**SARS-CoV-2 : Recommendations and Guidance for**

**Organ Donor Testing and Evaluation**

**Updated on June 30, 2022**

***The AST's Infectious Disease Community of Practice has received queries regarding the coronavirus (SARS-CoV-2). The following FAQs were developed with input of members from both the organ donation and transplantation communities to relay information on the current state of knowledge. This document is subject to change as more information becomes available.***

***Also see UNOS information link: https://unos.org/covid/***

## Donor screening in the era of COVID-19

The epidemiology of SARS-CoV-2 continues to evolve, and our knowledge base is rapidly expanding. The recommendations suggested below are to assist with specific considerations regarding donor screening that may arise and are subject to revision as data accumulate. Some screening considerations are pertinent to both living and deceased donation while other recommendations refer only to one or the other. Finally, it should also be recognized that no test is 100% sensitive or specific and both false positive and false negative results may occur. Accordingly, the risk: benefit ratio for an individual living donor and transplant candidate should always be taken into consideration when making the final decision to perform a transplant. This includes the risk of proceeding with a transplant as well as the risk of deferring and/or potentially foregoing transplantation.

## Can SARS-CoV-2 be transmitted from living or deceased donors?

The precise risk of COVID-19 infection from an infected living or deceased donor remains unclear at this time. However, the risk appears to be highest for lung transplant recipients. To date, four cases of deceased lung donors who initially tested negative for SARS-CoV-2 infection by real-time polymerase chain reaction (RT-PCR) testing from the upper respiratory tract testing were subsequently found to have positive RT-PCR testing from the lower respiratory tract (OPTN DTAC Meeting Summary; OPTN Proposal). Proven or probable transmission occurred in three bilateral lung transplant recipients, one of whom died of SARS-CoV-2 complications (Kaul et al. 2021). In the fourth case, lower respiratory tract RT-PCR was performed at the transplanting center, and the lungs were discarded upon receipt of positive test results (Kumar et al. 2021). The six non-lung recipients from these four donors did not develop signs or symptoms of COVID-19 (OPTN Summary of Evidence). Given the potential for disease transmission to lung transplant recipients in the absence of lower respiratory tract testing, starting May 27, 2021 OPTN

policy requires organ procurement organizations to perform lower respiratory tract SARS-CoV-2 testing for all potential lung donors.

To date, SARS-CoV-2 transmission has only been confirmed from the airway, and an increasing number of non-lung organs are being recovered and transplanted from donors with positive upper or lower respiratory tract test results without evidence of disease transmission. Epidemiologic exposures and clinical history need to be considered when assessing a donor's risk for infection. As always, when assessing an organ for transplantation, one must also consider the competing risks of the transplant candidate's mortality while on the transplant waitlist, and the impact that a COVID-19 donor-derived infection could have on the recipient's medical system and community.

## How should deceased donors be screened and tested?

All donors should be screened for known contacts with COVID-19 and for a history of known or suspected COVID-19 infection.
Deceased donors should be assessed for SARS-CoV-2 infection by RT-PCR of the respiratory tract, with lower respiratory tract testing being performed in all potential lung donors.

## Additional donor testing considerations

Positive and negative predictive values of SARS-CoV-2 tests will be impacted by the amount of locally circulating virus, specimen quality, and assay performance.

We do not recommend use of NAT from blood, urine, or stool, nor antigen testing from respiratory samples at this time.

Adjunctive testing

- Serologic assays for SARS-CoV-2 are increasingly available. At this time, there is no recommendation to include these tests in the deceased or living donor screening process. Application and interpretation of serologic results is evolving; it varies with the different testing platforms and test specificity is impacted by the prevalence of SARS-CoV-2 in the region.

Evidence supporting the use of SARS-CoV-2 antigen testing for the purpose of donor evaluation is also limited at this time and not recommended.

Cycle threshold (Ct) values, which indicate the number of amplification cycles needed to achieve a positive test from a real-time PCR test, may be reported from authorized molecular SARS-CoV-2 diagnostic tests. In general, higher Ct values tend to correlate with lower viral loads and culture negativity. However, the FDA and CDC currently recommend against the use of Ct values for assessment of a person's degree of infectivity or disease severity. If a Ct value is obtained on a donor respiratory tract sample, results should be viewed as adjunctive data points rather than definitive information to determine the disposition of the potential donor.

In addition, while ground glass opacification has been well-described in patients with confirmed SARS-CoV-2 infection, it is a non-specific finding. Accordingly, a computerized tomography (CT) scan of the chest cannot be relied upon either to exclude or diagnose SARS-CoV-2 infection in potential deceased or living donors and should not be used as the sole diagnostic modality.

OPTN Policy 2.2 (OPO Responsibilities), #15, requires storage of blood for all deceased donors which could be used to retrospectively look for positive donor serology if needed.

- While not mandated, storage of respiratory or other specimens in a fashion suitable for PCR testing may also be valuable if subsequent donor-derived infection is suspected. Storage of donor lower respiratory tract specimens may be of particular value when thoracic organs are procured.

Donor testing recommendations:

- All deceased donors should be tested for SARS-CoV-2 infection using RT-PCR from the upper respiratory tract within 72 hours, but ideally as close to organ recovery as possible.
    - In accordance with OPTN policy, all potential lung donors must be tested for SARS-CoV-2 infection using RT- PCR from the lower respiratory tract (i.e., samples obtained from the glottis or below, including sputum, tracheal aspirate, bronchial wash, bronchoalveolar lavage, or lung biopsy)
- There is insufficient evidence to support the use of SARS-CoV-2 RT-PCR testing from non-respiratory sites, SARS-CoV-2 rapid antigen testing, or SARS-CoV-2 antibody testing in deceased donors.
- Radiographic findings should not be used as a sole diagnostic modality for evidence of SARS-CoV-2 infection but should be taken into consideration along with the donor's clinical history and SARS-CoV-2 test results
- Results of additional donor SARS-CoV-2 testing that may have been performed prior to donation should also be reviewed and made available to evaluating centers.

Recommendations for transplantation of organs from donors with a positive SARS-CoV-2 PCR:

- Donors with a history of resolved COVID-19 and a positive SARS-CoV-2 PCR 21-90 days after disease onset
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    - Donors are unlikely to transmit infection and should be considered for organ acceptance
    - There is very limited experience with lung transplantation in this context. In situations in which lungs have been recovered and transplanted, donors first tested positive >20 days prior, had no evidence of active pulmonary infection, and were PCR-negative on bronchoalveolar lavage. If lungs are being considered in this situation, consultation with local ID experts is recommended.
- Donors with mild COVID-19 between 10-21 days of symptom onset, positive SARS-CoV-2 PCR, and resolution of symptoms
    - Donors are unlikely to transmit infection to non-lung recipients. Use of non-lung organs from immunocompetent donors >10 days from disease onset and with resolved symptoms should be considered taking into account limited long-term outcome data at this time.
- Donors with resolved COVID-19 and a positive SARS CoV-2 PCR >90 days from the date of disease onset.
    - SARS-CoV-2 test results may reflect re-infection and would proceed as below (donors with a positive SARS-CoV-2 PCR and no known history of previous infection).

    - When variants are circulating, it is possible that reinfection can happen earlier than 90 days from prior infection.
- Donors with a positive SARS-CoV-2 PCR and no known history of previous infection
    - Donors are unlikely to transmit infection to non-lung recipients and should be considered for non-lung acceptance provided no evidence of end-organ dysfunction or thrombosis and taking into account limited long-term outcome data at this time.
- Donors with a positive SARS-CoV-2 PCR and who died of COVID-19-related complications
    - Donors should be considered for non-lung acceptance taking into account limited long-term outcome data at this time.

- While SARS-CoV-2 transmission has only been reported in the setting of lung transplantation to date, data regarding long-term outcomes of organ donation from donors with positive SARS-CoV-2 PCR results are limited at this time. In this context, decisions regarding whether to proceed with transplantation must include discussions and informed consent with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation. Given multiple organ involvement with SARS-CoV-2 infection and unclear long-term implications, close follow up will be required.
- At present, there is insufficient evidence to determine whether recipient COVID-19 vaccination is protective against disease transmission through organ donation and it is does not appear that pre-emptive COVID-19-directed therapies in non-lung recipients are needed.

Recommendations for transplantation of organs from donors with a history of COVID-19 and a negative SARS-CoV-2 PCR, regardless of whether the donor died from COVID-19 related causes

- Deceased donors are unlikely to transmit infection and should be considered for organ acceptance

Recommendations for transplantation of organs from donors with a significant exposure to COVID-19 within the prior 72 hours and a negative SARS-CoV-2 PCR

- The risk of SARS-CoV-2 transmission in this scenario is unknown, and there have been no reported cases of transmission in this context.

**How should living donors be screened and tested?**

- Once the surgery date is finalized, the living donors should be counseled to contact the transplant center if they or one of their close contacts develops COVID-19 so that the timing of the donation surgery can be reassessed in a timely fashion.
- Counseling should be given regarding practices to minimize risk of infection, and these recommendations should be balanced against feasibility and practicality for donors. This strategy is vital for programs to continue live donor kidney and liver transplants during COVID-19 pandemic.
    - Living donors and their support persons should be counseled on and encouraged to use preventive strategies (e.g., masking, physical distancing, good hand hygiene), particularly in the 14 days prior to donation to avoid infection.
    - While self-quarantine is recommended as a preventive strategy, it should not be mandatory, as some donors may not have an option to work from home. However, self-quarantine is recommended if possible after the pre-operative COVID-19 testing is performed (see below).
    - Living donors should be strongly encouraged to be fully vaccinated and boosted with any of the available COVID-19 vaccines, preferably with vaccine completion at least 2 weeks in anticipation of donation. https://www.cdc.gov/vaccines/covid-19/index.html

<u>Donor testing recommendations:</u>

- All living donors should undergo respiratory tract SARS-CoV-2 RT PCR testing within 3 days of donation and as close to organ recovery as possible.
    - The exact timing should be guided by local transplant center and hospital policy and the turn-around time of the test. The test results should be available at least

one day before surgery.
    - Living donors who are part of KPD programs should be tested based on the policy of the procuring transplant center.
- The use of organs from a living donor with active COVID-19 should be avoided until considered no longer infectious and with consideration of potential morbidity to the donor as outlined below.
- Consider delaying transplant for asymptomatic living donors with a known exposure history within the previous 14 days.
- For living donors who were previously known to have had COVID-19, we would recommend proceeding to transplant under the following circumstances:
    - Consideration should be given to the potential for perioperative morbidity and mortality in the first 6 weeks following COVID-19 (COVIDSurg Collaborative).
    - Repeat NAT testing is ideally negative.
    - Symptoms have resolved and the initial COVID infection occurred between 21 and 90 days prior to donation, irrespective of repeat NAT test results.
        - For individuals who have recovered from SARS-CoV-2 infection, another positive PCR within 90 days after the onset of illness most likely reflects persistent shedding of viral RNA rather than active or new infection (CDC.gov) with a gradual risk decline to baseline risk by 7 weeks after COVID19 infection.
        - Consultation with local ID experts should be considered prior to acceptance of those donors.
    - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days (and possibly sooner if variants are circulating) after the initial infection should be considered true positives. Consultation with local ID experts should be obtained prior to consideration of these donors.
    - Given the renal dysfunction associated with SARS-CoV-2 infection and unclear long-term implications thereof, additional evaluation may be required when considering kidney transplantation from living donors with previous COVID-19.
    - Data regarding the safety of organ donation from donors with previous COVID-19 are limited at this time. The long-term outcomes remain unknown, including the possibility of thrombotic events. In this context, decisions regarding whether to proceed with transplantation must include discussions with the transplant candidate and his or her proxy, as well as consideration of the risk associated with not proceeding with transplantation.

The COVID-19 pandemic is unpredictable. During widespread community-transmission, healthcare infrastructure and capacity issues may have further impact on donation and transplantation. These recommendations will be regularly updated to account for the changing epidemiology and new information regarding treatment and testing.

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