

## **OPTN Ad Hoc Disease Transmission Advisory Committee Summary of Evidence Workgroup**

### **Meeting Summary**

**August 15, 2022**

**Conference Call**

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

**Stephanie Pouch, MD, MS, Vice Chair**

### **Introduction**

The Ad Hoc Disease Transmission Advisory Committee Summary of Evidence Workgroup met via Citrix GoToMeeting teleconference on 08/15/2022 to discuss the following agenda items:

1. Overview of the SARS-CoV-2 Summary of Evidence
2. BA.4/BA.5 Update
3. Updated Literature
4. Data Request for SARS-CoV-2 Positive Organ Utilization Manuscript Update

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

#### **1. Overview of the SARS-CoV-2 Summary of Evidence**

UNOS Staff explained that the Workgroup began drafting the SARS-CoV-2 Summary of Evidence in 2021 and the Committee reviews the Summary of Evidence quarterly. UNOS Staff noted that this is a plain language document for the community and the information added will be current as of July 2022. UNOS Staff explained that this version of the document is set to be published on 8/22/22 after the OPTN Executive Committee votes on the document on 8/19/22.

#### Summary of discussion:

There was no further discussion by the Workgroup.

#### **2. BA.4/BA.5 Update**

The Vice Chair updated the document to include BA.4 and BA.5 sublineage information. The Vice Chair summarized these changes, stating that the "Omicron Sublineage..." section was updated to indicate the dominant sublineage circulating is BA.4 and BA.5. She noted there is a brief comment on transmissibility, reinfection, and she kept the document's original comment regarding the subvariants inability to avoid detection.

#### Summary of discussion:

CDC staff asked if the phenomenon for repetitive testing for sublineages until an individual is positive is evident in transplant recipients as well. He recommended removing the "does not evade detection" comment. A Workgroup member stated they have not seen an increase in individuals who are presenting for symptomatic, respiratory illness. Another member stated the issue is that a lot of the time donors are asymptomatic from a SARS-CoV-2 standpoint, so it is hard to assess for that phenomenon. A Workgroup member noted there are a lot of individuals who are active PCR positive or have died from SARS-CoV-2 associated disease, but have appeared to have reasonable renal function, indicating the trajectory has changed significantly.

A Workgroup member clarified the Vice President's edits by highlighting the distinction between laboratory sensitivity and clinical sensitivity between the tests. She explained that these tests may work in the lab for sublineages, but clinically do not provide the needed information. She explained the comment in the document refers to a consistency in lab sensitivity, but clinical sensitivity is up for debate. The Chair suggested editing this portion to state, "current molecular testing platforms do detect BA.4/BA.5." The Workgroup members agreed.

### **3. Updated Literature**

The past Chair updated the document to include current information in terms of publications and available information on SARS-CoV-2 positive organ utilization. He updated a couple of case series that were published, including: an update on thoracic donors that tested positive and had favorable outcomes, a series that detailed 10 heart recipients' short-term outcomes after receiving organs from 11 lower respiratory tract (LRT) NAT positive donors, and a series that describes the use of 9 LRT NAT positive kidney donors.

The past Chair created a new section, "Analysis of the OPTN SARS-Cov-2 LRT Emergency Policy Monitoring Plan" to better analyze the outcomes. He explained that this details significant outcomes that the Chair presented at the ATC conference. The past Chair also added a manuscript that analyzes 6-month graft survival for kidney, liver, and heart recipients of positive organs. After hearing and discussing the updates, the Workgroup voted unanimously to send this document to the OPTN Executive Committee.

#### Summary of discussion:

A Workgroup member flagged the verbiage of "adequate short-term outcomes" and stated "adequate" is unclear. The members agreed to change it to "good." Members emphasized the need to keep the document readable and to highlight that there are no transmissions to non-lung recipients.

A member asked if there is any discussion on granular non-lethal graft related issues by the OPTN, such as the use of anticoagulation on a routine basis, the death of a bowel duct in a SARS-CoV-2 positive recipient, etc. The past Chair stated the abstract presented at ATC has a lot of that information with 30-day graft survival and failure. He stated it is important to note that these donors pose an increased risk, but this has may have been amplified in the community. Another member stated as these types of heterogenous donors increase we will be able to subcategorize this and answer these specific questions. The Chair stated we can consider this for the future of the Summary of Evidence.

#### Next steps:

The Executive Committee will be presented these updates on 8/19/22.

### **4. Data Request for SARS-CoV-2 Positive Organ Utilization Manuscript Update**

UNOS Staff stated organ utilization and discard rates for SARS-CoV-2 positive NAT donors and an analysis of the Donor Risk Assessment Interview forms will be added to the manuscript.

#### Summary of discussion:

The Past Chair asked to look at utilization rate over time to reflect the changes throughout the pandemic. UNOS staff asked if this should be stratified by waves of SARS-CoV-2. A Workgroup member stated it may be easier to stratify by year. UNOS Staff stated a wave would need to be clearly defined for the data request. Members agreed stratifying by a six-month period would be the most effective way to do this, since the waves progressed across the country.

UNOS staff asked if organ decline rates could be examined to see if this is attributed to SARS-CoV-2 positivity. The Past Chair urged the Workgroup to balance additions with timeliness in submitting the manuscript. The Chair stated a short letter could be submitted that describes this. CDC staff stated that if a table is presented with a crude utilization and discard rate it may be hard to interpret without appropriate statistical adjustments. Another member agreed and urged the Workgroup to be cautious on attributing declination reasoning to SARS-CoV-2 positivity because the reason stated for declination is often what is easiest to put. UNOS Staff emphasized the Committee is aware that not every OPO is using the DRAI, but most are, so missingness should be small.

### **Upcoming Meeting**

- TBD

## Attendance

- **Committee Members**
  - Ann E. Woodley
  - Cindy Fisher
  - Debbie Levine
  - Emily Blumberg
  - Jason D. Goldman
  - Judith Anesi
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Marian Michaels
  - Michelle Kittleson
  - Ricardo La Hoz
  - Sam Ho
  - Stephanie Pouch
  - Timothy Pruett
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **CDC Staff**
  - Sridhar Basavaraju
  - Ian Kracalik
- **FDA Staff**
  - Brychan Clark
- **UNOS Staff**
  - Amelia Devereaux
  - Courtney Jett
  - Kelsi Lindblad
  - Sandy Bartal
  - Susan Tlusty
  - Taylor Livelli