



Summary of Current Evidence and Information– Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19

Aim

This document is a summary of evidence and information regarding donor screening for SARS-CoV-2 and considerations for organ acceptance from donors with a history of COVID-19. It is based on peer-reviewed literature, and Organ Procurement and Transplantation Network (OPTN) and Centers for Disease Control and Prevention (CDC) data to date. This resource is subject to revision as new data accumulate. It will be reviewed annually or as needed for currency. The overarching objective of this document is to compile the latest information known for minimizing the risk of donor derived COVID-19 while maximizing donor utilization.

Terms to know

- **Nucleic Acid Test (NAT):** Nucleic acid tests are laboratory tests that detect viral genetic material. These include nucleic acid amplification tests (NAAT), RNA tests, and Polymerase Chain Reaction (PCR) tests
- **Upper respiratory tract (URT) specimen:** A sample taken from the respiratory system above the glottis that includes a nasopharyngeal (NP) swab, NP wash or NP aspirate, nasal wash or nasal aspirate, mid-turbinate (MT) swab, anterior nasal swab, or oropharyngeal (OP) swab sample.
- **Lower respiratory tract (LRT) specimen:** A sample taken from the respiratory system from below the glottis that includes a sputum, tracheal aspirate, bronchial suction or wash, bronchoalveolar lavage (BAL), and lung biopsy.

- **Cycle threshold (Ct) value:** Cycle threshold values indicate the number of amplification cycles needed to achieve a positive result from a PCR test.
- **Date of disease onset:** In this document will refer to the date of onset of [COVID-19 symptoms](#) or the initial date of test positivity if onset of symptoms cannot be confirmed or if asymptomatic.
- **Asymptomatic COVID-19 Infection:** Detection of SARS-CoV-2 in a respiratory sample without current ~~or past~~ symptoms compatible with COVID-19.

Methods

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) and relevant stakeholders from the Centers for Disease Control and Prevention (CDC), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), and Health Resources & Services Administration (HRSA) reviewed published literature and data reported to the OPTN (from March 2020 to December 2023). Specifically, DTAC and relevant stakeholders assessed the available evidence as it relates to living and deceased donor evaluation and testing and recovery of organs from living or deceased donors with a history of positive test for SARS-COV-2.

Discussion

SARS-CoV-2 Deceased Donor Evaluation and Testing

1. OPOs and transplant teams should adhere to [CDC Interim Infection Prevention and Control Recommendations for healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) to minimize the risk of disease transmission to the procurement and transplant teams.
 - The CDC recommends that healthcare workers caring for patients with confirmed or suspected SARS-CoV-2 infection adhere to standard precautions and use a NIOSH-approved N95 or equivalent or higher-level respirator, gown, gloves, and eye protection.
 - The CDC recommends performing aerosol-generating procedures on patients with confirmed or suspected SARS-CoV-2 infection in an airborne infection isolation room, if possible.
 - The CDC recommends [COVID-19 vaccination](#) for all healthcare workers.
2. [The Food and Drug Administration \(FDA\)](#) provides information about the impact of viral mutations on COVID-19 tests, recommendations for clinical laboratory staff and health care providers, and information about certain tests for which the FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations.
 - Antigen tests are generally less sensitive and less likely to detect

very early infections compared to molecular tests. In following the FDA's long-standing rapid test recommendations, if a person tests negative with an antigen test ([immunoassays that detect the presence of a specific viral antigen](#)) but is suspected of having COVID-19, such as experiencing symptoms or having a high likelihood of infection due to exposure, follow-up molecular testing ([polymerase chain reaction \(PCR\) and other nucleic acid amplification tests \(NAATs\) tests, which detect genetic material called RNA from the virus](#)) is important for determining a COVID-19 infection.

- The FDA's analysis to date has identified certain EUA-authorized molecular tests whose performance may be impacted by mutations in the SARS-CoV-2 omicron variant. [Some molecular tests are expected to fail to detect some SARS-CoV-2 omicron variants, and the FDA is collaborating with government partners and test developers to evaluate the impact of the Omicron variant and subvariants on SARS-CoV-2 diagnostic tests.](#)
3. Available evidence indicates that testing deceased donors for SARS-CoV-2 by NAT from a respiratory sample within 72 hours of organ procurement, but ideally as close as possible to organ recovery, could decrease the risk of unrecognized infection.
 4. When lungs will be recovered for transplantation, testing for SARS-CoV-2 by NAT in a lower respiratory sample is anticipated to significantly decrease the risk of unrecognized infection.
 5. Based on prior donor-derived infections in lung transplant recipients, effective May 27, 2021, [OPTN policy](#) requires OPOs to perform LRT

SARS-CoV-2 testing on all potential lung donors and have test results available prior to transplant of the lungs. Between May 27, 2021 and May 31, 2023, 278 donors were identified as having negative URT but positive LRT SARS-CoV-2 tests. The only confirmed donor-derived transmissions have been through the airway; demonstration of non-airway transmission has not been confirmed at this time.

- The Food and Drug Administration (FDA) under Emergency Use Authorization (EUA) provides validated specimen types for all SARS-CoV-2 assays. [There are over 80 tests currently validated for lower respiratory tract specimens.](#)

6. In December 2020, the FDA permitted laboratory reporting of cycle threshold (Ct) values for authorized molecular diagnostic SARS-CoV-2 tests.

- A Ct value indicates the number of amplification cycles needed to achieve a positive result from a real-time PCR test. Low Ct values are generally considered to reflect a higher viral load, and high Ct values are generally considered to reflect a lower viral load.
- Higher Ct values tend to correlate with culture negativity. The CDC reported that attempts to recover SARS-CoV-2 in culture of upper airway samples was generally unsuccessful when their assay Ct values were >35. However, due to the multiple factors known to

impact Ct values (testing platform, specimen collection and storage), caution is advised when applying published correlations of Ct values with the presence of infectious virus detectable in culture, and hence as a predictor of transmissibility.

- The CDC and FDA currently recommend against the use of Ct values for assessment of an individual's degree of infectivity or risk for disease severity.
7. Currently there is insufficient evidence to support the use of SARS-CoV-2 antibody donor testing as a marker for assessing safety or potential transmission risk to recipients.
 8. NAT testing of non-respiratory samples is not standardized, and there is insufficient evidence to support its use for clinical evaluation of donors at this time.
 9. Available evidence supports an assessment for potential end-organ dysfunction in donors with COVID-19.
 10. OPOs collecting a history and timeline of COVID-19 exposure and COVID-19 symptoms in a potential donor could contextualize SARS-CoV-2 test results and lower the risk of undetected infection and maximize organ utilization.

Recovery of Organs from Deceased Donors given SARS-CoV-2 Test Results

1. Prior guidance stratified risk to all recipients based on the recency of positive testing in the donor. Current guidance stratifies lung and non-lung donation separately as transmission from donor to lung recipient is known to occur, yet no proven transmission to non-lung recipients has been documented to date.

Deceased Donors for Non-Lung Transplants:

1. SARS-CoV-2 NAT negative non-lung donors, even if exposed, are considered safe.
2. Given no proven transmission of SARS-CoV-2 from NAT positive non-lung donors to respective recipients, these donors should be considered, provided no evidence of end-organ dysfunction or thrombosis related to active SARS-CoV-2 infection and considering limited, [but evolving, longer-term outcome data at this time](#).
3. [Evidence suggests](#) that short-term outcomes are similar between non-lung recipients receiving organs from SARS-CoV-2 NAT positive and SARS-CoV-2 NAT negative donors.
4. It is likely that donors were selected for either high organ quality, low risk of active disease or both in the early experience with the use of SARS- CoV-2 NAT+ organs.

5. There is not currently enough experience to comment on the safety of intestinal or vascularized composite allograft transplant from donors who are SARS-CoV-2 NAT+ within 21 days of organ recovery. It is noted that the gastrointestinal tract is thought to be a reservoir of persistence of SARS-CoV-2.

Deceased Donors for Lung Transplants:

1. Transmission from donor to lung recipient has been documented in cases where the donor was SARS-CoV-2 NAT negative on an upper respiratory track (LRT) specimen, but testing of a specimen from the lower respiratory tract was not performed. Since implementation of the policy requiring LRT testing for lung donors, no proven or probable transmission events have occurred.
2. A [recent analysis](#) of lung transplantation performed in the United States between January 2020 and June 2022 described similar 30-day and 3-month outcomes comparing recipients of lungs from donors with positive SARS-CoV-2 test results within 21 days of organ recovery and recipients of lungs from donors with negative SARS-CoV-2 testing within the same timeframe. Notably, donor data in this cohort did not include presence of symptoms, clinical history, or previous SARS-CoV-2 test results.
3. Published data suggest two potential approaches to the use of SARS-CoV-2 NAT + donors. The first is to recover lungs from SARS-CoV-2 NAT positive donors only when symptom onset or test positivity occurred >20 days prior. The second is to recover all organs from SARS-CoV-2 NAT positive donors who never experienced symptoms of COVID-19, stratifying the risk of disease transmission using the Ct value. The former emphasizes safety while the latter maximizes organ utilization at the expense of a higher risk of disease transmission given limitation of Ct values to determine infectivity.
 - a. A [case series](#) described the use of two SARS-CoV-2 URT NAT + LRT NAT donors – with a history of asymptomatic SARS-CoV-2 infection more than 20 days after the onset of symptoms. The donors had no evidence of terminal illness complicated by hypercoagulability or hyperinflammatory syndrome. One of the recipients had 3 doses of

an mRNA vaccine and the other 2 doses and a prior history of COVID-19; there was no evidence of disease transmission.

- b. A second [case series](#) described the use of eight SARS-CoV-2 URT NAT + (Ct value >35) donors with a LRT NAT that was either negative or positive with a Ct value >35. The donors were asymptomatic and had no known history of COVID-19. There was no evidence of disease transmission, and all recipients were alive at a median time of 161 days.

SARS-CoV-2 Living Donor Testing and Precautions

1. [CDC recommendations regarding COVID-19 Prevention Actions](#) can help living donors reduce the risk of SARS-CoV-2 infection prior to donation and during recovery.
2. [COVID-19 vaccination](#) including up-to-date boosters are strongly encouraged for living donors, preferably with vaccine completion at least 2 weeks prior to anticipation of donation
3. Testing for SARS-CoV-2 with NAT in an upper respiratory sample as close to organ recovery as possible but within 72 hours prior to recovery, is recommended to reduce the risk of undetected infection. Performance and exact timing of testing should be guided by institutional policies, but the result should be made available prior to surgery.
4. The FDA has identified [certain EUA-authorized molecular tests](#) whose performance is potentially impacted by mutations in the SARS-CoV-2 Omicron variant and Omicron sub-variants. Some molecular tests are expected to fail to detect the SARS-CoV-2 Omicron variant and its sub-variants.

Recovery of Organs from Living Donors with a History of Resolved COVID-19

Evidence suggests the decision to recover and transplant organs from living donors with resolved COVID-19 include the following:

1. Consideration of data on peri-operative mortality in relation to diagnosis of COVID-19.

- a. The COVIDSurg Collaborative, which pre-dated the Omicron variant and widespread vaccine availability, evaluated timing of surgery in relation to pre-operative diagnosis of COVID-19 and impact on early post-operative mortality. Results demonstrated an increased 30-day post-operative mortality among patients with COVID-19 diagnosed ≤ 6 weeks preceding surgery. For surgeries performed ≥ 7 weeks from COVID-19 diagnosis, the post-operative mortality was similar to the baseline mortality among patients who were asymptomatic. It was, however, higher than baseline mortality among those who had ongoing symptomatic SARS-CoV-2 infection at that time point.
 - b. A retrospective cohort [study](#) of patients who underwent elective surgery between January 1st 2018 and February 28th 2022, evaluated the association between post-surgical complications and timing of surgery after pre-operative COVID-19 diagnosis, and the impact of vaccination on this association. The investigators found that in comparison to patients without pre-operative COVID-19, among [fully vaccinated](#) patients who underwent surgery as early as 0-4 weeks of COVID-19 diagnosis had a similar risk of perioperative complications in comparison to patients without pre-operative COVID-19.
 - c. [COVIDSurg-3](#) is an ongoing study which will be looking at surgical outcomes in relation to the current landscape of the COVID-19 pandemic and will provide information on the impact of predominant global SARS CoV-2 variants and vaccinations.
 - d. [Current guidelines](#) consider previously published data but recognize the impact of public vaccination and circulation of less virulent variants. With respect to elective procedures, they recommend that the clinical picture, surgical risk, and potential impact of delayed surgery inform decisions regarding proceeding with the planned procedure between two and seven weeks following SARS-CoV-2 infection.
2. Current additional considerations based on gaps in knowledge and risk/benefit balance:

- a. Currently unknown long-term effects, including the possibility of thrombotic events, of COVID-19 infection for the living donor
- b. There is unclear evidence on the need for a negative SARS-CoV-2 NAT for asymptomatic living donors. It is always important to follow local infection prevention and control policies.

- c. The candidate risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
 - d. Currently unknown long-term outcomes, including the possibility of thrombotic events, of recipients of organs from living donors with COVID-19
3. Infectious diseases experts can offer subject matter expertise when evaluating living donors who are found to be SARS-CoV-2 positive in the pre-donation period.

Timing of Transplant for Recipients with a History of COVID-19 or Incidental Test Positivity at the Time of Organ Offer

1. Although previous data demonstrated an increased risk of peri-operative mortality in the first 6 weeks after the diagnosis of COVID-19, the survival benefit of transplantation may offset this risk.
2. The optimal approach to transplantation of asymptomatic candidates who test positive for SARS-CoV-2 at the time of organ offer, particularly in the context of lung transplantation, remains unclear.
 - A [recently published case series](#) described experience transplanting 12 patients (7 kidney, 4 liver, 1 heart) with positive SARS-CoV-2 testing at the time of organ offer. Ten of 12 were asymptomatic and proceeded with transplant; 2 had mild symptoms and received 3 days of remdesivir prior to transplantation. All received standard induction immunosuppression, none developed complications of COVID-19, and patient and graft survival were 100% at a median follow up of 143 days.
 - [Another case series](#) described two successful lung transplant procedures performed on recipients with positive nasopharyngeal SARS-CoV-2 PCRs at the time of transplantation and unclear timing of infection onset. Ct values from both recipients were >30 (39.2 and 30.9, respectively), and neither was treated for SARS-CoV-2. Both received basiliximab and pulse steroids as induction immunosuppression and had favorable graft function at 3 months.
 - Infectious diseases experts can offer subject matter expertise regarding transplant candidacy and potential treatment of asymptomatic candidates testing positive for SARS-CoV-2 at the time of organ offer.

Themes

- COVID-19
- SARS-CoV-2 donor testing

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