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**SARS-CoV-2 (Coronavirus, 2019-nCoV):  
Recommendations and Guidance for Organ Donor Testing**

Updated on **July 7, 2021**

*The AST's Infectious Disease Community of Practice has received queries regarding the novel 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 new 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, OPTN

policy now requires organ procurement organizations to perform lower respiratory tract SARS-CoV-2 testing for all potential lung donors effective May 27, 2021.

Other factors that could impact the transmission of SARS-CoV-2 from an organ donor include viability of the virus within the blood and its viability within specific organ compartments of an infected donor. Epidemiologic exposures and clinical history need to be considered when assessing a donor's risk for infection. Other factors to consider when assessing an organ for transplantation is the risk of the transplant candidate's mortality while on the transplant waitlist, as well as 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?**

Donors should be screened epidemiologically, including for known contacts, and by clinical history of known or suspected COVID-19 infection and COVID-19 vaccination history. 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. If used, results should be viewed as adjunctive data points rather than as primary definitive information to determine final disposition of a potential donor. Issues to keep in mind include:

- IgM assays in general have a higher rate of false positive results compared to IgG assays. However, IgM true positive assays usually reflect recent infections, and in this setting the risk of transmission to the procurement team and the recipient must be considered.
- IgG positive assays may reflect passive antibody from blood products or immunoglobulin.
- A person with prior COVID-19 vaccination or COVID-19 disease who has recovered may be IgG positive, but it is not certain how long IgG positivity is maintained nor its impact on infectivity via transplantation.

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

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
  - All potential lung donors should be tested for SARS-CoV-2 infection using RT-PCR from the lower respiratory tract (i.e., samples obtained from the trachea 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 history of COVID-19 or active COVID-19:

- For donors previously known to have had COVID-19, we currently recommend consideration for organ acceptance under the following circumstances:
  - Negative SARS-CoV-2 RT-PCR testing from the respiratory tract, including lower respiratory tract testing in potential lung donors, symptoms of COVID-19 have resolved, AND at least 21 days have transpired since the date of disease onset
    - For immunocompetent donors who were asymptomatic or had mild COVID-19, acceptance of non-lung organs for high-urgency transplantations can be considered beginning at least 10-14 days since the donor's initial diagnosis if the donor has a negative RT-PCR test from a respiratory sample AND symptoms of COVID-19 had resolved. Consultation with local ID experts should be considered prior to acceptance of these donors.
  - Positive SARS-CoV-2 RT-PCR testing from the respiratory tract, resolved symptoms of COVID-19 AND between 21 and 90 days have transpired since the date of disease onset
    - A positive SARS-CoV-2 RT-PCR within 21 days of initial COVID-19 diagnosis may reflect replication-competent virus and likely represents a higher risk for transmission
    - A positive SARS-CoV-2 RT-PCR between 21-90 days following initial COVID-19 diagnosis in a donor who is no longer symptomatic is likely to represent persistent shedding of SARS-CoV-2 RNA rather than replication-competent virus or new infection in an immunocompetent donor (CDC.gov)

- Consultation with local ID experts should be considered prior to acceptance of these donors.
- Data regarding the safety of organ donation from donors with previous COVID-19 are limited at this time. 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. Given multiple organ involvement with SARS-CoV-2 infection and unclear long-term implications, close follow up will be required.
- Reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days after the initial infection should be considered as potentially true positives. Consultation with local ID experts should be obtained prior to consideration of these donors. Given presumed active COVID-19 in this scenario, the decision about whether to proceed with non-lung transplantation should include the potential risk of SARS-CoV-2 transmission to the recipient and recovery and transplant teams, urgency of transplant, risk associated with not proceeding with transplantation, and unknown long-term allograft outcomes. Further, currently, there is insufficient evidence to determine whether recipient COVID-19 vaccination is protective against disease transmission through organ donation. The optimal recipient evaluation and management strategies are currently unknown.

### **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.
- Careful consideration should be given regarding recommending 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 after the pre-operative COVID-19 testing is performed (see below).
  - Living donors should be strongly encouraged to be fully vaccinated with any of the available COVID-19 vaccines, preferably with vaccine completion at least 2 weeks in anticipation of donation.

#### Donor testing recommendations:

- All living donors should undergo respiratory tract SARS-CoV-2 RT PCR testing within 3 days of donation.
  - 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.
  - 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 only considering 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 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).
      - 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 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 extremely limited at this time. 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 current outbreak 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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