

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**April 14, 2021**

**Conference Call**

**Alexandra Glazier, JD, MPH, Chair**

**Nicole Turgeon, MD, FACS, Vice Chair**

### **Introduction**

The Policy Oversight Committee met via Citrix GoToMeeting teleconference on 04/14/2021 to discuss the following agenda items:

1. Multi-Organ Transplantation Committee Update and Planned Project Sequencing
2. Project Review
3. Special Public Comment Approval
4. Emergency Policy Review

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

### **1. Multi-Organ Transplantation Committee Update and Planned Project Sequencing**

UNOS staff shared an update on the status of the proposed Multi-Organ Transplantation (MOT) Committee and their planned projects.

#### Data summary:

The proposed MOT committee includes a roster consisting of representatives from Ethics, Heart, Kidney, Liver, Lung, Minority Affairs, Operations and Safety, OPO, Pancreas, Patient Affairs, Pediatrics, Transplant Coordinators, Vascular Composite Allograft, and the Policy Oversight Committee. In addition, the committee includes a chair, an additional OPO representative, a visiting Board member, and a representative from the Histocompatibility Committee for discussions on safety nets and medical eligibility of different organ combinations.

The charge for the Ad Hoc Multi-Organ Transplantation Committee is to develop and propose allocation policies that address multiple organ groups and the practice of multi-organ allocation. The Committee ensures proposed policies are in alignment with the OPTN Final Rule and the transition of organ allocation to a continuous distribution framework.

The MOT Committee would allow for the opportunity to take a more coordinated, holistic approach to standardizing many processes across organs in continuous distribution, except where there are clinical differences. In addition, it would allow consideration for the allocation priority between medical urgency in a single organ candidate versus the priority of an MOT candidate.

Proposed project sequence:

- April 2021, Establish Ad Hoc MOT Committee
- January 2022 Public comment, eligibility and safety net criteria for heart-kidney and lung-kidney, consider updates to simultaneous liver kidney (SLK) allocation
- August 2022 Public comment (alongside Kidney/Pancreas Continuous Distribution), prioritization between Kidney MOT and single organ transplant candidates

- January 2023 Public comment, eligibility and safety net criteria for heart-lung, lung-liver, and liver-heart
- August 2023 Public comment, match run prioritization for OPOs
- January 2024 Public comment, MOT considerations for heart and VCA continuous distribution

#### Summary of discussion:

Members agreed with the establishment of an MOT committee, as well as the proposed project sequencing by itself and in relation to continuous distribution of the different organs. Members also agreed that the Data Advisory Committee (DAC) may not need to be involved initially, but likely should be involved in later stages, for instance in the development of certain eligibility or safety net criteria that would likely require new data elements.

## **2. Project Review**

The POC reviewed one previously approved project:

- Data Collection to Evaluate Logistical Impact of Broader Distribution (Operations and Safety Committee)

#### Summary of discussion:

Members discussed whether this project was planned as a policy evaluation of continuous distribution, or whether it was to evaluate needed policy changes in the future. Members agreed that based on the timing of the project, there will not be sufficient data collection to compare the current allocation framework for all organs to the continuous distribution proposals.

In addition, one member brought up that it would likely be beneficial to look at the time between when an organ arrives at the transplant hospital to the time of transplant, as delays can also happen at the transplant program.

A member brought up that some of this data may be able to be obtained more easily and accurately via GPS organ tracking. The Operations and Safety (OSC) Vice Chair brought up that while that would be the ideal data source, it isn't something that is implemented or embraced across the country. UNOS staff brought up that now there are 15 OPOs in a GPS organ tracking pilot project, and that this may be able to test some of the assumptions made about how organs travel.

Another member brought up the question of whether or not this data would get at costs of shipping organs. The OSC Vice Chair explained that it is not within the scope of the project currently.

One member brought up that collaborating with the Data Advisory Committee (DAC) project on late turndowns could prove highly beneficial in terms of assessing potential implications related to organ transportation and time.

Members were supportive of collecting additional cold ischemic time and machine perfusion data.

#### Next steps:

POC would like OSC to consider whether any of their proposed data elements are able to be measured instead in an objective way, and whether there is any overlap with other current efforts or the ability for additional collaboration.

## **3. Special Public Comment Approval**

The POC reviewed a Special Public Comment project:

- Refine Lung Data Fields (Lung Committee)

#### Summary of discussion:

Members had no questions or concerns. Attendees did not express any concerns about the scope of this project or the OPTN's authority to work on this project. The POC voted to recommend approval of the release of this proposal to a special public comment period (18-yes, 0-no, 0-abstain).

#### Next steps:

The Executive Committee will consider the release of this proposal at their next meeting on 04/26/2021.

#### **4. Emergency Policy Review**

The POC reviewed an Emergency Policy being considered under OPTN *Bylaw 11.7*:

- Lower Respiratory SARS-CoV-2 Testing for Lung Donors (Ad Hoc Disease Transmission Advisory Committee)

#### Data summary:

The Ad Hoc Disease Transmission Advisory Committee (DTAC) is submitting a proposal to require lower respiratory testing for all lung donors due to transmission of COVID-19 in lung transplantation. This policy change would include:

- A requirement for test results to be back prior to procurement, but no requirement for test results prior to allocation or organ offer
- Flexibility on lower respiratory specimen type to account for DCD donation
- A 30-day delay in implementation to allow OPOs to develop necessary testing partnerships

While lower respiratory SARS-CoV-2 testing has risen from 30% to 60% of all deceased lung donors in recent months, there is still a significant gap in testing that poses a patient safety risk.

#### Summary of discussion:

One member asked if there was a concern about this policy change causing non-compliance or underutilization of lungs. UNOS staff explained that DTAC did consider this as well as solicited feedback from representatives from 27 unique OPOs. Due to concerns expressed about the ability to obtain a bronchoalveolar lavage (BAL) in rural hospitals or on DCD donors, they chose to allow any lower respiratory specimen type, including a tracheal aspirate. In addition, due to concerns about turnaround time for testing, they chose not to require the testing prior to allocation or organ offer.

One member recommended that the testing be required prior to transplant instead of prior to procurement.

The DTAC Vice Chair brought up that the committee and staff have provided a resource and multiple communications to ensure that OPOs are developing resources to obtain the appropriate testing in a reasonable turnaround time. In addition, DTAC is developing a comprehensive monitoring plan for potential adverse effects on utilization or organ offers.

One member asked why this is being proposed as an emergency policy instead of a special public comment, especially as there will be a 30-day delay in implementation and there has already been a fair amount of feedback solicited. The DTAC Vice Chair explained that recently there have been more cases of potential transmission that have been reported and are under investigation, and that this is an emergency issue that needs to be addressed rapidly.

One member asked if there are going to be changes in the ability to accept organs, based on the vaccination status of donors and/or recipients, and how would the candidate's medical urgency affect

that. The DTAC Vice Chair brought up that right now there isn't much data on the ability to utilize organs in those situations, and that immunocompromised patients may not have the same response to vaccination. In addition, the POC Chair brought up that this policy does not preclude the use of COVID positive organs, it only requires the testing and the result. In addition, the DTAC Vice Chair pointed out that this policy will continue to be assessed for relevance.

One member asked if this testing may be required for non-pulmonary organs. The DTAC Vice Chair explained that this is only being considered as a requirement for potential lung donors, and that this was discussed at length with the OPO, lung, and DTAC committees, but there is no evidence at this time to require additional testing for non-pulmonary donors. The OPO committee Vice Chair affirmed this, and that currently OPOs are struggling to place lungs without lower respiratory testing. He also recommended that DTAC create guidance on different testing types and FDA validation of specimen types for platforms.

One member asked if this testing would have prevented all of the cases of transmission so far. The DTAC Vice Chair explained that it would have, as all of these cases of proven or probable transmission are to lung donors who had a negative NP swab around the time of transplant, and an archived lower respiratory specimen that was not tested for SARS-CoV-2 until after the recipients developed symptoms of COVID. In all of those cases, the archived sample collected pre-transplant and tested retrospectively did test positive for SARS-CoV-2.

#### Next steps:

The Executive Committee will consider this proposal at their next meeting on 04/26/2021.

#### **Upcoming Meetings**

- May 12, 2021
- June 9, 2021

## Attendance

- **Committee Members**
  - Alden Doyle
  - Alex Glazier
  - Andrew Flescher
  - Emily Perito
  - Garrett Erdle
  - Heung Kim
  - Kurt Shutterly
  - Lara Danziger-Isakov
  - Marie Budev
  - Martha Pavlakis
  - Nicole Turgeon
  - PJ Geraghty
  - Paulo Martins
  - Rocky Daly
  - Sandra Amaral
  - Stacy McKean
  - Sumit Mohan
  - Susan Zylicz
- **HRSA Representatives**
  - Marilyn Levi
  - Shannon Dunne
  - Shannon Taitt
  - Vanessa Arriola
- **SRTR Staff**
  - Jon Snyder
- **UNOS Staff**
  - Abby Fox
  - Brian Shepard
  - Chelsea Haynes
  - Courtney Jett
  - Elizabeth Miller
  - James Alcorn
  - Joann White
  - Julia Chipko
  - Kaitlin Swanner
  - Kayla Temple
  - Kimberly Uccellini
  - Krissy Laurie
  - Kristine Althaus
  - Laura Schmitt
  - Lauren Mauk
  - Liz Robbins Callahan
  - Matt Prentice
  - Maureen McBride
  - Meghan McDermott

- Nicole Benjamin
- Rebecca Murdock
- Roger Brown
- Ross Walton
- Sara Rose Wells
- Sarah Konigsburg
- Sharon Shepherd
- Susan Tlusty
- Tina Rhoades
- **Other Attendees**
  - Alejandro Diez
  - Jennifer Prinz
  - Molly McCarthy
  - Natalie Blackwell
  - Oyedolamu Olaitan