OPTN

Briefing to the OPTN Board of Directors on

Promote Efficiency of Lung Allocation

OPTN Lung Transplantation Committee

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Promote Efficiency of Lung Allocation

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Executive Summary

Continuous distribution of lungs was implemented on March 9, 2023.[1] 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. 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.[2] 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. The changes have also resulted in redistributed organ offer patterns across the country and affected the logistics of allocation. Impacts of the changes can be viewed via upward trends in the median transplant program number at acceptance; median offer number at acceptance; and the number of transplant programs notified per lung donor.[3]

This paper proposes new data collection in the OPTN Donor Data and Matching System to aid in the evaluation of lung offers and so that analysis of the two additional data elements could be considered in any proposed future refinement of the current lung offer filters. It also describes two proposed system enhancements that aim to increase efficiency of the organ management process and promote organ utilization.

After reviewing the public comment feedback, the OPTN Lung Transplantation Committee (the Committee) determined a non-substantive change should be made to clarify the history of anaphylaxis to peanut and/or tree nut data definition.[4] Following this change, the Committee voted in support of the two new proposed data elements. The Committee also voted in support of the two system enhancements with no post-public comment changes.[5]

[1] "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.
[2] Ibid.
[3] Ibid.
[4] https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/
[5] Ibid.

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 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:

- Adds new data collection
  - Previous sternotomies
  - History of anaphylaxis to peanut and/or tree nut
- Describes 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

Background

Continuous distribution of lungs was implemented on March 9, 2023.[6] 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**.[7] 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.[8] 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.

[6] "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.

[7] 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.

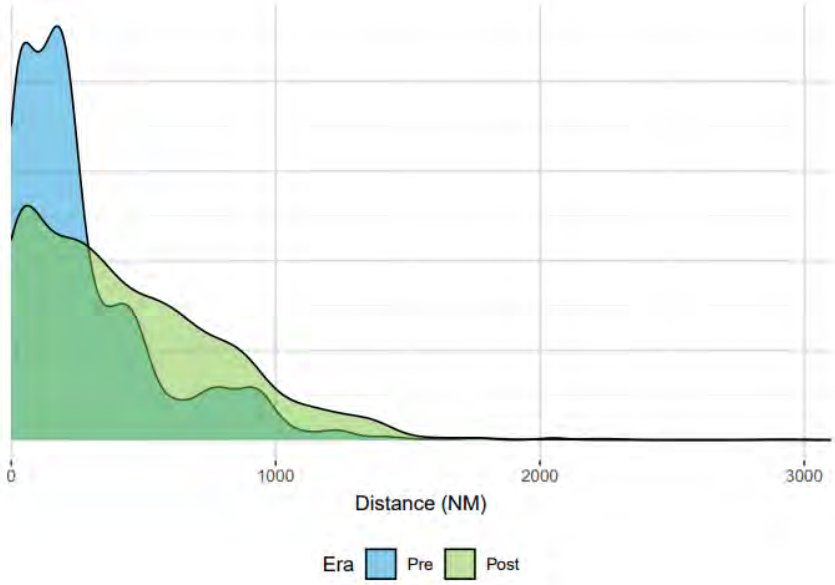
[8] Proximity was estimated to account for 81% of the score in the former allocation system, as opposed to the 10% weighting in the lung CAS. See Darren E. Stweart, Dallas W. Wood, James B. Alcorn et al., "A revealed preference analysis to develop composite scores approximating lung allocation policy 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.

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**

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 the 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[9] 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 program has increased precisely with what was anticipated based on the modeling, from 195 to 353 nautical miles (**Figure 1**).[10]

Figure 1. Distribution of Distance (in Nautical Miles) from Donor Hospital to Transplant Program for Lung Transplants by Era[11]



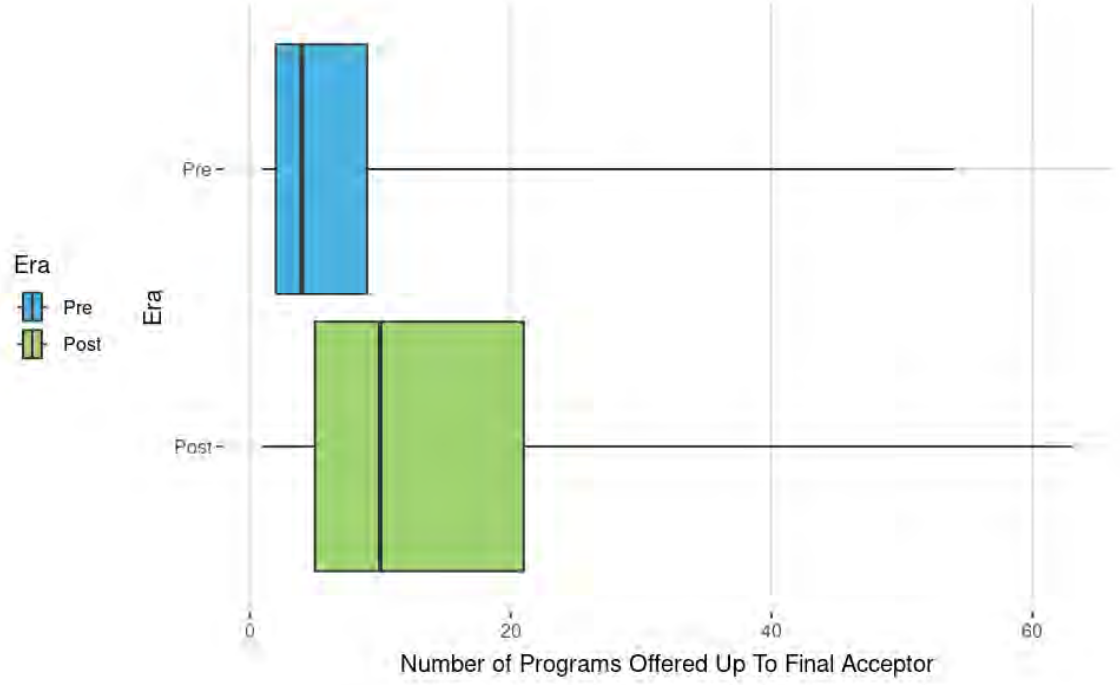
Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1387	0	0	78	195	279.35	391.0	2069
Post	1543	0	0	129	353	433.55	662.5	2920

The changes in the allocation score and corresponding increase in travel distance appear 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).[12] 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 relatively stable. However, the reordering of allocation priority has redistributed organ offer patterns across the country, which has complicated the logistics of allocation[13] and

[9] 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.
[10] 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.
[11] 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.
[12] 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.
[13] 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.

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.[14] 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 program 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.

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

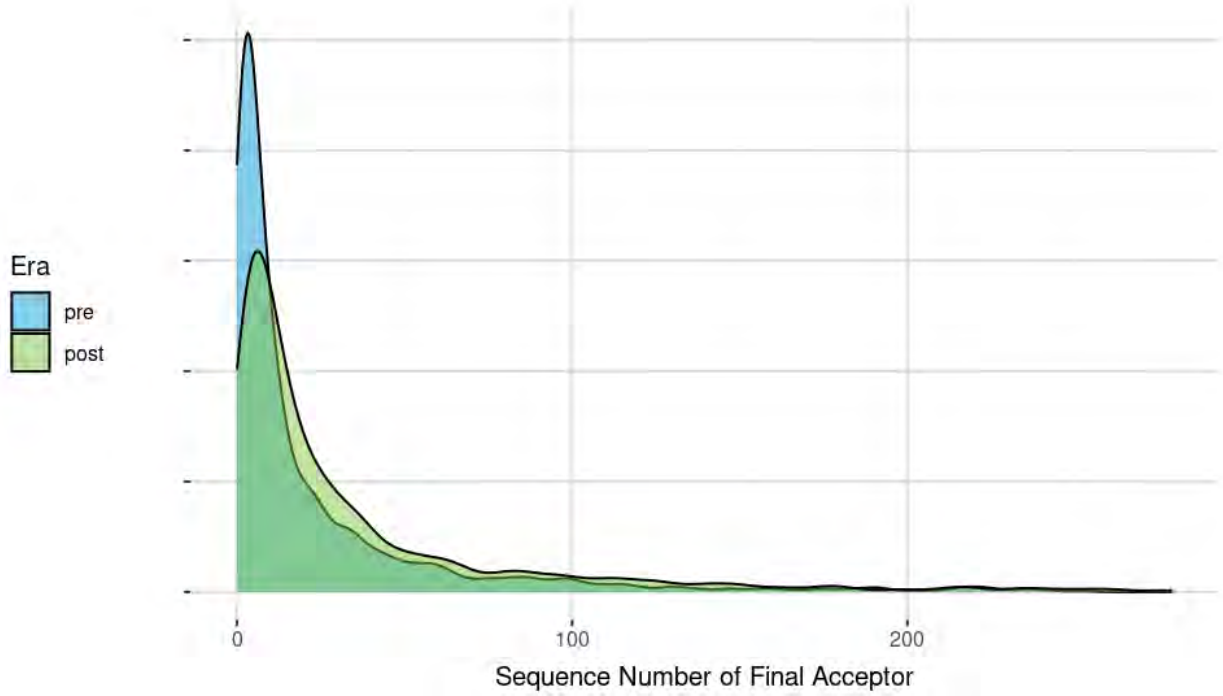


Era	N	N Missing	Min	25th Percentile	Median	Mean	75th Percentile	Max
Pre	1506	0	1	2	4	7.02	9	54
Post	1676	0	1	5	10	14.69	21	63

[14] "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.

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.

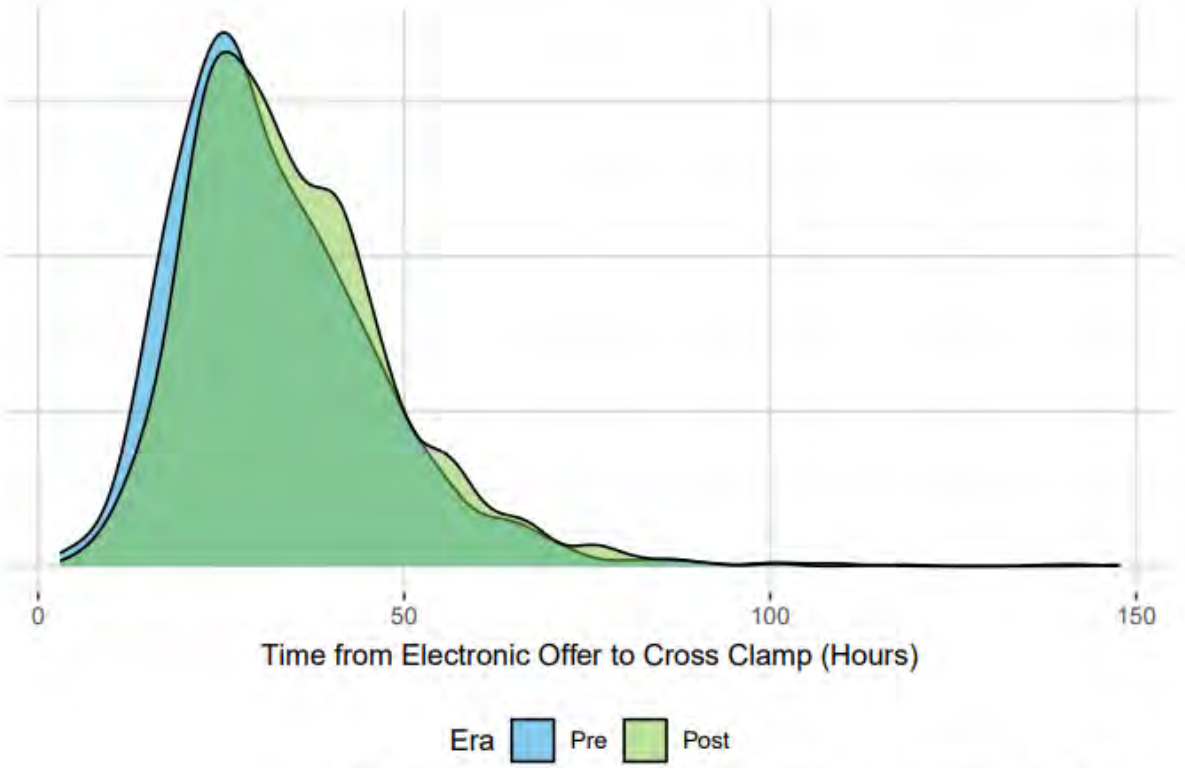
Figure 3. Distribution of the Sequence Number of the Final Acceptor on Lung Match Run by Era



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



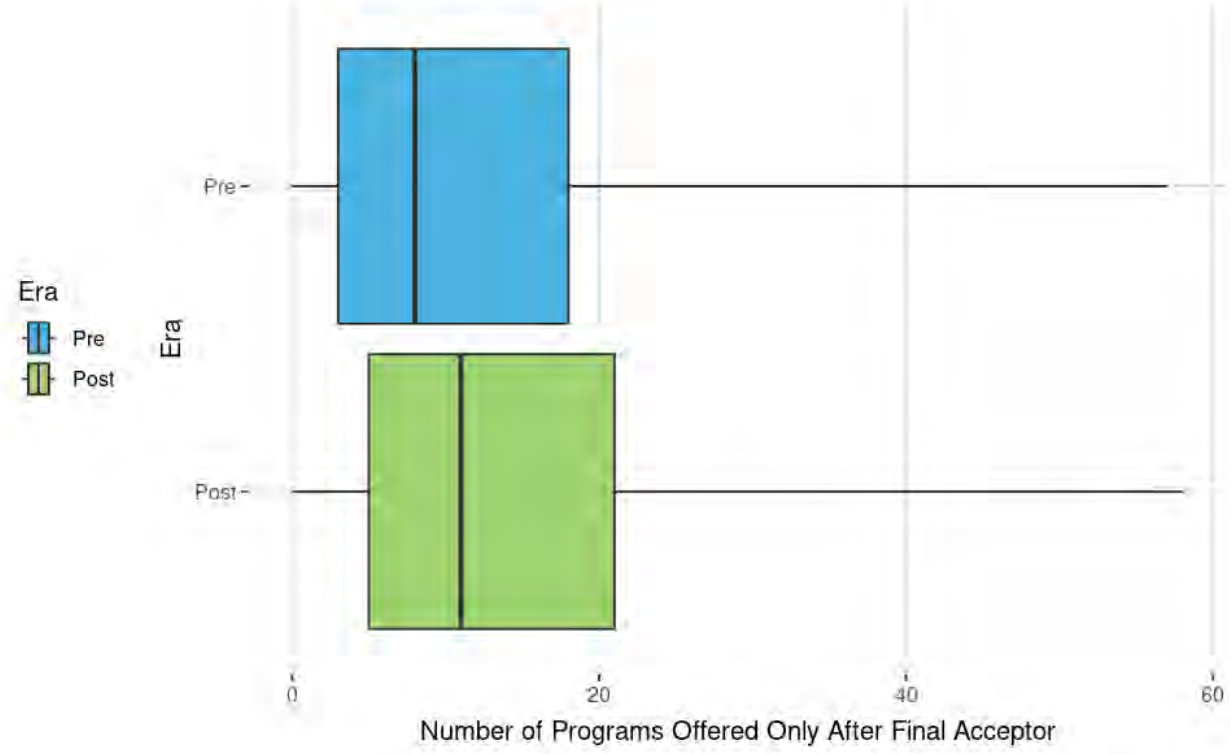
There were 5 values not yet reported at the time of this report's creation. This report was created before the 90 day data lag allowed by the OPTN had passed.

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

[a] 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 Committee sponsored the Promote Allocation of Lung Efficiency Workgroup (the Workgroup), comprised of members of the Lung and OPTN OPO Committees, to review data on lung allocation and discuss potential solutions to address inefficiencies.

Proposal for Board Consideration

The Committee proposes adding data collection in the OPTN Donor Data and Matching System as criteria that will assist lung transplant programs in evaluating offers and providing a timely response. The Committee also proposes system enhancements that aim to increase efficiency of the organ management process and promote organ utilization.

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. Once the data has 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. 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. 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. 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.[15] 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%,[16] and individuals with anaphylactic reactions represent a smaller subset of that population. However, most anaphylaxis deaths are due to peanut or tree nut exposure[17] and the prevalence of these allergies has been rising over the last few decades.[18] Some members of the

[15] 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.

[16] 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.

[17] Ibid.

[18] 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.

Committee indicated they may rule out donors with a history of anaphylactic peanut or tree nut 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)[19] and therefore would likely be available for entering in the OPTN Donor Data and Matching System.

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.[20] 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 (CABG) surgery, but not donors who had a sternotomy to support a heart valve replacement. 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."[21] While lung transplants have been performed successfully from donors who had previous cardiac surgery, including CABG,[22] transplant program members have noted that they may not accept these donors in conjunction with other criteria like donor age and/or smoking history.[23] 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).[24]

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)

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.

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[19] "Uniform Donor Risk Assessment Interview," American Association of Tissue Banks, Guidance Document, accessed November 15, 2023, https://www.aatb.org/guidance-documents.

[20] "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.

[21] "Coronary artery bypass grafting," Mayo Clinic, accessed November 11, 2023, https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589.

[22] 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.

[23] 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.

[24] 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.

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.

Post-Public Comment Discussion

The proposal asked lung transplant programs and OPOs for feedback on the proposed new data fields to assist in evaluating offers. Overall, respondents supported the collection of previous sternotomies and history of anaphylaxis to peanut and/or tree nut and did not believe the addition of these fields would create undue burden on OPOs. Some supportive feedback expressed that these fields could be obtained easily and without additional burden, as they are currently collected on the DRAI. When the Committee discussed this feedback, they expressed that while minding data burden is important, previous sternotomies and history of anaphylaxis to peanut and/or tree nut need to be collected as discrete fields so that these data elements can be analyzed for potential future use as lung offer filters. Feedback specific to history of anaphylaxis to peanut and/or tree nut expressed support for the addition of this data field, as current collection only accounts for allergies. Some comments questioned the need for the addition of this data field, as the occurrence of anaphylaxis is rare, and the risk of transmission is low. The Committee considered the low transmission risk, but determined that adding history of anaphylaxis to peanut and/or tree nut to data collection did not have the potential to do harm and supported erring on the side of caution for the recipient. To differentiate between an allergic reaction and an anaphylactic reaction, the Committee determined that the word "allergic" should be removed from the data definition of history of anaphylaxis to peanut and/or tree nut (**Appendix B**). The Committee determined that no post-public comment changes should be made to the previous sternotomies data field.

System Enhancements

The Committee proposes 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.[25] 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

[25] 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.

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 requested feedback on whether OPOs would support this system enhancement.

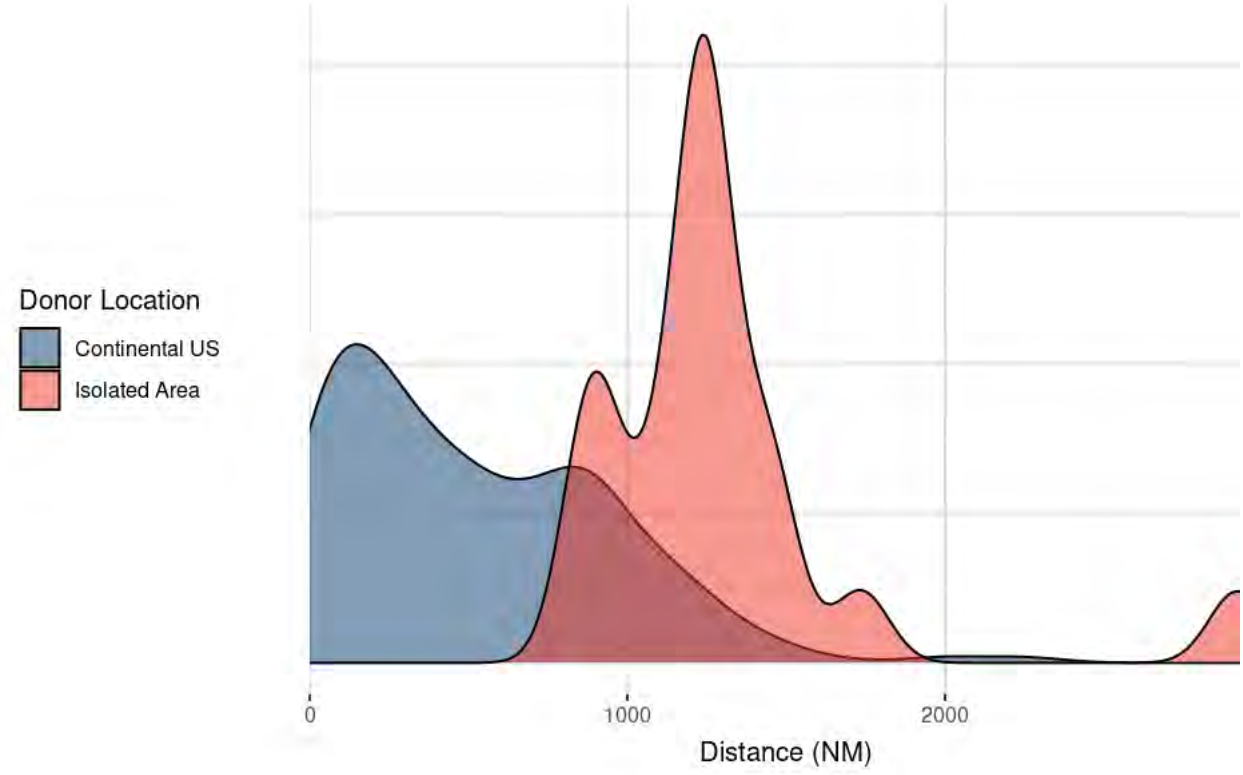
The lung candidate record in OPTN Waiting List could also be updated to indicate that transplant programs are reporting "acceptable lung laterality" rather than "lung preference" since this information would be used to bypass candidates on match runs. The Committee requested feedback on whether lung transplant programs support this change. If lung transplant programs are currently declining offers based on unacceptable laterality, the implementation 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[26]



A 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

[26] OPTN data as of database copy dated November 10, 2023. "Isolated area" refers to offers from Alaska or Puerto Rico.

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).

Post-Public Comment Discussion

The proposal asked the community for input on the two system enhancements. Sentiment supporting the bypass bilateral and other lung button expressed that this system enhancement would increase efficiency in the offer management process by preventing the unintentional screening out of viable organ opportunities for candidates who may need to cast a wider net. Feedback also indicated that this system enhancement would save time in scenarios where an offer does not meet a program's needs. One comment expressed support and provided a suggestion for a "reverse" option in scenarios where an OPO chooses to bypass bilateral lung candidates (because one lung has been accepted), but then the accepting program rescinds offer acceptance. When this feedback was discussed by the Committee, staff confirmed that the proposed enhancement would include the ability of the OPO to "roll back" the bypass. The Committee also confirmed that OPOs would use their discretion with allocation of bilateral lungs after use of the reverse feature but would not be able to rescind an offer from an already placed lung. After this discussion the Committee confirmed their recommendation for the bypass bilateral and other lung button system enhancement.[27]

Sentiment supporting opt in to offers from geographically isolated areas expressed that this system enhancement promotes organ utilization and improves the efficiency of organ allocation by:

- Ensuring that organs from geographically isolated areas are not overlooked simply because they fall outside the typical recovery distance specified by transplant programs.
- Allowing programs to expand their potential donor pools to include more remote areas without receiving excessive offers.
- Creating an increased layer of efficiency for those programs that have no intention of accepting organs from Alaska, Hawaii, or Puerto Rico due to their relative geographic separation.
- Allowing programs to take advantage of recent improvements involving perfusion technology to utilize donor organs they maybe would not have considered previously.

Respondents also recommended the Committee monitor for changes regarding organs traveling to and from isolated areas.

The Committee reviewed this feedback and confirmed their recommendation for the opt in to offers from geographically isolated areas system enhancement.[28]

Overall Sentiment from Public Comment

The Lung Transplantation Committee requested 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?
- For adult and pediatric lung transplant programs, what additional donor information or offer filters would be useful for your program?

[27] OPTN Lung Transplantation Committee. https://optn.transplant.hrsa.gov/about/committees/lung-transplantation-committee/.
[28] Ibid.

- 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?

The Lung Transplantation Committee presented the proposal to 8 committees for feedback, and a video presentation describing the proposal was posted to the OPTN website.[29] The proposal received 332 comments, including 31 substantive, written comments from all member types. Sentiment by member type and region are shown below in **Figures 7** and **8**.[30]

Figure 7 shows sentiment collected from participants who submit an individual public comment and from regional meeting participants. Overall sentiment was supportive, as indicated by a total sentiment score of 4.0 and no opposing or strongly opposing sentiment. Sentiment scores by region range from 3.7 to 4.4.

[29] The proposal was presented in full to five OPTN Committees, while the efficiency enhancements were presented to three OPTN Committees.
[30] Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support).

Figure 7. Sentiment by Region, *Promote Efficiency in Lung Allocation,* 2024 [31]

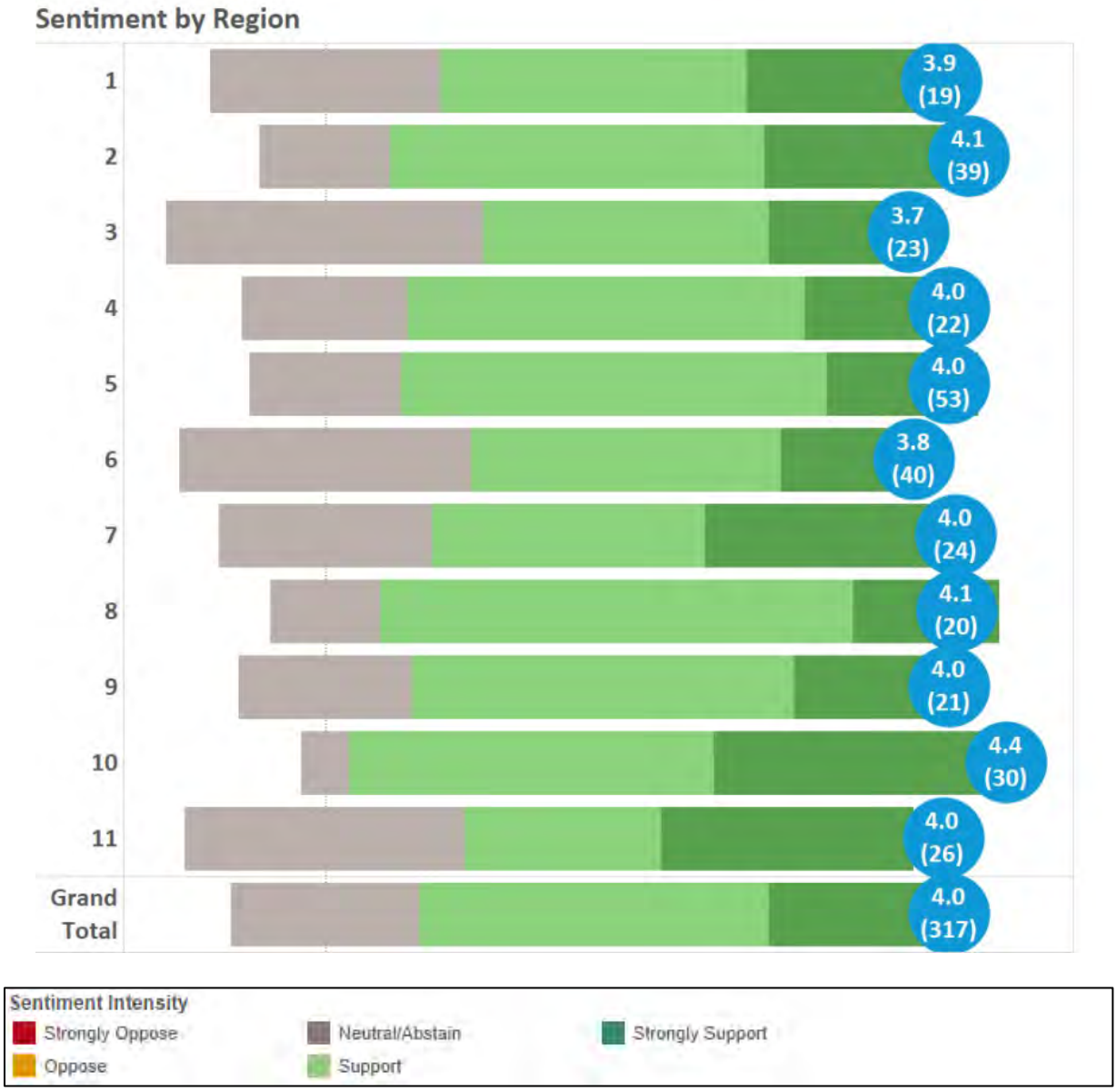
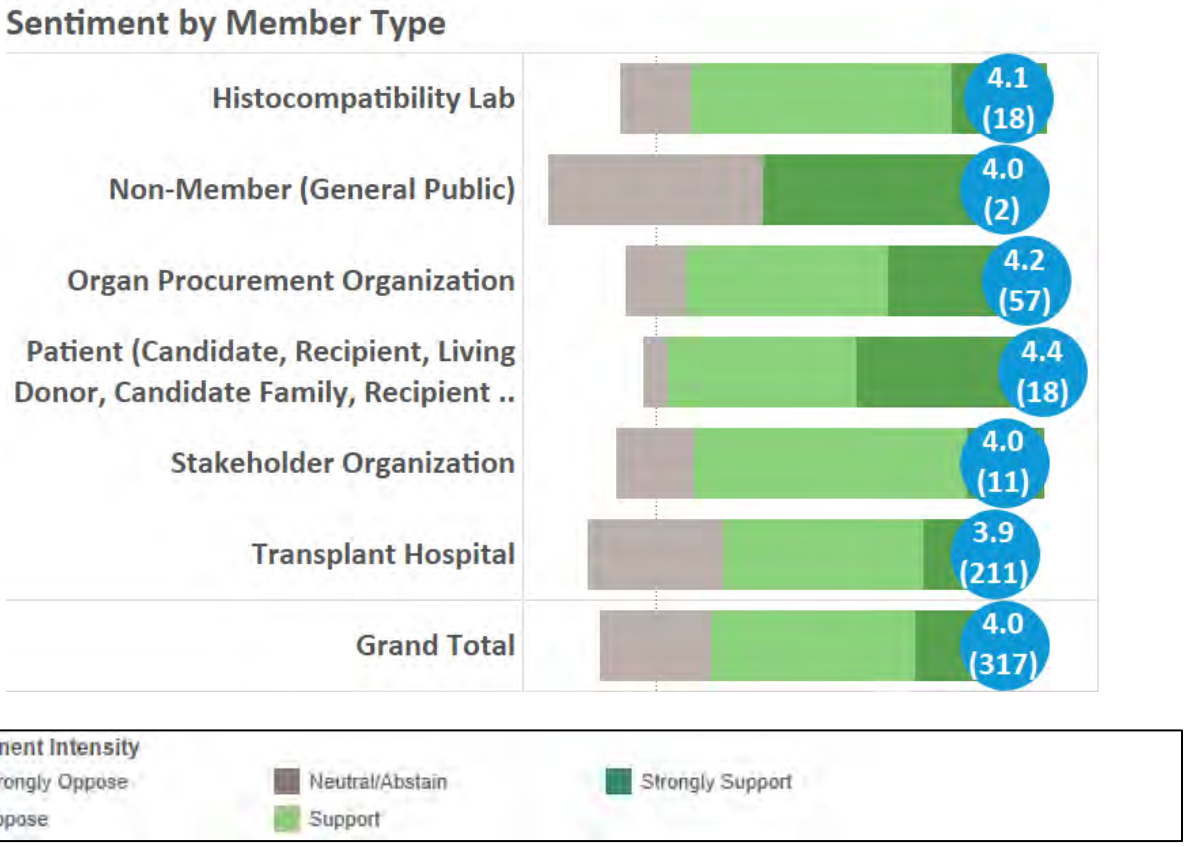


Figure 8 shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. There was overall support for the proposal from all member types, demonstrated by a sentiment score of 4.0 and no opposing or strongly opposing sentiment. Sentiment scores by member type range from 3.9 to 4.4.

[31] The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 8. Sentiment by Member Type, *Promote Efficiency of Lung Allocation*, 2024 [32]



Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list,"[33] 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,”[34] 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."[35] This proposal would add new data fields in the OPTN computer system on donor medical criteria to aid lung transplant programs in making decisions on organ acceptance. In the future these data elements will be analyzed for potential use as offer filters. This proposal also includes system enhancements intended to improve the efficiency of the organ offer and acceptance process for lung transplant programs and OPOs.

[32] The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.
[33] 42 U.S.C. §274(b)(2)(A)(ii).
[34] 42 CFR 121.11(a)(1)(i).
[35] 42 CFR 121.6(c).

OPTN Strategic Plan

Increase the number of transplants: The proposed data collection in the OPTN Donor Data and Matching System and proposed system enhancements aim to aid the evaluation of lung offers, thereby encouraging utilization of donor lungs and increasing lung transplants.

OPTN Data Collection Principles

Institutional members must provide sufficient data to the OPTN to allow it to develop transplant, donation, and allocation policies.

Implementation Considerations

Histocompatibility Laboratories

Operational Considerations

This proposal is not anticipated to have any operational impact on Histocompatibility Laboratories.

Fiscal Impact

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

Organ Procurement Organizations

Operational Considerations

OPOs would be able to report information on a history of anaphylaxis to peanut and/or tree nut and previous sternotomies for all donors. OPOs would also be able to use the bypass bilateral and other lung system enhancement 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.

Fiscal Impact

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

Transplant Programs

Operational Considerations

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. Transplant programs would also be able to use the opt in to offers from geographically isolated areas system enhancement to indicate if they would accept lung offers from a donor located in Hawaii, Puerto Rico, or Alaska.

Fiscal Impact

This proposal is anticipated to have low fiscal impact on transplant programs to train staff on additional data and system enhancements.

OPTN

Operational Considerations

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN contract requires 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.

Resource Estimates

It is estimated that 3,965 hours would be needed to implement this proposal. 3,700 of these would be technical implementation hours, broken down as follows:

- 2,200 of these hours to update the OPTN Donor Data and Matching System to add new data collection that aid evaluation of lung offers.
- 1,500 of these hours to implement the "Bypass bilateral and other lung" and Opt-in to offers from isolated areas system enhancements

It is estimated that 325 hours would be needed for ongoing support. Ongoing support includes research post-implementation monitoring, ongoing technical implementation support, and answering member questions, as necessary.

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.

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.

Data Collection Monitoring

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[36] A summary of the new data collection fields will be provided to the Committee approximately six months

[36] 42 CFR §121.8(a)(6).

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 so that analysis of the two additional data elements could be considered in any proposed future refinement of the current lung offer filters. 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. A post-public comment clarification was made to the history of anaphylaxis to peanut and/or tree nut data definition. The Committee also proposes two system enhancements that aim to increase efficiency of the organ management process and promote organ utilization. The Committee is asking the OPTN Board of Directors to approve the proposed data fields and system enhancements.

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, cross-references, and footnotes affected by the numbering will be updated as necessary.

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

Data Field	Form	Response Option 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

Appendix A: Public Comment 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.

Appendix B: Post Public-Comment Changes

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

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.

Appendix C: Updates to the OPTN Board of Directors

The *Promote Efficiency of Lung Allocation* proposal that was presented for public comment in Winter 2024, provided an overview of lung offer filters, which were released on January 31, 2024. Additionally, this paper requested community feedback on potential areas for future development, such as lung donor testing. **Appendix C** includes updates on the continued development of these items, which are not currently being presented for OPTN Board consideration.

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.[37] 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.[38] Offer filters do not modify organ allocation policies and do not change the order in which potential transplant recipients appear on the match run.

Offer filters are different from the donor acceptance criteria entered in OPTN Waiting List on a candidate record.[39] 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.[40] 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.[41]

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 OPOs. On January 31, 2024, lung offer filters were released as an optional tool for lung transplant programs. 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:

[37] Finnie, J. & Moriarty, S. "Better organ offer screening", https://unos.org/news/innovation/reducing-unwanted-organ-offers/.
[38] "Optimizing Usage of Offer Filters," OPTN, Briefing Paper, accessed October 4, 2023, available https://optn.transplant.hrsa.gov/media/vyonuirf/optn_osc_offer-filters_bp_june23.pdf.
[39] "Optimizing Usage of Kidney Offer Filters," OPTN, Concept Paper, accessed October 4, 2023, available at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/optimizing-usage-of-kidney-offer-filters/.
[40] Ibid.
[41] "Optimizing Usage of Offer Filters," OPTN, Policy Notice, accessed October 4, 2023, available at https://optn.transplant.hrsa.gov/media/xdvgftub/osc_offer-filters_policy-notice_jun-2023.pdf.

- Candidate age less than
- Calculated Panel Reactive Antibody (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.

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.[42] 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 included 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

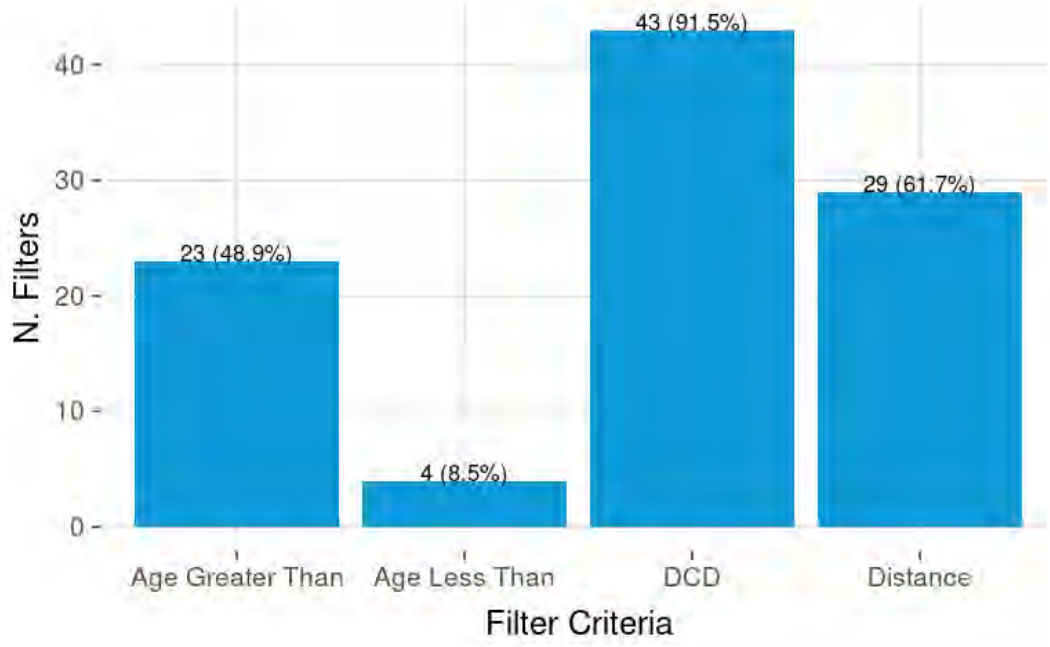
While the initial release of lung offer filters is limited to four filter criteria (donor type, distance, and donor age maximum and minimum), this is a starting point for development of additional lung-specific criteria.

Update on lung offer filters

Since implementation on January 31, 2024, 20 (28%) active transplant programs have turned on at least one offer filter criteria.[43] In total, 47 distinct filters have been enabled across the 20 programs; **Figure 9** shows the specific types of filters that have been created.[44] Overall, there are 43 (91.5%) filters with a DCD component, 29 (61.7%) filters with a Distance component, 23 (48.9%) filters with an Age Greater Than component, and 4 (8.5%) 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.

[42] "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-syst.pdf.
[43] Data as of April 22, 2024.
[44] Number of filters can exceed 20 as a program can enable multiple filters.

Figure 9. Types of filters enabled, 1/31/24- 4/22/24



On February 12, 2024, the OPTN and Committee held a lung offer filters webinar for professionals. The webinar provided the 177 attendees with the opportunity to learn more about how offer filters could improve efficiency for candidate matching at their own programs. Attendees also provided feedback on filters the Committee might consider developing in the future. The Committee continues to discuss ways to support lung transplant programs in the usage of offer filters, such as targeted outreach. The OPTN is also offering individualized assistance to programs that have program-specific questions regarding optimization of lung offer filters.

Feedback on potential offer filters

The Committee's request for recommendations for additional donor information for offer filters received broad feedback, including predicted Total Lung Capacity (pTLC), cigarette use, lung compliance, respiratory viral testing, sequence on the match run, and Epstein-Barr Virus (EBV) & Cytomegalovirus (CMV).

When the Committee discussed this feedback, they expressed interest in screening for pTLC and noted the need to determine which formula to use for calculating pTLC values.[45] The Committee also agreed that a filter for smoking history would be useful but pointed out that the current data collection on cigarette use in "pack years" may not fully capture smoking history and does not account for other inhalants. When discussing lung compliance data, the Committee expressed that this data would be too variable across institutions and difficult to reliably collect, making it a poor choice for an offer filter. As a potential alternative to lung compliance, the Committee suggested documenting peak airway pressure as it may correlate with lung compliance. When discussing respiratory viral testing, such as COVID-19, Influenza, and respiratory syncytial virus (RSV) as a filter, concerns were raised about uniform availability of testing across donor hospitals. Members talked through the possibility of using sequence on the

[45] See OPTN Lung Transplantation Committee meeting summary. March 21, 2024. https://optn.transplant.hrsa.gov/media/5n4bhzku/20240321_lung_msfinal.pdf.

match run as filter, which could help avoid review of organ offers that had already been turned down by many other centers. However, concerns were raised that such a filter may prevent acquisition of organs that could be viable later in that match run due to changing clinical circumstances. The Committee discussed that offer filters for EBV and CMV may be helpful to pediatric transplant programs.

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/H20/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.

Update on lung donor testing

Lung transplant program members have expressed concern about the quality of the organ offers they are receiving. Most often they 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 experienced by both OPOs and lung transplant programs, the Workgroup has been refining solutions that will help

both OPOs and lung transplant programs to improve the efficiency of lung donor testing. This project aims to increase efficiency of the donor candidate matching process by improving the quality of information and completeness of data for organ offers received by lung transplant programs.[46] The workgroup discussions to date have focused on providing arterial blood gas (ABG) results and chest x-rays on a timelier basis, adding Chest Computed Tomography (CT) Scan and echocardiogram to policy, and language changes in guidance to align with updated terminology.[47]

In Workgroup conversations, members have emphasized the importance of updating lung donor testing requirements while considering the varying capabilities of OPOs across the country. The Workgroup aims to strike a balance between requiring OPOs to provide additional information that will help lung programs make decisions on offers more quickly with the potential delay of offers if too many lung donor testing requirements are established. The Committee aims to sponsor this project during an upcoming public comment cycle.

Conclusion

The OPTN Lung Transplantation Committee will continue to pursue efficiency efforts related to lung offer filters and lung donor testing.

[46] Promote Efficiency of Lung Allocation Workgroup Summary. Marcg 12, 2024. https://optn.transplant.hrsa.gov/media/fkhj515q/20240312_lungefficiencywg_msfinal.pdf
[47] Ibid.