

*Retrospective Public Comment for Emergency Policy*

# **Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors**

*OPTN Ad Hoc Disease Transmission Advisory Committee*

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## *Retrospective Public Comment for Emergency Policy*

# Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors

<i>Affected Policies:</i>	<i>1.2: Definitions</i> <i>2.9: Required Deceased Donor Infectious Disease Testing</i>
<i>Sponsoring Committee:</i>	<i>Ad Hoc Disease Transmission Advisory</i>
<i>Executive Committee Date:</i>	<i>April 26, 2021</i>
<i>Public Comment Date:</i>	<i>August 3, 2021 – September 30, 2021</i>

## Executive Summary

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) reviews potential donor-derived transmission events reported to the OPTN in an effort to confirm transmission where possible. The aggregated information has the goal of educating the transplant community towards preventing future disease transmission and guides policy development to improve the safety of organ donation through the reduction of donor-derived transmission events.<sup>1</sup> Over a three-month period, the DTAC received notice of four cases in which deceased lung donors tested negative for SARS-CoV-2 (COVID-19) by upper respiratory specimen then retrospectively tested positive by lower respiratory specimen. Three cases resulted in donor-derived transmission to lung recipients while one resulted in a “near miss” after the lungs were tested pre-transplant and ultimately discarded. One lung recipient died as a result of the donor-derived transmission.

The DTAC unanimously supported emergency policy requiring lower respiratory testing for all lung donors to address the significant patient safety implications of donor-derived COVID-19 and the subsequent risk of patient mortality. Prior to implementation, OPTN data indicated that 75% of lung donors were tested by lower respiratory specimen while a quarter of lungs still were not; testing of lower respiratory specimens increased from 30% to 75% from January to April 2021.<sup>2</sup> The Executive Committee considered the DTAC’s proposal and approved policy and an updated Summary of Current Evidence on April 26, 2021 to require lower respiratory testing by nucleic acid test (NAT) for SARS-CoV-2 for all lung donors prior to transplant. The policy was implemented on May 27, 2021.

In accordance with the OPTN Final Rule and OPTN *Bylaw 11.7: Emergency Actions*, this emergency policy is being submitted for retrospective public comment prior to OPTN Board of Directors review in December 2021.<sup>3</sup> The Board will determine in its December 2021 review whether the emergency policy should be made permanent or expire one year from implementation. The DTAC will provide a

<sup>1</sup> OPTN Ad Hoc Disease Transmission Advisory Committee Charge. Available at <https://optn.transplant.hrsa.gov/members/committees/disease-transmission-advisory-committee/>.

<sup>2</sup> “Final Report: Descriptive Data Request. Recipient Outcomes of Donors who Tested Positive for COVID-19 and COVID-19 Testing Type for Lung Donors.” Prepared by Laura Cartwright and Sarah Booker. OPTN DTAC: January 25, 2021 (updated March, April, May, June 2021).

<sup>3</sup> 42 C.F.R. §121.4(b)(1)

OPTN Bylaws 11.7: Emergency Actions. Available at [https://optn.transplant.hrsa.gov/media/1201/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf) (Accessed May 24, 2021)

recommendation to the Board on the permanence of the policy post-public comment, to reflect DTAC consideration of public comment feedback as well as the accumulating post-implementation monitoring data. This proposal aligns with the OPTN strategic goal to promote living donor and transplant recipient safety by requiring lower respiratory testing on all deceased lung donors to minimize the risk of donor-derived COVID-19 disease transmission to lung recipients.

## Background

The DTAC helps the OPTN identify patient safety risks by assessing cases of potential disease transmission through organ transplantation.<sup>4</sup> The committee works closely with members from the Centers for Disease Control and Prevention (CDC) to assess whether certain disease transmissions are donor-derived through transplantation. The CDC reviews COVID-19 cases reported to the OPTN and provides recommended adjudications to the DTAC, which reviews and discusses the CDC recommendation before providing a final adjudication on the likelihood of donor-derived transmission and the severity of the impact on the recipient.

## Patient Safety Risk

Over a three-month period from December 2020 through February 2021, there were four cases identified by report to the OPTN or medical literature publication in which a deceased lung donor initially tested negative for SARS-CoV-2 by upper respiratory specimen sample then retrospectively tested positive by lower respiratory specimen sample. A lower respiratory specimen is a sample obtained within or below the trachea, and examples include bronchoalveolar lavage (BAL), tracheal aspirate and bronchial wash.

One of the four cases had genetic testing that led to a final adjudication as “proven” (a DTAC term for a case that is shown to be a donor-derived transmission); the transmission resulted in death of the lung recipient. Another case was adjudicated as “probable” (an adjudication indicating a high degree of likely donor-derived transmission but less replete evidence than “proven”) and the resulting severity as “severe.” The third case is currently being adjudicated and considered “probable” but may become “proven” once genetic testing is complete. In these cases, other organs were transplanted as well and were either excluded from being cases of COVID-19 donor-derived transmission or there is no current evidence these recipients acquired COVID-19, highlighting that lung recipients are particularly vulnerable. In a fourth case, a “near miss” happened when the lung transplant program took it upon itself to test a lower respiratory specimen from donor lungs even though the lungs had negative upper respiratory test results – the lower respiratory test came back positive and the lungs were not transplanted. If not for the vigilance of the lung program there could have been four transmissions in a three-month period of COVID-19 into a vulnerable immunocompromised patient population with severe risk of mortality with COVID-19, even compared to other organ transplant recipients.<sup>5</sup>

There is additional evidence that detection of SARS-CoV-2 can be missed when only upper respiratory tests are used and that lower respiratory tract samples test positive for the virus more often than other specimens.<sup>6</sup> Within the general population, lung and heart comorbidities indicate severe risk factors for

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<sup>4</sup> OPTN Ad Hoc Disease Transmission Advisory Committee Charge. Available at <https://optn.transplant.hrsa.gov/members/committees/disease-transmission-advisory-committee/>

<sup>5</sup> Lara Danziger-Isakov et al., “Impact of COVID-19 in solid organ transplant recipients,” *American Journal of Transplantation* 21, no. 3, (December 14, 2020): 925-937, <https://doi.org/10.1111/ajt.16449>

<sup>6</sup> Kathleen J Ramos et al., “Detection of SARS-CoV-2 by bronchoscopy after negative nasopharyngeal testing: Stay vigilant for COVID-19,” *Respiratory medicine case reports* 30, (October 11, 2020). <https://doi.org/10.1016/j.rmcr.2020.101120>

Wenling Wang et al., “Detection of SARS-CoV-2 in Different Types of Clinical Specimens,” *JAMA* 323, no. 18 (2020): 1843–1844,

mortality with COVID-19.<sup>7</sup> There is evidence that COVID-19 attacks the lungs, which would explain why the viral shed lasts longer in that part of the body and could contribute to particular risk of donor-derived transmission for lung recipients.<sup>8</sup> Recognition of the need for lower respiratory testing is reflected in the current guidelines of the International Society for Heart and Lung Transplantation (ISHLT), updated April 2021, which strongly recommends obtaining lower respiratory tract for all lung donors.<sup>9</sup> It is also important to note that some potential lung recipients at risk from a patient safety perspective have already suffered from COVID-19 and are listed for transplant precisely because of the damage that COVID-19 incurred in their lungs.<sup>10</sup>

Available evidence indicates higher risk of COVID transmission to lung recipients and the higher risk of mortality for lung recipients if transmission occurs compared to other organ recipients. While the evidence is compelling to require lower respiratory testing for all lung donors, there is less data accumulated to demonstrate a sufficient risk to non-lung recipients. In two of the three cases of proven/probable COVID-19 disease transmission to lung recipients, both kidneys and the livers were transplanted but no transmission occurred in these recipients. The risk of transmission must also be weighed against the potential for unintended consequences with any donor intervention, and any broadening of the testing requirement would need to be grounded in sufficient evidence which is currently lacking for non-lung donors.

## Consideration of Emergency Policy

The DTAC previously emphasized the risk of potential transmission of donor-derived COVID-19 through deceased donor lungs in a **Summary of Current Evidence and Information- Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19** document for the community.<sup>11</sup> In January 2021 when only one case of potential transmission was known, the DTAC considered that there was insufficient evidence to warrant a requirement for lower respiratory testing for all lung donors, but that the Summary of Evidence would help the community weigh relevant, current data in considerations of COVID-19 and potential donor transmission.<sup>12</sup> The Summary of Evidence was approved by the Executive Committee on February 8, 2021 by unanimous email vote.

By March 2021, the DTAC agreed that accumulating evidence in the form of two additional probable transmissions and one “near miss” demonstrated a need to consider policy to require lower respiratory testing for all lung donors. The DTAC reviewed aggregate data presented by the CDC at their March 19, 2021 open session meeting; participants in the meeting agreed the DTAC should consider policy as an option.<sup>13</sup> Given the growing number of donor-derived transmissions and the safety implications for lung

doi:10.1001/jama.2020.3786

<sup>7</sup> “People with Certain Medical Conditions,” *Centers for Disease Control and Prevention*. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html> (Accessed April 16, 2021).

<sup>8</sup> Lara Danziger-Isakov et al., “Impact of COVID-19 in solid organ transplant recipients,” *American Journal of Transplantation* 21, no. 3, (December 14, 2020): 925-937, <https://doi.org/10.1111/ajt.16449>

<sup>9</sup> “Deceased donor and recipient selection for cardiothoracic transplantation during the COVID-19 pandemic: Recommendations from the ISHLT COVID-19 Task Force”, April 12, 2021. [https://ishlt.org/ishlt/media/documents/COVID-19\\_GuidanceDocument\\_Deceased-donor-and-recipient-selection-for-cardiothoracic-transplantation.pdf](https://ishlt.org/ishlt/media/documents/COVID-19_GuidanceDocument_Deceased-donor-and-recipient-selection-for-cardiothoracic-transplantation.pdf) Accessed on June 24, 2021.

<sup>10</sup> JoNel Aleccia, “Covid Spawns ‘Completely New Category’ of Organ Transplants,” KHN (April 13, 2021). <https://khn.org/news/article/covid-spawns-new-category-of-organ-transplants/> (Accessed April 16, 2021)

<sup>11</sup> OPTN ad hoc Disease Transmission Advisory Committee, “Summary of Current Evidence and Information- Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19,” Available at <https://optn.transplant.hrsa.gov/media/4424/sars-cov-2-summary-of-evidence.pdf> (June 27, 2021)

<sup>12</sup> OPTN DTAC meeting summary, January 25, 2021. Available at [https://optn.transplant.hrsa.gov/media/4432/20210125\\_dtac\\_meeting\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4432/20210125_dtac_meeting_summary.pdf)

<sup>13</sup> OPTN DTAC meeting summary, March 19, 2021. Available at

recipients in light of the ongoing COVID-19 pandemic, DTAC agreed an emergent policy pathway was warranted to ensure expedient implementation and to minimize risk for a vulnerable patient population.

## Gap in Lower Respiratory Testing: Lung Utilization

During development of the emergency policy and after implementation, the DTAC regularly reviewed the percent of lung donors receiving lower and upper respiratory testing to identify whether OPOs were testing lungs by lower respiratory test.<sup>14</sup> Figure 1 shows the percent of lung donors receiving lower and upper respiratory testing by week as of June 28, 2021. It is important to note that COVID-19 testing was performed on all donors; Figure 1 highlights the gap in lower respiratory testing in particular.

**Figure 1: Percent of Lung Donors Receiving Lower and Upper Respiratory Testing by Week (as of June 28, 2021)**

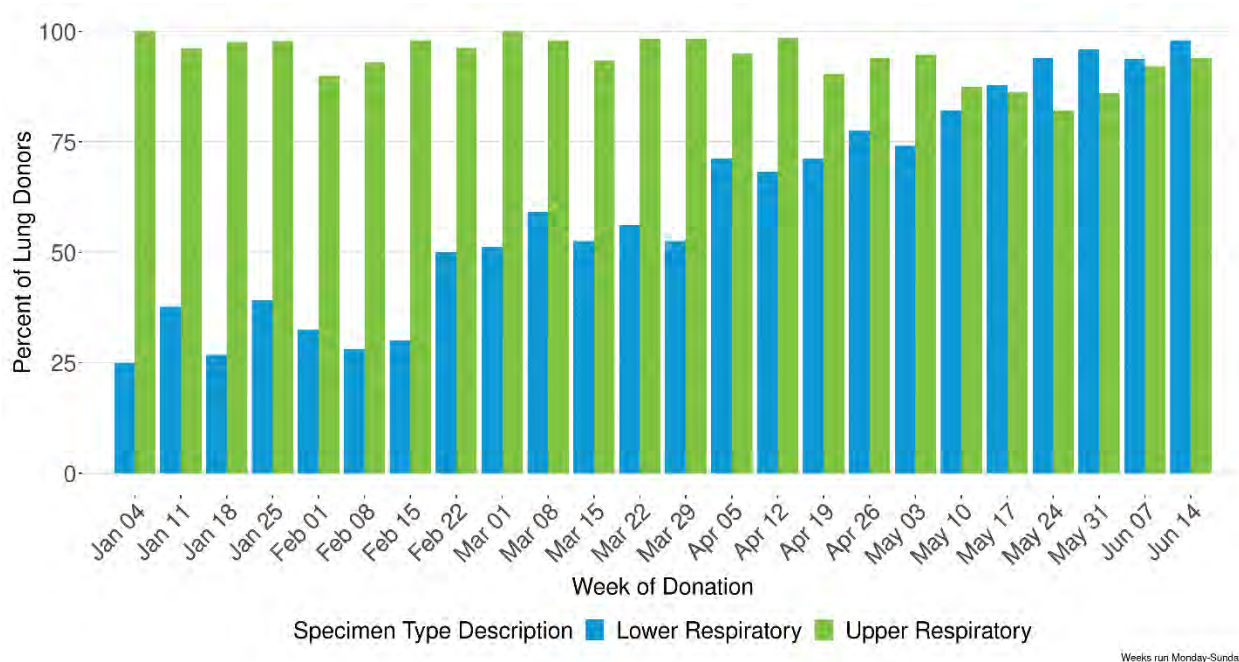


Figure 1 shows an increase in lower respiratory testing as evidence accumulated of the potential transmission of COVID-19 through lung transplantation. Prior to their vote to send the proposal for Executive Committee approval, the DTAC reviewed data showing 60% of lungs received lower respiratory testing for the week of March 29, 2021. While 60% represents an increase in lower respiratory testing for lung donors (only 30% were tested as of January 2021), the data indicated that 40% of potential deceased lung donors were not receiving lower respiratory testing. The DTAC considered that the data could indicate underutilization of lungs as programs turn down lungs without lower respiratory testing, a concern expressed by the Lung Committee in response to DTAC solicitation of feedback on potential emergency policy.<sup>15</sup> The Lung Committee provided feedback that utilization could be negatively impacted if policy were *not* implemented because lung programs would not accept

[https://optn.transplant.hrsa.gov/media/4571/2021\\_03\\_19\\_dtac-full-mtg-summary.pdf](https://optn.transplant.hrsa.gov/media/4571/2021_03_19_dtac-full-mtg-summary.pdf)

<sup>14</sup> OPTN DTAC meeting summaries: March 19, 2021; April 6, 2021; May 24, 2021. Available at

<https://optn.transplant.hrsa.gov/members/committees/disease-transmission-advisory-committee/>

<sup>15</sup> OPTN Lung Committee meeting summary, April 1, 2021. [https://optn.transplant.hrsa.gov/media/4582/20210401\\_lung-meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/4582/20210401_lung-meeting-summary.pdf)

lungs without lower respiratory testing. The Lung Committee was fully supportive of an emergency policy to require lower respiratory testing in all lung donors.<sup>16</sup>

DTAC members also considered this data highlighted the need for policy to ensure OPOs use lower respiratory specimen testing for all lung donors, given that some OPOs are still not performing this testing. The DTAC reviewed updated data on May 24, which showed an increase to 75% of OPOs performing lower respiratory testing on lung donors.<sup>17</sup> This also demonstrates, however, that prior to implementation of the lung emergency policy on May 27, 2021 that a quarter of lungs were still not being tested by lower respiratory specimen and could be a source of disease transmission. This gap disappeared after implementation of the emergency policy, with lower respiratory testing performed on all lung donors post-implementation (while percentage shows slightly less than 100%, this is only because a few OPOs entered information in text fields instead of the discrete fields from which both figures are derived; lower respiratory testing was still performed for 100% of lung donors).

## Coordination with Summary of Evidence, Updated 4/26/2021

In accordance with policy changes, the DTAC reviewed changes to the COVID-19 Summary of Evidence document to ensure it was up to date and reflective of the accumulating evidence; both the updated Summary of Evidence and the policy change were approved by the OPTN Executive Committee on their April 26, 2021 teleconference call.<sup>18</sup> The Summary of Evidence serves to provide the community with risk assessment of transplantation in the era of COVID-19, and its review of potential risk reflects the concern for lung recipients that led to developing policy. The Summary of Evidence document and policy change are thus complimentary solutions to the problem of potential COVID-19 donor-derived transmission impacting lung recipient safety.

## Purpose

The purpose of this policy is to address the patient safety risk of donor-derived COVID-19 transmission in lung recipients by ensuring lower respiratory testing is performed on all lung donors, with results available pre-transplant. Accumulating evidence of lung recipient safety risk when deceased donors are not tested by lower respiratory sample led the DTAC to agree that emergency policy was necessary.

The policy will expire a year from implementation on May 27, 2021 unless the Board of Directors establishes the policy as permanent, a decision that will be made at the December 2021 Board of Directors meeting after this policy is distributed for retrospective public comment. The DTAC will consider post-implementation data and public comment feedback in providing a recommendation to the Board of Directors regarding the potential permanence of the emergency policy. The DTAC appreciates any feedback from the public, especially lung programs and OPOs, regarding the potential for this policy to be permanent.

<sup>16</sup> Ibid.

<sup>17</sup> "Final Report: Descriptive Data Request. Recipient Outcomes of Donors who Tested Positive for COVID-19 and COVID-19 Testing Type for Lung Donors." Prepared by Laura Cartwright and Sarah Booker. OPTN DTAC: January 25, 2021 (updated March, April, May, June 2021).

<sup>18</sup> OPTN DTAC meeting summary, April 6, 2021. Available at [https://optn.transplant.hrsa.gov/media/4593/2021\\_04\\_06\\_dtac-full-cmte-mtg-summary.pdf](https://optn.transplant.hrsa.gov/media/4593/2021_04_06_dtac-full-cmte-mtg-summary.pdf)

OPTN Executive Committee meeting summary, April 26, 2021. Available at [https://optn.transplant.hrsa.gov/media/4665/20210426\\_executive\\_committee\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4665/20210426_executive_committee_summary.pdf)  
OPTN DTAC Emergency Proposal, Lower Respiratory SARS-CoV-2 Testing for Lung Donors. Available at <https://optn.transplant.hrsa.gov/media/4561/lower-respiratory-sars-cov-2-testing-for-lung-donors.pdf>

## Overview of Proposal

The policy approved by the Executive Committee requires lower respiratory testing by NAT for all lung donors, with results available prior to lung transplant.<sup>19</sup> The policy is currently effective, in accordance with OPTN *Bylaw 11.7: Emergency Actions*, as “required due to an emergency public health issue or patient safety factors.”<sup>20</sup> The DTAC worked with OPTN Lung and OPO Committees and solicited additional feedback from OPO members on other OPTN committees to ensure the proposed policy change appropriately addresses the patient safety risk while providing enough flexibility operationally for OPOs to effectively implement the change and avoid unintended consequences with lung underutilization.

## OPO Operational Considerations

Prior to presenting the proposal to the Executive Committee, the DTAC elicited feedback from members on various OPTN committees who collectively represented perspectives from 27 different OPOs about the operational considerations related to requiring lower respiratory testing.<sup>21</sup> Feedback highlighted how OPOs were increasingly able to obtain lower respiratory testing in a timely manner as relationships strengthened with labs, knowledge increased and as OPOs received more requests for lower respiratory testing from lung programs following an article in the *American Journal of Transplantation* on the proven transmission of COVID-19 in a lung recipient.<sup>22</sup> Feedback also identified potential challenges with donation after cardiac death (DCD) lung transplantation and the turnaround time for lower respiratory tests results, particularly for obtaining BALs, a specific type of lower respiratory specimen.

DTAC leadership requested additional feedback from the OPO Committee to further understand operational concerns. The OPO Committee indicated support for an emergency policy change in response to the proven transmission and the increasing ability of OPOs to obtain lower respiratory testing in a timely manner.<sup>23</sup> While earlier in the pandemic obtaining these tests was more difficult, relationship building and education resulted in an increasing number of OPOs being able to obtain tests within a reasonable turnaround time, including for DCD donors. The OPO Committee stipulated in their support that the policy should not require test results prior to organ offer or require a specific lower respiratory specimen type, discussed below.

### *Timing of Test Results*

In consideration of when lower respiratory tests should be available to lung transplant programs, the DTAC sought a balance between minimizing a negative impact on lung utilization and organ offer efficiency with ensuring patient safety concerns are addressed. The OPO Committee indicated that requiring test results prior to organ offers could lead to organ discard. Requiring results prior to procurement or transplant would minimize unintended consequences (organ offer delay and potential

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<sup>19</sup> Notice of OPTN Emergency Policy Change: Lower Respiratory SARS-CoV-2 Testing for Lung Donors. OPTN ad hoc Disease Transmission Advisory Committee. Available at

[https://optn.transplant.hrsa.gov/media/4576/policy\\_notice\\_lunglowerrespiratorytesting\\_20210426.pdf](https://optn.transplant.hrsa.gov/media/4576/policy_notice_lunglowerrespiratorytesting_20210426.pdf)

<sup>20</sup> OPTN Bylaws, 11.7: Emergency Actions. [https://optn.transplant.hrsa.gov/media/1201/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf) (Accessed April 16, 2021)

<sup>21</sup> OPTN DTAC meeting summary, March 19, 2021. Available at

[https://optn.transplant.hrsa.gov/media/4571/2021\\_03\\_19\\_dtac-full-mtg-summary.pdf](https://optn.transplant.hrsa.gov/media/4571/2021_03_19_dtac-full-mtg-summary.pdf)

<sup>22</sup> Daniel R. Kaul et al., “Donor to recipient transmission of SARS-CoV-2 by lung transplantation despite negative donor upper respiratory tract testing,” *American Journal of Transplantation* (February 10, 2021), <https://doi.org/10.1111/ajt.16532>

<sup>23</sup> OPTN OPO Committee summary, March 31, 2021. Available at [https://optn.transplant.hrsa.gov/media/4544/20210331\\_opo-committee\\_-meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/4544/20210331_opo-committee_-meeting-summary.pdf)

lung discard). Specifically, requiring results pre-procurement or pre-transplant rather than pre-organ offer allows OPOs to make offers and send electronic notifications to transplant programs while test results are pending, which is more conducive to an efficient organ allocation process that avoids unintentional lung discard due to organ offer delay. OPO feedback indicated more time would minimize the likelihood of lung discard. The Lung Committee stipulated that results should be available prior to transplant to ensure programs comprehensively evaluate the risk of donor-derived COVID-19 to the potential recipient.<sup>24</sup>

In reflection of the feedback from stakeholder committees, the DTAC reviewed three options for when test results should be available: 1) pre-organ offer, 2) pre-procurement, or 3) pre-transplant. The first option of requiring pre-organ offer results could have a negative unintended consequence on lung utilization by delaying organ offers and the organ allocation process generally. The second and third options would both provide more time to OPOs in obtaining results. The DTAC considered potential staff exposure to COVID-19 that could occur during procurement in its recommendation to the Executive Committee that the policy require results be available pre-procurement. In one of the donor-derived COVID-19 transmissions through lung, a transplanting surgeon also became ill with COVID-19.<sup>25</sup> If exposed to COVID-19 through the procurement process, transplant program staff could expose patients with whom they interact. However, several members of the Executive Committee expressed concern that requiring the results of the lower respiratory test to be back pre-procurement could impede lung utilization of DCD and other donors, and the potential impact on utilization was more significant than the potential risk associated with requiring the tests to be available pre-transplant versus pre-procurement.<sup>26</sup> This concern was in line with general OPO feedback regarding the need for additional time in processing tests for certain type of donors including DCDs. The Executive Committee therefore approved a modified version of the policy language submitted by the DTAC, changing the test availability requirement to be pre-transplant of lungs rather than pre-procurement.

The implemented policy did not change electronic notifications in UNet<sup>SM</sup>; notifications can be sent out by the OPO regardless of the lower respiratory testing status. Current programming still requires OPOs indicate whether COVID-19 testing has occurred, per previously Board-approved COVID-19 policy changes.<sup>27</sup>

### *DCD Procurement*

While some feedback from OPO members expressed concern about obtaining lower respiratory samples for DCD donors, the OPO Committee provided feedback that increased cooperation with donor hospitals indicated DCD lungs could still be procured and meet the potential requirement of lower respiratory testing. As long as any lower respiratory specimen type is acceptable, the OPO Committee considered that DCD lungs can still be safely procured and allocated in accordance with policy requiring lower respiratory testing with results available pre-procurement or pre-transplant.<sup>28</sup> Ultimately the DTAC agreed the significant patient safety risk warranted the policy requirement while still providing flexibility for OPOs in allowing all lower respiratory specimen types (including BAL, tracheal aspirate, bronchial wash) and by requiring results be available pre-procurement rather than pre-organ offer. The Executive

<sup>24</sup> OPTN Lung Committee summary, April 1, 2021.

<sup>25</sup> Daniel R. Kaul et al., "Donor to recipient transmission of SARS-CoV-2 by lung transplantation despite negative donor upper respiratory tract testing," *American Journal of Transplantation* (February 10, 2021), <https://doi.org/10.1111/ajt.16532>

<sup>26</sup> Executive Committee Meeting Minutes, April 26, 2021.

<sup>27</sup> "COVID-19 Emergency Policy Package," OPTN (December 2020).

[https://optn.transplant.hrsa.gov/media/4242/covid\\_19\\_er\\_policy-notice-december-2020.pdf](https://optn.transplant.hrsa.gov/media/4242/covid_19_er_policy-notice-december-2020.pdf) (Accessed April 16, 2021)

<sup>28</sup> OPTN OPO Committee meeting summary, March 31, 2021.



Committee change to require tests be available pre-transplant rather than pre-procurement also supported additional flexibility for OPOs with DCD or other donor procurement.

### *Lower Respiratory Specimen Type*

The DTAC discussed whether potential policy should require only specific lower respiratory tests (e.g. BALs) but agreed that doing so would be too prescriptive and inflexible for OPOs. Instead, providing flexibility in the type of lower respiratory test may avoid underutilization of lungs since OPOs that have difficulty obtaining BALs in a timely manner could comply with policy by performing other lower respiratory tests, such as tracheal aspirates. This is consistent with feedback from the OPO Committee and OPO members on other OPTN committees that requiring BALs specifically could be more challenging.

## **NOTA and Final Rule Analysis**

The DTAC submits this proposal under the authority of the National Organ Transplantation Act (NOTA), which states that the OPTN shall "adopt and use standards of quality for the acquisition and transportation of donated organs."<sup>29</sup> Lower respiratory testing is needed to ensure organ quality for the acquisition of donated lungs by avoiding acquisition of deceased donor lungs with active SARS-CoV-2 infection.

This proposal is also authorized by the OPTN Final Rule, which states that the OPTN "shall be responsible for developing... [p]olicies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases."<sup>30</sup> Requiring the testing of lung organ donors for SARS-CoV-2 will help prevent the spread of the infectious disease, COVID-19. The CDC has not published a recommendation regarding this testing to date.

### **Projected Fiscal Impact**

This policy is projected to have a fiscal impact on the OPTN and organ procurement organizations, but it is not anticipated to have any fiscal impact on transplant hospitals or histocompatibility laboratories.

#### *Projected Impact on the OPTN*

This policy does not require IT programming, but resources will be required for post-implementation monitoring and compliance.

#### *Projected Impact on Organ Procurement Organizations*

This policy required OPOs to cover costs for lower respiratory testing, update contracts with laboratories and train staff to obtain samples. Anticipated workflow impacts included delayed submission of other tests, and additional time to obtain results during or following organ recovery to ensure results are returned prior to transplant. It was not anticipated that this policy will require additional staff or extended hours. Implementation time was one month. The risk of not implementing this policy was potential transmission of disease to transplant recipients.

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<sup>29</sup> 42 USC §274(b)(2)(E)

<sup>30</sup> 42 C.F.R. §121.11(a)(2)

## Post-Implementation Monitoring

### Member Compliance

Member Quality staff review lung donor testing data reported in DonorNet® to verify that OPOs are testing all deceased lung donors for SARS-CoV-2 by nucleic acid test performed on a lower respiratory specimen.

### Policy Evaluation

Because this policy is emergent it will be evaluated monthly following implementation for 6 months and then again at 1-year post-implementation.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the policy after implementation:

- Has the utilization rate of lungs changed following the implementation of this policy?
- Has the utilization of heart, kidney, liver, or pancreas changed following implementation of this policy?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available and compared to an appropriate pre-implementation cohort.

- The number (and percent) of lung donors with no lower respiratory specimen testing reported each month post-implementation, overall and for DCD vs brain death donors
- Timing of lower respiratory test result reporting relative to lung transplant
- The number (and percent) of OPOs with recovered lung donors with no lower respiratory testing post-implementation
- Lung utilization rates by month, overall and for DCD vs brain death donors
- Heart utilization rates by month
- Kidney, liver, and pancreas discard rates by month
- Number and type of organs recovered/transplanted from donors with a positive SARS-CoV-2 lower respiratory test
- Number of donors with discordant lower vs upper respiratory SARS-CoV-2 test results

## Conclusion

This policy change addressed an emergent patient safety issue that required an expedited timeline to prevent future donor-derived COVID-19 transmission to lung recipients by requiring lower respiratory testing on all lung donors with results available pre-transplant. As per OPTN *Bylaw 11.7: Emergency Actions*, this proposal is being distributed for retrospective public comment, and the OPTN Board of Directors will review the policy in December 2021 to determine whether the policy should expire or be made permanent.

## Policy Language

Policy language changes approved by the Executive Committee on April 26, 2021 are underlined (example) and language that was removed is struck through (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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