OPTN Executive Committee
Meeting Minutes
April 3, 2020
Teleconference

Maryl Johnson, M.D., Chair
David Mulligan, M.D., FACS, Vice Chair

Introduction

The Executive Committee (EC) met via teleconference on 04/03/2020 to discuss the following agenda items:

1) Overview of OPTN authority and Final Rule compliance pertaining to *OPTN Bylaw 11.7 Emergency Pathway*
2) Proposed emergency policy actions
   a) Relax data submission requirements
   b) Modification to wait time initiation for non-dialysis kidney candidates
   c) Incorporation of COVID-19 into DonorNet®
   d) Use of local recovery teams for organ procurement
3) Review of currently active emergency policy
4) Informational items related to COVID-19 pandemic
   a) Membership & Professional Standards Committee (MPSC) monitoring and enforcement
   b) Wait time continuation for candidates who are inactivated due to COVID-19

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

1. Overview of OPTN authority and Final Rule compliance pertaining to *OPTN Bylaw 11.7 Emergency Pathway*

Through Bylaw 11.7, Emergency Actions relate to data collection on the scope of authority, with the Executive Committee as the proxy for the public crisis policies, and which expire not more than 12 months beyond the policy's effective date and then go out for public comment for at least 30 days within 6 months of approval. The following actions were identified by the community and prioritized by the Policy Oversight Committee and others.

2. Proposed emergency policy actions

UNOS staff presented the policy proposal, which was structured as a composite resolution. It will be one resolution with each respective policy entered as further resolved resolutions. Like the other Emergency Action Policy, the composite resolution specifies that the EC will review the emergency policies at every meeting or at least every 3 months, and will expire in 180 days on September 30, 2020.

a) <u>Relax data submission requirements</u>

The purpose of the proposal is to be responsive to concerns from members regarding putting living donors at risk to unnecessary exposure to COVID-19 during outpatient visits when not sick. Some centers are grappling with the data burden while their attention is on

COVID-19. This proposal focuses on the follow-up forms and data submission requirements only.

Policy modifications would be to suspend submission requirements for the living donor follow-up and transplant recipient follow-up forms within TIEDI, to implement policy language in the associated policies that require form submission. Recommended policy action includes extended timelines for reporting recipient death and graft failure from 14 to 30 days, as well as explicitly relax all liver donor follow-up requirements in Policy 18.5 specific to living donor follow-up. The requirement to report living donor death within 72 hours in the Improving Patient Safety Portal would remain.

The Membership and Professional Standards Committee (MPSC), Data Advisory Committee (DAC), and Living Donor Committee (LDC) leadership agreed on the proposed policy changes, but there was some disagreement on operational approach to the policies. From the LDC perspective, oftentimes for living donors the in-depth evaluation of post-transplant experience only occur when doing the living donor follow-ups.

Many different options were considered when operationalizing the proposal, but two were discussed in more detail. Effective dates of the COVID-19 emergency policy will be 3/13/20 to 09/30/20.

The LDC Chair clarified policy 18.5, which explicitly relaxes benchmark levels of living donor follow-up, stating that the relaxation of the targets applies only to those suspending living donor follow-up. Once the emergency policy is rescinded, policy 18.5 will go back into effect and follow-ups would reinitiate at due dates and follow-up dates, a minimum of a 2-year window where the follow-up targets would not be applied to centers.

The resolution of the proposal will be based on the policy, but feedback from the Executive Committee about how that will be implemented is requested. Both approaches have the required data submissions forms generated within the system. The difference comes down to user experience, but both are equally efficient. Option two would put the forms in queue, and if incomplete by the due date, the system will automatically move it to "amnesty" status, removing it from view. However, this would create an additional list form and there could be confusion on whether it needs to be completed or not, such as for those who are unaware of the policy. In option three, the forms automatically move to "amnesty" status immediately upon generation, never entering the workflow. However, if a center would like to complete a form, it would take extra effort. Some members use API feeds to get forms for normal workflow, so this process would be disrupted with option three.

The DAC Chair explained why DAC preferred option two. They felt that COVID-19 has had a wide spectrum of impact on different centers. For centers that can submit forms, even if lab data is not available, the process should be as easy as possible and not require the additional work of manually removing it from amnesty status. This will prevent centers from getting overwhelmed with accumulation of overdue forms and allow APIs to work.

The MPSC preferred option three and its Chair stated they were not aware of the API issue, but in general they wanted to relieve the compliance burden for everybody. The pandemic will eventually reach everybody, so if the forms do not need to be filled out, they should just not show up for the centers.

One Committee Member asked which would greater impact the present FTE demand. Once data submissions are required again, there will be a lot of catch-up. Option two will help across a significant number of platforms with ultimately less overall burden.

The DAC Chair stated if the main difference is communication of the policy, perhaps there could be a header on the forms page to clearly communicate to the form filler the new, more lenient policy during this period. Indeed, this idea when previously brought up was referred to as a splash page and remains a possibility.

One Committee Member showed support for option two, so that the burden is on the transplant center. Option two would also allow tracking of which forms had to move to amnesty or not. Another Committee Member felt that option two makes it easier for centers to utilize the APIs to get what they need.

Another Committee Member clarified that centers will still be encouraged to include follow-up form data. They should submit what they can, but catch-up will not be required.

The MPSC Chair stated if they had known about the API issue when discussing the options, they would have inquired next as to how many APIs would be affected by the policy.

b) Modification to wait time initiation for non-dialysis kidney candidates

This proposal refers to policy 8.4 and the requirements for initiating kidney waiting time once candidates are registered. The purpose is to create a pathway to allow candidates to apply for modifications that will establish wait time start dates that correspond to the date which the program would have listed and prevent potential disadvantages to those who meet GFR criteria for starting time, but unable to complete evaluation during COVID-19 crisis. This would go into effect today, 4/3/20.

The Kidney Committee representative stated the Kidney Committee supports this concept and they feel that after the crisis, resources will be limited, so things like testing will be delayed perhaps for a few months.

c) Incorporation of COVID-19 into DonorNet®

The proposal is for allowing COVID-19 test results to be entered into DonorNet. The data field will be optional. UNOS IT is currently validating data exchange with EMR vendors.

One Committee Member wondered if the test used should be included, as the sensitivity of the each test varies in different parts of the country with different tests and different labs. Another Committee Member pointed out that sensitivity and specificity data will change the idea of a standard. The current discussion is what the OPO needs to document up-front. The Disease Transmission Advisory Committee (DTAC) Chair stated the data should be uniform in terms of clinical risk factors and from exposure, but there is question on how granular to be on the specimen type (nasopharyngeal, bronchoalveolar, sputum) because it impacts the risk of false positive. She will take today's feedback to the DTAC for further consideration.

Another Committee Member stated he had to scramble to find a hospital to do the tests and would not know the sensitivity or specificity. UNOS staff clarified the option to upload the actual test form from the lab will be available. Others agreed that determining the sensitivity of the test at the time of entry into DonorNet may not be realistic currently.

One comment was whether the data field should be mandatory, as there may be benefit in the future in determining whether or not the testing has been done. DTAC did have discussion on this issue. They felt that having the optional data field could have expedited approval at this time, with the idea of making the data field mandatory in the future.

d) Use of local recovery teams for organ procurement

The idea for use of local recovery teams for organ procurement was circulating two weeks ago with discussion on several different ideas, as well as whether official policy is needed. There are several related OPTN policies on organ recovery and recovery teams. OPOs are already able to select a recovery team. Major societies such as ASTS, AST and AOPO have offered guidance on their websites strongly encouraging the use of local recovery teams to help limit COVID-19 exposure.

Guidance is not on the OPTN website, but UNOS has offered outreach and collaboration with the community regarding this. OPTN Committees were asked to provide feedback via email. There were 24 responses from committee leaders and 21 of those preferred a non-policy approach, but all agreed local recovery is a good idea when possible. Others were concerned with unintended consequences of a policy action.

The comments were assimilated into a draft of a potential policy mandate. The two options before the EC are emergency policy to mandate local recovery or offering strong guidance and allowing OPOs to individually manage the issue.

One Committee Member stated guidance is sufficient and additional policy is not needed. A mandate would decrease the flexibility needed at this time. Several Committee Members were in agreement and made similar comments in support of offering guidance only. One comment was that much of the discussion is motivated by fear and anxiety during the crisis, and that OPOs can currently operationalize what is needed and comfortable for the donor at that time according to current policy. Another Committee Member felt that perhaps there may have been an attempt to push other policy issues as part of this, and that enacting a policy would be a step too far at this time. There was no expression of support for a policy mandate during the discussion.

The Executive Committee Chair stated that since there was unanimity of EC members, they will continue to offer strong guidance only. The statement on the UNOS website is as far as the guidance will go without anything additional from the OPTN side pending discussion with HRSA leadership. UNOS staff clarified that the guidance would require HRSA approval to be on the OPTN website and HRSA currently does not believe the OPTN has authority to make any recommendation on restrictions on individuals involved in recovery.

Following the discussion, the Executive Committee voted to approve the Composite Resolution. They will not address the local recovery teams for procurement, but address the other three issues (a, b, and c) as discussed.

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

3. Review currently active emergency policy

The existing emergency action items include:

1. MPSC monitoring & enforcement
2. Wait time continuation for candidates who are inactivated due to COVID-19

Clinical data can be carried forward as needed. In monitoring plans, staff will be tracking all organs; about 5% have used the emergency policy. The Committee expressed support for continuing the emergency policy, with comments that it has been helpful in managing the crisis without disadvantaging patients on the waitlist.

4. Informational items related to COVID-19 pandemic

MPSC compliance monitoring during emergency changes to policy remains in place. Any bylaw changes require a majority vote of the entire OPTN Board of Directors. The issue is members indicating the need for temporary relief from reporting requirements during COVID-19 pandemic. There is still an expectation for communication with patients, but the changes allow for more flexibility about how that is done.

Additional clarification was given on wait time continuation while in "status 7." OPTN plans operational instructions to program targeted at heart. Rather than going to inactive status, centers should consider sending in organ acceptance criteria, which is unrealistic. Guidance is just for consistency and measurement purposes for donor age 98-99 years.

Executive Director thanked committee members for convening on short notice, as well as staff working extra hours to ensure timely implementation.

Upcoming Meetings

- April 20, 2020 at 9am ET