OPTN Executive Committee
Meeting Minutes
November 2, 2020
Conference Call

David Mulligan, MD, Chair
Matthew Cooper, MD, Vice Chair

Introduction

The Executive Committee (EC) met via teleconference 11/2/2020 to discuss the following agenda items:

1. Welcome and Roll Call
2. COVID Emergency Action Recommendations to the Board
3. OPTN Strategic Plan Discussion and Next Steps
4. 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. A new issue of roughly 420 hospitals and healthcare systems being hacked by a European group in the midst of COVID-19 reemergence across the country was briefly touched upon. The continuing goal of transplant centers will be to keep patients safe and to keep transplants moving forward.

2. COVID Emergency Action Recommendations to the Board

The OPTN Executive Director presented the emergency action proposals in response to COVID-19. These proposals were continuously evaluated, along with monitoring data on their use, at the Executive Committee meetings on April 3, April 20, June 7, and July 30. The three latter actions originally had an expiration date of September 30, 2020, but the executive committee voted to extend it to December 31, 2020 at their meeting on July 30. This extension puts all emergency action expiration dates after the December Board of Directors meeting, so that they all have time for full Board evaluation.

<u>Data summary:</u>

The EC will ask the Board to delegate to repeal to the EC, but completely remove the expiration date of the testing status field, in anticipation that it will continue to be used for an indefinite amount of time. In addition, clarification is needed as to what will be requested of the Board regarding retrospective submission of those forms.

Relevant delegation language in the resolutions makes it clear that the EC has the authority to act at any time on behalf of the Board. While the resolutions to the emergency actions are no longer in status of being a temporary, once they are approved by the Board, they are still considered to be temporary and the EC is still expected to take the policies back in relatively short order without going to a new policy creation process.

The resolution draft was presented. It is not critical that this order go before the Board, as the amnesty is not being repealed, so it is possible to move this to a later date. The three items that need clarification from the EC prior to going before the Board are: all data; without any retrospective data,

there are still deaths and graft failures, so the resolution calls for any other data on those forms that are collected within the expected timeframe; and the forms should be returned within 90 days, as suggested by Data Advisory Committee (DAC), of the date the emergency concluded as determined by the EC.

The transition procedures analysis was also presented. The EC needs to consider whether there are transition effects and whether accommodation needs to be made for patients who are losing ground in a transition. The transition procedures were made to prevent patients from losing ground because they could not turn the form in or could not complete testing in light of the COVID pandemic. The result of the analysis is that transition procedures are currently unnecessary, but should still be taken into consideration by the EC.

Summary of discussion:

One comment was that it would be difficult for large centers to know whether they have all the necessary data and whether they can gather it all within 90 days. Indeed, it will be difficult to know whether there are data that meet the definition that centers simply chose not to enter retrospectively. This issue will be discussed with site survey to determine whether there is a way to get that information. Eventually, things such as graft failure and death will be discovered, but these are the types of things that are already being collected during the amnesty period. Volumes vary from center to center, but there are already 50,000 forms in amnesty status. About 30% to 40% are missing, so there will not be enough data to do detailed member improvement analysis for this period. The majority of the DAC felt it better to get at least some data. Again, the 90-day requirement could instead be determined at the time of the repeal because if the emergency state continues for a much longer period of time, the backlog will become greater.

A follow-up question was whether there would be benefit to doing the resolution now versus waiting to see when the action is withdrawn and then define based on the number of outstanding forms at that point in time what the timeline would be. The concern would be letting the community know what the expectations are going forward. OPTN staff responded that regardless of today's discussion, the community will be reminded of how important the data are and will be encouraged through the website, email, and committee and regional meetings to enter as much data as they have. The only advantage to adding this resolution would be further warning that enforcement of data collection is eventually coming, but it will be up to the Board will decide whether it will become mandatory. There was agreement that if the COVID emergency state continues for another year, 90-day requirement will be an insufficient amount of time. There must be a balance between encouragement and punishment for gathering or not gathering the data. A long-term amnesty might be a better option. If the EC could still evaluate whether the records needing updating are occurring across the centers evenly and determine, for example, a more nuanced time period, as well as which data are most important.

Another concern was whether the lack of data would lead to inaccurate SRTR data. Most of the calculation is graft failure and death, but there are some more nuanced evaluations that are dependent on these data. In the midst of COVID, there is so much variability in data collection, so it will be difficult trying to measure what the expected rates of graft and patient survival will be. There are a lot of unknowns that create challenges in the future. It will be important to reiterate to the transplant centers the purpose and value of the living donor followup forms and recipient malignancy forms, in addition to the transplant recipient forms. Removing the 90-day requirement may be more helpful right now. The comment was made that the EC should determine what data are really needed to affect some measurement. Post-donation forms and post-transplant recipient forms don't have a huge impact on compared to looking at one-year graft survival/patient survival.

The Committee Chair added that in light of the hacking of the healthcare system issue, if it gets to the point that EMR is lost, that will influence data collection as well. Extension of emergency actions deadlines will be important going forward and key pieces will the importance of 18-month data if 12-month data are not available. Centers should feel comfortable reaching out for help.

Next steps:

The OPTN will provide data on the current status of data submission of TRF/LDF/PTM forms under the emergency amnesty policy. They will also have more information about whether the encouragement has worked and whether centers are voluntarily entering the data.

3. OPTN Strategic Plan Discussion and Next Steps

Data summary:

OPTN is in the process of compiling a draft, which will be brought to the Board at their December meeting for their feedback. The feedback will be incorporated and brought back to the EC, followed by going out for public comment in the February/March cycle.

The following are suggestions from the EC on each of the areas of the OPTN Strategic Plan.

Increase the Number of Transplants

- The interaction between OPOs and centers system metrics include monitoring of late declines should be made explicit.
- There should be encouragement for collaboration and effective practices regarding DCD organs and machine perfusion, especially overlap in multiorgan recoveries from DCDs.
- Implementation of artificial intelligence to improve allocation was another suggestion.
- Consider whether allocation rules need to take machine perfusion technology into account.

Equity and Access to Transplants

- The main suggestion was to do some demographic data review of key populations to help set benchmarks. The demographics of the M.D. population may differ from the demographics of the OPO personnel and the patient population. Breakdown in demographic data might help with setting targets and measuring whether targets are met.

Promote Efficiency in Donation and Transplant

- The question is whether efficiency is its own goal or it's a way of working in the service of getting more organs transplanted. One suggestion was for a metric to decrease organ discards over time.

Improve Waitlisted Patient, Living Donor, and Transplant Recipient Outcomes

- Improve the process/management of donor information that becomes available after transplantation.

There were almost no suggestions given regarding Promoting Living Donor and Transplant Recipient Safety, other than perhaps broad continuation of knowledge sharing, education, and collaboration.

Summary of discussion:

Increase the Number of Transplants:

The Committee member who made the suggestion about artificial intelligence clarified that there is information that could greatly improve the efficiency of organ allocation based upon hundreds of thousands of organ offers, and that the transplant community needs to start it, at least for at-risk organs. Indeed, there are many people working on that with DCD organs and with allocation in general, looking for ways to use machine learning and artificial intelligence together to come up with better strategies for organ utilization.

Machine perfusion will be going through the FDA. There are lungs getting shipped to a perfusion center in Philadelphia now, and the question would be whether the lung gets allocated to a recipient before it actually gets there or whether it gets perfused, rejuvenated, and then get allocated. These types of discussions are ongoing within the thoracic community, so machine perfusion definitely needs to be considered. However, it is early to be putting machine perfusion into the allocation strategy at this time, as there are not enough machines, the machines that are being used are being done so on experimental protocols, and there is not enough experience with the technology yet to be designated for this purpose and to determine how it should best be used for DCD recoveries. There was agreement that it is too early, as there is no financial wherewithal for all programs to have it and it may disadvantage programs that don't have it. One comment was that everyone should be cognizant of changes in allocation that may be required as machine perfusion becomes more standard of care.

The Policy Oversight Committee Chair noted it was great to see the efficient recipient matching in the category of increasing the number of transplants. That is the goal of making the system smoother. Efficiency with the goal of increasing the number of transplants rather than its own category is the right way to envision it. The expanded use of offer filters and attacking how to better orchestrate provisional "yes" is work that is underway, but probably need to be done in a stepwise fashion, as it will take time to accomplish.

One other point with the goal of increasing transplant was the idea that the OPTN Kidney Paired Donation (KPD) program is steady, but small, and whether or not it is still worth doing. One committee member coming from a program that does KPDs felt that anything that can be done to enhance and increase KPDs will increase transplants overall and especially increase the quality of the transplants that are being done. Looking at what factors will have the biggest impact on increasing kidney paired donation will be important. It might mean coming up with allocation opportunities to start a chain with a deceased organ donor. There is an appreciation from everyone that KPD is an untapped opportunity and unutilized by many transplant programs.

From a strategic plan perspective, the EC can discuss utilizing deceased donors and removing disincentives for programs, so that they could potentially begin KPD. Transplant programs that do living donor transplants, whether through compatible living donors who prepare exchange or not, should be following living donor policies, but not be a KPD program per se. One comment was that using deceased donors becomes more problematic because the disadvantaged groups, such as minorities, have a low rate of living donor transplants and less access to kidney transplants as a whole.

Equity and Access to Transplants:

Evaluating changes for broader sharing for the geography at least, and whether the disparity has been improved to monitor, evaluate, and adjust is important. There are issues with access to healthcare that can't be addressed through the allocation system that have be recognized, but everything that can be done to equitably get organs to patients is important.

One question was whether there was any clarity to the boundary of access to transplantation in terms of access to the waitlist. There is a boundary in OPTN authority and the question is whether the authority could be explored further and defined better in the strategic plan so that everybody is on the same

page. Everyone has been focused on disparity in access to the waitlist and there is no good data on the perceived barrier to collecting that. Understanding the barrier from the OPTN perspective would help shape and formulate what could be effective strategies in this strategic plan. In the past, there has been discussion on putting that into the UNOS side of the strategic plan.

Promote Efficiency in Donation and Transplant:

From a practicing transplant nephrologist perspective, one comment was that the real issue is access to the waiting list. It is unclear how to go about accessing that information. HRSA has funded a study that will try to address that issue and test the concept of doing matching of the OPTN database and outside databases. From a policy perspective, telling a transplant center what they can or cannot do based on access to transplant would be fairly limited. What is being monitored through authority by OPTN policies is whether the waitlist candidates are being treated equitably. The first step is to determine how many patients are on dialysis and know about the benefits are transplant and getting access to it.

Dialysis companies clearly would like help in tracking who is being referred. What the OPTN can do about that and what data can be shared is currently undefined. There is another data project that will definitely be done in the future with dialysis companies on that side. OPTN staff clarified that HRSA's analysis was similar to OPTN's, in that they only have authority over aspects to transplantation that are clearly listed under the Final Rule. Whether someone is placed on the waitlist or not is a clinical decision. There may be an analysis to come up with a framework in which the OPTN can monitor the nonclinical decision part of that decision. OPTN does not have the same authority as CMS and ESRD, which is why collaboration between them is important.

One comment was that since the Final Rule does allow OPTN to evaluate equity in access to transplantation, access to being evaluated for the waitlist is a necessary precondition to access to transplant, and it pulls in that part of the process. It is time to push harder on that.

Promote Efficiency in Donation and Transplant:

When Share 35 was enacted, all organ transplantation for livers increased, except for two regions. Discards went up in those two regions because centers were going out in more force to look at more donors that they weren't looking at in the past to try to see if they could utilize them. Even though they increased the total number of transplants they did, they also increased the discards on some of those transplants that they couldn't use because they were going out. When pushing to go after every organ, more organs that the centers tried to use, but couldn’t, will be seen.

Waitlisted Patient, Living Donor, and Transplant Recipient Outcomes:

Regarding the new key metric, the problem is that policy says the organ has to be sent to the centers, but a lot of times the center doesn't know what information is important or not important. It is trying to assist the community in knowing the relevance of post-procurement donor information that becomes available. One comment was to also make sure donor hospitals are doing everything possible to obtain the follow-up culture information as quickly as possible so they can get it to the transplant centers that are caring for those patients, as that does not always happen smoothly.

Promote Living Donor and Transplant Recipient Safety:

The question is whether or not this goal is something that needs to be evaluated and how it can be evaluated. Recipient safety is difficult to follow when programs have a 40% to 50% take-back rate or three operations for every kidney transplant. There may be early flags prior to one-year events and high loss of grafts at one year, so it would be better to help a center much earlier if they are struggling due to high number of safety events.

A transplant-specific quality improvement database might help to try to look at the benchmark for events like number of post-transplant infections or returns to the OR, and how the data can be used to help improve the quality of the transplants at all transplant centers collectively going forward. Currently the TransQIP Quality Improvement Program is ongoing. There are 27 transplant centers are involved, but enrollment of centers into the program was slowed because of COVID. It might be a good start to get TransQIP more integrated into UNOS.

One suggestion was to begin to lay the groundwork for getting more up-to-date information about short-term safety events and collaborating with partners in the community.

This strategic plan category is the place to pull in UNOS research department collaboration with external parties like members orsocieties, a targeted statement that they're looking to do more collaborative research on enhancement of patient safety. That will then open the door for committees and others to get creative about potential projects.

Next steps:

OPTN will incorporate all the feedback and send it back to the Committee for any last comments. Each Committee member will be asked to allocate percentage of resources up to 100% for each of the five strategic plan goals. The revised draft will be presented to the Board in December, with public comment in the spring cycle, and probable approval by June 2021.

4. Adjourn

Upcoming Meeting

- December 6, 2020, 4-5pm ET

Attendance

- **Committee Members**
  - David Mulligan, Chair
  - Atsi Yoshida
  - Denise Alveranga
  - Jeff Orlowski
  - Lisa Stocks
  - Maryl Johnson
  - Mindy Dison
  - Matthew Cooper
  - Medhat Askar
  - Robert Goodman
  - Valinda Jones
  - Brian Shepard, OPTN Executive Director
  - Christopher McLaughlin (HRSA)
  - Shannon Dunne (HRSA)
  - Shannon Taitt (HRSA)
- **SRTR Staff**
  - Bertram Kasiske
- **UNOS Staff**
  - Chelsea Haynes
  - Susie Sprinson
  - Craig Connors
  - Jason Livingston
  - Maureen McBride
  - Henri Haskell
  - Jaqueline O'Keefe
  - Liz Robbins Callahan
  - Steve Harms
  - David Klassen
  - Alex Tulchinksy
- **Other Attendees**
  - Alexandra Glazier, POC Chair