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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 quarterly 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. If a donor date of onset of symptoms or symptoms are unknown, this person should not be considered asymptomatic.
- **Mild COVID-19:** Detection of SARS-CoV-2 in a respiratory sample in patients with symptoms consistent with COVID-19 infection who did not require oxygen supplementation or inpatient hospitalization for COVID-19.
- **Severe COVID-19:** Detection of SARS-CoV-2 in a respiratory sample in patients with symptoms consistent with COVID-19 infection who required oxygen supplementation or inpatient hospitalization for COVID-19.
- **Resolved COVID-19:** A donor with a history of confirmed COVID-19, with resolution of symptoms and more than 21 days from the date of onset of symptoms.

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 during the time period corresponding to the COVID-19 pandemic (from March 2020 to July 2022). 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 resolved or active COVID-19.

Discussion

Omicron Sublineages

The Omicron variant of concern is the dominant circulating SARS-CoV-2 variant globally and is comprised of several sublineages, including BA.4, and BA.5. BA.5 has become the dominant circulating SARS-CoV-2 variant in the United States. Data suggest that BA.4 and BA.5 exhibit higher transmissibility than the BA.2 sublineage, and reinfection with BA.4 or BA.5 following infection with another Omicron sublineage has been reported. Current molecular SARS-CoV-2 testing platforms do detect BA.4 and BA.5, and the FDA provides updated information about the impact of viral mutations on COVID-19 tests.

SARS-CoV-2 Deceased Donor Evaluation and Testing

1. OPOs and transplant teams should adhere to CDC Infection Prevention and Control Recommendations for Health Care 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 use a NIOSH-approved N95 or equivalent or higher-level respirator, gown, gloves, and eye protection.
    - The CDC recommends the use of eye protection and NIOSH-approved N95 or equivalent or higher-level respirator for the following procedures, even if SARS-CoV-2 infection is not suspected:
        - All aerosol-generating procedures, including extubation
        - All surgical procedures that may pose a higher risk for transmission if the patient were to have COVID-19, including those which could generate aerosols or involve the nose, throat, or respiratory tract
    - 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 pick up 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 but is suspected of having COVID-19, such as experiencing symptoms or have a high likelihood of infection due to exposure, follow-up molecular testing 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 the SARS-CoV-2 omicron variant.

3. 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.

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.
    - The CDC has investigated all potential donor derived COVID-19 events reported to DTAC. There have been three donor derived transmissions to lung recipients. In these events, the donor tested negative for SARS-CoV-2 in an URT specimen but retrospectively tested positive in a LRT specimen. Prospective testing of a LRT sample would have informed the lung programs and recipients of the risk of transmission.
    - 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 February 28, 2022, 93 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 United Kingdom National Health Service Blood and Transplant mandates testing for SARS-CoV-2 RNA in URT and LRT specimens in all potential deceased donors. As of January 2021, 987 deceased donors with negative upper and lower respiratory tract testing enabled 2469 transplants of which 75 were lung transplants. There was no evidence of donor derived COVID-19, suggesting that this strategy minimizes the risk of SARS-CoV-2 transmission to lung transplant recipients.
- 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.

5. The FDA has issued notification of potential false positive and false negative results associated with certain SARS-CoV-2 testing platforms. These notifications can inform selection of testing platforms in order to minimize the possibility of donor deferral due to false test results.

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. At this time 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. While evidence supports the use of chest computed tomography (CT) and chest x-ray in conjunction with other testing methods for SARS-CoV-2 infection, it does not currently support radiographic imaging as the sole diagnostic method for SARS-CoV-2 infection.
10. Available evidence supports an assessment for potential end-organ dysfunction if a donor has a history of COVID-19.
11. 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 with a Positive SARS-CoV-2 Test

1. Donors with <u>resolved COVID-19 and a positive SARS-CoV-2 NAT</u> test 21-90 days after the date of disease onset
   - These donors are unlikely to transmit infection. A positive SARS-CoV-2 NAT test likely represents non-viable virus.

- Evidence suggests the decision to recover organs in this case include the following:
    - The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
    - Current unknown long-term outcomes, including the possibility of thrombotic events, from donors with a history of resolved COVID-19 and allograft quality.
    - Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

2. Donors with a history of mild COVID-19 more than 10 and less than 21 days after the date of disease onset and resolution of symptoms
    - The safety of deceased donors in this scenario is unknown. It is believed that these donors are unlikely to transmit COVID-19 to non-lung recipients.
    - Evidence suggests the decision to recover organs in this case include the following:
        - The medical urgency of the candidate.
        - The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
        - Current unknown long-term outcomes, including the possibility of thrombotic events, from donors with a history of resolved COVID-19 and allograft quality.
        - Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

3. Donors with resolved COVID-19 and a positive SARS-CoV-2 NAT more than 90 days after the date of disease onset may reflect re-infection which may place the recipient at risk for disease transmission from these donors.
    - Acceptance of these donor non-lung organs should proceed with caution (as noted below in section donors who test positive for COVID-19).

4. Donors who test positive for COVID-19 and no known history of previous infection

- The CDC has investigated 3 cases of donor derived COVID-19 to 3 lung recipients. The six non-lung recipients did not develop clinical evidence of SARS-CoV-2 infection.
- The CDC has also identified lack of transmission from four donors with infection identified around the time of organ recovery. The six non-lung recipients did not develop clinical evidence of SARS-CoV-2 infection.
- Emerging evidence shows that non-lung organs are being recovered and transplanted from deceased donors who test positive for SARS-CoV-2 at the time of OPO evaluation. However, donor and recipient characteristics are variable, data regarding long-term outcomes are unknown
    - In a recent report, 10 kidneys were transplanted from 5 deceased donors who newly tested positive for SARS-CoV-2 by PCR within 3 days of donation. None of the donors had evidence of symptoms consistent with COVID-19 nor pulmonary infiltrates. There was no evidence of disease transmission or adverse allograft outcomes in 8-16 weeks of follow up.
    - A case report describes the use of two SARS-CoV-2 LRT NAT positive liver donors without a known history of COVID-19 infection with adequate short-term outcomes. The recipients did not have a prior history of COVID-19, nor did they receive antivirals or monoclonal antibodies post-transplantation; one was unvaccinated.
    - A case series describes the use of nine SARS-CoV-2 LRT NAT positive kidney donors. Seven of them without a history of COVID-19 infection had good short-term outcomes. The recipients did not receive antivirals or monoclonal antibodies post-transplantation; two of them were unvaccinated.
    - A case series describes the use of eleven SARS-CoV- NAT + donors for ten heart transplant recipients. Four of the donors tested positive for SARS-CoV-2 in a LRT sample by PCR. One heart-liver recipient of an URT NAT+ donor, developed severe intraoperative coagulability with massive hemorrhage and thrombosis requiring re-transplantation on day 6 post-transplant

with a SARS-CoV-2 LRT + donor. The other recipients had good short-term outcomes.

- Although the published data are encouraging, the safety of deceased donors in these scenario is unknown given the small sample size of the published studies. Organs from these donors should be considered for non-lung recipients only.
- Evidence suggests that the decision to recover organs from donors who test positive for COVID-19 with no known history of previous infection should include the following:
    - Unknown transmissibility of SARS-CoV-2 through non-lung organs.
    - The recipients' risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
    - Current unknown long-term outcomes, including the possibility of thrombotic events, from donors with active COVID-19 and allograft quality.
    - Risk of transmission to the OPO and recovery team, despite vaccination status.
    - Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

5. Analysis of the OPTN SARS-CoV-2 LRT Emergency Policy Monitoring Plan
    - Retrospective cohort study from May 27, 2021 to January 31, 2022 included 617 SARS-CoV-2 NAT+ donors had at least one organ recovered for 1241 recipients (776 kidney, 316 liver, 106 heart and 43 other)
    - Fifty-three of the fifty-seven OPO's offered organs from a SARS-CoV-2 NAT+ donor during the study period
    - In univariate analysis, there was no statistical difference, in patient survival and graft failure at 30-days stratified by SARS-CoV-2 NAT donor status.

6. Retrospective Cohort Studies Using the OPTN Dataset
    - A retrospective study from March 12, 2020 to August 31, 2021 included 284 SARS-CoV-2 NAT+ donors. There was no statistical difference in 6-month graft survival for kidney, liver and heart when stratified by SARS-CoV-2 NAT donor status.

Recovery of Organs from Deceased Donors with a History of Resolved COVID-19 and a Negative SARS-CoV-2 Test

1. Deceased donors in this scenario are unlikely to transmit infection. Evidence suggests the decision to recover and transplant organs in this case include the following:
    - The recipient risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
    - Current unknown long-term outcomes, including the possibility of thrombotic events, from donors with a history of resolved COVID-19 and the potential for changes in organ quality, in particular lungs.

Recovery of Organs from Deceased Donors with a Significant Exposure to COVID-19 and a Negative SARS-CoV-2 Test

1. The risk of SARS-CoV-2 transmission from deceased donors who test negative for SARS-CoV-2 but who have had a household contact who tested positive for COVID-19 in the last 10 days is unknown. There have been no reported cases of transmission from donors in this scenario to date.

SARS-CoV-2 Living Donor Testing and other precautions to minimize the risk of Donor-Derived COVID-19

1. CDC recommendations on infection control practices can help living donors reduce the risk of SARS-CoV-2 infection prior to donation and during recovery.

2. Self-quarantine during the 14 days prior to organ recovery could reduce the risk of SARS-CoV-2 infection for living donors and recipients.
3. Testing for SARS-CoV-2 with NAT in a respiratory sample as close to organ recovery as possible, but within 72 hours prior to recovery could reduce the risk of undetected infection.
4. 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 the SARS-CoV-2 omicron variant.

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

1. Evidence suggests the decision to recover and transplant organs from living donors with resolved COVID-19 include the following:
    - Consideration of emerging data showing the risk of peri-operative mortality is increased after COVID-19, with a gradual decrease in risk over time to baseline risk by 7 weeks after COVID-19.
    - Currently unknown long-term effects, including the possibility of thrombotic events, of COVID-19 infection for the living donor
    - Living donors with resolved COVID-19 are unlikely to transmit infection.
        - There is unclear evidence on the need for a negative SARS-CoV-2 NAT for living donors with a history of COVID-19 prior to donation within 90 days of disease onset. It is always important to follow local infection prevention and control policies.
        - Living Donors with resolved COVID-19 and a positive SARS-CoV-2 NAT more than 90 days after the date of disease onset may reflect reinfection.
    - The candidate risk of mortality or further complications while delaying transplantation and remaining on the waiting list.
    - The estimated risk of donor-derived COVID-19 transmission to the recipient

    - Currently unknown long-term outcomes, including the possibility of thrombotic events, of recipients of organs from living donors with resolved COVID-19
2. Infectious diseases experts can offer subject matter expertise when accepting organs from these donors.

Timing of Transplant for Recipients with a History of COVID-19

Although emerging data shows 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.

Themes

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

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