

## *Public Comment Proposal*

# Promote Efficiency of Lung Allocation

*OPTN Lung Transplantation Committee*

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## Contents

Executive Summary	2
Purpose	4
Background	4
Overview of Proposal	12
Potential System Enhancements	15
Potential Areas for Further Development	17
NOTA and OPTN Final Rule Analysis	19
Implementation Considerations	20
Post-implementation Monitoring	21
Conclusion	21
Considerations for the Community	22
Proposed Changes to Data Collection	23
Appendix A: Data Definitions	24

# Promote Efficiency of Lung Allocation

*Affected Data Collection:* OPTN Donor Data and Matching System  
*Sponsoring Committee:* Lung Transplantation  
*Public Comment Period:* January 23, 2024 – March 19, 2024

## Executive Summary

Continuous distribution of lungs was implemented on March 9, 2023.<sup>1</sup> This continuous allocation system was designed to promote access to transplant for certain populations of lung candidates, including those who are very medically urgent or who face substantial challenges finding a match due to biological traits. Simulation modeling performed ahead of implementation estimated that median travel distance would increase because of the allocation changes<sup>2</sup> and monitoring data shows that median travel distance has increased precisely with what was anticipated based on the modeling.<sup>3</sup>

The reordering of allocation priority and corresponding increase in travel distance appears to have advanced progress towards the stated goals of the continuous distribution system, particularly reduced waiting list mortality and access to transplant for the most medically urgent candidates.<sup>4</sup> The most medically urgent candidates receive lung offers from farther away than they would have in the former allocation system, allowing them to match with a donor more quickly. Lung transplants have increased following implementation of continuous distribution relative to the former allocation system, while national utilization rates and non-use rates have remained stable. However, the changes have redistributed organ offer patterns across the country and complicated the logistics of allocation. This has introduced new inefficiencies into allocation as demonstrated by upward trends in the median transplant center number at acceptance; median offer number at acceptance; and the number of transplant centers notified per lung donor.<sup>5</sup>

The OPTN plans to release lung offer filters in early 2024 to assist lung transplant programs in managing their offer volume and to improve allocation efficiency for organ procurement organizations (OPOs). This proposal provides an overview of lung offer filters and proposes new data collection in the OPTN Donor Data and Matching System to aid evaluation of lung offers. This proposal also describes potential areas for further development, including two potential system enhancements.

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

- Do patients and donor family members support efforts to improve the efficiency of lung allocation and place donor lungs more rapidly with a potential transplant recipient?
- Do lung transplant programs support the proposed new data fields to assist in evaluating offers?

<sup>1</sup> “Establish Continuous Distribution of Lungs,” OPTN, Policy Notice, accessed October 2, 2023, [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).

<sup>2</sup> Andrew Wey, Jon Miller, Melissa Skeans et al., “Continuous distribution simulations for lung transplant: Round 2,” SRTR, May 28, 2021, accessed November 11, 2023, [https://optn.transplant.hrsa.gov/media/4646/lu2021\\_01\\_cont\\_distn\\_report\\_final.pdf](https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf).

<sup>3</sup> Samantha Weiss and Chelsea Weibel, “Lung Continuous Distribution Six Month Monitoring Report,” OPTN, October 27, 2023, accessed November 11, 2023, [https://optn.transplant.hrsa.gov/media/4feooi1h/data\\_report\\_lung\\_cd\\_6month\\_20231027.pdf](https://optn.transplant.hrsa.gov/media/4feooi1h/data_report_lung_cd_6month_20231027.pdf).

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

- For adult and pediatric lung transplant programs, what additional donor information or offer filters would be useful for your program?
- Do OPOs anticipate any challenges with reporting the additional donor data?
- Are the proposed data definitions easy to understand or is additional clarification needed regarding the intent of the data collection?
- Do OPOs and lung transplant programs support the potential system enhancement to add a “Bypass bilateral and other lung” button to bypass candidates who would not accept an offer if only a single lung is available?
- Do lung transplant programs support the potential system enhancement to opt in to offers from geographically isolated areas (Hawaii, Alaska, and Puerto Rico)?
  - Would transplant programs support adding this feature for other organs as well as lung?
- How else might the OPTN improve the efficiency of lung allocation for both transplant programs and OPOs?

## Purpose

The purpose of this proposal is to promote efficiency of lung allocation. This proposal would add new data collection in the OPTN Donor Data and Matching System to aid evaluation of lung offers.

Additionally, this proposal provides an overview of planned and potential system enhancements that are intended to make it easier for lung transplant programs to say “yes” to organ offers and to facilitate timely placement of organs by organ procurement organizations (OPOs). Specifically, this proposal:

- Provides an overview of lung offer filters (slated for release in early 2024)
- Describes potential system enhancements that would:
  - Allow OPOs to quickly bypass candidates who cannot accept an offer if only a single lung is available from a donor
  - Enable transplant programs to opt in to receiving offers from geographically isolated areas outside of the “maximum miles the organ or recovery team will travel” specified in donor acceptance criteria
- Requests community feedback on these system enhancements and other potential changes that would make the allocation process more efficient for transplant programs and OPOs

## Background

Continuous distribution of lungs was implemented on March 9, 2023.<sup>6</sup> This continuous allocation system was designed to promote access to transplant for medically urgent lung candidates; lung candidates who face challenges finding a match due to biological traits (height, sensitization, and blood type); lung candidates who warrant special consideration for access to transplant (pediatric candidates and prior living donors); and lung candidates who are expected to live longer after transplant. The lung composite allocation score (CAS) provides points to lung candidates within these categories, as shown in **Table 1**.<sup>7</sup> The lung CAS also assigns points for placement efficiency based on the distance between the donor hospital and the transplant hospital where the candidate is registered, though the weight assigned to placement efficiency is much less in the continuous distribution system than in the former classification-based system.<sup>8</sup> Candidates who are located far from the donor hospital but have a high CAS based on other factors (medical urgency, biological disadvantages, etc.) have higher priority for transplant in the continuous distribution allocation system relative to the former allocation system.

<sup>6</sup> “Establish Continuous Distribution of Lungs,” OPTN, Policy Notice, accessed October 2, 2023, [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).

<sup>7</sup> 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](https://optn.transplant.hrsa.gov/media/jhcppfnd/guide_to_calculating_lung_composite_allocation_score.pdf).

<sup>8</sup> Proximity was estimated to account for 81% of the score in the former allocation system, as opposed to the 10% weighting in the lung CAS. See Darren E. Stewart, Dallas W. Wood, James B. Alcorn et al., “A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S.,” *BMC Medical Informatics and Decision Making* 21 no. 8 (2021): 1-11, <https://doi.org/10.1186/s12911-020-01377-7>. The Committee discussed the analysis on October 8, 2020. See [https://optn.transplant.hrsa.gov/media/4144/20201008\\_lung\\_meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/4144/20201008_lung_meeting-summary.pdf).

**Table 1. Lung CAS Attribute Weights**

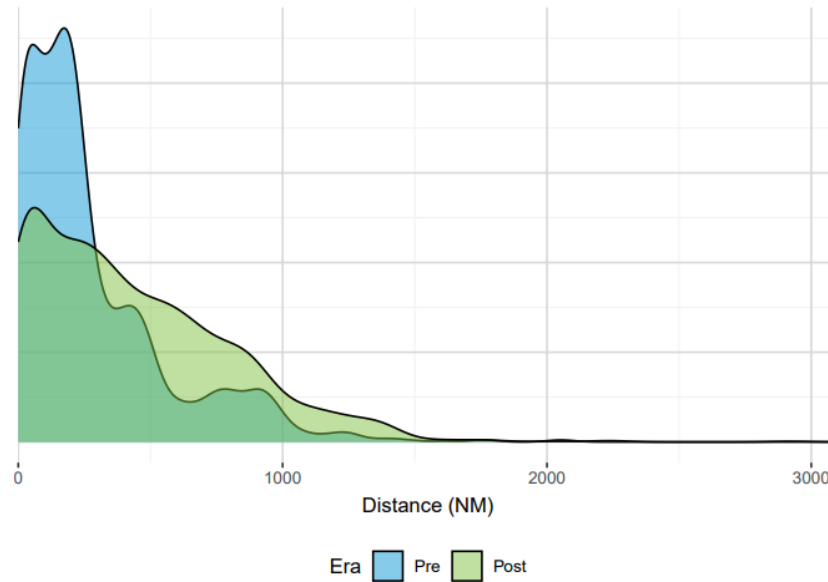
Attribute	Weight (out of 100)
Waiting list Survival (1 year)	25
Post-Transplant Survival (5 year)	25
Candidate Biology	15
Blood type (ABO)	5
CPRA	5
Height	5
Patient Access	25
Pediatric	20
Prior Living Donor	5
Placement Efficiency	10
Travel Efficiency	5
Proximity Efficiency	5
<b>Total</b>	<b>100</b>

As a result, the order in which candidates appear on the match run is determined less by the location of a candidate's transplant program than in previous allocation system since more weight is placed on other factors. Simulation modeling performed ahead of implementation estimated that median donor-to-recipient distance would increase from 195 nautical miles to 353 nautical miles<sup>9</sup> because of these changes, and monitoring data from the first six months of lung continuous distribution shows that median distance between the donor hospital and the transplant center has increased precisely with what was anticipated based on the modeling, from 195 to 353 nautical miles (**Figure 1**).<sup>10</sup>

<sup>9</sup> Andrew Wey, Jon Miller, Melissa Skeans et al., "Continuous distribution simulations for lung transplant: Round 2," SRTR, May 28, 2021, accessed November 11, 2023, [https://optn.transplant.hrsa.gov/media/4646/lu2021\\_01\\_cont\\_distn\\_report\\_final.pdf](https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf).

<sup>10</sup> Samantha Weiss and Chelsea Weibel, "Lung Continuous Distribution Six Month Monitoring Report," OPTN, October 27, 2023, accessed November 11, 2023, [https://optn.transplant.hrsa.gov/media/4fe001h/data\\_report\\_lung\\_cd\\_6month\\_20231027.pdf](https://optn.transplant.hrsa.gov/media/4fe001h/data_report_lung_cd_6month_20231027.pdf).

**Figure 1. Distribution of Distance (in Nautical Miles) from Donor Hospital to Transplant Program for Lung Transplants by Era<sup>11</sup>**



Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1387	0	0	78	195	279.35	391.0	2069
Post	1543	0	0	129	353	433.55	662.5	2920

The changes in the allocation score and corresponding increase in travel distance appears to have advanced progress towards the stated goals of the continuous distribution system, particularly reduced waiting list mortality (26.1% decrease) and prioritized access to transplant for the most medically urgent candidates (median waiting time of 6 days for candidates with a medical urgency score at listing of 2.5 points or greater).<sup>12</sup> Lung-alone transplants have increased by 11.2% following implementation of continuous distribution relative to the former allocation system, while utilization rates and non-use rates have remained stable. However, the reordering of allocation priority has redistributed organ offer patterns across the country, which has complicated the logistics of allocation<sup>13</sup> and introduced new inefficiencies into the system. In the former system, OPOs first offered organs from donors at least 18 years old to candidates located at transplant programs within 250 nautical miles of the donor hospital.<sup>14</sup> In the current system, candidates from transplant programs across the country may appear at the top of the match run, which means OPOs may be making offers to many different transplant programs. The median transplant center number at acceptance increased from four to ten (**Figure 2**), meaning that more lung transplant programs are evaluating and responding to organ offers before the lungs are placed with a potential transplant recipient.

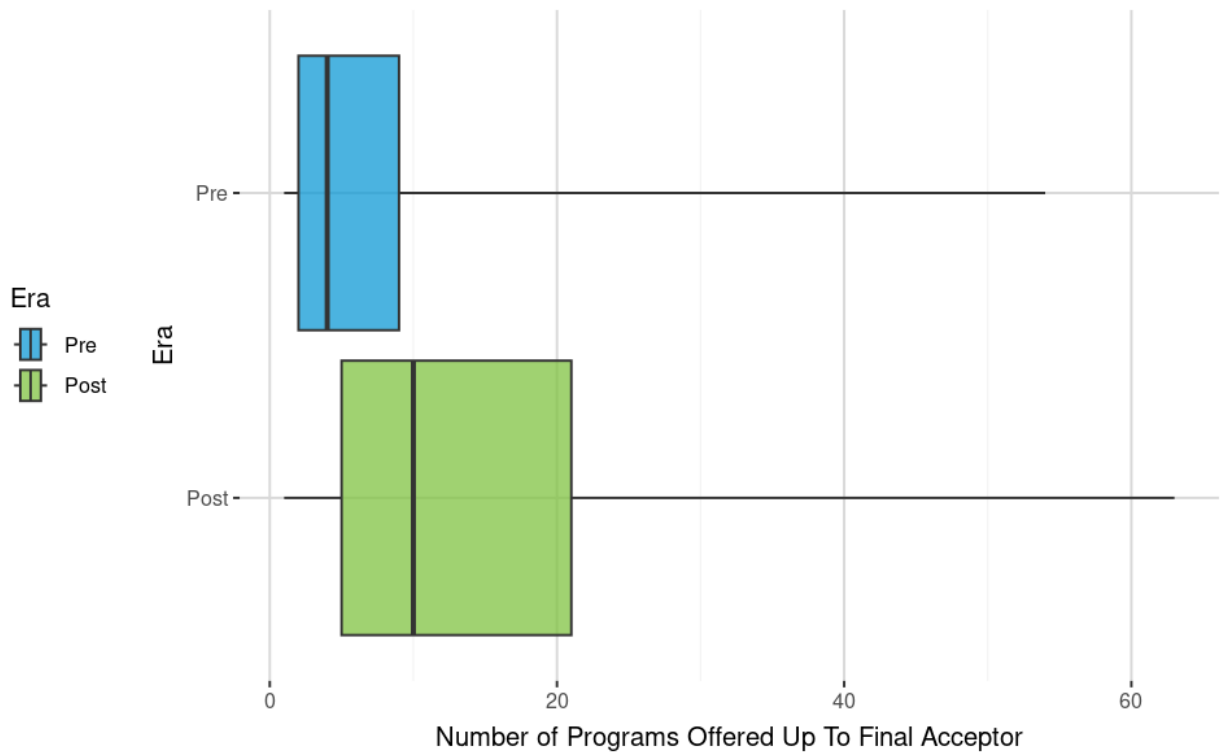
<sup>11</sup> The pre-policy era was September 6, 2022, to March 8, 2023, and the post-policy era was March 9, 2023, to September 8, 2023.

<sup>12</sup> Samantha Weiss and Chelsea Weibel, “Lung Continuous Distribution Six Month Monitoring Report,” OPTN, October 27, 2023, accessed November 11, 2023, [https://optn.transplant.hrsa.gov/media/4fe0011h/data\\_report\\_lung\\_cd\\_6month\\_20231027.pdf](https://optn.transplant.hrsa.gov/media/4fe0011h/data_report_lung_cd_6month_20231027.pdf).

<sup>13</sup> Per OPTN data presented to the OPTN Promote Efficiency of Lung Allocation Workgroup on June 23, 2023. Meeting summary accessed October 4, 2023, available [https://optn.transplant.hrsa.gov/media/xl2ds0ji/20230623\\_promote-efficiency-ms.pdf](https://optn.transplant.hrsa.gov/media/xl2ds0ji/20230623_promote-efficiency-ms.pdf).

<sup>14</sup> “Eliminate the Use of DSAs in Thoracic Distribution,” OPTN, Policy Notice, accessed December 12, 2023, [https://optn.transplant.hrsa.gov/media/3003/thoracic\\_policynotice\\_201906.pdf](https://optn.transplant.hrsa.gov/media/3003/thoracic_policynotice_201906.pdf).

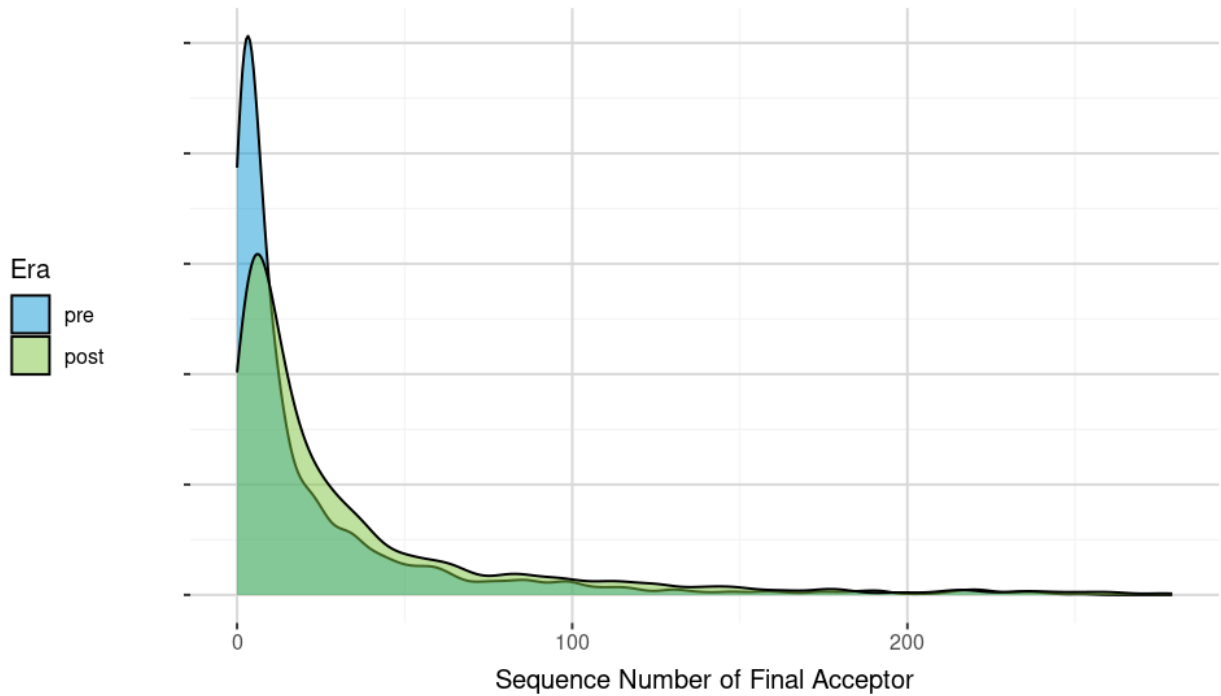
**Figure 2. Distribution of the Number of Unique Programs Offered Up to the Final Acceptor on Lung Match Run by Era**



Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1506	0	1	2	4	7.02	9	54
Post	1676	0	1	5	10	14.69	21	63

The median offer number at acceptance has also increased from eight to fifteen (**Figure 3**). The median offer number at acceptance refers to the offer number for the potential transplant recipient who accepted the organ. This means that lung offers are also being evaluated for more candidates before the lungs are placed with potential transplant recipients.

**Figure 3. Distribution of the Sequence Number of the Final Acceptor on Lung Match Run by Era**

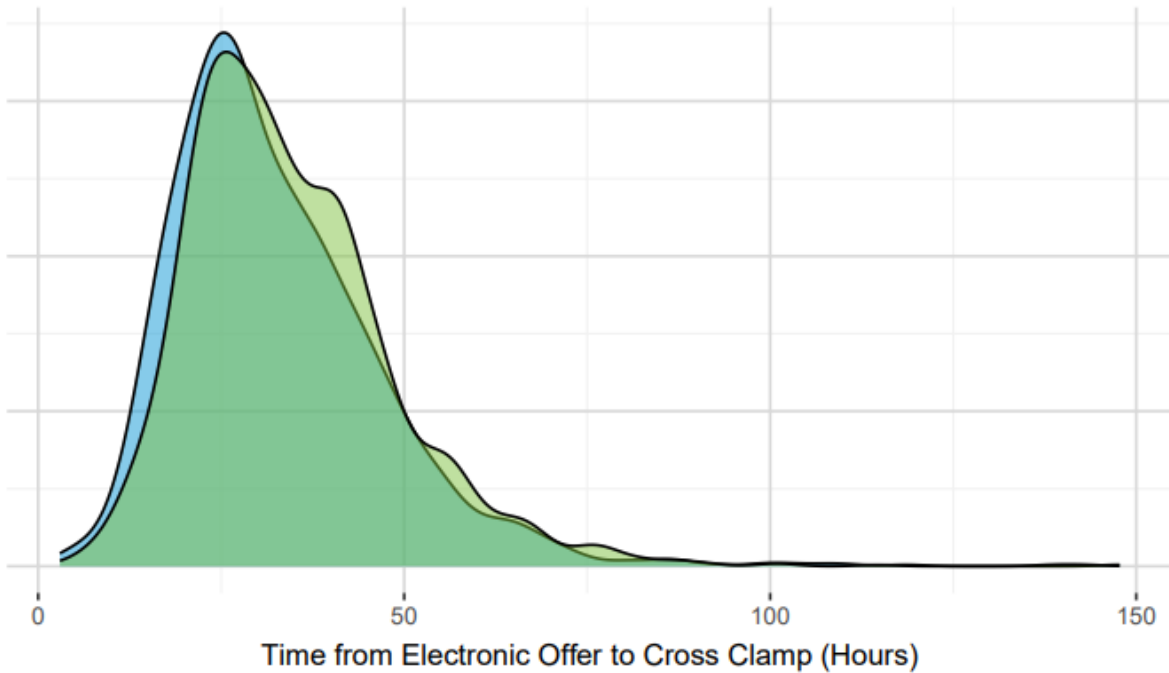


Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1506	0	1	2.25	8	24.28	25	359
Post	1676	0	1	6.00	15	39.73	41	550

Per OPTN Policy 5.6.B Time Limit for Review and Acceptance of Organ Offers, a transplant hospital has one hour to respond to an initial organ offer with a provisional yes or organ offer refusal. Once the OPO has provided all the deceased donor information required by OPTN policies, the transplant hospital for the primary potential transplant recipient must respond to the OPO within an hour with either an organ offer acceptance or refusal. All other transplant hospitals who entered a provisional yes must respond with an acceptance or refusal within 30 minutes of receiving notification that their potential transplant recipient has become primary. Accordingly, each additional offer prior to final acceptance may increase the overall allocation time. In fact, the median time from the first electronic offer to cross clamp increased in the first six months of continuous distribution of lungs by about 2.5 hours (Figure 4). The number of offers prior to final acceptance may have contributed to this increased allocation time, but given the longer median travel distance, the increased allocation time may also reflect additional time needed to coordinate logistics between the time of offer acceptance and the time of organ recovery.



**Figure 4. Time from First Electronic Offer to Cross Clamp (Hours) for All Lungs Recovered by Era**



Era ■ Pre ■ Post

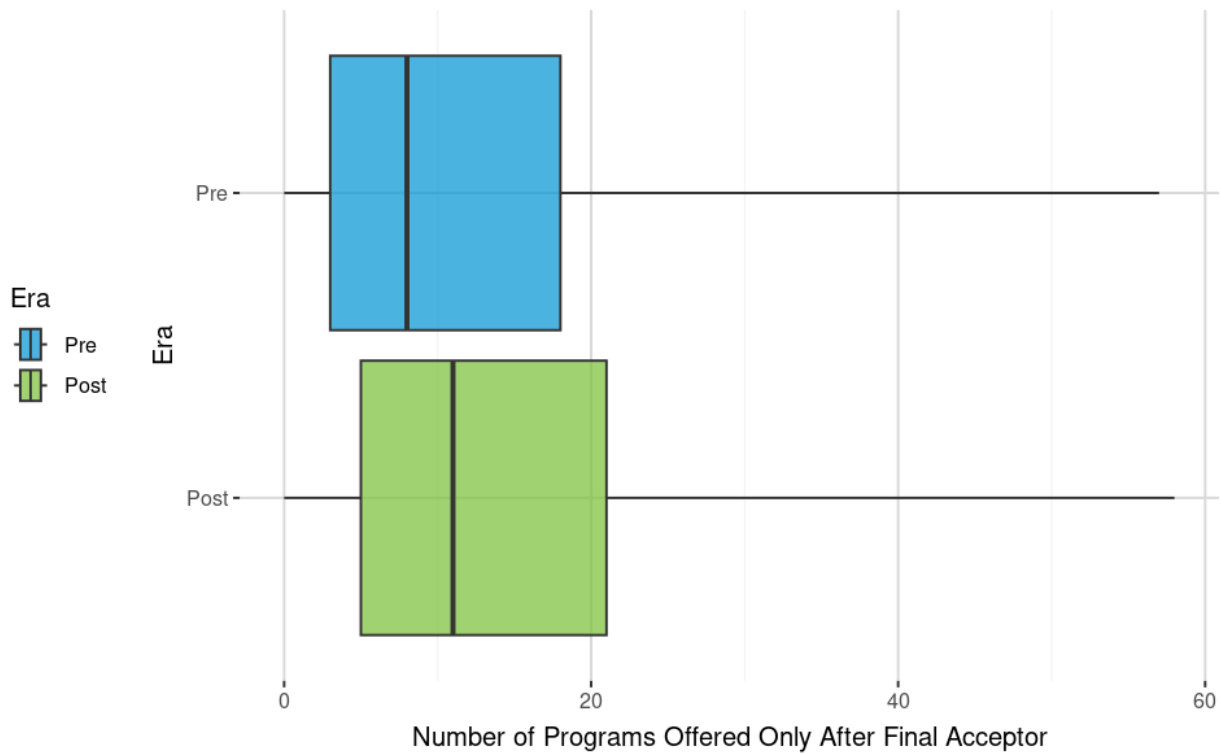
There were 5 values not yet reported at the time of this report's creation. This report was created before the 90 day data lag allowed by the OPTN had passed.

Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1559	1	2.98	22.67	29.66	32.53	39.92	147.73
Post	1740	4	3.42	24.42	32.14	34.56	41.88	143.01

<sup>a</sup> There were 5 values not yet reported at the time of this report's creation. This report was created before the 90 day data lag allowed by the OPTN had passed.

The median number of new transplant programs notified after the final acceptor has also increased from eight to eleven (**Figure 5**), which means that more transplant programs may be expending time and resources evaluating organ offers for which they never receive a primary offer.

**Figure 5. Distribution of the Number of Unique Programs Offered Only After the Final Acceptor on Lung Match Run by Era**



Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1506	0	0	3	8	12.37	18	57
Post	1676	0	0	5	11	14.13	21	58

Based on these findings and feedback from OPTN members, the OPTN Lung Transplantation Committee (Committee) sponsored the Promote Allocation of Lung Efficiency Workgroup (Workgroup), comprised of members of the Lung and OPTN Organ Procurement Organization Committees, to review data on lung allocation and discuss potential solutions to address inefficiencies.

## Lung Offer Filters

Organ 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.<sup>15</sup> The purpose of offer filters is to get to organ offer acceptance 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>16</sup> Offer filters do not modify organ allocation policies and do not change the order in which potential transplant recipients appear on the match run.

<sup>15</sup> Finnie, J. & Moriarty, S. "Better organ offer screening", <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

<sup>16</sup> "Optimizing Usage of Offer Filters," OPTN, Briefing Paper, accessed October 4, 2023, available [https://optn.transplant.hrsa.gov/media/vyonuif/optn\\_osc\\_offer\\_filters\\_bp\\_june23.pdf](https://optn.transplant.hrsa.gov/media/vyonuif/optn_osc_offer_filters_bp_june23.pdf).

Offer filters are different from the donor acceptance criteria entered in OPTN Waiting List on a candidate record.<sup>17</sup> Donor acceptance criteria are applied to screen candidates from the match run when an OPO runs a match. Offer filters are applied at the time the OPO makes an offer, which may be later in the allocation process than when the OPO ran the match. This design allows offers to be filtered based on the most recent information, for example, if the OPO ran the match before some donor information was available. The multi-factorial design of offer filters means that offer filter criteria can be combined so that offers are only filtered if two or more criteria are met.

Offer filters for kidney transplant programs were released nationally as an optional tool in January 2022 following testing in a two-phase pilot.<sup>18</sup> In June 2023, the OPTN Board of Directors approved a proposal to implement default offer filters for kidney transplant programs so that data-derived filters will be applied every six months, with transplant programs retaining the option to opt out of these filters, or to modify or remove filters.<sup>19</sup>

The OPTN began development of lung offer filters in summer 2023 to assist lung transplant programs in managing their offer volume and to improve allocation efficiency for organ procurement organizations (OPOs). The expected release date for lung offer filters as an optional tool for lung transplant programs is early 2024. This initial release of lung offer filters enables lung transplant programs to filter offers based on four criteria:

- Donor type – donation after brain death (DBD), or donation after circulatory death (DCD)
- Distance – transplant program enters in a distance in nautical miles
- Donor age is less than – transplant program enters age in years
- Donor age is more than – transplant program enters age in years

Offer filters are set at the transplant program level, but lung transplant programs may also exclude certain candidates from their program-level filters using the following criteria:

- Candidate age less than
- CPRA exceeds
- Candidate blood type
- Candidate match score is less than
- Candidate match score exceeds

The candidate match score refers to a candidate's total lung CAS, including placement efficiency points and any approved CAS exceptions.

Lung transplant programs can combine the offer filter criteria to create multi-factorial filters. For example, a transplant program may set a filter for their candidates to be bypassed for any DCD offers where the distance between the donor hospital and the transplant hospital exceeds 300 nautical miles. The transplant program may also choose to exclude select candidates from this filter, for example, candidates with a match score (lung CAS) of 40 or greater. Those candidates excluded from the filter due to high CAS would still receive DCD offers from donors located more than 300 nautical miles away.

Below are additional examples of potential offer filters:

<sup>17</sup> "Optimizing Usage of Kidney Offer Filters," OPTN, Concept Paper, accessed October 4, 2023, available <https://optn.transplant.hrsa.gov/policies-by-laws/public-comment/optimizing-usage-of-kidney-offer-filters/>.

<sup>18</sup> Ibid.

<sup>19</sup> "Optimizing Usage of Offer Filters," OPTN, Policy Notice, accessed October 4, 2023, [https://optn.transplant.hrsa.gov/media/xdvgtub/osc\\_offer\\_filters\\_policy\\_notice\\_jun-2023.pdf](https://optn.transplant.hrsa.gov/media/xdvgtub/osc_offer_filters_policy_notice_jun-2023.pdf).

- Example of a filter that combines multiple criteria
  - Filter lung offer if donor meets ALL of the following criteria:
    - Donor is DCD AND
    - Donor age is more than 65 years AND
    - Distance exceeds 75 nautical miles
  - Program would only receive offers from DCD donors 65 years and older if they are within 75 nautical miles
  - Program would still receive offers beyond 75 nautical miles for DBD donors, and beyond 75 nautical miles for DCD donors 64 years and younger.
- Example of a filter that excludes certain candidates
  - Filter lung offer if donor meets ALL of the following criteria:
    - Distance exceeds 950 nautical miles
  - Unless candidate meets ANY of the following criteria:
    - CPRA exceeds 90% OR
    - Match score exceeds 40
  - Program would only receive offers within 950 nautical miles for most candidates but would receive offers beyond 950 nautical miles for candidates with high CPRA (greater than 90%) and/or high CAS (greater than 40)

Offer filters are applied as a bypass on the match run and are excluded from a transplant program's offer acceptance metric. If a program never receives an offer because a candidate was screened off the match by donor acceptance criteria, or because a candidate was bypassed due to offer filters, the offer is not included in the calculation of the program's organ offer acceptance rate.<sup>20</sup> Using offer filters can improve a transplant program's offer acceptance metric by filtering out those offers rather than having those offers counted in the metric as offers that the transplant program declined.

The initial release of lung offer filters also includes the following:

- *Offer Filters Model*: A tool that identifies potentially effective filters unique to each lung transplant program based on that transplant program's acceptance patterns
- *Offer Filters Explorer*: A tool that allows lung transplant programs to assess the impact of potential filters and view reports of donors and candidates being filtered
- *Offer Filters Manager*: An application that allows lung transplant programs to manage the filters to be applied in lung allocation, including turning filters on, adding custom filters, and editing existing filters
- Updates to the lung match in the OPTN Donor Data and Matching System to apply the filters

While the initial release of lung offer filters is limited to four filter criteria (donor type, distance, and donor age maximum and minimum), this is a starting point for development of additional lung-specific criteria. The Committee requests feedback on other criteria that lung transplant programs would use to filter offers.

## Overview of Proposal

The Committee proposes adding data collection in the OPTN Donor Data and Matching System on criteria that will assist lung transplant programs in evaluating offers and providing a timely response.

<sup>20</sup> "Enhance Transplant Program Performance Monitoring System," OPTN, Briefing Paper, accessed November 11, 2023, <https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-svst.pdf>.

Once data have been collected, the OPTN may perform modeling to determine if these criteria would filter a threshold of additional donors beyond the available filter criteria and therefore should be added as offer filters for lung.

## Add Data Collection to Assist in Offer Evaluation

The Committee proposes adding data collection on two criteria to the OPTN Donor Data and Matching System, as summarized in **Table 2**. Entering these data would not be required to run a match or make lung offers.

**Table 2: Proposed New Data Fields in OPTN Donor Data and Matching System**

Data Field	Form	Description
History of anaphylaxis to peanut and/or tree nut	Donor Field Add/Edit Medical & Social History	Yes/No/Unknown
Previous sternotomies	Donor Field Add/Edit Medical & Social History	Yes/No/Unknown  If yes – option to select one or more of the following: Coronary artery bypass grafting (CABG) Congenital heart defect surgery Maze procedure Heart valve replacement Other, specify

The Committee proposes adding data collection on these criteria as lung transplant programs may rule out donors with these characteristics in combination with other criteria. Collecting these data will allow the OPTN to assess in the future if these criteria would assist lung transplant programs in filtering offers they will not accept. 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.

### *History of anaphylaxis to peanut and/or tree nut*

Transmissions of anaphylactic peanut and tree nut allergies have been reported in lung transplants, with some resulting in recipient death.<sup>21</sup> The Committee acknowledges that the prevalence of peanut and tree nut allergies in the general population (and presumably the donor population) is low, estimated between 1-6%,<sup>22</sup> and individuals with anaphylactic reactions represent a smaller subset of that population. However, most anaphylaxis deaths are due to peanut or tree nut exposure<sup>23</sup> and the prevalence of these allergies has been rising over the last few decades.<sup>24</sup> Some members of the Committee indicated they may rule out donors with a history of anaphylactic peanut or tree nut

<sup>21</sup> R. Bag, S. Tlusty, G. Vece, et al., “Don’t Pass the Peanuts: Donor-Derived Nut Allergy in Lung Transplant,” *The Journal of Heart and Lung Transplantation* 37 no. 4 (2018): S247, <https://doi.org/10.1016/j.healun.2018.01.614>.

<sup>22</sup> Vicki McWilliam, Jennifer Koplin, Caroline Lodge, et al., “The Prevalence of Tree Nut Allergy: A Systematic Review,” *Current Allergy and Asthma Reports* 15 (2015): 1-13, DOI 10.1007/s11882-015-0555-8.

Jay A. Lieberman, Ruchi S. Gupta, Rebecca C. Knibb, et al., “The global burden of illness of peanut allergy: A comprehensive literature review,” *Allergy* 76 no. 5 (2021): 1367-1384, doi: 10.1111/all.14666.

<sup>23</sup> Ibid.

<sup>24</sup> Lars Lange, Ludger Klimek, Kirsten Beyer, et al., “White paper on peanut allergy – part 1: Epidemiology, burden of disease, health economic aspects,” *Allergo Journal International* 30 (2021): 261-269, <https://doi.org/10.1007/s40629-021-00189-z>.

allergies. Other members indicated they would still accept these donors, particularly if the lungs are otherwise a good match for a young pediatric candidate who cannot accept offers from most donors due to size. OPO members of the workgroup indicated this information is generally collected via the Donor Risk Assessment Interview (DRAI)<sup>25</sup> and therefore would likely be available for entering in the OPTN Donor Data and Matching System. The Committee requests feedback on the utility of collecting this information to aid in evaluating offers and for potential inclusion as an offer filter in the future.

### *Previous sternotomies*

A sternotomy is a surgical incision through the sternum, or breastbone, and is often used to provide access to the heart for heart surgeries.<sup>26</sup> In Workgroup and Committee discussions with OPO and lung transplant program representatives, members reported that lung transplant programs may rule out DCD donors based on any history of sternotomy, regardless of procedure type. However, for DBD donors, lung transplant programs may not rule out a donor based on history of sternotomy alone. For example, lung transplant programs may rule out donors who had a previous sternotomy as part of a coronary artery bypass grafting surgery, but not donors who had a sternotomy to support a heart valve replacement. Coronary artery bypass grafting (CABG) is a major heart surgery that involves creating “a new path for blood to flow around a blocked or partially blocked artery in the heart.”<sup>27</sup> While lung transplants have been performed successfully from donors who had previous cardiac surgery, including CABG,<sup>28</sup> transplant program members have noted that they may not accept these donors in conjunction with other criteria like donor age and/or smoking history.<sup>29</sup> The Committee proposes including CABG and valve replacement as selection options if a donor previously had a sternotomy to distinguish between these surgeries, as well as selection options for congenital heart defect surgery and maze procedure. A maze procedure involves making a series of incisions in the heart to create a “maze” of scar tissue to treat irregular heart rhythms (atrial fibrillation).<sup>30</sup> The Committee requests feedback on the utility of collecting this information to aid in evaluating offers and for potential inclusion as an offer filter in the future.

### *Other criteria considered*

The Workgroup and the Committee evaluated the following criteria as potential new data fields to aid in evaluating or filtering lung offers but opted not to propose collecting these data at this time:

- Gross aspiration/food particles in the airway
- Tracheostomy
- Length of time post-extubation permitted for potential DCD donor
- Glasgow Coma Scale (DCD donors only)

<sup>25</sup>“Uniform Donor Risk Assessment Interview,” American Association of Tissue Banks, Guidance Document, accessed November 15, 2023, <https://www.aatb.org/guidance-documents>.

<sup>26</sup>“Sternotomy.” Merriam-Webster.com Medical Dictionary, Merriam-Webster, accessed November 24, 2024, <https://www.merriam-webster.com/medical/sternotomy>. See also “Sternotomy,” Cleveland Clinic, accessed November 24, 2023, <https://my.clevelandclinic.org/health/treatments/24016-sternotomy>.

<sup>27</sup>“Coronary artery bypass grafting,” Mayo Clinic, accessed November 11, 2023, <https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589>.

<sup>28</sup>Joseph Costa, Sowmyashree Sreekanth, Alex Kossar, et al., “Donors with a prior history of cardiac surgery are a viable source of lung allografts,” *European Journal of Cardio-Thoracic Surgery* 50 (2016): 822-825, doi:10.1093/ejcts/ezw157.

<sup>29</sup>A. Palleschi, P. Mendogni, D. Tosi, et al., “Lung Transplantation From Donors After Previous Cardiac Surgery: Ideal Graft in Marginal Donor?” *Transplant Proceedings* 49 no. 4 (2017): 686-691, <https://doi.org/10.1016/j.transproceed.2017.02.021>.

<sup>30</sup>Chawannuch Ruaengsri, Matthew R. Schill, Ali J. Khiabani et al., “The Cox-maze IV procedure in its second decade: still the gold standard?” *European Journal of Cardio-Thoracic Surgery* 53 supplement no. 1 (2018): i19 – i25, <https://doi.org/10.1093/ejcts/ezx326>.

For the first three criteria, the Workgroup determined that the criteria could change throughout the allocation process in ways that would impact whether a transplant program would accept the lungs. Accordingly, the Workgroup determined these criteria should be communicated directly between the OPO and the transplant program at the time of the offer rather than reported at an earlier point in time in the OPTN Donor Data and Matching System. For Glasgow Coma Scale, members expressed concerns about the reliability of the assessment and its utility in decision-making for offer acceptance. The Committee requests feedback on other criteria that would aid lung transplant programs in evaluating organ offers.

## Potential System Enhancements

The Committee requests feedback on potential system enhancements that would:

- Allow OPOs to quickly bypass candidates who cannot accept an offer if only a single lung is available from a donor (“Bypass bilateral and other lung” button)
- Enable transplant programs to opt in to offers from geographically isolated areas like Hawaii, Puerto Rico, and Alaska at the program level

### “Bypass Bilateral and Other Lung” Button

Lung transplant programs indicate on each candidate’s record in OPTN Waiting List whether the candidate’s “lung preference” is “right”, “left”, or “both” lungs. The candidate’s lung preference is displayed on the lung match run so that OPO users can view it when making lung offers. In the six months since implementation of continuous distribution, about 85% of lung transplants performed were bilateral or en bloc double lung transplants, and about 15% were single lung transplants.<sup>31</sup> This means OPOs sometimes have only a single lung to allocate with several candidates remaining on the match who can only accept a bilateral lung transplant, or can only accept a single lung of the opposing laterality (e.g. needs left lung and only right lung is available). The OPO may bypass these candidates manually, or offer the single lung to candidates and have transplant programs respond to the offer. However, the OPTN could develop a “Bypass bilateral and other lung” button to allow the OPO to bypass all the bilateral candidates on the match run at once, as well as any candidates who need a lung of the opposing laterality. This would allow the OPO to more quickly identify the candidates who may accept the remaining single lung. A similar functionality currently exists on the kidney-pancreas match via the “No Kidneys Available” button. If at some point in the allocation process neither kidney is available, the OPO user can click the “No Kidneys Available” button and the OPTN Donor Data and Matching System enters a special bypass code for the remaining candidates on the match who need a kidney as well as a pancreas. This allows the OPO to continue allocation to isolated pancreas and pancreas islet candidates on the match. The Committee requests feedback on whether OPOs would support this system enhancement.

If this change is supported by the community, the lung candidate record in OPTN Waiting List could also be updated to indicate that transplant programs are reporting “acceptable lung laterality” rather than “lung preference” since this information would be used to bypass candidates on match runs. The Committee requests feedback on whether lung transplant programs support this change. If lung transplant programs are currently declining offers based on unacceptable laterality, the implementation

<sup>31</sup> Weiss and Weibel, “Lung Continuous Distribution Six Month Monitoring Report,” page 75. There was a slight increase in the number of bilateral sequential lung procedures performed between the pre- and post-policy eras.



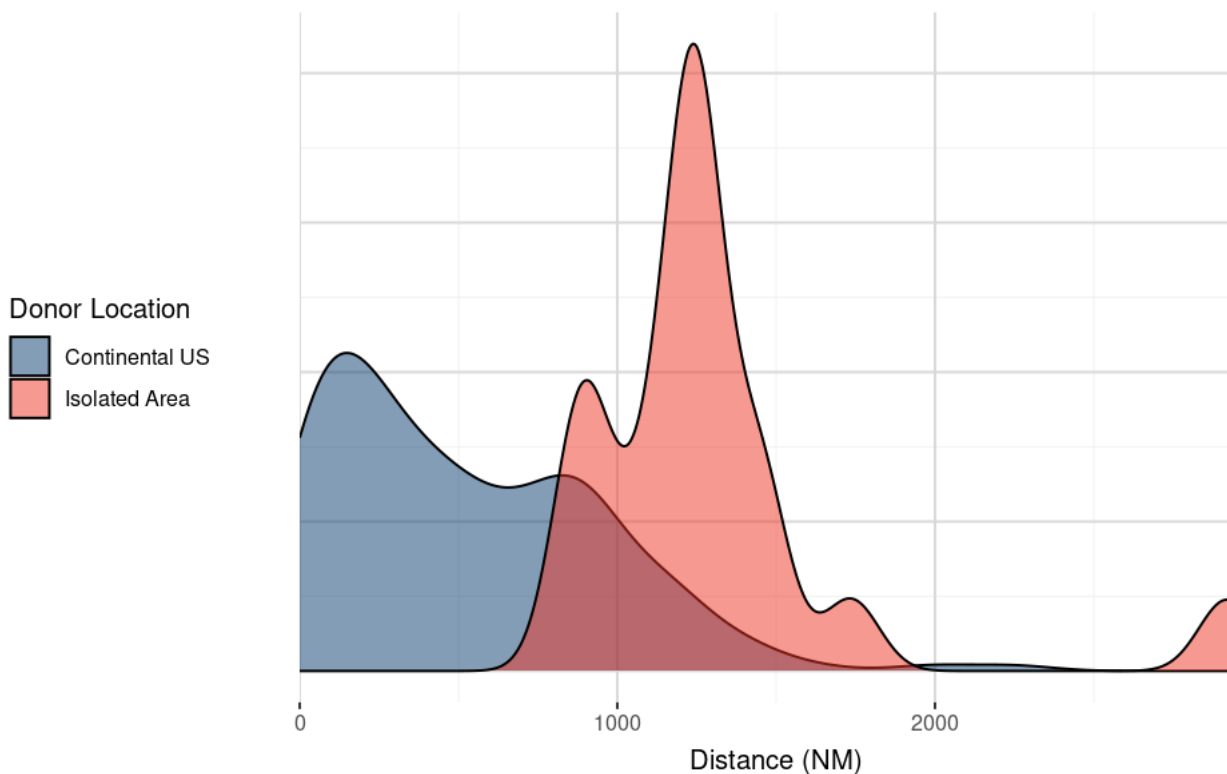
of this bypass button may also help lung transplant programs to improve their offer acceptance ratio since they would be bypassed for these offers instead of having to decline them.

## Opt In to Offers from Geographically Isolated Areas

Via donor acceptance criteria, transplant programs may indicate whether a candidate is willing to accept an organ from a donor based on various donor characteristics. The donor acceptance criteria for lung includes an option to specify the “maximum miles the organ or recovery team will travel.” This allows lung transplant programs to specify a maximum nautical mile radius in which they can recover donor lungs, and the system screens out offers beyond that radius. This feature does not allow special consideration for geographically isolated donor hospitals like those in Hawaii, Alaska, and Puerto Rico. The Committee discussed that some lung transplant programs may be willing to travel to these areas to recover lungs that would otherwise go unused, but those transplant programs may not be able to travel the same nautical mile distance across the continental United States, where there are many other lung transplant programs who would recover and transplant available lungs.

Between implementation of continuous distribution of lungs and November 2023, lung transplant programs that accepted offers from Alaska or Puerto Rico traveled further to recover lungs from those donors relative to donors located in the continental United States, as shown in **Figure 6**. No lungs were recovered from Hawaii and transplanted during this period.

**Figure 6. Distance between Donor Hospital and Transplant Program for Lung Transplants by Donor Location from March 9, 2023 – November 10, 2023<sup>32</sup>**



<sup>32</sup> OPTN data as of database copy dated November 10, 2023. “Isolated area” refers to offers from Alaska or Puerto Rico.



A potential system enhancement in OPTN Waiting List could allow lung transplant programs to indicate at a transplant program level if they would accept lung offers from a donor located in:

- Hawaii
- Puerto Rico
- Alaska

If a lung program reported in the system that it wants to receive offers from an isolated area, then their candidates would not be screened from a match run for donors from those areas, even if the donor hospital distance exceeds the “maximum miles the organ or recovery team will travel” indicated on the candidate record, or the distance(s) specified in offer filters.

For example, consider a lung candidate registered at the University of Washington Medical Center in Seattle, Washington.

- Donor acceptance criteria indicates the maximum nautical miles the organ or recovery team will travel: 500 NM
- University of Washington Medical Center lung transplant program opts in to offers from Hawaii and Alaska
- Offer filters: Filter offer if donor is DCD and distance exceeds 300 NM

This candidate would not appear on a match for a donor recovered in Las Vegas (~870 NM) but would appear on a match for a donor in Honolulu (~2,700 NM).

The Committee requests feedback on whether lung transplant programs would support this system enhancement to opt in to offers from geographically isolated areas (Hawaii, Alaska, and Puerto Rico). The Committee also requests feedback from other transplant programs on whether this feature would be useful for other organs as well as for lung.

## Potential Areas for Further Development

The Lung Committee, the OPO Committee, and the Workgroup have discussed other potential approaches for promoting the efficiency of lung allocation, including changes to lung donor testing and OPO offer practices.

### Lung Donor Testing

OPTN *Policy 2.11.D Required Information for Deceased Lung Donors* lists information that OPOs must provide for deceased lung donors:

- 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
- Bronchoscopy results, if performed
- Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
- 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
- Sputum gram stain, with description of sputum
- Lung laterality

The OPTN Donor Data and Matching System does not enforce all these requirements strictly. For example, while arterial blood gas information must be entered for an OPO to send an electronic offer

notification, the system does not require that information to have been entered within 2 hours prior to the offer. Similarly, a chest x-ray image is not required, but comments regarding the chest x-ray must be entered prior to making organ offers.

Accordingly, lung transplant program representatives supported exploring updates to this policy, which could include requiring a bronchoscopy prior to sending organ offers and requiring a chest x-ray image to be uploaded prior to sending organ offers. Lung transplant program representatives also supported updating *OPTN Policy 2.9 Required Deceased Donor Infectious Disease Testing* to require lower respiratory specimen test results for SARS-CoV-2 to be available earlier in the allocation process than required by current policy, which says the results must be reported “pre-transplant.” However, OPO representatives expressed concern that they may not be able to get bronchoscopies or chest x-rays from remote donor hospitals, and sometimes it is challenging to get testing completed by metropolitan donor hospitals that have reduced staff or have outsourced laboratory testing. OPO representatives emphasized that they must begin lung allocation quickly since sometimes the candidates high on the match run are located far away from the donor hospital and it would take time for a recovery team to arrive. OPO representatives said that if additional lung donor testing requirements are added, then “not available” should be an option within the system so that OPOs can continue with allocation in the absence of those tests.

While providing additional information at the time of organ offer may enable lung transplant programs to respond to offers faster, requiring additional information to be reported by OPOs prior to making organ offers may delay lung allocation altogether and risk losing a lung donor. Accordingly, the Committee requests feedback on how the OPTN may better facilitate communication between transplant programs and OPOs regarding donor information to make allocation more efficient.

## OPO Offer Practices

Following implementation of continuous distribution of lungs, some lung transplant programs reported receiving offers for potential transplant recipients at high sequence numbers, meaning that there are many potential transplant recipients with a higher lung CAS ahead of their program’s candidates on the match run and they are unlikely to receive the lung(s). Offer filters do not address this challenge as the lung transplant program would accept the lungs if their potential transplant recipient became primary.

One approach could include modifying OPO notification limits. In the OPTN Donor Data and Match System, offer notification limits are divided into “local” and “non-local.” The distances that define “local” and “non-local” vary by organ (**Table 2**).

**Table 2. Local OPO Notification Limit Ranges by Organ**

Organ(s)	Range of “local” offers
Adult heart and heart-lung	<ul style="list-style-type: none"> <li>• 1000 nm for Adult Status 1</li> <li>• 500 nm for Adult Status 2</li> <li>• 250 nm or within OPO’s DSA</li> </ul>
Pediatric heart and heart-lung	<ul style="list-style-type: none"> <li>• 500 nm for Adult Status 1 and 2 and pediatric status 1A and 1B</li> <li>• 250 nm or within OPO’s DSA</li> </ul>
Liver and liver-intestine	<ul style="list-style-type: none"> <li>• 500 nm for Status 1A and 1B</li> <li>• 150 nm or within OPO’s DSA</li> </ul>
Lung	<ul style="list-style-type: none"> <li>• 1000 nm or within OPO’s DSA</li> </ul>
Kidney-pancreas, pancreas, and pancreas islets	<ul style="list-style-type: none"> <li>• Candidates who are 0-ABDR mismatched within the donor and have CPRA ≥ 80</li> <li>• 250 nm or within OPO’s DSA</li> </ul>
Kidney	<ul style="list-style-type: none"> <li>• 250 nm or within OPO’s DSA</li> <li>• Select classifications based on KDPI and whether kidneys are offered en bloc</li> </ul>

Within the “local” range, OPOs may set limits on how many candidates and/or how many transplant programs will receive offers at a time. These limits apply across organs within the “local” ranges and OPOs are not currently able to vary the limits by organ. For “non-local” offers, system limits apply. The system allows “non-local” offers to three transplant programs pre-cross clamp and five transplant programs post-cross clamp. The limits stop further offers from going out until a response (e.g., a provisional yes) is received from a transplant program, which frees up another offer to go out. The limits are rolling so that as more responses come in from transplant programs, the OPO may send additional offers.

The Workgroup discussed whether changes to the OPO notification limits would improve the efficiency of the allocation process. Changes could include modifying the distance threshold that defines “local” offers for lung or removing the “local” vs. “non-local” distinction and defining the threshold based on other criteria, like number of transplant programs notified. Lung transplant program representatives were concerned that modifying the offer notification limits alone would not decrease the volume of unwanted offers, since OPOs may send additional offers as soon as transplant programs enter “provisional yes.” OPO representatives were concerned that changing the notification limits would slow down their ability to place lungs and recommended focusing on solutions like offer filters that have the potential to reduce offer volume. However, OPO representatives generally agreed that OPOs should not be sending out large volumes of lung offers at a time (e.g., 300-400 offers at once) and suggested that it may be helpful if OPOs could set organ-specific notification limits. The Committee requests feedback on other potential enhancements that would help both lung transplant programs and OPOs to manage organ offer volume.

## NOTA and OPTN 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,"<sup>33</sup> as

<sup>33</sup> 42 U.S.C. §274(b)(2)(A)(ii).

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>34</sup> and that “transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.”<sup>35</sup> This proposal would add new data fields in the OPTN computer system on medical criteria to aid lung transplant programs in making decisions on organ acceptance.

## Implementation Considerations

### Member and OPTN Operations

This proposal would impact organ procurement organizations, transplant hospitals, and the OPTN, but would not impact histocompatibility laboratories.

#### *Operations affecting Organ Procurement Organizations*

OPOs would be able to report information on history of anaphylaxis to peanut and/or tree nut and previous sternotomies for all donors.

#### *Operations affecting Transplant Hospitals*

Transplant hospital staff reviewing lung organ offers would need to become familiar with the new information available in the OPTN Donor Data and Matching System. Transplant hospitals with lung transplant programs are advised to explore and use lung offer filters when available.

#### *Operations affecting the OPTN*

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN’s regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

To implement this proposal, the OPTN would add new data fields in the OPTN Donor Data and Matching System and communicate the changes to the transplant community. The OPTN would provide help documentation for the new data fields to provide additional instruction for submitting these data.

### 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.

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<sup>34</sup> 42 CFR 121.11(a)(1)(i).

<sup>35</sup> 42 CFR 121.6(c).

## Projected Fiscal Impact

### *Projected Impact on Histocompatibility Laboratories*

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

### *Projected Impact on Organ Procurement Organizations*

This proposal is anticipated to have a low fiscal impact on OPOs to accommodate additional donor data entry and to train staff on requirements.

### *Projected Impact on Transplant Hospitals*

This proposal is anticipated to have a minimal fiscal impact on transplant hospitals. This proposal does not require transplant hospitals to use lung offer filters, but if transplant hospitals choose to use lung offer filters, hospital staff may expend time to set up the organ offer filters and train staff, and may require additional IT support in personalizing candidate filters.

### *Projected Impact on the OPTN*

The OPTN contractor estimates 2,255 hours would be needed to implement this proposal. Implementation would involve updates to the OPTN Donor Data and Matching System to add new data collection that aid evaluation of lung offers. In addition, implementation would include updates about planned and potential system enhancements that will facilitate lung organ offers and timely placement. The OPTN contractor estimates 55 hours for ongoing support. Ongoing support includes answering member questions, as necessary.

## Post-implementation Monitoring

### Member Compliance

The proposal will not change the current routine monitoring of OPTN members. Any data entered in the OPTN Computer System may be reviewed by the OPTN, 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." A summary of the new data collection fields will be provided to the Committee approximately six months after implementation, and then annually for 2-3 years, as the Committee sees fit. Each report will include summary statistics for each new data collection field. Because both new data elements are categorical variables, reports will include the number and percent of donors for which each option was selected (i.e., Yes, No, Unknown).

## Conclusion

The Committee proposes new data collection in the OPTN Donor Data and Matching System to aid evaluation of lung offers and requests feedback on two potential system enhancements aimed at promoting the efficiency of lung allocation. The Committee's overall goal is to make it easier for lung

transplant programs to say “yes” to organ offers and to facilitate timely placement of donor lungs for OPOs. The Committee requests feedback on other opportunities to improve allocation efficiency.

## Considerations for the Community

- Do patients and donor family members support efforts to improve the efficiency of lung allocation and place donor lungs more rapidly with a potential transplant recipient?
- Do lung transplant programs support the proposed new data fields to assist in evaluating offers?
- For adult and pediatric lung transplant programs, what additional donor information or offer filters would be useful for your program?
- Do OPOs anticipate any challenges with reporting the additional donor data?
- Are the proposed data definitions easy to understand or is additional clarification needed regarding the intent of the data collection?
- Do OPOs and lung transplant programs support the potential system enhancement to add a “Bypass bilateral and other lung” button to bypass candidates who would not accept an offer if only a single lung is available?
- Do lung transplant programs support the potential system enhancement to opt in to offers from geographically isolated areas (Hawaii, Alaska, and Puerto Rico)?
  - Would transplant programs support adding this feature for other organs as well as lung?
- How else might the OPTN improve the efficiency of lung allocation for both transplant programs and OPOs?

## Proposed Changes to Data Collection

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.

### 1 Data Additions: OPTN Donor Data and Matching System

Data Field	Form	Description
History of anaphylaxis to peanut and/or tree nut	Donor Summary Medical & Social History	Yes/No/Unknown
Previous sternotomies	Donor Summary Medical & Social History	Yes/No/Unknown  If yes – option to select one or more of the following: Coronary artery bypass grafting (CABG) Congenital heart defect surgery Maze procedure Heart valve replacement Other, specify

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## Appendix A: Data Definitions

**History of anaphylaxis to peanut and/or tree nut:** Select **Yes** if the donor has any history of anaphylactic allergic reaction to peanuts and/or tree nuts. Select **No** if the donor had no history of anaphylaxis to peanuts or tree nuts. Select **Unknown** if donor historian or donor medical records are not available and it is not clear if the donor had a history of anaphylaxis to peanuts or tree nuts.

**Definition:** Anaphylaxis is an acute, potentially life-threatening, IgE-mediated allergic reaction that occurs in previously sensitized people when they are re-exposed to the sensitizing antigen.

**Previous sternotomies:** Select **Yes** if the donor had one or more previous sternotomies and select the applicable procedure type(s). If median sternotomy scar is present but procedure type is unknown, select “Yes” for “previous sternotomies” and enter “unknown” under “Other, specify.” Select **No** if the donor had no previous sternotomies. Select **Unknown** if it is not clear whether the donor had previous sternotomies.

**Definition:** Sternotomy is a surgical incision through the sternum, often used for open heart surgeries.