

## Notice of OPTN Policy and Guidance Changes

# Promote Efficiency of Lung Donor Testing

<b>Sponsoring Committee:</b>	<b>Lung Transplantation</b>
<b>Policy Affected:</b>	<b>2.11.D: Required Information for Deceased Lung Donors</b>
<b>Guidance Affected:</b>	<b>Guidance on Requested Deceased Donor Information</b>
<b>Public Comment:</b>	<b>July 31, 2024 - September 24, 2024</b>
<b>Board Approved:</b>	<b>December 2-3, 2024</b>
<b>Effective Date:</b>	<b>Pending implementation and notice to OPTN members</b>

### Purpose of Policy and Guidance Changes

These policy and guidance changes are the Committee's response to the community after hearing 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expressed concern about the quality of the organ offers they are receiving in that the information available may be outdated or incomplete. Once implemented, the policy will make changes to required lung donor testing in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and *Guidance on Requested Deceased Lung Donor Information*.<sup>1, 2</sup> The goal of these changes is to improve the efficiency of lung allocation for OPOs and lung transplant programs by making it easier for lung transplant programs to respond to organ offers.

### Proposal History

*Promote Efficiency of Lung Donor Testing* is a continuation of the Committee's ongoing efficiency work. 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.

Specifically, the Committee's efficiency efforts to date include:

- Lung offer filters, implemented January 2024<sup>3, 4</sup>
  - Allow transplant programs to apply custom-designed, program-specific, multi-factorial filters to bypass donor offers that they do not want to receive.
- New data collection in the OPTN Donor Data and Matching System, approved June 2024<sup>5</sup>
  - (1) previous sternotomies and (2) anaphylaxis to peanut and/or tree nut to aid evaluation of lung offers for lung transplant programs, as some programs rule out donors with these characteristics in combination with other criteria.

<sup>1</sup> *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*.

<sup>2</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>3</sup> "Offer Filters now available for lung allocation," <https://unos.org/news/offer-filters-now-available-for-lung-allocation/>.

<sup>4</sup> Finnie, J. & Moriarty, S. "Better organ offer screening," <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

<sup>5</sup> "Promote Efficiency of Lung Allocation," OPTN, Policy Notice, 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)

- System changes, approved June 2024<sup>6</sup>
  - “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.
  - “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.

The Committee has continued their efficiency efforts, utilizing a workgroup to ensure adequate representation from the OPO Committee. They prepared a public comment proposal for summer 2024 to change both policy and guidance regarding information obtained and provided to transplant programs when making lung offers. The proposal was supported overall during public comment. The Committee made the following changes to OPTN Policy 2.11.D:

- More flexibility for OPOs for both Donation after Brain Death (DBD) and DCD donors by:
  - Extending timeframe for reporting Arterial Blood Gases (ABGs) prior to initial offer (from within 2 hours to within 4 hours)
  - Adding language that OPOs “must make reasonable efforts to obtain”:
    - Subsequent ABGs and chest x-rays
    - Bronchoscopy
    - Chest CT scan
    - Either echocardiogram or right heart catheterization
    - OPO must document reason if information cannot be obtained
  - Added National Heart, Lung, and Blood Institute (NHLBI) formula for Ideal Body Weight (IBW) to determine ventilator settings for ABGs
  - Clarified initial offer is “initial offer made by the host OPO on a lung match run”

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<sup>6</sup> “Promote Efficiency of Lung Allocation,” OPTN, Policy Notice, 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)

## Summary of Changes

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

Test	Current	Board Approved Policy Change
Arterial blood gases (ABGs)	<ul style="list-style-type: none"> <li>Arterial blood gases and ventilator settings on 5 cm/H2O/Positive End-Expiratory Pressure (PEEP) including partial pressure of oxygen to fraction of inspired oxygen (PO<sub>2</sub>/FiO<sub>2</sub>) ratio and preferably 100% FiO<sub>2</sub>, 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 cmH<sub>2</sub>O, FiO<sub>2</sub> 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>7</sup></li> <li>Any challenge gases drawn after a recruitment maneuver must be drawn at least 30 minutes following that recruitment maneuver.</li> </ul>
Bronchoscopy	<ul style="list-style-type: none"> <li>Bronchoscopy, if performed.</li> </ul>	<ul style="list-style-type: none"> <li>Bronchoscopy results.<sup>8</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>9</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>10</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>11</sup></li> </ul>

<sup>7</sup> Application of reasonable efforts language. See Policy language.

<sup>8</sup> Application of reasonable efforts language. See Policy language.

<sup>9</sup> Ibid

<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

### Changes to Guidance: *Guidance on Requested Deceased Donor Information*

- Change “Mycology sputum smear” to “Fungal and bacterial culture results”
- Remove CT Scan language, as this test was moved to policy
- Additional guidance for providing information required by *OPTN Policy 2.11.D Required Information for Deceased Lung Donors*:
  - When providing a chest CT scan for lung donors, the host OPO should provide the CT within 72 hours prior to the initial offer, and the host OPO should provide images with lung windows.
  - When providing chest-x ray results, images are preferred.
  - If an echocardiogram is provided, the transplant program may also request a right heart catheterization if pulmonary hypertension is suspected in the donor.

## Implementation

This policy change requires OPOs to provide additional information for deceased lung donors, including more prescribed frequencies of certain tests. Obtaining this additional lung donor information may require staff training, adjustments to existing workflows, and increased staff time spent on each lung donor offer. No action is required from lung transplant programs, but additional education will be needed to notify staff of policy changes. This policy change has no impact on histocompatibility laboratories.

To implement this policy, the OPTN will need to make changes to the OPTN Computer System to support policy requirements and enable monitoring. For ongoing support, the OPTN will need to provide member support, community education, site survey monitoring, and answering member questions as necessary. Additionally, monitoring reports will be provided for the 6-month, 1-year, and 2-year timeframes

## Affected Policy and Guidance Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

### 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.

- ~~2. 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
- 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 on Requested Deceased Donor Information

[...]

### Lung

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

- Measurement of chest circumference at the level of nipples
- Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm

- ~~Mycology sputum smear Fungal and bacterial culture results~~
- ~~Non-contrast computed tomography (CT) scan of the chest in the following situations:~~
  - ~~Significant smoking history~~
  - ~~Chest trauma with suspected pulmonary contusions~~
  - ~~Documentation of suspected aspiration or evidence of it upon bronchoscopy~~

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

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

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

[...]