

Briefing to the OPTN Board of Directors on

Update Multi-Organ Allocation for Continuous Distribution of Lungs

OPTN Lung Transplantation Committee

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Update Multi-Organ Allocation for Continuous Distribution of Lungs

<i>Affected Policies:</i>	<i>5.10.F: Allocation of Lung-Kidneys</i> <i>5.10.G: Allocation of Heart-Liver and Lung-Liver</i> <i>6.6.F: Allocation of Heart-Lungs</i>
<i>Sponsoring Committee:</i>	<i>Lung Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022 – September 28, 2022</i>
<i>Board of Directors Meeting:</i>	<i>December 5, 2022</i>

Executive Summary

In December 2021, the OPTN Board of Directors approved the proposal *Establish Continuous Distribution of Lungs*.^{1,2} The proposal updated lung multi-organ allocation policies to reflect that lung candidates will be ranked according to a lung composite allocation score (CAS). Current multi-organ allocation policies use classifications, distance, and lung allocation score thresholds to indicate when an organ procurement organization must offer another organ along with a lung. The continuous distribution proposal replaced these thresholds with a lung CAS threshold for required multi-organ offers. The score threshold was selected to preserve eligibility for required multi-organ offers for about 95% of patients who receive lung multi-organ transplants in the current allocation system. Updated analysis with more recent data suggested that the selected threshold would not maintain access for as many patients as originally expected. Accordingly, the purpose of this proposal is to update the lung CAS threshold for multi-organ allocation (specifically for lung-liver, lung-kidney, and heart-lung) to ensure qualifying candidates maintain eligibility for required multi-organ shares with the implementation of continuous distribution of lungs.

¹ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 4, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

² Executive Summary of the OPTN Board of Directors Meeting, December 6, 2021. (Accessed May 26, 2022) <https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf>.

Purpose

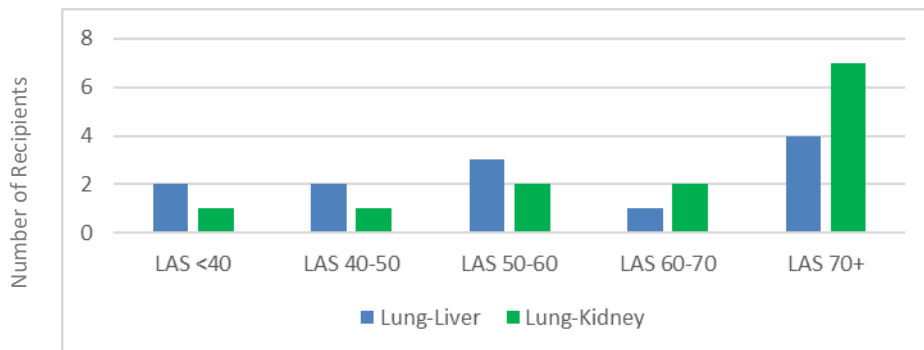
The purpose of this proposal is to update the lung composite allocation score (CAS) threshold for multi-organ allocation from 28 to 25 to ensure that qualifying lung-liver, lung-kidney, and heart-lung candidates maintain eligibility for required multi-organ shares with the implementation of continuous distribution of lungs.

Background

The OPTN released the proposal *Establish Continuous Distribution of Lungs* for public comment in August 2021.³ This proposal aimed to maintain similar rules surrounding multi-organ allocation to be in effect during the transition period while lung allocation is in a continuous distribution system and other organs remain in a classification-based system. To accomplish that end, the Lung Transplantation Committee (Committee) selected a lung CAS threshold to replace the classification, distance, and lung allocation score (LAS) thresholds used in current policy.

When selecting the CAS threshold for lung multi-organ allocation, the Committee aimed to maintain about the same level of access to transplant for lung-liver, lung-kidney, and heart-lung candidates as in the current system. Current policy for lung-liver and lung-kidney allocation was implemented on February 10, 2022, and requires offering livers and kidneys to lung candidates with an LAS of 35 or greater, or less than 12 years old.⁴ The LAS threshold was determined using the data shown in **Figure 1**.⁵

Figure 1: Number of Recipients by LAS at Transplant (2019)⁶



For multi-organ transplants performed in 2019, all of the lung-liver and lung-kidney transplants performed (12 and 13, respectively) would meet the criteria of having an LAS of 35 or greater, or being a candidate less than 12 years old.⁷

Current policy for heart-lung allocation refers to lung classifications, which are being eliminated in continuous distribution since candidates will be assigned a CAS. The classifications order candidates on the match run based on their medical urgency, age, blood type, and distance from the donor hospital (see *OPTN Policy 10.4 Lung Allocation Classifications and Rankings*). Current heart-lung policy directs OPOs to make organ offers to medically urgent heart and heart-lung candidates in classifications 1-4 on

³ “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed June 5, 2022, https://optn.transplant.hrsa.gov/media/4772/continuous_distribution_of_lungs-public_comment.pdf.

⁴ “Clarify Multi-Organ Allocation Policy,” Notice of OPTN Policy Change, accessed July 1, 2022, https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.

⁵ OPTN Public Comment Proposal, Clarify Multi-Organ Allocation Policy, January 21, 2021 – March 23, 2021. (Accessed June 28, 2021)

https://optn.transplant.hrsa.gov/media/4354/2021_pc_opo_clarify_multi_organ_allocation_policy.pdf.

⁶ *Ibid.*

⁷ *Ibid.*

the heart match run before offering the heart along with the lungs on the lung match run to candidates in classifications 1 through 12.

To determine the lung CAS threshold that should replace the LAS threshold and lung classifications, the Committee considered the expected distribution of CAS scores for patients who received lung-liver, lung-kidney, and heart-lung transplants in the current allocation system. The Committee set a CAS threshold of 28 to include most multi-organ lung recipients while preserving access to transplantation for single-organ heart, kidney and liver candidates. As an OPO makes offers down the lung match run, the OPO would be required to offer the heart, kidney, or liver to lung candidates registered for both organs if the candidate’s CAS was 28 or greater. The OPO would not be required to offer a heart, kidney, or liver to lung candidates with a CAS below 28. At that point, the OPO would proceed with allocation by following other multi-organ policies or offering the organs individually.

Table 1 shows the data that the Committee initially reviewed when selecting the CAS threshold of 28. This table shows the cumulative percent of lung multi-organ recipients that would be captured if the multi-organ threshold were set at a specified composite allocation score. The Committee sought to capture 99% of the lung-kidney recipients and therefore chose 28 as the cutoff for the composite allocation score. Overall, this cut-off was expected to capture about 95% of the recipients who received heart-lung, lung-liver, and lung-kidney transplants.

Table 1: Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011-05/13/2021⁸

Composite Allocation Score	Heart	Kidney	Liver	Total
32	23.84%	70.59%	46.94%	39.60%
31	50.19%	91.27%	68.23%	62.93%
30	74.28%	97.21%	82.02%	80.24%
29	83.76%	98.96%	92.39%	89.44%
28	89.19%	99.62%	98.09%	94.55%
27	93.02%	99.88%	99.36%	96.79%
26	95.15%	99.88%	99.47%	97.72%
25	97.24%	99.91%	99.52%	98.61%
24	98.59%	99.91%	99.52%	99.17%
23	99.13%	99.91%	99.52%	99.40%
22	99.41%	99.91%	99.52%	99.51%

The Committee also proposed some additional changes to heart-lung policy. OPOs will continue to offer organs to high-status heart and heart-lung candidates within 500 NM first. After that, OPOs will offer lungs and heart-lungs on the lung match run to candidates with a CAS of at least 28 before a heart alone would be offered from the heart match run to candidates further than 500 NM from the donor hospital, or listed at status three or lower. These changes provided more direction to OPOs than current allocation policies, by not permitting heart-alone allocation to continue until the heart was offered to all heart-lung candidates on the lung match run with a CAS of at least 28. However, if the lungs are placed with lung-alone candidates on the lung match run, then the OPO can proceed with heart-alone allocation. Fundamentally, the Committee sought to balance the difficulty in finding an appropriate donor for a candidate who requires multiple organs with the desire to provide earlier access to

⁸ OPTN Data as of June 11, 2021.

transplant for heart-alone candidates who are the most medically urgent, according to their status, and with the desire to save the largest number of lives possible with the limited supply of organs for transplant. The Heart Transplantation Committee supported this approach.⁹

Public comment responses were generally supportive of the changes to lung multi-organ allocation included in the proposal *Establish Continuous Distribution of Lungs*.¹⁰ There were some concerns from OPOs who wanted to ensure there was sufficient room for discretion when allocating several organs. The Committee retained the same level of OPO discretion as current policy in relation to lung-liver and lung-kidney allocation. In relation to heart-lung, the Committee decided that their approach balanced the comments supporting the prescriptive order between the heart and lung match with the feedback requesting more flexibility.

In December 2021, the OPTN Board of Directors approved the proposal *Establish Continuous Distribution of Lungs*.^{10,11} The OPTN subsequently began implementing the proposal. In spring 2022, further analysis indicated that the composite allocation score threshold of 28 would not preserve eligibility for required shares for as many multi-organ lung candidates as originally expected. Accordingly, the Committee determined that the threshold should be updated for the implementation of continuous distribution of lungs.

Proposal for Board Consideration

The Committee proposes changing the lung CAS threshold for lung-liver, lung-kidney, and heart-lung allocation from 28 to 25, and clarifying the policy language for heart-lung allocation.

Update the Lung CAS Threshold

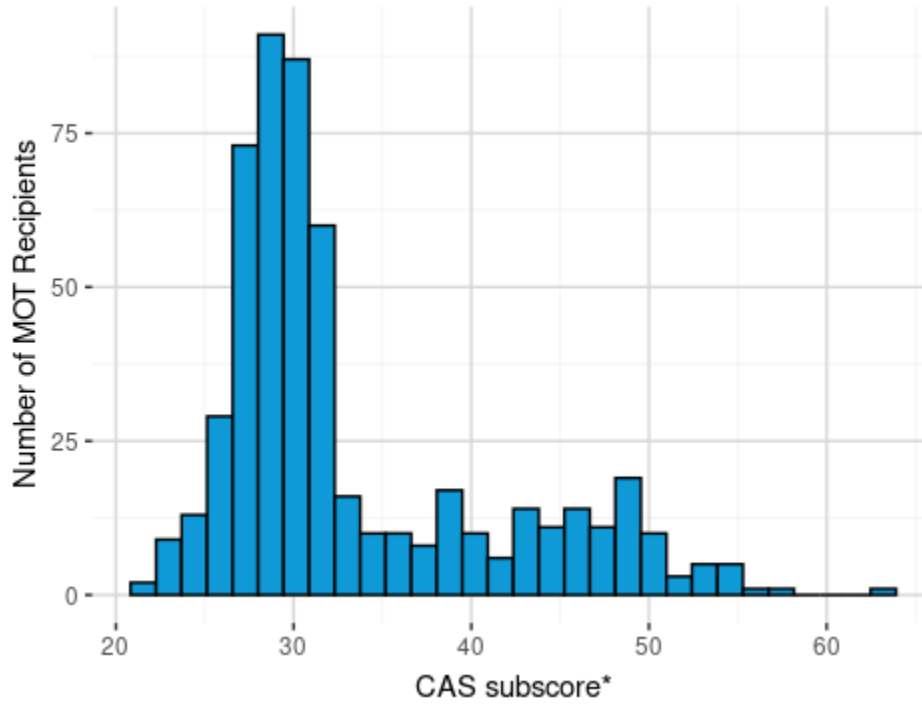
The Committee reviewed **Figure 2**, which shows the distribution of calculated lung CAS for patients who previously received lung-liver, lung-kidney, or heart-lung transplants based on match run data from January 1, 2011, to May 24, 2022. This analysis includes an additional year of data relative to the original analysis reviewed by the Committee. These scores do not include points for sensitization or prior living donor status, since those factors are not currently considered in lung allocation, and the OPTN does not have data to estimate how many points previous recipients would have received for those parts of the CAS. However, these scores do account for the patient's expected waitlist survival, expected post-transplant outcomes, blood type, height, pediatric status, travel efficiency, and proximity efficiency. The efficiency scores were calculated based on the patient's distance from the donor hospital on the match run on which they received their lung multi-organ transplant.

⁹ Heart Transplantation Committee Meeting Summary for September 21, 2021, OPTN, accessed June 19, 2022, https://optn.transplant.hrsa.gov/media/ju1jptbx/20210921_heart-committee-meeting-summary_final.pdf.

¹⁰ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

¹¹ Executive Summary of the OPTN Board of Directors Meeting, December 6, 2021. (Accessed May 26, 2022) <https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf>.

Figure 2. Distribution of Calculated Lung CAS for Patients Who Received Lung Multi-Organ Transplants between January 1, 2011 and May 24, 2022¹²



*Does not include points for CPRA and prior living donor

Most of the calculated CAS scores for lung multi-organ recipients fall within a range of 25 to 32. Accordingly, **Figure 3** below shows that a CAS threshold of 28 would be expected to capture only about 76% of those patients who previously received lung multi-organ transplants. **Table 2** shows that a CAS threshold of 25 would be expected to capture 95% of those patients who previously received lung multi-organ transplants.

¹² OPTN Data as of May 2022.

Figure 3. Percent of Lung Multi-Organ Recipients by Calculated Lung CAS¹³

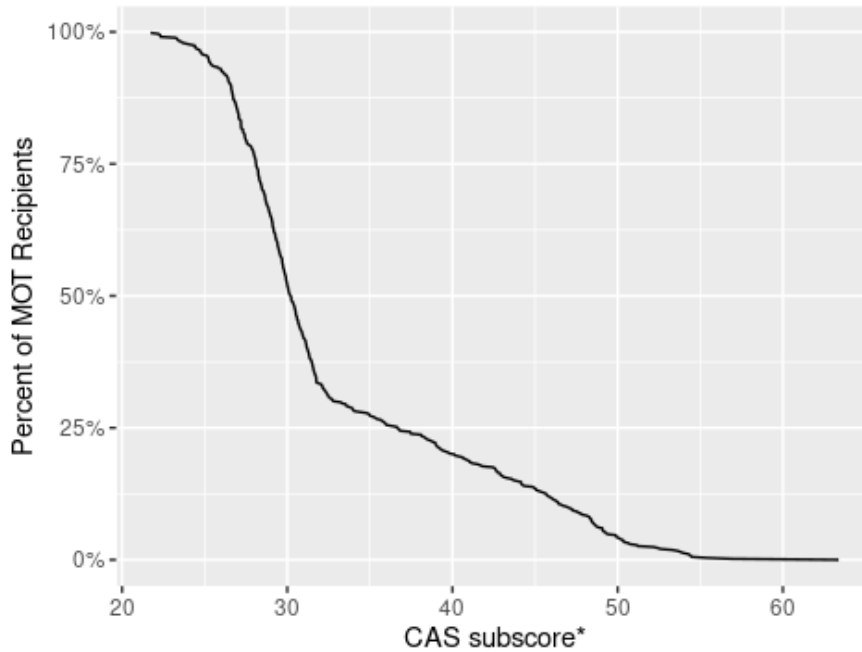


Table 2. Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011 to 05/24/2022¹⁴

Percentage of Recipients	Composite Allocation Score Threshold			
	Heart	Kidney	Liver	Total
90%	26.6	26.2	28.0	26.6
95%	25.2	24.0	27.7	25.2

Based on this more recent data, the Committee proposes changing the CAS threshold for required lung-liver, lung-kidney, and heart-lung organ offers from 28 to 25. This change will preserve eligibility for multi-organ allocation for about 95% of patients who receive those offers currently, consistent with the Committee’s original intent as presented previously in public comment and to the OPTN Board of Directors.

Clarify Heart-Lung Policy

The Committee proposes clarifications to heart-lung policy to reinforce that OPOs must always follow the match run when allocating both the heart and lungs from the same donor. These clarifications do not substantively change the heart-lung policy changes approved as part of the proposal *Establish Continuous Distribution of Lungs*.¹⁵ The clarifications indicate that once the OPO shifts to the lung match run after making required offers to heart and heart-lung candidates, then the OPO must offer organs to lung-alone and heart-lung candidates on the lung match run until offers have been made to all heart-lung candidates meeting the CAS threshold. At that point, the OPO must continue offering to heart and

¹³OPTN Data as of May 2022.

¹⁴ Ibid.

¹⁵ “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed June 18, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

heart-lung candidates. If the lungs are placed with lung-alone candidates on the lung match run, then the OPO can proceed with heart-alone allocation.

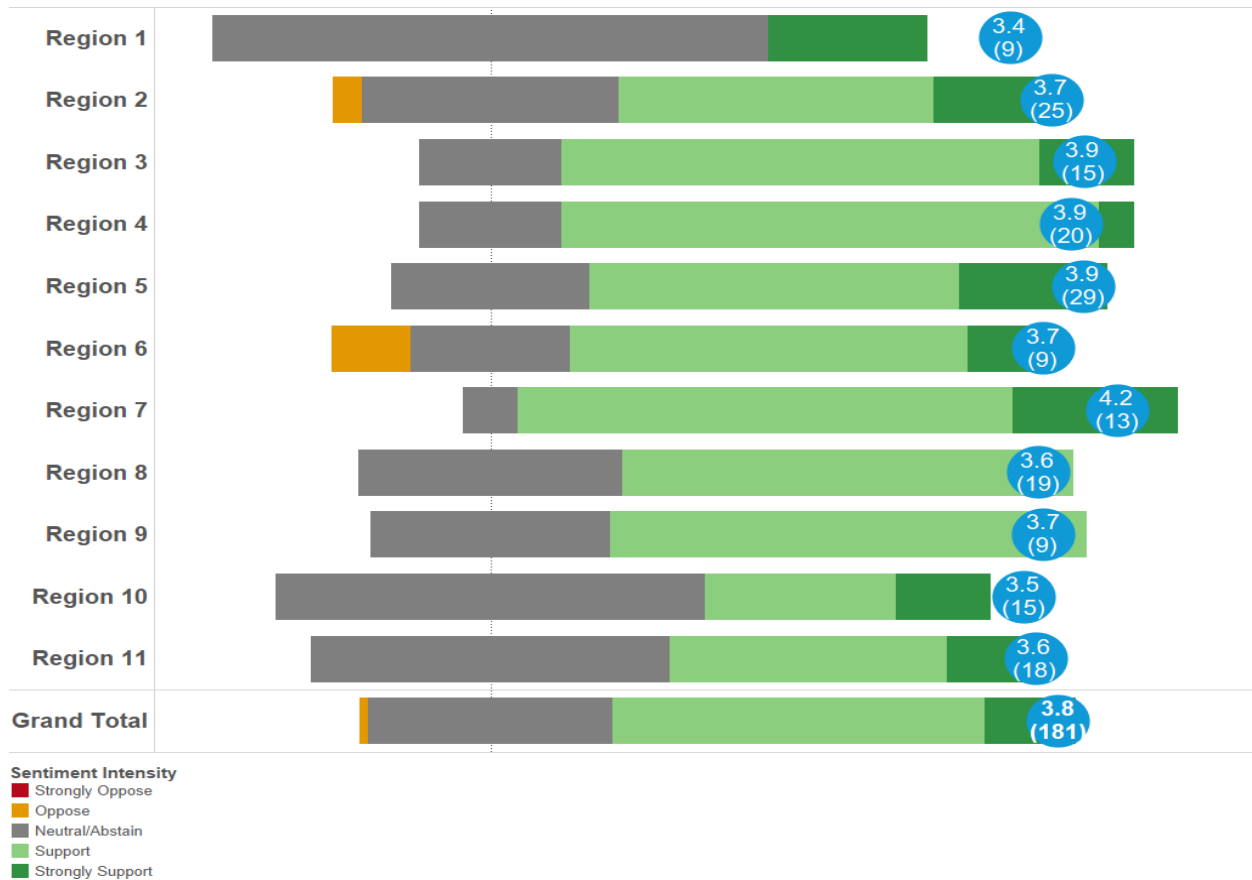
Overall Sentiment from Public Comment

The purpose of public comment is to gather feedback from stakeholders in the transplant community. This proposal was released for public comment from August 3, 2022, to September 28, 2022. The Committee has discussed this feedback to finalize this proposal for the December 2022 Board of Directors meeting. Public comment feedback for this proposal touches on several themes. The proposal received overall support and was recommended for advancement by most stakeholders. There was minimal opposition received from regional meetings and public comment.

The committee reviewed and discussed the results of public comment and concluded the public sentiment supports sending the proposal to the Board with no changes.

Figure 5 shows the overall sentiment received at regional meetings. Overall sentiment was supportive, indicated by the total score of 3.8. The table reflects that 181 members submitted sentiment on this proposal at regional meetings. The proposal received some opposition in region 2 due to the opposition towards extension of multi-organ allocation in general. There was an opposed vote from region 6 with no commentary or feedback.

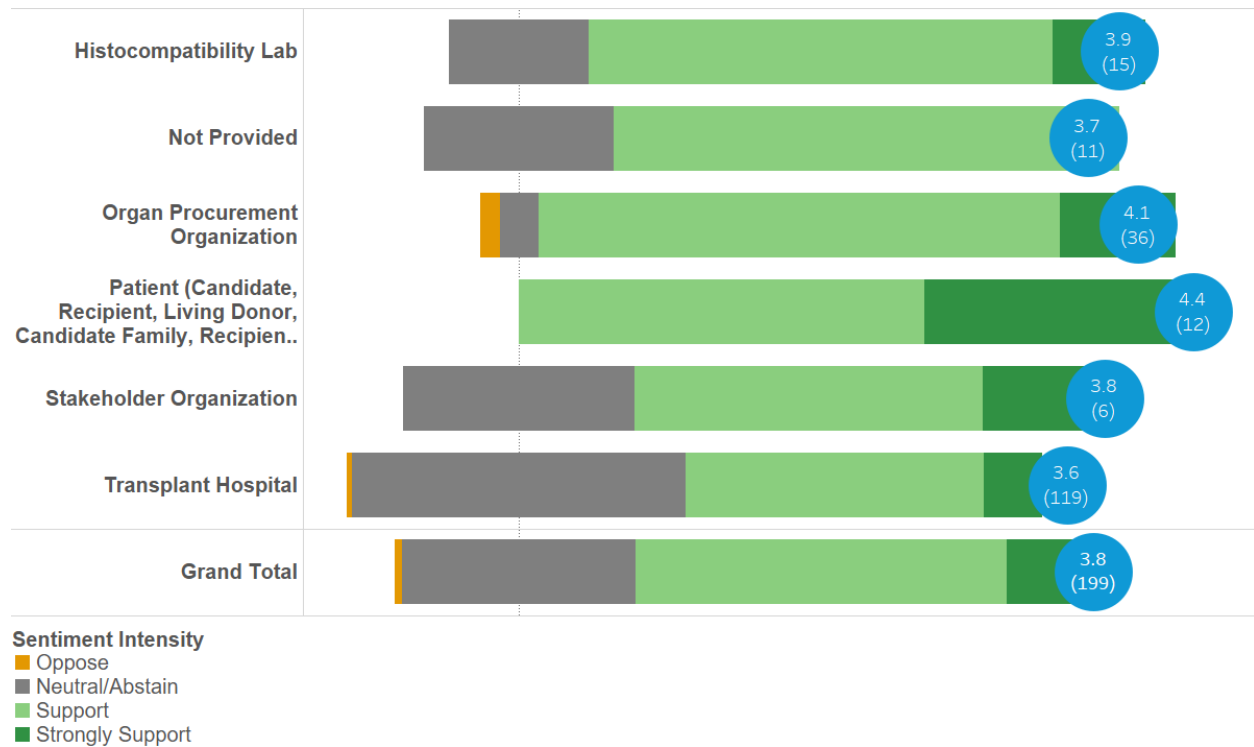
Figure 5: Regional Sentiment, Lung Multi-Organ Proposal, 2022¹⁶



¹⁶ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 4 reflects the sentiment of each member type. There was overall support for this proposal, with a total sentiment score of 3.8. This was an average sentiment gathered from 199 respondents. Many transplant hospitals supported this proposal or chose to abstain, but these members had minor opposition. The highest average sentiment is held by patients. One OPO opposed this proposal but did not provide rationale.

Figure 4. Sentiment by Member Type, Lung Multi-Organ Proposal, 2022¹⁷



In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit written comment. Responses are submitted by members of the public at large, as well as on behalf of regions and committees.¹⁸

Commenters covered many different topics, including the following themes:

- Support for the proposal
- Concern about the impact on kidney-alone candidates
- Concern with multi-organ allocation in general
- Concern about application to other organs

¹⁷ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

¹⁸ For comments submitted on behalf of the region or committees, the public comment item is discussed at the meeting, OPTN staff draft a summary of the discussion, and the Regional Councillor or Committee leadership review the comment, confirming it is an accurate representation of the discussion that occurred.

Support for Proposal

Several comments supported this proposal and stated that changing the CAS threshold from 28 to 25 is appropriate in order to preserve access to multi-organ transplant for lung candidates in the continuous distribution allocation system. One commenter noted that quality of life suffers greatly when experiencing failure in multiple organs, and another commenter stated that multi-organ recipients are often young and have no other options for life-saving treatments.

Impact on Kidney Candidates

Members attending regional meetings and the American Society of Transplantation (AST) voiced concern that this proposal may lead to allocation of additional kidneys to multi-organ candidates over kidney-only candidates. They noted there has been a large increase in multi-transplants including kidneys. AST noted that multi-organ candidates often have a shorter life expectancy than kidney-only candidates, and high-quality kidneys are used for multi-organ allocation rather than kidney-only transplants with long waiting times. A member in a regional meeting recommended appropriate use of lung-kidney multi-organ listing and argued the proposal provides no data regarding whether historic lung-kidney multi-organ transplantation was appropriate. A few participants throughout regional meetings shared these sentiments.

The Committee noted that this proposal is not intended to expand multi-organ transplantation and is instead just intended to maintain access that lung candidates have under the current allocation system while the MOT Committee considers more comprehensive updates to kidney multi-organ allocation. Additionally, the OPTN Board of Directors approved a proposal in June 2022¹⁹ to establish eligibility criteria and a safety net for lung-kidney allocation,²⁰ which addresses the concern about appropriate use of lung-kidney multi-organ listing.

General Concerns with Multi-Organ Allocation

Some comments expressed concerns regarding multi-organ allocation. The Transplant Coordinators Committee noted the absence of policy for combinations of more than two organs, and expressed concern that multi-organ candidates will be farther down the match run in continuous distribution and other organs may have already been placed.

These concerns will be shared with the OPTN Ad Hoc Multi-Organ Transplantation (MOT) Committee, as these concerns are out of the scope of this proposal.

Application to Other Organs

A concern mentioned in regional meetings was how this proposal will be updated across a continuous spectrum once all organs move to continuous distribution for allocation. AST stated organs should be aligned with the same process as much as possible after the lung composite allocation score is implemented. AST suggested the proposal include monitoring to assess whether medical eligibility criteria should be developed in the future. Some regional meeting feedback shared this sentiment.

¹⁹ Board of Directors Executive Summary, OPTN, June 27, 2022, accessed October 7, 2022, https://optn.transplant.hrsa.gov/media/hv3p3alg/20220627_board-of-directors_executive-summary.pdf.

²⁰ "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, Policy Notice, accessed October 7, 2022, https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice_est-elgblty-crit-and-safety-for-hrt-kid-and-lung-kid-alloc_mot.pdf.

As indicated in the proposal to *Establish Continuous Distribution of Lungs*,²¹ monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 3 months, 6 months and then annually for 3 years following the allocation change, and will include metrics such as the number of multi-organ candidates on the waiting list, and the number of multi-organ transplant recipients. The OPTN has established medical eligibility criteria for lung-kidney, heart-kidney, and liver-kidney, and the MOT Committee plans to consider medical eligibility criteria for other organ combinations in the future.²²

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal for the Board consideration under the authority of NOTA, which requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,”²³ and the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”²⁴ The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.” This proposal:

- **Is based on sound medical judgment:**²⁵ The proposed composite allocation score threshold for lung multi-organ allocation is an evidence-based change, based on OPTN data analysis, intended to preserve access to organ offers for candidates previously deemed by the OPTN to warrant this priority based on OPTN data analysis of previous lung multi-organ transplants.
- **Seeks to achieve the best use of donated organs:**²⁶ By ensuring organs are allocated and transplanted according to medical urgency. Multi-organ allocation is necessary for some candidates to achieve a successful transplant outcome, in terms of patient and graft survival, whereas reasonable limits on multi-organ allocation allows organs to be offered to single-organ candidates. This proposal is consistent with recommendations from the OPTN white paper *Ethical Implications of Multi-Organ Transplants* to “establish allocation policies that prioritize [multi-organ] candidates who have medical urgency in both organs, but generally do not prioritize [multi-organ] candidates who do not have medical urgency in one organ.”²⁷

²¹ “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed May 26, 2022,

<https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

²² “Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation,” OPTN, Public Comment Proposal, accessed October 7, 2022, https://optn.transplant.hrsa.gov/media/npslvryi/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation_winter-2022-pc.pdf.

²³ 42 U.S.C. §274(b)(2)(B).

²⁴ 42 CFR §121.4(a).

²⁵ 42 CFR §121.8(a)(1).

²⁶ 42 CFR §121.8(a)(2).

²⁷ “Ethical Implications of Multi-Organ Transplants,” OPTN, Briefing Paper, accessed June 19, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

- **Is specific for each organ or combination of organs:**²⁸ In this case, lung-liver, lung-kidney, and heart-lung combinations.
- **Is designed to avoid wasting organs:**²⁹ The Committee does not expect impacts on organs recovered but not transplanted. Although the modeling results for the continuous distribution of lungs proposal showed a lower transplant rate, they did not show a decrease in the number of transplants. The change in transplant rate is a result of an increase in waiting time for candidates who can wait longer for a transplant.³⁰
- **Is designed to...promote patient access to transplantation:**³¹ Setting a composite allocation threshold for multi-organ allocation balances access to transplantation for multi-organ and single-organ candidates by ensuring that more medically urgent lung candidates who need a second organ will receive those offers, and allowing the OPO to offer the second organ to single-organ candidates when the lung multi-organ candidates do not have as much medical urgency for transplantation.
- **Is designed to...promote the efficient management of organ placement:**³² Reasonable, evidence-based, and clear limits in multi-organ allocation policy allow OPOs to move through the organ allocation process without excessively delaying allocation, ensuring that organs get to the right candidate expeditiously.
- **Is not based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:**³³ This proposal is not based on a candidate's place of registration or place of listing, except to the extent required to achieve efficient management of organ placement, as captured by the placement efficiency component of the CAS.³⁴

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.³⁵

OPTN Strategic Plan

1. *Improve equity in access to transplants:*

Multi-organ policies are intended to provide access to transplant for multi-organ candidates who need more than one organ to have a good outcome, while preserving access to transplant for single-organ candidates. This update will ensure that multi-organ lung candidates maintain their access to transplant with implementation of continuous distribution of lungs.

2. *Improve waitlisted patient, living donor, and transplant recipient outcomes:*

Candidates who qualify for required multi-organ shares gain a survival benefit from multi-organ transplantation relative to lung-alone transplantation, so preserving access to required shares for these candidates will prevent increases in transplant recipient mortality.

²⁸ 42 CFR §121.8(a)(4).

²⁹ 42 CFR §121.8(a)(5)

³⁰ SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf

³¹ 42 CFR §121.8(a)(5)

³² *Id.*

³³ 42 CFR §121.8(a)(8)

³⁴ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

³⁵ 42 CFR §121.8(a)(3).

Implementation Considerations

Member and OPTN Operations

This proposal is not expected to have any fiscal impact on transplant hospitals, organ procurement organizations, or histocompatibility laboratories, but would have a small impact on the OPTN. This proposal will not require operational changes due to the threshold change.

Operational Considerations

The OPTN is distributing educational materials related to the new lung allocation system. This includes a playlist in our OPTN Learning Management System-UNOS Connect.³⁶ In September 2022, the OPTN released a training entitled “Scoring and Exceptions Under Lung Continuous Distribution,” and the OPTN is developing a new training for Lung Review Board members. Additionally, the OPTN published a set of CAS summary reference statistics so that transplant programs can see how the calculated CAS for their currently registered candidates compare to the broader lung candidate population.³⁷ In September 2022, the OPTN released a training entitled “Scoring and Exceptions Under Lung Continuous Distribution,” and the OPTN is developing a new training for Lung Review Board members. The OPTN maintains a Tool Kit page to alert the community of additional educational offering on lung continuous distribution policy.³⁸

Resource Estimates

The OPTN contractor does not estimate implementation hours for this proposal as the hours required to update lung multi-organ allocation were accounted for in the *Establish Continuous Distribution of Lungs* effort. The OPTN contractor estimates 0 hours for ongoing support since this will be covered in the hours include in the continuous distribution monitoring plan. Ongoing support will involve answering member questions and monitoring as outlined in the *Establish Continuous Distribution of Lungs* effort.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”³⁹ As indicated in the proposal *Establish Continuous Distribution of Lungs*,⁴⁰ the OPTN will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and the OPTN will investigate potential policy violations that are identified.

³⁶ “Lung Continuous Distribution,” UNOS Connect, accessed October 14, 2022, <https://unoslearn.csod.com/ui/lms-learner-playlist/PlaylistDetails?playlistId=08e98b86-896c-4946-9045-5596d9aa8e60>

³⁷ “Lung CAS Summary,” UNOS, September 27, 2022, accessed October 14, 2022, <https://unos.org/news/lung-cas-score-summary/>

³⁸ ‘Lung Continuous Distribution Policy,’ OPTN, Toolkit, accessed October 14, 2022, <https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/>

³⁹ 42 CFR §121.8(a)(7)

⁴⁰ “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”⁴¹ As indicated in the proposal to *Establish Continuous Distribution of Lungs*,⁴² monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 3 months, 6 months and then annually for 3 years following the allocation change, and will include metrics such as the number of multi-organ candidates on the waiting list, and the number of multi-organ transplant recipients.

Conclusion

The Committee proposes changing the lung composite allocation score threshold for required lung-liver, lung-kidney, and heart-lung offers from 28 to 25 to preserve access to multi-organ allocation for about 95% of patients who receive those offers currently.

⁴¹ 42 CFR §121.8(a)(6).

⁴² “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

Policy Language

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

5.10.F: Allocation of Lung-Kidneys

When an OPO is offering a lung, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a lung and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR was less than 18 years old when registered on the lung waiting list, or
- PTR has a Lung Composite Allocation Score of 2825 or greater, and meets eligibility according to *Table 5-5: Medical Eligibility Criteria for Lung-Kidney Allocation*

If a host OPO is offering a kidney and a lung from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the lung to candidates who meet either of the eligibility criteria described in Policy 5.10.F. [...]

5.10.G Allocation of Heart-Liver and Lung-Liver

When an OPO is offering a heart or lung, and a liver is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver* must be offered the liver. When an OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-6*, the OPO has the discretion to offer the liver to either PTR.

Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver

If an OPO is offering a heart or lung, and a PTR is also registered for a liver:	The OPO must offer the liver if the PTR meets the following criteria:
Heart	<ul style="list-style-type: none"> • Registered at a transplant hospital at or within 500 NM of the donor hospital • Heart Adult Status 1, 2, 3 or any active pediatric status
Lung	Has a Lung Composite Allocation Score of <u>2825</u> or greater

It is permissible for the OPO to offer the liver to other PTRs who do not meet the criteria in Policy 5.10.G.

28 **6.6.F. Allocation of Heart-Lungs**

29 **6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old**

30 If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must
31 offer the heart and lung in the following order:

- 32
- 33 1. To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy*
34 *6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*
 - 35 2. To all lung and heart-lung PTRs ~~with a lung composite allocation score of 28 or higher~~
36 according to *Policy 10.1 Allocation of Lungs* until offers have been made to all heart-lung
37 PTRs with a lung composite allocation score of 25 or higher
 - 38 3. To heart and heart-lung PTRs in classifications 5 or later according to *Policy 6.6.D: Allocation*
39 *of Hearts from Donors at Least 18 Years Old*.

40 The host OPO must follow the order on each match run, including heart-lung, heart, and lung
41 candidates.

42

43 **6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old**

44 If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must
45 offer:

- 46 1. To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to *Policy*
47 *6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*
- 48 2. To all lung and heart-lung PTRs ~~with a lung composite allocation score of 28 or higher~~
49 according to *Policy 10.1 Allocation of Lungs* until offers have been made to all heart-lung
50 PTRs with a lung composite allocation score of 25 or higher
- 51 3. To heart and heart-lung PTRs in classifications 13 or later according to *Policy 6.6.E:*
52 *Allocation of Hearts from Donors Less Than 18 Years Old*

53 The host OPO must follow the order on each match run, including heart-lung, heart, and lung
54 candidates.

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