

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**April 23, 2020**

**Conference Call**

**Alexandra Glazier, JD, Chair**  
**Nicole Turgeon, MD, Vice Chair**

### **Introduction**

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 04/23/2020 to discuss the following agenda items:

1. COVID-19: POC and Emergency Actions
2. Multi-Organ Policy Review Workgroup Update
3. Board Resolution Review

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

#### **1. COVID-19: POC and Emergency Actions**

The Chair explained the role of the POC in the emergency action process, which is to generate and evaluate ideas, and to prioritize and refer ideas for further work by committees. The POC reviewed 11 projects related to COVID-19 during their March meeting, and referred five ideas for additional immediate action.

#### Summary of discussion:

The Chair asked POC members if they have new ideas for urgent changes that should be considered by POC or by a committee, especially related to barriers for conducting their work safely and continuously. There were no suggestions from the POC. The Chair asked members to send forward ideas from their committees since the OPTN has a pathway to make changes quickly if need be.

UNOS staff shared ideas that were introduced during the OPTN Operations and Safety Committee (OSC) call held earlier on the same day, noting that these ideas may come forward to the POC following internal review by UNOS. UNOS staff explained that the purpose of the internal review is to use a situation-background-assessment-recommendation approach to explore potential solutions, which are shared with select Committee leaders to assess if the ideas warrant further discussion. If the ideas make it through Committee leadership, an internal cross-functional team assesses the feasibility of the idea and resources required. At this point, UNOS staff would bring the proposal forward to the POC, and if the proposal includes a policy change, it would then go to the Executive Committee.

The two ideas introduced during the OSC call were guidance on testing for COVID-19 and modifying the definition of eligible death.

#### *COVID-19 Testing Guidance*

During the OSC call, there was robust discussion regarding the variability in testing practices and the lack of consistent guidance about what testing should be conducted for candidates, donors and recipients. A POC member from an organ procurement organization (OPO) emphasized the need for this guidance, noting that so far, guidance has not been forthcoming from the OPTN or from other organizations like

the American Society of Transplantation (AST). The Chair noted that the OPTN may not be able to establish consistent practice but asked if the goal is to get a resource that is continually updated regarding testing, or if the goal is to change acceptance standards about what testing should be required on donors. The member said that it would be helpful to have some sort of flow chart for testing, identifying which test is preferred, and what to do if that test is not available. The member said that there is disagreement right now between OPOs and transplant programs about what testing should be conducted and it would be helpful for OPOs to have guidance to back up their methodology. The member agreed with the Chair that achieving this goal would not involve a policy solution. Members noted that the OPTN may not have the authority to issue guidance on testing practices but the OPTN may be able to collaborate with other organizations to improve consensus or assist in resource collection. The Vice Chair of the Disease Transmission Advisory Committee (DTAC) volunteered to work with the OPO member and POC leadership to see how DTAC can be helpful.

### *Definition of Eligible Death*

During the OSC call, members discussed the eligible death definition in policy and if it should be modified to account for COVID-19 test results. Members had concerns about the unintended consequences of changing the definition and generally agreed that OPOs should use their discretion. UNOS staff said that there is currently no action planned on this issue. A member said the OPTN should consider developing general guidance for pandemics, which may be to clarify that OPOs and transplant programs should follow federal and state guidance, given the regional nature of viral outbreaks.

## **2. Multi-Organ Policy Review Workgroup Update**

The OPO Committee Vice Chair (OPO VC) presented an update on the progress of the Multi-Organ Policy Review Workgroup, which is aligned with the strategic policy priority to improve equity for multi-organ candidates. The Workgroup has been evaluating Policy 5.10.C and proposes new allocation policies for heart-liver and lung-liver candidates that account for the Ethics Committee's recommendations to prioritize multi-organ transplant (MOT) candidates with medical urgency.

### Summary of discussion:

One member asked if the Liver Committee had weighed in on the proposed policy changes to heart-liver allocation, since it seems like the heart status would take priority over liver status. The OPO VC said that there are Liver Committee representatives on the Workgroup, and that proposed policy changes will be shared with other committees for their input. The OPO VC noted that heart-liver candidates are a small population. The member acknowledged that it is hard to figure out whether the heart or the liver should take priority.

A member asked that the Workgroup consider the impact on allocation based on the number of multi-organ candidates that are listed, noting that OPOs have concerns about holding organs for multi-organ candidates that could be offered to other very sick liver candidates. The OPO VC acknowledged that multi-organ allocation can slow down OPO operations, but said there may be other solutions to this issue, like reaching out to transplant programs about multi-organ offers before their candidate is primary to see if the program would be likely to accept the organs.

The Chair asked about the project timeline. UNOS staff said that the Workgroup will continue to refine heart-liver and lung-liver criteria and start to evaluate multi-organ policies for intestine, followed by kidney, with the goal of releasing the project for public comment in spring of 2021. The Chair and Vice Chair emphasized the importance of evaluating multi-organ policies involving kidneys. The Vice Chair said that the community is longing for guidance on when the kidney gets allocated to multi-organ candidates, and if the kidney should always go to a heart, or liver, or lung candidate before some of the

more vulnerable population in the kidney alone queue, like high CPRA, pediatric, or prior living donor candidates. The Vice Chair said community members may not be pleased if kidney is not included in the proposal in the spring, and if not included, it will be important for the OPO Committee to communicate to the community that there is ongoing work on this issue. The Vice Chair said that the primary intent of this project was to provide guidance on when to use kidneys, and to address concerns that Sequence A kidneys were always being used at a high percentage for multi-organ offers at the expense of other vulnerable populations. A member noted there was interest in developing qualifying criteria for kidneys in multi-organ offers, which is currently only in policy for simultaneous liver-kidney candidates. The Vice Chair agreed, saying there was interest in mirroring the approach for liver-kidney with heart-kidney and lung-kidney by developing criteria, but that the workgroup should also focus on the allocation challenges. The Chair noted that they selected multi-organ as a strategic priority not just to clarify policy by adding criteria, but to pursue a consistent framework that aligns with the principles identified by the Ethics Committee. The Chair agreed that if multi-organ policy updates will be released piecemeal, then the OPO Committee will need to note in public comment that the kidney updates are forthcoming.

Next steps:

The Workgroup will reconsider their timeline for evaluating multi-organ policies for kidney.

### **3. Board Resolution Review**

The Chair led the POC in a discussion of the board resolution related to the strategic policy priority for more efficient donor/recipient matching. The Chair recommended that the POC request committees to commence work on two new policy projects: tracking performance on backup centers that turn down organ offers, and address challenges with the use of “provisional yes.” The Chair recommended that the Data Advisory Committee take on the performance tracking project, and recommended the establishment of a workgroup to evaluate “provisional yes” practices.

The Chair recommended the establishment of two additional workgroups focused on (1) expectation and rules for local recovery, and (2) rules or guidance regarding biopsy practices. The purpose of these workgroups is to evaluate the ideas further to see if they should move forward as new policy projects. The Chair also provided recommendations for committee representation in the workgroups.

The Chair mentioned non-policy ideas that came out of the board resolution, which do not require POC action. The Chair noted two additional ideas that may require discussion in the future but are currently low priority: (1) consistent terminology and expectations regarding waivers and (2) rules regarding pulsatile perfusion and other ex vivo devices. The Chair requested feedback from the POC.

Summary of discussion:

POC members did not have any questions or concerns.

Next steps:

The Chair asked the Vice Chairs to identify and recommend participants from their committees for these workgroups. UNOS staff will work on finalizing the workgroups and moving forward with the projects.

### **Upcoming Meetings**

- May 20, 2020
- June 25, 2020

- Jennifer Wainwright
  - Emily Ward
  - Joann White
- **Other Attendees**
  - Shelley Hall