OPTN Executive Committee
Meeting Summary
December 6, 2020
Virtual Meeting

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

Introduction

The Executive Committee (EC) met via virtual meeting on December 6, 2020, to discuss the following agenda items:

1. Welcome & Roll Call
2. Liver Policy Clarification
3. New Project: Reporting Immediate Graft Dysfunction in Heart Transplant Recipients
4. COVID-19 Emergency Policies
5. Continuous Distribution Projects Update
6. Adjourn

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

1. Welcome & Roll Call

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

2. Liver Policy Clarification

UNOS staff presented the first action item. During the acuity circles for liver policy development, all references to "local" and "regional" should have been removed from the policy language. Policy 9.9.A, not often used, is the eligibility for liver candidates under age 18, and still contains the words "local" and "regional" in a context not related to allocation. The proposal is to remove the words "local" and "regional", as well as the word "national".

A motion was made and seconded for the Executive Committee to amend Policy 9.9.A, as presented.

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

3. New Project: Reporting Immediate Graft Dysfunction in Heart Transplant Recipients

The Policy Oversight Committee (POC) Chair presented one new project for approval, which comes from the Heart Transplantation Committee.

The project is to develop measures for primary graft dysfunction. Of note, it is broken into two phases. Phase I will be to gather information from the public as part of the January public comment cycle. The Committee will then use the feedback to work on a full data collection proposal. Phase II will be to submit the data collection proposal for the public comment cycle of August through October 2021. The Transplant Coordinators Committee will be collaborating with the Heart Committee on this project. The project falls within "Improving Outcomes" in the Strategic Plan Alignment. Overall resource allocation is "very small"

Summary of discussion:

One Committee Member asked if there was a primary graft failure for lung. UNOS staff clarified that primary graft dysfunction, which is also based on International Society for Heart and Lung Transplantation definition, is already collected for lungs on the Transplant Recipient Registration form. In addition, the lung continuous distribution project is underway, but heart is still several years out in terms of overall policy development work. Since Heart and Lung are now separate committees, Thoracic organs will not necessarily be on the same timeline as they previously were.

A motion was made and seconded for the Executive Committee to approve the Develop Measures for Heart Primary Graft Dysfunction project, as recommended by the POC.

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

4. COVID-19 Emergency Policies

The goal is to review results of further analysis from the 11/2/20 Executive Committee data request specifically addressing the Transplant Recipient Forms (TRF), Living Donor Follow-up Forms (LDF), and the Post-Transplant Malignancy Forms (PTM) that were placed under amnesty in COVID-19 Emergency Policy Action #2.

David Mulligan, Chair of the Executive Committee, reminded the group of the emergency actions:

- Action 1: Updating Candidate Data During 2020 COVID-19 Emergency
- Action 2: Relax Data Submission Requirements for Follow-Up Forms
- Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates
- Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet

UNOS staff reviewed the latest updates to the monitoring data. There is no significant change in the data related to Action #1. There remains to be consistent utilization of the policy, especially with adult liver. For Action #2, there is a slight uptick in percent of TRF forms in amnesty status over the last few weeks, but no significant change. For Action #3, the percentage of registrations on the waiting list for non-dialysis patients and using this policy has remained steady since January. This number of registrations with modification requests is about a third of the total number of patients not on dialysis. For Action #4, about 84% of recovered donors utilize the COVID-19 testing field for the entire time period the action has been in place, and this has gone up to about 95% in recent weeks.

Further analysis was done on Action #2. The data elements on the TRF, LDF and PTM were first placed in three categories:

- The first category is data elements that continue to be collected through amnesty. On the TRF, transplant centers are still required to provide the date of death or graft failure within 30 days, if known. The concern is that when transplant centers are putting many forms in amnesty and not scheduling regular follow-up visits, events could be occurring without the center's knowledge. There are no specific elements on the LDF or PTM required under amnesty, but adverse outcomes within the first two years are still required.

- The second category is data elements that are required for performance monitoring. The most recent patient and graft status with date seen is needed for SRTR monitoring of outcomes through the six-month, and one-, two-, and three-year follow-up forms. The exact number of patients with death or graft failure in that three-year period could then be determined.

- The third category is data elements that are not collected in amnesty and are not necessarily needed for performance monitoring, but are frequently used for other purposes that are vital to the OPTN, including policy monitoring and research around understanding the impact of COVID-19.

Analysis was done on current amnesty data trends by center, by organ, by form type, and by time period. The status of the TRF/LDF/PTM forms in amnesty from 3/13/20 through 10/31/20 by active centers was evaluated on 11/18/20. This revealed variation in percentage of forms in amnesty across transplant centers with a median of 14%. The total volume of forms in amnesty ranged from 0 to over 3,000 at a single institution.

Of most importance on the follow-up form is the patient/graft status date reporting. The percentage of forms in amnesty status is similar between follow-up forms expected in the first three years post-transplant and then all others (at about 20%). 80% of the forms are either validated or in amnesty status, but have patient/graft status information entered already. TRFs make up the majority of forms in amnesty status, and almost two-thirds of the forms in amnesty are 4 years or greater post-transplant.

An email was sent out to transplant centers on 12/2/20 to make them aware of the importance of data collection, as well as the brand new report posted on the data services portal, which included information on the number and percent of forms currently in amnesty for each center compared to national results. This report will be updated on a weekly basis. An email with similar information was also sent to primary physicians, primary surgeons, and transplant administrators.

Jon Snyder from the SRTR presented additional information on the amnesty policy. The SRTR uses follow-up data to look at graft failures and deaths to support program-specific reports and various performance metrics, some of which support the MPSC activities. In addition, there is a very detailed COVID-19 monitoring application on the SRTR website. The SRTR specifically analyzed whether Emergency Action #2 has led to a lower-than-expected capture of reported graft losses and deaths, and whether there is variation by transplant program.

It was recognized that graft failures and deaths continue to be required during the amnesty period, with the reporting deadline extended to 30 days. Other sources of death beyond OPTN-reported deaths are also examined, such as limited access death master file made available from Social Security Administration deaths. If centers are not regularly contacting patients to fill in the forms, events such as return to dialysis will not be recorded in a timeframe similar to what was seen before the amnesty policy.

The SRTR specifically noted challenged with this analysis. The SRTR looked at graft failures that would be expected based on historic patterns. If it is assumed that COVID may be increasing the number of graft failures and deaths, as is seen in the general population, the amnesty policy may be affecting assessment of those deaths by decreasing the number of deaths seen. The determination was to look at predictions versus what is actually seen for graft failures and deaths across different organs once the amnesty policy went into effect, given the transplant recipients that were happening after the policy was implemented. Dr. Snyder explained that the bottom line is that the number of deaths and graft failures that should be seen is unknown.

The SRTR analysis so far goes through 8/2/20, or the first five months of the policy. Using historic patterns of failure and assuming that COVID did not increase the death or failure rate, there is not a large difference from that of expected to observed numbers of all-cause graft failures across the different organs.

Seventeen fewer all-cause kidney graft failures were reported, about a 3.5% lower rate than models would predict. In thoracic organs, the number is just three higher than predicted. This points to underreporting, but the magnitude may be underestimated if COVID increases that failure rate. In preliminary analyses, areas of the country experiencing higher COVID rates in certain months also had higher rates of forms missing. This finding will be evaluated further to see if it can help with failure prediction. It is difficult to ascertain a true number of missing graft failures, as the amnesty periods overlaps with the entire COVID era.

The SRTR is currently not evaluating any donor metrics for OPOs or transplant outcomes metrics after 3/12/20, the date the national emergency was declared. Therefore, the metrics published in January 2021 will exclude 3/13/20 through 6/30/20. Reports run in 2021 supplied to MPSC will exclude 3/13/20 through 12/31/20; therefore, the July 2021 evaluation will use data that are current as of 4/30/21. The committee has recommended status quo on the amnesty policy, and the SRTR recommends the committee consider the 4/30/21 date if the amnesty policy ends, as follow-up forms that may impact the first year of the three-year outcomes metrics could be caught up by the programs with a reporting of the patient and graft status if the form is still in amnesty.

Summary of discussion:

The Chair noted that the SRTR analysis assumes that all transplant centers are behaving the same way with their organ and patient selection, but there may be a selection bias by the centers because of COVID.

From the HRSA perspective, one comment was that the EC should carefully consider the balance of the situation in the community with the increasing importance of the need for data. The performance/safety evaluations and system performance reports used by patients provided to the MPSC will slowly disappear as the amnesty policy continues. Eventually, the SRTR will not be able to provide relevant findings to help either MPSC or the public.

The EC chair commented that as noted earlier, two-thirds of the data in amnesty are for TRFs greater than four years old, and the data within the first four-year window are of most importance. Dr. Snyder explained that according to SRTR analysis, the average for missing data in amnesty within the first three years post-transplant is 28% across programs, but more programs had 0% missing than had 100% missing.

The most recent recommendation by the EC was that the EC will conduct regular reviews of Emergency Action #2 and determine when it is safe and appropriate to repeal the action. The Committee discussed the options for retrospective data entry upon repeal of the amnesty status emergency policy action. The options are as follows.

- Option 1: Require all TRF, LDF and PTM data as available be entered on forms in amnesty status.
- Option 2: Require all TRF data <4 years from transplant as available be entered on forms in amnesty status.
- Option 3: Require a recent patient/graft status with date be entered on most recent TRF and LDF forms in amnesty status.
- Option 4: Require a recent patient/graft status with date be entered on TRFs <4 years from transplant in amnesty status.
- Option 5: Require no retrospective data collection.

The Membership and Professional Standards Committee (MPSC) leadership discussed this topic recently and ultimately agreed that Option 2 was in the best interest of patient safety, as well as from a research data perspective. Many centers upon receiving the recent SRTR data email were not aware of the number of forms that were triggered forward and that immediately went into amnesty. One member stated that it was not a high burden for his staff to do the retrospective data entry.

Another Committee member supported getting as much data as possible, but felt that there have been different effects of the pandemic in different parts of the country over time. For many colleagues, the pandemic is no better now than it was in the first six to nine months, so the transplant community has appreciated the EC listening to their needs with the emergency policies. She felt regional analyses, particularly in the last six months or so, are needed to figure out whether things are different or as expected. Therefore, she recommended Option 4 with the move to let people know what data are missing and to encourage them to include what they can is what is needed at this time.

Another Committee member noted that during the MPSC discussion about Option 4, some were worried that going forward with the pandemic, staff will lose resources to fill out these documents if they are not required. Some outlier programs have many forms that are not being addressed. As the performance improvement committee, the MPSC has the ability reach out to those centers representing the majority of the outstanding forms in amnesty to make sure they know that those resources are necessary and cannot just go away. They however do not have the ability to provide direct assistance with forms. The COR noted that the member quality department has initiatives to target support to centers for improvement. These sorts of activities could be targeted through some of those efforts.

The EC Chair emphasized the importance of considering patient protection and agreed it is important to continue to support the workforce members who are struggling during the pandemic. The Vice Chair agreed that getting the information to the program directors will be helpful so that transplant centers can make a plan to work through outstanding forms. Recognizing that the EC's purpose is to help programs get through this will be a win in the long run. One transplant recipient on the committee noted that many patients are afraid of going in for appointments, and this is an important factor to consider.

The COR noted that Option 5 is not a viable option at this time. The COR asked a question regarding the direction from EC to contractor staff about the support that is being provided to centers. The EC Chair clarified that the contractor staff are supporting all transplant programs as they always have through the MPSC and performance improvement. Collecting and reporting of the data is a job that can only be done by the transplant programs.

Following discussion, there was consensus to keep the previous recommendations in place. 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 will be repealed. An end date cannot be determined at this time. When the time comes to repeal the Emergency Action #2, progress was made in narrowing down their options for retrospective data entry to Options 2 and 4. Providing centers with the weekly report on what is in amnesty and comparing that to national data, while encouraging retrospective data entry as much as safely possible, is a good first step.

Next steps:

The COVID-19 emergency actions will be reviewed again at the next committee meeting in January.

5. Continuous Distribution Projects Update

Craig Connors presented an update on continuous distribution, explaining that it is the concept of a composite allocation score. There are five broad attributes that make up composite allocation score,

with multipliers on each attribute. The match run is not done by a classification, but is rather a rank-ordered match. The Lung Transplantation Committee just finalized their modeling request, so the SRTR is working on the request. The goal continues to be to have a policy proposal out for public comment in the summer 2021 and then to the Board in December 2021. Kidney and pancreas have started their modeling requests in earnest and Heart and VCA are forthcoming.

With continuous distribution, there are some components and attributes that are similar across the organs, such as blood type, sensitization, and some placement efficiency metrics. However, there are attributes that have not been covered so far under the lung development that kidney and pancreas will have to address, such as how to address non-utilization of organs in pancreas.

6. Adjourn

The committee was reminded that a request for participation will come if the Secretary of Health and Human Services (HHS) asks the OPTN for input on the critical comment received by the Secretary's office. The Chair thanked attendees for their continued work. The meeting was adjourned.

Upcoming Meeting

- January 2021

Attendance

- **Committee Members**
  - David Mulligan
  - Matthew Cooper
  - Atsi Yoshida
  - Maryl Johnson
  - Medhat Askar
  - Lisa Stocks
  - Robert Goodman
  - Valinda Jones
  - Jeff Orlowski
  - Frank Holloman
  - Christopher McLaughlin (HRSA)
  - Brian Shephard, OPTN Executive Director
- **SRTR Staff**
  - Jon Synder
- **UNOS Staff**
  - Craig Connors
  - Chelsea Haynes
  - Eric Messick
  - Sarah Taranto
- **Other Attendees**
  - Alexandra Glazier, POC Chair
  - Ian Jamieson