

**OPTN Policy Oversight Committee  
Meeting Summary  
March 26, 2020  
Conference Call**

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

## **Introduction**

The Policy Oversight Committee met via Citrix GoTo teleconference on 03/26/2020 to discuss the following agenda items:

1. New Committee Projects
2. COVID-19 Discussion
3. Other Committee Business

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

### **1. New Committee Projects**

The Chair introduced two new committee projects. The Committee approved both projects.

#### Summary of discussion:

The first project, proposed by the Disease Transmission Advisory Committee (DTAC), will update OPTN policy regarding increased risk criteria based on forthcoming guidance from the Centers for Disease Control and Prevention (CDC). The CDC is expected to release the updated guidance in June. The second project, proposed by the Vascularized Composite Allograft (VCA) Committee, will program VCA allocation into UNet. There were no questions from the Committee, and members voted unanimously to approve the projects.

### **2. COVID-19 Discussion**

The Chair led the Committee in a discussion regarding potential emergency policy changes in response to the COVID-19 pandemic. The Chair emphasized that the ideas presented on the call were not necessarily those that should be implemented, and that the Committee's role was to prioritize these ideas, or to dismiss ideas that do not need to be addressed urgently or do not require a policy change.

UNOS leadership noted that urgent issues could be implemented through emergency policies passed by the OPTN Executive Committee, and longer-term projects could be referred to a committee for further action. UNOS leadership shared that UNOS would gather feedback from the appropriate committee leadership at a minimum before bringing any emergency policies to the Executive Committee.

#### Summary of discussion:

#### *Waive Testing Requirements for Listing for Non-Dialysis Kidney Candidates*

The Committee supported a policy change to allow kidney candidates to accrue wait time even if they are unable to get creatinine clearance or glomerular filtration rate (GFR). The Committee noted that while this project may require some technical implementation, the policy change is worth the effort as

kidney programs do not expect to return to normal transplant operations until at least June or July. The Chair recommended that the Kidney Committee take this idea for action to address immediately.

A member asked if the emergency policy could include all kidney laboratory test requirements that would require bringing a candidate into a center. Kidney Committee leadership said that they are thinking about that issue and working with the Histocompatibility Committee leadership to address it.

#### *Allow Candidates to Accrue Wait Time While Inactivated for COVID-19*

The Committee agreed that it is a high priority issue to consider allowing candidates to accrue waiting time while inactivated for COVID-19. Members noted that current policy varies by organ, as it does not apply to kidney or lung candidates but it is a concern for heart candidates – heart programs are hesitant to use inactivation codes that could limit opportunities for transplant. UNOS staff agreed to handle project coordination across committees.

#### *Require Informed Consent from Candidates to Receive an Organ from a COVID-19 Positive Donor*

The Committee agreed that requiring informed consent from candidates to receive an organ from a COVID-19 positive donor is not currently a priority issue but may need to be considered in the future. The Chair noted that informed consent is a requirement regardless of OPTN policy, and that organ procurement organizations (OPOs) are not pursuing COVID-19 positive donors. A member said that their transplant program would not pursue COVID-19 positive donors even if they were offered since the risk of disease transmission is unknown. Another member noted that this issue will probably need to be addressed over time as COVID-19 becomes more prevalent in society and treatments are developed. The member said that in the future, the OPTN might consider identifying COVID-19 donors as increased risk so offers could be turned down if desired.

#### *Address Hospitalization Requirement for Higher Statuses (Heart Status 1-3)*

The Committee agreed that modifying the hospitalization requirement for high status heart candidates is not a priority currently because it is a limited circumstance and policy changes would interfere with the intent of the status criteria. The Heart Subcommittee Chair noted that most candidates at higher statuses have devices inserted and cannot leave the hospital, except for some candidates at Status 3. The Heart Subcommittee Chair noted that the OPTN has received some questions about discharging Status 3 patients, but if candidates are stable enough to be discharged from the hospital, then they probably do not need to be assigned to Status 3 as the intent of the Status 3 criteria is to capture those patients who need that clinical support.

#### *Extend Data Submission Deadlines*

The Committee agreed that it is appropriate for the OPTN to consider adjustments to data submission requirements during the pandemic. A member encouraged leniency for data submission deadlines during this time period but suggested keeping existing policy in place. UNOS leadership noted that the Membership and Professional Standards Committee (MPSC) is not inclined to provide broad waivers of all reporting requirements but will take the circumstances into account when conducting reviews. UNOS leadership reported that programs are still submitting forms, but noted that one particular area of interest is laboratory tests for living donor forms. UNOS leadership agreed that leniency can be provided without a specific policy change, and shared that UNOS is focused on consistently messaging to the community that they should use their clinical judgment and put patient safety first.

#### *Require COVID-19 Donor Testing*

The Committee agreed not to pursue required COVID-19 testing for donors at this time. The Chair noted that mandating testing could limit donations due to lack of tests, and said that it would be better for

transplants to move forward. Another member agreed, noting that it can take 24 to 48 hours to get a test result back and OPOs do not have the luxury to wait that long. A member noted that the American Society of Transplantation (AST) website has been a domain for public comment on this issue and the general agreement has been that it is not UNOS's domain to make this decision. The Chair agreed that the community is not yet in a position to do this testing every time.

The member recommended that everyone follow the AST discussion and noted that there are comments that UNOS is not leading on communication and guidance related to COVID-19. The Chair noted seeing similar feedback but suggested that the same group would be concerned by OPTN policies that hamper clinical decision-making and reduce the ability to get critical organs to those in need of transplant. The Chair suggested that UNOS increase communication around why UNOS is not issuing more mandates, and said that the community should be working to develop best practices rather than looking for OPTN policy that would box in the community in ways that would not be tolerable.

Another member agreed that the OPTN should not require testing for donors when hospitals do not have enough tests for sick patients, and expressed a general concern about how limited resources like personal protective equipment (PPE) and ventilators are being used when there are more patients in the intensive care unit (ICU). The member said that transplants should not stop but noted that a transplant could cause a COVID-19 outbreak because screening by questionnaire may not effectively identify people who are asymptomatic. The member said there needs to be other considerations about the priority of transplantation in the big picture of a pandemic. The Chair said that if organs that are available today are not pursued, there will be significant downstream impacts on the whole system, but that OPOs understand the living patient priority for ventilators.

#### *Require Re-running the Match if a Donor Tests Positive for COVID-19*

The Committee agreed that re-running the match if a donor tests positive for COVID-19 might need to be addressed down the road but that this issue is not an immediate priority. The Chair noted that this is probably a rare occurrence.

#### *Add COVID-19 to Label of Infectious Diseases*

The Committee agreed that it is a priority to add fields to the label of infectious diseases to indicate that a donor is high-risk for COVID-19, that a COVID-19 test is pending, and the results of any completed COVID-19 testing. A member said that this would help inform transplant centers as to whether an OPO is conducting COVID-19 testing, and it would also provide a mechanism to track the number of donors lost due to a positive COVID-19 test. UNOS staff agreed to identify the fastest pathway forward to implement these changes, which may or may not include a policy change.

#### *Address Living Donor Follow-Up Requirements – Extend Timelines*

The Committee agreed that modifying living donor follow-up requirements is a priority and a concern for patient safety as living donors should avoid going to hospitals. The Committee noted that many living donation programs across the country have temporarily closed for the pandemic. UNOS leadership said that it might be reasonable to eliminate requirements for living donor laboratory tests during this time period, and that the MPSC and the Data Advisory Committee are working on a proposal to address this. UNOS leadership said that UNOS wants to retain as much data collection as possible while also eliminating unnecessary risk to patients. A member thought it might be helpful if UNOS noted on their website that most programs in the country are pausing living donation, but that it is up to each center to make their own operating decisions.

### *Include COVID-19 in Required Medical Screening for Living Donors*

The Committee agreed that including COVID-19 in required medical screening for living donors is not an urgent priority, particularly since most living donation programs are paused, but may need to be considered in the future. Another member said that such a requirement would fall under hospital policies and would not be an issue that UNOS needs to address.

### *Other COVID-19 Response Actions*

UNOS staff shared that MPSC is making changes to operational guidelines to address performance monitoring standards in light of the pandemic, so the Committee did not discuss this issue further.

UNOS leadership discussed using expedited MPSC review of requests for transplant programs to use alternate locations due to shortages of resources or attempts to isolate from COVID-19 patients. The Committee agreed that this approach is adequate for now.

UNOS staff noted that current bylaws require patients to be informed of inactivation reasonably and fairly, and that UNOS has shared guidance on how these guidelines should be applied during the pandemic via the COVID-19 page on the UNOS website. UNOS leadership recommended this website to members who expressed concerns about lack of communication from UNOS regarding the pandemic.

### Next steps:

UNOS staff will coordinate action on the projects identified by the Committee as priority issues.

### **3. Other Committee Business**

The Chair told the Committee that their next call is scheduled for April 23, and there will be a lot of topics to discuss related to a previous board resolution.

### **Upcoming Meetings**

- April 23, 2020
- May 20, 2020