

OPTN Executive Committee

Meeting Summary

March 17th, 2020

Conference Call

Maryl Johnson, MD, FACC, Chair

David Mulligan, MD, FACS, Vice Chair

Introduction

The OPTN Executive Committee met via Citrix GoToMeeting teleconference on 03/17/2020 to discuss the following agenda items:

1. COVID-19 Candidate Score Protection Emergency Policy Change
2. OPTN COVID-19 Reponse Discussion

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

1. COVID-19 Candidate Score Protection Emergency Policy Change

Craig Connors, UNOS Director of Policy and Communications, presented an emergency policy proposal that would prevent candidates from automatic downgrades in eligibility or prioritization who are unable to undergo required periodic testing due to the COVID-19 pandemic. Prior to discussing the details of the proposal, Catherine Monstello, UNOS Director of Enterprise Data Management, presented all of the potential options that were considered before arriving at the proposal that was ultimately recommended. There were seven options evaluated:

1. Offer guidance, no system changes: This option would allow the system to behave normally. It would be applicable to all organs. However, candidates may miss transplant opportunities or risk their health in order to obtain updated data.
2. Extend current expirations by 6 months: This option would only apply to lung. In order to implement this option, the system that checks for updated values would need to be updated, and there would be a high level of monitoring needed to ensure the system was appropriately handling increased acuity. This option would require significant effort to revert back to regular functioning.
3. Create approved LAS exceptions = Current score, valid for 6 months: This option would only apply to lung. These approved exceptions would not go through the review Board. This option would require significant testing, and there was concern that users may accidentally withdraw scores. This option would also require significant effort to revert back to regular functioning.
4. Write policy to allow centers to re-enter existing values with a new (current) date: This option applies to all organs, and would allow the transplant hospital to enter the same data as previously entered, except with new dates. There are no system changes required for this option.
5. Extend current expiration dates by X days (Liver): This option applies to liver only and would require significant system changes and monitoring.
6. Extend current expiration by X days (Heart): This option applies to heart only. This solution would extend form justification dates (only when the status required updated data). This would require complex testing and system changes.

7. Turn off nightly jobs that downgrade candidates: This would apply to all organs, and suspend the nightly processing to prevent candidates from downgrading to a lower score or status. This would require significant testing and system changes.

After considering and evaluating the options listed above, Option #4 was determined to be the most feasible option. Option #4 would allow candidates to maintain existing eligibility and priority by “carrying forward” past clinical data when obtaining updated data is not possible or advisable. This option only applies to candidates for whom transplant programs have previously submitted data required for listing. Transplant programs would use the most recent candidate data they previously entered for the data submission update, replacing the original date of collection with the date of submission for the update. If a transplant program decides to use this emergency policy, they must note its use in the candidate’s medical records. Transplant programs must continue to make reasonable efforts to collect and report clinical data as is currently required by OPTN policy.

Mr. Connors explained that the emergency policy change is consistent with the OPTN’s policy development requirements in NOTA and the Final Rule. *OPTN Bylaw 11.7: Emergency Actions* states that proposals “required due to...emergent public health issue or patient safety factors” may be adopted prior to public comment. According to Bylaw 11.7, the policy must circulate for a public comment period of at least 30 days within 6 months of adoption. Emergency actions must expire within 12 months of the effective date. Leadership from the Transplant Coordinators Committee, Transplant Administrators Committee, Thoracic Committee, Liver and Intestinal Organ Committee, Policy Oversight Committee, and Membership and Professional Standards Committee all endorsed the proposal. The Data Advisory Committee (DAC) preferred a systems-fix approach, despite the implementation time, because they were concerned about endorsing inaccurate data entry. Other committee leaders were made aware of the concerns from the DAC, but felt that the COVID-19 pandemic warranted this type of efficient approach.

The Executive Committee began discussion of the proposal. One member of the Executive Committee asked how many times the data could be re-entered with the current date. Mr. Connors explained that per OPTN Bylaw 11.7, this policy will expire 12 months after implementation. Given the uncertainty of the COVID-19 pandemic timeline, it was decided to not restrict the policy by a timeframe other than the 12 months outlined in Bylaw 11.7. Additionally, it was asked if it was possible to assess if some waiting list candidates are being advantaged or disadvantaged by this proposal. Mr. Connors stated that the policy does not prevent hospitals from providing updated lab values (when possible), and that things will likely even out. One Board member commented that as long as people continue to receive transplants during the pandemic, there should not be patients who are disadvantaged by this proposal. It was asked whether the proposal has been examined by UNOS General Counsel, and Mr. Connors confirmed that it has. Jason Livingston, UNOS General Counsel explained that this proposal complies with the OPTN Bylaws, and that it is unlikely patients will be disadvantaged by the proposal.

A representative from the HRSA Division of Transplantation remarked that the policy should be revisited frequently, instead of in one year. Committee leadership agreed that revision (or reversion) of the policy should take place as the COVID-19 situation changes. Mr. Connors remarked that as soon as the COVID-19 situation improves, the policy will be brought before the Executive Committee again. One Board member requested that the resolution language be modified to a 6 month expiration date with an optional 6 month extension. A representative from the Policy Oversight Committee commented that the COVID-19 situation is unpredictable, and so the proposal should not be limited by a 3 or 6 month expiration date. It was suggested that instead of modifying the expiration date in the resolution, a review of the proposal could be included in every Executive Committee meeting over the next 12 months to ensure regular consideration of the policy’s relevance. A committee member commented

that the process for considering options has been thorough, and they support the proposed policy, as long as the policy goes out for public comment. HRSA staff requested that the resolution be updated to include information about regular revisions of the policy. This was supported by members of the Executive Committee. The resolution was revised to include that the Executive Committee will review the policy at least every three months for the duration of the COVID-19 emergency.

A member of the Committee inquired about data analysis following the reversion of this policy. UNOS staff commented that they will consider different ways to utilize and analyze the data that was collected while the emergency policy was in place. There was no further discussion. The Executive Committee voted to approve the resolution, and the votes were as follows: 100% yes; 0 no; 0 abstained.

2. OPTN COVID-19 Response Discussion

Brian Shepard, OPTN Executive Director, presented an update on the OPTN COVID-19 response. Mr. Shepard reported that all OPTN committee meetings through April 10th have been converted to virtual. All other committee meetings beyond April 10th will be evaluated 3-4 weeks before the meeting start date. Additionally, all previously scheduled site surveys have been converted to virtual. Should a member indicate that they are unable to complete their previously scheduled site survey due to staffing issues related to COVID-19, they will be able to reschedule. The OPTN is working with ISHLT, AOPO, AST, ASTS, NATCO, and various European transplantation societies to design a webinar for the transplant community. The MPSC is not suspending any requirements or review procedures, but they understand the complicated environment that COVID-19 has created. When the MPSC evaluates events during this time frame, they will be looking for evidence that members were committed to patient safety, were being good stewards of resources, and were using the best judgement they could, given the circumstances. A new "COVID-19 Precautions" inactivation code has been created, in the event that centers would like to inactivate candidates due to the COVID-19 pandemic. The OPTN is working on a method for centers to indicate whether they require a COVID-19 test prior to accepting an organ offer. This information will help OPOs to efficiently distribute organs.

A member of the Executive Committee asked about webinars or public information with content designed for patients and families. Mr. Shepard said that the OPTN will speak with Patient Affairs Committee regarding the best way to provide additional COVID-19 information designed for patients and families. One Executive Committee member asked about the possibility of centers being inactivated in the event that they cannot perform transplants due to the strain related to COVID-19. Mr. Shepard said that the OPTN is working with HRSA regarding a statement from HHS or CMS informing hospitals that donation and transplantation remain priorities. If a center is unable to perform transplants and is able to communicate with their patients, then patients should be informed of this change. Mr. Shepard ended his report by encouraging members to contact the OPTN with their experiences and suggestions throughout the COVID-19 pandemic. The Chair thanked the Committee and UNOS staff for their efforts.

Upcoming Meetings

- April 20th, 2020

Attendance

- **Committee Members**
 - Maryl Johnson, Chair
 - David Mulligan, Vice Chair
 - Theresa Daly
 - Robert Goodman
 - Deanna Santana
 - Denise Alveranga
 - Sharon Bartosh
 - Sue Dunn
 - Luis Fernandez
 - Mary Francois
 - Walter Herczyk
 - Joseph Hillenburg
 - Brian Shepard (non-voting)
- **HRSA Representatives**
 - Chris McLaughlin
- **UNOS Staff**
 - Craig Connors
 - Chelsea Haynes
 - Catherine Monstello