

## **OPTN Ad Hoc Disease Transmission Advisory Committee**

### **Meeting Summary**

**August 23, 2021**

**Conference Call**

**Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair**

**Lara Danziger-Isakov, MD, MPH, Vice Chair**

### **Introduction**

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 08/23/2021 to discuss the following agenda items:

1. Lower Respiratory SARS-CoV-2 Testing for Lung Donors Two-Month Monitoring Report
2. PHS Specimen Storage Data Request
3. Closed Session: Confidential Medical Peer Review

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

### **1. Lower Respiratory SARS-CoV-2 Testing for Lung Donors Two-Month Monitoring Report**

UNOS Research staff presented on the two-month post-implementation monitoring report for the policy *Lower Respiratory SARS-CoV-2 Testing for Lung Donors*.

#### Data summary:

Metrics used included:

- Frequency of lower respiratory testing (LRT)
- Timing of LRT result reporting relative to lung transplant
- Number of donors with positive or discordant LRT results
- Organ utilization and discard rates

Based on the first 2 months of data post-policy:

- Data consistent with 1-month report
- Compliance with the LRT requirement remains high
- 98.3% of lung donors had LRT results reported on/before the day of transplant

The policy will be assessed again at 3 months post-implementation.

#### Summary of discussion:

A CDC member asked for clarification on why there were 13 donors with a negative upper respiratory test for SARS-CoV-2 and a positive lower respiratory test, and whether that represented potential transmissions that were prevented.

The Vice Chair stated that these may have represented potential lung donors, and an OPO representative on the committee agreed and said that often the sample is taken prior to when an OPO knows if the donor is eligible for lung donation based on their pO<sub>2</sub>. The OPO representative then asked if there was a way to know if a positive result represented a true positive or false positive.

The Chair clarified that it isn't possible to tell if any of the results were false positives, but that the DTAC has reviewed three cases in which there was a negative upper respiratory sample and a positive lower respiratory sample, and so these 13 donors could truly represent prevented transmissions. The Chair posed that it's hard to tell which situation these donors truly represent based on the data available.

A UNOS staff member also pointed out that in previous data reviews, sometimes the positive results reported are distant to transplant. Sometimes the donor hospital knows of a positive test up to nine months previously, and some OPOs are reporting this in the testing field.

One of the committee representative asked if the next monitoring report could look at the timing of all of the test results, and whether or not they occurred within the admission and represent a donor who is positive or negative at the time of transplant.

UNOS staff said that we can look at the specimen dates and see their time since transplant.

Another member asked if the test results reported are by PCR or another methodology. The Chair clarified that almost all donors are being tested by PCR. UNOS staff clarified that all or almost all of the lower respiratory tests have been by PCR, but that there are potentially different modalities for upper respiratory tests.

Members asked to clarify the numbers for DCD lungs over the past two months, and whether or not it's comparable to a pre-COVID timeframe. Another member pointed out that a pre-COVID timeframe might not be a fair comparison, especially with the current impact of the Delta variant. Two other members agreed that the pre-COVID cohort might be interesting, but that it may not be an accurate comparison to the current situation.

A committee member posed that increasing confidence in utilization of non-pulmonary organs with a positive results could be beneficial to the committee. The chair stated that it may not be within the purview of the monitoring plan, but that it might be helpful to look at. An OPO member asked how positive organs are being procured safely. Another OPO member mentioned that they have been doing so while wearing proper PPE, like fit-tested N-95s, with 2 weeks of follow-up testing for OPO personnel. The member posed that DTAC could consider making a statement to that effect. The chair mentioned that the current revision of the Summary of Evidence will have a comment on ensuring the safety of OPOs and recovery teams.

#### Next steps:

UNOS Research staff will modify the next monitoring report based on committee discussions.

## **2. PHS Specimen Storage Data Request**

UNOS Research staff presented on a committee data request on the time from transplant to reporting of potential transmission events. This report was stratified by living versus deceased donors, pathogens versus malignancies, CDC-led vs. non CDC-led cases, and HIV/HBV/HCV vs. all other pathogens. This report also looked at events reported via the OPTN Patient Safety Portal that were not pursued by DTAC for medical peer review.

#### Data summary:

1. DTAC-reviewed cases reported to the OPTN between 2008-2019. DTAC reviewed 2,774 cases reported between 2008-2019. The CDC led the review for 354 (14.6%) of these cases.

Distribution of time from recovery date to case reporting

CDC-led cases vs all other cases

By year of case report

By HIV/HBV/HCV, all other pathogens, and malignancies

By donor type (deceased vs living donor)

## 2. Cases not pursued by DTAC for medical peer review

Cancellation reasons for cases reported between 2008-2019 that were not pursued for full committee review, specifically for reports submitted >3 years after transplant

- 1,583 PDDTEs reported between 2008-2019 were not pursued by DTAC for medical peer review.
- 50 (3.2%) were reported >3 years after transplant.

### Summary of discussion:

One member posed that it would be helpful to present this information to the broader community, since there was a lot of concern expressed in public comment and after that there would not be transmissions reported up to 10 years after transplant.

The chair agreed, and posed that there is compelling data that there are events reported up to 10 years after transplant for both deceased and living donors.

The CDC representative said that the main reason the CDC had proposed the requirement is due to a transmission event in a living donor that occurred years after transplant, with no sample available. In addition, he said that it would be a difficult argument for them to change this to a shorter time period, especially since there have been HIV, HBV, or HCV cases that were reported years after transplant.

A lab representative agreed that this data should be disseminated, and posed that the committee should release more information on specimen types. He said that he's heard a lot of concern from community members about what specimens they need to store, and it's difficult to understand which specimens would be the most accurate, and what needs to be archived and under what conditions. He also posed that while the cost shouldn't be the driver of the policy, the committee should still keep in mind that over the community it's still significant.

One member asked about whether cases reported long after transplant were likely to be transplant-related. The CDC representative said that had been a long conversation with HHS, and that while the probability of a transmission being recognized ten years after transplant is low, it's not zero. In addition, living donor specimens that are collected years after transplant aren't reflective of whether or not the donor had the disease at time of transplant. In addition, the CDC has had other cases where they have needed to track down samples for public health benefit and potential disease transmissions, to ensure public confidence.

The chair asked if the committee had an obligation to investigate a potential donor-derived disease, and make sure there was a good system to investigate the concern. The CDC representative strongly stated there is an obligation to investigate whether any infections were of donor origin, and that collection of these samples is necessary to conducting investigations.

A representative asked if the main concern of the data request was about donor sample storage in general, or the requirement for the sample to be drawn within 24 hours of organ recovery.

The CDC representative said the concern was because living donor centers were concerned about sample storage in general, and that while OPOs have expressed some concerns about timing, they have been collecting these samples for years without an issue. Two members agreed that the concern was from living donor centers about sample storage in general.

The chair asked if committee members agreed that the data supported maintaining the 10 year time period for sample storage. Multiple members agreed, and none raised concerns.

### **3. Closed Session: Confidential Medical Peer Review**

#### Summary of discussion:

The Committee had a closed session review of potential donor-derived transmission events.

#### **Upcoming Meetings**

- September 7, 2021, 3 pm EDT, Teleconference
- September 28, 2021, 10 am EDT, Teleconference
- October 5, 2021, 3 pm EDT, Teleconference

## Open Session Attendance

- **Committee Members**
  - Avi Agarwal
  - Charles Marboe
  - Debbie Levine
  - DongHeun Lee
  - Gary Marklin
  - Gerald Berry
  - Helen Te
  - Jason Goldman
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Ricardo La Hoz
  - Sam Ho
  - Sarah Taimur
  - Stephanie Pouch
- **HRSA Representatives**
  - Jim Bowman
- **CDC Staff**
  - Ian Kracalik
  - Pallavi Annambhotla
  - Sridhar Basavaraju
- **FDA Staff**
  - Brychan Clark
  - Scott Brubaker
- **UNOS Staff**
  - Abby Fox
  - Anne McPherson
  - Courtney Jett
  - Darby Harris
  - Emily Womble
  - Leah Slife
  - Nicole Benjamin
  - Sandy Bartal
  - Sarah Booker
  - Susan Tlusty

## Closed Session Attendance

- **Committee Members**
  - Avi Agarwal
  - Charles Marboe
  - DongHeun Lee
  - Gary Marklin
  - Gerald Berry
  - Helen Te
  - Jason Goldman
  - Kelly Dunn

- Lara Danziger-Isakov
- Ricardo La Hoz
- Sam Ho
- Sarah Taimur
- Stephanie Pouch
- **HRSA Representatives**
  - Marilyn Levi
- **CDC Staff**
  - Ian Kracalik
  - Pallavi Annambhotla
  - Sridhar Basavaraju
- **FDA Staff**
  - Scott Brubaker
- **UNOS Staff**
  - Abby Fox
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  - Emily Womble
  - Sandy Bartal