

Public Comment Proposal

Promote Efficiency of Lung Donor Testing

OPTN Lung Transplantation Committee

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Promote Efficiency of Lung Donor Testing

<i>Affected Policy:</i>	<i>2.11.D: Required Information for Deceased Lung Donors</i>
<i>Affected Guidance:</i>	<i>Guidance on Requested Deceased Donor Information</i>
<i>Sponsoring Committee:</i>	<i>Lung Transplantation</i>
<i>Public Comment Period:</i>	<i>July 31, 2024 - September 24, 2024</i>

Executive Summary

On March 9, 2023, the lung allocation policy transitioned to a continuous distribution framework.¹ 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. All lung candidates are prioritized using a composite allocation score (CAS), which is determined based on their medical urgency, post-transplant survival, aspects of candidate biology (blood type, CPRA, height), patient access (pediatric, prior living donor), and efficiency (proximity to donor). One of the main goals of removing the strict geographic boundaries from allocation was to reduce the waiting list mortality rate by better prioritizing medically urgent candidates across the country.² Post-implementation monitoring showed that in the first year of continuous distribution the lung transplant rate increased and the waiting list mortality rate decreased.³ Additionally, the most medically urgent candidates had the highest transplant rate and the shortest median time to transplant.⁴ 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. Over the last year, the OPTN Lung Transplantation Committee (Committee) has been working to propose policy changes and system enhancements that aim to reduce burden and increase allocation efficiency overall, including the introduction of lung offer filters and the recent approval of new data collection and system enhancements.⁵

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. Transplant programs have expressed concern about the quality of the organ offers they are receiving. Most often members state that the donor data available at the time they are expected to review and respond to offers is outdated or incomplete. Based on the increased workload for both OPOs and lung transplant programs associated with allocating lungs nationally, the Committee has reconvened the Promote Efficiency in Lung Allocation Workgroup (the Workgroup), comprised of members from the OPTN Lung Transplantation and Organ Procurement Organization (OPO) Committees, to refine solutions that improve the efficiency of lung donor testing.⁶

¹ "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, available at https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

² Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf

³ Ibid.

⁴ Ibid.

⁵ "Promote Efficiency of Lung Allocation," OPTN, Briefing Paper, available at https://optn.transplant.hrsa.gov/media/jnpd0icf/lung_efficiency_board_briefing_paper_draft.pdf.

⁶ 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.

This paper 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*.⁷ The goal of this proposal 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.

The Committee is requesting public comment feedback, including input on the following questions:

- Do community members think the proposed lung donor testing requirements strike the proper balance between requiring information transplant programs need to decide on an offer and what OPOs are reasonably able to provide?
- Do community members believe any of the proposed requirements for *OPTN Policy 2.11.D* should be moved to *Guidance on Requested Deceased Lung Donor Information*?
- Are OPOs able to provide the proposed lung donor testing results for arterial blood gasses (ABGs), chest computed tomography (CT) scans, chest x-rays, and echocardiograms/right heart catheterizations (RHCs) in the *OPTN Donor Data and Matching System*?
- Is the proposed guidance for fungal and bacterial cultures, chest CT scans, chest x-rays, and RHCs appropriate?
- Do community members support the use of the National Heart, Lung, and Blood Institute (NHLBI) Acute Respiratory Distress Syndrome (ARDS) Network formula for Ideal Body Weight (IBW), or prefer to use a different formula when calculating IBW?

The NHLBI ARDS Network formula is as follows:^{8,9}

- Male: Ideal Body Weight (IBW) (kg) = 50 + 2.3 (height (in) – 60)
- Female: IBW (kg) = 45.5 + 2.3 (height (in) – 60)
- Do patients and donor family members support modified donor testing requirements to make it easier for lung transplant programs to assess whether lungs can be accepted for their candidates?

⁷ “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/>.

⁸ “Tools”, NHLBI ARDS Network, accessed June 11, 2024, available at <http://www.ardsnet.org/tools.shtml>.

⁹ Ideal Body Weight (IBW) is also referred to as Predicted Body Weight (PBW).

Purpose

The purpose of this proposal is to promote efficiency of deceased donor lung allocation. This proposal considers 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*. The goal of this proposal 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.

Background

On March 9, 2023, the lung allocation policy transitioned to a continuous distribution framework.¹⁰ 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. This point-based system replaces the previous, classification-based system. Under the classification-based allocation system, candidates were first arranged into ordered groups (e.g., “blood type identical, within 250 nautical miles of the donor hospital”) and then, within each group, ordered by Lung Allocation Score (LAS). In contrast, continuous distribution does not use candidate groupings in allocation. Instead, all candidates are prioritized on a match run using a composite allocation score (CAS), which is calculated based on the candidate’s medical urgency, post-transplant survival, biology (blood type, CPRA, height), patient access (pediatric, prior living donor), and efficiency (proximity to donor). Each attribute of the lung CAS contributes a specific weight to the total score (**Table 1**); 90% of the CAS is determined by candidate-alone attributes and the remaining 10% is dependent on how far the transplant program is from the donor hospital.¹¹ One of the main goals of removing the strict geographic boundaries from allocation was to reduce the waiting list mortality rate by better prioritizing medically urgent candidates across the country.¹²

¹⁰ “Establish Continuous Distribution of Lungs,” OPTN, Policy Notice, available at https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

¹¹ The weight indicates how many possible points out of 100 are assigned for each attribute of the score. Each attribute is defined by a rating scale and the attribute weight is multiplied by a candidate’s rating to determine the number of points assigned. For more information, refer to A guide for calculating the lung Composite Allocation Score, available at https://optn.transplant.hrsa.gov/media/jhcppfnd/guide_to_calculating_lung_composite_allocation_score.pdf.

¹² “Lung Continuous Distribution One Year Monitoring Report,” OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

Table 1. Lung CAS Attribute Weights

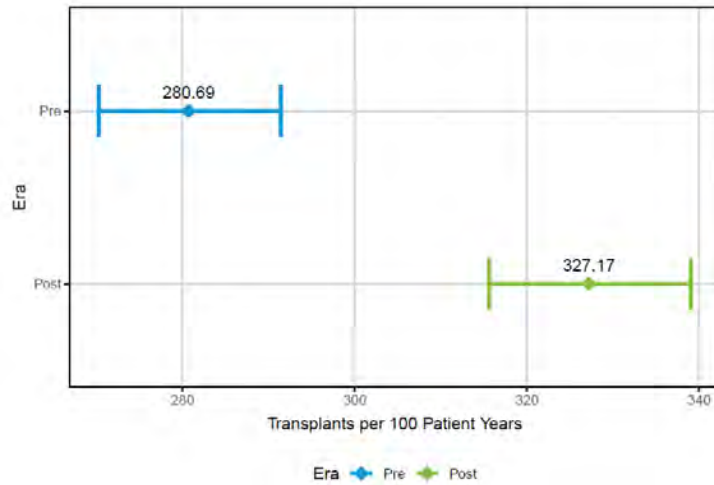
Attribute	Weight (out of 100)
Waiting list Survival (1 year)	25
Post-Transplant Survival (5 year)	25
Candidate Biology	15
Blood type (ABO)	5
CPRA	5
Height	5
Patient Access	25
Pediatric	20
Prior Living Donor	5
Placement Efficiency	10
Travel Efficiency	5
Proximity Efficiency	5
Total	100

Monitoring began upon implementation of continuous distribution on March 9, 2023. Based on the first year of data collection, compared to pre-policy era (March 09, 2022 - March 08, 2023), in the post-policy era (March 09, 2023 - March 08, 2024), the lung transplant rate increased, and the waiting list mortality rate decreased. Additionally, in the post-policy era the most medically urgent candidates had the highest transplant rate and the shortest median time to transplant.¹³

¹³ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

Figure 1 displays the 16.6% increase in the transplant rate in the post-policy era. In the pre-policy era, 281 transplants were recorded for every 100 patient years on the waitlist and in the post-policy era, this increased to 327 transplants per 100 patient years.¹⁴ While this increase in the transplant rate is promising, there has also been an increase in the transplant rate over the last several years, so this increase is likely explained more by an increase in the number of lung donors secured, rather than a response to the change in the lung allocation policy.

Figure 1. Lung Transplants per 100 Patient Years on the Waiting List by Era

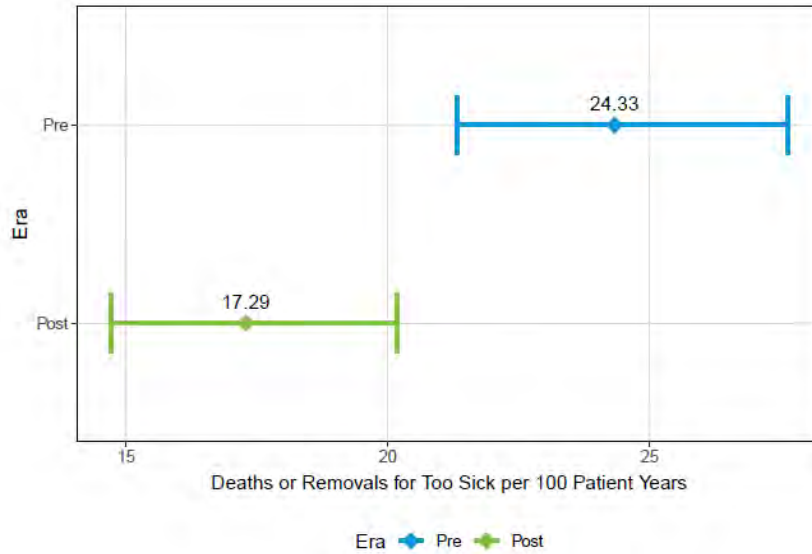


Era	N Patients	Transplants per 100 Patient Years	95% Confidence Interval
Pre	3985	280.69	(270.24, 291.43)
Post	4180	327.17	(315.62, 339.03)

¹⁴ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at, https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

Figure 2 displays the 28.9% decrease in the waiting list mortality rate in the post-policy era.¹⁵ In the pre-policy era, for every 100 patient years spent on the waitlist, 24 patients were removed for death or too sick to transplant. In the first year of continuous distribution, this number decreased to 17 removals for death or too sick to transplant per 100 patient years.

Figure 2. Deaths or Removals for Too Sick per 100 Patient Years on the Waiting List by Era

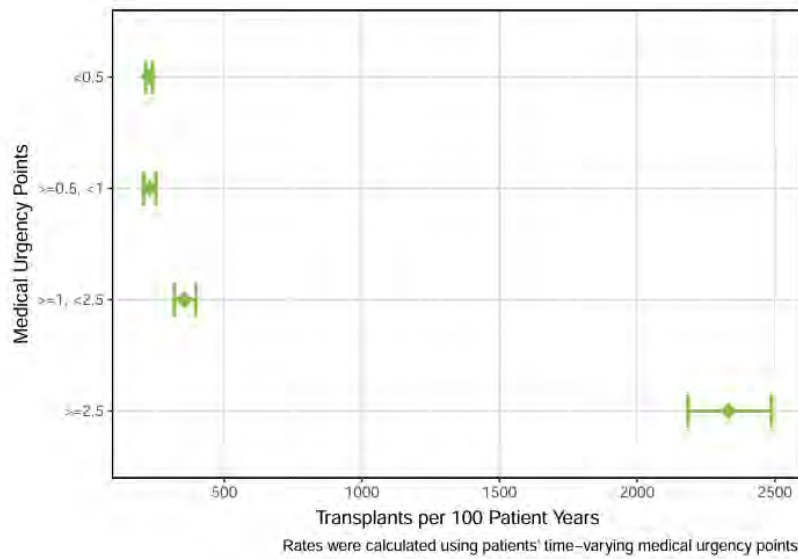


Era	N Patients	Deaths or Removals for Too Sick per 100 Patient Years	95% Confidence Interval
Pre	3985	24.33	(21.32, 27.64)
Post	4180	17.29	(14.71, 20.18)

¹⁵ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

While the goal is always to increase the number of transplants, one of the specific goals of lung continuous distribution was to increase transplants for the most medically urgent patients to reduce the number of deaths on the waiting list.¹⁶ **Figure 3** shows transplants rates in the post policy era by medical urgency groupings; in this figure, the most medically urgent candidates are defined as those with 2.5 or more medical urgency points, which corresponds to an estimated survival on the waiting list of 226 days or less. This figure reveals that under continuous distribution the most medically urgent lung candidates had a transplant rate that was 6-10 times higher than that of all other medical urgency groups.¹⁷

Figure 3. Lung Transplants per 100 Patient Years on the Waiting List by Time-Varying Medical Urgency Points in the Post Policy Era



Medical Urgency Points	N Patients	Transplants per 100 Patient Years	95% Confidence Interval
<0.5	2483	226.78	(214.85, 239.19)
>=0.5, <1	1114	228.69	(207.29, 251.70)
>=1, <2.5	869	355.65	(318.37, 396.11)
>=2.5	1153	2331.92	(2184.12, 2487.08)

^a Rates were calculated using patients' time-varying medical urgency points.

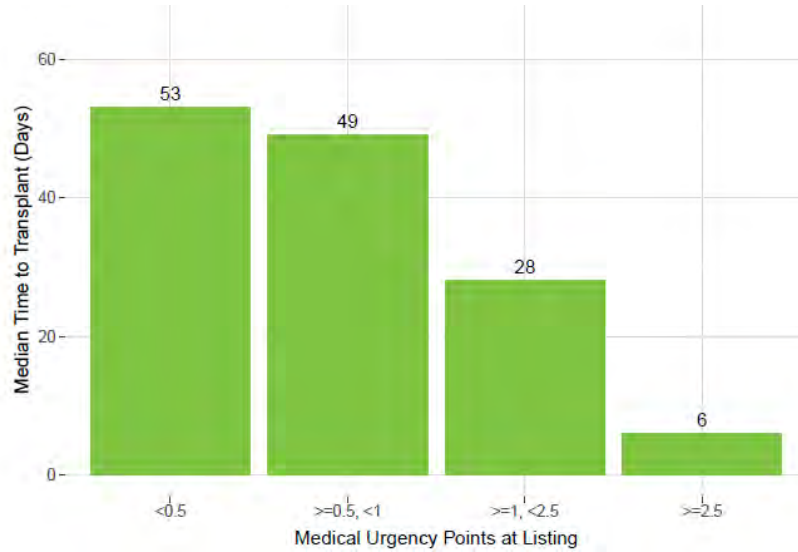
¹⁶

“Lung Continuous Distribution One Year Monitoring Report,” OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

¹⁷ Ibid.

In addition to having the highest transplant rates, **Figure 4** displays that the most medically urgent candidates (those with 2.5 or more medical urgency points) also waited the least amount of time for a transplant. Specifically, these candidates waited a median of only 6 days for a transplant, demonstrating their high access to transplant under continuous distribution.¹⁸ In contrast, candidates with the lowest medical urgency (less than 0.5 medical urgency points) waited a median of 53 days for a transplant.

Figure 4. Median Time to Transplant (Days) by Medical Urgency Points at Listing in the Post Policy Era

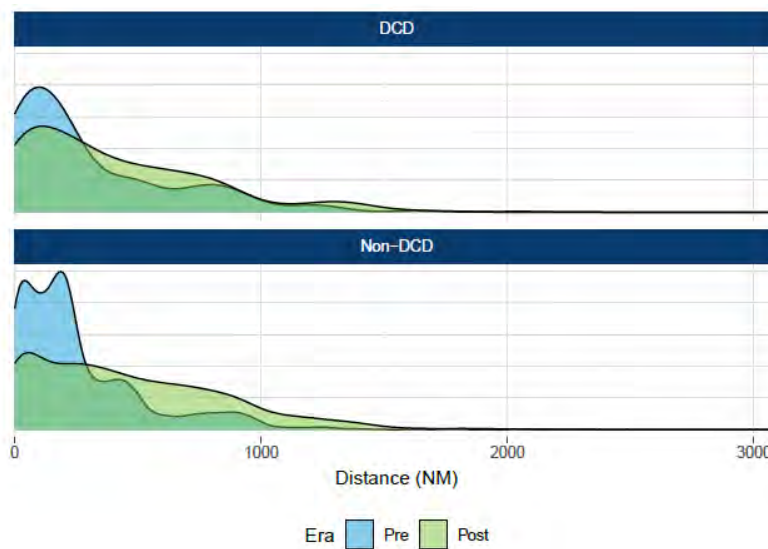


Medical Urgency Points at Listing	N Registrations	Median Time to Transplant (Days)
<0.5	1731	53
>=0.5, <1	635	49
>=1, <2.5	374	28
>=2.5	576	6

¹⁸ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

The figures presented above demonstrate how the shift to continuous distribution has decreased waiting list mortality by better prioritizing medically urgent patients. However, the shift to a national distribution system has also introduced efficiency challenges. In the simulation modeling completed before the implementation of lung continuous distribution, the Scientific Registry of Transplant Recipients (SRTR) predicted approximately an 80% increase in travel distance from the donor hospital to transplant program (from 195 nautical miles to 353 nautical miles). **Figure 5** displays the distance from the donor hospital to transplant program for lung recipients in the pre-policy era and the post-policy era. Overall, the median travel distance doubled in the first year of continuous distribution from a median of 192 nautical miles to a median of 385 nautical miles.^{19, 20} Importantly, increased distances were observed for both donation after circulatory death (DCD) and non-DCD donors, though they were slightly greater for non-DCD donors.

Figure 5. Distribution of Distance (in Nautical Miles) from Donor Hospital to Transplant Program by Era and Donor Type



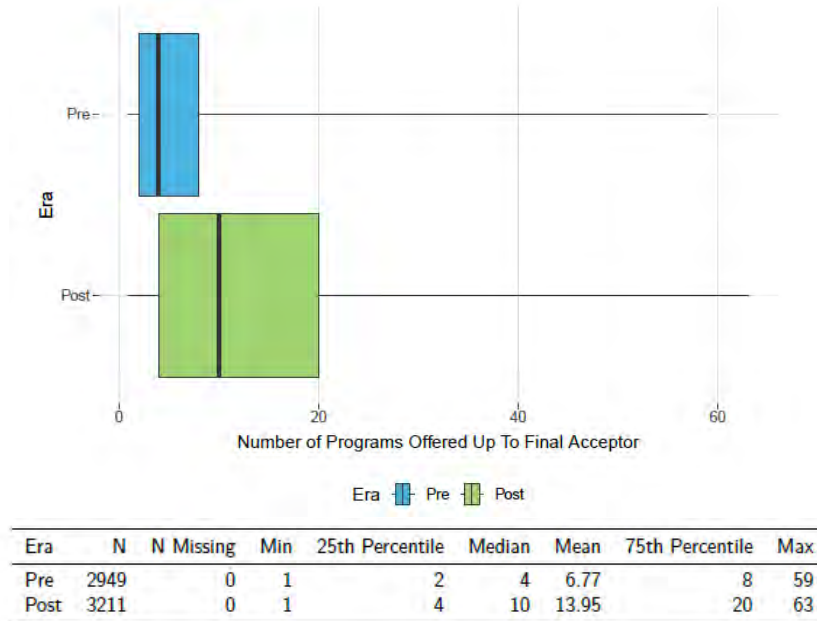
Donor Type	Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
DCD	Pre	206	0	0	52.25	176.5	304.76	467.50	1624
	Post	360	0	0	99.50	309.5	414.77	632.25	2055
Non-DCD	Pre	2535	0	0	78.00	192.0	266.15	370.00	2225
	Post	2687	0	0	155.50	397.0	471.66	718.50	2920
Total	Pre	2741	0	0	77.00	192.0	269.06	378.00	2225
	Post	3047	0	0	152.50	385.0	464.94	710.50	2920

¹⁹ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

²⁰ Analysis completed for the modified blood type rating scale implemented on September 27, 2023, estimated an additional increase in travel distance relative to the continuous distribution policy in place from March 9, 2023, to September 26, 2023, which may explain the difference in travel distance between the SRTR modeling completed ahead of implementation relative to the observed travel distance in the one-year monitoring report. See "Modify Lung Allocation by Blood Type," OPTN, available at, https://optn.transplant.hrsa.gov/media/acjasz90/lung_blood-type_bp_sep-2023.pdf.

Figure 6 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.²¹ However, under continuous distribution this metric increased to a median of 10 programs evaluating each lung offer before the final acceptor.

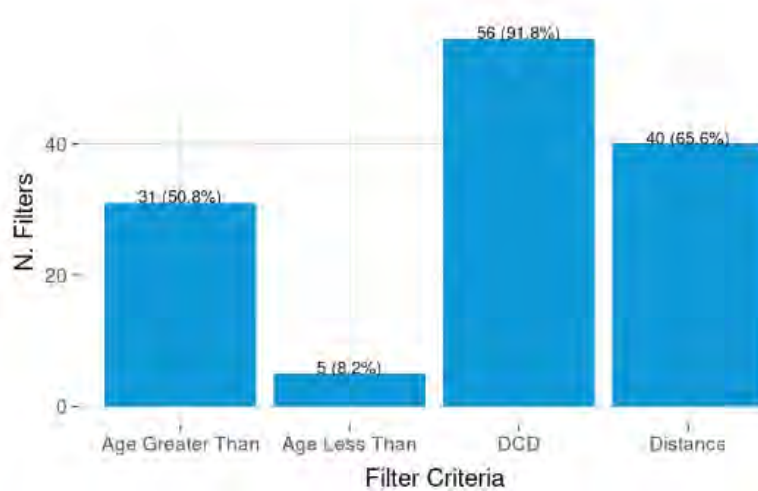
Figure 6. Distribution of the Number of Unique Programs Offered Up to the Final Acceptor on Lung Match Runs by Era



²¹ "Lung Continuous Distribution One Year Monitoring Report," OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf.

Over the last year, the Committee has been working to propose policy changes and system enhancements that aim to reduce burden and increase allocation efficiency overall. These changes include the introduction of Lung Offer Filters in January 2024.²² Offer filters allow transplant programs to apply custom-designed, program-specific, multi-factorial filters to bypass donor offers that they do not want to receive.²³ 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.²⁴ Since implementation on January 31, 2024, 26 (35%) active transplant programs have turned on at least one offer filter criteria.²⁵ In total, 61 distinct filters have been enabled across the 26 programs; **Figure 7** shows the specific types of filters that have been created. Overall, there are 56 (91.8%) filters with a DCD component, 40 (65.6%) filters with a Distance component, 31 (50.8%) filters with an Age Greater Than component, and 5 (8.2%) filters with an Age Less Than component. Across these four components the total exceeds 100% because filters can be multi-factorial and consist of multiple components.

Figure 7. Types of offer filters enabled 1/31/24- 6/13/24



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.²⁶ 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.²⁷

²² "Offer Filters now available for lung allocation," <https://unos.org/news/offer-filters-now-available-for-lung-allocation/>.

²³ Finnie, J. & Moriarty, S. "Better organ offer screening," <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

²⁴ "Optimizing Usage of Offer Filters," OPTN, Briefing Paper, available at: https://optn.transplant.hrsa.gov/media/vyonuirf/optn_osc_offer_filters_bp_june23.pdf.

²⁵ Data as of June 13, 2024.

²⁶ "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

²⁷ "Promote Efficiency of Lung Allocation," OPTN, Briefing Paper, available at https://optn.transplant.hrsa.gov/media/inpd0icf/lung_efficiency_board_briefing_paper_draft.pdf.

An approved system enhancement includes the “Bypass Bilateral and Other Lung” button, 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. Additionally, the “Opt In to Offers from Geographically Isolated Areas” enhancement has also been approved, which enables transplant programs to indicate if they would accept an organ from geographically isolated areas including Hawaii, Puerto Rico, and Alaska at the program level.²⁸

The Committee has heard that the increase in the total number of lung offers from across the country has placed additional burden on hospitals and OPOs. Transplant programs have expressed concern about the quality of the organ offers they are receiving. Most often members state that the donor data available at the time they are expected to review and respond to offers is outdated or incomplete. Based on the increased workload for both OPOs and lung transplant programs associated with allocating lungs nationally, the Committee has reconvened the Promote Efficiency in Lung Allocation Workgroup (the Workgroup), comprised of members from the OPTN Lung Transplantation and Organ Procurement Organization (OPO) Committees, to refine solutions that improve the efficiency of lung donor testing.²⁹

Overview of Proposal

The Committee proposes the changes detailed below to OPTN *Policy 2.11.D: Required Information for Deceased Lung Donors*. These changes impact the following testing:

- Arterial blood gases (ABGs)
- Chest computed tomography (CT) scan
- Chest x-ray
- Sputum gram stain
- Echocardiogram/Right heart catheterization (RHC)

Additionally, the Committee proposes updates to *Guidance on Requested Deceased Lung Donor Information*. These updates include the following tests:

- Fungal and bacterial culture results
- Chest CT scan
- Chest x-ray
- RHC

²⁸ “Promote Efficiency of Lung Allocation,” OPTN, Briefing Paper, available at https://optn.transplant.hrsa.gov/media/jnpd0icf/lung_efficiency_board_briefing_paper_draft.pdf.

²⁹ 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.

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 ABG, Chest CT, Chest x-Ray, sputum gram stain, Echocardiogram/RHC requirements. **Table 2** displays current requirements and proposed changes to changes to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*.

Table 2. Proposed Changes to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors*³⁰

Test	Current	Proposed
Arterial blood gases (ABGs)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Ventilator settings for challenge gases: (PEEP) of 5-8 cmH₂O, (FiO₂) 100%, Tidal volume of 6-8 mL/kg ideal body weight Challenge gases obtained 2 hours prior to the initial offer, at least every 4 hours between the time of the initial offer and organ offer acceptance; and at least every 8 hours between organ offer acceptance and the organ recovery Challenges gases must not be drawn within 30 minutes after any recruitment maneuver
Chest computed tomography (CT) scan	<ul style="list-style-type: none"> Included in <i>Guidance on Requested Deceased Lung Donor Information</i> 	<ul style="list-style-type: none"> Add to <i>OPTN Policy 2.11.D</i> with <i>if performed</i> specification
Chest x-ray	<ul style="list-style-type: none"> Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer 	<ul style="list-style-type: none"> Images or interpretation by a radiologist or qualified physician within 3 hours prior to the initial offer Updated chest x-ray interpretation or images at least every 24 hours between the time of the initial offer and organ recovery
Sputum gram stain	<ul style="list-style-type: none"> Sputum gram stain, with description of sputum 	<ul style="list-style-type: none"> Removal of description of sputum requirement
Echocardiogram/Right heart catheterization (RHC)	<ul style="list-style-type: none"> Echocardiogram included in <i>Guidance on Requested Deceased Lung Donor Information</i> 	<ul style="list-style-type: none"> Either echocardiogram or right heart catheterization (RHC) to screen for pulmonary hypertension

³⁰ Table 2 displays tests in *OPTN Policy 2.11.D* with proposed changes. All requirements of *OPTN Policy 2.11.D* are displayed in the *Policy Language* on page 24.

Table 3 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 2 hours prior to the first electronic notification on the lung match with the following ventilator settings:
 - PEEP of 5-8 cmH2O
 - 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.
- Echocardiogram/right heart catheterization (RHC): Echocardiogram or Angiography comments.
- Sputum gram stain: Positive, Negative, or Pending

Table 3. 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	
Heart rate	Only 1 value is required	
ABG: Date	<p style="color: red;">At least one complete record within 2 hours prior to the first electronic notification on the lung match is required in ABG / Ventilator settings where the:</p> <ul style="list-style-type: none"> • FiO2% = 100, • Vt within 6-8 mL/kg of donor’s ideal body weight, and • PEEP between 5-8 cmH2O 	
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?		UNK is a valid value
Chest x-ray comments		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

Field	Details
	first electronic notification on the lung match.
Echocardiogram or Angiography	At least one is required: <ul style="list-style-type: none"> An Echocardiogram or Angiography comments
Sputum gram stain	Pending is a valid value

Red text = new requirement

Arterial Blood Gases

Current policy requires an ABG with ventilator settings on 5 cm/H2O/ positive end-expiratory pressure (PEEP) including partial pressure of oxygen (PO2)/ Fraction of inspired oxygen (FiO2) ratio and preferably 100% FiO2, within 2 hours prior to the offer.³¹ The Committee proposes changes to the required ventilator settings and frequency of ABGs, along with timing requirements for drawing challenge gases following any recruitment maneuver.

The proposed changes to the ventilator settings for ABGs include requirements for PEEP of 5-8 cmH2O, FiO2 100%, and tidal volume of 6-8 mL/kg ideal body weight (IBW).³² The Committee defines ABGs using these ventilator settings as “challenge gases” and proposes 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 ABGs would promote accuracy in the representation of lung function and allow for observation of the PaO2/FiO2 (P/F) ratio over time.³³ 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.³⁴ 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.³⁵ 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.³⁶ The IBW formula the Committee is considering for the purposes of this policy was developed by the National Heart, Lung, and Blood Institute (NHLBI) to aid in the development of effective therapy for Acute Respiratory Distress Syndrome (ARDS).³⁷ The NHLBI ARDS Network formula is as follows:^{38, 39}

³¹ OPTN Policy: 2.11.D, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

³² 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>

³³ See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at

https://optn.transplant.hrsa.gov/media/5n4bhkzku/20240321_lung_msfinal.pdf.

³⁴ 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.

³⁵ See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at

https://optn.transplant.hrsa.gov/media/5n4bhkzku/20240321_lung_msfinal.pdf.

³⁶ 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.

³⁷ “About the NHLBI ARDS Network”, NHLBI ARDS Network, accessed June 10, available at <http://www.ardsnet.org/index.shtml>.

³⁸ “Tools”, NHLBI ARDS Network, accessed June 11, 2024. Available at <http://www.ardsnet.org/tools.shtml>.

³⁹ Ideal Body Weight (IBW) is also known as Predicted Body Weight (PBW).

- Male: IBW (kg) = 50 + 2.3 (height (in) – 60)
- Female: IBW (kg) = 45.5 + 2.3 (height (in) – 60)

The proposed changes to the frequency of challenge gas draws include retaining the current requirement for “within 2 hours of the initial offer” and the addition of requirements to obtaining challenge gases at least every 4 hours between the time of the initial offer⁴⁰ and organ offer acceptance, and at least every 8 hours between organ offer acceptance and organ recovery. The Committee defines 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.⁴¹ 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. Workgroup members recommend a requirement for an ABG 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.⁴² The Committee also proposes adding the requirement for obtaining an ABG at least every 8 hours between organ offer acceptance and the organ recovery.⁴³ The 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 manage donor lungs and identify any forthcoming issues.^{44, 45} The Committee proposes 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 gasses at the prescribed 4- hour and 8-hour interval described above is important, the Committee proposes that the system provides a “warning” to the offering OPO but does not halt allocation, as this would decrease allocation efficiency.⁴⁶

The Committee also proposes that challenge gases should not be drawn within 30 minutes after any recruitment maneuver.^{47, 48} 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.⁴⁹

Chest computed tomography (CT) scan, if performed

Currently, chest CT scan resides in *Guidance on Requested Deceased Donor Information* and includes recommendations for this test to be completed by the host OPO if the donor has any of the following:

⁴⁰ Prior to the first notification on the match.

⁴¹ 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.

⁴² Ibid.

⁴³ See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf.

⁴⁴ See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf.

⁴⁵ See Promote Efficiency in Lung Allocation workgroup meeting summary, April 23, 2024, available at https://optn.transplant.hrsa.gov/media/4feexkuu/20240423_lungefficiencywg_ms.pdf.

⁴⁶ Ibid.

⁴⁷ See Promote Efficiency in Lung Allocation workgroup meeting summary, February 13, 2024, available at https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf.

⁴⁸ 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>

⁴⁹ See OPTN Lung transplantation Committee meeting summary, May 23, 2023, available at <https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/>.

- Significant smoking history
- Chest trauma with suspected pulmonary contusions
- Documentation of suspected aspiration or evidence of it upon bronchoscopy.

The Committee proposes removing chest CT scan recommendations from guidance and adding this test to policy. 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.^{50, 51} 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.⁵² 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 realizes 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 the lungs altogether.⁵³ 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.⁵⁴ Structuring the policy in this way will not prevent OPOs from sending offers when no chest CT scan is available.

Chest x-ray

Currently, policy requires a chest x-ray interpretation by a radiologist or qualified physician within three hours prior to the offer. The Committee proposes adding images as an option to the requirement within three hours prior to the initial offer and including 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. The Workgroup 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.⁵⁵ 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.⁵⁶ The Committee proposes that the images or interpretation by a radiologist or qualified physician within 3 hours prior to the initial offer 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 with data

⁵⁰ See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf.

⁵¹ 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>.

⁵² Ibid.

⁵³ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf

⁵⁴ See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf.

⁵⁵ Ibid.

⁵⁶ Ibid.

submitted to the OPTN Donor Data and Matching System. While providing updated chest x-rays at least every 24 hours is important, the Committee proposes that the system provides a “warning” to the offering OPO but does not halt allocation, as this would decrease allocation efficiency.

Sputum Gram Stain

Currently, Policy 2.11.D requires a sputum gram stain, with description of sputum. The Committee determined that the requirement for “description of sputum” should be removed, as historically this information has not been crucial when making decisions about a lung organ offer.⁵⁷

Echocardiogram/Right Heart Catheterization

Currently, recommendations for echocardiogram reside 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.⁵⁸ The Committee proposes 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 this oftentimes this specific type of RHC cannot be done due to limited staff trained to perform this procedure.⁵⁹ 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.⁶⁰ The addition of echocardiogram to policy would require this information to be available at the time of the offer, thereby increasing allocation efficiency.⁶¹ Members discussed that an echocardiogram is typically used to assess if the donor has PH. An RHC is more invasive procedure, but sometimes needed to identify pulmonary hypertension in a donor if the echocardiogram results are inconclusive.⁶² 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.⁶³

⁵⁷ See Promote Efficiency in Lung Allocation workgroup summary, May 21, 2023, available at <https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/>.

⁵⁸ “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/>.

⁵⁹ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁶⁰ OPTN Policy 2.11.D: *Required Information for Deceased Heart Donors*.

⁶¹ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁶² See Promote Efficiency in Lung Allocation workgroup summary, April 23, 2024, available at https://optn.transplant.hrsa.gov/media/4feexkuu/20240423_lungefficiencywg_ms.pdf.

⁶³ Ibid.

Updates to *Guidance on Requested Deceased Lung Donor Information*

The Committee proposes 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. **Table 4** displays current and proposed changes to *Guidance on Requested Deceased Lung Donor Information*.

Table 4. Proposed Changes to *Guidance on Requested Deceased Lung Donor Information*⁶⁴

Test name	Current	Proposed
Mycology sputum smear	<ul style="list-style-type: none"> • Mycology sputum smear 	<ul style="list-style-type: none"> • Change name of Mycology sputum smear to Fungal culture • Add bacterial culture results
Additional guidance for providing information required by OPTN Policy 2.11.D Required Information for Deceased Lung Donors:		<ul style="list-style-type: none"> • When providing chest- x ray results, images are preferred. • 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. • If an echocardiogram is provided, the transplant program may also request a right heart catheterization if pulmonary hypertension is suspected in the donor.

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.⁶⁵ Committee members also agreed that “bacterial culture results” should also be added to this guidance.⁶⁶ 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.⁶⁷

Chest CT scan

Currently, recommendations for Chest CT Scan reside in guidance.⁶⁸ As explained previously, these recommendations will be removed from guidance and chest CT scan will be added to OPTN Policy 2.11.D with an “if performed” specification.⁶⁹ In guidance, the Committee recommends that the host OPO

⁶⁴ Table 4 displays *Guidance on Requested Deceased Lung Donor Information* with proposed changes. All *Guidance on Requested Deceased Lung Donor Information* is displayed in the Policy Language on page 25.

⁶⁵ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁶⁶ See Promote Efficiency in Lung Allocation workgroup summary, May 21, 2023, available at <https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/>.

⁶⁷ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁶⁸ “*Guidance on Requested Deceased Donor Information*”, OPTN, June 2018, available at <https://optn.transplant.hrsa.gov/policies-by-laws/public-comment/guidance-on-requested-deceased-donor-information/>.

⁶⁹ See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf.

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.⁷⁰ 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.⁷¹ 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.⁷² Windowing is the process in which 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.⁷³

Chest x-ray

As explained previously, the Committee proposes adding images as an option to the chest x-ray requirement within 3 hours of the initial offer and including a requirement for updating chest x-ray or interpretation at least every 24 hours.⁷⁴ The Committee also proposes 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.⁷⁵

Right Heart Catheterization

Currently, RHC does not reside in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* or guidance on requested lung deceased donor information. As explained previously, the Committee proposes requiring the host OPO to provide either an echocardiogram or RHC in Policy 2.11.D.⁷⁶ 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.⁷⁷

⁷⁰ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁷¹ Ibid.

⁷² See OPTN Lung transplantation Committee meeting summary, March 21, 2024, available at https://optn.transplant.hrsa.gov/media/5n4bhkku/20240321_lung_msfinal.pdf.

⁷³ "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>.

⁷⁴ See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf.

⁷⁵ See Promote Efficiency in Lung Allocation workgroup summary, February 13, 2024, available at https://optn.transplant.hrsa.gov/media/budhzkne/20240213_lungefficiencywg_msfinal.pdf.

⁷⁶ See Promote Efficiency in Lung Allocation workgroup summary, March 12, 2024, available at https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf.

⁷⁷ See Promote Efficiency in Lung Allocation workgroup summary, April 23, 2024, available at https://optn.transplant.hrsa.gov/media/4feexkuu/20240423_lungefficiencywg_ms.pdf.

NOTA and Final Rule Analysis

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,"⁷⁸ 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,"⁷⁹ 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".⁸⁰ 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.

Implementation Considerations

Member and OPTN Operations

This proposal is expected to affect the operations of organ procurement organizations, transplant hospitals, and the OPTN, but is not expected to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

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.

Operations affecting Transplant Hospitals

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.

Operations affecting Histocompatibility Laboratories

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

Operations affecting the OPTN

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.

Potential Impact on Select Patient Populations

This proposal is intended to improve the efficiency of the organ offer and acceptance process for lung transplant programs and OPOs so that donor lungs can more quickly be placed with the appropriate lung transplant candidate. This proposal is not expected to have a disproportionate impact on any select populations of lung transplant candidates.

⁷⁸ 42 USC §274(b)(2)(A)(ii).

⁷⁹ 42 CFR §121.11(a)(1)(i).

⁸⁰ 42 CFR §121.7 (3)(b)(3).

Projected Fiscal Impact

The Fiscal Impact Advisory Group, 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.

Projected Impact on Organ Procurement Organizations

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.

Projected Impact on Transplant Hospitals

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

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact on Histocompatibility Laboratories.

Projected Impact on the OPTN

It is estimated that 1,677 hours (\$120,671) 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 600 hours (\$40,802) would be needed for ongoing support. Ongoing support includes ongoing 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 and 2-year timeframes.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance.”⁸¹ 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:

⁸¹ 42 CFR §121.8(a)(7).

- Challenge gasses and associated timing requirements as specified
- Chest CT results, if performed
- Chest x-ray and associated timing requirements as specified
- Echocardiogram or right heart catheterization to screen for pulmonary hypertension

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.”⁸² 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

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 burden on transplant hospitals and OPOs by requiring essential information in each lung donor offer, so transplant programs can make timely and efficient decisions.

⁸² Ibid.

Considerations for the Community

- Do community members think the proposed lung testing requirements strike the proper balance between requiring information transplant programs need to decide on an offer and what OPOs reasonably able to provide?
- Do community members believe any of the proposed requirements for OPTN Policy 2.11.D be moved to *Guidance on Requested Deceased Lung Donor Information*?
- Are OPOs able to provide the proposed lung donor testing results for ABGs, chest CT scans, chest x-rays, and echocardiograms/RHCs throughout allocation in the OPTN Donor Data and Matching System?
- Is the proposed guidance for fungal and bacterial cultures, chest CT scans, chest x-rays, and RHCs appropriate recommendations?
- Do community members support the use of the NHLBI ARDS Network formula for IBW or prefer to use a different formula when calculating IBW?
The NHLBI ARDS Network formula is as follows:
 - Male: $PBW \text{ (kg)} = 50 + 2.3 \text{ (height (in)} - 60)$
 - Female: $PBW \text{ (kg)} = 45.5 + 2.3 \text{ (height (in)} - 60)$
- Do patients and donor family members support modified donor testing requirements to make it easier for lung transplant programs to assess whether lungs can be accepted for their candidates?

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 all the following additional information for all deceased lung donor offers:

- ~~1. 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~~
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 cmH2O
 - Fraction of inspiratory oxygen concentration (FiO2) 100%
 - Tidal volume of 6-8 mL/kg ideal body weight

Challenge gases must be obtained within 2 hours prior to the initial offer. The challenge gases must be obtained every 4 hours between the time of the initial offer and organ offer acceptance; and at least every 8 hours between organ offer acceptance and the organ recovery.

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

2. Bronchoscopy results, if performed
3. Chest computed tomography (CT) scan, if performed
4. Chest x-ray ~~images or interpretation~~ ed by a radiologist or qualified physician within 3 hours prior to the initial offer and updated chest x-ray interpretation or images at least every 24 hours between the time of the initial offer and organ recovery
5. 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
6. Sputum gram stain, ~~with description of sputum~~
7. Lung laterality
8. Either echocardiogram or right heart catheterization to screen for pulmonary hypertension

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 the time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.

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.

Guidance on Requested Deceased Donor Information

36 [...]

37 Lung

38

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

- 41 • Measurement of chest circumference at the level of nipples
- 42 • Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm
43 and transverse at the level of the diaphragm
- 44 • ~~Mycology sputum smear~~ Fungal and bacterial culture results
- 45 • ~~Non-contrast computed tomography (CT) scan of the chest in the following situations:~~
 - 46 ○ ~~Significant smoking history~~
 - 47 ○ ~~Chest trauma with suspected pulmonary contusions~~
 - 48 ○ ~~Documentation of suspected aspiration or evidence of it upon bronchoscopy~~

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

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

62

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

65 [...]

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