2020. There was support for making this emergency action permanent to prevent having to continually discuss it. There was agreement to make the field mandatory, but past discussion brought up the issue of slowing the allocation process because of the timing of the testing. It was decided that "pending" would still be acceptable in the mandatory field in order to move the allocation process forward. Currently, this is similarly done with hepatitis C and HIV testing.

A motion was made and seconded that the recommendation to the Board be that the Action 4: COVID-19 Data Fields be permanent and required in DonorNet.

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

Next steps:

The Board of Directors will take action on the recommendations of the Executive Committee at their December meeting.

**4. OPTN Strategic Plan and Next Steps**

Mr. Shepard provided an update on the OPTN Strategic Plan. A draft of the plan will be distributed to the EC, which contains feedback from the Board and other stakeholders. The EC will be asked to provide additional feedback by October 30<sup>th</sup>. Following additional review by the EC, the draft will be sent to the Board of Directors. Once the Board comments have been incorporated, the EC will approve it for public comment. Following public comment, the Board will take action on the final plan at their June 2021 meeting.

**5. Adjourn**

The closed session following today's conference call will be rescheduled due to time constraints.

**Upcoming Meetings**

- November 2, 2020
- December 6, 2020

## Attendance

- **Committee Members**
  - David Mulligan, Chair
  - Atsushi Yoshida
  - Denise Alveranga
  - Jeffrey Orłowski
  - Lisa Stocks
  - Maryl Johnson
  - Mindy Dison
  - Matthew Cooper
  - Medhat Askar
  - Robert Goodman
  - Timothy Snyder
  - Valinda Jones
  - Brian Shepard, OPTN Executive Director
  - Christopher McLaughlin (HRSA)
  - Shannon Dunne (HRSA)
  - Shannon Taitt (HRSA)
- **SRTR Representatives**
  - Jon Snyder
- **UNOS Staff**
  - Chelsea Haynes
  - Susie Sprinson
  - Craigonors
  - Jason Livingston
  - Maureen McBride
  - Sarah Taranto
  - Henri Haskell
  - Laura Cartwright
- **Other Attendees**
  - Alexandra Glazier, POC Chair