OPTN Ad Hoc Disease Transmission Advisory Committee
SARS-CoV-2 Summary of Evidence Workgroup
Meeting Summary
September 13, 2021
Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair
Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

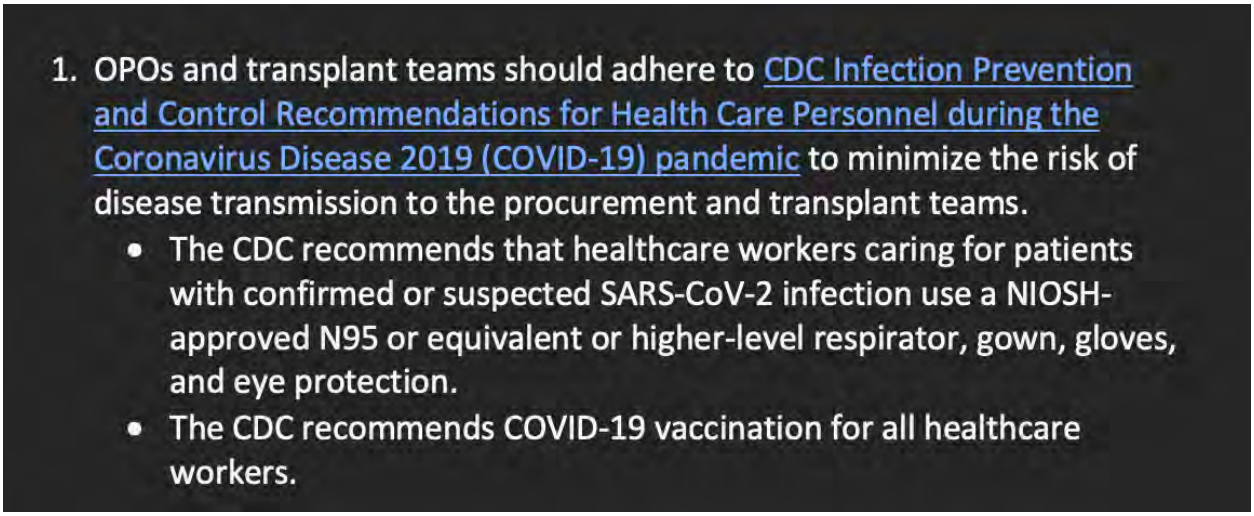
The SARS-CoV-2 Summary of Evidence Workgroup met via Citrix GoToMeeting teleconference on 09/13/2021 to discuss the following agenda items:

1. Safety of OPOs and Recovery Teams
2. Timing of Donor Testing
3. Delta Variant
4. Document Structure
5. Vote

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

1. Safety of OPOs and Recovery Teams

The Committee chair presented the following as the proposed structure of this section of the document:



Summary of discussion:

The ASTS representative emphasized that healthcare workers are a major element of continuing to provide patient care, and that we need to ensure they are as protected as possible. He also mentioned that a large number of all death notifications are either from confirmed or suspected COVID-19, and that in order for the transplant system as a whole to function we need to ensure that OPO staff, procurement teams, and recovery teams are protected from COVID-19. In addition, he mentioned that the ASTS was recommending vaccination for all recovery staff, and recommending that they carry proof

of vaccination with them to all hospitals due to a number of donor hospitals currently requiring proof of vaccination.

The AOPO representative agreed with the recommendations proposed by the workgroup, and stated that while there are many moving targets in the pandemic, the stated recommendations will not change. In addition, he pointed out that there was a proven case of inadvertent transmission of COVID-19 from a donor to a recovery team when they did not wear N-95s in the OR.

2. Timing of Donor Testing

The Committee chair presented the following as the proposed structure of this section of the document:

> 2. Available evidence indicates that testing deceased donors for SARS-CoV-2 by NAT from a respiratory sample within 72 hours, but ideally as close as possible to organ recovery, could decrease the risk of unrecognized infection.

Summary of discussion:

A committee laboratory representative stated that 72 hours is a reasonable timeline that most OPOs and labs are able to adhere to in most situations. He stated that if the timeline were to shorten to 48 hours, there would need to be sufficient evidence to support the increased risk of transmission to justify the logistical constraints. Both committee OPO representatives agreed with these statements, and one expressed a concern that a 48 hour requirement could provide a barrier to organ allocation.

The AOPO representative agreed, and stated that while a BAL sample would likely be ideal, it isn't feasible in many cases, and could limit DCD donation. He also pointed out that there is more sensitivity in lower respiratory samples than NP swabs.

The chair mentioned that DTAC cannot create a requirement of 72 hours for the timeframe at this point, since there is currently an emergency policy that does require lower respiratory testing for SARS-CoV-2 for lung donors.

An AST representative agreed with the OPO and AOPO representatives, and stated that in Canada the 48 hour requirement for samples can cause allocation delays, and it likely does not increase safety. The other AST representative agreed, and stated that any recommendation has to be able to be implemented practically in order to provide safety. Multiple other workgroup members agreed.

One workgroup member proposed removal of the phrase "ideally as close as possible to organ recovery" in order to avoid logistical concerns. Others stated that logistically, the OPOs are going to be taking repeat samples closer to organ recovery regardless, in order to protect recipient safety and safety of their teams. They stated that they didn't see any harm in keeping the phrase currently, and the workgroup member agreed that if the OPO members didn't think it would create concerns she agreed with keeping it.

3. Delta Variant

The Committee chair presented the following as the proposed structure of this section of the document:

Delta Variant

1. Data suggests that the SARS-CoV-2 Delta variant is more infectious than previous variants. Among individuals with infection due to the Delta variant, time from infection to PCR positivity appears shorter and Ct values are lower at the time of diagnosis. At this time, the duration of infectivity of the Delta variant has not been comprehensively assessed. Further studies will inform the period of infectivity and thus risk of donor derived infection and transmission to the OPO and recovery teams, despite vaccination status.

Summary of discussion:

One member made a clarifying recommendation to include that lower CT values indicate a higher viral load.

No other members expressed concerns.

4. Document Structure

The Committee chair presented the following as proposed changes to the overall structure of the document, for clarity:

- Members agreed with the CDC recommended clarifications to the United Kingdom SARS-CoV-2 testing requirements for organ transplantation.
- Members agreed to structure the document based on SARS-CoV-2 NAT results at time of organ procurement, rather than using the term "Active COVID-19" as was in previous versions of the document.
- The CDC asked about the potential to add a section on monoclonal antibody use for post-transmission treatment in lung recipients
    - Multiple members agreed that the data is currently very preliminary, and that most of the data is difficult to interpret due to the wide variety of different treatments patients are given in addition, such as alteration of immunosuppression and use of remdesivir
    - Members agreed that this could be a future addition to the document if additional information becomes available
- A HRSA representative brought forward a concern from the public about potential living donors rescinding due to transplant hospital vaccination requirements. The DTAC Vice Chair clarified that the OPTN does not have policy or guidance addressing living donor vaccination for SARS-CoV-2, and asked where the requirement was coming from. The ASTS representative stated that many individual hospitals are requiring this in order to protect their living donors, as even asymptomatic COVID-19 patients have been shown to have increased morbidity and mortality in operations.

5. Vote

The Committee chair called for a vote to approve the proposed changes to the Summary of Evidence. 22 yes, 0 abstain, 0 no.

Upcoming Meetings

- TBD

Attendance

- **Workgroup Members**
  - Ann Woolley
  - Avi Agarwal
  - Charles Marboe
  - Deborah Levine
  - Deepali Kumar
  - DongHeun Lee
  - Emily Blumberg
  - Gary Marklin
  - Gerald Berry
  - Jason Goldman
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Marian Michaels
  - Meenakshi Rana
  - Michelle Kittleson
  - Nicole Theodoropoulos
  - R Patrick Wood
  - Ricardo La Hoz
  - Sam Ho
  - Sarah Taimur
  - Stephanie Pouch
  - Timothy Pruett
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **CDC Staff**
  - Rebecca Free
  - Pallavi Annambhotla
  - Sridhar Basavaraju
- **FDA Staff**
  - Brychan Clark
  - Scott Brubaker
- **UNOS Staff**
  - Abby Fox
  - Carrie Caumont
  - Courtney Jett
  - Sarah Booker
  - Susan Tlusty
  - Susie Sprinson