OPTN

Notice of OPTN Emergency Policy Change

Lower Respiratory SARS-CoV-2 Testing for Lung Donors

Sponsoring Committee:	**Ad Hoc Disease Transmission Advisory**
Policies Affected:	***1.2: Definitions***
	2.9: Required Deceased Donor Infectious Disease Testing
Public Comment:	**August 3, 2021-September 30, 2021**
Board Approved:	**April 26, 2021 (emergency policy)**
	December 6, 2021 (policy made permanent)
Effective Date:	**May 27, 2021**

Summary of Changes

This policy defines lower respiratory specimen, requires all lung donors to receive lower respiratory specimen testing by nucleic acid test (NAT), and specifies that testing results must be available pre-transplant of lungs. Originally enacted as an emergency action effective May 27, 2021, the Board of Directors has adopted this policy as permanent and therefore it will not expire at one year post implementation.

Purpose of Policy Change

The Board voted to make the policy permanent so that the policy would not expire in 2022 and leave lung recipients more vulnerable to donor-derived SARS-CoV-2 transmission. It is important to continue to protect lung recipients through the required donor testing, given the ongoing threat of the COVID-19 pandemic. The policy has been successful in achieving patient safety with no donor-derived transmissions to lung recipients of SARS-CoV-2 having occurred since implementation. Prior to the policy, there were three cases of donor-derived transmission to lung recipients in which the donor tested negative by upper respiratory specimen but positive by lower respiratory specimen. The OPTN will continue to monitor the effects of the policy with trends in the COVID-19 pandemic and modify the policy if necessary.

Proposal History

The OPTN ad hoc Disease Transmission Advisory Committee (DTAC) first considered proposing emergency policy to be necessary after accumulating evidence in the first quarter 2021 of cases in which lung donors tested negative for SARS-CoV-2 by upper respiratory specimen and later tested positive by lower respiratory specimen. The DTAC reached out to OPTN stakeholder committees (OPO and Lung) and incorporated their feedback in a proposed solution to require lower respiratory testing on all lung donors.

On April 26, 2021, the Executive Committee unanimously approved policy language to require SARS-CoV-2 lower respiratory testing for all lung donors with results available pre-transplant of lungs.

The emergency policy went out for retrospective public comment in August 2021. Feedback was solicited whether the policy should extend beyond the one-year time period or whether it should expire. Several members indicated support for extending the applicability of the policy beyond one year, and no members expressed opposition to the policy being made permanent. The policy was widely supported across member type and regionally; it was placed on the consent agenda for the Board's review at their December 2021 meeting. The DTAC recommended the Board make the policy permanent and the Board concurred with the recommendation given the ongoing threat of the COVID-19 pandemic to an already vulnerable population.

Implementation

The policy is already implemented. Evaluation of the effect of the policy has occurred at one month intervals for the first six months post-implementation. The DTAC and Board will continue to review post-implementation data to consider if conditions warrant modification of policy.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~). Policy made permanent is in italics (*example*).

1.2 Definitions

Lower respiratory specimen

A sample taken from the respiratory system within the trachea or below. Sputum, tracheal aspirate, bronchial suction, bronchial wash, bronchoalveolar lavage (BAL), and lung biopsy are considered lower respiratory specimens.

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
   a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
   b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   c. Hepatitis B surface antigen (HBsAg) donor screening test
   d. Hepatitis B core antibody (total anti-HBc) donor screening test
   e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
   f. Hepatitis C antibody donor screening test (anti-HCV)
   g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
   i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
   j. Syphilis donor screening *or* diagnostic test
   k. Toxoplasma Immunoglobulin G (IgG) antibody test

   Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.
3. *Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)*

   Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.

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