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**SARS-CoV-2: Recommendations and  
Guidance for Organ Donor Testing and  
Evaluation**

**Updated on Jan 18, 2023**

*The AST's Infectious Disease Community of Practice continues to receive 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?**

Emerging data suggest that the risk of transmitting SARS-CoV-2 infection from an infected living or deceased non-lung or intestinal donor is low. The risk is 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 upper respiratory tract samples were subsequently found to

have positive RT-PCR results from lower respiratory tract samples (OPTN Summary of Evidence) (<https://optn.transplant.hrsa.gov/media/kkhn1wah/sars-cov-2-summary-of-evidence.pdf>). Proven or probable transmission occurred in three bilateral lung transplant recipients, one of whom died of SARS-CoV-2 complications (Kaul et al. 2021; Kumar 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 requires organ procurement organizations to perform lower respiratory tract SARS- CoV-2 testing for all potential lung donors effective May 27, 2021.

To date, SARS-CoV-2 transmission has only been confirmed from infected lung donors, 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. Recently published larger-scale experience from the United States has shown that recipients of non-lung organs from SARS-CoV-2 PCR- positive donors have short-term patient and graft survival similar to those who received organs from SARS-CoV-2 PCR-negative donors. 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.

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 PCR or other nucleic acid testing assay, 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)
  - 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. 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.
  
- 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 COVID-19 and a positive SARS-CoV-2 PCR
  - Non-lung donors are unlikely to transmit infection and should be considered for organ acceptance provided no evidence of end-organ dysfunction or thrombosis is present and considering inadequate long-term outcome data at this time.
  - There is very limited experience with lung transplantation in this context. Only bronchoalveolar lavage PCR negative lung donors should be considered at this time. If lungs are being considered when the upper respiratory tract PCR is positive consultation with local ID experts is recommended.
  
- SARS-CoV-2 transmission has only been reported in the

setting of lung transplantation to date. Reported short-term patient and graft survival among recipients of SARS-CoV-2 PCR positive versus negative donors appear to be similar but 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. Likewise, it does not appear that pre-emptive COVID-19-directed therapies in non-lung recipients are warranted.

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, but 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 an expedited 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 the 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, particularly after the pre-operative COVID-19 testing is performed, it should not be mandatory, as some donors may not have an option to work from home

- Living donors should be strongly encouraged to be fully vaccinated and have up-to-date boosters with 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>

#### Donor testing recommendations:

- All living donors should undergo upper 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 prior to surgery.
  - Living donors who are part of KPD programs should be tested based on the policy of the procuring transplant center but as close as possible to time of procurement and at a maximum of three days prior to donation.
- The use of organs from a living donor with active COVID-19 should be avoided until the donor is considered no longer infectious. This may reduce the donor's operative risk and the risk of transmission to personal contacts and hospital staff.
- Consider delaying transplant for asymptomatic living donors with a known exposure history within the previous 7 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 2021).
  - At present, there are limited data regarding postoperative mortality rates in vaccinated patients with a recent diagnosis of SARS-CoV-2 infection compared with those who are unvaccinated; while the impact of the Omicron variant on peri-operative outcomes is not well elucidated, there are encouraging data from a CDC report demonstrating a substantial reduction of in-hospital mortality in patients hospitalized for SARS-CoV-2 during the period of Omicron variant predominance as compared to a period of Delta variant predominance (Adeji et al 2022). Existing guidelines regarding the timing of elective surgery following SARS-CoV-2 infection have been informed by collaborative international multicenter prospective data that demonstrated an excess mortality, pulmonary complications, and thromboembolic events in patients undergoing surgery up to 7 weeks following a SARS-CoV-2 diagnosis (COVIDSurg Collaborative 2021). These studies, however, predated the widespread availability of SARS-CoV-2 vaccinations as well

- as the predominance of the omicron variant.
- A recent retrospective cohort study of patients who underwent scheduled surgery in an integrated health system from January 1, 2018 to February 28, 2022 demonstrated that surgery within 0-4 weeks following SARS-CoV-2 infection was not associated with higher mortality among fully vaccinated patients (Le et al Ann Surg 2022 I.). Further studies are needed to confirm these findings and guide the optimal timing of surgery in living donors with a previous SARS-CoV-2 infection. The COVIDSurge-3 study is currently ongoing and aims to elucidate the optimal timing of surgery following SARS-CoV-2 infection during the Omicron predominant period and will include data on vaccinated patients.
  - Repeat PCR testing is ideally negative.
  - Symptoms have resolved and the initial COVID infection occurred between 14 and 90 days prior to donation, irrespective of repeat PCR test results.
  - Following infection, reinfection with SARS-CoV-2 has been reported. Consequently, repeat positive PCR tests >90 days (and possibly sooner if newer or multiple 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 remains 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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