

Public Comment Proposal

Modify Lung Allocation by Blood Type

OPTN Lung Transplantation Committee

*Prepared by: Kaitlin Swanner
UNOS Policy and Community Relations Department*

Contents

Executive Summary	2
Purpose	3
Background	3
Overview of Proposal	11
NOTA and Final Rule Analysis	17
Implementation Considerations	20
Post-implementation Monitoring	21
Conclusion	22
Considerations for the Community	22
Policy Language	23

Modify Lung Allocation by Blood Type

Affected Policy: 10.1.C.1 Blood Type
Sponsoring Committee: Lung Transplantation
Public Comment Period: August 24, 2023 – September 7, 2023

Executive Summary

Continuous distribution of lungs was implemented on March 9, 2023. One of the goals of continuous distribution is to increase transplant opportunities for patients who are medically harder to match¹ based on biological characteristics like blood type. Simulation modeling reviewed in the development of the lung continuous distribution policy indicated that the policy would increase transplants for blood type O candidates, who are blood type compatible with fewer donors than candidates of other blood types. However, since implementation of continuous distribution of lungs, the proportion of lung transplants performed for blood type O transplant recipients has declined. Accordingly, the Lung Transplantation Committee proposes modifying how blood type is incorporated into lung allocation to provide more proportional access to lung transplantation for candidates of all blood types, and to improve access to lung transplantation for blood type O candidates.

¹ "Continuous distribution," OPTN, accessed August 16, 2023, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>.

Purpose

The purpose of this proposal is to modify how blood type is incorporated into lung allocation to provide more proportional access to lung transplantation for candidates of all blood types and to improve access to lung transplantation for blood type O candidates.

Background

A candidate's blood type can limit their ability to find a compatible organ donor.² Accordingly, blood type is accounted for in OPTN organ allocation policies.³ With the transition from a classification-based allocation system to continuous distribution, the OPTN implemented changes to how blood type is incorporated into lung allocation.⁴ In both the former classification system and the newer continuous distribution system, the OPTN sought to provide equitable access for candidates regardless of biological differences like blood type. The two frameworks used different approaches to achieve this common goal. In the former allocation system, which used the lung allocation score (LAS), offers to candidates with a blood type identical to the donor's blood type were generally prioritized over offers to candidates with a compatible blood type.

The continuous distribution system does not give priority for identical blood types over compatible blood types. Instead, the continuous distribution lung composite allocation score (CAS) uses a continuous rating scale for blood type based on the likelihood of finding a compatible donor (**Table 1**). This approach reflects that the primary purpose of incorporating blood type into the allocation score is to promote patient access and provide equity in the system, rather than to prioritize identical blood type transplants for a clinical reason.⁵ This approach also allows very medically urgent candidates to get priority for blood type compatible donor lungs over blood type identical candidates who are less medically urgent, which is expected to reduce waiting list mortality for lung candidates overall.

Table 1. Estimated Proportion of Blood Type Compatible and Incompatible Donors by Candidate Blood Type⁶

Candidate blood group	Blood type compatible donors	Proportion compatible	Proportion incompatible	Rating
O	1,375	0.50	0.50	9.10%
A	2,367	0.86	0.14	0.91%
B	1,698	0.62	0.38	4.88%
AB	2,751	1.00	0.00	0.00%

While equity in access to transplant is the primary reason for assigning points for blood type, there are also clinical considerations regarding blood type that are incorporated into the allocation system via

² Yaron D. Barac, Mike S. Mulvihill, Morgan L. Cox, et al., "Implications of blood group on lung transplantation rates: A propensity-matched registry analysis," *The Journal of Heart and Lung Transplantation* 38 (2019): 73-82, <https://doi.org/10.1016/j.healun.2018.09.013>.

³ "OPTN policies," OPTN, accessed August 16, 2023, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

⁴ "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, accessed August 9, 2023, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

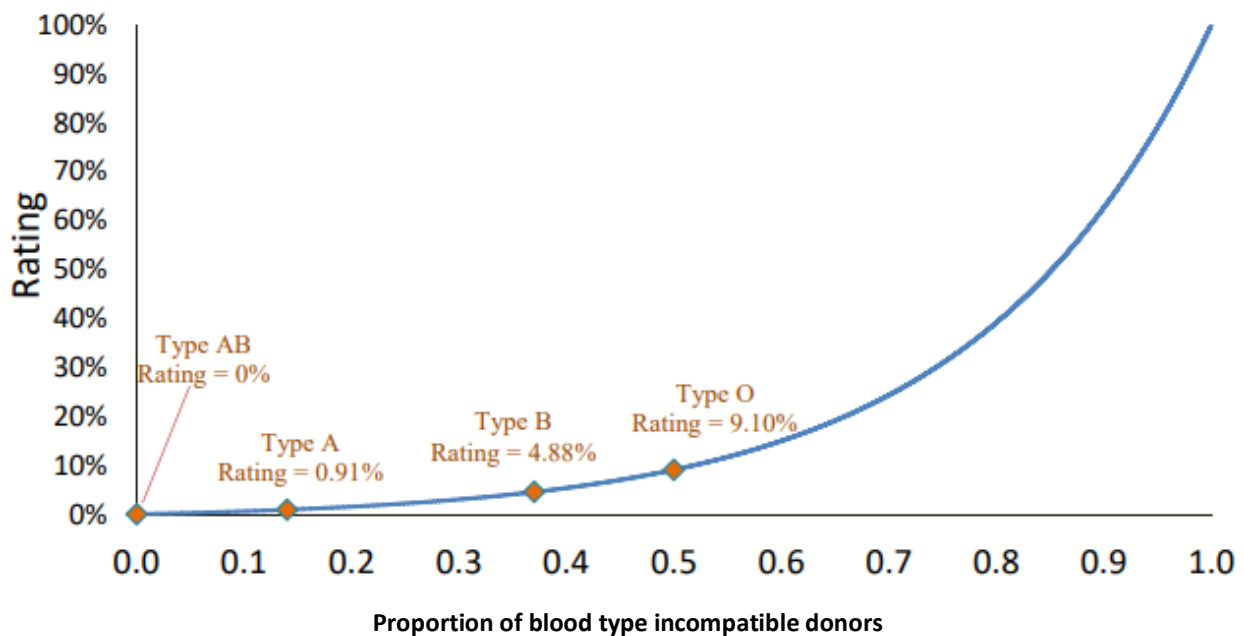
⁵ "Update on the Continuous Distribution of Organs Project," OPTN, Request for Feedback, accessed August 9, 2023, https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf.

⁶ Per OPTN data on donor lungs recovered in 2019. See "A guide to calculating the Lung Composite Allocation Score (Lung CAS)," OPTN, accessed August 16, 2023, https://optn.transplant.hrsa.gov/media/jhcppfnd/guide_to_calculating_lung_composite_allocation_score.pdf.

screening. Except in rare cases,^{7,8} lung candidates generally cannot receive organs from donors with an incompatible blood type. The OPTN has long had screening rules for blood type incompatible organs as a patient safety measure. Those screening rules remained in place with the implementation of continuous distribution of lungs. Candidates with a blood type incompatible with a donor's blood type are screened off the match runs and do not receive lung offers from those donors.⁹

Since blood type O candidates may only receive donor organs from blood type O donors, blood type O candidates receive the most points for blood type in the lung CAS. Blood type B candidates are compatible with organs from blood type B and O donors and receive the second highest number of points. Blood type A candidates receive fewer points as they are compatible with organs from blood type A donors, which are more common than blood type B donors, as well as O donors. Finally, blood type AB candidates receive no points for blood type because they are compatible with donors of all blood types. The points assigned for each blood type were determined by the proportion of blood type incompatible donors in a cohort of lung donors recovered in 2019.¹⁰ These proportions were then converted into a rating using a steep nonlinear curve, as shown in **Figure 1**. Since the rating scales for blood type, Calculated Panel Reactive Antibody (CPRA), and height are all based on the proportion of incompatible donors, these three rating scales are aligned on the same curve. The steep nonlinear curve was selected to give the largest boost in points to candidates who face the greatest challenges in finding a compatible donor based on these traits.

Figure 1. Lung CAS Blood Type Rating Scale



⁷ Toyofumi F. Check-Yoshikawa, "ABO blood type incompatible lung transplantation," *Journal of Thoracic Disease* 15 no. 6 (2023): 3427- 3442, doi: 10.21037/jtd-23-48.

⁸ Pediatric ABOi lung transplants are permitted by OPTN *Policy 10.4 Eligibility Criteria* in certain circumstances given that "newborn infants do not produce isohemagglutinins, and serum Anti-A or Anti-B antibody titers usually remain low until the age of 12 to 14 months" per West, Lori J, Stacey M Pollock-Barziv, Anne I Dipchand, K. Jin Lee, Carl J Cardella, Leland N Benson, Ivan M Rebeyka, and John G Coles. "ABO-Incompatible Heart Transplantation in Infants." *The New England Journal of Medicine* 344, no. 11 (2001): 793– 800. <https://doi.org/10.1056/NEJM200103153441102>.

⁹ Except for pediatric candidates who qualify for incompatible blood type offers per OPTN *Policy 10.4 Eligibility Criteria*.

¹⁰ "A guide to calculating the Lung Composite Allocation Score (Lung CAS)," OPTN, accessed August 16, 2023, https://optn.transplant.hrsa.gov/media/ihcoppfd/guide_to_calculating_lung_composite_allocation_score.pdf.

In the lung CAS, blood type is assigned a weight of 5 out of 100, as shown in **Table 2**.

Table 2: 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

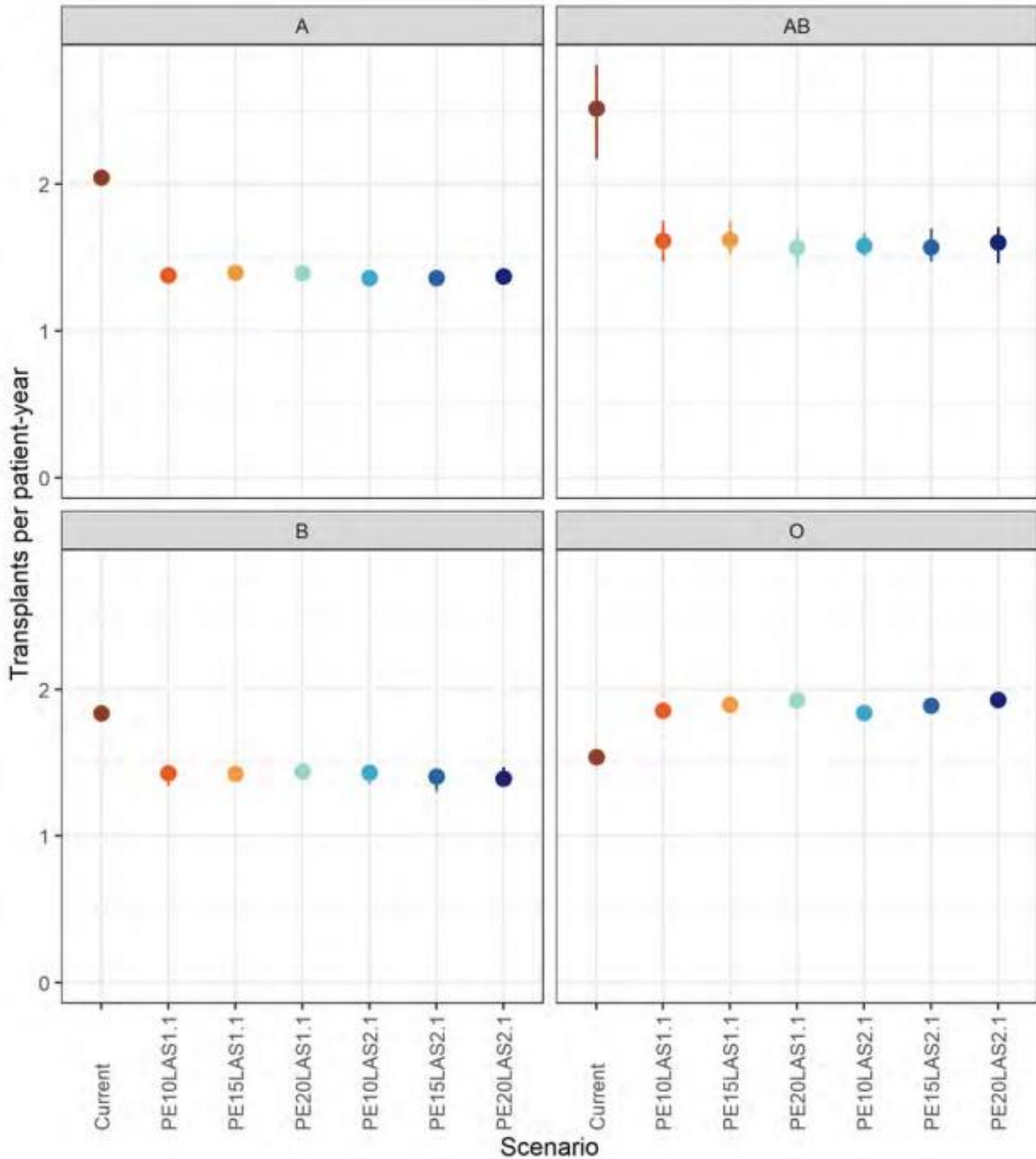
The points assigned for blood type are calculated by multiplying the blood type rating (e.g., 9.10% for blood type O) by the weight for blood type (which is 5) to yield the values shown in **Table 3**, which are listed in *OPTN Policy 10.1.C.1 Blood Type*.

Table 3: Lung CAS Points By Blood Type Per Current Policy

A candidate with a blood type of	Will receive this many lung blood type points
AB	0
A	.0455
B	.2439
O	.4550

In developing the lung continuous distribution system, the OPTN Lung Transplantation Committee (Committee) considered placing additional weight on blood type to ensure blood type O candidates had appropriate access to transplant. However, simulation modeling completed by the SRTR in 2021 suggested that transplant rates for blood type O candidates would increase under all continuous allocation scenarios considered by the Committee, as shown in **Figure 2**. The scenario labeled “PE10LAS1:1” refers to the allocation system that was implemented by the OPTN on March 9, 2023.

Figure 2: 2021 Lung Continuous Distribution Simulations: Transplant Rates by Blood Type¹¹

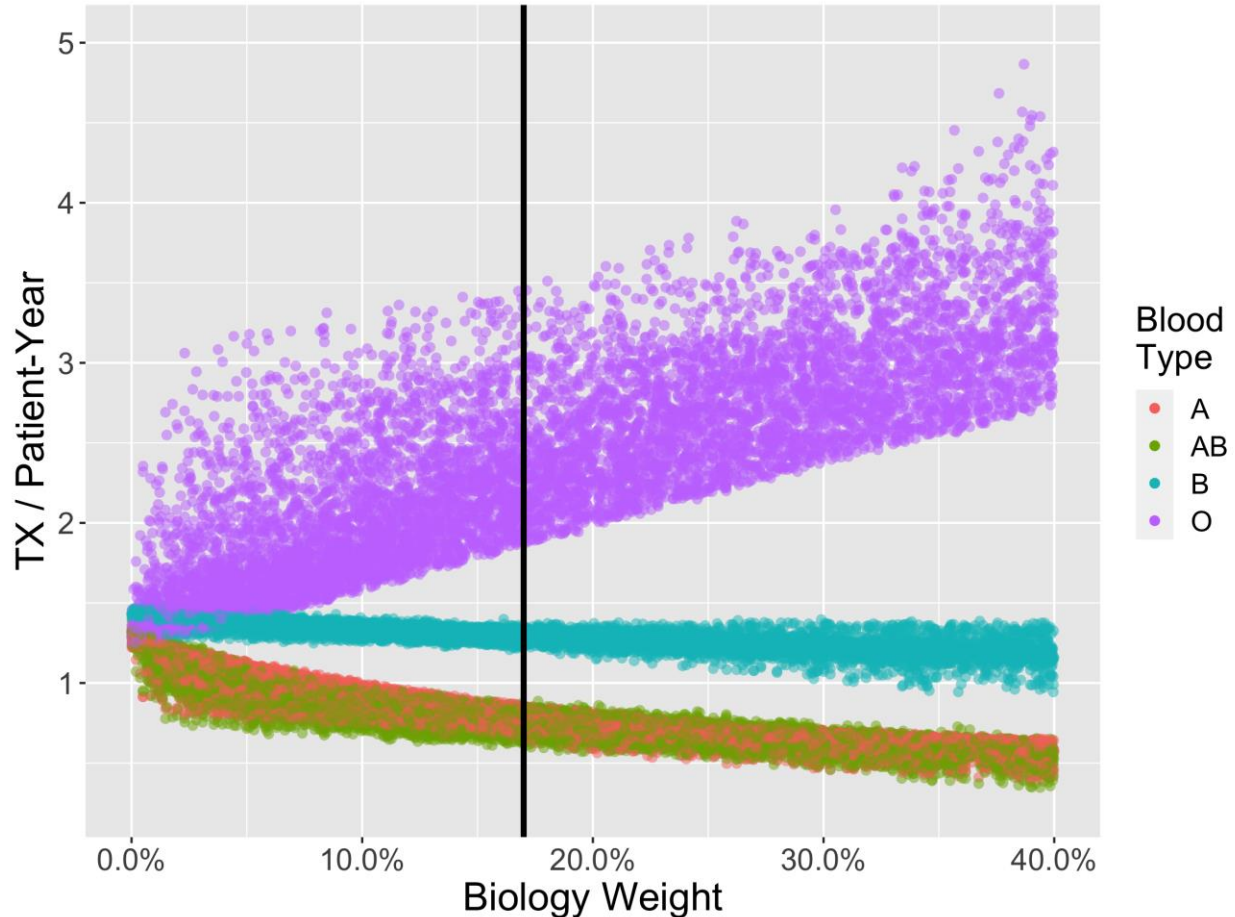


Accordingly, the Committee believed that placing additional weight on blood type or giving more weight to blood type O candidates would potentially give excess priority for transplant to blood type O

¹¹ “Continuous distribution simulations for lung transplant: Round 2,” SRTR, May 28, 2021, accessed August 3, 2023, available https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf. “Current” refers to the policy in place prior to implementation of continuous distribution (which used the lung allocation score or LAS); “PE10,” “PE15” and “PE20” refers to the weight placed on placement efficiency, and “LAS 1:1” and “LAS 2:1” refers to whether medical urgency and post-transplant outcomes carried equal weight or whether medical urgency was weighted twice as much as post-transplant outcomes.

candidates, thereby introducing a disparity in access to transplant for candidates of other blood types, as shown in **Figure 3**.

Figure 3. 2021 Analysis of Estimated Transplant Rates by Blood Type for Varying Weights on Candidate Biology Rating Scale¹²



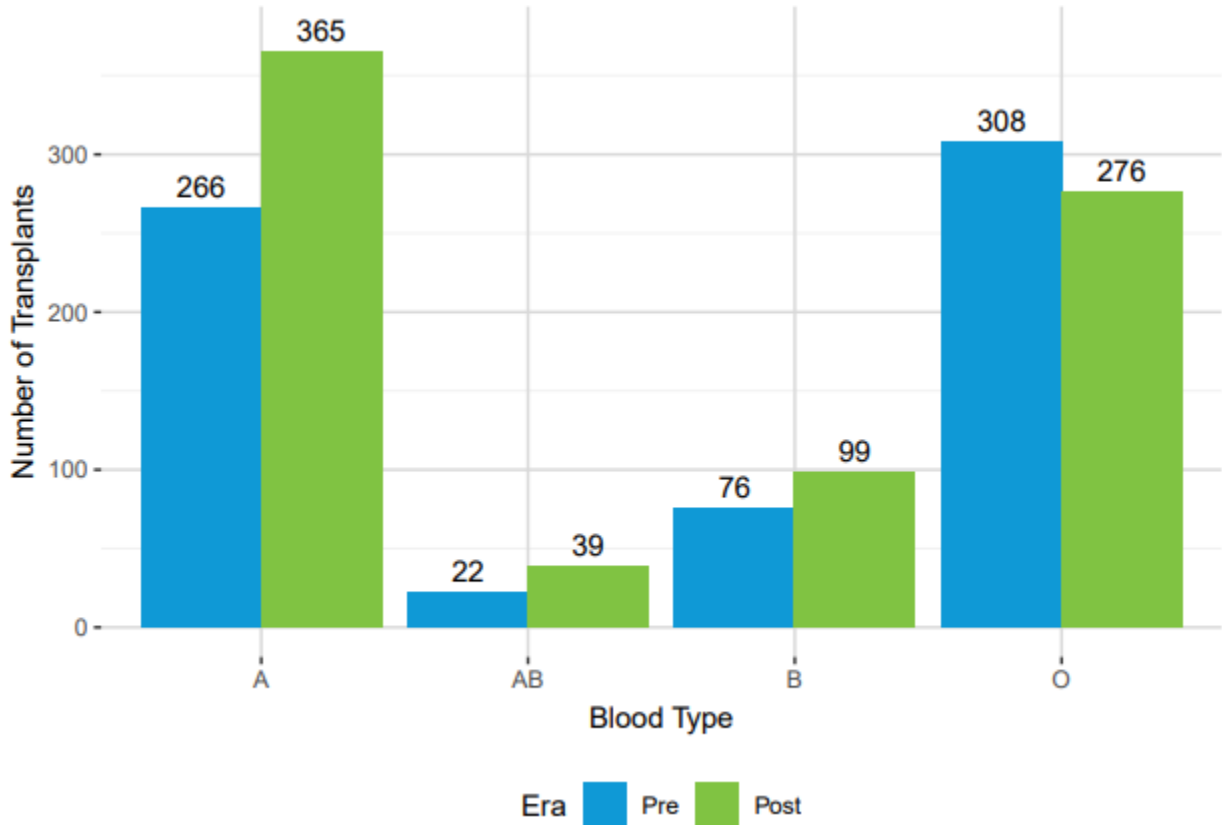
The Committee decided to include transplant volume by blood type in the monitoring plan for continuous distribution of lungs in order to closely monitor access to transplant based on blood type.

In July 2023, the Committee received the monitoring report for the first three months of continuous distribution of lungs. Transplants for blood type O candidates declined from 308 in the 3 months prior to implementation (the pre-policy era) to 276 in the 3 months following implementation (the post-policy era), whereas transplants increased for candidates of all other blood types, as shown in **Figure 4**.¹³

¹² MIT optimization analysis presented to the OPTN Lung Transplantation Committee on March 31, 2021, meeting summary accessed August 3, 2023, https://optn.transplant.hrsa.gov/media/4579/20210331_lung_meeting_summary.pdf.

¹³ "Lung Continuous Distribution Three Month Monitoring Report," OPTN, July 13, 2023, accessed August 3, 2023, https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf. The pre-policy era was December 7, 2022 – March 8, 2023, and the post-policy era was March 9, 2023 – June 8, 2023.

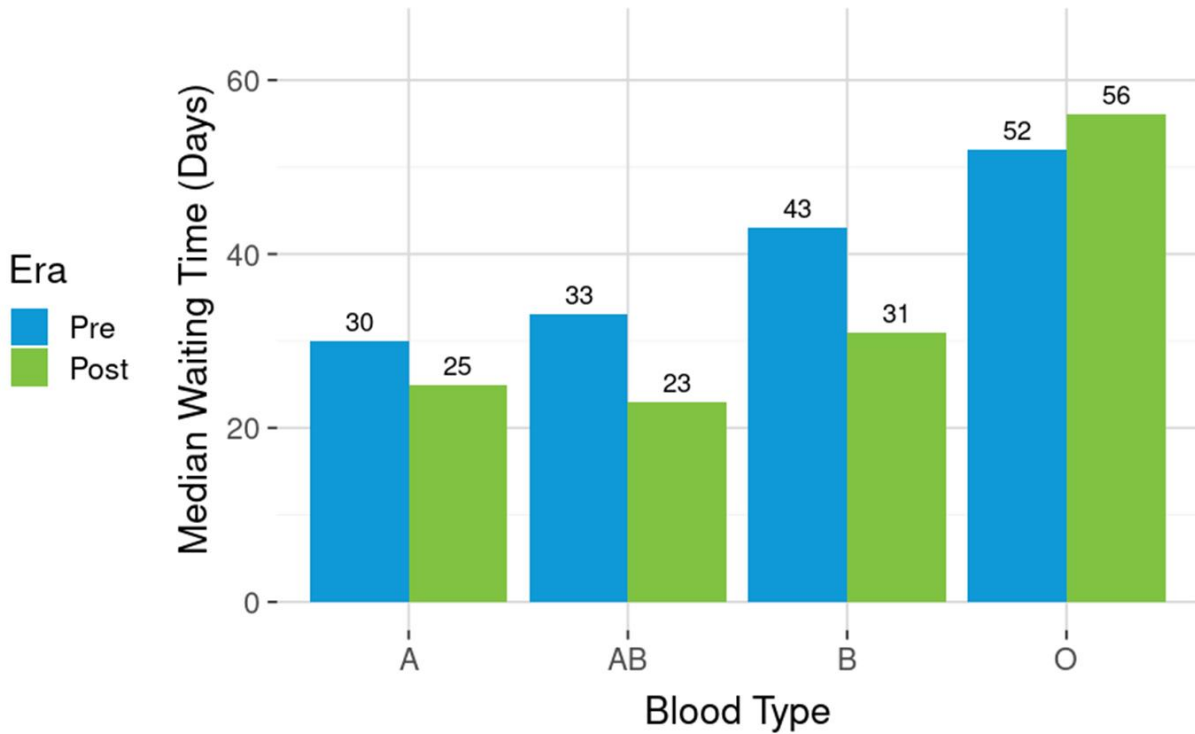
Figure 4: Number of Lung Transplants by Blood Type in the Pre-Policy Era (December 7, 2022 – March 8, 2023) and Post-Policy Era (March 9, 2023 – June 8, 2023)



In the pre-policy era (3 months prior to implementation of continuous distribution), 45.8% of transplants were for blood type O recipients compared to 35.4% of transplants in the post-policy era. The proportion of blood type O candidates ever waiting remained around 50% in both the pre- and post-policy eras. Further analysis requested by the Committee indicated that a higher proportion of blood type O donor lungs went to blood type compatible recipients (blood types A, B, or AB) than to blood type identical recipients (blood type O) in the post-policy era. In the pre-policy era, 86.3% of blood type O donor lungs went to blood type O recipients whereas in the post-policy era, 67.5% of blood type O donor lungs went to blood type O recipients. Further analysis indicated that median waiting time for transplant increased for blood type O candidates and declined for candidates of other blood types, as shown in **Figure 5**. Anecdotally, lung transplant program members have provided feedback to the OPTN that they are seeing this trend at their programs in that they have a growing queue of blood type O lung candidates awaiting transplant.¹⁴

¹⁴ As reported by attendees of the virtual listening session for lung program directors held on July 25, 2023, as well as by members of the Committee.

Figure 5. Median Waiting Time for Transplant by Blood Type in the Pre-Policy Era (December 7, 2022 – March 8, 2023) and Post-Policy Era (March 9, 2023 – June 8, 2023)



Additionally, blood type O candidates had higher medical urgency points at the time of transplant relative to candidates of other blood types, as shown in **Figure 6** and **Table 4**. This difference is statistically significant (Kruskal-Wallis $p < 0.001$), though there is no statistically significant difference in medical urgency points by blood type in candidates at the time of listing, or for candidates ever waiting in the three months following implementation of continuous distribution of lungs. Taken together, these analyses suggest that blood type O candidates are becoming more medically urgent than candidates of other blood types before they are able to receive a transplant.

Figure 6: Medical Urgency Points at Transplant by Blood Type in the Post-Policy Era (March 9, 2023 – June 8, 2023)

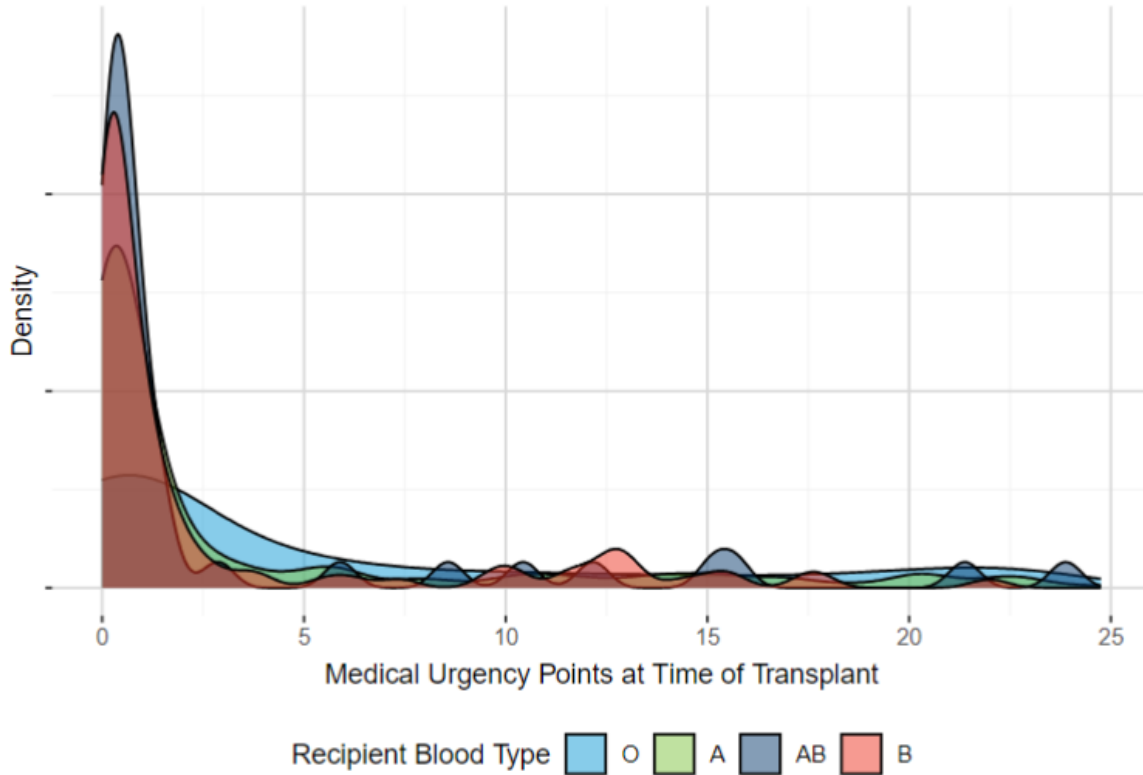


Table 4: Medical Urgency Points at Transplant by Blood Type

Recipient Blood Type	N Candidates	Min	25th Percentile	Mean	Median	75th Percentile	90th Percentile	Max
O	276	0.0275	0.25750	5.685288	1.2325	9.41500	20.01625	23.2250
A	365	0.0175	0.18000	3.679479	0.5925	3.42250	14.76950	24.7500
AB	39	0.0475	0.26375	3.379039	0.6200	1.46375	12.75850	23.8775
B	99	0.0000	0.18000	2.926818	0.4950	1.94625	12.52750	21.9750

While evaluating why actual transplant volume for blood type O recipients did not match the trends suggested by the modeling, SRTR staff determined that their modeling overestimated blood type O transplant rates because the simulation allowed for recipients to receive lungs from donors of any blood type, regardless of compatibility. In other words, the increase in blood type O transplants observed in the simulation modeling reflected blood type incompatible transplants that would not actually occur in practice. Based on this finding, the trends observed in the monitoring report, and concerns from the community about access to transplant for blood type O candidates, the Committee proposes modifying how blood type is incorporated into lung allocation to provide more equitable access to transplant for blood type O candidates.

Overview of Proposal

The Committee proposes modifying the blood type rating scale so that blood type O candidates receive the full 5 points allocated for blood type in the lung CAS. The proposed points assigned by blood type based on this rating scale are shown in **Table 5**.

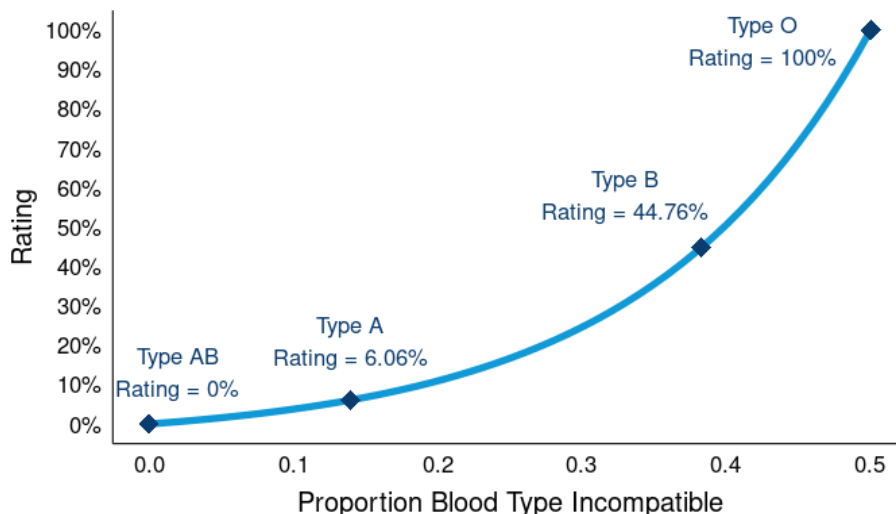
Table 5: Proposed Lung CAS Points By Blood Type

A candidate with a blood type of	Receives this many lung blood type points under current policy	Would receive this many lung blood type points under the proposed policy
AB	0	0
A	0.0455	0.3032
B	0.2439	2.2382
O	0.4550	5.0000

These points were determined by the following method:

- The proportion of incompatible donors shown in **Table 1** were scaled up by dividing by the range of incompatibility so that the blood type with the highest proportion of incompatibility (which is blood type O) achieves a rating of 1.000.
 - Blood type O: $(0.5002)/(0.5002 - 0) = 1$
 - Blood type B: $(0.3828)/(0.5002 - 0) = 0.7653$
 - Blood type A: $(0.1396)/(0.5002 - 0) = 0.2791$
 - Blood type AB: $(0)/(0.5002 - 0) = 0$
- A nonlinear curve was applied using the equation $[(25^{(\text{upscaled proportion incompatible})} - 1)/24]$ to get the rating scale (**Figure 7**). This nonlinear curve uses a base of 25 and is shallower than the current rating scale, which uses a base of 100.
- The ratings were multiplied by the 5-point weight assigned to blood type in the lung CAS to determine the blood type points.

Figure 7. Proposed Blood Type Rating Scale



The Committee proposes adopting this rating scale for blood type in lung allocation based on modeling and analysis (summarized below) estimating that these changes would increase access to transplant for blood type O candidates, thereby providing more proportional access to transplant for candidates of all blood types, without substantial increases in overall waiting list mortality or median distance traveled between the donor hospital and the recipient hospital.

The Committee is issuing this proposal for a two-week public comment period, which is shorter than the usual public comment period,¹⁵ due to the decline in blood type O transplants observed in the monitoring report; concerns from the community about access to transplant for blood type O candidates; and the finding that the initial modeling reviewed by the OPTN to develop the current blood type rating scale overestimated blood type O transplants.

Rationale and Supporting Analysis for Proposed Blood Type Rating Scale

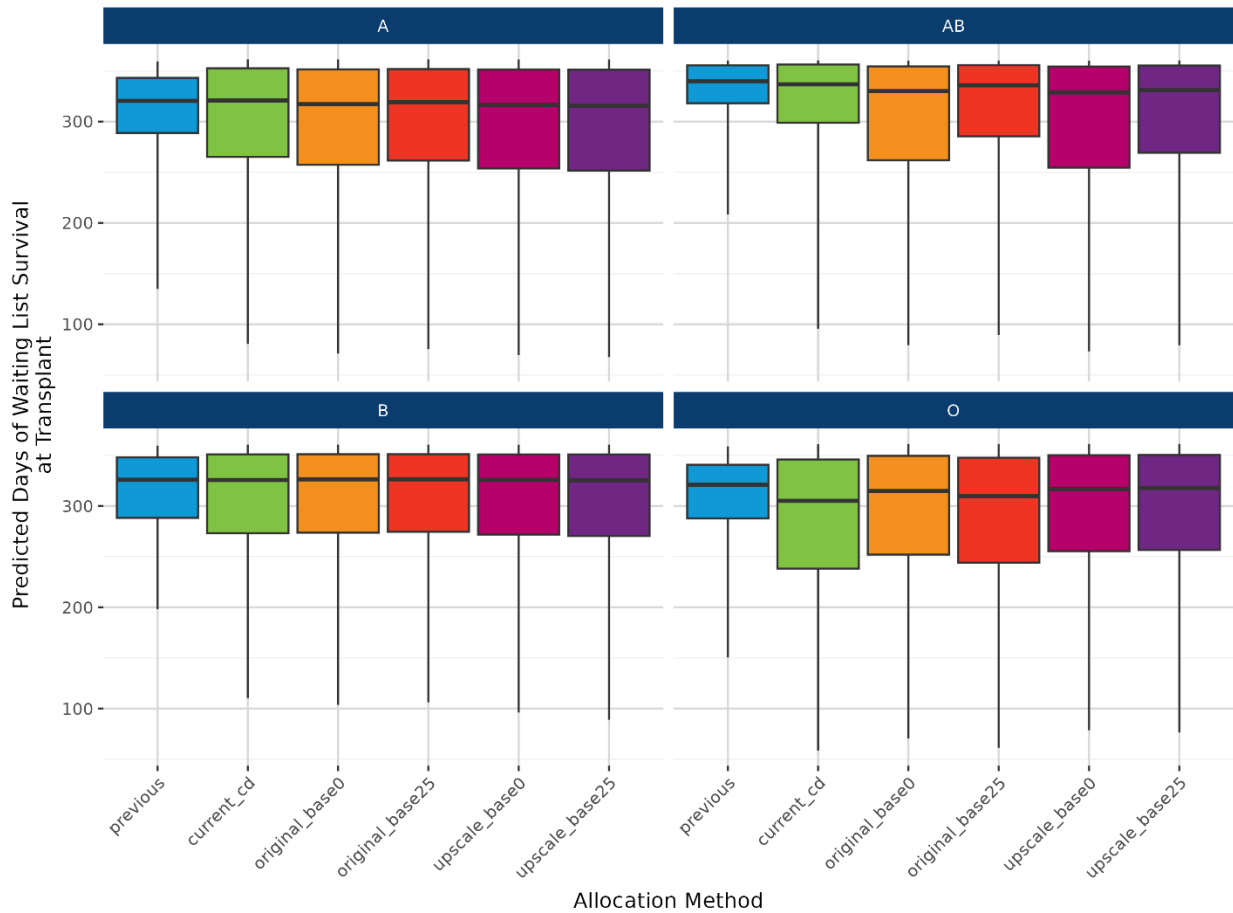
To assess options for modifying how blood type is incorporated into lung allocation, the Committee reviewed simulated allocation modeling and match run analysis. The simulation modeling was prepared by a team associated with the Massachusetts Institute of Technology (MIT) using the 2015 version of Thoracic Simulated Allocation Model (TSAM) with adjustments to correct the blood type issue identified in the 2021 version of TSAM, as well as other updates to approximate the 2021 TSAM (which was the model used by the SRTR in support of the original continuous distribution of lungs proposal). This modified version of TSAM was used to deliver analysis to the Committee on an expedited timeline in order to address the concern about blood type more quickly than would be possible if the Committee had waited for newer versions of simulation models. The analysis from the modified TSAM provided several metrics for each simulated blood type rating scale, including transplant counts and transplant rates, overall and by blood type; waitlist mortality counts, overall and by blood type; and median donor-to-recipient distance. The Committee used this analysis to identify blood type rating scale options that:

- (1) Improved transplant rates for blood type O candidates
- (2) Preserved reductions in waitlist mortality seen in the continuous distribution simulation relative to the previous allocation system
- (3) Did not substantially increase the median donor-to-recipient distance relative to the simulated distance for the current continuous distribution policy

One of the Committee's primary concerns was that blood type O candidates seem to be waiting longer and becoming more medically urgent before receiving a transplant relative to candidates of other blood types. Accordingly, the Committee requested analysis on median predicted days of waiting list survival at transplant by blood type. **Figure 8** shows analysis from the modified TSAM of the predicted days of waiting list survival at transplant by blood type for rating scales considered by the Committee. The rating scale labeled "Upscale_Base25" is the option that the Committee proposes implementing. This blood type rating scale (the last plot, in purple) increases the predicted days of waiting list survival at transplant for blood type O candidates relative to the simulation of current policy (the second plot, in green), which means blood type O candidates would not be as medically urgent at the time of transplant with the proposed changes.

¹⁵ OPTN Bylaw 11.1.A: The Public Comment Period. While proposals are "usually" distributed for at least a 45 day public comment period, NOTA, the OPTN Final Rule, and the OPTN Bylaws do not specify a minimum time period for public comment. This proposal does not meet the criteria for "Emergency Action" under OPTN Bylaw 11.7, nor "Expedited Action" under OPTN Bylaw 11.8.

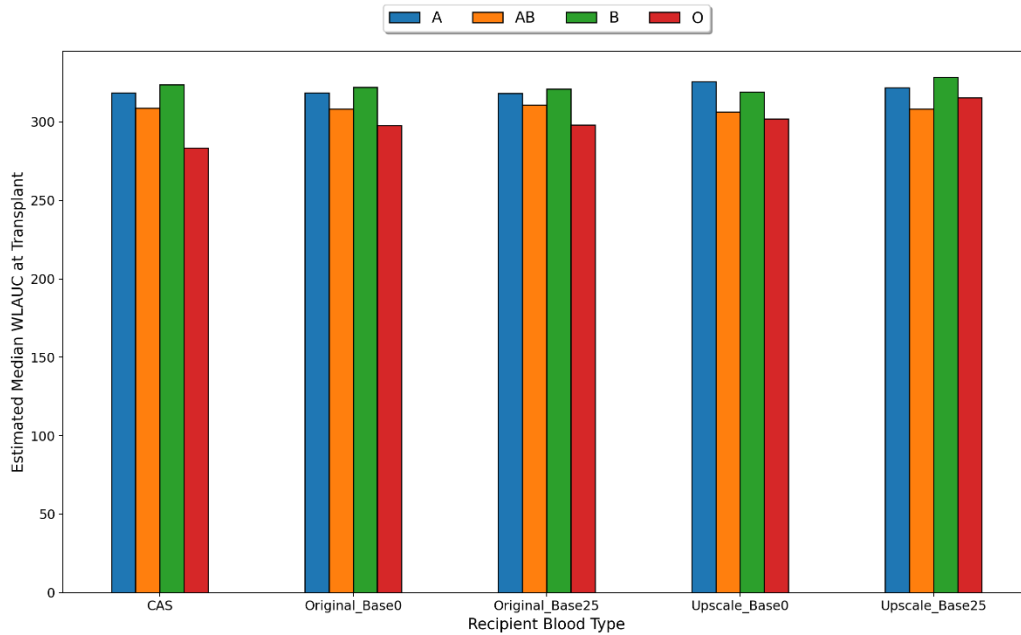
Figure 8. Modified TSAM Analysis of Predicted Days of Waiting List Survival at Transplant



Allocation Method
 The minimum value shown in the above plots corresponds to the 5th percentile whereas the maximum value shown corresponds to the 95th percentile

The Committee also reviewed match run analysis provided by the SRTR. Match run analysis is prepared by reordering historic match runs based on proposed changes to the allocation score, and assuming that the organ was accepted at the same sequence number on the match as in the historic match runs. While simulation modeling provides a more comprehensive analysis with more metrics, the TSAM used by MIT used an older cohort and acceptance model. The match run analysis used match runs from March 9, 2023, through July 1, 2023, and is expected to give a better estimate of current offer acceptance practices under the continuous distribution system. As shown in **Figure 9**, match run analysis concurred with the TSAM analysis that the “Upscale_Base25” rating scale proposed by the Committee is expected to increase the estimated median WLAUC (waiting list area under the curve, or estimated survival days on the waiting list within one year) for blood type O candidates relative to current policy (CAS).

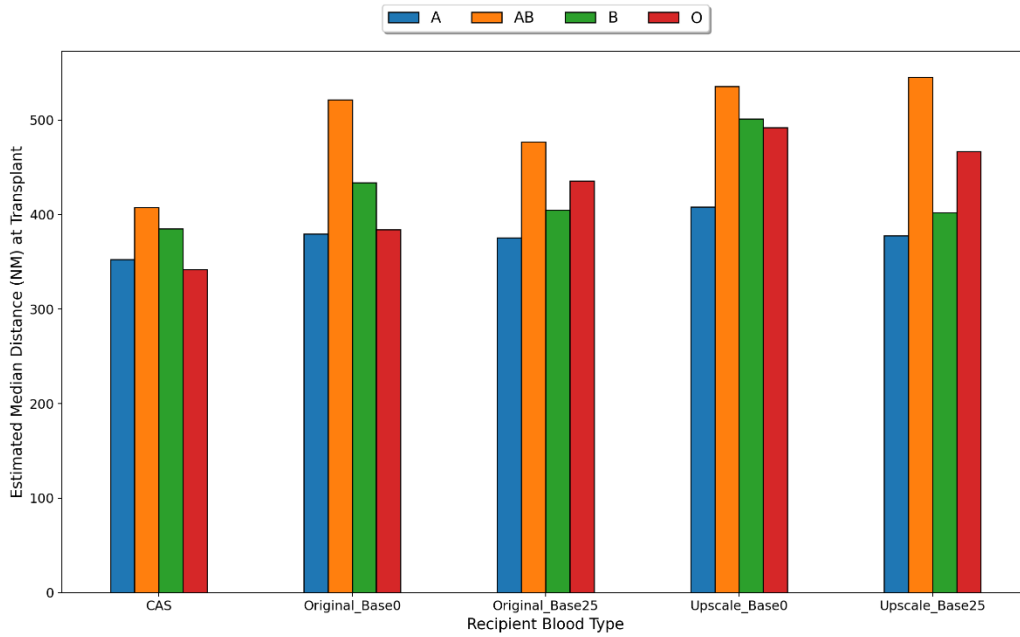
Figure 9. Match Run Analysis of Estimated Median WLAUC at Transplant by Recipient Blood Type



It was also important to the Committee to assess any estimated increase in the median distance between the donor hospital and recipient hospital for the rating scales under consideration, given concerns about efficiency of allocation in the new system.¹⁶ As shown in **Figure 10**, the “Upscale_Base25” rating scale may require transplant programs to travel slightly farther to recover lungs for blood type O candidates. However, since the match run analysis assumes donor lungs were placed at the same sequence number as on historic match runs, this analysis may slightly overestimate median distance traveled if transplant programs do not accept all organs available at longer distances. In other words, the match run analysis is not expected to capture any behavior changes that result from this proposed policy change.

¹⁶ Promote Efficiency of Lung Allocation Workgroup, OPTN, Summary of June 23, 2023 meeting, accessed August 16, 2023, https://optn.transplant.hrsa.gov/media/xl2ds0ji/20230623_promote-efficiency-ms.pdf.

Figure 10. Estimated Median Distance (Nautical Miles) at Transplant by Blood Type



Based on **Figures 9 and 10**, the Committee determined that the “Original_Base0” and “Upscale_Base25” options would provide the necessary boost in access to transplant for blood type O candidates without the additional travel distance observed for the “Upscale_Base0” option. The Committee also reviewed the overall median distance between the donor hospital and candidate’s transplant hospital for accepted offers for each of these rating scale options, as shown in **Table 6**.

Table 6. Median Distance Between Donor Hospital and Transplant Hospital Accepting Lung Offer

Policy Era	Median distance between donor hospital and transplant hospital accepting lung offer (NM)
Pre-continuous distribution (LAS)	~200 ¹⁷
Continuous distribution (lung CAS)	359 ¹⁸
Rating Scale	Estimated median distance between donor hospital and transplant hospital accepting lung offer (NM)
Original_Base0	399
Original_Base25	408
Upscale_Base0	467
Upscale_Base25	409

Since the overall median distance was similar between the “Original_Base0” and the “Upscale_Base25” options (399 NM vs. 409 NM), the Committee supported the “Upscale_Base25” rating scale to provide the most proportional access to transplant for blood type O candidates relative to candidates of other blood types. The Committee aims to continue evaluating solutions to address allocation efficiency concerns via a workgroup focused on this topic.¹⁹

Alternatives Considered

Analysis prepared for the Committee assessed varying the weight on the blood type rating scale between 0-20%. Generally, keeping the weight on blood type at 5% of the overall lung CAS (i.e. 5 points out of 100, as shown in **Table 2**) and adjusting the blood type rating scale did a better job of boosting access to transplant for blood type O candidates without negatively impacting overall waiting list mortality for all candidates.

Committee leadership reviewed analysis from the modified TSAM and match run analysis of 11 different rating scales while maintaining the overall weight on blood type at 5%. These rating scales generally followed one of three different approaches:

1. Identical vs. compatible: Prioritize identical transplants over compatible transplants (e.g. assign 5 points for identical blood type and 0 points for compatible blood type, or only assign points for identical blood type to the most medically urgent candidates)
2. ABO: Adjust points assigned by blood type by changing the shape of the rating scale or scaling up the points
3. Ratio: Assign points based on estimates of how many candidates are listed per blood type compatible donor (e.g. blood type A candidates would receive more points than blood type B candidates because there are more blood type A candidates on the waiting list)

¹⁷ Per the 3-month monitoring report for continuous distribution of lungs, the median distance from donor hospital to transplant program for lung transplants was 193 NM in the pre-policy era (December 7, 2022 – March 8, 2023).

¹⁸ Per SRTR analysis of match runs from March 9, 2023, to July 1, 2023.

¹⁹ Policy Oversight Committee, OPTN, Summary of June 12, 2023 meeting, https://optn.transplant.hrsa.gov/media/kqgp2aus/20230612_poc-meeting-summary.pdf.

Committee leadership recommended six rating scales that best achieved the Committee’s goals for further review by the Committee. These six options are summarized in **Table 7**. All of these options followed the "ABO" approach rather than the identical vs. compatible or ratio approach.

Table 7: Blood Type Rating Scale Options Evaluated by the Committee

#	Rating Scale	Approach	Points Assigned			
			O	B	A	AB
1	MedUrgency1	Give blood type O candidates the median number of medical urgency points for O candidates at transplant	1.2500	0.2439	0.0455	0
2	MedUrgency2	Give blood type O candidates the 95 th percentile of medical urgency points for all candidates at transplant	2.4000	0.2439	0.0455	0
3	Original_Base0	Same rating as current CD but linear	2.5009	1.9138	0.6979	0
4	Original_Base25	Same rating as current CD but shallow nonlinear	0.8340	0.5059	0.1182	0
5	Upscale_Base0	Scale Os up to 5 points, linear	5.0000	3.8263	1.3953	0
6	Upscale_Base25	Scale Os up to 5 points, shallow nonlinear	5.0000	2.2382	0.3032	0

Since the first two options (MedUrgency1 and MedUrgency2) are based on analysis from a point in time, the Committee was concerned that these point adjustments would need to be modified more frequently in the future and the Committee would be "chasing" solutions. The Committee favored the remaining four options because they are based on the estimated proportion of blood type incompatible donors, which tends to be more stable over time and therefore is less likely to require periodic updates. The Committee requested additional analysis on median waitlist survival score at transplant by blood type to assess the remaining four options, as summarized above. Based on this additional analysis, the Committee supported the "Upscale_Base25" rating scale.

NOTA and Final Rule Analysis

This proposal is submitted under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA 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."²⁰ The OPTN Final Rule states the OPTN "shall be responsible for developing...policies for the equitable allocation for cadaveric organs."²¹

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;

²⁰ 42 USC §274(b)(2)(B)

²¹ 42 CFR §121.4(a)(1)

(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."²² This proposal:

- **Is based on sound medical judgment²³** because it is a change relying on the following evidence:
 - Data showing that blood type O candidates are receiving fewer transplants relative to their representation on the waiting list, and that blood type O candidates are waiting longer for transplant and are more medically urgent at transplant relative to candidates of other blood types.
 - Modeling and analysis estimating that the proposed changes to the blood type rating scale will provide more proportional access to transplant for candidates of all blood types without substantially impacting overall waiting list mortality for all candidates.
- **Seeks to achieve the best use of donated organs²⁴ by** ensuring organs are allocated and transplanted according to medical urgency. This proposal is intended to preserve the goal of continuous distribution to reduce waiting list mortality. The lung CAS will continue to account for medical urgency holistically as well as blood type so that blood type is not given excess priority in a way that would prevent more medically urgent candidates from receiving a timely transplant.
- **Is designed to...promote patient access to transplantation²⁵ by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal will give more access to transplant to blood type O candidates so that candidates of all blood types have more equitable access to transplant.
- **Is designed to... promote the efficient management of organ placement²⁶ by** taking into account the costs and logistics of procuring and transplanting organs. The Committee ruled out blood type rating scale options that were anticipated to greatly increase median distance between donor hospital and recipient hospital and selected the proposed rating scale based on its anticipated balance between providing more proportional access to transplant by blood type without significantly increasing travel distance.
- **Is not based on the candidate's place of residence or place of listing.**

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,²⁷ and it is specific to an organ type, in this case lung.²⁸

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Is designed to avoid futile transplants²⁹:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes. The lung CAS will continue to account for post-transplant survival holistically as well as blood type.

²² 42 CFR §121.8(a)

²³ 42 CFR §121.8(a)(1)

²⁴ 42 CFR §121.8(a)(2)

²⁵ Id.

²⁶ Id.

²⁷ 42 CFR §121.8(a)(3)

²⁸ 42 CFR §121.8(a)(4)

²⁹ Id.

- **Designed to avoid wasting organs³⁰** by decreasing the number of organs recovered but not transplanted. The three-month monitoring of continuous distribution of lungs found that utilization rates did not change substantially at the national level between the pre- and post-policy eras, and non-use rates remained relatively stable at the national level.³¹ This proposal is not anticipated to impact either utilization rates or non-use rates.

Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.³² The Committee determined that candidates with exceptions to their biological disadvantages score may be impacted by this proposed policy change. As of 8/15/2023, 16 candidates had received approved exceptions to their biological disadvantages score since the implementation of continuous distribution of lungs. The biological disadvantages score includes points for blood type, height, and Calculated Panel Reactive Antibody (CPRA). The proposed policy change would increase the biological disadvantages score for candidates with blood types O, A, and B due to the increase in blood type points assigned. The Committee proposes the following transition plan for candidates with resolved and pending biological disadvantages exception requests at the time of implementation:

- Exception requests for the biological disadvantages score that are pending at the time of implementation will be withdrawn by the system
 - Pending exception requests are those that have not been resolved by the Lung Review Board (i.e. have not been approved or denied)
 - Pending exceptions at the time of implementation would not incorporate the updated points for blood type
 - These requests would be withdrawn by the system so that the Lung Review Board is not considering requests with outdated information
 - If the transplant program believes the candidate's lung composite allocation score with the blood type points adjustment does not appropriately prioritize the candidate for transplant, the candidate's transplant program may submit a new exception request
- Approved exceptions to the biological disadvantages score will remain in place
 - If the candidate's calculated biological disadvantages score is higher than the approved exception, then the system will use the calculated score (the system will use whichever value is greater between an approved exception and the calculated score)
 - If the exception is no longer needed, the transplant program could choose to withdraw the exception
 - If the transplant program believes the candidate's approved exception does not appropriately prioritize the candidate for transplant, the candidate's transplant program may submit a new exception request
- Previously denied exceptions to the biological disadvantages score will remain denied

³⁰ 42 CFR §121.8(a)(5)

³¹ "Lung Continuous Distribution Three Month Monitoring Report," OPTN, July 13, 2023, accessed August 3, 2023, https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf.

³² 42 CFR § 121.8(d)

- If the transplant program believes the candidate's current lung composite allocation score does not appropriately prioritize the candidate for transplant, the candidate's transplant program may submit a new exception request

Prior to implementation, the OPTN would contact transplant programs with candidates holding approved or unresolved exceptions to their biological disadvantages scores to notify them of this transition plan. Upon implementation, the OPTN would also contact any transplant programs who had candidates with unresolved exception requests for the biological disadvantages score to notify them that those exception requests were withdrawn by the system and that the transplant programs would need to submit a new exception request for those candidates if needed.

Implementation Considerations

Member and OPTN Operations

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

Operations affecting Transplant Hospitals

Transplant hospitals would need to educate staff on the changes to the points assigned to candidates for blood type as part of the lung CAS and update any professional and patient education materials accordingly. Transplant programs who have candidates with approved or pending exceptions to the biological disadvantages score would need to review their candidates and assess if approved exceptions should be withdrawn by the transplant program; if pending exceptions withdrawn by the system should be resubmitted by the transplant program; and if any new exception requests should be submitted by the transplant program.

Operations affecting the OPTN

The OPTN would need to update the OPTN Computer System with the modified points for candidate blood type so that the appropriate scores display in OPTN Waiting List, and so that the appropriate scores are used for allocation in the OPTN Donor Data and Matching System.

The OPTN would implement these changes on an expedited timeline following approval by the OPTN Board of Directors in order to address the reduced access to transplant that blood type O lung candidates are experiencing.

Potential Impact on Select Patient Populations

This proposal is expected to provide more proportional access to transplant for candidates of all blood types and improve access to transplant for blood type O candidates.

Projected Fiscal Impact

This proposal is not anticipated to have any fiscal impact on organ procurement organizations or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

Transplant hospitals may need to dedicate resources to updating patient education materials regarding the lung composite allocation score.

Projected Impact on the OPTN

In addition to modifying and testing changes to the match function in the OPTN Donor Data and Matching System and ensuring the appropriate scores display in OPTN Waiting List, the OPTN would need to update educational materials and resource guides on continuous distribution of lungs and disseminate the changes to OPTN members.

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."³³ During site surveys of transplant hospitals, the OPTN will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System are consistent with source documentation available at the time of entry.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."³⁴ The blood type rating scale change will be monitored three months post-implementation. After the initial three-month post-implementation monitoring report, monitoring of the blood type rating scale change will be incorporated into ongoing continuous distribution monitoring reports, which will be presented to the committee annually for 3 years following the allocation change.³⁵ Within each of these reports, there will be a separate section that evaluates the outlined changes to the blood type rating scale. The analyses will compare metrics from before continuous distribution, under continuous distribution with the previous blood type rating scale, and under continuous distribution with the updated rating scale.

Metrics to be evaluated include:

- Number of candidates ever waiting by blood type
- Number of waiting list removals for death or too sick by blood type
- Median waiting time for transplant by blood type
- Number of transplants by recipient blood type
- Number of transplants by recipient blood type and diagnosis group
- Number of transplants by donor blood type and recipient blood type
- Distribution of medical urgency points at the time of transplant by recipient blood type
- Distribution of distance traveled by recipient blood type
- Post-transplant outcomes by recipient blood type

All analyses will be performed after sufficient follow-up data have accrued, which is dependent on submission of follow-up forms. The OPTN and SRTR contractors will work with the Committee to define the specific analyses requested for ongoing monitoring of each annual update. The [OPTN equity in](#)

³³ 42 CFR §121.8(a)(7)

³⁴ 42 CFR §121.8(a)(6)

³⁵ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed August 15, 2023, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

[access dashboard](#) will also be used to evaluate the impact of this policy on transplant rates by various candidate attributes.

Conclusion

The Committee proposes modifying how blood type is incorporated into lung allocation to provide more proportional access to transplant by blood type, balanced against the impact on overall waiting list mortality and median travel distance. The proposed blood type rating scale would assign the full 5 points available for blood type in the lung CAS to candidates with blood type O and scale the points for other blood types proportionally along a more shallow, nonlinear scale.

Considerations for the Community

- Do you support implementation of the blood type rating scale proposed by the Committee?
- Of the rating scales the Committee assessed, is there another rating scale that you think should be adopted?
- Would you propose an alternative blood type rating scale or other adjustments to the lung composite allocation score not addressed in this proposal?
- Do you support the transition plan for candidates with unresolved biological disadvantages exception requests at the time of implementation?
- What is most important to you as the Committee monitors this allocation change (e.g. access to transplant by blood type, waitlist mortality, etc.)?

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.

1 **10.1.C.1 Blood Type**

2 Each lung candidate is assigned lung blood type points determined based on the proportion of donors
 3 the candidate could accept based on blood type compatibility, according to *Table 10-1: Points by Blood*
 4 *Type*. Candidates who are eligible to accept blood group incompatible donors according to *Policy 10.4.A*
 5 *Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs* receive the same
 6 blood type points as other candidates in their blood group.

7 **Table 10-1: Points by Blood Type**

A candidate with a blood type of	Will receive this many lung blood type points
AB	0
A	.0455 <u>0.3032</u>
B	.2439 <u>2.2382</u>
O	.4550 <u>5.0000</u>

9

#