

## *Briefing to the OPTN Board of Directors on*

# **Promote Efficiency of Lung Donor Testing**

*OPTN Lung Transplantation Committee*

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# Promote Efficiency of Lung Donor Testing

|                                    |  |
|------------------------------------|--|
| <i>Affected OPTN Policy:</i>       | <i>2.11.D: Required Information for Deceased Lung Donors</i> |
| <i>Affected Guidance:</i>          | <i>Guidance on Requested Deceased Lung Donor Information</i> |
| <i>Sponsoring Committee:</i>       | <i>Lung Transplantation</i>                                  |
| <i>Public Comment Period:</i>      | <i>July 31, 2024-September 24, 2024</i>                      |
| <i>Board of Directors Meeting:</i> | <i>December 2-3, 2024</i>                                    |

## Executive Summary

Over the last year, the OPTN Lung Transplantation Committee (Committee) has proposed policy changes and system changes that aim to reduce burden and increase allocation efficiency overall, including the introduction of lung offer filters and approval of new data collection.<sup>1</sup> The Committee has heard that the increase in the total number of lung offers from across the country has placed an additional burden on transplant hospitals and Organ Procurement Organizations (OPOs). Transplant programs have expressed concern about the quality of the organ offers they are receiving in that the information available may be outdated or incomplete. Based on the increased workload for both OPOs and lung transplant programs associated with allocating lungs nationally, the Committee reconvened the Promote Efficiency in Lung Allocation Workgroup (the Workgroup), comprised of members from the OPTN Lung Transplantation and OPO Committees, to refine solutions that improve the efficiency of lung donor testing.<sup>2</sup>

The proposal recommended changes to lung donor testing in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and *Guidance on Requested Deceased Lung Donor Information*.<sup>3,4</sup> The goal of these recommendations is to improve the efficiency of lung allocation for OPOs and lung transplant programs by making it easier for lung transplant programs to say “yes” to organ offers.

Based on public comment feedback, the Committee made changes to provide more flexibility for OPOs, including extending the time frame for reporting arterial blood gas test results and indicating that the OPO must make reasonable efforts to obtain tests that may be challenging to obtain in rare situations.

<sup>1</sup> “Promote Efficiency of Lung Allocation,” OPTN, Briefing Paper, available at [https://optn.transplant.hrsa.gov/media/jnpd0icf/lung\\_efficiency\\_board\\_briefing\\_paper\\_draft.pdf](https://optn.transplant.hrsa.gov/media/jnpd0icf/lung_efficiency_board_briefing_paper_draft.pdf).

<sup>2</sup> See OPTN Promote Efficiency in Lung Allocation workgroup meeting summary, January 30, 2024, available at [https://optn.transplant.hrsa.gov/media/beumdbd4/20240130\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/beumdbd4/20240130_lungefficiencywg_msfinal.pdf).

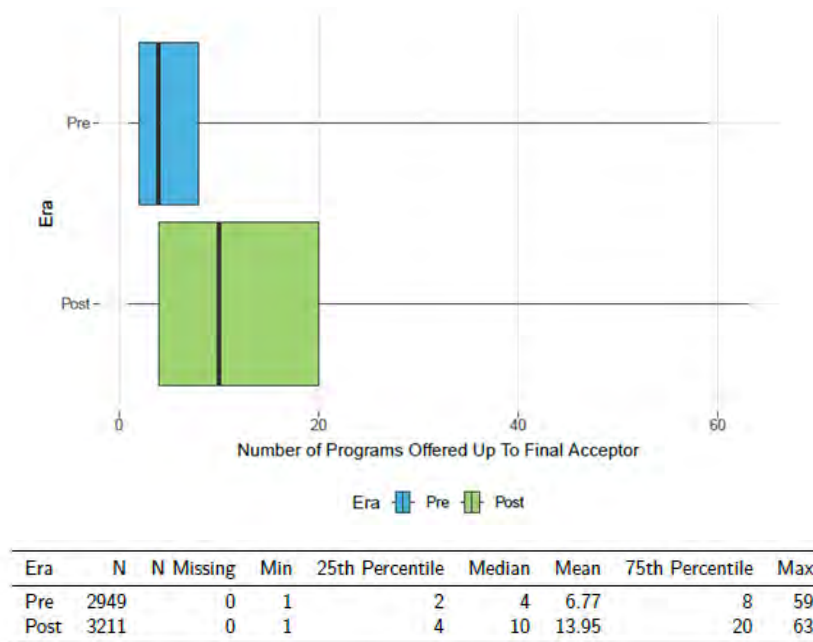
<sup>3</sup> *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*

<sup>4</sup> “Guidance on Requested Deceased Donor Information,” OPTN, June 2018, available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/guidance-on-requested-deceased-donor-information/>.

## Background & Purpose

On March 9, 2023, the lung allocation policy transitioned to a continuous distribution framework.<sup>5</sup> Continuous distribution uses a point-based system to determine the order of candidates on a match run when a medically suitable lung donor becomes available. Post-implementation monitoring showed that in the first year of continuous distribution the lung transplant rate increased, and the waiting list mortality rate decreased. Additionally, the most medically urgent candidates had the highest transplant rate and the shortest median time to transplant. Despite the benefits of continuous distribution, the shift to a national distribution system has also introduced efficiency challenges, including increased distances from the donor hospital to the transplant center and an increase in the median number of programs that received lung offers on a match run. **Figure 1** displays the number of unique programs that received lung offers before the final acceptor before and after continuous distribution implementation. In the year prior to continuous distribution implementation, a median of four programs evaluated each lung before a final acceptor. However, under continuous distribution this metric increased to a median of 10 programs evaluating each lung offer before the final acceptor.

**Figure 1. Distribution of the Number of Unique Programs Offered Up to the Final Acceptor on Lung Match Runs by Era**



Over the last year, the Committee has proposed policy changes that aim to reduce burden and increase allocation efficiency overall. These efforts include new data collection that can be used to improve the evaluation of organ offers and system changes to help streamline the allocation process for OPOs and transplant programs.

Lung Offer Filters was implemented in January 2024 and allow transplant programs to apply custom-designed, program-specific, multi-factorial filters to bypass donor offers that they do not want to

<sup>5</sup> "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, available at [https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice\\_lung\\_continuous-distribution.pdf](https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf).

receive.<sup>6,7</sup> The purpose of offer filters is to get organs accepted faster by reducing the number of unwanted organ offers that OPOs need to make and transplant programs need to review, thereby decreasing allocation time and increasing organ acceptance.<sup>8</sup> Since implementation on January 31, 2024, 31 (40.1%) active transplant programs have turned on at least one Offer Filter. In total, 70 distinct filters have been enabled across the 31 programs. 92,430 lung offers that would have gone out have instead been bypassed by Offer Filters.<sup>9</sup>

Additionally, on June 17, 2024 the OPTN Board of Directors approved new data collection and system enhancements that intend to promote efficiency in lung allocation.<sup>10</sup> New data collection in the OPTN Donor Data and Matching System on (1) previous sternotomies and (2) anaphylaxis to peanut and/or tree nut aims to aid evaluation of lung offers for lung transplant programs, as some programs rule out donors with these characteristics in combination with other criteria. Once collected, analysis of the two additional data elements could be considered in any proposed future refinement of the current lung offer filters. In the interim, having these criteria reported in the donor record will assist lung transplant programs in evaluating and providing a timely response to lung offers.<sup>11</sup>

The OPTN Board of Directors also approved two system changes. The “Bypass Bilateral and Other Lung” button is a functionality which will allow OPOs to quickly bypass all the bilateral candidates on the match run at once, as well as any candidates who need a lung of the opposing laterality if they have already placed a single lung. In addition, the “Opt In to Offers from Geographically Isolated Areas” modification will enable transplant programs to indicate if they would accept an organ from geographically isolated areas including Hawaii, Puerto Rico, and Alaska at the program level.<sup>12</sup>

The Committee has heard that the increase in the total number of lung offers from across the country has placed an additional burden on transplant hospitals and OPOs. In addition, transplant programs have expressed concern about the quality of the organ offers they are receiving in that the information available may be outdated or incomplete. Based on the increased workload for both OPOs and lung transplant programs associated with allocating lungs nationally, the Committee reconvened the Promote Efficiency in Lung Allocation Workgroup (the Workgroup), comprised of members from the OPTN Lung Transplantation and OPO Committees, to refine solutions that improve the efficiency of lung donor testing.<sup>13</sup>

<sup>6</sup> “Offer Filters now available for lung allocation,” <https://unos.org/news/offer-filters-now-available-for-lung-allocation/>.

<sup>7</sup> Finnie, J. & Moriarty, S. “Better organ offer screening,” <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

<sup>8</sup> “Optimizing Usage of Offer Filters,” OPTN, Briefing Paper, available at: [https://optn.transplant.hrsa.gov/media/vyonuirf/optn\\_osc\\_offer\\_filters\\_bp\\_june23.pdf](https://optn.transplant.hrsa.gov/media/vyonuirf/optn_osc_offer_filters_bp_june23.pdf).

<sup>9</sup> Dat as of October 11, 2024

<sup>10</sup> “Notice of OPTN Data Collection Change”, OPTN, Promote Efficiency of Lung Allocation, available at [https://optn.transplant.hrsa.gov/media/sbvpaop1/lung\\_efficiency-of-lung\\_june-2024\\_pn.pdf](https://optn.transplant.hrsa.gov/media/sbvpaop1/lung_efficiency-of-lung_june-2024_pn.pdf)

<sup>11</sup> “Promote Efficiency of Lung Allocation,” OPTN, Briefing Paper, available at [https://optn.transplant.hrsa.gov/media/jnnp0jcf/lung\\_efficiency\\_board\\_briefing\\_paper\\_draft.pdf](https://optn.transplant.hrsa.gov/media/jnnp0jcf/lung_efficiency_board_briefing_paper_draft.pdf).

<sup>12</sup> Ibid.

<sup>13</sup> See OPTN Promote Efficiency in Lung Allocation workgroup meeting summary, January 30, 2024, available at [https://optn.transplant.hrsa.gov/media/beumdbd4/20240130\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/beumdbd4/20240130_lungefficiencywg_msfinal.pdf).

## Proposal for Board Consideration

### Updates to OPTN Policy 2.11.D: Required Information for Deceased Lung Donors

The Committee proposes changes to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* including updates to arterial blood gases, bronchoscopy, chest CT scan, chest x-ray, sputum gram stain, and echocardiogram/RHC requirements. **Table 1** displays current requirements and proposed changes for consideration by the Board of Directors.

**Table 1. Proposed Changes to OPTN Policy 2.11.D: Required Information for Deceased Lung Donors<sup>14</sup>**

| Test                        | Current   | For Board Consideration  |
|-----------------------------|---|--|
| Arterial blood gases (ABGs) | <ul style="list-style-type: none"> <li>Arterial blood gases and ventilator settings on 5 cm/H2O/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer.</li> </ul> | <ul style="list-style-type: none"> <li>Ventilator settings for challenge gases: PEEP of 5-8 cmH2O, FiO2 100%, Tidal volume of 6-8 mL/kg ideal body weight (IBW).                             <ul style="list-style-type: none"> <li>For donors 18 years or older, and 5 feet or taller, IBW must be calculated using the National Heart, Lung, and Blood Institute (NHLBI) formula.</li> <li>For donors less than 18 years old or shorter than 5 feet, IBW may be calculated using any race-neutral IBW equation.</li> </ul> </li> <li>Challenge gases obtained 4 hours prior to the initial offer made by the host OPO on a lung match run.</li> <li>Challenge gases at least every 6-8 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery.<sup>15</sup></li> <li>Any challenge gases drawn after a recruitment maneuver must be drawn at least 30 minutes following that recruitment maneuver.</li> </ul> |

<sup>14</sup> Table 1 displays tests in OPTN Policy 2.11.D with changes for board consideration. Changes proposed during public comment for OPTN Policy 2.11.D are displayed in the Policy Language on pages 23-24.

<sup>15</sup> Application of reasonable efforts language. See Policy language on page 21.

| Test   | Current  | For Board Consideration  |
|--|--|--|
| Bronchoscopy                                     | <ul style="list-style-type: none"> <li>Bronchoscopy, if performed.</li> </ul>  | <ul style="list-style-type: none"> <li>Bronchoscopy results.<sup>16</sup></li> </ul>   |
| Chest computed tomography (CT) scan              | <ul style="list-style-type: none"> <li>Included in <i>Guidance on Requested Deceased Lung Donor Information</i>.</li> </ul>                          | <ul style="list-style-type: none"> <li>Add chest CT scan to OPTN Policy 2.11.D.<sup>17</sup></li> </ul>  |
| Chest x-ray                                      | <ul style="list-style-type: none"> <li>Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer.</li> </ul> | <ul style="list-style-type: none"> <li>Images or interpretation by a radiologist or qualified physician of a chest x-ray performed within 3 hours prior to the initial offer made by the host OPO on a lung match run.</li> <li>Updated images or interpretation of a chest x-ray performed at least every 24 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery.<sup>18</sup></li> </ul> |
| Sputum gram stain                                | <ul style="list-style-type: none"> <li>Sputum gram stain, with description of sputum</li> </ul>  | <ul style="list-style-type: none"> <li>Removal of description of sputum requirement.</li> </ul>  |
| Echocardiogram/Right heart catheterization (RHC) | <ul style="list-style-type: none"> <li>Echocardiogram included in <i>Guidance on Requested Deceased Lung Donor Information</i>.</li> </ul>           | <ul style="list-style-type: none"> <li>Either echocardiogram or right heart catheterization (RHC) to screen for pulmonary hypertension.<sup>19</sup></li> </ul>  |

**Table 2** displays the fields required in the OPTN Computer System prior to sending out an electronic offer notification on a lung match. Fields in red are proposed system changes to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*. These proposed changes are summarized below:

- ABG: At least one complete record within 4 hours prior to the first electronic notification on a lung match with the following ventilator settings:
  - Positive end-expiratory pressure (PEEP) of 5-8 cmH2O
  - Fraction of inspired oxygen (FiO2) 100%
  - Tidal volume of 6-8 mL/kg ideal body weight
- Chest x-ray: A chest x-ray image or interpretation with test date and test time. Test date and Test time must be within 3 hours prior to the first offer.
- Sputum gram stain: Positive, Negative, or Pending

**Table 2. Fields required prior to sending out an electronic offer notification on a lung match**

| Field  | Details  |
|--|--|
| Weight   |  |
| Cause of death   |  |
| I.V. drug usage  | UNK is a valid value   |
| According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne disease transmission? | Read-only field. Value is calculated by answering the 10 detailed risk questions below it. This field is not required to run matches, but it is required in order to send electronic organ offers. |
| Average or actual blood pressure   | Only 1 value is required   |

<sup>16</sup> Application of reasonable efforts language. See Policy language on page 21.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

| Field   | Details   |
|---|---|
| Heart rate  | Only 1 value is required  |
| ABG: Date   | <p>At least one complete record within 4 hours prior to the first electronic notification on a lung match is required in ABG / Ventilator settings where the:</p> <ul style="list-style-type: none"> <li>• FiO2% = 100,</li> <li>• For donors 18 years or older, and 5 feet or taller Vt within 6-8 mL/kg of donor's ideal body weight</li> <li>• For donors less than 18 years old or shorter than 5 feet, valid value in field and</li> <li>• PEEP between 5-8 cmH2O</li> </ul> |
| ABG: Time   |   |
| ABG: pH   |   |
| ABG: PaCO2 (mmHg)   |   |
| ABG: PaO2 (mmHg)  |   |
| ABG: HCO3 (mEq/L)   |   |
| ABG: SaO2 (%)   |   |
| ABG: Mode   |   |
| ABG: FiO2 (%)   |   |
| ABG: RR   |   |
| ABG: Vt (cc)  |   |
| ABG: PEEP (cmH2O)   |   |
| Was COVID-19 (SARS-COV-2) testing performed on the donor? |   |
| Chest x-ray <del>comments-</del>                          | A chest x-ray image or interpretation with test date and test time. Test date and test time must be within 3 hours prior to the first electronic notification on a lung match.  |
| Sputum gram stain   | Pending is a valid value  |

Red text = new requirement

## Arterial Blood Gases (ABGs)

Current OPTN policy requires an ABG with ventilator settings on 5 cm/H2O/ PEEP including partial pressure of oxygen (PO2) FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer.

For the public comment proposal, the Committee proposed changes to the ventilator settings for ABGs to include requirements for PEEP of 5-8 cmH2O, FiO2 100%, and tidal volume of 6-8 mL/kg ideal body weight (IBW). The Committee defined ABGs using these ventilator settings as “challenge gases” and proposed each ABG obtained for the purposes of OPTN Policy 2.11.D: *Required Information for Deceased Lung Donors* be a challenge gas. During discussions, the Committee expressed that requiring consistent settings for all challenges gases would promote accuracy in the representation of lung function and allow for observation of the PaO2/FiO2 (P/F) ratio over time. The Workgroup initially agreed with current ventilator settings in policy requiring PEEP of 5 cmH2O, but determined a range of 5-8 cmH2O should be recommended, as adjustments to PEEP may be necessary based on weight and tidal volume. The Committee determined that the FiO2 100% should be retained, but the word “preferably” should be removed as this language does not align with the nature of policy as a requirement. Members also supported the proposed inclusion of a standard tidal volume of 6-8 ml per kg based on IBW for the donor, as this reflects current practice for OPOs. The IBW formula the Committee asked the community to consider for the purposes of this policy was developed by the NHLBI to aid in the development of effective therapy for Acute Respiratory Distress Syndrome (ARDS).

The NHLBI ARDS Network formula is as follows:

- Male:  $IBW (kg) = 50 + 2.3 (\text{height (in)} - 60)$
- Female:  $IBW (kg) = 45.5 + 2.3 (\text{height (in)} - 60)$

During public comment, the Committee proposed the following requirements for frequency of challenge gases:

- Within 2 hours of the initial offer: The Committee defined the initial offer as prior to the first notification on the match. During initial discussions on these timeframe requirements, the Workgroup considered that a challenge gas should be obtained at least every 2 hours between the time of the initial offer and organ offer acceptance. Workgroup members reported varying degrees of difficulty with obtaining ABG results at least every 2 hours and stated that the ability to obtain ABGs is dependent on donor hospital infrastructure
- At least every 4 hours between the time of the initial offer and organ offer acceptance: The Committee recommended at least every 4 hours between the time of the initial offer and organ offer acceptance as opposed to at least every 2 hours, with the rationale that this would better accommodate OPOs restricted by donor hospital resources
- At least every 8 hours between organ offer acceptance and organ recovery: The Committee's rationale for the inclusion of this requirement is that it reduces the burden on OPOs from at least every 4 hours to at least every 8 hours while aiming to provide the accepting program with enough information to assess donor lungs and identify any forthcoming issues.

The Committee proposed that the challenge gas “within 2 hours prior” should be required before an offer can be made, meaning that OPOs would not be able to send out lung offers unless the requirement is met. While providing challenge gases at the prescribed 4- hour and 8-hour intervals described above is important, the Committee proposed that the system provides a “warning” to the offering OPO but does not halt allocation, as this would decrease allocation efficiency.

The Committee also proposed that challenge gases should not be drawn within 30 minutes after any recruitment maneuver. Members discussed that drawing a challenge gas just after a recruitment maneuver may artificially elevate the arterial oxygen pressure. Allowing 30 minutes after recruitment will ensure challenge gases are reflective of the donor's true lung function. The Committee defines a recruitment maneuver as any temporary increase in airway pressure during mechanical ventilation used in an attempt to open areas of collapsed alveoli or atelectasis.

### Public comment feedback on Arterial Blood Gases (ABGs)

Public comment responses to the proposed challenge gas requirements expressed concerns regarding the frequency of testing, definition of a recruitment maneuver, and how ideal body weight should be calculated for pediatric and short adult donors. Respondent suggestions for modifications included an extension to the timing and frequency of challenge gases and additional flexibility for DCD donors.

To address community concerns with the frequency of ABG testing, the Committee revised their recommendations for Board consideration:

- A challenge gas must be obtained within 4 hours prior to the initial offer made by the host OPO on a lung match run



- Challenge gases at least every 6-8 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery<sup>20</sup>

When revising this timeline, the Committee considered recommending separate challenge gas timeframes for providing testing between the time of the initial offer made by the host OPO on a lung match run and the organ recovery for Donation after Brain Death (DBD) and Donation after Cardiac Death (DCD) donors. Initially, challenge gases every 6 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery was considered for DBD donors and every 12 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery was considered for DCD donors. Ultimately, the Committee decided to recommend 6-8 hours for both types of donors. They discussed that having one timeline requirement of 6-8 hours for both DBD and DCD donors streamlined the policy, while also providing additional time for OPOs to obtain challenge gases for both donor types between the time of the initial offer made by the host OPO on a lung match run and the organ recovery. This solution aims to address timeline concerns related to both DCD donor type and challenge gas timeline management for host OPOs.

With these revised recommendations, one ABG that meets the definition of a challenge gas must be entered into the OPTN Donor Data and Matching System within 4 hours prior to the initial offer made by the host OPO on a lung match run. If a challenge gas has not been entered within 4 hours, the OPO will not be able to send the initial offer on the lung match. As proposed in July 2024, allocation will not be halted if challenge gas requirements are not met during allocation (between the time of the initial offer made by the host OPO on the lung match run and the organ recovery), as this could contribute to inefficiency in the system. However, the Committee is aware of how important access to updated challenge gases is for lung transplant programs and has included language requiring host OPOs that cannot obtain ABGs at least every 6-8 hours between the time of the initial offer made by the host OPO on the lung match run and the organ recovery to document the reason and make this information available to the OPTN upon request. The Committee also supported clarifying that the “initial offer” referenced in the challenge gas frequency timeline is the “initial offer made by the host OPO on a lung match run”.

Regarding recruitment maneuvers, the Committee supported changing the policy language to clarify that a recruitment maneuver is defined as any procedure done to temporarily reinflate the donor lungs to assist in assessing organ quality. They discussed that there are many types of recruitment maneuvers, therefore it would be difficult to provide an exhaustive list.

For the public comment proposal, the Committee asked the community if they supported the use of the NHLBI formula for calculating IBW. The community concurred and stated that the NHLBI formula is the current standard for calculating IBW for adults that are 5 feet or taller. Commenters asked for guidance on how to calculate IBW for pediatrics or small adults, as the NHLBI formula is not validated for donors less than 18 years old or shorter than 5 feet. When the Committee investigated this topic, they learned that there currently is no standard IBW formula for pediatrics and short adults, and that many usable formulas exist. Therefore, the Committee supported that for donors less than 18 years old or shorter than 5 feet, IBW may be calculated using any race-neutral IBW equation.

The Committee also made a small language change from “on the lung match run” to “on a match run” to acknowledge that that challenge gas requirements will not only apply to the lung match run, but also the heart- lung match run.

### *Echocardiogram and Right Heart Catheterization (RHC) requirements*

Currently, recommendations for echocardiogram resides in *Guidance on Requested Deceased Lung Donor Information* and specify that the transplant program may request an echocardiogram or a Swan Ganz if there is suspected pulmonary hypertension in the donor.<sup>21</sup>

For the public comment proposal, the Committee proposed adding echocardiogram and right heart catheterization (RHC) to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and requiring the host OPO to provide either echocardiogram or RHC. The Committee determined that Swan Ganz should be removed from guidance, as often this specific type of RHC cannot be done due to limited staff trained to perform this procedure.<sup>22</sup> The Workgroup agreed that an echocardiogram is needed to evaluate potential lung donors for pulmonary hypertension (PH), especially for donors at increased risk. Echocardiograms are required for heart allocation, but in instances where the heart is not allocated, lung transplant teams typically must request an echocardiogram upon receiving the offer.<sup>23</sup> The addition of echocardiogram to policy would require this information to be available at the time of the offer, thereby increasing allocation efficiency.<sup>24</sup> Members discussed that an echocardiogram is typically used to assess if the donor has PH. An RHC is a more invasive procedure but is sometimes needed to identify pulmonary hypertension in a donor if the echocardiogram results are inconclusive.<sup>25</sup> Members reported that there may be situations when RHC has already been completed and in these instances, it would be inefficient to still require an echocardiogram, since RHC provides more information. To accommodate these instances, the Workgroup determined RHC should reside in policy alongside echocardiogram, so either of these tests would meet the policy requirement.<sup>26</sup>

### Public comment feedback on Echocardiogram Right Heart Catheterization (RHC) requirements

Responses to this proposed requirement noted that due to resource limitations and the challenges that can accompany DCD donation, not all host OPOs and donor hospitals would be able to perform these tests prior to every lung offer.

The Committee considered scenarios in which echocardiograms or RHCs could not be performed, noting that preventing an offer from being sent because one of these tests had not been obtained could contribute to inefficiency and ultimately discourage OPOs from pursuing lungs. For this reason, the Committee determined that an echocardiogram or RHC would not be required to send a lung offer. However, the Committee did discuss the importance of the inclusion of an echocardiogram or RHC in lung offers and decided that the host OPO must make reasonable efforts to obtain the echocardiogram

<sup>21</sup> “Guidance on Requested Deceased Donor Information”, OPTN, June 2018, available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/guidance-on-requested-deceased-donor-information/>.

<sup>22</sup> See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at [https://optn.transplant.hrsa.gov/media/fkhj515q/20240312\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf).

<sup>23</sup> *OPTN Policy 2.11.D: Required Information for Deceased Heart Donors*.

<sup>24</sup> See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at [https://optn.transplant.hrsa.gov/media/fkhj515q/20240312\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf).

<sup>25</sup> See Promote Efficiency in Lung Allocation workgroup summary, April 23, 2024, available at [https://optn.transplant.hrsa.gov/media/4feexkuu/20240423\\_lungefficiencywg\\_ms.pdf](https://optn.transplant.hrsa.gov/media/4feexkuu/20240423_lungefficiencywg_ms.pdf).

<sup>26</sup> *Ibid.*

or RHC; if one of these tests is not obtained, the host OPO must document the reason and make this documentation available to the OPTN upon request.

### *Chest Computed Tomography (CT) Scan*

For the public comment proposal, the Committee proposed removing chest CT scan recommendations from guidance and adding this test to policy with the “if performed” specification, which does not require a chest CT scan to be performed before a lung offer can be sent.

During Workgroup meetings, members discussed that the majority of donor offers have a chest CT scan completed between the time of admission and donor death.<sup>27, 28</sup> Members explained that a chest CT scan often provides a more detailed view of the lungs for volume management and the ability to cross reference the chest x-ray and chest CT scan can provide further insight on donor lung quality. Some members noted that donor hospitals in rural areas or those with limited access to imaging may be unable to obtain chest CT scans. Additionally, they are not completed for some pediatric donors and repeat chest CT scans can be challenging to obtain.<sup>29</sup> In an ideal state, the policy would require a chest CT scan for a deceased lung donor before the offer could be sent to a transplant program. The Committee realized that preventing allocation in a situation in which a chest CT scan could not be obtained has the potential to decrease efficiency in allocation or even stop the OPO from pursuing allocation of the lungs altogether.<sup>30</sup> The Committee aims to strike a balance between emphasizing the importance of obtaining a chest CT scan for every lung donor offer while allowing flexibility in policy for cases where a chest CT scan cannot be completed. Due to the expressed concerns regarding availability of imaging for all donor hospitals, the Committee is proposing moving chest CT scan to policy with the condition “if performed”, similar to current policy for bronchoscopies.<sup>31</sup> Structuring the policy in this way would not prevent OPOs from sending offers when no chest CT scan is available.

### **Public comment feedback on Chest Computed Tomography (CT) Scan**

This portion of the proposal received a range of comments, with some respondents expressing concern regarding host OPO and donor hospital ability to obtain a chest CT and others voicing that a chest CT scan should be made mandatory with every lung offer.

The Committee discussed that while most lung offers do include a chest CT scan, they would not want to prevent an OPO with limited resources from offering viable lungs due to the absence of a chest CT scan. The Committee determined that the “if performed” language was too lenient and instead applied the language stating that host OPOs must make reasonable efforts to obtain a chest CT scan for all lung donors. If a chest CT scan is not provided, the host OPO must document the reason and make this documentation available to the OPTN upon request.

<sup>27</sup> See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at [https://optn.transplant.hrsa.gov/media/budhzkne/20240213\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf).

<sup>28</sup> Copeland, H. et al., “Donor heart and lung procurement: A consensus statement,” *The Journal of Heart and Lung Transplantation* 39, no. 6 (2020): 502-516: <https://doi.org/10.1016/j.healun.2020.03.020>.

<sup>29</sup> Ibid.

<sup>30</sup> See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at [https://optn.transplant.hrsa.gov/media/fkhj515q/20240312\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf)

<sup>31</sup> See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at [https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321\\_lung\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf).

### *Chest X-Ray*

For the public comment proposal, the Committee proposed adding chest x-ray images as an alternative option for OPOs to meet the requirement of providing chest x-ray interpretation within three hours prior to the initial offer. They also included a requirement for updated chest x-ray images or interpretation at least every 24 hours between the time of the initial offer and organ recovery. For public comment, the Committee proposed that the chest x-ray images or interpretation within 3 hours prior to the initial offer would be required and OPOs could not send the initial offer on a lung match if this criterion was not met. Conversely, the Committee proposed that if OPOs could not meet the updated chest x-ray interpretation or images at least every 24 hours between the time of the initial offer and organ recovery requirement, allocation would not be halted, as stopping allocation mid-process would contribute to inefficiency.

During Workgroup discussions it was confirmed that obtaining chest x-ray imaging is essential for making decisions about potential lung offers and therefore, it should remain in policy. Members also emphasized that clinicians read any x-ray imaging sent from an OPO themselves, so waiting on a staff member at the host OPO to provide image interpretation results is unnecessary and oftentimes inefficient.<sup>32</sup> Members from lung transplant programs expressed the need for policy to require updated chest x-ray imaging or interpretation on a regular cadence, ideally at least every 12 to 24 hours. OPO representatives on the Workgroup expressed preference for 24 hours so that chest x-rays occurring in the middle of the night could be interpreted the following day if they are unable to share the x-ray images. Transplant program representatives agreed, noting that more frequent chest x-rays could be requested if the status of the donor changes.<sup>33</sup>

#### Public comment feedback on chest x-ray

Public comment responses were mixed, with some support for this portion of the policy as proposed and some support for mandating images or mandating images and interpretation.

The Committee discussed that images were proposed to provide OPOs with a choice between images and interpretation to increase efficiency in a situation where the images are available, but the interpretation is not, and vice versa. For this reason, the Committee determined they would move forward with this portion of the proposal as is but applied language requiring host OPOs to document any inability to obtain a chest x-ray image or interpretation every 24 hours and make this information available to the OPTN upon request.

The Committee made two other small changes to the chest x- ray language:

- Ensure that the image or interpretation provided to the transplant program by the OPO was from a chest x- ray performed within the timeframes outlined in proposed policy (within 3 hours, every 24 hours thereafter)
- Change from “on the lung match run” to “on a match run” to acknowledge that that challenge gas requirements will not only apply to the lung match run, but also the heart- lung match run.

<sup>32</sup> See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at [https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321\\_lung\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf)

<sup>33</sup> See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at [https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321\\_lung\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf)

## Bronchoscopy

For the purposes of consistency, the Committee removed the “if performed” specification from the bronchoscopy testing requirement. Policy language stating that the host OPO must make reasonable efforts to obtain the bronchoscopy and requiring the host OPO to document any instances where it could not be obtained and provide to the OPTN upon request was applied.

## Updates to *Guidance on Requested Deceased Lung Donor Information*

The Committee proposed updates to *Guidance on Requested Deceased Lung Donor Information* including fungal and bacterial culture results, chest CT scan, chest x-ray, and RHC. While the Committee determined these recommendations too prescriptive to reside in policy, they serve as effective practices that should be incorporated into host OPOs’ regular protocols.

While this guidance did receive some feedback, the Committee felt it did not receive enough discussion to support altering their initial recommendations and therefore decided to move forward with the additions to *Guidance on Requested Deceased Lung Donor Information* as proposed.

### *Fungal and bacterial culture results*

Current guidance includes a recommendation for the collection of “mycology sputum smear.” The Committee proposes updating the name of “mycology sputum smear” to “fungal culture results” as this language is used more commonly in practice.<sup>34</sup> Committee members also agreed that “bacterial culture results” should also be added to this guidance.<sup>35</sup> The Workgroup discussed that these tests should remain in guidance as results are not needed for offer acceptance, but they are helpful in determining the need for prophylaxis treatment post-transplant. The Workgroup expressed that the need for fungal and bacterial culture testing is based on geographical differences across the country, so not all OPOs complete these tests regularly.<sup>36</sup>

### *Chest CT scan*

The Committee proposed guidance that the host OPO performs the chest CT within 72 hours prior to the initial offer. During discussions, members emphasized the importance of having current and relevant information during the decision-making process.<sup>37</sup> They noted that a chest CT scan from several or more days prior to the offer may no longer be clinically relevant and would elicit additional chest CT scan requests during allocation, decreasing efficiency of the offer review process. Initially, transplant program representatives suggested the host OPO should perform the chest CT scan within 24-48 hours prior to the initial offer but determined within 72 hours prior to the initial offer would provide a more appropriate balance in terms of usefulness to transplant programs and burden on OPOs.<sup>38</sup> Additionally, the Committee proposes guidance stating that the host OPO should provide images with lung windows, as sometimes only images with abdominal windows are provided.<sup>39</sup> Windowing is the process in which

<sup>34</sup> See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at [https://optn.transplant.hrsa.gov/media/fkhj515g/20240312\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/fkhj515g/20240312_lungefficiencywg_msfinal.pdf).

<sup>35</sup> See Promote Efficiency in Lung Allocation workgroup summary, May 21, 2023, available at <https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/>.

<sup>36</sup> See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at [https://optn.transplant.hrsa.gov/media/fkhj515g/20240312\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/fkhj515g/20240312_lungefficiencywg_msfinal.pdf).

<sup>37</sup> Ibid.

<sup>38</sup> Ibid.

<sup>39</sup> See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at [https://optn.transplant.hrsa.gov/media/5n4bhkzku/20240321\\_lung\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/5n4bhkzku/20240321_lung_msfinal.pdf).

the CT image greyscale component of an image is manipulated to change the appearance of the picture to highlight particular structures. Different structures (lung, abdominal, brain, etc.) need specific window settings to be properly interpreted.<sup>40</sup>

### *Chest x-ray*

The Committee also proposed guidance specifying that x-ray images are preferred to interpretation. Clinicians read their own x-rays, so waiting for interpretation can slow allocation and contribute to inefficiencies in the system. By adding this guidance, the Committee aims to promote the timely review of lung organ offers.<sup>41</sup>

### *Right Heart Catheterization (RHC)*

The Committee determined that supplemental guidance on RHC should be proposed, such that transplant programs may request a RHC in addition to an echocardiogram if they have additional concerns about the donor lungs. A RHC is a more invasive procedure but may be necessary to assess pulmonary hypertension in a donor.<sup>42</sup>

## Overall Sentiment from Public Comment

Generally, public comment sentiment was supportive of this proposal, as indicated by the total sentiment score of 3.7 by member type and 3.7 by region, with some pockets of concern. Below are graphics that illustrate the sentiment received during the July 31, 2024 - September 24, 2024, public comment period.

Sentiment is collected on public comment proposals and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5). Generally, public comment sentiment has been supportive of this proposal, as indicated by the total sentiment score of 4.0, with few pockets of concern. Below are graphics that illustrate the sentiment received through public comment.

<sup>40</sup> "Windowing (CT)", Radiopaedia.org, available at <https://radiopaedia.org/articles/windowing-ct?lang=us#:~:text=Windowing%2C%20also%20known%20as%20grey,picture%20to%20highlight%20particular%20structures.>

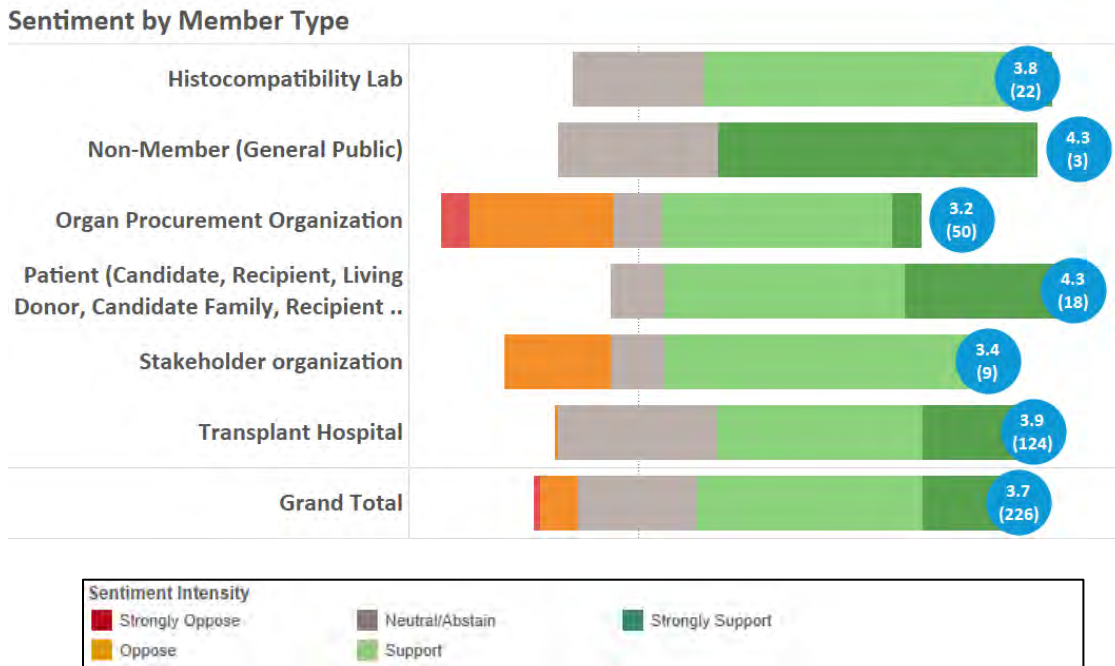
<sup>41</sup> See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at [https://optn.transplant.hrsa.gov/media/budhzkne/20240213\\_lungefficiencywg\\_msfinal.pdf](https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf).

<sup>42</sup> See Promote Efficiency in Lung Allocation workgroup summary, April 23, 2024, available at [https://optn.transplant.hrsa.gov/media/4feexkuu/20240423\\_lungefficiencywg\\_ms.pdf](https://optn.transplant.hrsa.gov/media/4feexkuu/20240423_lungefficiencywg_ms.pdf).



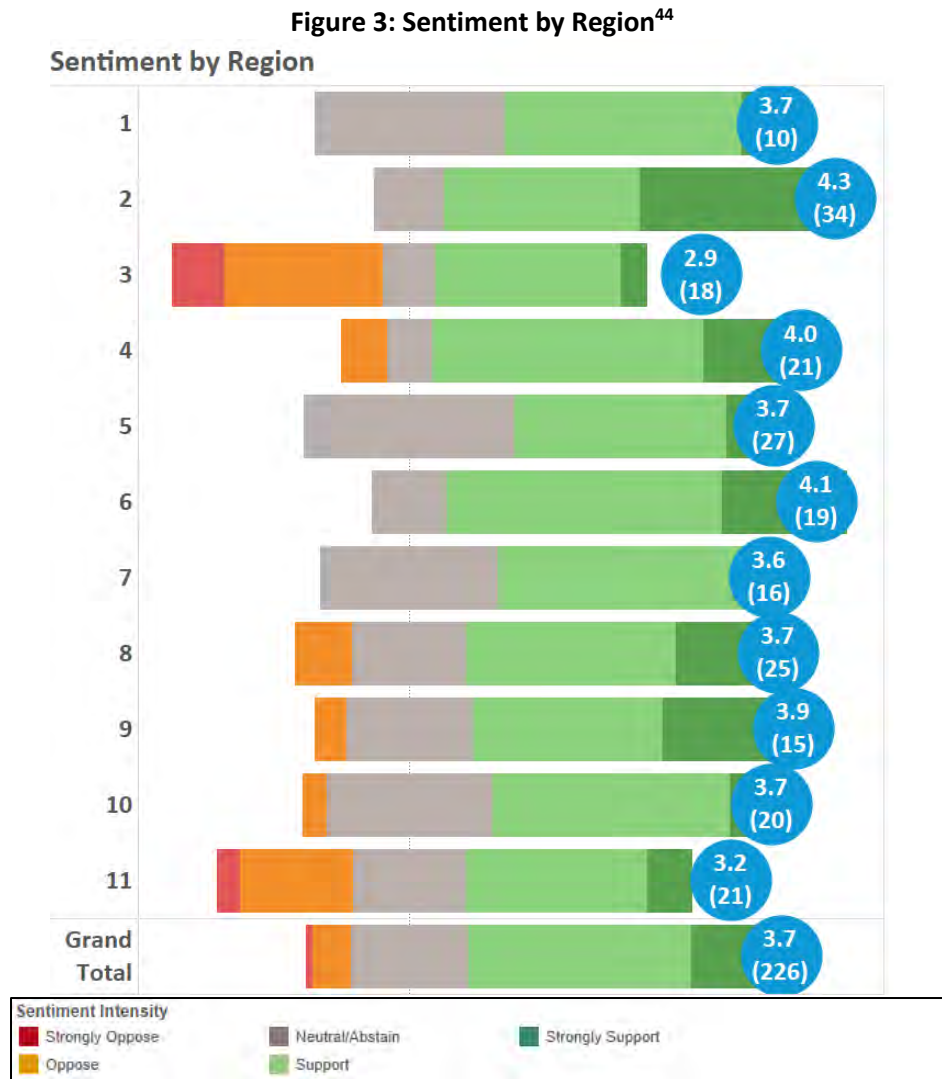
**Figure 2** shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. Across member types, the average sentiment was supportive (3.8), and scores ranged from 3.2 to 4.3. Of all member types, OPOs (3.2) and stakeholder organizations (3.4) showed the most opposition.

**Figure 2: Sentiment by Member Type<sup>43</sup>**



<sup>43</sup> The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

**Figure 3** shows sentiment received at regional meetings and region of online commenters. Across OPTN regions, the average sentiment was supportive (3.7), and scores ranged from 2.9 (region 3) to 4.3 (region 2). Opposition was raised in about half the regions (3, 4, 8, 9, 10, and 11).



Overall, public comment respondents appreciated the efficiency-focused goals of the proposal. Some commenters voiced concern that the proposed testing requirements and timeframes may be unattainable for under resourced, small, and rural OPOs and donor hospitals. Additionally, others expressed concern and asked questions regarding compliance with all proposed testing requirements and timeframes for the allocation of DCD donors. These respondents suggested the Committee consider scenarios in which the lung donor testing could not be obtained or obtaining the testing would cause inefficiency. To address these challenges, commenters recommended the inclusion of language that provides flexibility for a host OPO that is unable to obtain proposed lung donor testing.

<sup>44</sup> The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.



## Compliance Analysis

### NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list,"<sup>45</sup> as well as the OPTN Final Rule, which states that the OPTN shall "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors,"<sup>46</sup> and that "An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital".<sup>47</sup> This proposal aims to provide lung transplant programs with complete and updated offer information by making changes to the deceased lung donor testing required by the host OPO.

### OPTN Strategic Plan <sup>48</sup>

**Increase Opportunities for Transplants:** Improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.

If the quality of information and completeness of data for organ offers received by lung transplant programs improves, these programs will be able to review/respond to offers more quickly and accept organs earlier in the sequence.

## Implementation Considerations

The OPTN, organ procurement organizations, and transplant hospitals that perform lung and lung-heart transplants would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of histocompatibility laboratories.

The Fiscal Impact Group (FIG) comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

The proposal was determined to have a low-medium fiscal impact on transplant hospitals, and a medium-high fiscal impact on organ procurement organizations. No fiscal impact was recorded for histocompatibility labs.

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<sup>45</sup> 42 USC §274(b)(2)(A)(ii).

<sup>46</sup> 42 CFR §121.11(a)(1)(i).

<sup>47</sup> 42 CFR §121.7 (3)(b)(3).

<sup>48</sup> OPTN Executive Committee. *Briefing to the OPTN Board of Directors on Strategic Plan 2024-2027*. June 2024. Available at: <https://optn.transplant.hrsa.gov/media/h51awrli/exec-strategic-plan-briefing-paper.pdf>.

## Organ Procurement Organizations

### *Operational Considerations*

OPOs would be required to provide additional information for deceased lung donors. Obtaining this additional lung donor information may require staff training, adjustments to existing workflows, and increased staff time spent on each lung donor offer.

### *Fiscal Impact*

This proposal is expected to have a medium-high fiscal impact on OPOs, as new testing requirements will need to be updated. These testing requirements will have a substantial impact on OPO and hospital staff, especially in understaffed and under-resourced or remote facilities.

## Transplant Programs

### *Operational Considerations*

While this proposal does not require any action from lung transplant programs, these programs will need to ensure staff are educated on the changes to the required information for deceased lung donors that must be provided by the host OPO.

### *Fiscal Impact*

This proposal is expected to have a low-medium fiscal impact. Additional education will be needed to notify staff of policy changes.

## Histocompatibility Laboratories

### *Operational Considerations*

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

### *Fiscal Impact*

There is no expected fiscal impact on histocompatibility laboratories.

## OPTN

### *Operational Considerations*

To implement this proposal, the OPTN would update the OPTN Computer System with validation capabilities. The OPTN would provide help documentation and education as needed and will update the Evaluation Plan with monitoring requirements for OPTN members.

### *Resource Estimates*

It is estimated that \$157,484 would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the policy requirements and enable monitoring of information in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*. In addition, implementation would include outreach and education to the community regarding these new requirements. It is estimated that \$39,345 would be needed for ongoing support. Ongoing support includes member support, community education, and site survey monitoring, and answering member questions as necessary. In addition, ongoing support will

include a monitoring report at the 6-month, 1-year, and 2-year timeframes. The total for implementation and ongoing support is estimated to be \$196,829.<sup>49</sup>

## Post-implementation Monitoring

### Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance.”<sup>50</sup> During site surveys of OPOs, the OPTN will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System are consistent with source documentation available at the time of entry, which may include:

- Challenge gases
- Chest CT results
- Bronchoscopy
- Chest x-ray Echocardiogram or right heart catheterization to screen for pulmonary hypertension
- Documentation of the reason any of these tests weren't able to be completed when applicable

In addition to the changes to current routine monitoring of OPTN members outlined above, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

### Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”<sup>51</sup> The impact of changes to donor testing requirements will be monitored six months post-implementation and then annually for two years, as the Committee sees fit. Each report will evaluate the following metrics, using pre and post comparisons when appropriate:

- Percent of lung offers declined due to unavailable donor testing results (refusal code 716)
- Sequence number of the final acceptor
- Number of programs notified before the final acceptor
- Number of programs notified for the first time after the final acceptor
- Allocation time (time from first electronic notification to offer acceptance)
- Utilization rate by donor type
- Non-use rate by donor type
- Percent of donors that had the following results available in OPTN Donor Data and Matching System at the time the first electronic lung offer was sent:
  - Bronchoscopy
  - Chest CT
  - Echocardiogram or right heart catheterization

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<sup>49</sup> Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

<sup>50</sup> 42 CFR §121.8(a)(7).

<sup>51</sup> 42 CFR §121.8(a)(7).

All analyses will be performed after sufficient follow-up data have accrued, which is dependent on submission of follow-up forms. The OPTN and SRTR contractors will work with the Committee to define the specific analyses requested for ongoing monitoring of each annual update. The OPTN [Equity in Access](#) and [Lung Monitoring](#) dashboards will also be used to evaluate the impact of this policy.

## Conclusion

The Committee proposes changes to lung donor testing in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and *Guidance on Requested Deceased Lung Donor Information*. Proposed policy changes include ABGs, chest CT scan, chest x-ray, sputum gram stain, and echocardiogram/RHC and proposed guidance recommendations include, fungal and bacterial culture results, chest CT scan, chest x-ray, and RHC. The goal of this proposal is to decrease the burden on transplant hospitals and OPOs by requiring essential information in each lung donor offer, so transplant programs can make timely and efficient decisions. Based on public comment feedback, the Committee made changes to provide more flexibility for OPOs, including extending the time frame for reporting ABGs and indicating that the OPO must make reasonable efforts to obtain tests that may be challenging to obtain in rare situations.

## OPTN Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 2.11.D. Required Information for Deceased Lung Donors

The host OPO must ~~provide~~ ensure that all the following additional information for all deceased lung donors ~~is obtained and provided with the lung donor offers:~~

- ~~1. Arterial blood gases and ventilator settings on 5 cm/H<sub>2</sub>O/PEEP including PO<sub>2</sub>/FiO<sub>2</sub> ratio and 4 preferably 100% FiO<sub>2</sub>, within 2 hours prior to the offer~~

1. Challenge gases as specified below. A challenge gas is defined as an arterial blood gas obtained with all of the following:

- Positive end-expiratory pressure (PEEP) of 5-8 cmH<sub>2</sub>O
- Fraction of inspiratory oxygen concentration (FiO<sub>2</sub>) 100%
- Tidal volume of 6-8 mL/kg ideal body weight (IBW)
  - i. For donors 18 years or older, and 5 feet or taller, IBW must be calculated using the National Heart, Lung, and Blood Institute (NHLBI) formula
  - ii. For donors less than 18 years old or shorter than 5 feet, IBW may be calculated using any race-neutral IBW equation.

A challenge gas must be obtained within 4 hours prior to the initial offer made by the host OPO on a lung match run.

Any challenge gases drawn after a recruitment maneuver must be drawn at least 30 minutes following that recruitment maneuver. A recruitment maneuver is defined as any procedure done to temporarily reinflate the donor lungs to assist in assessing organ quality.

- ~~1. Bronchoscopy results, if performed~~
2. Images or interpretation by a radiologist or qualified physician of a chest x-ray performed within 3 hours prior to the initial offer made by the host OPO on a lung match run.
- ~~3. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer~~
3. Sputum gram stain, with description of sputum
- ~~4. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ acceptance~~
4. Lung laterality
- ~~5. Sputum gram stain, with description of sputum~~
- ~~6. Lung laterality~~

The host OPO must make reasonable efforts to obtain the following information for all deceased lung donors. If the host OPO obtains any of the following information, it must be provided with the lung donor offer. If the host OPO cannot obtain this information, the host OPO must document the reason and make this documentation available to the OPTN on request.

- Challenge gases at least every 6-8 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery

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- Updated images or interpretation of a chest x-ray performed at least every 24 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery.
  - Bronchoscopy, if performed results. If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.
  - Chest computed tomography (CT) scan
  - HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ acceptance
  - Either echocardiogram or right heart catheterization to screen for pulmonary hypertension

#

## Guidance Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 53 **Guidance on Requested Deceased Donor Information**

54 [...]

#### 55 **Lung**

56

57 With each lung offer, the host OPO should provide all of the following information to the receiving  
58 transplant program:

- 59 • Measurement of chest circumference at the level of nipples
- 60 • Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm  
61 and transverse at the level of the diaphragm
- 62 • Mycology sputum smear Fungal and bacterial culture results
- 63 • ~~Non-contrast computed tomography (CT) scan of the chest in the following situations:~~
  - 64 ○ ~~Significant smoking history~~
  - 65 ○ ~~Chest trauma with suspected pulmonary contusions~~
  - 66 ○ ~~Documentation of suspected aspiration or evidence of it upon bronchoscopy~~

67 Additional guidance for providing information required by OPTN Policy 2.11.D Required Information for  
68 Deceased Lung Donors:

- 69 • Every attempt should be made to obtain a bronchoscopy, however, there may be certain  
70 circumstances where this is not possible, such as no qualified individual or physician available,  
71 lack of equipment in certain small donor hospitals, or DCD donor situations.
- 72 • When providing a chest computed tomography (CT) scan for lung donors, the host OPO should  
73 provide the CT within 72 hours prior to the initial offer, and the host OPO should provide images  
74 with lung windows.
- 75 • When providing chest-x ray results, images are preferred.
- 76 • If an echocardiogram is provided, the transplant program may also request a right heart  
77 catheterization if pulmonary hypertension is suspected in the donor.
- 78 • ~~The transplant program may request an echo or a Swan Ganz if suspected pulmonary~~  
79 ~~hypertension in donor~~

80

81 **Note:** Transplant programs may request access to view digital imaging remotely and request a copy of  
82 imaging on a disk

83 [...]

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (example).

## Appendix A: Post- Public Comment Changes

### 84 2.11.D. Required Information for Deceased Lung Donors

85 The host OPO must ~~provide~~ ensure that all the following additional information for all deceased lung  
86 donors ~~is obtained and provided with the lung donor offers:~~

87 1. ~~Arterial blood gases and ventilator settings on 5 cm/H2O/PEEP including PO2/FiO2 ratio and 4~~  
88 ~~preferably 100% FiO2, within 2 hours prior to the offer~~

89 1. Challenge gases as specified below. A challenge gas is defined as an arterial blood gas obtained  
90 with all of the following:

- 91 a. Positive end-expiratory pressure (PEEP) of 5-8 cmH2O  
92 b. Fraction of inspiratory oxygen concentration (FiO2) 100%  
93 c. Tidal volume of 6-8 mL/kg ideal body weight (IBW)

94 i. For donors 18 years or older, and 5 feet or taller, IBW must be calculated using  
95 the National Heart, Lung, and Blood Institute (NHLBI) formula

96 ii. For donors less than 18 years old or shorter than 5 feet, IBW may be calculated  
97 using any race-neutral IBW equation.

98 A challenge gas must be obtained within 2 4 hours prior to the initial offer made by the host  
99 OPO on a lung match run. The challenge gases must be obtained every 4 hours between the  
100 time of the initial offer and organ offer acceptance; and at least every 8 hours between organ  
101 offer acceptance and the organ recovery.

102  
103 Any challenge gases drawn after a recruitment maneuver must be drawn at least 30 minutes  
104 following that recruitment maneuver. A recruitment maneuver is defined as any procedure  
105 done to temporarily reinflate the donor lungs to assist in assessing organ quality.

106  
107 Challenge gases should not be drawn within 30 minutes of any recruitment maneuver. A  
108 recruitment maneuver is defined as any temporary increase in airway pressure during  
109 mechanical ventilation used in an attempt to open areas of collapsed alveoli or atelectasis.

110 ~~2. Bronchoscopy results, if performed~~

111 2. Images or interpretation by a radiologist or qualified physician of a chest x-ray performed within  
112 3 hours prior to the initial offer made by the host OPO on a lung match run.

113 ~~3. Chest computed tomography (CT) scan, if performed~~

114 ~~3. Sputum gram stain, with description of sputum~~

115 4. Chest x-ray images or interpretation ed by a radiologist or qualified physician within 3 hours  
116 prior to the initial offer and updated chest x-ray interpretation or images at least every 24 hours  
117 between the time of the initial offer and organ recovery

118 4. Lung laterality

119 ~~5. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52,  
120 ~~DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ acceptance~~~~

121 ~~4. Sputum gram stain, with description of sputum~~

122 5. Lung laterality

123 6. Either echocardiogram or right heart catheterization to screen for pulmonary hypertension



124 The host OPO must make reasonable efforts to obtain the following information for all deceased  
125 lung donors. If the host OPO obtains any of the following information, it must be provided with the  
126 lung donor offer. If the host OPO cannot obtain this information, the host OPO must document the  
127 reason and make this documentation available to the OPTN on request.

- 128
- 129 • Challenge gases at least every 6-8 hours between the time of the initial offer made by  
130 the host OPO on a lung match run and the organ recovery\
- 131 • Updated images or interpretation of a chest x-ray performed at least every 24 hours  
132 between the time of the initial offer made by the host OPO on a lung match run and the  
133 organ recovery. Updated chest x-ray interpretation or images at least every 24 hours  
134 between the time of the initial offer and organ recovery.
- 135 • Bronchoscopy, if performed results. If the host OPO cannot perform a bronchoscopy, it  
136 must document that it is unable to provide bronchoscopy results and the receiving  
137 transplant hospital may perform it. The lung recovery team may perform a  
138 confirmatory bronchoscopy provided unreasonable delays are avoided and deceased  
139 donor stability and time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance*  
140 *of Organ Offers* are maintained.
- 141 • Chest computed tomography (CT) scan
- 142 • HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR,  
143 DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ  
144 acceptance
- 145 • Either echocardiogram or right heart catheterization to screen for pulmonary  
146 hypertension