

Briefing to the OPTN Board of Directors on

Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors Emergency Policy

OPTN Ad Hoc Disease Transmission Advisory Committee

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Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors Emergency Policy

<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>Public Comment Period:</i>	<i>August 3, 2021 – September 30, 2021</i>
<i>Board of Directors Meeting:</i>	<i>December 6, 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.¹ 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. While the proportion of lung donors tested by lower respiratory specimen increased from 30% to 75% from January to April of 2021, one quarter of lung donors were still not being tested by lower respiratory specimen prior to implementation of the emergency policy.² 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.³ The policy was implemented on May 27, 2021.⁴

In accordance with the OPTN Final Rule⁵ and OPTN *Bylaw 11.7: Emergency Actions*, this emergency policy was submitted for retrospective public comment from August 3 to September 30, 2021. Based on

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

² “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).

³ OPTN Board of Directors Executive Committee Meeting Summary, April 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4665/20210426_executive_committee_summary.pdf

⁴ 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

⁵ 42 C.F.R. §121.4(b)(1)

the public comment feedback and accumulating post-implementation monitoring data, the DTAC recommends to the Board that the policy be made permanent so that it does not automatically expire upon one year of implementation (which would be May 27, 2022). The DTAC recommendation stems from the continued risk to lung recipients of donor derived transmission from the COVID-19 pandemic, and from the success of the emergency policy in preventing further transmissions. The DTAC will continue to review monitoring data and provide additional recommendations to the Executive Committee if the pandemic subsides to the point where the required testing is no longer necessary to protect lung recipients. The DTAC will continue regular monitoring and may provide a future recommendation to the Board of Directors to repeal the policy if the pandemic subsides to the point the policy is no longer needed. This change to remove the “emergency” status of the policy 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.

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

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 Executive Committee to pass emergency policy recommended by the DTAC.

Unless the Board of Directors (Board) takes action to make the policy permanent, the current policy will expire one year from its implementation date of May 27, 2021, which would set a date of expiration of May 27, 2022. The DTAC considered post-implementation data and public comment feedback and recommends the Board of Directors make the emergency policy permanent to continue to protect lung recipients from the risk of donor derived COVID-19 transmission. The importance of protecting lung recipients and the ongoing threat of COVID-19 indicate that the policy should not expire upon one year of implementation but be made permanent to avoid a situation in which lung recipients may derive COVID-19 due to the lack of policy requiring lower respiratory testing. The DTAC will continue to monitor data and make recommendations to the Board if evidence suggests the policy is no longer needed for patient safety.

Background

The DTAC helps the OPTN identify patient safety risks by assessing cases of potential disease transmission through organ transplantation.⁶ 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.

Two 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); one of the transmissions 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”) with a severe outcome (possible severity classifications to indicate the impact on the recipient of the potential transmission include non-severe, severe and death). In these cases, other organs were transplanted as well and were either excluded from being cases of COVID-19 donor-derived transmission or no evidence emerged in

⁶ OPTN Ad Hoc Disease Transmission Advisory Committee Charge. Available at <https://optn.transplant.hrsa.gov/members/committees/disease-transmission-advisory-committee/>.

the six+ months that 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.⁷

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.⁸ Within the general population, lung and heart comorbidities indicate severe risk factors for mortality with COVID-19.⁹ There have been 247 COVID-19 related lung waiting list additions and 191 COVID-19 related lung transplants to date (as of October 15, 2021).¹⁰ 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.¹¹ 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.¹² 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.¹³

Coordination with Summary of Evidence, Updated 9/22/2021

The DTAC developed the SARS-CoV-2 Summary of Evidence in a Workgroup with representation from the American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), Health Resources & Services Administrations (HRSA) and the Centers for Disease Control and Prevention (CDC).¹⁴ 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

⁷ 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>

⁸ 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, doi:10.1001/jama.2020.3786

⁹ “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).

¹⁰ 2021 OPTN Data. Available at <https://optn.transplant.hrsa.gov/data/> (Accessed October 15, 2021)

¹¹ 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>

¹² “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

¹³ 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)

¹⁴ 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> (October 11, 2021)

COVID-19 donor-derived transmission impacting lung recipient safety. The DTAC has continued to collaborate with the Workgroup to update the SARS-CoV-2 Summary of Evidence quarterly to reflect current evidence and discuss the implications of that evidence as it accumulates.

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. In the months since the emergency policy was implemented in May 2021, more evidence has accumulated that the risk to non-lung recipients from COVID-19 differs from that of lung recipients. The SARS-CoV-2 Summary of Evidence currently notes that there are a few non-lung organs being recovered and transplanted that test positive for SARS-CoV-2, but identifies that “acceptance of these donor non-lung organs should proceed with caution,” acknowledging the limitations to available evidence while also recognizing that the demonstrated risk to lung recipients is greater.¹⁵

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 has never emerged for non-lung donors.

Post-Implementation Monitoring

Because this emergency policy was implemented in May 2021, the DTAC had the opportunity to review post-implementation monitoring data during the retrospective public comment. Figure 1 shows transplanted lung donors by month and whether lower respiratory testing was performed.

Figure 1: Number of transplanted lung donors by month and lower respiratory test

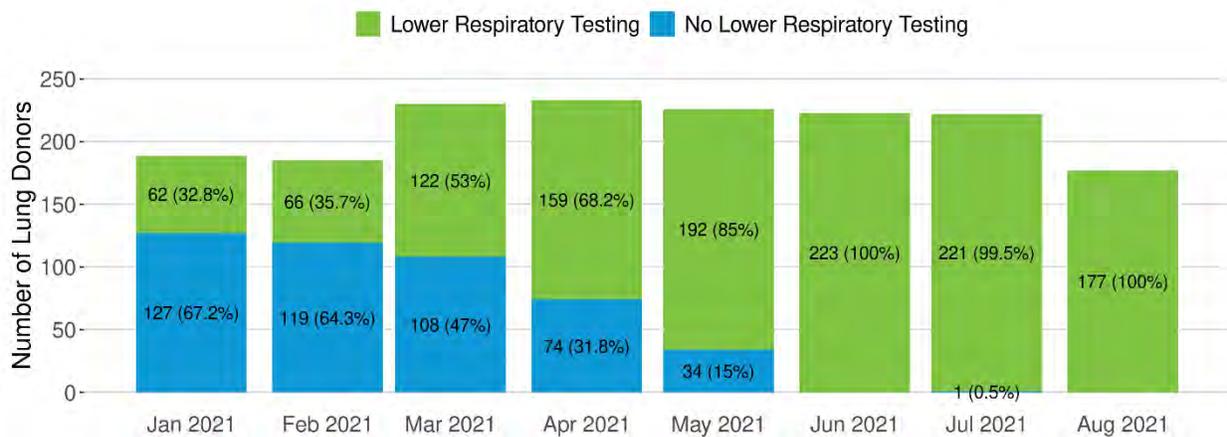


Figure 1 shows that compliance has been high with this policy, and that implementation of the emergency policy has coincided with OPOs performing lower respiratory testing on nearly all lung donors. It also shows that lower respiratory testing was less utilized prior to implementation of the

¹⁵ Ibid.

policy. The monitoring report that the DTAC has reviewed at monthly intervals shows that 22 donors had a positive lower respiratory test result in the first three months after policy implementation, including 16 donors who had discordant test results with a positive lower respiratory test and a negative upper respiratory test.¹⁶ This indicates that if this policy were not in place, organs from 22 donors could have been transplanted and transmission could have occurred to those lung recipients. These data suggest that potential transmissions to lung recipients from 16 donors may have been averted as a result of this policy, as lungs were not recovered or transplanted from these donors. To the DTAC, these data highlight the importance of having a policy that requires lower respiratory testing for all lung donors, and its success in avoiding donor derived transmissions.¹⁷ There has been a small decrease in utilization of DCD and non-DCD lung donors. It is uncertain if this decrease is significant due to low numbers overall and the potential impact of the Delta variant. The impact is seen mostly from July to August, vs June to July, where the utilization rate remained more flat. The DTAC will continue to monitor this change, but does not consider that the data demonstrate that the policy has a significantly negative impact on utilization that would warrant not having the policy, given the significant impact on patient safety and potential transmissions that could have occurred without the policy being in place.¹⁸

Proposal for Board Consideration

The policy approved by the Executive Committee requires lower respiratory testing for SARS-CoV-2 by NAT for all lung donors, with results available prior to lung transplant.¹⁹ 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.”²⁰ The DTAC worked with OPTN Lung Transplantation 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. Given the feedback from public comment, the DTAC voted to send the policy to the Board without any changes. The DTAC recommends that the policy be permanent, but that the Board continue to assess its necessity and modify or repeal the policy if the changes with the COVID-19 pandemic indicate such a step would be appropriate and not cause a negative patient safety impact. The DTAC will continue to monitor post-implementation data and update the Board if the data imply the policy may no longer be necessary.

Overall Sentiment from Public Comment

The emergency policy was supported by all 11 regions, five societies (AOPO, ASTS, AST, ASHI – American Society for Histocompatibility and Immunogenetics, NATCO - North American Transplant Coordinators Organization) and the OPTN OPO Committee which reviewed the proposal. Figure 2 shows the public comment sentiment by region, while Figure 3 shows public comment sentiment by member type.

¹⁶ Descriptive Data Request. Lower Respiratory SARS-CoV-2 Testing for Lung Donors: Three Month Post-Implementation Monitoring. Prepared by Sarah Booker. OPTN DTAC: September 28, 2021.

¹⁷ OPTN Ad Hoc Disease Transmission Advisory Committee meeting summary, September 28, 2021.

¹⁸ Ibid.

¹⁹ 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

²⁰ OPTN Bylaws, 11.7: Emergency Actions. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (Accessed April 16, 2021)

Figure 2: Sentiment by Region

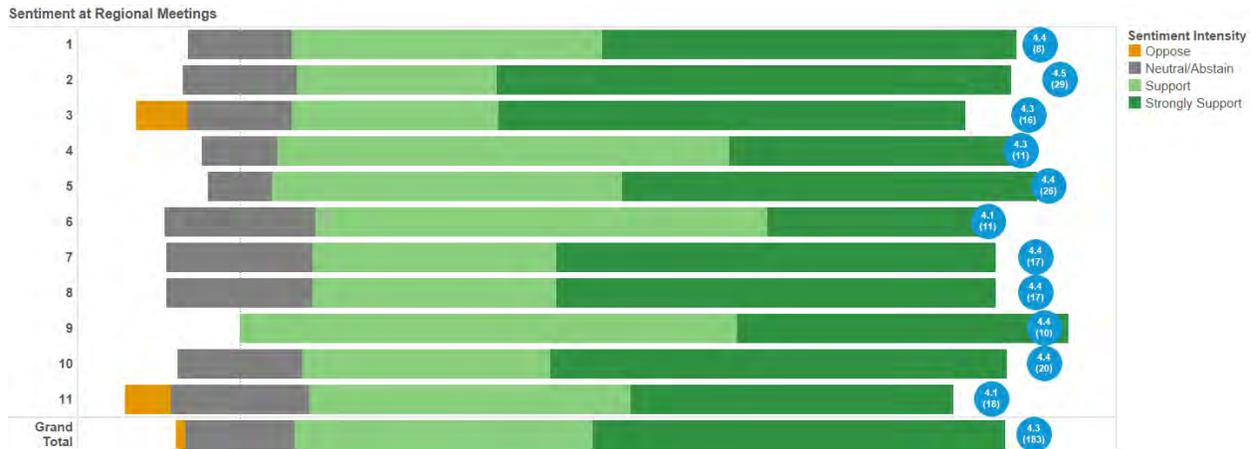
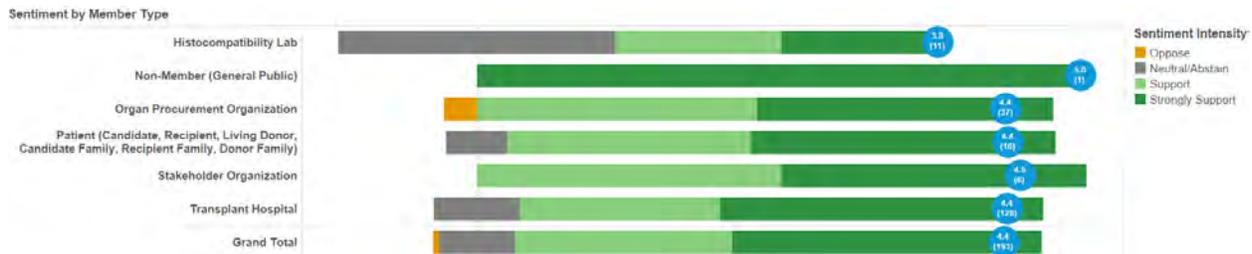


Figure 3: Sentiment by Member Type



General Support

As the above figures show, the emergency policy change was supported across region and member type. Comments in support of the proposal highlighted recipient safety and the importance of reducing the risk of transmission. Members from Region 5 noted that this is an important test for recipient safety, especially given the ongoing pandemic. The OPO Committee noted the requirement is consistent with what lung programs are asking for anyway, and a member from Region 8 commented that requiring the testing likely reduces the risk of transmission. ASTS noted the significant impact of COVID-19 on transplant outcomes in their support of the proposal, and an individual commenting noted the particularly significant impact of COVID-19 on lungs. The societies and all 11 regions that reviewed the emergency policy all expressed support.

Permanence of Policy

The ASTS noted the benefit of the proposal being made permanent, given the impact on patient safety of donor derived COVID-19 and risk to patient mortality. AOPO also supported the policy being made permanent, and noted that AOPO members moved quickly to adapt and implement the change. A commenter from Region 3 also supported the policy becoming permanent given the risk of death from SARS-CoV-2 in lung transplant recipients. No public comments indicated opposition to the potential permanence of the policy. The DTAC agrees with the comments stating that the policy should be permanent and not automatically expire upon 1 year from implementation on May 27, 2022. The DTAC recommends the Board make the policy permanent, while still allowing for review, repeal or modification to the policy if necessary and if no negative impact on patient safety is anticipated.

Timeframe of Testing

The AST strongly supported the emergency policy as a “necessary and reproducible safeguard” to protect lung recipients.²¹ The AST suggested that the timeframe for testing be made more explicit in the policy than it is now. The DTAC reviewed and considered this suggestion at their October 5, 2021 teleconference.²² The DTAC noted that 72 hours is discussed as an acceptable timeframe in the SARS-CoV-2 Summary of Evidence.²³ However, including this timeframe as a hard cutoff in policy could have unintended consequences if (for example) testing occurs 75 hours prior, the required re-testing could impact organ placement and utilization. A DTAC member also noted that the policy sought to protect lung recipients while avoiding a negative impact on utilization and it has accomplished this objective by having zero donor-derived transmissions to lung recipients since implementation, so including the timeframe is not necessary to accomplish the overall objective of the policy.

The DTAC also discussed that the OPO Committee expressed concern about adding a timeframe in policy and preferred the flexibility of the current approach in their public comment. In a related comment, NATCO noted the potential impact on delays in procurement, a concern that the DTAC previously reviewed and considered prior to implementation that led to their flexibility in both the timeframe and the type of lower respiratory specimen that can be used and still comply with policy.²⁴ The Executive Committee approved a policy that provides flexibility to OPOs by not including a timeframe of when the testing must occur, and allowing the testing to be back prior to transplant rather than earlier (pre-procurement or pre-organ offer).

Because of the concerns about a potential impact on utilization if a timeframe were to be included, the inclusion of this topic for reference to the community in the SARS-CoV-2 Summary of Evidence, and the fact that the current policy has been effective at avoiding donor-derived COVID-19 transmission to lung recipients, the DTAC recommends no changes to the policy regarding this issue.

Other Feedback

A couple members noted the difficulty of obtaining BALs for OPOs. The DTAC deliberately made the lower respiratory specimen more broadly defined to allow the possibility of OPOs utilizing other types of lower respiratory specimen types such as tracheal aspirates, which are easier to obtain. The policy will continue to allow testing of different types of lower respiratory specimen as defined in policy: sputum, tracheal aspirate, bronchial suction, bronchial wash, and BAL are all considered lower respiratory specimens.²⁵ As part of the current policy, no post-public comment changes are needed.

²¹ OPTN Public Comment, Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors. Available at <https://optn.transplant.hrsa.gov/governance/public-comment/require-lower-respiratory-sars-cov-2-testing-for-lung-donors/> (Accessed October 11, 2021)

²² OPTN Ad Hoc Disease Transmission Advisory Committee meeting summary, October 5, 2021.

²³ 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> (October 11, 2021)

²⁴ OPTN Public Comment Proposal, *Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors*. Available at https://optn.transplant.hrsa.gov/media/4785/minibrief_lower-respiratory-sars-cov-2-testing-for-lung-donors.pdf

²⁵ OPTN Policy 1.2 Definitions

The NATCO stipulated the importance of monitoring for potential false positives and timeliness of performing the test, a comment echoed by the AST. The DTAC has been following the monitoring report closely for exactly those reasons, to ensure the impact on utilization and safety is understood and unintended consequences avoided or quickly identified, and will continue to do so.²⁶

Other feedback included questions about the impact on non-lung recipients, and a question about the consensus regarding the known COVID-19 positive status and whether a test represents non-viable virus, implying the donor is unlikely to transmit infection. These questions are covered in the SARS-CoV-2 Summary of Evidence updated by the DTAC on a quarterly basis, but are not appropriate to add to the requirements of the current policy.²⁷

Compliance Analysis

NOTA and OPTN Final Rule

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."²⁸ 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."²⁹ Requiring the testing of lung organ donors for SARS-CoV-2 will help prevent the spread of the infectious disease, COVID-19. The DTAC has CDC ex-officio representation and the CDC has been part of DTAC discussions on the requirement for all lung donors to receive lower respiratory testing for SARS-CoV-2. The CDC has not published a separate recommendation on this topic.

OPTN Strategic Plan

1. *Promote living donor and transplant recipient safety:* This policy change 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.

²⁶ OPTN Ad Hoc Disease Transmission Advisory Committee meeting summary, July 26, 2021. Available at https://optn.transplant.hrsa.gov/media/50uprvkx/20210726_dtac_meeting_summary.pdf

OPTN Ad Hoc Disease Transmission Advisory Committee meeting summary, August 23, 2021. Available at https://optn.transplant.hrsa.gov/media/d5set4ft/2021_08_23_dtac_meeting-summary.pdf

OPTN Ad Hoc Disease Transmission Advisory Committee meeting summary, September 28, 2021.

Descriptive Data Request. Lower Respiratory SARS-CoV-2 Testing for Lung Donors: One Month Post-Implementation Monitoring. Prepared by Sarah Booker. OPTN DTAC: July 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4769/data_report_dtac_full_20210726_rptn.pdf

²⁷ 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> (October 11, 2021)

²⁸ 42 USC §274(b)(2)(E)

²⁹ 42 C.F.R. §121.11(a)(2)

Implementation Considerations

Member and OPTN Operations

This policy was approved per *OPTN Bylaw 11.7* authorizing emergency policy due to an emergent public health issue. The emergency policy was implemented on May 27, 2021.

Operations affecting Histocompatibility Laboratories

This policy change did not affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This policy requires OPOs to perform lower respiratory testing on all lung donors with results available prior to lung transplant.

Operations affecting Transplant Hospitals

This policy change did not affect the operations of transplant hospitals.

Operations affecting the OPTN

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

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This policy change was not anticipated to have any fiscal impact on histocompatibility laboratories.

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. Potential workflow impacts included delayed submission of other tests, and additional time to obtain results during or following organ recovery to ensure results were returned prior to transplant. The risk of not implementing this policy was potential transmission of disease to transplant recipients.

Projected Impact on Transplant Hospitals

This policy change was not anticipated to have any fiscal impact on transplant hospitals.

Projected Impact on the OPTN

PCR continued to support the Ad-hoc Disease Transmission Advisory Committee with this retrospective public proposal following adoption of emergency policy by the Executive Committee requiring lower respiratory testing for SARS CoV-2 for deceased lung donors. The policy change that defines the requirements for specimen type and testing was already implemented in May 2021.

As this is current emergency policy in effect being submitted for review, minimal implementation hours are expected from any department, amounting completely to 115 implementation hours across all.

Research will require 100 ongoing hours to prepare and present post-implementation of monitoring reports.

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

This policy will be evaluated monthly following implementation for 6 months and then again 9 months, 1-year, 18 months, and 2 years post-implementation. As of October 25, 2021, the DTAC has reviewed 3 monthly reports of post-implementation data. These data have also been shared with the Executive Committee. Post public comment, to ensure adequate data for the DTAC and Board to consider in reviewing the policy, 9 month, 18 month and 2 year reports were added to the evaluation plan. To better assess trends in positive donors, a metric was added for number and percent of donors with a positive lower respiratory test by month and number and percent of donors with discordant test results by month. Following Board of Directors review in December 2021, the next update (9 months following implementation) would be in March 2022; this report would be shared with the Executive Committee as previous reports have been.

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 percent of donors with a positive SARS-CoV-2 lower respiratory test, overall and 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, overall and by month

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 was 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. Given widespread public comment support for the proposal, the DTAC voted to send the emergency policy to the Board with no changes. The DTAC recommends the Board make the policy permanent to reflect the ongoing patient safety risk to lung recipients from potential SARS-CoV-2 transmission.

Policy Language

Language that is proposed for extension 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.

#