OPTN

Briefing to the OPTN Board of Directors on

Establish Continuous Distribution of Lungs

OPTN Lung Transplantation Committee

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Establish Continuous Distribution of Lungs

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Sponsoring Committee:	*Lung Transplantation*
Public Comment Period:	*August 3, 2021 – September 30, 2021*
Board of Directors Meeting:	*December 6, 2021*

Executive Summary

This proposal will improve the current lung allocation policy by reducing waitlist deaths for lung candidates while decreasing the percentage of organ recoveries that require flying, reducing geographic disparities, and increasing access for pediatric candidates through smarter distribution.

The Lung Transplantation Committee (Committee)[1] proposes using a continuous distribution framework for lung allocation; in which candidates are ranked on the match run according to a composite allocation score (CAS) that incorporates:

- Candidate's expected 1-year waiting list survival
- Candidate's expected 5-year post-transplant outcomes
- Candidate's blood type
- Candidate's CPRA
- Candidate's height
- Whether a candidate is under 18 years old
- Whether the candidate is a prior living organ donor
- Travel efficiency
- Proximity efficiency

Below, the Committee outlines how each of these factors will be used and to what degree. To ensure that these changes work within the system, the Committee has included related changes for lung exceptions and allocation of heart-lung, lung-kidney, and lung-liver combinations.

[1] The Lung Transplantation Committee was officially created on July 1, 2020, and work before that time was performed by the OPTN Thoracic Organ Transplantation Committee. "Committee" in this proposal means either the Thoracic Committee or the Lung Committee, depending on the point in time. OPTN, Notice of OPTN Policy, Bylaw, and Guidelines Changes, *Creation of OPTN Heart and Lung Committees*. https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf (Accessed June 11, 2021).

This change will make lungs the first organ to move to the new system of continuous distribution, removing rigid boundaries and replacing them with a system that considers a host of individual factors as part of a single composite allocation score for each candidate.[2]

Purpose

This change better aligns lung allocation policy with community, ethical, and regulatory requirements, goals, and medical advancements, while considering each candidate holistically. It moves lung allocation into a new era of allocation, continuous distribution, to remove rigid boundaries in lung allocation and create a smarter allocation system, improving adaptability and consistency across organs.

Moving Beyond Separate Classifications

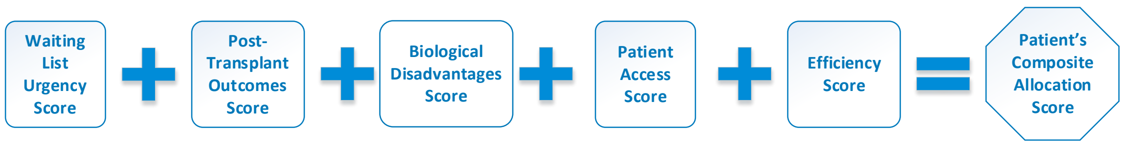
The current system of classifications and separate allocation order based on donor characteristics, so-called "hard boundaries," will be dissolved as part of the transition to a single, unified score to rank candidates on the lung list. Candidates are currently classified and ranked in a different order depending on the age of the lung donor (under 18 or at least 18). This change will remove that distinction, and all donors' lungs will be allocated the same way, with the same scoring system and ordering approach applied for each donor. This allows the system to provide more equity for patients and more transparency in the allocation system while allowing more efficiency in allocation policy changes.

Further, within the current allocation system, each list is divided into 36 classifications such as "candidates who are at least 12 years old, with an identical blood type to the donor within 250NM", which comes before "candidates who are at least 12 years old, with a compatible blood type to the donor within 250NM". Once grouped in these classifications, the current system ranks candidates individually. This "hard boundary" does not have the flexibility to allow a candidate with a compatible blood type who is much more medically urgent and possibly only 251 NM away from the donor to move ahead of a single candidate with an identical blood type who is 249 NM away. This system will address precisely that sort of nuance and flexibility by removing such rigid boundaries.

The new system uses multiple scores together to allow candidates to be considered in a holistic way. **Figure 1** shows how these scores combine into a composite score. The committee determined which components are included in the composite allocation score and how much importance to place on each component. The weight (or percentage of the total) placed on each determines how much of an effect that component has on the final score.

[2] The OPTN Board of Directors adopted the framework of continuous distribution for future organ allocation and directed the OPTN Lung Transplantation Committee to "move toward the Continuous Distribution allocation framework as they consider future amendments and improvements to their respective allocation policies." However, the Board resolution does not prescribe that this particular proposal must be adopted. This proposal should be evaluated on its merits. OPTN Policy Notice, Frameworks for Organ Distribution, December 4, 2018. https://optn.transplant.hrsa.gov/media/2789/geography_policynotice_201901.pdf (Accessed June 13, 2021).

Figure 1: Components of Composite Allocation Score



Background

This change will make lungs the first organ to move to the new system of continuous distribution, removing hard boundaries and replacing them with a system that considers a host of individual factors as part of a single composite allocation score for each candidate.[3]

Lung was selected as the first organ to consider changing to the continuous distribution framework in part because lung allocation already includes formulaic measures of both waiting list survival and post-transplant outcomes, which provide a pre-existing foundation for the new composite allocation score. The current lung allocation score (LAS) is derived from two included scores: waiting list urgency measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list, and post-transplant survival measure, which is the expected number of days a candidate will live during the first year post-transplant.[4] As part of the move to this new framework, the Committee separated the waitlist measure and the post-transplant measure and considered the appropriate balance between these two factors anew as they discussed how to balance all of the parts of the new lung composite allocation score.

The relative weights for each attribute proposed for the CAS were developed using multiple novel methods to identify the relative importance of each attribute. These included:

Revealed Preference Analysis (RPA) The Committee considered analyzing the current system and how it would translate into a points-based system like continuous distribution. The study was conducted in conjunction with the Research Triangle Institute.[5] The OPTN chose RPA to allow the Committee to view the relative weights inherent in the current system since it had not been evaluated from that perspective before.

In that analysis, proximity was the primary factor, with medical priority (measured by LAS score, a combination of waiting list urgency and post-transplant outcomes) second, candidate blood type third, and candidate age the least important, when keeping separate allocation systems for adult donors and pediatric donors. In the adult donor model, proximity made up 81% of the score; medical priority made

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[4] OPTN Policy 10.1.5: The LAS Calculation.

[5] Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf

up 10% of the score; blood type made up 5% of the score; and candidate age made up 4%.[6] Notably, these weights were very different from those revealed as the apparent preference of the transplant community and policymakers through the Analytical Hierarchy Process (AHP) exercise described below.

Analytical Hierarchy Process (AHP) AHP is a method for eliciting and quantifying values judgments from participants.[7] The AHP exercise performed as part of developing this policy proposal enabled members of the public, the transplant community, and many OPTN Committees to contribute their value judgments by ranking pairs of attributes relative to one another. This method was chosen as an approachable way for a broader selection of people to provide detailed feedback. The *Continuous Distribution of Lungs: Summer 2020 Prioritization Exercise – Community Results* report describes this in more detail.[8] The Committee chose to use an AHP prioritization exercise specifically because other health care groups had effectively used it to involve patients in clinical decisions.[9] Also, it had been used to develop theoretical organ allocation schemas.[10]

The exercise was promoted on the OPTN website and directly to the Patient Affairs Committee, lung community (which included health care administrators, organ donation and transplantation professionals, patients, and interested public), Regional Meeting attendees in all 11 regions, professional societies, and patient organizations via targeted emails and presentations. These encouraged the recipients to participate in the exercise and pass along the information and encourage participation by others, such as their transplant patients and families. The exercise was available for participation from August 31, 2019 to October 1, 2020, and 196 individuals submitted responses.[11]

The results from the 196 participants in that exercise showed an overall preference for prioritizing pediatric candidates, post-transplant survival, waiting list survival, and factors in a candidate's biology that make them hard to match. (See **Figure 2**.) Generally, improving efficiency and ensuring access for prior living donors ranked lower, except among respondents associated with organ procurement organizations (OPOs).

[6] *Ibid.*

[7] T. L. Saaty, "Multicriteria Decision Making: The Analytic Hierarchy Process, 1988; Revised and published by te author; Original version published by McGraw-Hill, New York, 1980.

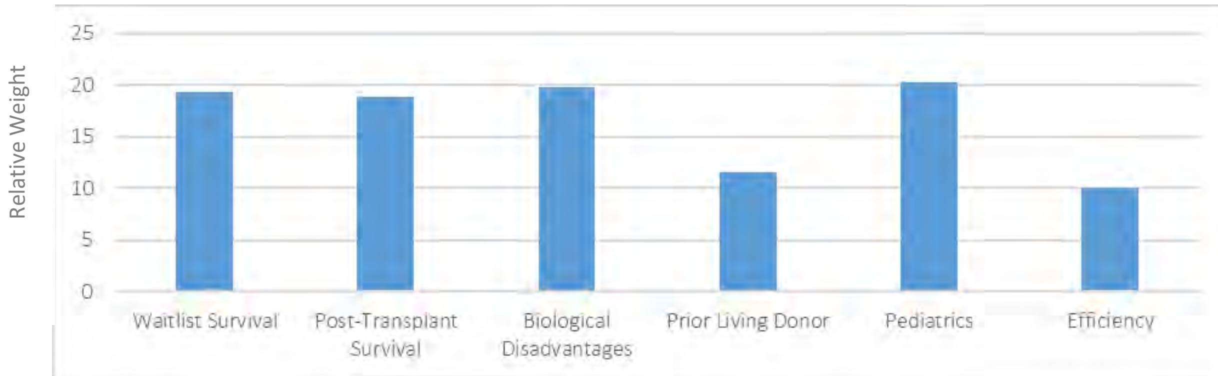
[8] https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf

[9] Dolan JG. Multi-criteria clinical decision support: A primer on the use of multiple criteria decision making methods to promote evidence-based, patient-centered healthcare. Patient. 2010;3(4):229-248. doi: 10.2165/11539470-000000000-00000. PMID: 21394218; PMCID: PMC3049911.

[10] Lin CS, Harris SL. A unified framework for the prioritization of organ transplant patients: analytic hierarchy process, sensitivity and multifactor robustness study. J Multi-Criteria Decis Anal. 2013;20(3–4):157–72.

[11] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020.

Figure 2: Overall Weights from Prioritization Exercise



Thoracic Simulated Allocation Model (TSAM) The Scientific Registry of Transplant Recipients (SRTR) provided simulation modeling of specific potential policy scenarios. Organ-specific simulated allocation models are typically used to evaluate the expected impact of significant allocation changes, and results are discussed in further detail below.

Optimization Analysis Researchers from the Massachusetts Institute for Technology (MIT) applied artificial intelligence and machine learning to a dataset from the TSAM to optimize specific outcomes.[12] This work was similar to earlier analyses the researchers did with kidney and liver allocation.[13] This analysis produced two types of visualizations that were particularly useful to the committee. The first set showed the efficiency frontier or how much could be gained for a particular goal. For example, it showed that, with this construct, there was no additional gain for pediatric priority by raising it above 30%. In addition, the optimization also showed the relative tradeoff that changes to a specific weight would have on other goals.

Sensitivity Tool The OPTN developed an interactive dashboard to allow the Committee and the public to see the effect of specific changes on sample match runs as they adjusted individual pieces of the overall policy. The tool is publicly available at https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home, and will continue to be available during the implementation of these changes to help OPTN members and others anticipate the impact of these changes.

Please see another view of the Committee work and the results published so far https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution/continuous-distribution-lung/.

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[12] OPTN Lung Transplantation Committee, Meeting Summary, March 18, 2021. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/media/4549/20210318_lung_meeting_summary.pdf.

[13] Dimitris Bertsimas, Vivek F. Farias, Nikolaos Trichakis, (2013) Fairness, Efficiency, and Flexibility in Organ Allocation for Kidney Transplantation. Operations Research 61(1):73-87. https://doi.org/10.1287/opre.1120.1138.
Dimitris Bertsimas, Theodore Papalexopoulos, Nikolaos Trichakis, Yuchen Wang, Ryutaro Hirose, Parsia A. Vagefi, Balancing Efficiency and Fairness in Liver Transplant Access: Tradeoff Curves for the Assessment of Organ Distribution Policies, May 2020, Transplantation, Volume 104, Number 5.

Deliberative Process

The Committee modeled four scenarios in the first round of TSAM modeling. (See **Table 1**.) The Committee chose to model two versions closest to the weights preferred in the AHP prioritization exercise. The first weighs 1-year waitlist survival and 1-year post-transplant outcomes using a 2:1 ratio, the same relative weight as the current LAS system. The second scenario changes to 1:1, or equal weighting between 1-year waitlist survival and 1-year post-transplant outcomes, to simulate the impact of the preference expressed through the AHP exercise.

The third scenario was used to compare the impact of placing more weight on proximity since the current system is primarily based on proximity, as match runs sort first on candidates within a specified distance (250 nautical miles of the donor) before sorting the candidates on any other factors. The RPA showed that the current weight placed on geographic proximity is more than 80%.[14]

The final scenario evaluated placed more weight on the candidate biology factors since these were the most critical factor to respondents in the AHP exercise, where it was given approximately 40% priority.[15]

Table 1: Modeled Weights by Goal and Attribute (TSAM round 1)[16]

Component	2:1 LAS	1:1 LAS	Proximity Preference	Candidate Biology Preference
Waitlist Survival	**28%**	**21%**	**14%**	**14%**
Post-Transplant Outcomes	**14%**	**21%**	**14%**	**14%**
Biological Disadvantages	**17%**	**17%**	**11%**	**40%**
Blood Type	5.6%	5.6%	3.6%	13.3%
CPRA	5.6%	5.6%	3.6%	13.3%
Height	5.6%	5.6%	3.6%	13.3%
Patient Access	**35%**	**35%**	**21%**	**21%**
Pediatric	31%	31%	20%	20%
Prior Living Donor	4%	4%	1%	1%
Efficiency	**6%**	**6%**	**40%**	**11%**
Travel Efficiency	3%	3%	20%	5.5%
Proximity Efficiency	3%	3%	20%	5.5%

While the scenarios were being modeled, the Committee chose to expand the post-transplant outcomes measure to include outcomes predicted out to five years rather than the one-year measure included in the first request.[17] This decision was based on the analysis provided to the Committee by the SRTR of

[14] Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf.
[15] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.
[16] SRTR Continuous distribution simulations for lung transplant, Data Request ID#: LU2020_05. February 12, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4450/lu2020_05_cont_distn_srtr_1.pdf.
[17] OPTN Lung Transplantation Committee *Meeting Summary*, March 18, 2021. (Accessed June 14, 2021)

the reliability of predicting 5-year outcomes.[18] The Committee also considered the expected impact on candidates by diagnosis and age, among other stratifications, and compared those to their clinical experience.[19] The 5-year outcomes have a similar level of confidence to 1-year outcomes while allowing for consideration of a more extended period of outcomes and greater stratification of utility of the transplants.[20] Additionally, the 5-year outcomes address a concern that was voiced in the comments provided with the AHP exercise that 1-year outcomes are too short-term to measure long-term survival, and the long-term survival is more important as a measure of utility to include in the composite allocation score.[21]

After reviewing the results of the first modeling request, the Committee also considered optimization visualizations.[22] For any two attributes within the continuous distribution model, one can evaluate the impact on one attribute of changing the point assignment for the other. For example, suppose all else is equal between an adult candidate and a pediatric candidate. How much more medically urgent would an adult candidate have to be to be ranked above a pediatric candidate? The Committee used these optimization visualizations to narrow down the scope of the second continuous distribution modeling request to the SRTR, mainly the weights for placement efficiency, pediatric status, and candidate biology.

The Committee submitted a second continuous distribution modeling request, with an additional six scenarios. In the second request, the Committee chose again to compare relative weights between waiting list survival and post-transplant outcomes, this time using the 5-year post-transplant outcomes measure.[23]

The Committee chose to model three options for combined weight on waitlist survival and post-transplant outcomes - 40%, 45%, and 50%, in line with the range of community responses to the AHP exercise.

The complete list of weights modeled in the second round by both goals and attributes under each goal is listed in **Table 2** below.

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https://optn.transplant.hrsa.gov/media/4549/20210318_lung_meeting_summary.pdf.
[18] SRTR *The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant*, February 17, 2021.
[19] *Ibid.*
[20] *Ibid.*
[21] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.
[22] OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325_lung_meeting_summary.pdf.
[23] 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

Table 2: Modeled Weights by Goal and Attribute (TSAM Round 2) [24]

Goals Attributes	1:1 LAS 10% PE	1:1 LAS 15% PE	1:1 LAS 20% PE	2:1 LAS 10% PE	2:1 LAS 15% PE	2:1 LAS 20% PE
Waitlist survival	**25%**	**22.5%**	**20%**	**33.3%**	**30%**	**26.3%**
Post-transplant outcomes	**25%**	**22.5%**	**20%**	**16.7%**	**15%**	**13.7%**
Biological Disadvantages	**15%**	**15%**	**15%**	**15%**	**15%**	**15%**
Blood Type	5%	5%	5%	5%	5%	5%
CPRA	5%	5%	5%	5%	5%	5%
Height	5%	5%	5%	5%	5%	5%
Patient Access	**25%**	**25%**	**25%**	**25%**	**25%**	**25%**
Pediatric	20%	20%	20%	20%	20%	20%
Prior living donor	5%	5%	5%	5%	5%	5%
Efficiency	**10%**	**15%**	**20%**	**10%**	**15%**	**20%**
Proximity Efficiency	5%	7.5%	10%	5%	7.5%	10%
Travel Efficiency	5%	7.5%	10%	5%	7.5%	10%

As shown in **Table 3**, waiting list deaths decreased significantly, the proportion of organs expected to fly decreased, and the median travel distance increased in all of the modeled scenarios.

Table 3: Overall Outcomes by Scenario (Round 2)[25]

Outcome	Current	Efficiency 10% LAS 1:1	Efficiency 15% LAS 1:1	Efficiency 20% LAS 1:1	Efficiency 10% LAS 2:1	Efficiency 15% LAS 2:1	Efficiency 20% LAS 2:1
Transplant Rate (per patient-year)[26]	1.77	1.60	1.63	1.64	1.59	1.61	1.62
Waitlist Mortality Count	435	260	269	280	231	236	247
Percent Died by two years Post-transplant	23.38	23.44	23.64	24.08	23.71	24.07	23.86
Median Donor-Recipient Distance (NM)	195	353	283	236	345	288	245
Percent Expected to Fly (>75NM)	81.32	79.02	73.12	69.42	78.17	73.53	70.63

[24] Scenarios are identified by shortened titles. PE is the proximity efficiency score for the scenario and LAS represents the balance between waitlist survival and post-transplant outcomes points.
[25] 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.
[26] Although the modeling results show a lower transplant rate, they do not show a decrease in the number of transplants. Transplant rate is calculated by dividing the total transplants but the total waiting time of all candidates. The change in transplant rate is a result of an increase in waiting time for candidates who can wait longer for a transplant rather than a decrease in the number of transplants. 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.

Throughout this process, the Committee shared information and solicited input from a variety of stakeholders via traditional and non-traditional methods and broader outreach over two years, to ensure adequate feedback and data analysis.

Community Education

To educate the community about continuous distribution, a presence on the OPTN website was established to explain concepts and plans for development. Progress specific to the development of lung continuous distribution was shared on its own OPTN webpage and included:

2019

- Concept paper on the continuous distribution of lungs[27]

2020

- Request for feedback and update on work that had been completed so far[28]
- Results of community feedback on priorities that was provided through a prioritization exercise[29]
- Results of an analysis to reveal the preferences inherent in the current lung allocation system[30]
- An interactive tool for visualizing what a match would look like under continuous distribution[31]

2021

- Results from the first round of SRTR modeling[32]
- Results from modeling impact of 5-year post-transplant outcomes[33]
- Results from the second round of SRTR modeling[34]
- Continuous Distribution public comment proposal[35]

This briefing paper does not attempt to repeat the background content contained in all the earlier publications but to set forth the specific changes to the existing lung allocation policy proposed by the Committee and their rationale.

[27] Concept Paper, *Continuous Distribution of Lungs*, OPTN Thoracic Organ Transplantation Committee. Public Comment Period August 2, 2019-October 2, 2019. https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf.
[28] OPTN Request for Feedback, Update on the Continuous Distribution of Organs Project, OPTN Lung Transplantation Committee. Public Comment Period August 4, 2020-October 1, 2020. https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf.
[29] Continuous Distribution of Lungs, Summer 2020 Prioritization Exercise – Community Results, October 12, 2020. https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.
[30] Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf.
[31] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.
[32] SRTR, Continuous Distribution Simulations for Lung Transplant, Data Request ID# LU2020_05, February 12, 2021. https://optn.transplant.hrsa.gov/media/4450/lu2020_05_cont_distn_srtr_1.pdf.
[33] SRTR The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant, February 17, 2021. (Accessed June 18, 2021) https://optn.transplant.hrsa.gov/media/4675/lu_posttx_5y_2_2021.pdf.
[34] 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.
[35] Public Comment Proposal, Establish Continuous Distribution of Lungs, OPTN Lung Transplantation Committee. Public Comment Period August 3, 2021- September 30, 2021. https://optn.transplant.hrsa.gov/media/4772/continuous_distribution_of_lungs-public_comment.pdf.

In addition to the multiple public comment cycles, the Committee regularly shared progress with the community and provided opportunities for feedback and input regarding continuous distribution:

- at Patient Affairs Committee meetings
- at Regional Meetings in all 11 regions
- in targeted emails to the lung community and with professional societies, including:
  - the American Society of Transplantation
  - American Society of Transplant Surgeons
  - North American Transplant Coordinators Organization
  - Association of Organ Procurement Organizations
  - International Society for Heart and Lung Transplantation
  - American College for Chest Physicians
  - American Association of Transplant Surgeons
  - Society of Transplant Surgeons
- and to patient and donor family groups, including:
  - the Alpha-1 Foundation
  - American Lung Association
  - Children's Interstitial & Diffuse Lung Disease Foundation
  - Children's Organ Transplant Association
  - COPD Foundation
  - Cystic Fibrosis Foundation
  - Donate Life America
  - Emphysema Foundation for Our Right to Survive
  - Hermansky-Pudlak Syndrome Network, Inc.
  - Histiocytosis Association
  - Lung Transplant Foundation
  - Lymphangiomatosis & Gorham's Disease Alliance
  - Pulmonary Alveolar Proteinosis Foundation
  - Pulmonary Fibrosis Foundation
  - Pulmonary Hypertension Association
  - Second Wind: Lung Transplant Association Inc.
  - The Lymphangioleiomyomatosis Foundation
  - Transplant Recipients International Organization

Additionally, leaders of OPTN Heart Transplantation, Liver and Intestine Transplantation, Kidney Transplantation, Pancreas Transplantation, Vascularized Composite Allocation Transplantation, Policy Oversight, and Multi-Organ Transplantation Committees were consulted regarding several areas where decisions would be best made in alignment across organs, such as providing points for prior living donors.

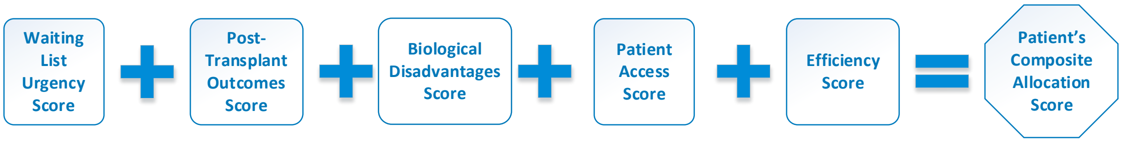
Composite Allocation Score Regulatory Alignment

The National Organ Transplant Act (NOTA)[36] and the OPTN Final Rule[37] contain multiple requirements for organ allocation policies. The Committee proposes a composite allocation score that combines five different scores. These component scores align with the conditions found in NOTA and the OPTN Final Rule.

[36] National Organ Transplant Act, 42 U.S.C. 274 (P.L. 98-507), 1984.
[37] 42 C.F.R. Part 121, https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121.

Figure 3 shows how these five scores combine into a composite score. A description of each score follows **Figure 3.**

Figure 3: Components of Composite Allocation Score



- *Waiting list urgency score*: The Final Rule requires the OPTN to rank candidates from most to least medically urgent through "objective and measurable medical criteria"[38] and to develop allocation policies in part to achieve the "best use of donated organs."[39] OPTN policies use several different approaches to prioritize candidates based upon their medical urgency: model for end-stage liver disease (MELD), pediatric model for end-stage liver disease (PELD), heart statuses, lung pediatric priorities[40], etc. A portion of the lung allocation score (LAS) is the predicted waiting list survival, or medical urgency of lung candidates. This proposal uses the medical urgency calculation that is currently part of the LAS to determine the waitlist urgency score, one of the five goal-level scores that together form a new composite allocation score.
- *Post-transplant outcomes score*: The Final Rule requires allocation policies be designed to "avoid futile transplants."[41] This is currently part of the LAS score, and the Committee proposes treating this component separately as the post-transplant outcomes score.
- *Biological disadvantages score*: The Final Rule requires allocation policies be designed to "promote patient access to transplantation."[42] This policy uses scores to make access more equitable based on candidate blood type, calculated panel reactive antibodies (CPRA), and height.
- *Patient access score*: The Final Rule requires allocation policies be designed to "promote patient access to transplantation"[43] and "recognize the differences in health and in organ transplantation issues between children and adults … and adopt criteria, policies, and procedures that address the unique health care needs of children."[44] OPTN policies use several approaches for this purpose; this proposal provides additional access to transplantation for pediatric candidates and priority for prior living donors.
- *Placement Efficiency score*: The Final Rule requires allocation policies be designed to "promote the efficient management of organ placement." [45] One can evaluate "efficient" organ placement in multiple ways. For example, much attention has been given to the number of organs transported by air travel in recent years, given the potential for greater costs and logistical challenges with air versus ground travel. The Final Rule contemplates incorporating into allocation policies consideration of a candidate's place of residence or place of listing if required to achieve other Final Rule requirements, such as to achieve efficient organ placement or to

[38] 42 C.F.R. §121.8(b)(2).
[39] *Ibid.* at §121.8(a)(2).
[40] In lung allocation, pediatric priorities are akin to statuses in other organs.
[41] 42 C.F.R. §121.8(a)(5).
[42] *Ibid.*
[43] *Ibid.*
[44] 42 C.F.R. §274(b)(2)(M).
[45] 42 C.F.R. §121.8(a)(5).

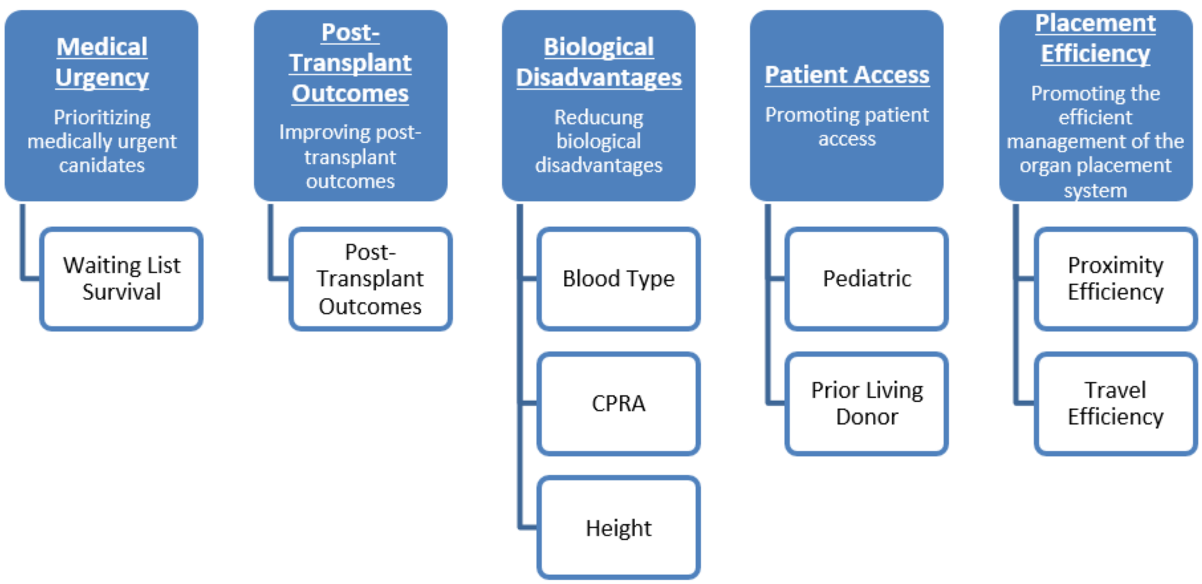
avoid "wasting" organs.[46, 47] The Committee, therefore, proposes including measures of travel efficiency and proximity efficiency.[48]

Combining multiple scores allows simultaneous, instead of sequential, consideration of all of these goals in lung allocation. It will also promote transparency in the similarities and differences between the roles of each score across organs. Finally, by constructing the CAS around the requirements of the OPTN Final Rule, this system will clarify the alignment with the OPTN Final Rule.

Proposal for Board Consideration

This proposal replaces the current lung allocation system that categorizes candidates in classifications and ranks the candidates within each classification. The new system assigns each lung candidate a lung composite allocation score (CAS). This CAS will rank-order candidates on the lung match run with the highest score listed first. The CAS includes five main goals, including sub-parts called attributes, as outlined in **Figure 4**: Scores by Goals and Attributes.

Figure 4: Scores by Goals and Attributes



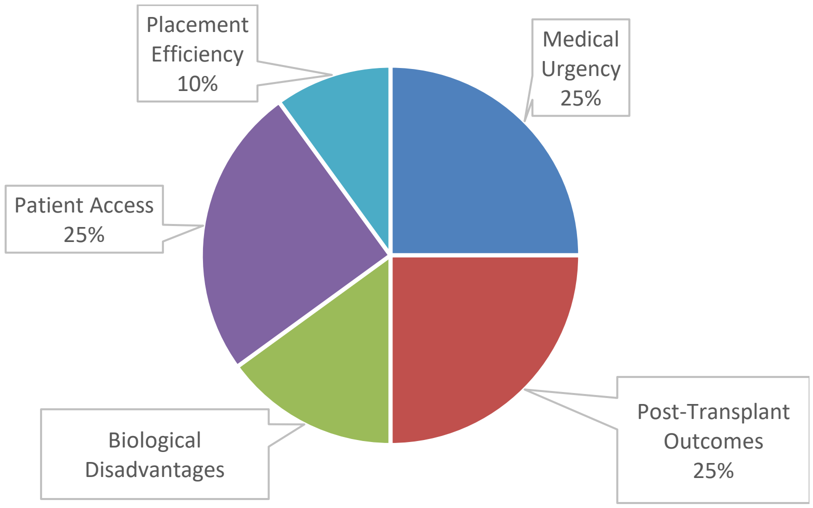
[46] 42 C.F.R. §121.8(a)(8).

[47] The Federal Register notice related to the development of the OPTN Final Rule noted the connection between the possibility of "wasting organs" as a result of excessive transportation times and efficient management of organ allocation. "Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest-ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient." 63 FR 16315 (1998).

[48] The use of the candidate's "place of listing" is only used in order to promote efficient management of organ placement. This limitation is in line with the requirement that allocation policies "shall not be based on the candidate's place of residence of place of listing, except to the extent required by paragraphs ()(1)-(5) of this section.", which include the requirement that allocation policies shall "promote the efficient management of organ placement". 42 C.F.R. §121.8.a.

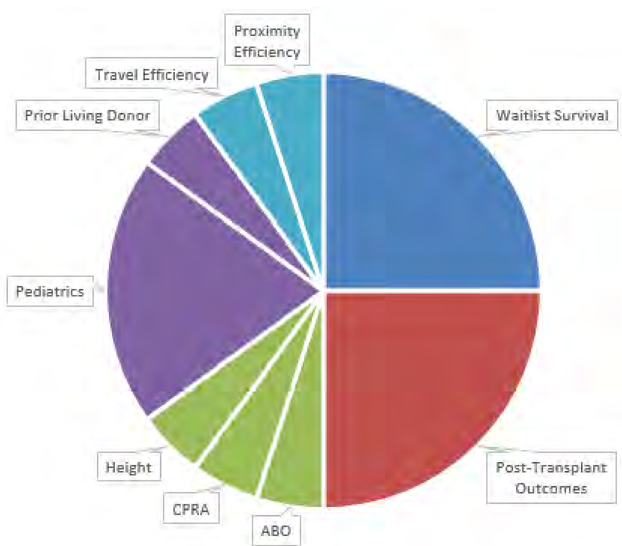
The maximum total composite allocation score available for any candidate is 100, and each goal has a specific weight within that total. The weight determines the top score for that goal or the percentage of the potential total for each goal. **Figure 5** shows the weight the Committee assigned to each goal.

Figure 5: Percent of Composite Allocation Score (by Goal)



Each attribute is assigned a relative weight that equates to a percentage of the score or a maximum number of points within the score available for that attribute. The weight for waiting list survival is 25, so it accounts for 25% of the score, and no candidate will be able to have a waiting list survival score of more than 25 points. **Figure 6** shows the weights proposed for each specific attribute.

Figure 6: Percent of Composite Allocation Score (by Attribute)



Attribute	Weight
Waiting list Survival	**25%**
Post-Transplant Survival	**25%**
Candidate Biology	**15%**
Blood Type	5%
CPRA	5%
Height	5%
Patient Access	**25%**
Pediatric	20%
Prior Living Donor	5%
Placement Efficiency	**10%**
Travel Efficiency	5%
Proximity Efficiency	5%

For each attribute, there is also a rating scale. The rating scale is used to determine precisely how many points will be awarded to a specific candidate based on their characteristics. Prior living donor status is a binary scale, so a candidate either receives all the points available (five) for that attribute or none. Post-transplant outcomes has a linear scale, so for each additional day a candidate is expected to survive post-transplant, that candidate's score increases a set amount.

The lung match run will be ordered with the highest CAS first, in descending order. CAS will range from 0-100 and be calculated to the ten-thousandth of a point (four decimal places), and ties are not expected to be frequent. However, in the rare event of a tie, the order will be decided in favor of the candidate who has been on the lung waiting list for longer.

For candidates whose score does not appropriately prioritize them for transplant, the lung review board will continue to review exceptions. The review board will be expanded from nine to twelve reviewers. Nine of the twelve will be assigned to each exception request. Exceptions may be requested for any goals that can be determined before the match run (waiting list survival, post-transplant outcomes, candidate biology, or patient access). They will not be available for placement efficiency. Exceptions will not expire and will be reviewed prospectively by the review board.

This proposal revises the allocation of heart-lungs to require that the OPO offer first to candidates on the heart list at Status 1 or 2 within 500 nautical miles (NM), then to candidates on the lung list with a CAS of at least 28 before returning to offer from the heart list. This proposal also requires that available kidneys and livers be offered with the lung if the composite allocation score is at least 28.

Calculating the Composite Allocation Score (CAS)

Within the total available points for each attribute, a candidate's specific points for that attribute are determined based on a rating scale. Each attribute uses a rating scale that ranges from 0-100. Candidates are assigned a score from 0-100 according to the rating scale specific to that attribute. Each attribute's rating scale score is then multiplied by the weight (0-100%) given for that attribute. These weighted scores are then aggregated to produce the candidate's composite allocation score.

For example, within the 25 points available for waiting list survival, a candidate could receive any portion of those points based on their expected mortality within a year while awaiting transplant. A transplant candidate who is unlikely to survive one day without a transplant might receive the full 25 points. In contrast, a candidate who would be expected to live nearly a year without a transplant might receive only a fraction of a point for medical urgency. The rating scale determines precisely how many points a candidate will receive out of the available points. The equation for the composite score is:

Score = $(W_{MU} \times R_{MU} + W_{PTO} \times R_{PTO} + W_{ABO} \times R_{ABO} + W_{CPRA} \times R_{CPRA} + W_{HGT} \times R_{HGT} + W_{PED} \times R_{PED} + W_{PLD} \times R_{PLD} + W_{TE} \times R_{TE} + W_{PE} \times R_{PE})$

In this equation, W represents the weight placed on the attribute, and R represents the points for the candidate based on the rating scale for that attribute. For the subscripts:

MU = Medical Urgency
PTO = Post-Transplant Outcomes
ABO = Blood Type
CPRA = CPRA
HGT = Height
PED = Pediatric
PLD = Prior Living Donor
TE = Travel Efficiency

PE = Proximity Efficiency

So W_{MU} x R_{MU} will be the weight for medical urgency (25) times the particular candidate's expected waitlist survival score. For instance, if a candidate's waitlist survival score, based on the multiple factors used to predict waitlist survival, was 75.608, that would be multiplied by 25% (the waiting list urgency weight) and result in 18.9020 points for waitlist urgency. That 18.9020 would be added to the points from the other attributes and result in that candidate's CAS.

Rating Scales

Each attribute has a rating scale. The Committee chose the following rating scales:

1. Waitlist survival: A non-linear curve where y=points and x= the waitlist area under the curve (WLAUC), based on the calculations included in the recent LAS updates implemented on September 30, 2021.
2. Post-transplant outcomes: A linear relationship between points and the post-transplant area under the curve (PTAUC) based on changes to the PTAUC from what is currently in policy to include 5-year post-transplant outcomes.
3. Biological disadvantages: A steep non-linear curve for each of the three attributes. Each attribute is assigned a third of the weight given to "candidate biology" in the table.
   a. Blood type
   b. CPRA
   c. Candidate height
4. Patient access: Binary for both attributes. Pediatric weight (20%) is more significant than prior living donor weight (5%).
   a. Pediatric: Points assigned to candidates under 18 years old at listing.
   b. Prior living donor: Points assigned to candidates who previously donated any organ for transplant.
5. Placement Efficiency: There are two components (travel efficiency and proximity efficiency), each of which gets half the weight given to "placement efficiency."
   a. The proximity efficiency curve combines a sigmoidal curve and a line segment, capturing the efficiencies of proximity other than cost.
   b. The travel efficiency curve is a piecewise linear curve, with four segments between 0 and 100 miles and one segment from 100 to 6,000 miles.

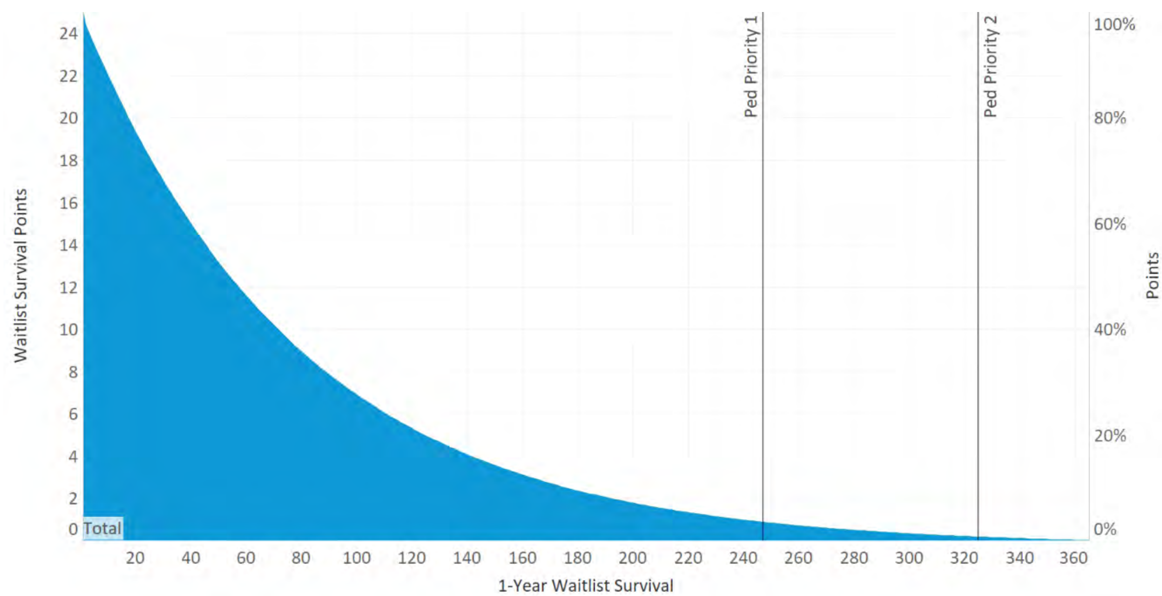
Waitlist Survival Scale

The proposal uses the same measure of waitlist survival as the current system –Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list. It is currently one portion of the LAS, but is considered separately under continuous distribution.

A candidate will receive waitlist survival points based on their expected number of days to live without a transplant. The number of points awarded per day changes as the waitlist survival risk changes using the curved scale. For example, the candidate will be assigned more points for a 1-day difference when the candidate has only a few days expected to live if they do not receive a transplant than a 1-day difference when a candidate has nearly a year expected to live if they do not receive a transplant. In **Figure 7** below, you can see that the distance between waiting list urgency points is fewer days on the left, among the candidates with the least time left, and there are more days between score changes on the right, among candidates with longer life-expectancy while awaiting transplant.

This decision was based on the Committee's concern that the likelihood of another appropriate offer also decreases in a nonlinear fashion, and it is more appropriate to increase access more quickly as the life expectancy decreases to preserve equity. In considering ethical principles, waitlist urgency is a measure of equity rather than utility.[49] If it were a utility measure, a linear scale would be appropriate (as with post-transplant outcomes below) because each day of life is equal from a utility perspective. However, as an equity measure, points are provided for waiting list urgency to help candidates receive a transplant before they are removed from the waiting list for death or because they are too sick to be transplanted. Using that analysis, each day is not the same. For a person that can wait four days, each day lost is a 25% reduction in their access. For a person that can wait 100 days, each day lost is a 1% reduction in their access.

Figure 7: Waiting List Urgency Rating Scale[50]



As seen in **Figure 7**, candidates with the longest expected waiting list survival (shown in days on the bottom of the figure) receive the smallest percentage of the available waiting list survival points (shown on the right), which is the smallest waiting list survival points (shown on the left) out of the 25 possible points for waiting list survival. The percentage and therefore the number of points increases more steeply for candidates with the fewest days of expected waiting list survival.

Less than 12 years old

LAS is based on and used for candidates who are 12 years old or older.[51] The current system uses two levels of priority for candidates who are less than 12 years old, priority 1 and priority 2. Priority 1 candidates are more medically urgent than priority 2 candidates. Since LAS and the priorities are used to

[49] OPTN Ethical Principles in the Allocation of Human Organs, June 2015. Accessed June 27, 2021. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/.
[50] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.
[51] OPTN Briefing Paper, Proposal to Revise the Lung Allocation Score (LAS) System. 2012.

express a candidate's waitlist urgency, the Committee converted the priorities to the same scale used for candidates who currently have an LAS.

This proposal assigns candidates under the age of 12 a waitlist survival score based on the average survival of candidates in the same priority. As shown in **Figure 7**, Priority I candidates are estimated to have 247 days of survival without a transplant[52] and receive a waiting list survival score of 1.9075. Priority II candidates are estimated to have 325 days of survival without a transplant, which translates to a waiting list survival score of 0.44. This will allow candidates of all ages to use the same lung composite allocation score math and be ranked relative to one another, a significant advantage and step forward for lung allocation.

The Committee received feedback during public comment that some people were concerned about the relatively low waiting list scores assigned to candidates under the age of 12. In the current system, these candidates are always ranked ahead of adolescent candidates (12-17 years old), but in the new system, an adolescent candidate with a high medical urgency score might receive a specific offer before the candidate who is less than 12.

However, modeling of the changes showed that while the proposal does increase transplant rates and improve waiting list survival for adolescents, this is not expected to be at the expense of candidates under 12. The modeling predicts fewer waiting list deaths for both groups and more transplants for both groups of pediatric candidates.[53] As seen in the figure below, the result of all the changes combined is that the transplant rate is expected to improve significantly for adolescent candidates. While the gains are not as large for candidates under 12, that is because they are already highly prioritized. This removal of the hard boundary and ability to prioritize the adolescent candidate when appropriate is intentional. However, the impact by age group will be one aspect of the changes that the Committee will carefully monitor to ensure that it does not unintentionally harm patients in any age group.

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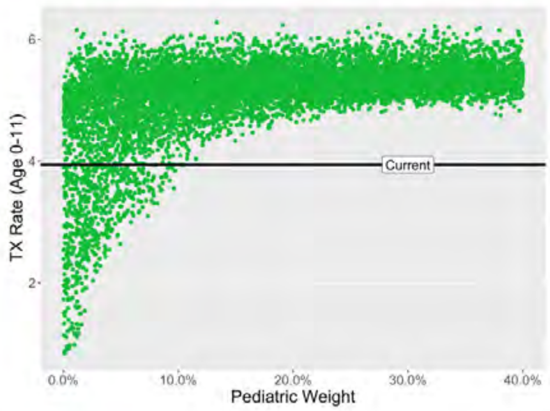
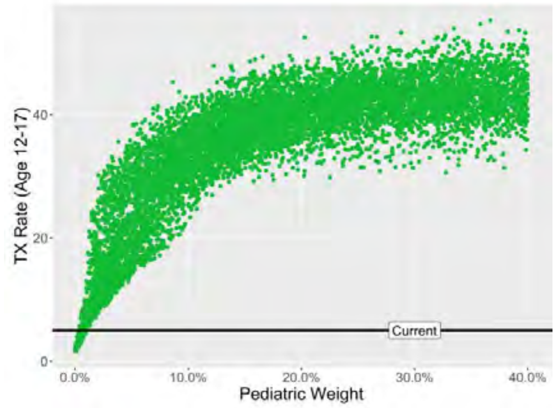
[52] Based on SRTR analysis presented to the OPTN Lung Transplantation Committee during policy development.
[53] "Waitlist deaths were similar for children aged 0-11, with 11 deaths under current rules and 8 for each continuous distribution scenario; ranges of waitlist deaths in this age group overlapped for all scenarios (Table 2, Figure 6). Waitlist deaths among children aged 12-17 declined from 12 under current rules to 2 or 3 under all continuous allocation rules." 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.

Figure 8: Transplant Rates for Children 0-11 and 12-17 by Pediatric Status Weight[54]





Post-transplant Outcomes Scale

Five-Year Outcomes

Although the current LAS includes a measure of post-transplant outcomes, Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first-year post-transplant, this proposal includes a change to that measure. It will be extended to include the expected number of days a candidate will live during the first five years post-transplant. This will allow consideration of longer-term outcomes and more stratification of candidates and is aligned with comments received in the AHP exercise.[55] It also aligns with the July 2021 ISHLT Consensus Statement on Selection of Lung Transplant Candidates, which sanctions the use of long-term survival in the distribution of organs because the principle of utility requires maximizing survival when using lifesaving severely limited resources[56]

The Committee considered feedback received at several points during the development of this change. Feedback provided through the AHP exercise supported extending the post-transplant outcomes period beyond one year, with some specifically suggesting five years.[57] There was additional feedback received during public comment. That feedback was mixed, with some supporting the proposed extension to five years and others supporting a shorter time horizon, such as three years, to align with the SRTR's reports for post-transplant outcomes measures that are used in program-specific reports (PSRs) to evaluate transplant program performance.[58] A smaller number of respondents supported limiting consideration of post-transplant outcomes to the first-year post-transplant.

[54] OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. https://optn.transplant.hrsa.gov/media/4567/20210325_lung_meeting_summary.pdf.

[55] Continuous Distribution of Lungs, Summer 2020 Prioritization Exercise – Community Results, October 12, 2020. https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.

[56] [56] Lorriana E. Leard MD, Are M. Hold MD PhD, Maryam Valapour MD MPP, et al.,"Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation", *The Journal of Heart and Lung Transplantation*, Article in Press published online July 24,2021, https://doi.org/10.1016/j.healun.2021.07.005.

[57] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.

[58] SRTR, *Technical Methods for the Program-Specific Reports*, Reports Released July 6, 2021, for the Spring 2021 Cohorts. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#tablec11c16

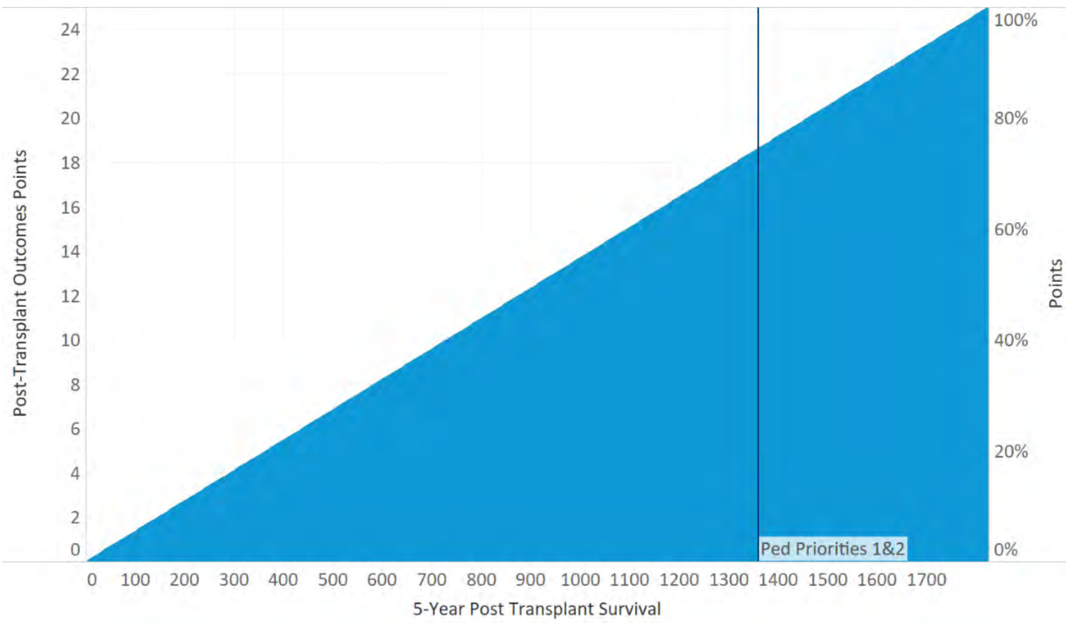
Most of the concerns around considering expected survival for five years centered around skepticism about the ability to accurately predict over a longer time frame. The Committee considered whether it would be appropriate as a first step to use the same three-year outcomes measure reported in the PSRs since that was something more familiar to the community. However, that measure looks at different things – it is center-specific and includes information not known at the time of the match (as would be needed for scoring).[59] The Committee is reassured by the fact that the level of confidence in the 5-year measure is very similar to the level of confidence in the 1-year measure. The C-statistic for the one-year model was 60.6% at one year, while the C-statistic for the five-year model is 59.3%.[60] The Committee believes the slight decrease in the confidence is offset by the benefit of being able to stratify candidates by longer-term outcomes. 90% of candidates are expected to survive for one year, so a measure that only accounts for differences within that year means that 90% of candidates would receive the same score since they are all expected to survive at least a year. [61] Using expected outcomes over five years allows the system to further stratify the candidates, accounting for differences among more patients and only grouping together those expected to live at least five years.

Linear Scale

The Committee proposes a linear scale for post-transplant outcomes since there is not an urgency that increases over time as there is with waitlist survival. This aligns with the ethical goal of utility, giving points to candidates based on how much use will be gained from the transplant in terms of the longevity of the graft. It also aligns with the requirement of the Final Rule that allocation policies be designed to achieve the best use of a donated organ.[62] The scale is below, in **Figure 9**, and shows that the points increase steadily through the five years.

[59] SRTR, *Technical Methods for the Program-Specific Reports*, Reports Released July 6, 2021, for the Spring 2021 Cohorts. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#tablec11c16.
[60] SRTR, The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant, February 17, 2021. https://optn.transplant.hrsa.gov/media/4675/lu_posttx_5y_2_2021.pdf. (The policy language was modified post-public comment to include the updated PTAUC formula modeled by the SRTR.)
[61] SRTR, *Program-Specific Reports*, https://www.srtr.org/reports/program-specific-reports/.
[62] 42 C.F.R. §121.8(a)(2).

Figure 9: Post-Transplant Survival Rating Scale[63]



Candidates with the longest expected post-transplant survival will receive the full 25 possible points (100% of available points). As shown in **Figure 9**, as a candidate's expected post-transplant survival shortens, the candidate would receive a smaller percentage of the available points (as shown on the right axis), and therefore a smaller number of points (as seen on the left axis).

Less than 12 years old

For candidates less than 12 years old, the modeling used to determine PTAUC has historically been less reliable because of the differences in these smaller pediatric patients and the very small sample sizes.[64] Instead, lung uses a two-priority system for candidates under 12; priority 1 for the sickest candidates and priority 2 for all others.

To calculate a composite allocation score for candidates less than 12 years old, the Committee needed to assign post-transplant outcomes scores to these candidates. The Committee took the same approach to convert pediatric priority levels to a post-transplant outcome score for converting pediatric priority levels to waitlist survival scores. However, when the Committee reviewed the modeling for one and five-year post-transplant outcomes for candidates less than 12, the confidence intervals for each priority's predicted 2-year post-transplant mortality overlapped, showing that there was not a significant difference in post-transplant outcomes between the two priorities.[65] In light of that information, the Committee proposes using the same post-transplant outcomes score for all candidates less than 12, a score of 18.6325.

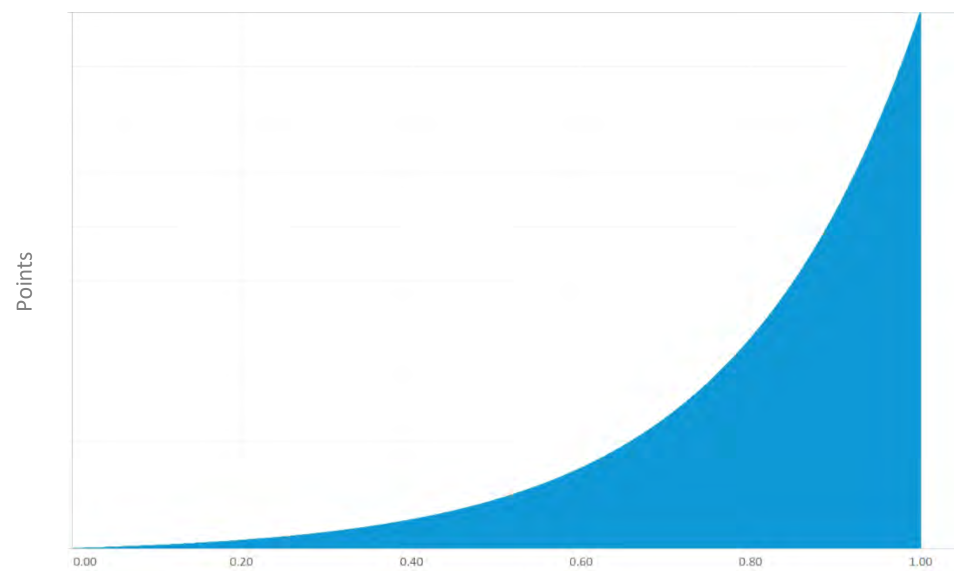
[63] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.
[64] OPTN Briefing Paper, Proposal to Revise the Lung Allocation Score (LAS) System. 2012.
[65] SRTR *The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant*, February 17, 2021. (Accessed June 18, 2021) https://optn.transplant.hrsa.gov/media/4675/lu_posttx_5y_2_2021.pdf.

Biological Disadvantages Scales

Candidate's access to transplant is affected by many factors, including biological differences between candidates, such as blood type, height, and sensitization. The OPTN has long addressed these inequities through allocation policies. These typically appear in the form of creating new classifications (such as by prioritizing candidates with blood types identical to the donor ahead of candidates with compatible blood types to the donor). The committee proposes a systematic approach whereby candidates are awarded points for their biological disadvantages according to a common scale. The clinical data drives how many points to award through a common calculation of that disadvantage.

The Committee is aligning all three candidate biology rating scales (blood type, CPRA, and height) to a single curve, most clearly represented by the CPRA curve, because all three are measures of how hard it is for the candidate to match with a compatible donor or incompatibility. For example, if a candidate could match with any donor based on that characteristic, 0 points would be awarded. Blood type AB candidates do not receive blood type points since they can accept any donor blood type. A candidate would receive the maximum points if very few donors would be a match based on that characteristic, so, for example, candidates with a CPRA of 100% would get the most points for the CPRA factor. The scales are aligned so that candidates who only match half of the donor pool (such as a candidate with either blood type O or CPRA of 50%) would get the same number of points. This common curve shifts the conversation of weights regarding blood type versus sensitization or height from an ethical conversation to one based on "objective and measurable medical criteria."[66]

Figure 10: Shape of Biological Disadvantages Rating Scales[67]



The common curve is a steep curve that reflects a much larger difference in points awarded to candidates who are the hardest to match and less of a difference among the candidates who are easier to match. The Committee also considered whether to adopt a linear scale or a scale with a shallower curve. However, the Committee chose the steep curve because, much like waiting list survival, the difference in being compatible with only 1/100 donors or 2/100 donors impacts a candidate's likelihood of transplant more than the difference between being able to match with 97/100 and 98/100 donors.

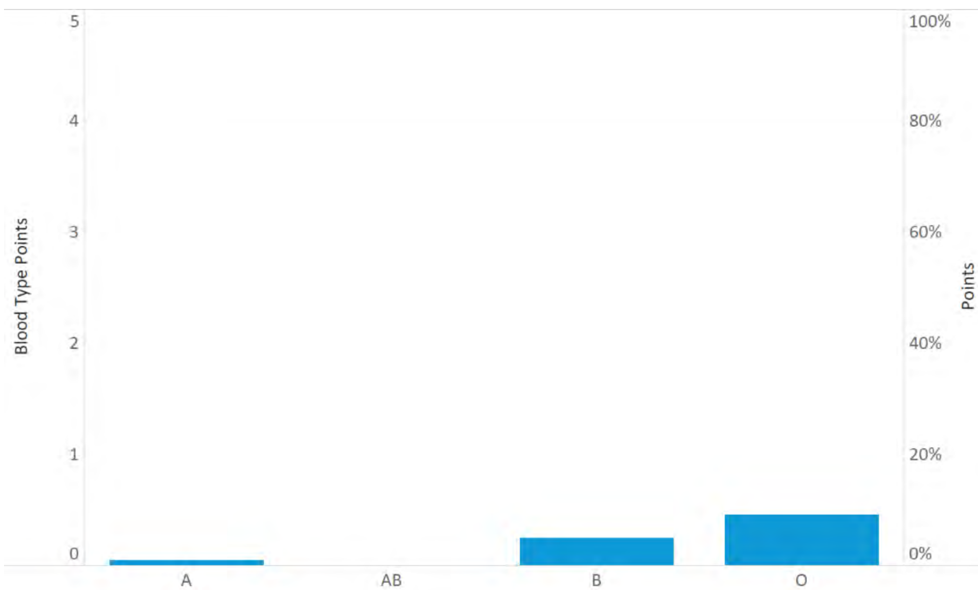
[66] 42 C.F.R. §121.8(b)(2).
[67] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

The OPTN Histocompatibility Committee was supportive of this approach, which aligns with the current approach to CPRA in kidney allocation. The common curve all biological disadvantages scales are aligned to is shown in **Figure 10** above.

Blood Type (ABO) Rating Scale

The blood type rating scale is based on the proportion of donors incompatible with a candidate based on the candidate's blood type. This proportion is then aligned with the overall candidate biology scale to develop the ratings for blood type. Because even the hardest to match candidate blood type (O) can still accept approximately 50% of donors based on blood type, the blood type scale never awards the full points available under this attribute. Furthermore, the use of a curved candidate biology scale provides more distinction among the candidates who are hardest to match, resulting in less than 50% of the possible points being awarded for O candidates, as seen in **Figure 11** below. This is the result of the alignment across the candidate biology scales.

Figure 11: Blood Type Rating Scale[68]



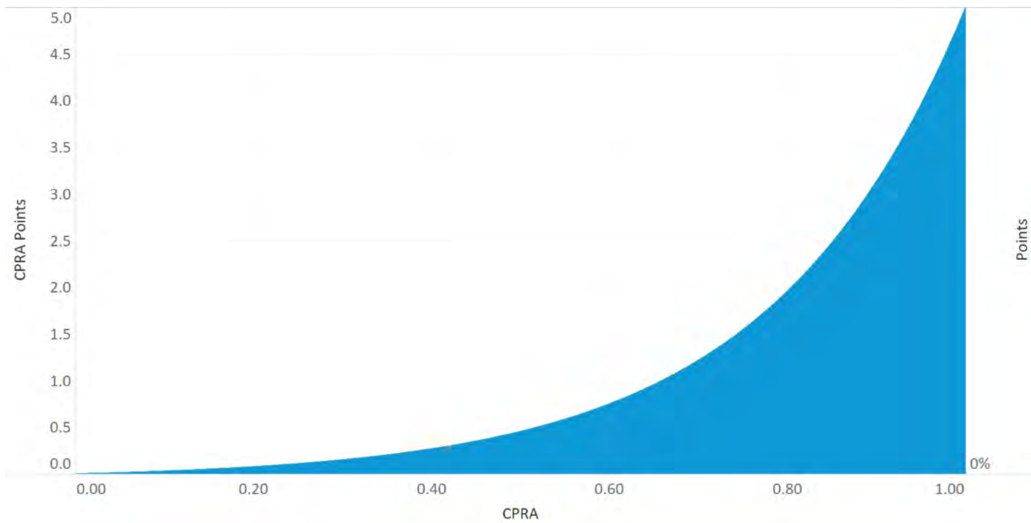
Sensitization (CPRA) Rating Scale

Calculated panel reactive antibody (CPRA) values directly estimate the proportion of donors with which a HLA-sensitized candidate is HLA incompatible. CPRA is already in use in kidney allocation and is a screening option for lung but is not currently used in allocation sequencing for lung.[69] However, antibody sensitivity is a concern that affects the suitability of an organ for lung patients and, therefore, limits the pool of appropriate donors for these lung candidates.[70] Therefore, the Committee decided to incorporate the CPRA attribute into the composite score. Although kidney allocation currently employs hard cutoffs of 98 or 99% CPRA, this change incorporates CPRA in a more nuanced way, smoothing that

[68] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.
[69] OPTN Policies.
[70] Y.D. Barac, M. Mulvihill, O. Jawitz, J. Haney, J. Klapper, M. Daneshmand, M. Hartwig, *High Calculated Panel Reactive Antigen (cPRA) is Associated with Decreased Rates of Transplantation and Increased Waitlist Mortality in Lung Transplantation: A UNOS/OPTN Registry Analysis*, The Journal of Heart and Lung Transplantation, Volume 38, Issue 4, S148.

hard boundary using the steeply curved scale.[71] This approach received favorable feedback in public comment, and therefore the Committee did not make any changes to the CPRA rating scale from the public comment proposal. The CPRA rating scale is depicted in **Figure 12** below.

Figure 12: CPRA Rating Scale



Height Rating Scale

The Committee also discussed other biological conditions that impact a candidate's access to transplant. In addition to blood type and CPRA, the Committee is awarding points to candidates based upon their height.[72] Height is not currently used in lung allocation other than as a screening criteria that a transplant program can select, optionally, to exclude receiving offers from donors outside of the transplant program's height preferences for a particular candidate.

As shown in **Figure 13** below, the height rating scale awards the highest points to the smallest and tallest candidates, as they have the most trouble finding an appropriate match.[73] The Committee proposed this new factor due to the known need for size matching, and difficulty finding an appropriately sized donor for candidates who are especially small or tall.[74]

[71] Kransdorf EP, Pando MJ. Calculated panel reactive antibody with decimals: A refined metric of access to transplantation for highly sensitized candidates. Hum Immunol. 2017 Mar; 78(3):252-256. doi: 10.1016/j.humimm.2016.12.009. Epub 2017 Jan 6. Erratum in: Hum Immunol. 2017 Jul - Aug;78(7-8):522. PMID: 28069404.

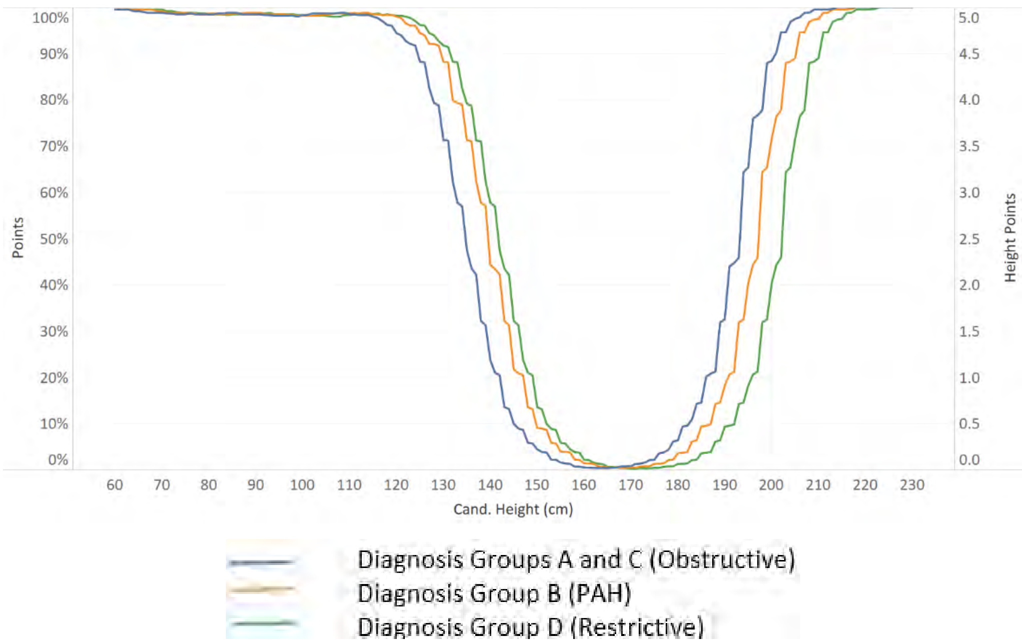
[72] The Committee also discussed size matching as a potential attribute related to post transplant outcomes. But due to community debates about the best way to measure lung cavity size, the Committee opted to address this in future iterations. Compare Reyes J. Perkins J, Kling C, Montenovo M. Size mismatch in deceased donor liver transplantation and its impart of graft survival. Clin Transplant. 2019; 00:e13662. https://doi.org/10.1111/ctr.13662 (DR_BSAR, donor to recipient body surface area ratio); Ganapathi AM, Mulvihill MS, Englum BR, et al. Transplant size mismatch in restrictive lung disease. Transpl Int. 2017; 30(4):378-387. https://doi.org/10.1111/tri.12913 (pTLC, predicted total lung capacity); Eberlein M, Reed RM. Donor to recipient sizing in thoracic organ transplantation. World J Transplant. 2016; 6(1):155-64; Barnard JB, Davies O, Curry P, et al. Size matching in lung transplantation: an evidence-based review. J Heart Lung Transplant. 2013; 32(9):849-60. https://doi.org/10.1016/j.healun.2013.07.002.)

[73] OPTN Lung Transplantation Committee, Continuous Distribution Data Workgroup, Meeting Summary, August 12, 2020.

[74] Keeshan BC, Rossano JW, Beck N, Hammond R, Kreindler J, Spray TL, Fuller S, Goldfarb S., Lung transplant waitlist mortality: height as a predictor of poor outcomes, Pediatr Transplant. 2015 May; 19(3):294-300. doi: 10.1111/petr.12390. Epub 2014 Nov 19. PMID: 25406495. Sell JL, Bacchetta M, Goldfarb SB, Park H, Heffernan PV, Robbins HA, Shah L, Raza K, D'Ovidio F, Sonett JR, Arcasoy SM, Lederer DJ. Short Stature and Access to Lung Transplantation in the United States. A Cohort Study. Am J Respir Crit Care Med. 2016 Mar 15; 193(6):681-8. doi:

The Committee proposes using separate height scales by diagnosis because the chest cavity size is affected by the type of lung disease, whether it is obstructive, restrictive, or pulmonary arterial hypertension (PAH).[75] The proportion of incompatible donors was based on an analysis of the range of donor height accepted for candidates according to candidate height. This proportion of height incompatible donors was then combined with the candidate biology curve to create the rating scale for height.

Figure 13: Height Rating Scales[76]



Patient Access Scales

Age

The Committee proposes a binary rating scale to assign points for pediatric access. Candidates under the age of 18 when they are registered on the waiting list will receive the full benefit of the pediatric points, and candidates who are over the age of 18 will receive none. During public comment, the Committee received feedback suggesting a sliding scale for these points. However, the Committee remained with a binary approach to this attribute for this iteration of the policy. A candidate either receives all the points or none, for the reasons below.

The Committee also considered and rejected a sliding scale or stepwise system where a candidate might get more points for being the youngest candidate than for being 17 years old, for example. The two primary reasons for using a sliding scale would have been 1) to account for the additional difficulties in matching candidates who are especially small and 2) the lack of a clinical difference between a candidate just before and after their 18th birthday. As it relates to the first concern, the Committee was

10.1164/rccm.201507-1279OC. PMID: 26554631; PMCID: PMC5440846. Weill D. Access to Lung Transplantation. The Long and Short of It. Am J Respir Crit Care Med. 2016 Mar 15; 193(6):605-6. doi: 10.1164/rccm.201511-2257ED. PMID: 26977969.

[75] *Ibid.*

[76] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

able to include points for height awarded in proportion to the difficulties in finding a match. The use of the height scale can more directly address the specific factor and align the points with the specific disadvantage.[77]

As it relates to the second concern, generally, NOTA requires the OPTN to "recognize the differences in health and in organ transplantation issues between children [under the age of 18] and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children."[78] For the Committee to develop a sliding scale based on age, the Committee would need to first evaluate and show the connection between age and relevant clinical criteria.[79] For example, one approach would be to show how age, combined with other factors, might predict how likely the transplant is to provide the patient with long-term benefit. The Committee expressed interest in exploring this topic for a future enhancement.

This is a shift from the current lung policy, which groups candidates into three age groups, under 12, 12-17 (adolescent) and 18 and over (adult). It is also consistent with the advice from the Pediatric Transplantation Committee to adopt a consistent approach for all organs as they transition to continuous distribution.[80]

The Committee received feedback during public comment expressing concerns about whether this approach can disadvantage children under 12 relative to adolescent (12-17 year old) candidates. Although both groups benefit from the pediatric points, the waiting list and post-transplant outcomes scores are calculated differently for the two groups. Candidates under 12 will still be assigned either pediatric priority 1 or 2. In the current system, adolescent candidates receive an LAS calculated in the same was as an adult, since the variables used to calculate it are still predictive for this group. The approach to calculating waitlist and post-transplant survival used in the LAS calculation will also be used to calculate the waiting list survival and post-transplant outcomes measures used in the CAS. Priority 1 and 2 will each be assigned a specific waiting list survival score and post-transplant survival score. Although the post-transplant survival score assigned to all candidates under 12 is fairly high (18.6336), the waiting list survival score for a priority 1 candidate is 1.9073, and 0.4406 for priority 2 is not very high. The commenters expressed concerns that while adolescent candidates will have a waitlist survival score that could be as high as 25, in addition to the pediatric points, the candidates under 12 will not have as high of a potential score.

Finally, the Committee reviewed the interactive sensitivity tool to probe this question. (See **Figure 14.**) Using the weights proposed by the Committee, they could see that adolescent and infant candidates would 1) generally be near the top of most match runs and 2) that adolescent and infant candidates would mix together based upon the specifics of each candidate. In other words, adolescents didn't categorically come before infant candidates.

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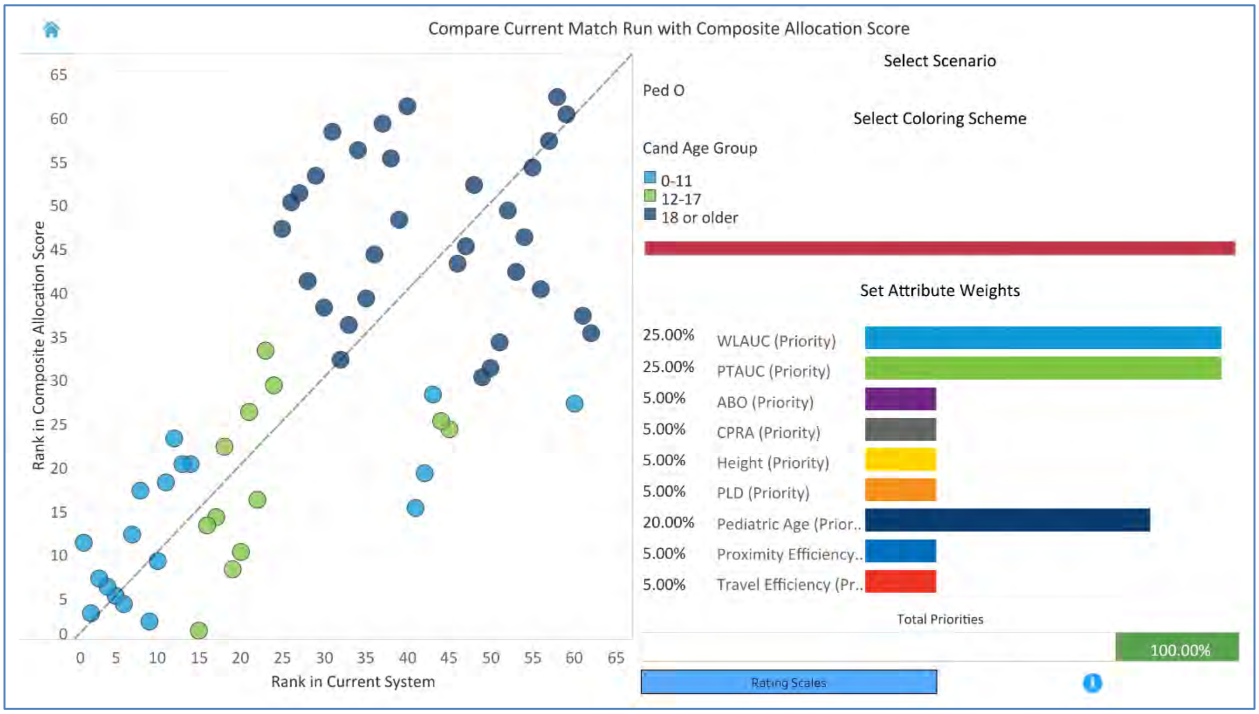
[77] OPTN Lung Transplantation Committee, Continuous Distribution Data Workgroup, Meeting Summary, August 12, 2020.
[78] 42 USC § 274(b)(2)(M).
[79] Govind Persad, Evaluating the Legality of Age-Based Criteria in Health Care: From Nondiscrimination and Discretion to Distributive Justice, 60 B.C. L. Rev. 889 (2019), https://lawdigitalcommons.bc.edu/bclr/vol60/iss3/4. Eidelson, Benjamin. "Kidney Allocation and the Limits of the Age Discrimination Act." The Yale Law Journal 122, no. 6 (2013): 1635-652, https://digitalcommons.law.yale.edu/ylj/vol122/iss6/6.
[80] OPTN Pediatric Transplantation Committee *Meeting Summary*, January 20, 2021. https://optn.transplant.hrsa.gov/media/4427/20210120_pediatric_committee_summary.pdf.

Figure 14: Distribution of Candidates by Age in Sensitivity Tool



The Committee is reassured by the predicted improvements to the outcomes and transplant rates for pediatrics in both age groups, the points assigned for likelihood of height compatibility, and their medical experience that size matching is an important consideration in lung transplantation, so the very youngest candidates are likely not a good match for the same donors as many adolescent or adult candidates.

This is consistent with the OPTN determination that it is ethically appropriate to preference pediatric candidates.[81] The OPTN Ethical Principles of Pediatric Organ Allocation cite Norman Daniel's Prudential Lifespan Account[82], the Fair Innings Principle[83], and John Rawl's Maximin Principle[84] to justify pediatric prioritization.[85] The principles also justify the priority using utility considerations ("[A]cross the entire population of pediatric versus adult transplant recipients, pediatric transplant recipients will on average enjoy lower mortality rates due to the strong association between younger age and longer survival.")[86] In other words, these ethical principles support the Committee's determination that prioritizing pediatric candidates is the best use of donated organs. Additionally, these justifications used in the OPTN Ethical Principles of Pediatric Organ Allocation also meet the requirement of the National Organ Transplant Act (NOTA) to "recognize the differences in health and in organ transplantation issues

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[81] OPTN Ethical Principles of Pediatric Organ Allocation, November 2014. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation.
[82] Daniels, N. Just Health: Meeting Health Needs Fairly. New York: Cambridge University Press, 2008.
[83] Williams, A., "Intergenerational Equity: An Exploration of the 'Fair Innings' Argument." Health Economics 6 (1997): 117-32.
[84] Rawls, J. A Theory of Justice. Cambridge: Belknap Press, 1971.
[85] OPTN Ethical Principles of Pediatric Organ Allocation.
[86] OPTN Ethical Principles of Pediatric Organ Allocation.

between children [under the age of 18] and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[87]

The Committee discussed the potential for inequitable impact on candidates based on whether they were referred for transplant ahead of their 18th birthday, which may reflect differences by race, ethnicity or other access to care.[88] Although specific waiting time on the list is only used as a final tiebreaker, the Committee was concerned with whether basing the pediatric priority on the candidate's listing date would treat candidates unfairly based on late referral.

One idea suggested during public comment was allowing the points assigned to pediatrics to taper off for candidates above 18, so that even if the candidate was listed prior to their 18th birthday, they would not retain those points for more than six months or a year. While Committee members believed that in most cases, a candidate listed while pediatric would be treated in these time frames, they did not have sufficient data available to determine what exact time frame would be appropriate. They also did not want to unintentionally disadvantage a candidate who was appropriately listed while pediatric and was unable to get transplanted within a shorter time frame. The numbers of candidates listed as adolescents are very small (less than ten on the waiting list as of October 24, 2021), and creating additional rules around how long these candidates maintain their priority is not seen as the most effective solution to the concern for candidates who are referred for transplant later. Instead, these candidates have the option to apply for an exception, which would be justified with that candidate's specific situation. The Committee plans to monitor any changes to listing practices or increase in exception applications, discuss this with other organ committees, and pursue a more targeted consideration of these candidates in future Committee work.

Prior Living Donors

The Committee has included points for prior living donors. Candidates who have previously donated any organ would receive the full benefit of the five prior living donor points, and candidates who have not donated would not receive any prior living donor points. Feedback received in public comment was supportive of this approach to points for prior living donors. The Committee did adjust the policy language slightly to more carefully delineate the administrative requirements to qualify for the priority and align more closely with the wording used in OPTN kidney policy.

This concept exists in kidney allocation policy now and the Committee proposes extending this benefit to lung allocation. There are both ethical and legal justifications for providing this priority to prior living donors. The ethical reasons include the ethical principle of making one whole and the physician's maxim to protect patients. For these reasons, the Ethics Committee supported prior living donor priority for any organ needed.[89] However, the OPTN must develop organ allocation policies consistent with our legal obligations. NOTA requires that the OPTN create allocation policies "in accordance with established medical criteria,"[90] while the OPTN Final Rule requires, amongst other requirements, that allocation

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[87] 42 USC § 274(b)(2)(M).
[88] "a center's decision to list a candidate could occur at different age or illness thresholds by race/ethnicity and contribute to differences in illness severity and age at transplant listing." Joshua Mooney, Haley Hedlin, Paul Mohabir, Jay Bhattacharya, Gundeep Dhillon, *Racial and Ethnic Disparities in Lung Transplant Listing and Waitlist Outcomes*, H Heart Lung Transplant, 2018 Mar; 37(3): 394–400. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6312552/
[89] OPTN Ethics Committee Meeting Summary, March 11, 2021.
[90] 42 U.S.C. §274(b)(2)(A)(ii)

policies be “based on sound medical judgment,”[91] “seek to achieve the best use of donated organs,”[92] and “promote patient access to transplantation.”[93] There is also a federal prohibition on offering valuable consideration for organ donation. In developing this specific aspect of the proposal, the Committee sought to keep all of these requirements in consideration and sought the advice of the Ethics Committee and Living Donor Committee.

First, the threshold question is whether being a living donor is a medical criterion in the same sense as respiratory failure. The answer is clearly yes; all of these individuals were medical patients who underwent a hospital surgical procedure. This distinguishes non-medical criteria such as donating money to transplant research, having a family member be a deceased donor, signing up to be a deceased donor, etc. which are excluded from organ allocation policy. As such, being a prior living donor is a criterion that the OPTN can consider when developing allocation criteria, while continuing to appropriately exclude rewarding those who donate in non-medical ways to the transplant system.

"Sound medical judgment" is not defined by NOTA or the OPTN Final Rule. It “is an ambiguous term that is synonymous with the term ‘decision-making.’ It results from critical thinking and clinical reasoning.”[94] One way this manifest is through consensus following thoughtful discussion among informed medical professionals. They would need to be informed of the risks, benefits, and tradeoffs regarding their decision. As it relates to prioritizing prior living donors, the Board and multiple committees have discussed this concept over the years. All of them have agreed that prior living donors should receive some priority.[95]

The "best use of donated organs" is an ambiguous term and can be candidate-specific or system-wide. Prior living donors provide a benefit to the entire system. There are roughly 500 living donors and maybe 40 prior living donors added to the waiting list each year.[96] Across the system, this brings a benefit to the transplant system. Anecdotally, several transplant professionals stated that the prior living donor priority is an important part when discussing living donation with potential prior living donors.

Like the best use requirement in the Final Rule, the regulation also requires the OPTN to promote patient access to transplantation.[97] While this priority promotes access for prior living donors, it also promotes access for other candidates. As mentioned above, more living donor organs are transplanted each year than prior living donors added to the waiting list. This has a net effect of lowering the number of candidates waiting for a transplant – or increasing access to transplant for those candidates that do not receive a living donor organ. Since the justification for providing points for prior living donors is the same for all prior living donors, the binary scale provides the same points for all prior living donors.

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[91] 42 C.F.R. §121.8(a)(1)
[92] 42 C.F.R. §121.8(a)(2)
[93] 42 C.F.R. §121.8(a)(5)
[94] Manetti, Wendy. “Sound Clinical Judgment in Nursing: A Concept Analysis.” Nursing Forum 54, no. 1 (January 2019): 102–10. https://doi.org/10.1111/nuf.12303.
[95] OPTN, Kidney Committee Report to Board, Dec 13, 2006. OPTN, Minutes from Meeting of Ethics Committee, April 2, 2012. Letter from Liver Committee to Living Donor Committee, Feb 23, 2015.
[96] J. Wainright, D. Klassen, A. Kucheryavaya, and D. Stewart, Delays in Prior Living Kidney Donors Receiving Priority on the Transplant Waiting List. Clinical journal of the American Society of Nephrology: CJASN, 11(11), 2047–2052 (2016). https://doi.org/10.2215/CJN.01360216.
[97] 42 C.F.R. §121.8(b)(2).

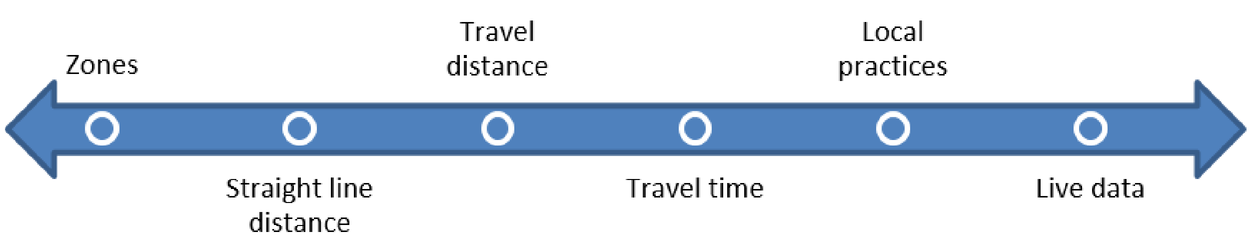
Promoting the Efficient Management of the Organ Placement System Scales

Although the Committee chose to use distance as the measure of placement efficiency, the amount of travel is not the goal of the Committee's use of distance; rather, as illustrated in **Figure 15**, travel impacts organ placement efficiency. Generally, the following statements are true: travel distance impacts travel time; the farther an organ is transported, the more likely it is to travel by air than ground; and air travel is more expensive than ground travel for the same distance;[98] finally, financial costs are only one aspect of overall system efficiency.

The Committee started with a focus on how to determine the mode of travel. The Committee reviewed information from the UNOS Organ Center, a recent Operations and Safety survey, and published literature regarding travel modes for organ transportation.[99] The Committee also solicited information from AOPO members, the SRTR, and other workgroup members about determining the mode of travel.

The Committee discussed several attributes that could influence the travel mode: distance between the donor and transplant hospital; travel time; time of day; donor organ characteristics; urbanicity; flight availability; etc. Some of these cannot be known at the time of organ offer and therefore could not be used to prioritize organ offers. (For example, time of procurement is not known before the organ is offered.) The Committee also discussed how granularly to predict travel mode or costs. There exists a spectrum of options available. These options can be considered from the least precise estimate of impact to system efficiency to the most precise estimates (**Figure 15**). This range also coincides with options that are the most transparent to the least transparent. In other words, more precise options typically rely upon live or proprietary information and would likely be less transparent to the community while less precise options typically rely upon easily obtainable information and are more transparent.

Figure 15: Options for Determining Travel Costs

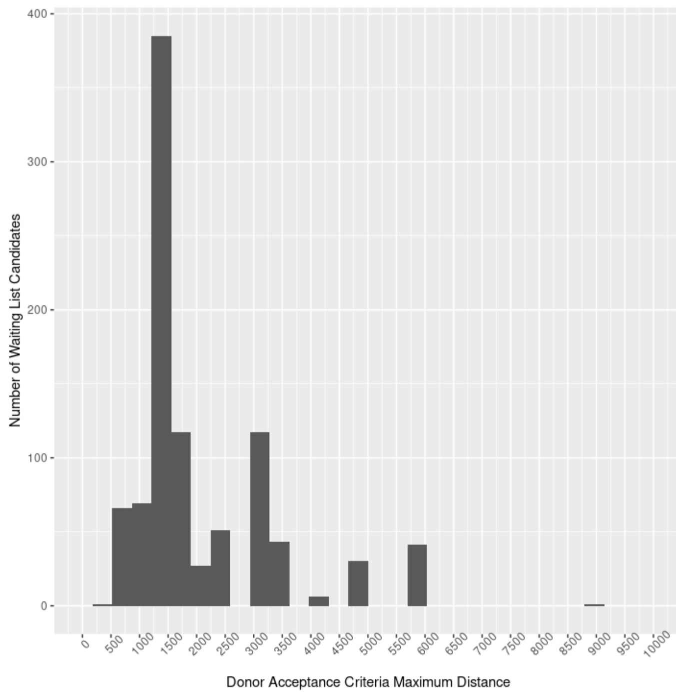


The Committee chose to use straight-line distances to calculate relative travel costs based on a desire to be as transparent as possible, especially as part of this large allocation change.[100] However, the Committee did consider this an area where it may be desirable to move to more specific measures in the future, an idea that was supported in the responses to public comment.

[98] S. Gentry, E. Chow, N. Dzebisashvili, et al. The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients. Am J Transplant. 2016; 16(2):583-93. Dubay DA, Maclennan PA, Reed RD, et al. The impact of proposed changes in liver allocation policy on cold ischemia times and organ transportation costs. Am J Transplant. 2015; 15(2):541-6.
[99] OPTN Operations and Safety Committee, Transportation Report (2018), available at: https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.
[100] OPTN Ethical Principles in the Allocation of Human Organs, 2015. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/. The OPTN will use the Haversine method to calculate these distances between the latitude and longitude of the donor and transplant hospitals. Due to differences in calculating these locations, the OPTN will round-down, or truncate, distances to the integer level.

The proximity and travel efficiency scales have multiple inflection points, based on certain changes to the way organs and procurement teams travel. Within 45 nautical miles (NM), lung procurement teams and procured lungs are more likely to travel via ground transportation. Within the 45-90 NM zone, the likelihood of travel by air is increasing, and over 90 NM, most travel for lung recovery is by private air transportation. The final inflection point is around 3,000 NM, beyond which most lung programs have their screening criteria set to exclude offers, as shown in **Figure 16**.

Figure 16: Donor Acceptance Criteria for Maximum Distance by Number of Lung Candidates[101]



The distance at which lungs are more likely to use air transportation than ground transportation is similar to livers but different from the distances where this change occurs for kidney recovery. Because cold ischemic time does not significantly negatively impact kidneys as soon as it does on lungs, kidney transportation patterns are different from the patterns seen with livers, hearts, and lungs. Livers, hearts, and lungs are more likely to use private air than kidneys, which are more often transported on commercial flights. Therefore, the Committee chose to anchor to the literature on travel methods for livers[102] rather than travel analysis conducted on kidneys.

The shape of these placement efficiency scales allows for smarter distribution of lungs. Instead of treating all lung offers within 250 NM the same, there is additional weight placed on those closest. Modeling suggests that more organ transplants will occur within the first 50 NM. In addition, the average distance organs will travel will increase, however, fewer organs will be transported by air. Continuous distribution achieves the goal of smarter distribution: shipping organs only for significant clinical differences. The number of lungs placed within 50NM increases and therefore flying is reduced,

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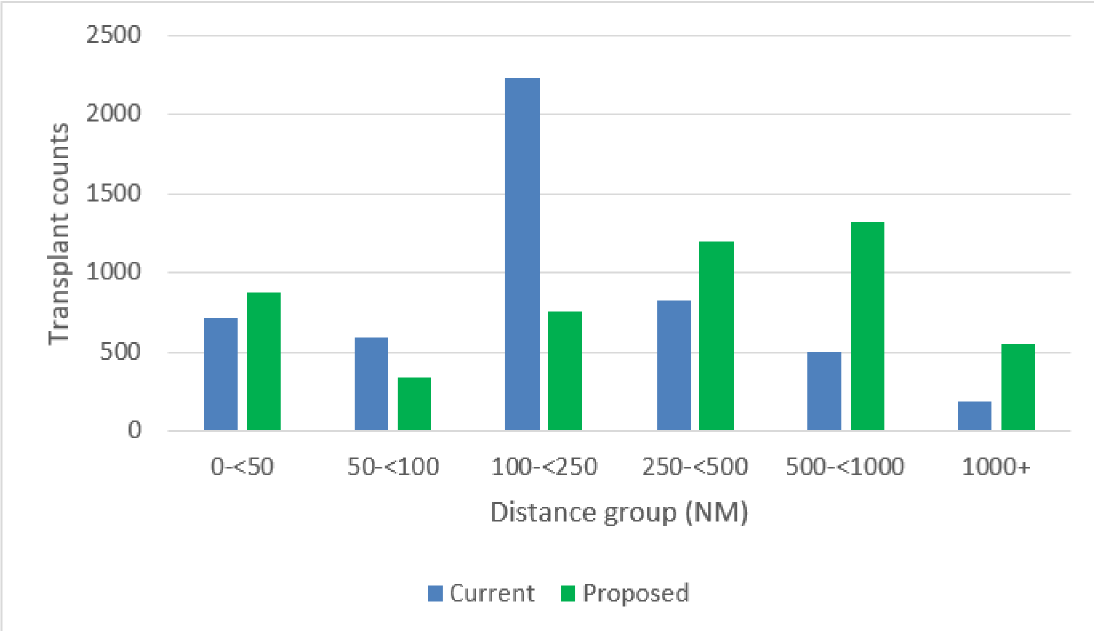
[101] OPTN data as of November 2020.

[102] Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL. The impact of redistricting proposals on health care expenditures for liver transplant candidates and recipients. American Journal of Transplantation. 2016 Feb; 16(2):583-93.

even though median travel distances increased. **Figure 17** shows the distribution of transplants by distance from the donor hospital in the proposed system compared to the current system.

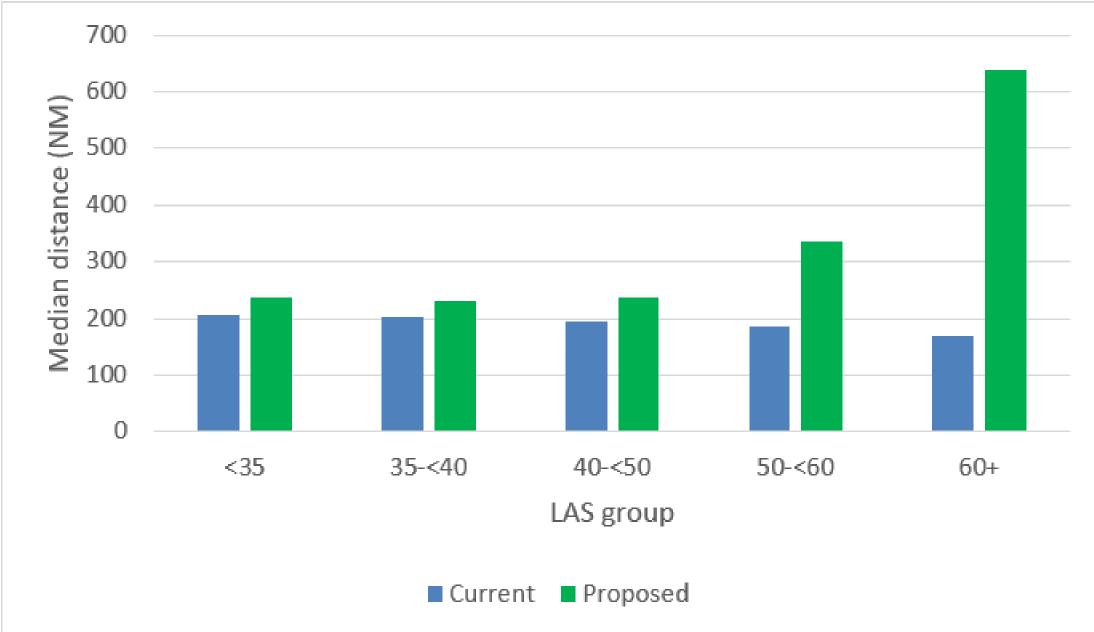
Figure 17: Transplant Counts by Distance Comparison to Current[103]



In fact, the modeling shows that most travel is for candidates with the lowest LAS in the current system. That means that transplant hospitals are traveling farthest for the least urgent candidates and the least for the most urgent candidates. In the proposed system, this is largely reversed. As seen in **Figure 18**, SRTR modeling shows that the highest LAS candidates (who need the lung the most urgently) will be able to accept offers from farther away, and transplant hospitals will be less likely to travel farther for the candidates who have lower LAS and may be able to wait for a closer offer.[104]

[103] 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.
[104] Note: The modelling shows that organs offered long distances will more frequently be offered to high LAS candidates. This does not mean that high LAS candidates will only receive offers from far away or with high cold ischemic time.

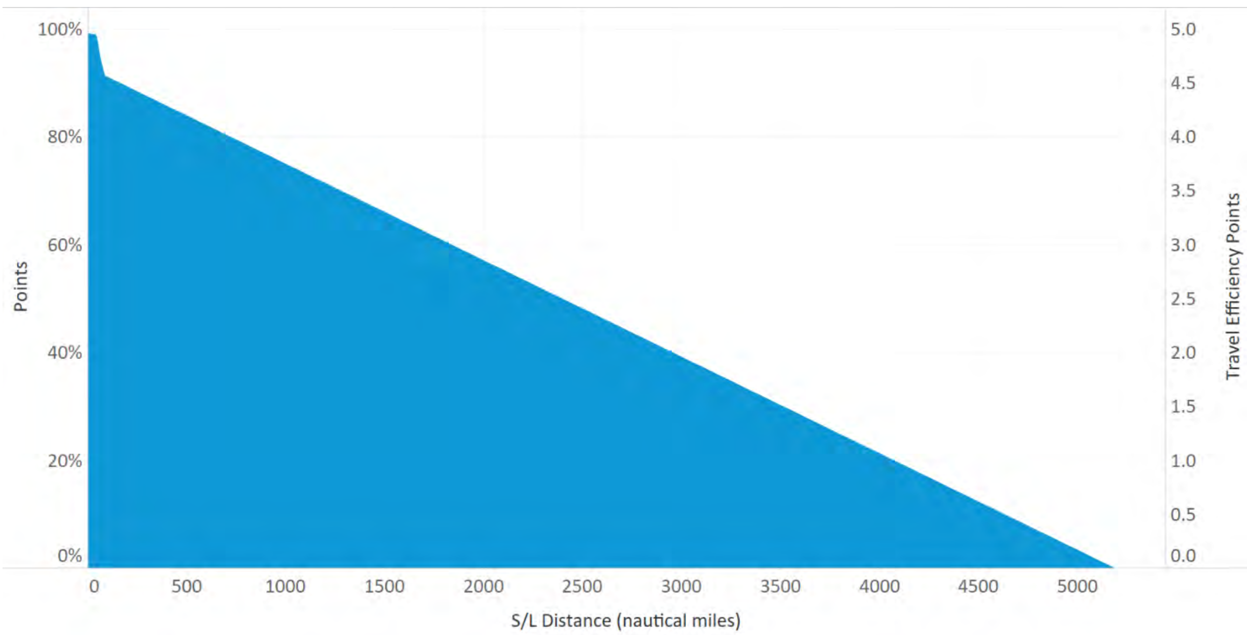
Figure 18: Median Distance from Donor Hospital to Recipient Hospital by LAS



Travel Efficiency Rating Scale

Travel efficiency measures the efficiency of traveling shorter distances and the associated reduction in travel costs. Since a direct measure of these costs is not available, the Committee chose approximate inflection points. The proposed scale for travel efficiency gradually decreases from 0-45 NM, reflecting small differences in costs associated with driving greater distances. Then the rating scale declines more sharply between 45 and 90 nautical miles, since air travel may be required in this range, based on polling clinicians and published literature on transportation of livers for transplantation.[105] Beyond about 90 nautical miles, it is estimated that lungs will nearly always be transported by air. Once traveling by air, the added cost of traveling further distances is incremental, as reflected in the relatively shallow, but steady rating scale slope.

Figure 19: Travel Efficiency Rating Scale[106]

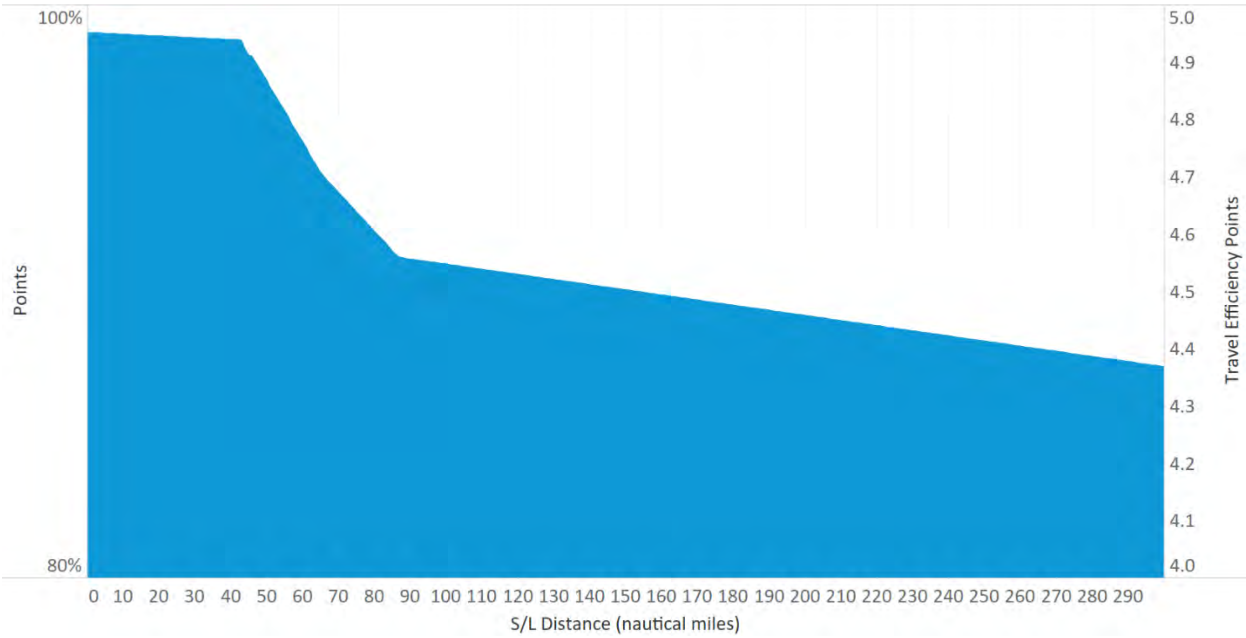


[105] OPTN Thoracic Committee Continuous Distribution of Lungs Workgroup Meeting Minutes, May 16, 2019. https://optn.transplant.hrsa.gov/media/3086/20190516_lungworkgroup_summary.pdf. Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL. The impact of redistricting proposals on health care expenditures for liver transplant candidates and recipients. American Journal of Transplantation. 2016 Feb; 16(2):583-93.

[106] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

The changes within the first 300 NM to adjust for travel methods are shown more closely in **Figure 20** below.

Figure 20: Travel Efficiency Rating Scale (Zoomed in to 0 to 300 Nautical Miles)[107]



Responses in public comment were particularly supportive of treating the differences in travel type differently, recognizing that there is a significant efficiency impact from adding air travel.

Proximity Efficiency Rating Scale

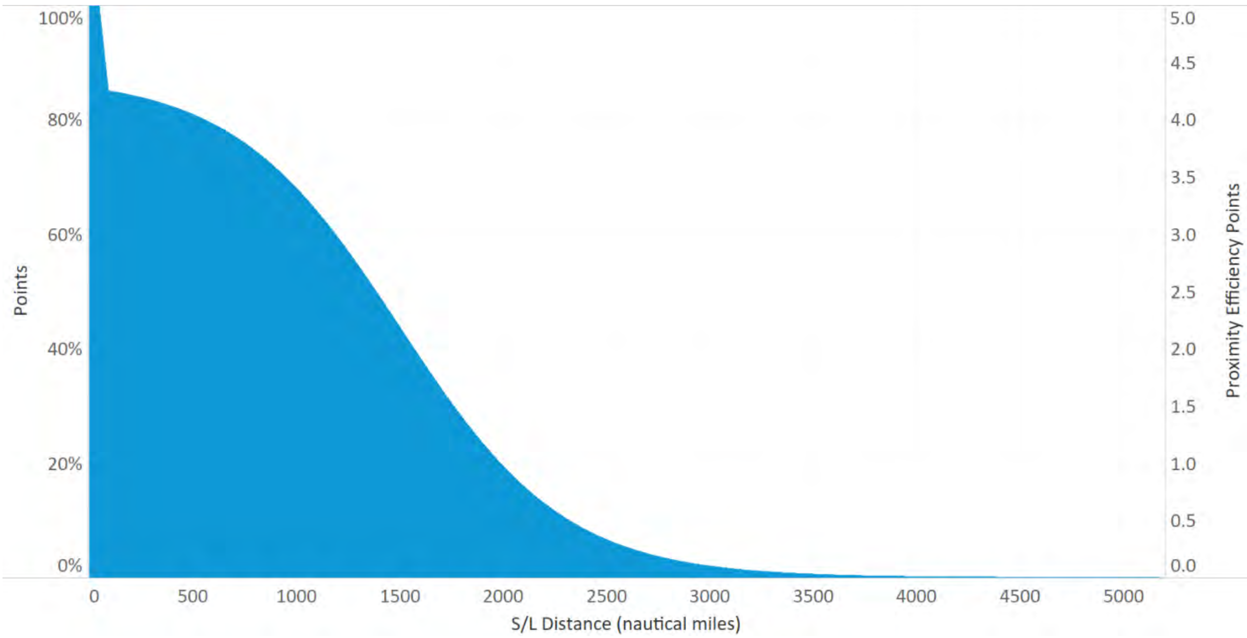
The proximity efficiency rating scale measures the efficiency of transporting lungs shorter distances other than decreased transportation costs. These include differences such as the time in transit for transplant teams, additional effort required to coordinate longer travel, and differences in the chance of something going wrong in transit the farther the personnel and lungs must travel.

The rating scale for proximity efficiency provides the most points for candidates listed closest to the donor hospital. Rather than providing a steady difference in points as distance changes, the rating scale for proximity points provides the maximum points for any distance within 45 NM, within which almost all travel would be expected to be by ground transportation. There is a steep decrease in points from 45-90 NM where there would be some air travel and some ground travel.

For distances beyond 90 NM, the rating scale follows a sigmoidal mathematical function (S-curve). This curve is gradual at first, accounting for little significant difference in the efficiency of a short flight compared to a slightly longer flight. The curve drops more steeply after 3,000 NM, the distance beyond which lung transplants are rarely performed. [108]

[107] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.
[108] OPTN Lung Committee Meeting Minutes, Nov. 12, 2020.

Figure 21: Proximity Efficiency Rating Scale[109]



There are times when a lung is imported from outside the United States of America and transplanted into a candidate inside the US.[110] In these instances, distance will be calculated based on the location of the US donor hospital closest to the recovery hospital outside of the US.

Relative Weights

The CAS is awarded on a 100-point scale. Each attribute is assigned a relative weight that equates to a percentage of the score, or a maximum number of points within the score available for that attribute. The weight for waiting list survival is 25, so it accounts for 25% of the score, and no candidate will be able to have a waiting list survival score of more than 25 points. The weights proposed for each specific attribute are listed below.

[109] https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

[110] Placement by the OPTN was attempted for lungs from one Canadian donor in the first quarter of 2021, and for lungs from six donors in the first quarter of 2020. OPTN data accessed July 1, 2021.

Figure 22: Attribute Weighting

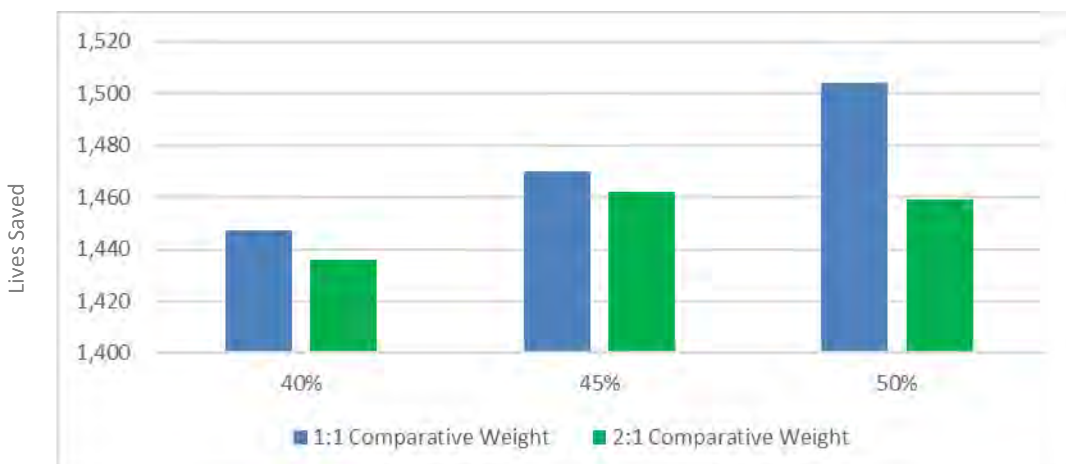
Attribute	*Weight*
Waiting list Survival	*25%*
Post-Transplant Outcomes	*25%*
Blood Type	*5%*
CPRA	*5%*
Height	*5%*
Pediatric	*20%*
Prior Living Donor	*5%*
Travel Efficiency	*5%*
Proximity Efficiency	*5%*

Waiting List Survival and Post-Transplant Outcomes

In the current LAS system, candidates are assigned an LAS based on their predicted waiting list survival and post-transplant outcomes. The LAS formula places twice as much weight on the waiting list survival measure as on the post-transplant outcomes measure. Community responses to the AHP prioritization exercise showed that most people responded that they are equally important and should have the same weight. They also revealed that the community believed that each should represent about one-quarter of the overall score. This is also a departure from the current LAS system, in which approximately 81% of the score for adults is placed on placement efficiency.[111]

SRTR modeling showed that the biggest improvements in combined waiting list survival and post-transplant survival could be achieved by placing 25% on each, to maintain a balance between the two weights.

Figure 23: Combined 1-Year Waiting List Survival and 2 Year Post-Transplant Survival[112]



[111] Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf.
[112] 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.

As seen in **Figure 23**, the highest candidate survival (combined waiting list and post-transplant) among the SRTR round 2 models is expected when 50% of the weight is divided evenly between waiting list survival and post-transplant outcomes (25% each).

The feedback received during the public comment period was largely supportive of the proposed weights for waiting list survival and post-transplant outcomes. There were some concerns expressed related to whether there should be less weight placed on post-transplant outcomes than waiting list survival, since we are able to predict waiting list survival with a greater degree of confidence than we are able to predict post-transplant survival. Those respondents suggested that post-transplant outcomes should not be weighted as heavily because they were not as precise. The Committee discussed this feedback, and was comfortable that post-transplant outcomes were still valuable to include, and the ethical direction to balance utility justified equal weight for post-transplant outcomes. In order to provide the most utility, considering combined waiting list and post-transplant survival as shown in **Table 3**, and balancing the longevity of the graft, the Committee is weighting waiting list survival and post-transplant outcomes equally, giving each a weight of 25%. The Committee will monitor the impact of the change on post-transplant outcomes carefully to ensure that the direction of changes aligns with the predicted positive impacts.

Candidate Biology

The Committee places 5% weight on each of the candidate biology factors: blood type, CPRA, and height. Although this approach was largely supported in public comment, there was some feedback suggesting that height and CPRA receive more weight than blood type. However, there was limited modeling available since CPRA is not often currently reported for lung candidates. MIT optimization analysis showed that weight over 10% risked overcompensating so that candidates with blood type AB and A would have worse transplant rates than candidates with blood types O and B.[113] SRTR modeling confirmed that the most benefit in terms of equalizing the variation in transplant rates and waitlist deaths based on blood type could be gained around 5%.[114] Additionally, the analysis of the current system showed approximately 5% is placed on blood type. Therefore, the Committee chose to maintain the weight of 15% for biological disadvantages (evenly split into 5% each for blood type, CPRA and height). This is an area that the Committee is committed to monitoring once the changes are implemented and there is more data available on the impact.

Patient Access

Patient access includes pediatric status and prior living donors. Pediatric status is weighted at 20%, and prior living donor status is weighted at 5%.

Feedback in the AHP prioritization exercise placed the pediatric priority weight at 20%.[115] The Committee also considered modeled transplant rates and mortality rates for pediatric candidates using different weights for pediatrics from the MIT optimization analysis. In **Figure 24**, each green dot represents the output of one simulation model run. The Committee used this analysis to narrow in on which weight for pediatric status guaranteed sufficient access for pediatric candidates. The goal was to

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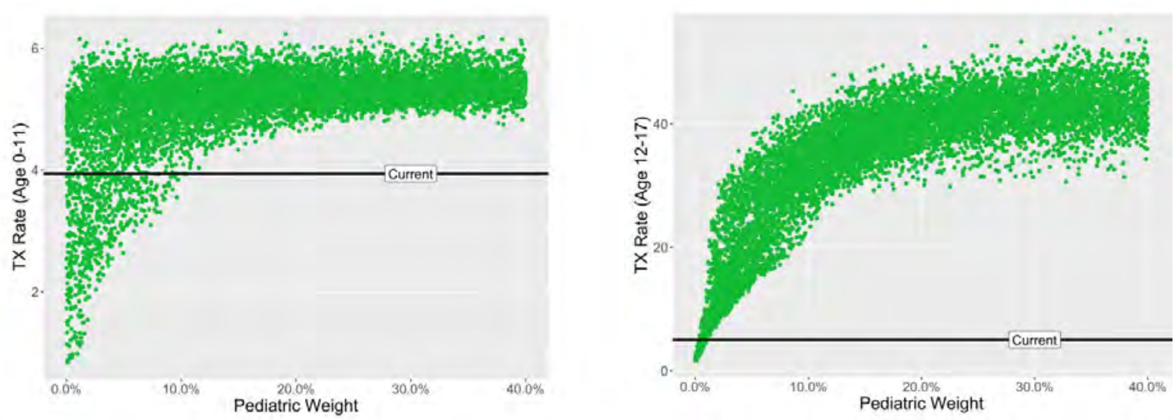
[113] OPTN Lung Transplantation Committee, Meeting Summary, March 31, 2021.
[114] SRTR, Continuous Distribution Simulations for Lung Transplant, Data Request ID# LU2020_05, February 12, 2021. https://optn.transplant.hrsa.gov/media/4450/lu2020_05_cont_distn_srtr_1.pdf.
[115] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.

ensure that pediatric candidates maintained at least as much access as they have in the current system, and that most pediatric candidates would have a high likelihood of transplant.

Figure 24: Transplant Rates for Children 0-11 and 12-17 by Pediatric Status Weight[116]



In **Figure 24**, the transplant rate for candidates under 18-years-old varies more and includes lower transplant rates when the weight placed on pediatric status is less than 10%. However, the transplant rate narrows into higher transplant rates when the pediatric weight is 10-20%, and there is not much difference in the transplant rates once the weight assigned pediatric candidates is above 20%.

The Committee chose a conservative approach and set a pediatric weight of 20% in consideration of the fact that the community placed access for pediatric candidates as one of the very highest priorities and to avoid the risk of disadvantaging this population.[117] Public comment responses largely supported this approach and there were no changes to the pediatric weight-based on public comment.

For prior living donor status, the responses to the AHP exercise favored a weight around 12%.[118] In response to the Committee's public comment proposal, there were some commenters that preferred a weight above 5% for prior living donors. While the Committee was in favor of providing some weight for prior living donors (who donated any organ), placing a weight of 12% would necessarily result in a lower weight on another factor, and it is incredibly rare to have a prior living donor in need of a lung transplant. Further, the Committee believes that the existing waiting list survival calculation will reflect any increase in urgency related to a prior living organ donation. Therefore, the Committee is placing 5% weight on this factor.

Placement Efficiency

The AHP feedback supported a total weight on placement efficiency of 10%.[119] Since this is a significant change from the current system (which prioritizes placement efficiency closer to 81%), the Committee

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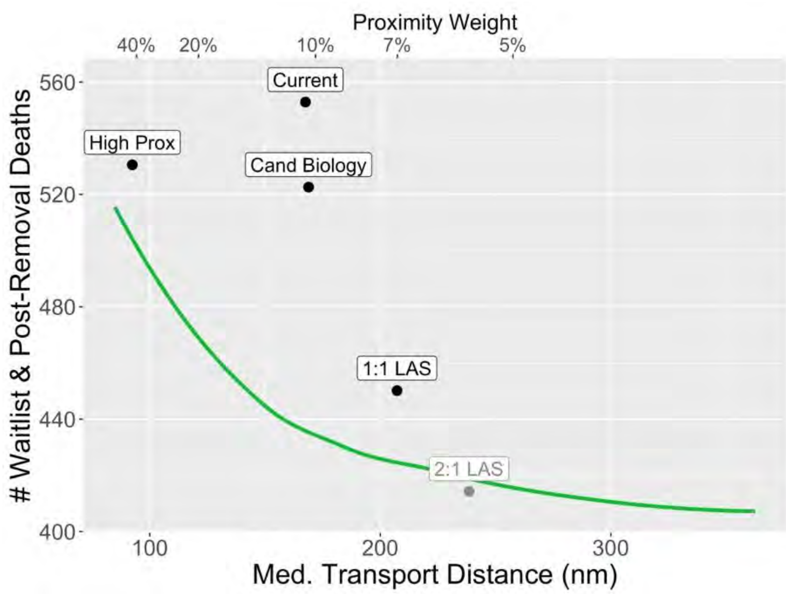
[116] OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325_lung_meeting_summary.pdf.
[117] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.
[118] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.
[119] Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June

modeled scenarios with the placement efficiency as wide-ranging as 40% and 6%.[120] The Committee also considered optimization visualizations.[121] For any two attributes within the continuous distribution model, one can evaluate the impact on one attribute of changing the point assignment for the other. For example, if all else is equal between an adult candidate and a pediatric candidate, how much more medically urgent would an adult candidate have to be to be ranked above a pediatric candidate? The Committee looked at curves that showed how this changes, including the curve below in **Figure 25** to focus in on where the most benefit could be gained from changes to the weight placed on efficiency.[122]

Figure 25: Impact of Changes in the Proximity Weight on Combined Waitlist and Post-Transplant Deaths[123]



In **Figure 25**, the green line represents the relationship between changes to the Efficiency weight (labeled here as "Proximity Weight") and the expected median transportation distance and combined waiting list and post-transplant deaths. As the efficiency weight (shown on the top of the figure) is decreased (moving to the right of the figure), the number of deaths (shown on the left) decreases and the median transportation (bottom) increases. The relationship is not linear; instead, the greatest impact on the number of deaths is seen among the higher proximity weights, and the greatest impact on median transportation distance is seen among lower proximity weights. Based on this analysis and the earlier scenario modeling, the Committee chose to focus on the difference between 10%, 15% and 20% weights on efficiency. The results of that modeling showed that placing 10%, as was indicated by the responses to the AHP exercise, resulted in significant improvements in waiting list mortality. Although it results in increased median travel distances, there are no increases in flights, and the candidate groups

13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.

[120] Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf.

[121] OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325_lung_meeting_summary.pdf.

[122] This analysis was conducted by Ted Papalexopoulos, Dimitris Bertsimas and Nikos Trichakis with the MIT Operations Research Center using the 2009-2011 TSAM cohort, with the acceptance model from 2015. It uses the LAS calculation approved at the 2020 OPTN Board of Directors and assumes waiting mortality and post-transplant outcomes are weighted evenly. CPRA and living donor priority are not included since that information was not included in the TSAM cohort.

[123] OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325_lung_meeting_summary.pdf.

with the farthest distances are those that would benefit from traveling farther in order to get a transplant sooner – the younger candidates and candidates with higher medical urgency.

There was a comment requesting that the two efficiency measures not be weighted equally but that travel efficiency be given greater weight. This is something the Committee is willing to consider once there is data on the performance of the new system, but the modeling based on the equal weights appears to appropriately avoid increasing flights unnecessarily, so the additional weight on the travel efficiency side does not appear to be needed. Proximity efficiency and travel efficiency will each have a weight of 5%, for a total of 10% weight on placement efficiency.

There was feedback during public comment both in support of the proposed weight of 10% (5% each on proximity efficiency and travel efficiency) and suggesting that perhaps more weight might be needed. Most of the concerned feedback was related to concerns that there might be logistical challenges that are not captured by the score. Commenters encouraged careful monitoring of how long placement takes and the availability of flights. The Committee will monitor the time from the first offer to cross-clamp, but flight and other logistic availability is not information that is currently available in the OPTN dataset. The Operations and Safety Committee is currently working on a project to collect better information about travel for organ recovery, which will hopefully improve the ability to monitor this in the future.[124] For this proposal, the Committee will monitor questions and concerns submitted for issues that may arise that are not captured by data analysis.

Exceptions

The Committee proposes certain changes to the exception process. These changes will adjust to allow for exceptions to the new scoring system and are also coordinated to allow for increased consistency between organs and to prioritize the most beneficial changes related to the costs of implementing a new system.

Review

Although no changes to the membership of the review boards were included in the public comment proposal, certain changes are included in this proposal. These changes are operational in nature, and do not require public comment. Where the lung review board is currently comprised of nine members and their alternates, the Committee proposes expanding the membership to 12 reviewers, and retaining the minimum of three from pediatric programs. There are currently 71 active lung programs, of which 36 have active pediatric programs.

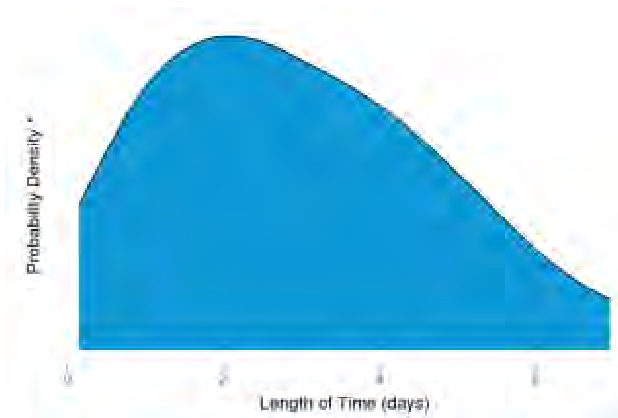
For each exception case, nine of the active reviewers for that year would be randomly selected to review that case. The system would automatically exclude reviewers from the submitting center when assigning reviewers. This change would allow for system efficiencies, and more consistency across organs. It is more similar to the heart and liver review board systems, which have larger review boards and assign cases to a smaller subset.

[124] OPTN Public Comment Proposal, *Data Collection to Evaluate Organ Logistics and Allocation*, OPTN Operations and Safety Committee, https://optn.transplant.hrsa.gov/media/4780/data_collection_to-evaluate_organ_logistics_and_allocation.pdf.

The Committee proposes reviewing all exceptions and appeals prospectively and removing the option to override (that is, to list a candidate at the exception status after the exception is denied, while the decision is under appeal). The override has not been used since DSAs were removed from lung allocation in 2017, and was only used 11 times between 2005 and 2017.[125] Sixty lung exception denials have been appealed since 2005, and of those slightly more than 1/3 (24) were granted on appeal. There is no record of any lung exception cases being appealed to the lung committee. Therefore, even though the committee appeal option remains available, it is highly unlikely for a case to remain actively under consideration until it could be reviewed by the committee. Instead, appeals could expect to be resolved by the time they are reviewed by the review board. In light of the recent lack of use of the override, and the fact that most appeals are denied, the Committee proposes removing the override.

In order to accommodate cases that may need to be adjudicated urgently, the Committee proposes shortening the time frame for review of all cases to five days (compared to the current 7 days). Past review board performance indicates that most cases are closed within that time frame (See **Figure 26**), however the Committee plans to monitor to ensure that this does not significantly increase the number of exception requests closed without sufficient votes.

Figure 26: Distribution of Lung Review Board Process Times for Exceptions Requested January 1, 2021 – March 31, 2021[126]



In cases where there is no majority by the end of the third day, the votes that have been cast to that point will be retained, but any voters who have not responded will be removed from the case, and one of the other review board members will be asked to vote in their place. This is also a change from the current system, in which either the reviewer or their alternate can vote at that point. By moving the vote to a new reviewer, the lung review board will better align with the other organ review boards, and we will maintain clarity on who should be voting at any point in a case.

Following public comment, the Committee chose to remove the quorum requirement for appeals to align it with the administrative process for initial exception requests. This will improve the clarity of the process by reducing the variation between stages in the process.

Although alternates will not necessarily be assigned to a case when the primary from their center does not vote, they will be assigned cases when the primary from their center is marked as out of the office in the review board system. During that time, the alternate will act as the primary representative from that

[125] OPTN Data as of June 8, 2021.
[126] OPTN, Lung Review Board, HRSA Quarterly Report, April 2021.

center. This is another change that was made following public comment in order to more closely align with other organs' review boards and streamline the process.

Exception Types

There are changes to the types of exceptions that may be requested, and the specifics of the review. These were generally supported in public comment.

All the current exception types (pediatric status 1, adolescent, LAS, diagnosis, and estimated value) would all end with the implementation of continuous distribution. In their place, this proposal would create exceptions based on a specific goal (waiting list survival, post-transplant outcomes, candidate biology or candidate access). A program would be able to request up to the maximum score within a given goal as an exception. No candidates would be able to get a composite allocation score above 100, with or without an exception. Existing exceptions will not be converted when the new allocation score takes effect. However, transplant programs will be allowed to submit CAS exception requests before the new scores are used for allocation.

Following public comment, the Committee chose to remove the option to request an exception score for the placement efficiency goal. This score is calculated at the time of the match, based on the location of the donor. Since this goal is not based solely on a candidate characteristic, and does not stay stable, the Committee did not anticipate a current justification for a placement efficiency exception that would apply to all matches with that candidate.

Although there will not be a specific pediatric priority 1 exception, candidates under 12 will have the same exception options available as older candidates and may request the waitlist survival score equivalent to the score assigned priority 1 candidates. Following public comment, the Committee also made a change to the eligibility requirements for a blood type incompatible transplant. Candidates are currently required to be priority 1 to qualify. To ensure that candidates who do not meet the priority 1 requirements but have an approved exception that indicates they are as sick as a priority 1 candidate, the Committee is changing the eligibility requirements for blood type eligibility to reference the waiting list survival score instead of the priority. This is a nomenclature change with the effect that the same candidates will be eligible. Candidates who wish to be considered for blood type incompatible transplant will still need to report eligible titers on the same schedule.

The Committee proposes allowing a candidate to maintain an exception indefinitely once granted, rather than requiring renewal of exceptions after a certain period. Based on the clinical experience of the Committee members and their experiences as lung review board members in the past, the Committee members noted that the situations in which exceptions are typically granted are circumstances either that do not improve, or that result in lasting impacts on the candidate's expected survival. This will reduce the administrative burden associated with exceptions.

Guidance related to LAS exceptions[127] will be retired, and new educational materials and guidance will be made available to assist lung programs in requesting exceptions and review board members in reviewing them. Proposed operational guidelines for the review board are included with this proposal. The Committee is also planning to develop additional clinical guidance and education for transplant

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[127] UNOS, Submitting LAS exception requests for candidates diagnosed with PH. (Accessed June 28, 2021) https://unos.org/news/submitting-las-exception-requests-for-candidates-diagnosed-with-ph/.

programs submitting exception requests and review board members that will be available as a future public comment proposal.

Other Considerations

Due to the structural changes inherent in converting from a classification-based system to a points-based system, the Committee is also proposing necessary changes to the other areas of policy. These include:

- clinical values update schedule
- waiting time
- decimal precision
- donor characteristics
- multi-organ allocation

Update Schedule

Given the new scoring system, the Committee considered what candidate clinical values would need to be updated, and on what frequency. The Committee proposes fundamentally shifting away from the concept of LAS and to the new system of scores for specific goals and attributes, and an overall CAS. In that system, the Committee does not want to continue anchoring choices to what the LAS would be. Therefore, the Committee is removing the current requirement for more frequent reporting (every 14 days) when a candidate's LAS is 50 or higher.

After considering several options, including setting a waiting list survival score, the Committee proposes keeping the updates for most clinical values set at once every six-month period. It also proposes listing the values that require a right heart catheterization and continuing to allow transplant hospitals to wait to update these only when they are being taken recognizing that the catheterization is an invasive procedure with risk. Further, the policy is restructured so that it specifically lists the values that must be updated every 28-days, every six-months, or whenever they are changed.[128]
Following public comment, the Committee chose to maintain the requirement that this same group of clinical variables must have been collected within the prior six-months when submitted at registration.

The Committee proposes a new requirement for more frequent updates. The current policy requires certain values to be updated every 14 days once a candidate's LAS is 50 or higher.[129] In the proposed policy, when a candidate is on an extracorporeal membrane oxygenation (ECMO) device, continuous ventilation, or high flow oxygen device, then the proposal would require that the transplant program update assisted ventilation and supplemental oxygen fields every 28 days. The Committee discussed ways to identify candidates who are likely to be the most medically urgent and so identify those most likely to receive a high CAS based on clinical values. High oxygen requirements were identified as the primary driver of candidate medical urgency which the Committee said is consistent with candidates dependent on ECMO, continuous ventilation, or high flow oxygen devices.

The Committee chose the 28-day update schedule based on a desire to balance administrative burden on the transplant hospital with the need to ensure that candidates are not unfairly advantaged if their condition improves. The Committee's experience has been that most candidates who are severely ill

[128] OPTN Lung Committee Meeting Minutes, June 17, 2021.
[129] OPTN Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher.

enough to fall into this category are unlikely to have their condition improve before they receive a transplant.

This will require updates to programming to collect ECMO and type of assisted ventilation on the waiting list, and not just when the candidate is removed from the waiting list. The Data Advisory Committee supported the inclusion of the new fields to better collect respiratory status of lung candidates.

Waiting Time

Waiting time is used as a tiebreaker in current lung allocation.[130] Because LAS is calculated to 16 decimal places, it is rare that waiting time is ever needed to break a tie LAS; however, waiting time is sometimes used to break ties between candidates with exceptions.[131] Waiting time is used to further the ethical principle of justice related to medical need.[132] In the current system, waiting time is based only on active time for adults, and includes both active and inactive time for pediatric candidates. The Committee proposes adjusting waiting time so that it is awarded for all time on the lung waiting list, whether active or inactive, regardless of candidate age, and using waiting time as the only tie-breaker.

The Committee discussed this approach with the leaders of the other organ committees, who supported it as an approach that would work well across all organs as they transition to continuous distribution. It would create a single tiebreaker that would always be unique since it would be anchored to the candidate's registration timestamp, which is recorded in order with unique time stamps. The Committee believed that the ideal measure would be the person whose disease began first but recognized that this would be too difficult to objectively measure. Therefore, they selected total waiting time as the acceptable available measure for those rare instances when a tie between candidates would need to be decided.

Decimal Precision

The Committee considered whether to round place values, attempting to use sufficient place values to differentiate between candidates while also avoiding placing too much emphasis on differences that are not indicative of a difference between candidates.[133] The Committee chose to allow for differences in the clinical importance of precision of different values by rounding to integers for distance, height, and days, but allowing more decimals for CPRA and other attributes, as well as for the results of equations and final scores. In public comment, there was support for 2, 4 or 6 decimal places for the CAS, as needed to ensure that there was sufficient precision to largely avoid ties. After consultation with the SRTR and UNOS statisticians, the Committee chose to round values as follows:

- Integer for NM, height & survival days
- Four decimal places for scores (CAS and goal-level) and points (attribute-level)

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[130] OPTN Policy 10.4.A Sorting Within Each Classification.

[131] Between 2006 and 2020, there were only four matches with ties, and those were between multiple listings for the same candidate. OPTN data as of November 6, 2020.

[132] Veatch & Ross, Transplantation Ethics, p. 302. For additional discussion of how ethical principals were integral to the development of this proposal, *see* OPTN Request for Feedback, Update on the Continuous Distribution of Organs Project, OPTN Lung Transplantation Committee. Public Comment Period August 4, 2020-October 1, 2020.

[133] Cole T. J. (2015). Too many digits: the presentation of numerical data. *Archives of disease in childhood*, *100*(7), 608–609. https://doi.org/10.1136/archdischild-2014-307149; Barnett, Adrian G. "Missing the Point: Are Journals Using the Ideal Number of Decimal Places?" *F1000Research* 7 (August 10, 2018): 450. https://doi.org/10.12688/f1000research.14488.3.

- Six decimal places for CPRA & baseline survival results
- 16 decimal places for coefficients used in waiting list survival and post-transplant outcomes calculations

Donor Characteristics

This scoring system focuses on candidate characteristics. All a candidate's scores except for proximity efficiency and travel efficiency points can be calculated without knowing anything about the donor. This is intentional but does not always need to be the case.

This change marks the first organ to enter a continuous distribution framework. It contains many fundamental shifts in how we approach organ allocation as a system. While this proposal does not shy away from making large-scale changes, there are areas where the Committee is choosing to monitor closely and evaluate once this moves from models into an active system in which many individuals make choices and behaviors might change.

For this iteration of the CAS, none of the formulas change based on the donor. The score is calculated the same way, regardless of the age of the donor, whether it was a donation after circulator death (DCD) donor, or any other donor specific characteristics. There were some requests during public comment to keep a distinction between pediatric donors and adult donors, or to incorporate whether the donor is on an ex vivo lung perfusion device.

With this proposal, the Committee challenged many assumptions about how we make a system that improves outcomes and ensures access for our vulnerable populations. Instead of creating several parallel scores to address differences, the Committee is trying to create a single score that accounts for those differences. Once the system is in place, the Committee will continue to work refining it, checking for any way that we can make it better. The Committee will watch to see if there is a need to calculate the score differently based on the donor.

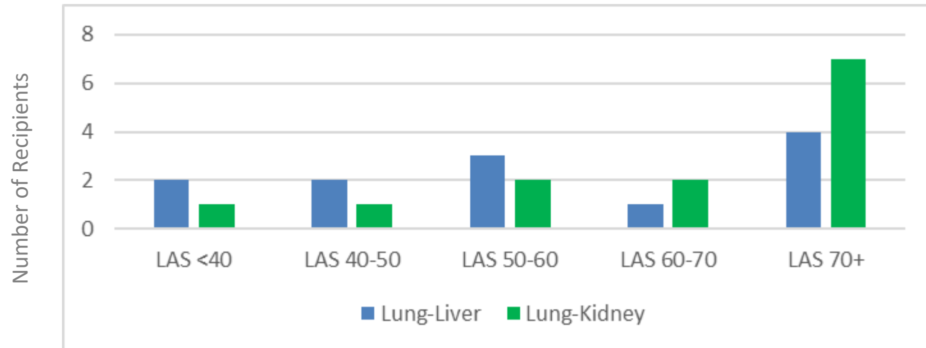
Multi-Organ Allocation

The current policy uses the classifications, distance cut-offs, and LAS cut-offs in the circles' allocation system to delineate when to offer lungs to multi-organ candidates relative to single organ candidates. This proposal addresses that by proposing maintenance of similar rules surrounding multi-organ allocation during the transition period of having lung allocation in a continuous distribution system and other organs not yet using continuous distribution. The plan is for the newly formed OPTN *ad hoc* Multi-Organ Transplantation Committee to address longer-term improvements to the multi-organ allocation system.

The Committee considered the distribution of heart-lung, lung-kidney, and lung-liver transplant recipients by what their CAS would be. The Committee chose to set a threshold of a CAS of 28 to include most multi-organ lung candidates while preserving access for single organ heart, kidney and liver candidates. The CAS cutoff (above which candidates are offered the second organ) will allow for a clean cutoff point on the match for OPOs.

The workgroup reviewed data on the statuses of multi-organ candidates who received heart-liver, lung-liver, heart-kidney, or lung-kidney transplants in 2019.[134] **Figure 27** shows the recipient statuses for these combinations of multi-organ transplants.

Figure 27: Number of Recipients by LAS at Transplant (2019)[135]



The OPTN Board of Directors approved changes to the allocation of lung-liver and lung-kidney combinations on June 14, 2021, which included offering livers and kidneys to lung candidates with a lung allocation score of greater than 35 or candidates less than 12 years old.[136] The statuses were determined using the data shown above in **Figure 27.**[137] For multi-organ transplants performed in 2019, the following multi-organ transplants would meet the recently approved criteria:

- Lung-liver – 12 of 12
- Lung-kidney – 13 of 13

The Committee wanted to balance access for single and multi-organ candidates similarly, and considered the distribution of lung-kidney, lung-liver, and heart-liver candidates by their estimated lung composite allocation score.

Figure 28 shows the projected distribution of composite allocation scores for lung candidates that need a second organ.

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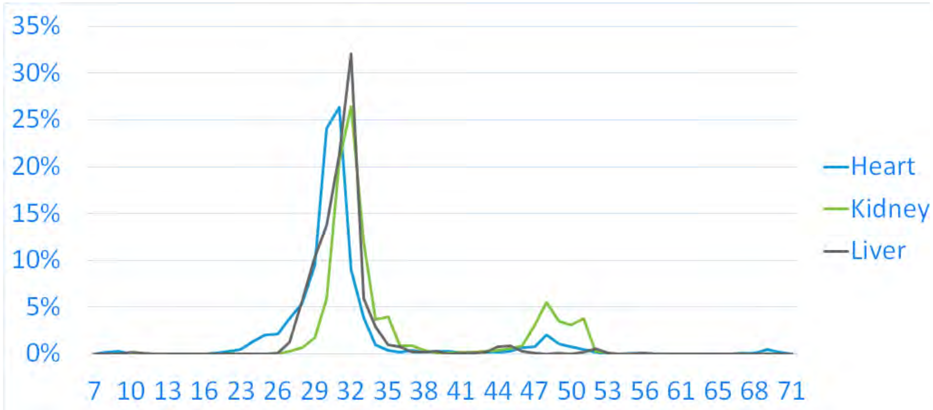
[134] Multi-Organ Policy Workgroup Meeting Summary, May 29, 2020. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/.
[135] *Ibid.*
[136] Notice of OPTN Policy Change, Clarify Multi-Organ Allocation Policy, Board Approved June 14, 2021. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.
[137] 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.

Figure 28: Percentage of Lung Multi-Organ Recipients (01/01/2011-05/13/2021) by Estimated Composite Allocation Score[138]



These were produced using lung matches performed in 2011 and afterward, which resulted in lung transplants simultaneously with kidney, liver, or heart. The data is grouped by the second organ needed. For each of the organs, there is a bimodal distribution. The first and larger distribution occurs for adult candidates around a composite allocation score of 32-36. The second and smaller distribution occurs for pediatric candidates around 50.

Figure 29 shows the cumulative percent of candidates that would be captured were the multi-organ cut-off set at a specified composite allocation score. Notice the large inflection in the curve around 23-33.

Figure 29: Lung Multi-Organ Recipients (01/01/2011-05/13/2021) by Percentage of Recipients with a Specific Estimated Composite Allocation Score or Higher[139]

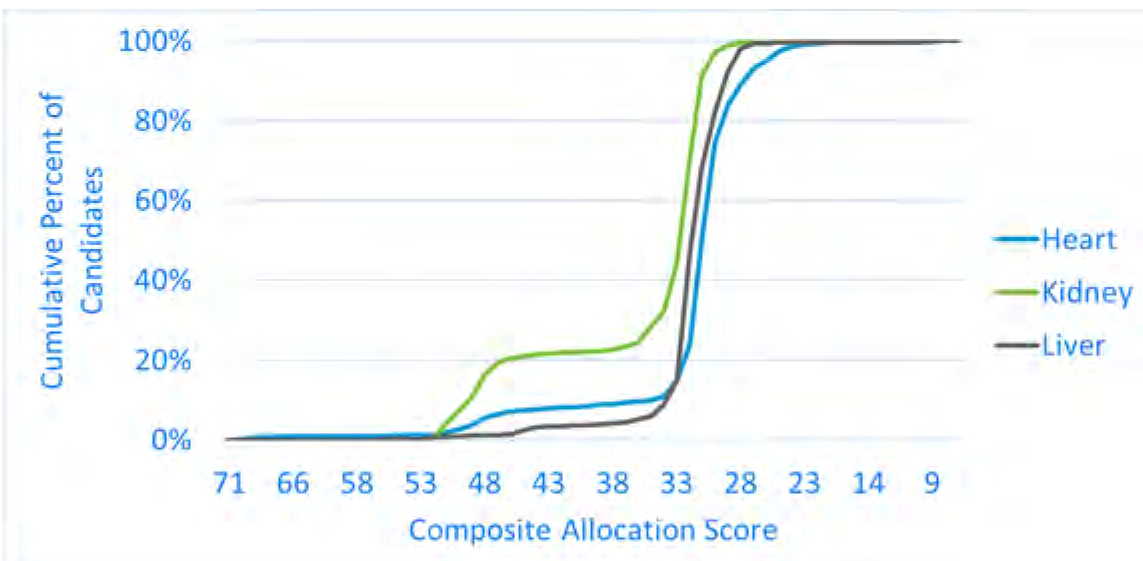


Table 4 is another look at the data displayed in the previous chart. The committee sought to capture 99% of the lung-kidney candidates and therefore chose 28 as the cutoff for the composite allocation score.

138 OPTN Data as of June 11, 2021.
139 OPTN Data as of June 11, 2021.

Table 4: Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011-05/13/2021[140]

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 Lung Committee chose a slightly more conservative cut-off that would include 94.55% of the heart-lung, lung-liver, and lung-kidney recipients. This threshold of a CAS of 28 will be used as a replacement for the threshold of LAS 35 in lung-kidney and lung-liver allocation. This is in line with the recently approved changes to lung-liver and lung-kidney, which create that cutoff of LAS of 25 based on similar data, showing all these candidates who were transplanted in 2019 had an LAS of 35 or higher.

For heart-lung combinations, the Committee proposes continuing to offer to high-status heart candidates within 500 NM first. The Committee then proposes requiring that lungs and heart-lungs be offered from the lung match run to candidates with a composite allocation score 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. This would be a cleaner cut-off than the current system, not permitting heart alone allocation to continue until the heart was offered to all heart-lung candidates with a CAS of at least 28. Fundamentally, the Committee sought to balance the difficulty in finding an appropriate match for a candidate who requires multiple organs with the desire to provide earlier access to transplant for heart-alone candidates who are the sickest, according to their status, and with saving the largest number of lives possible with the limited supply of organs for transplant. The leadership of the Heart Transplantation Committee supported this approach.

The Committee also considered requiring that the heart be offered to every candidate who needed one on the lung match run before returning to the heart match run or choosing a cutoff closer to 23 to include 99% of the heart-lung candidates, more like the cutoff effect for the other organ combinations. However, the Committee chose to use the cutoff of 28 to align with the lung-kidney and lung-liver cutoffs and continue to provide some flexibility when allocating and informed by the collaboration with the heart committee.

Public comment responses were generally supportive of this approach to multi-organ. 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 discretion as current policy in relation to lung-liver and lung-kidney combinations. In relation to heart-lung, the Committee balanced the comments

[140] OPTN Data as of June 11, 2021.

supporting the prescriptive order between the heart and lung match with the feedback requesting more flexibility, and believed that the flexibility allowed by keeping the cutoff at 28 instead of something lower was sufficient.

Potential Impact on Select Patient Populations

In the current system, female candidates have lower transplant rates and a higher number of waitlist deaths than male candidates. These changes do not make a noticeable change in the transplant rate for female candidates, but they do cut the number of waitlist deaths for female candidates nearly in half, and reduce the differences in transplant rate and waiting list deaths between male and female.

Figure 30: Transplant Rates by Sex[141]

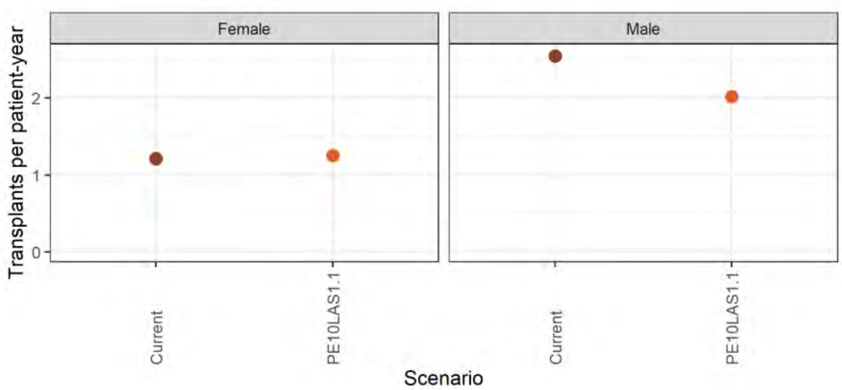
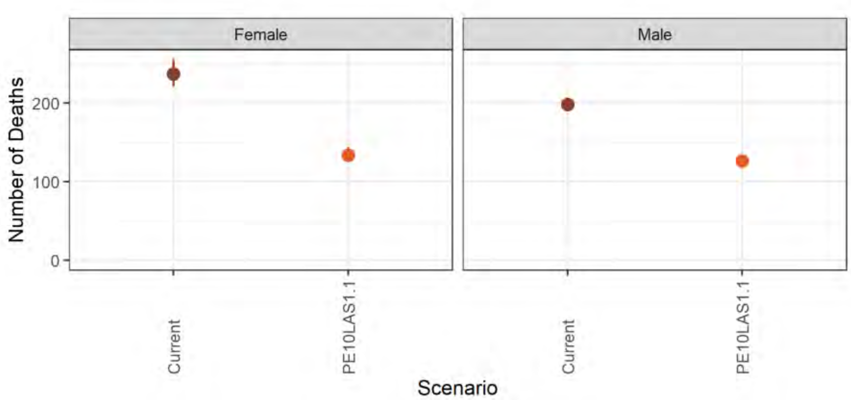


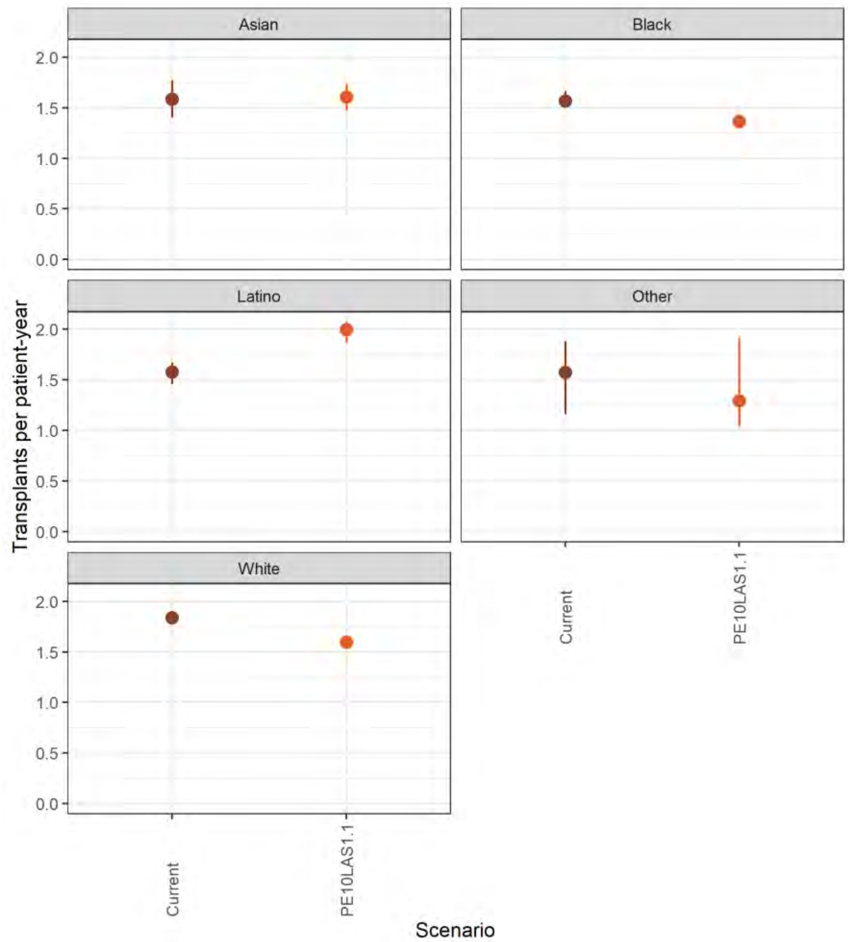
Figure 31: Waiting List Deaths By Sex[142]



The transplants per patient year differed by ethnicity, with increases for Latino candidates and decreases for white and black candidates. However, the waiting list deaths still declined for all groups

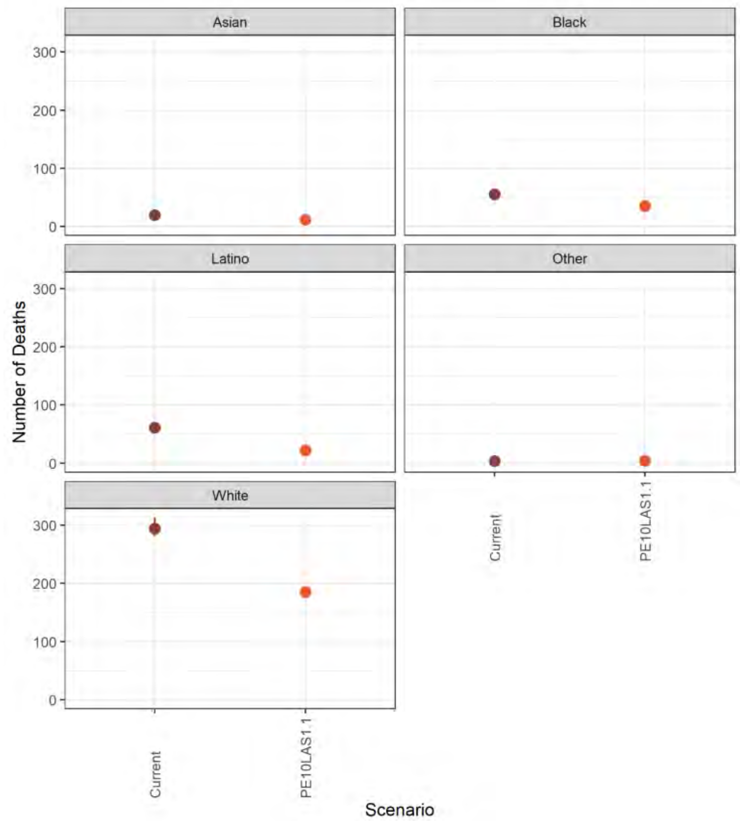
[141] For this and following figures from this report, the labels following the pattern: "Current rules was named the "Current" scenario. Ratio of WLAUC: PTAUC was represented by "LAS1.1" or "LAS2.1", meaning 1:1 WLAUC: PTAUC and 2:1 WLAUC: PTAUC, respectively. Weight given to proximity efficiency was represented by "PE20," "PE15," and "PE10,"representing 20%, 15%, and 10% PE, respectively. Thus, the scenario with 10% PE and 1:1 WLAUC: PTAUC ratios was called "PE10LAS1.1." The others follow a similar pattern." 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.
[142] *Ibid.*

Figure 32: Transplant Rates by Ethnicity[143]



[143] *Ibid.*

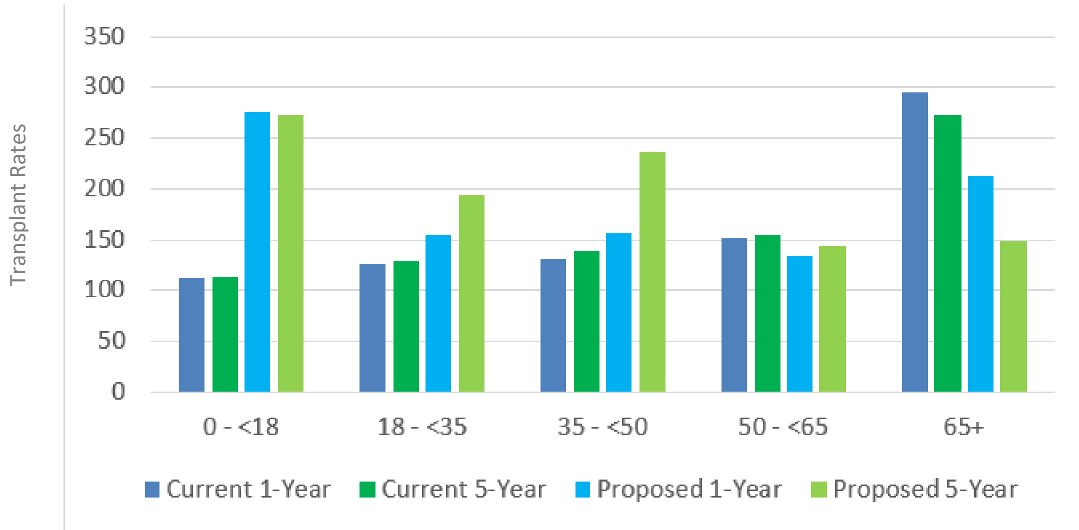
Figure 33: Waiting List Mortality by Ethnicity[144]



144 *Ibid.*

The change to a 5-year post-transplant survival model resulted in expected decreases in the transplant rate for candidates over 65 years old, who are less likely to have the longest post-transplant survival.

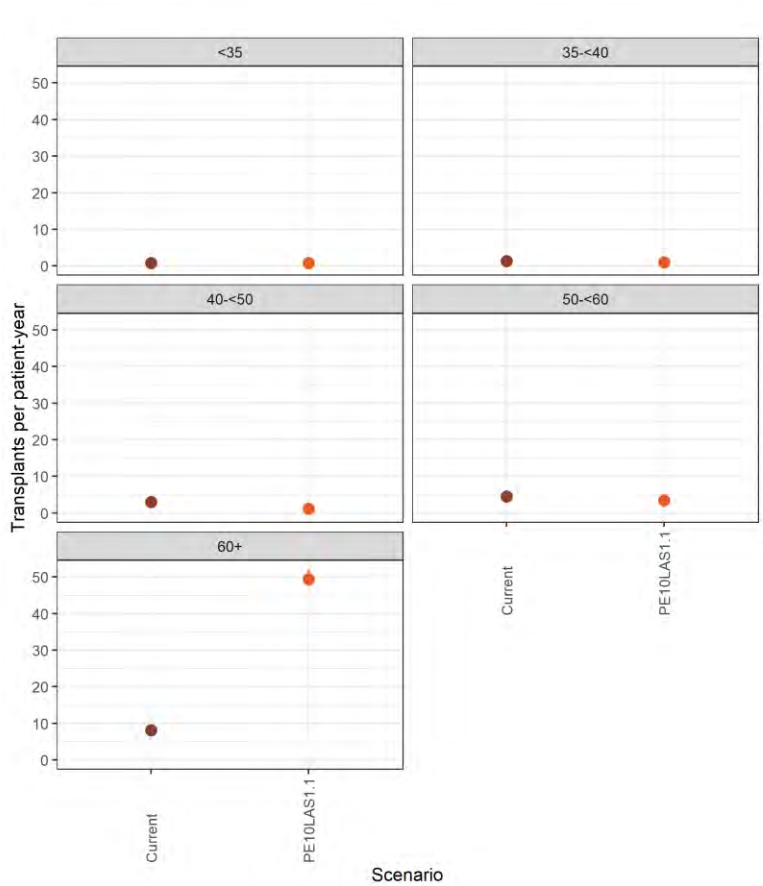
Figure 34: Transplant Rates by Age Group for 1-Year and 5-Year Post-Transplant Outcomes[145]



[145] *Ibid.*

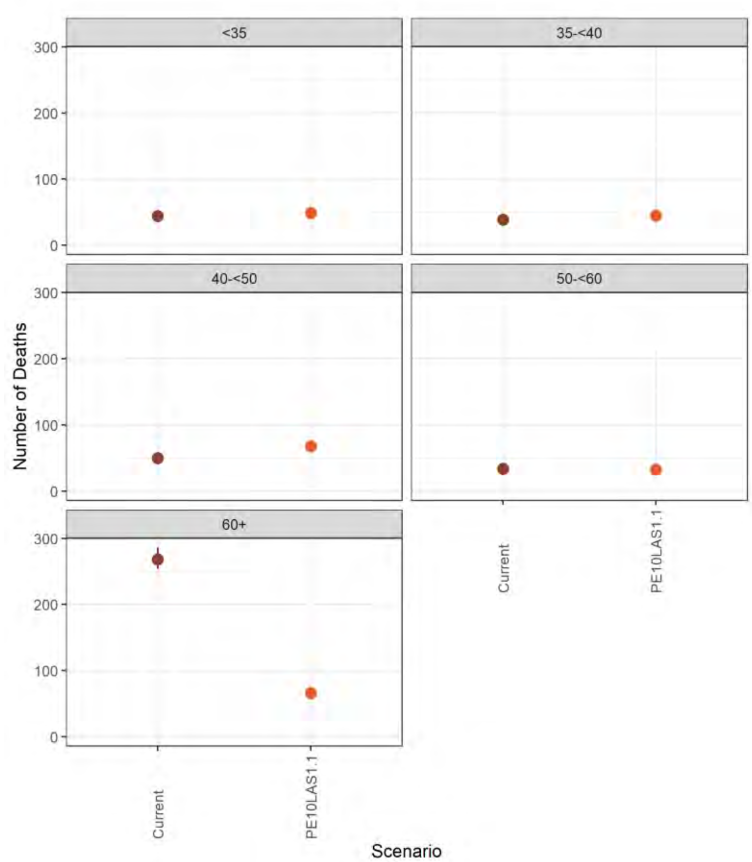
The greatest gains in transplants per patient year and improvements in waiting list mortality are expected to be for candidates who have an LAS of 60 or higher, those most medically urgent candidates, and the differences in the other LAS groups are not as significant.

Figure 35: Transplant Rates by LAS Group[146]



[146] *Ibid.*

Figure 36: Waiting List Deaths by LAS Group[147]

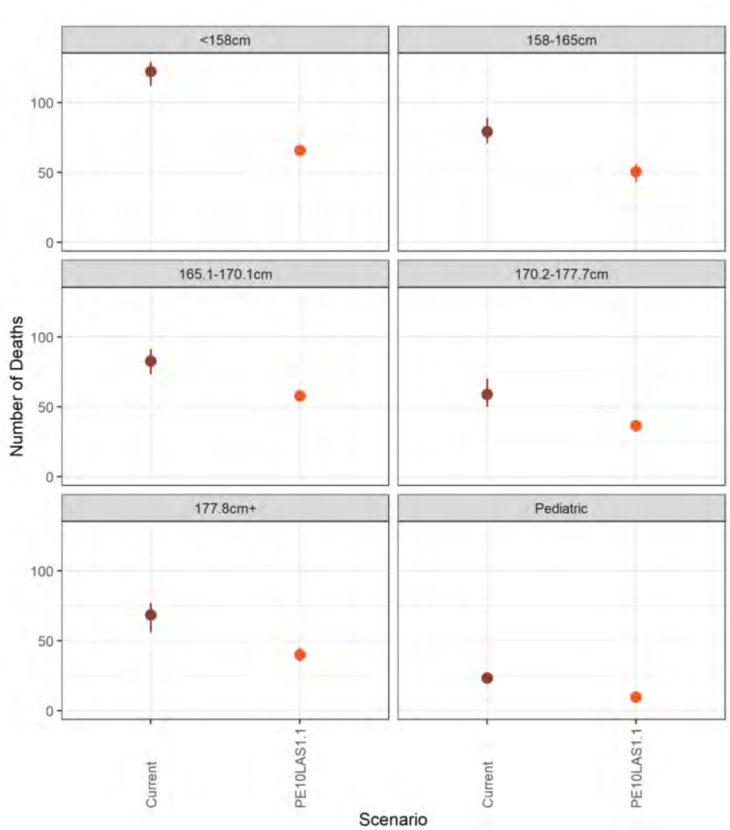


Candidates with a higher LAS are expected to receive organs from farther away in general, allowing teams to choose to travel farther for lung offers when the candidate's need is most urgent, as seen in **Figure 18** earlier.

[147] *Ibid.*

The addition of points for candidates who have trouble finding a match due to their height brought the number of expected waiting list deaths for the tallest candidates more in line with the candidates with easier to match heights.

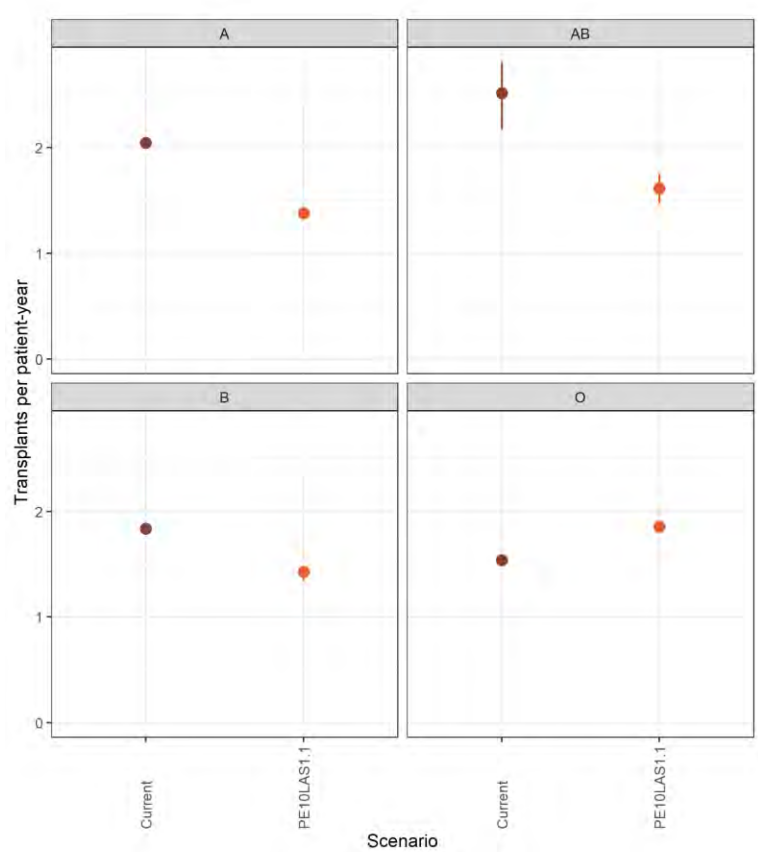
Figure 37: Waiting List Deaths by Height[148]



[148] *Ibid.*

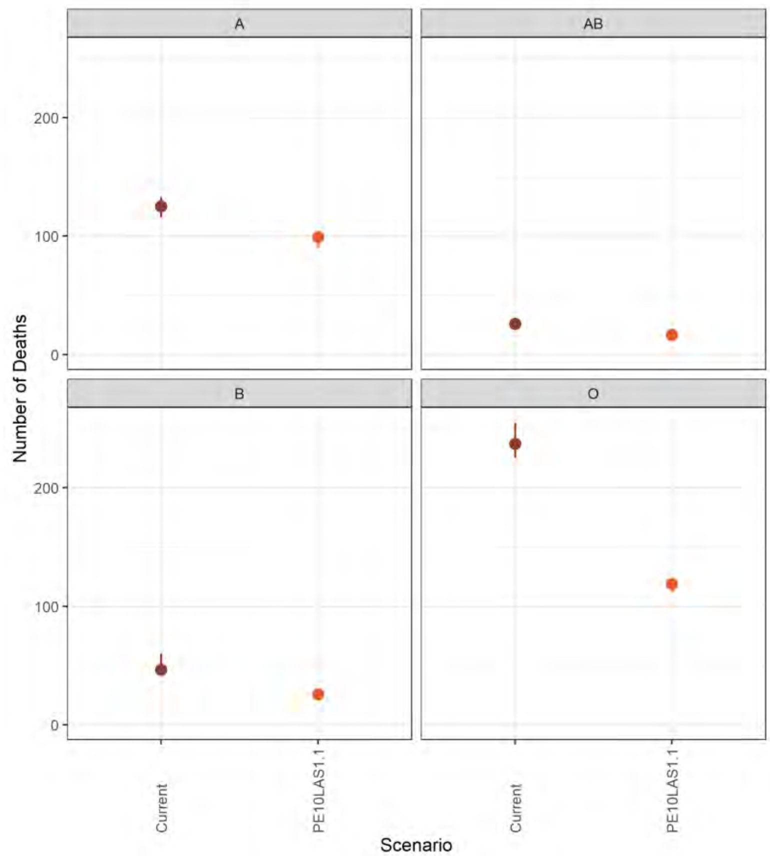
The Committee was concerned with ensuring that moving from blood type matching classifications to blood type points would assist with the challenges of matching a candidate with certain blood types. The modeling showed that placing 5% weight on blood type resulted in bringing the number of waiting list deaths for candidates with type O blood down significantly by increasing the number of transplants per patient year for this group. The impact on type O candidates is encouraging, especially since the other blood types are also expected to see a reduction in waiting list deaths.

Figure 38: Transplant Rates by Blood Type[149]



[149] *Ibid.*

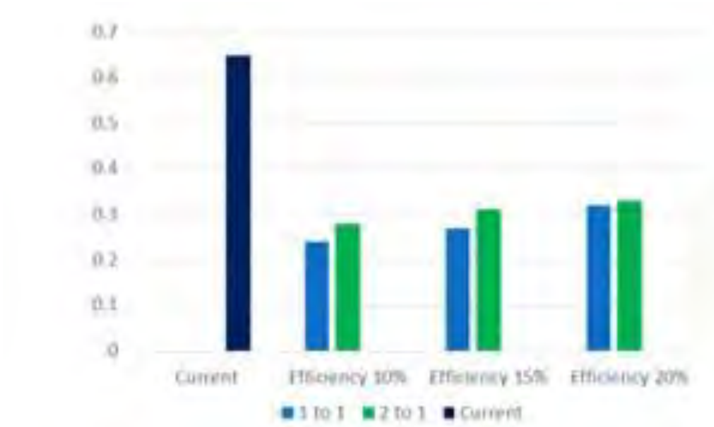
Figure 39: Waiting List Deaths by Blood Type[150]



[150] *Ibid.*

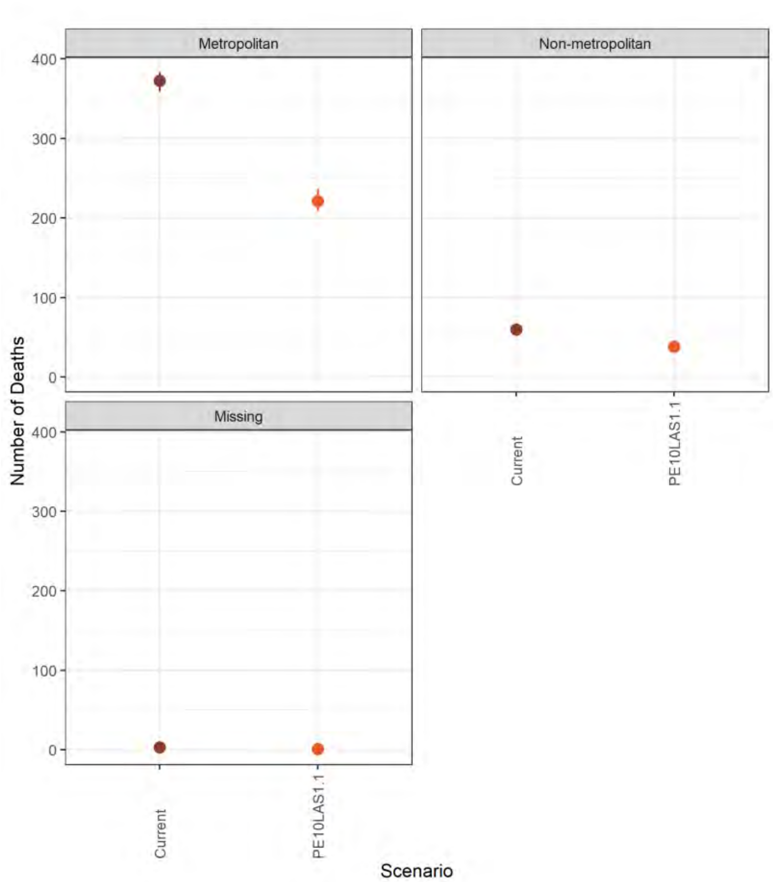
The Committee reviewed the impact on different geography, evaluating impact by region, by metropolitan and non-metropolitan area, and by center transplant volume. The proposed changes reduce variation between regions, as seen in **Figure 40.**

Figure 40: Variation in Transplant Rate by Region by Scenario



Metropolitan areas account for most of the waiting list deaths currently, so the biggest reduction in waiting list mortality is expected in these areas, although there is also an improvement for candidates in non-metropolitan areas.

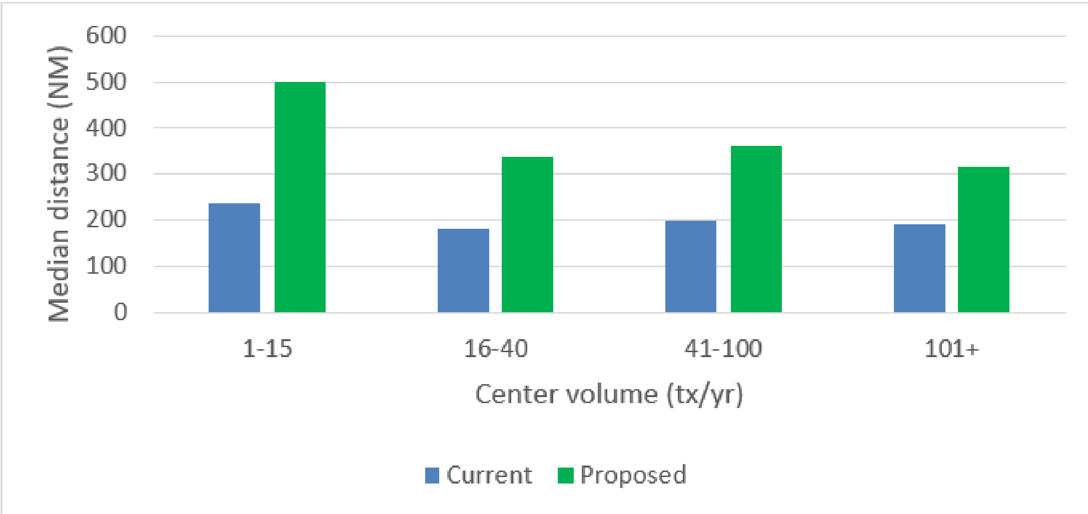
Figure 41: Waiting List Deaths by Candidate Urbanicity[151]



[151] *Ibid.*

Transplant hospitals with the smallest volumes (1-15 transplants per year) are expected to receive organs that travel farther more frequently, as shown in **Figure 42**. It is worth noting that these transplant hospitals are already traveling farther than the larger centers under the current system.

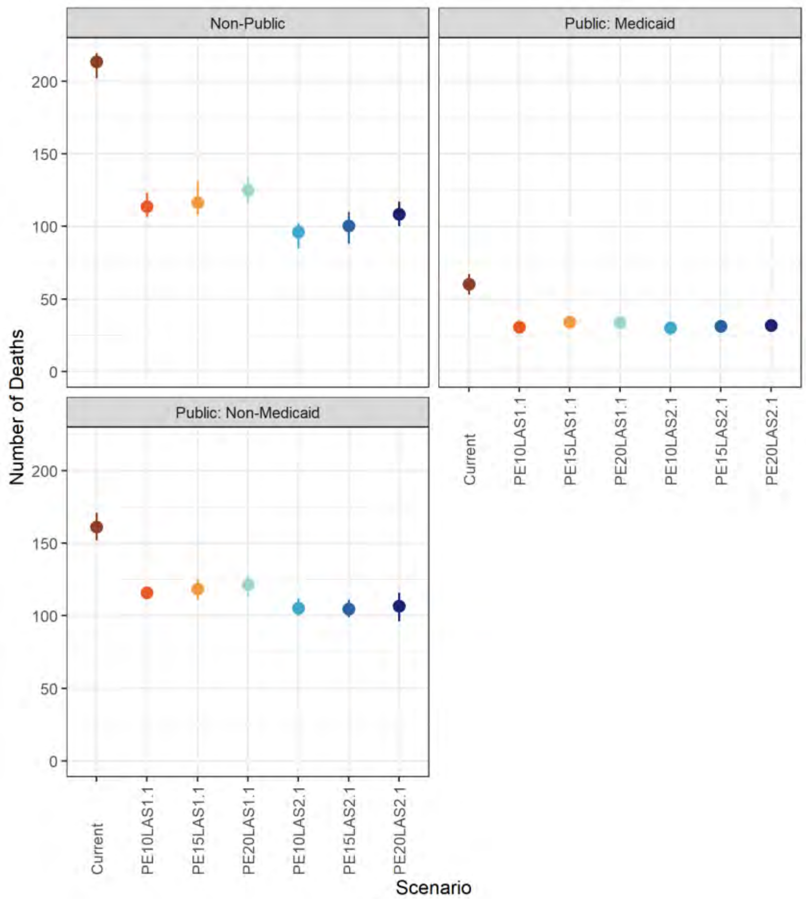
Figure 42: Median Distance from Donor Hospital to Recipient Hospital by Annual Center Volume[152]



[152] *Ibid.*

The Committee also evaluated the impact on candidates stratified by insurance status, as one proxy for socio-economic status. Waiting list mortality improved for all candidate groups, including those with Medicaid or other public insurance, as seen in **Figure 43**.

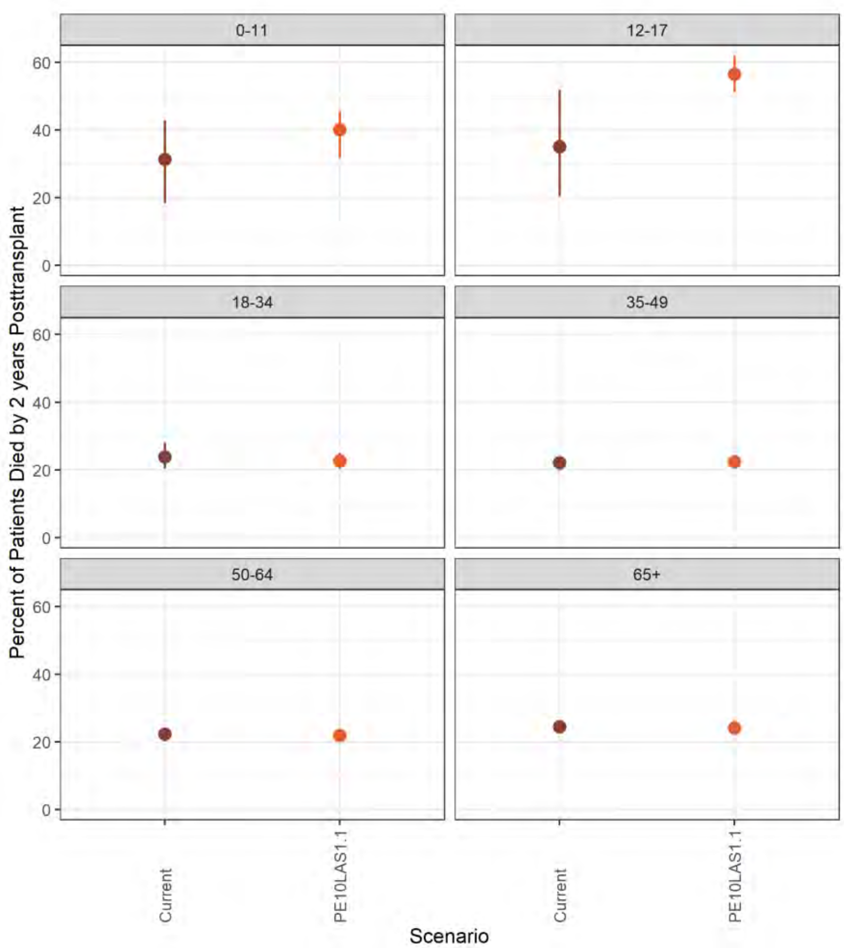
Figure 43: Waiting List Mortality by Insurance Status[153]



[153] *Ibid.*

Modeling showed a potential increase in post-transplant mortality for the adolescent candidate group, corresponding with an increase in the transplant rate for this group. However, the Committee believes that this is an artifact of the fact that post-transplant mortality for pediatric lung candidates is calculated solely based on the donor age, and expects actual mortality to be lower, based on the committee's medical judgment that clinicians are likely to be more discerning about donor quality than the model shows. The Committee plans to monitor this closely.

Figure 44: 2-Year Post-Transplant Mortality by Age[154]



Overall Sentiment from Public Comment

During the public comment period, the Committee solicited feedback on this proposal. While the Committee requested feedback on all aspects of the proposal, the following questions were asked specifically in the proposal:

[154] *Ibid.*

Are the weights on each attribute ideal?

- Should waitlist survival and post-transplant outcomes be equally weighted, or should waitlist survival receive twice as much weight as post-transplant outcomes?
- Is 10% the correct weight for efficiency (5% each for travel efficiency and proximity efficiency?)

Are the changes to exceptions appropriate?

- Is five days sufficient time to allow reviewers to vote on exception applications?
- Is there a need to allow centers to list a candidate at an exception score while awaiting a decision on appeal after an initial denial?

Are the changes to multi-organ allocation appropriate?

- Is a composite allocation score of 28 the right cut-off?
- Does the proposal need to be adjusted to allow OPOs more discretion to offer from the heart list before offering the heart to candidates in need on the lung list who have a composite allocation score of at least 28?

How many decimal places are useful for inclusion in reference numbers and equations?

The responses to the specific questions were generally supportive of the proposal as presented in public comment. The only aspect directly related to these questions that was changed was the decimal precision. The Committee's consideration of the feedback provided in each area is discussed above as part of the proposal in the context of the specific decisions made.

Participation

The proposal was released from August 3, 2021 to September 30, 2021. It received 237 comments, which was the most comments for any proposal this cycle. For comparison, the Membership and Professional Standards Committee's proposal to enhance transplant program performance monitoring received 233 comments during this cycle.

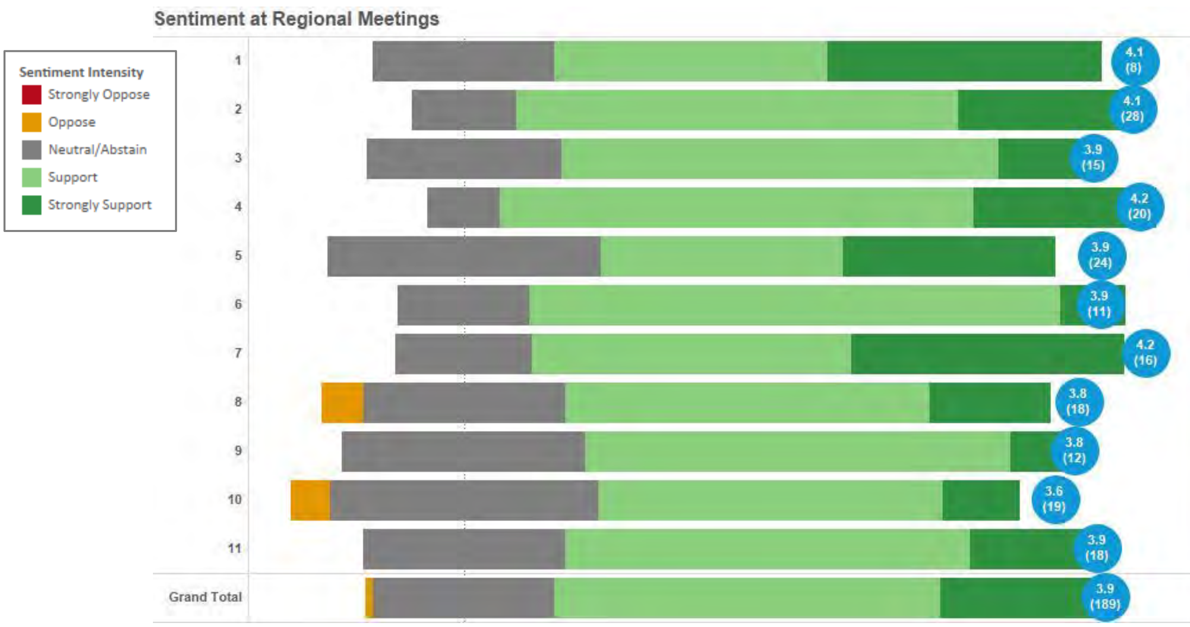
Respondents could participate through virtual regional meetings, committee meetings, and a public comment form on the OPTN website. All respondents submitted demographic information. However, respondents at regional meetings represent the perspective of an institution; therefore, they did not contain demographic information about the institution nor the individual submitting the comment. Sentiment questions were asked of online and regional respondents. Open text comments were available to responses collected through the online web form. Discussions at regional and committee meetings were summarized to gather the various perspectives voiced in those meetings.

Sentiment in Public Comment

Sentiment for public comment proposals is collected along a 5-point Likert scale from strongly oppose to strongly support (1-5). These reports are helpful to spot high-level trends, but they are not meant as public opinion polls or to replace the substantive analysis below. Generally, public comment sentiment has been very supportive of this proposal. Below are graphics that illustrate the sentiment received through public comment.

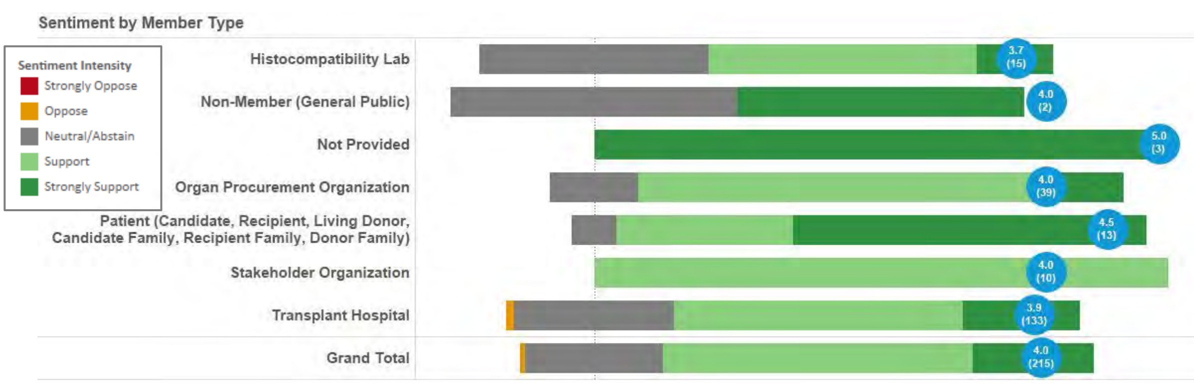
The following figure shows sentiment received at regional meetings. Again, the overall sentiment was very supportive. Only 1% of the regional meeting representatives opposed the proposal. This level of support is infrequent for a significant allocation change and typically only occurs with proposals on the non-discussion agenda during public comment.[155]

Figure 45: Sentiment at Regional Meetings[156]



The following figure shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. Again, less than 1% of all respondents opposed the proposal, and there was overall support. Patients have especially strong support for the proposal.

Figure 46: Sentiment by Member Type[157]



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155 Compare sentiment of this proposal with other proposals at https://optn.transplant.hrsa.gov/governance/public-comment/.
156 Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.
157 Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[158] 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:** The construction of the individual ratings scales and weights is based on objective clinical and operations evidence, including multiple rounds of simulation modeling, and research presented by multiple parties. The Committee also relied upon peer-reviewed literature as well its own clinical experience and judgment in making determinations regarding assigning weights and ratings to each attribute.
- **Seeks to achieve the best use of donated organs:** One of the best uses of a donated organ is that it is transplanted in the most medically urgent candidate; therefore, the proposal incorporates waiting list mortality as one of the attributes to be included in the candidate's composite allocation score. The policy was modeled by the SRTR to assess its impact on waitlist mortality and post-transplant outcomes and is expected to improve both compared to the current system.
- **Is specific for each organ,** in this case, the lungs.
- **Is designed to avoid wasting organs:** The Committee does not expect impacts on organ wastage (defined as organs recovered but not transplanted).[159]
- **Is designed to…promote patient access to transplantation:** The Committee included several attributes in the proposed composite allocation score specifically to ensure that similarly situated candidates have equitable opportunities to receive an organ offer. This includes the three attributes under the goal of candidate biology (CPRA, candidate blood type, and candidate height) and the two attributes under patient access (candidate age and prior living donors). The inclusion of these attributes will increase and make more equitable access to transplantation for these patients.
- **Is designed to…promote the efficient management of organ placement:** The Committee considered indicators of efficiency associated with procuring and transplanting lungs, including travel costs and the proximity between the donor and transplant. Travel costs have a more

[158] 42 CFR §121.4(a).

[159] Although the modeling results show a lower transplant rate, they do 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. 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

direct impact on the efficiency of the organ placement system than the current geographic zones because costs are a more direct measure of efficiency than distance based zones.

- **Is not based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** 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. The Committee used the MIT analysis so that the weight placed on efficiency (and thus the candidate's place of listing) is based on the ensuring the most benefit in the balance between waiting list and post-transplant deaths and the weight of the placement efficiency attributes.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.[160]

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[161] As discussed above, candidates on the lung waiting list are generally expected to be treated more favorably following these changes. However, there may be some individuals with a unique clinical situation, who are not accurately represented by the included variables. These unique situations are accounted for using exceptions. Members will have an opportunity to update candidate information before the new system is implemented in order to ensure that their score is calculated based on the most recent information. Prior to implementation, information will be provided to members to assist them in determining the impact of the new allocation system on their candidate, and members will be able to request exception scores so that candidates can use an exception score on the day the new system is implemented.

This proposal also includes operational guidelines for the Lung Review Board under the authority of the Final Rule, which requires the OPTN to establish performance goals for allocation policies, including "reducing inter-transplant program variance."[162] The operational guidelines for the Lung Review Board are in furtherance of reduction of variation amongst transplant programs with regard to their exception requests and with regard to how the Lung Review Board reviews exception requests, to improve equity in allocation. The Lung Committee will develop and release further updates to the Review Board operational guidelines and specific exceptions prior to the implementation of continuous distribution.

In addition to the allocation policy changes, this proposal recommends new data collection. The OPTN is authorized to collect data under the Final Rule, which states:

> An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…" and that the OPTN shall:
>
> > (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
> >
> > (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;

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160 42 CFR §121.8(a)(3).
161 42 C.F.R. § 121.8(d).
162 42 C.F.R. §121.8(b)(4).

(iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and
(iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.[163]

The new data collection included in the proposal includes various factors related to transplant candidates.

OPTN Strategic Plan

This project impacts multiple goals in the OPTN strategic plan:

- *Increase the number of transplants:*
  - This goal calls for the OPTN to "[p]ursue policies and systems tools that promote system efficiency and increase organ utilization." The new continuous distribution framework, for the first time, calls out a specific goal for placement efficiency. This proposal also uses new methods to achieve placement efficiency and lays the foundation for further work in this area.
- *Provide equity in access to transplants:*
  - Modeling results show that these changes are expected to decrease the variability in the transplant rates between regions. The results also show improvements to waitlist survival for female candidates and candidate with type O blood, who are currently more likely to die while awaiting transplant.
  - Additionally, this goal calls for the OPTN to "[i]ncrease the ability for allocation policies to be dynamic and incorporate changes in faster policy cycles to respond to post-implementation findings." The new continuous distribution framework is constructed in a modular fashion that should allow us to identify concerns or effective practices and implement changes across the organs in a more dynamic fashion. It is also worth noting that the policy development time for this proposal was around three years whereas former projects of this magnitude took two to three times as long to develop.
  - This goal also calls for the OPTN to "[i]ncrease patient involvement throughout the policy development process." The AHP exercise described above included more patient outreach and participation than most OPTN policy proposals. Furthermore, it allowed patients to contribute in a meaningful way without having to first become expert clinicians in organ transplant.
- *Improve waitlisted patient, living donor, and transplant recipient outcomes:*
  - Modeling results show that these changes will improve 1-year waitlisted patient survival and transplant recipient 2-year survival.
  - Additionally, the new continuous distribution framework is constructed with post-transplant outcomes as one of the key goals. This lays the foundation for other organs to begin or enhance their allocation systems with outcomes as a goal.

[163] 42 C.F.R. §121.11(a)(1)(i)-(iv).

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplant hospitals will need to educate staff and patients about the changes to the allocation system, and the impact it will have on scoring, offers, exceptions, and updates to certain testing. Review board members and transplant hospitals requesting exceptions will want to familiarize themselves with the review board changes. There will be limited changes to data collection related to supplemental oxygen, assisted ventilation, and prior living donation.

Operations affecting Organ Procurement Organizations

OPOs may need to train staff on the new match run and revised multi-organ allocation rules. This proposal is also likely to alter offer patterns, and OPOs may develop new relationships with transplant hospitals they did not work with frequently in the past.

Operations affecting Histocompatibility Laboratories

This proposal includes candidate CPRA as a factor in the composite allocation score. Histocompatibility laboratories may need to work with the lung transplant hospitals they serve to update candidate testing policies, and may be asked to test lung candidates more frequently.

Operations affecting the OPTN

This proposal will require extensive system changes and member education.

This proposal will require changes to UNet℠ and the review board system. There will be limited changes to data collection related to supplemental oxygen, assisted ventilation, and prior living donation. As part of the review board changes, the review of exceptions will move into UNet.

The OPTN plans to distribute educational materials related to the new system, including specific educational offerings related to the changes to the lung review board such as clinical exception guidance. It will also publish a new online CAS calculator and patient's guide to understanding the new composite allocation score.

This proposal may require the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule[164] will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, they 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.

[164] 42 CFR §121.11(a)(1)(i)-(iv)

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN, organ procurement organizations, transplant hospitals, and histocompatibility laboratories.

Projected Impact on the OPTN

A significant, multi-department development effort was spearheaded by the Lung Committee on the Establishment of Continuous Distribution of Lungs. The proposed changes seek to consider a number of factors found to be impactful in transplantation in order to create a composite score which more accurately reflects the candidate. This required significant development from all involved, and is the first of the organ-specific committees to implement Continuous Distribution.

This effort will require a Large number of implementation hours from PCR. Because this is the first conversion to Continuous Distribution, and there is no established process for the transition, the estimation is higher than it will be for future organs to encompass the planning, coordination, and outreach necessary for success. Communications also estimates 400 implementation hours will be necessary to create targeted member emails, news articles, member training, Frequently Asked Questions, and web design. Research similarly estimates 400 implementation hours will be necessary to cover document review and meetings, primarily with IT, over the 18 month implementation period.

IT expects an Enterprise number of implementation hours to produce the project, 9360. Because of the scale of this project, IT will have to update Waitlist, Lung Application Programming Interfaces (APIs), Lung Calculators, match runs, DonorNet, and provide updates to the Lung Review Board.

Research will need 350 ongoing hours, which reflect the time spent preparing and reporting the 6 month, 1 year, and 2 year monitoring reports. IT will not need significant time, 120 ongoing hours, primarily to provide maintenance to updated systems and assisting with Research. Communications also will require 120 hours to provide updates throughout the implementation process.

Projected Impact on Organ Procurement Organizations

Anticipated workflow impacts would include longer times to allocate lungs; longer notification times to allow for farther travel by incoming recovery teams; longer case times in the donor hospital; and the possibility of late declines impacting the ability to re-allocate lungs. OPOs may need to hire additional staff or require staff to work extended hours due to longer allocation and case times. OPO staff may need to travel with local recovery teams for import recoveries on request. This proposal may impact allocation of other organs due to extended case times for allocating lungs. Implementation will require 1-4 hours for staff training.

Projected Impact on Transplant Hospitals

The fiscal impact to transplant hospitals of implementing this proposal will vary based on how the continuous distribution allocation framework impacts travel for each center. Previous experience with the shift from Donation Service Area to 250 NM circle in lung allocation showed that the impact on transplant hospitals varied, but some transplant hospitals observed increases in travel and cost.

Transplant hospitals may experience changes in transplant volumes as a result of these changes. Transplant hospitals that experience increased volume as a result of this proposal may have additional costs for staff on call, crossmatching, and transport. Transplant hospitals that experience a decrease in volume may have difficulty recovering the lost costs via other revenue streams.

Since lungs may routinely travel farther for the most medically urgent candidates and stay with a smaller area for less urgent candidates in the new allocation system, transplant hospitals may need to manage increased logistical coordination and preparations for back-up candidates if they have mostly more urgent candidates. Additionally, the organ acquisition cost for lungs that travel may increase as a result of the fiscal impact on OPOs. However, for less urgent candidates, this proposal could potentially result in cost savings for transplant hospitals by achieving better utility of organs and decreasing the overall cost of care for patients, particularly those who are high priority for a lung transplant.

Implementation will require staff training on the new allocation system.

Projected Impact on Histocompatibility Laboratories

This proposal is anticipated to have a minimal fiscal impact on histocompatibility laboratories. Since this proposal incorporates CPRA into lung allocation for the first time, histocompatibility laboratories may need to perform additional testing. However, this is not expected to result in major changes in testing volume, and allocation efficiency will improve when more transplant centers are entering unacceptable antigens for their candidates.

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."[165]

At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that lung composite allocation score clinical values reported through UNet are consistent with source documentation. Site surveyors will also verify that the serum creatinine and bilirubin values reported for lung candidates were the most recent results available at the time they were entered into UNet.

Member Quality staff will also 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 staff will investigate potential policy violations that are identified.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[166] The Committee also received feedback during public comment from respondents encouraging careful monitoring of the impact of the changes and evaluation for any needed corrections or future improvements.

The OPTN will monitor listings, removals, exceptions, and match runs as well as questions received in the days and weeks immediately following implementation for any signs of unintended impacts.

[165] 42 CFR §121.8(a)(7).
[166] 42 CFR §121.8(a)(6).

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.

The Committee will consider overall waiting list deaths and post-transplant deaths, as well as variance in waiting list deaths, post-transplant deaths, and distance between donor and candidate transplant hospitals as key metrics to evaluate the effectiveness of the proposal.

Metrics to be evaluated include:

Waiting List

- Number of candidates ever waiting, additions, and removals
- Distribution of WLAUC and PTAUC
- Population characteristics such as CPRA, prior living donor, height, age group at time of listing, and diagnosis group
- Number of candidates by geographic area
- Candidate waiting time by geographic area
- Numbers of patient deaths, overall and by diagnosis group, WLAUC and PTAUC groups, and geographic area
- Overall waiting list mortality rate and transplant rate by diagnosis group, WLAUC and PTAUC groups, and geographic area
- Number of exception requests, overall and by diagnosis group
- Number of multi-organ candidates

Transplants

- Number of recipients
- Distribution of WLAUC and PTAUC
- Population characteristics such as CPRA, prior living donor, height, age group at time of listing, and diagnosis group
- Number of recipients by geographic area
- Patient post-transplant survival
- Number of recipients transplanted with an exception request, overall and by diagnosis group
- Distance between the donor hospital and transplant center
- Distance between the donor hospital and transplant center by medical urgency group and by composite allocation score group
- Transplant rate changes by transplant program size (small, medium, large)
- Distribution of ischemic time
- Number of multi-organ recipients

Deceased Donor Utilization

- Discard rate by geographic area and donation after circulatory death (DCD) vs. non-DCD
- Utilization rate by geographic area and DCD vs. non-DCD
- Number & percentage of perfused lungs by geographic area
- Number & percentage of DCD lungs transplanted by geographic area

- Time from first electronic offer to cross clamp
- Distribution of sequence number of the final acceptor

Analysis of post-transplant outcomes will be performed after sufficient follow-up data has 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 for each annual update. The OPTN equity in access dashboard will also be used to evaluate the impact of this policy on transplant rates by various candidate attributes.

Conclusion

The Committee proposes replacing the current lung allocation framework with a composite allocation score. The lung composite allocation score would be awarded in the proportions of:

Attribute	Percentage
Waitlist Survival	**25%**
Post-transplant Outcomes	**25%**
Biological Disadvantages	**15%**
Blood Type	5%
CPRA	5%
Height	5%
Patient Access	**25%**
Pediatric	20%
Prior living donor	5%
Placement Efficiency	**10%**
Travel Efficiency	5%
Proximity Efficiency	5%

Each candidate will be awarded a portion of the score for each attribute based on their individual characteristics relative to the rating scale for that attribute.

Changes to the exception review process will be put in place in order to align with the new system and improve alignment across organs. Standards in multi-organ allocation that are currently based on LAS or distance will be replaced with references to composite allocation scores of at least 28.

OPTN

Policy Structure

Given the significant changes to the allocation framework used in this proposal, the order of *Policy 10: Allocation of Lungs* has been changed to accommodate the new framework. The changes are summarized in **Table 5***.*

Table 5: Crosswalk of Changed References

Old Reference	New Reference
1.2 Definitions	1.2 Definitions
3.6.A Waiting Time for Inactive Candidates	3.6.A Waiting Time for Inactive Candidates
5.10.C Other Multi-Organ Combinations	5.10.C Other Multi-Organ Combinations
10.1 Priorities and Score Assignments for Lung Candidates	Deleted
10.1.A Candidates Less than 12 Years Old - Priority 1	10.1.B.2.A Candidates Less than 12 Years Old - Priority 1
10.1.B Candidates Less than 12 Years Old - Priority 2	10.1.2.2.B Candidates Less than 12 Years Old - Priority 2
10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old	10.3 Clinical Update Schedule
10.1.D Candidates at Least 12 Years Old – LAS	Deleted
10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old	10.3 Clinical Update Schedule
10.1.F The LAS Calculation	Deleted
10.1.F.i Lung Disease Diagnosis Groups	10.1.G Lung Disease Diagnosis Groups
10.1.F.ii PCO2 in the LAS	21.2.A.1 PCO2 Threshold Calculation in the Waiting List Survival Calculation
10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher	Deleted
10.2.A Allocation Exception for Highly Sensitized Patients	Deleted
10.2.B Lung Candidates with Exceptional Cases	10.2 Lung Composite Score Exceptions
10.2.B.i LRB Review Process	10.2 Lung Composite Score Exceptions
10.2.B.ii LRB Decision Overrides	Deleted
10.2.B.iii Estimated Values Approved by the LRB	Deleted
10.2.B.iv LAS Diagnoses Approved by the LRB	Deleted
10.2.B.v LAS Approved by the LRB	Deleted
10.3 Waiting Time (and subsections)	Deleted
10.4.A Sorting Within Each Classification	Deleted
10.4.B Allocation of Lungs by Blood Type	Deleted

Old Reference	New Reference
10.4.B.i Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs	10.4.A Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs
10.4.B.ii Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung	10.4.B Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung
10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old	Deleted
10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old	Deleted
10.5 Probability Data Used in the LAS Calculation	Deleted

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.

1.2 Definitions

Composite allocation score (CAS)

The scoring system used to prioritize candidates on the match run. It ranges from 0-100 and is an aggregate of separate goal level scores.

~~**Lung allocation score (LAS)**~~

~~The scoring system used to measure illness severity in the allocation of lungs to candidates 12 years and older.~~

3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
~~Lung and is at least 12 years old~~	~~No time~~
Lung ~~and is less than 12 years old~~	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any covered VCA	Unlimited time
~~All other organs~~	~~Up to 30 days~~

5.10.E Other Multi-Organ Combinations

When an OPO is offering a heart or lung, and a liver or kidney is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-4* must be offered the second organ.

Table 5-4 Second Organ for Heart or Lung PTRs

~~**If the OPO is offering the following organ:**~~	~~**And a PTR is also registered for one of the following organs:**~~	~~**The OPO must offer the second organ if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria:**~~
~~Heart~~	~~Liver or Kidney~~	~~Heart Adult Status 1, 2, 3 or any active pediatric status~~
~~Lung~~	~~Liver or Kidney~~	~~Lung allocation score of greater than or equal to 35 or candidates less than 12 years old~~

If the OPO is offering the following organ:	**And a PTR is also registered for one of the following organs:**	**The OPO must offer the second organ if the PTR meets *all* of the following criteria:**
Heart	Liver or Kidney	• 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	Liver or Kidney	Has a Lung Composite Allocation Score of 28 or greater

When the OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-4*, the OPO has the discretion to offer the second organ to either PTR.

It is permissible for the OPO to offer the second organ to other multi-organ PTRs that do not meet the criteria above.

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

~~If a host OPO is offering a heart and a lung from the same deceased donor, then the host OPO must offer the heart and the lung according to *Policy 6.6.F.i: Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old* or *Policy 6.6.F.ii: Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old*.~~

~~The blood type matching requirements described in *Policy 6.6.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* apply to heart-lung candidates when the candidates appear on the lung match run.~~

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

~~If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.*~~

~~If a lung or heart-lung PTR in allocation classifications 1 through 12 according to *Policy 10.4.C: Allocation of Lungs From Deceased Donors at Least 18 Years Old* requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.*~~

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

1. To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*
2. To all heart-lung PTRs with a lung composite allocation score of 28 or higher according to *Policy 10.1 Allocation of Lungs*
3. To heart PTRs in classifications 5 or later according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.

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

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

~~If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.~~

~~If a lung or heart-lung PTR in allocation classifications 1 through 10 according to *Policy 10.4.D: Allocation of Lungs From Deceased Donors Less Than 18 Years Old* requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 12 according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.~~

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

1. To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*
2. To all heart-lung PTRs with a lung composite allocation score of 28 or higher according to Policy 10.1 Allocation of Lungs
3. To heart PTRs in classifications 13 or later according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old

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

Policy 10: Allocation of Lungs

Repealed.

Policy 10: Allocation of Lungs

10.1 Lung Composite Allocation Score

The lung composite allocation score is the combined total of the candidate's lung medical urgency score, lung post-transplant outcomes score, lung biological disadvantages score, lung patient access score and lung efficiency score. The lung composite allocation score is awarded on a scale from 0 to 100.

Candidates will be rank-ordered by lung composite allocation score. If two or more candidates have the same lung composite allocation score, the tied candidates will be ranked by order of their registration date (oldest to newest).

10.1.A Prioritizing Medically Urgent Candidates

The lung medical urgency score is equal to the candidate's lung waitlist survival points.

10.1.A.1. Waitlist Survival Points for Candidates at least 12 Years Old

For candidates at least 12 years old at the time of the match run lung waitlist survival points are awarded based on the candidate's waiting list survival probability, based on the following factors:

- Age at the time of the match run (fractional calendar years)
- Bilirubin (mg/dL) value with the most recent test date and time
- Body mass index (BMI) (kg/m2)
- Assisted ventilation
- Creatinine (serum) (mg/dL) with the most recent test date and time
- Diagnosis Group (A, B, C, or D), as defined in Policy *10.1.F Lung Disease Diagnosis Groups*
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group A:
  - Bronchiectasis
  - Sarcoidosis with pulmonary artery (PA) mean pressure of 30 mm Hg or less
  - Sarcoidosis with PA mean pressure missing
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group D:
  - COVID-19: pulmonary fibrosis
  - Pulmonary fibrosis, other specify cause
  - Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Functional Status
- Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)
- PCO2 (mm Hg): current

- PCO2 increase of at least 15%
- PA systolic pressure (mm Hg) at rest, prior to any exercise
- Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.

Lung waitlist survival points are awarded on a scale of 0-25. *Policy 21.1.A: Waiting List Survival Formulas* details the calculation of lung waitlist survival points.

10.1.A.2 Waitlist Survival Points for Candidates Less than 12 Years Old

Lung candidates assigned pediatric priority 1 receive 1.9073 waitlist survival points based on the candidate's waitlist survival probability.
Lung candidates assigned pediatric priority 2 receive 0.4406 waitlist survival points based on the candidate's waitlist survival probability.

10.1.A.2.a Candidates Less than 12 Years Old - Priority 1

A lung candidate less than 12 years old may be assigned priority 1 if at least *one* of the following requirements is met:

1. Candidate has respiratory failure, evidenced by at least *one* of the following:
   - Requires continuous mechanical ventilation
   - Requires supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%
   - Has an arterial or capillary PCO_2 greater than 50 mm Hg
   - Has a venous PCO_2 greater than 56 mm Hg

2. Candidate has pulmonary hypertension, evidenced by at least *one* of the following:
   - Has pulmonary vein stenosis involving 3 or more vessels
   - Exhibits *any* of the following, in spite of medical therapy:
     - Cardiac index less than 2 $L/min/M^2$
     - Syncope
     - Hemoptysis
     - Suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate

The OPTN will maintain examples of accepted medical therapy for pulmonary hypertension. Transplant programs must indicate which of these medical therapies the candidate has received.

10.1.A.2.b Candidates Less than 12 Years Old - Priority 2

If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for priority 1, then the candidate is assigned priority 2.

10.1.B Improving Post-Transplant Outcomes

Each lung candidate is assigned a lung post-transplant outcomes score. The lung post-transplant outcomes score is equal to the candidate's lung post-transplant outcomes points.

10.1.B.1 Post-Transplant Outcomes Points for Candidates at Least 12 Years Old

For candidates at least 12 years old at the time of the match run, lung post-transplant outcomes points are awarded based on the candidate's post-transplant survival probability, based on the following factors:

- Age at the time of the match run(fractional calendar years)
- Creatinine (serum) (mg/dL) with the most recent data and time
- Cardiac index (L/min/m2) at rest, prior to any exercise
- Assisted ventilation
- Diagnosis Group (A, B, C, or D), as defined in *10.1.F: Lung Disease Diagnosis Groups*
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group A:
    - Bronchiectasis
    - Lymphangioleiomyomatosis
    - Sarcoidosis with PA mean pressure of 30 mm Hg or less
    - Sarcoidosis with PA mean pressure missing
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group D:
    - COVID-19: pulmonary fibrosis
    - Obliterative bronchiolitis (non-retransplant)
    - Constrictive bronchiolitis
    - Sarcoidosis with PA mean pressure greater than 30 mm Hg
    - Pulmonary fibrosis, other specify cause
- Functional Status
- Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test

Lung post-transplant outcomes points are awarded on a scale of 0-25. *Policy 21.1.B: Post-Transplant Outcomes Formulas* details the calculation of lung post-transplant outcomes points.

10.1.B.2 Post-Transplant Outcomes Points for Candidates Less than 12 years Old

Lung candidates who are less than 12 years old are assigned 18.6336 post-transplant outcomes points based on the candidate's post-transplant survival probability.

10.1.C Reducing Biological Disadvantages

Each lung candidate is assigned a lung biological disadvantages score. The lung biological disadvantages score is equal to the total of the candidate's lung blood type points, lung CPRA points, and lung height points.

10.1.C.1 Blood Type

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

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
B	.2439
O	.4550

10.1.C.2 CPRA

Each lung candidate is assigned lung CPRA points based on the proportion of donors the candidate could accept based on antigen acceptability. Lung CPRA points are awarded on a scale of 0-5. *Policy 21.1.C.1: Lung CPRA Points* details the calculation of lung CPRA points.

10.1.C.3 Height

Each lung candidate is assigned lung height points based on the proportion of donors the candidate could accept based on height compatibility. Lung height points are awarded on a scale of 0-5. *Policy 21.2.C.2: Lung Height Points* details the calculation of lung height points.

10.1.D Promoting Patient Access

The lung patient access score is equal to the total of the candidate's lung pediatric points and lung living donor points.

10.1.D.1 Pediatric Candidates

A candidate who was less than 18 years old at the time of registration on the lung waiting list will receive 20 lung pediatric points.

10.1.D.2 Prior Living Donors

A candidate who is a prior living organ donor will receive 5 lung living donor points.

A lung candidate will be classified as a prior living donor if the candidate donated for transplantation, within the United States or its territories, at least one organ and the candidate's physician reports all of the following information to the OPTN:

a. The name of the recipient or intended recipient of the donated organ or organ segment

b. The recipient's or intended recipient's transplant hospital

c. The date the donated organ was procured

10.1.E Promoting the Efficient Management of the Organ Placement System

The lung efficiency score is the total of the candidate's lung travel efficiency and lung proximity efficiency points.

10.1.E.1 Travel Efficiency

A candidate's lung travel efficiency points are determined based on the straight-line distance between the donor hospital and the transplant hospital where the candidate is listed. Lung travel efficiency points are awarded on a scale of 0-5. Policy *21.1.D.1: Lung Travel Efficiency Points* details the calculation of lung travel efficiency points.

10.1.E.2 Proximity Efficiency

A candidate's lung proximity efficiency points are determined based on the straight-line distance between the donor hospital and the transplant hospitals where the candidate is listed. Lung proximity efficiency points are awarded on a scale of 0-5. *Policy 21.1.D.2: Lung Proximity Efficiency Points* details the calculation of lung travel efficiency points.

10.1.F Lung Disease Diagnosis Groups

Each candidate is assigned a diagnosis group, based on their lung disease diagnosis, which is used in the calculation of their medical urgency score and their post-transplant survival score.

Group A

A candidate is in Group A if the candidate has *any* of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema

- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with either:
    - Pulmonary artery (PA) mean pressure of 30 mm Hg or less
    - PA mean pressure missing
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B

A candidate is in Group B if the candidate has *any* of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension
- Pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C

A candidate is in Group C if the candidate has *any* of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D

A candidate is in Group D if the candidate has *any* of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least one of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive

- Rheumatoid disease
- Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Scleroderma – restrictive
- Silicosis
- Sjogren's syndrome
- Surfactant protein B deficiency
- Surfactant protein C deficiency
- Teratoma
- Wegener's granuloma – restrictive

10.2 Lung Composite Score Exceptions

If a candidate's current lung composite allocation score does not appropriately prioritize the candidate for transplant, the candidate's transplant program may submit an exception request to the Lung Review Board. A candidate's lung composite allocation score cannot exceed 100, inclusive of score exceptions.

10.2.A Lung Review Board Composition

For lung exceptions, there is a Lung Review Board.

The Lung Review Board reviews lung medical urgency score, lung post-transplant outcomes score, lung biological disadvantages score, and lung patient access score exceptions.

The Lung Transplantation Committee will develop and approve operational guidelines that detail the administrative details of the Lung Review Board operations. The Lung Transplantation Committee may develop clinical guidance documents for specific clinical scenarios. These guidelines may include appropriate documentation for the Lung Review Board to consider, appropriate clinical values, and suggested (but not automatically accepted) exception requests.

10.2.B Exception Requests

An exception request must include all of the following:

1. Indication of the applicable goal in the composite allocation score
2. A request for a specific score
3. A justification of how the medical criteria supports the higher score for the candidate
4. An explanation of how the candidate's current condition is comparable to that of other candidates with the requested score

Approved exception scores are valid until the candidate is transplanted, is removed from the lung waiting list, or withdraws the exception.

10.2.C Review of Exceptions

The Lung Review Board must review exception requests within five days of the date the request is submitted to the Lung Review Board. If the Lung Review Board fails to make a decision on the initial exception request by the end of the five-day review period, the candidate will be assigned the requested exception score.

10.2.D Appeals to Lung Review Board

If the Lung Review Board denies an exception request, the candidate's transplant program may appeal to the Lung Review Board within seven days of receiving the denial. The Lung Review Board must review appeals within five days of the date the appeal is submitted to the OPTN. If the Lung Review Board fails to make a decision on the appeal by the end of the five-day appeal period, the candidate will be assigned the requested exception score.

10.2.E Appeals to Lung Transplantation Committee

If the Lung Review Board denies an exception request on appeal, the candidate's transplant program may appeal to the Lung Transplantation Committee within fourteen days of receiving the denial. The Lung Transplantation Committee must review appeals at its next scheduled meeting.

10.3 Clinical Values and Update Schedule

Transplant programs must report to the OPTN clinical data corresponding with the factors outlined in *Policy 10.1.A.1: Waitlist Survival Points for Candidates at least 12 Years Old* and *10.1.B.1: Post-Transplant Outcomes Points for Candidates at Least 12 Years Old.* The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date, with the exception of the following values:

- Cardiac index (L/min/m2) at rest, prior to any exercise
- PA mean pressure
- Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

10.3.A Lung Clinical Values That Must Be Updated Every 28 Days

A transplant hospital must update *all* of the following clinical values at least once in every 28 day period after the transplant hospital reports that a candidate on the lung waiting list is on continuous mechanical ventilation or ECMO, or requires supplemental oxygen provided via a high flow oxygen device:

- Supplemental oxygen requirements to maintain adequate oxygen saturation (88% or greater) at rest (L/min)
- Assisted ventilation status

10.3.B Lung Clinical Values That Must Be Updated Every Six Months

Transplant hospitals must update *all* of the following clinical values at least once in every six month period following registration for each candidate on the lung waiting list:

- Bilirubin (mg/dL) value with the most recent test date and time
- Weight to determine body mass index (BMI) (kg/m2)
- Creatinine (serum) (mg/dL) value with the most recent test date and time
- Functional Status

- Supplemental oxygen requirements to maintain adequate oxygen saturation (88% or greater) at rest (L/min)
- PCO_2 (mm Hg)
- Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.
- Assisted ventilation status

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

10.3.C Lung Clinical Values That Must Be Updated When Performed

Transplant hospitals must report updated values for the following clinical values if they were obtained within any six month period following registration for each candidate at an active or inactive status.

- Cardiac index (L/min/m2) at rest, prior to any exercise
- PA mean pressure, if candidate's diagnosis is Sarcoidosis
- Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

10.4 Eligibility Criteria

10.4.A Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

Incompatible blood types are defined in *Table 10-2: Incompatible Blood Groups for Deceased Donor Lungs*.

Table 10-2: Incompatible Offers Blood Groups for Deceased Donor Lungs

Deceased Donor's Blood Type	Candidate's Blood Type
A	O and B
B	O and A
AB	O, A, and B

Candidates with incompatible blood types will be screened from lung match runs unless the candidate meets the criteria for eligibility in *Table 10-3: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs* below.

Table 10-3: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

If the candidate is:	And meets *all* of the following:
Less than one year old at the time of the match run	1. Has a waiting list survival score of at least 1.9073 2. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days
At least one year old at the time of the match run	1. Is registered prior to turning two years old 2. Has a waiting list survival score of at least 1.9073 3. Has reported to the OPTN isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected

10.4.B Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood type incompatible lung, according to Table 10-4 below, at all of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood type incompatible lung.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood type incompatible lung.

Table 10-4: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Type Incompatible Lung

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	Anti-B
B	Anti-A

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
O	Anti-A and Anti-B

Accurate isohemagglutinin titers must be reported for recipients of an intended blood type incompatible lung, according to *Table 10-5*, as follows:

1. At transplant, from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 10-5: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Type Incompatible Lung

If the deceased donor's blood type is:	And the recipient's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

Policy 21: Composite Allocation Score Reference

21.1 Formulas

21.1.A Waiting List Survival Formulas

21.1.A.1 Lung Waitlist Area Under the Curve (WLAUC)

The area under the lung waiting list survival probably curve within one year (WLAUC) is calculated using the formula

$$WL_i = \sum_{k=1}^{365} S_{WL,i}(k-1)$$

The calculation for $S_{WL,i}$ is in *Policy 21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year*.

21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year

The formula used to calculate expected lung waiting list survival probability within one year is

$$S_{WL,i}(t) = S_{WL,0}(t)^{e^{\beta_1 X_{1i} + \beta_2 X_{2i} + \ldots + \beta_p X_{pi}}}$$

Table 21-1: Expected Lung Waiting List Survival Probability Within One Year Variables lists what each variable in the formula represents.

Table 21-1 Expected Lung Waiting List Survival Probability Within One Year Variables

The variable	Represents
$S_{WL,i}(t)$	the expected waiting list survival probability at time t for candidate i
$S_{WL,0}(t)$	the baseline waiting list survival probability at time t
$\beta_1, \beta_2, \ldots \beta_p$	the parameter estimates from the waiting list model (Table 21-5)
X_{ji}	the value of characteristic j for candidate i
I	1, 2, …, N is the candidate identifier

21.1.A.3 Converting Lung WLAUC to Lung Waiting List Survival Points

Waiting list Survival Points are equal to

$$((25^{(1-WLAUC/365)} - 1)/24)*25$$

21.1.B Post-Transplant Outcomes Formulas

21.1.B.1 Expected Five years Post-Transplant Area Under the Curve (PTAUC)

The area under the post-transplant survival probably curve during the first five years post-transplant (PTAUC) is calculated using the formula

$$\text{PT}_i = \sum_{k=1}^{1826} S_{TX,i}(k)$$

21.1.B.2 Expected Lung Post-Transplant Survival Probability Within Five Years

The formula used to calculate expected lung post-transplant survival probability within five years is

$$S_{TX,i}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$

Table 21-2: Expected Lung Post-Transplant Survival Probability Within Five Years Variables lists what each variable in the formula represents.

Table 21-2 Expected Lung Post-Transplant Survival Probability Within Five Years Variables

The variable	Represents
$S_{TX,i}(t)$	expected post-transplant survival probability at time t for candidate i
$S_{TX,0}(t)$	the baseline post-transplant survival probability at time t

The variable	Represents
$\alpha_1, \alpha_2, \ldots \alpha_q$	the parameter estimates from the post-transplant model (Table 21-8)
Y_{ji}	the value of characteristic j for candidate i
i	1, 2, …, N is the candidate identifier

21.1.B.3 Converting Lung PTAUC to Lung Post-Transplant Outcomes Points

Post-Transplant Outcomes Points are equal to

$$(PTAUC/1826)*25$$

21.1.C Biological Disadvantages Formulas

21.1.C.1 Lung CPRA Points

The Lung CPRA points are equal to

$$((100^{CPRA}-1)/99)*5$$

The variable CPRA represents the probability of incompatibility based on the candidate's CPRA.

21.2.C.2 Lung Height Points

The Lung Height points are equal to

$$((100^{HTIN}-1)/99)*5$$

The variable HTIN represents the probability of incompatibility based on the candidate's height found in *Policy 21.2.C.1: Probability of Incompatible Lung Donors Based on Height*.

21.1.D Efficient Management Formulas

21.1.D.1 Lung Travel Efficiency Points

The Lung travel efficiency points are equal to

$$(I\{NM \leq 45\} + I\{NM \in (45,90)\}*(1 - 0.15 / 45 * (NM - 45)) + I\{NM \geq 90\}*0.875 / [1 + \exp(0.0025 * (NM - 1500))])*5$$

The variable NM represents straight-line distance between donor hospital and candidate hospital in nautical miles, rounded down to the nearest integer.

21.1.D.2 Lung Proximity Efficiency Points

The lung proximity efficiency points are equal to

$$(1 - [6.3*NM + 247.63 * (NM - 43.44) * I\{NM > 43.44\} - 104.44 * (NM - 67.17) * I\{NM > 67.17\} - 128.34 * (NM - 86.9) * I\{NM > 86.9\}] / 116989.1)*5$$

The variable NM represents straight-line distance between donor hospital and candidate hospital in nautical miles, rounded down to the nearest integer.

21.2 Reference Values

21.2.A Values Used in the Calculation of Lung Waiting List Survival

Table 21-3 provides the covariates and their coefficients for the waiting list mortality calculation. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 21-3: Waiting List Survival Calculation: Covariates and their Coefficients

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
Age at the time of the match run (fractional calendar year)	All candidates	0.0281444188123287*age
Bilirubin (mg/dL) value with the most recent test date and time	Bilirubin is more than 1.0 mg/dL	0.15572123729572*(bilirubin – 1)
	1.0 mg/dL or less	0
Body mass index (BMI) (kg/m^2)	BMI less than 20 kg/m^2	0.10744133677215*(20 – BMI)
	BMI is at least 20 kg/m^2	0
Assisted ventilation	ECMO or continuous mechanical-hospitalized	1.57618530736936
	Not ECMO or continuous mechanical-hospitalized	0
Creatinine (serum) (mg/dL) with the most recent test date and time	Candidate is at least 18 years old	0.0996197163645* creatinine
	Candidate is less than 18 years old	0
Diagnosis Group	A	0
Diagnosis Group	B	1.26319338239175

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
Diagnosis Group	C	1.78024171092307
Diagnosis Group	D	1.51440083414275
Detailed diagnosis within group A	Bronchiectasis	0.40107198445555
	Sarcoidosis with PA mean pressure of 30 mm Hg or less	1.39885489102977
	Sarcoidosis with PA mean pressure missing	1.39885489102977
Detailed Diagnosis within group D	COVID-19: pulmonary fibrosis	0.2088684500011
	Pulmonary fibrosis, other	0.2088684500011
	Sarcoidosis with PA mean pressure greater than 30 mm Hg	-0.64590852776042
Functional Status	No assistance needed with activities of daily living	-0.59790409246653
	Some or total assistance needed with activities of daily living	0
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	Diagnosis Group B	$0.0340531822566417*O_2$
	Diagnosis Groups A, C, and D	$0.08232292818591*O_2$

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
PCO_2 (mm Hg): current	PCO_2 is at least 40 mm Hg	0.12639905519026*PCO_2/10
PCO_2 threshold change	PCO_2 increase is at least 15%	0.15556911866376
	PCO_2 increase is less than 15%	0
Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise	Diagnosis Group A and the PA systolic pressure is greater than 40 mm Hg	0.55767046368853*(PA systolic – 40)/10
	Diagnosis Group A and the PA systolic pressure is 40 mm Hg or less	0
	Diagnosis Groups B, C, and D	0.1230478043299*PA systolic/10
Six-minute-walk distance (feet)	Obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest.	-0.09937981549564*Six-minute-walk distance/100

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 21-4*, then the composite allocation score calculation will substitute normal or least beneficial values to calculate the candidate's waiting list survival score. *Table 21-4* lists the normal and least beneficial values that will be substituted.

Table 21-4: Values Substituted for Missing or Expired Actual Values in Calculating Waiting List Survival Score

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
Height or weight to determine body mass index (BMI)	Missing	100 kg/m^2
Weight to determine BMI	Expired	100 kg/m^2
Assisted ventilation	Missing or expired	No mechanical ventilation
Creatinine (serum) (mg/dL)	Missing or expired	0.1 mg/dL
Functional status	Missing or expired	No assistance needed
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	Missing or expired	No supplemental oxygen needed
PCO_2	Missing, expired, or less than 40 mm Hg	40 mm Hg
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg
Six-minute-walk distance	Missing or expired	4,000 feet

21.2.A.1 PCO2 Threshold Change in the Waiting List Survival Calculation

The LAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. PCO_2 Threshold Change

Current PCO_2

Current PCO_2 is the PCO_2 value reported to the OPTN with the most recent test date and time. A program may report a PCO_2 value from an arterial, venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

PCO_2 Threshold Change

There are two PCO_2 threshold change calculations:

- The PCO_2 Threshold Change Calculation

- The Threshold Change Maintenance Calculation

The PCO_2 Threshold Change Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's LAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The PCO_2 threshold change calculation uses the highest and lowest values of PCO_2 as follows:

- The test date and time of the lowest value reported to the OPTN used in the PCO_2 threshold change calculation must be earlier than the test date and time of the highest value used in the PCO_2 threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The PCO_2 threshold change calculation can use an expired lowest value, but cannot use an expired highest value.

If a current PCO_2 value expires according *to Policy 10.3 Clinical Update Schedule,* the candidate's LAS will lose the impact from the PCO_2 threshold change calculation. The equation for the PCO_2 threshold change calculation is:

$$\frac{\text{Highest } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater PCO_2 threshold change calculation impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the PCO_2 increase, the candidate's current PCO_2 value must be at least 15% higher than the lowest value used in the PCO_2 threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs either when the current PCO_2 value expires, according to *Policy 10.3 Clinical Update Schedule,* or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the PCO_2 threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the PCO_2 threshold change calculation. If a current PCO_2 value expires, the candidate's LAS will no longer be affected by the PCO_2 threshold change.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the PCO_2 threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the PCO_2 threshold change calculation, the candidate's LAS will again be affected by the PCO_2 threshold change calculation.

Normal PCO_2 Value

The normal clinical PCO_2 value is 40mmHg. If a current PCO_2 value is below 40 mmHg, or if the current PCO_2 value is missing or expired, the LAS calculation will use the normal clinical PCO_2 value.

21.2.A.2 Probabilities Used in Calculating Lung Waiting List Survival

Table 21-5: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$
0	1.000000	35	0.999178	70	0.998556	105	0.997980
1	0.999998	36	0.999155	71	0.998510	106	0.997980
2	0.999983	37	0.999130	72	0.998494	107	0.997976
3	0.999956	38	0.999128	73	0.998490	108	0.997965
4	0.999928	39	0.999103	74	0.998431	109	0.997944
5	0.999902	40	0.999080	75	0.998413	110	0.997877
6	0.999878	41	0.999060	76	0.998403	111	0.997872
7	0.999856	42	0.999048	77	0.998391	112	0.997828
8	0.999814	43	0.999048	78	0.998391	113	0.997824
9	0.999786	44	0.999036	79	0.998379	114	0.997824
10	0.999770	45	0.999036	80	0.998370	115	0.997824
11	0.999740	46	0.999002	81	0.998363	116	0.997824
12	0.999705	47	0.998978	82	0.998347	117	0.997824
13	0.999682	48	0.998967	83	0.998314	118	0.997824
14	0.999650	49	0.998949	84	0.998306	119	0.997783
15	0.999635	50	0.998922	85	0.998295	120	0.997777
16	0.999629	51	0.998886	86	0.998257	121	0.997767
17	0.999615	52	0.998852	87	0.998244	122	0.997761
18	0.999597	53	0.998843	88	0.998244	123	0.997734
19	0.999565	54	0.998843	89	0.998244	124	0.997656
20	0.999527	55	0.998821	90	0.998226	125	0.997656
21	0.999508	56	0.998815	91	0.998179	126	0.997650
22	0.999493	57	0.998772	92	0.998179	127	0.997637
23	0.999460	58	0.998734	93	0.998171	128	0.997610
24	0.999430	59	0.998725	94	0.998144	129	0.997610
25	0.999406	60	0.998703	95	0.998131	130	0.997610
26	0.999382	61	0.998703	96	0.998115	131	0.997599
27	0.999361	62	0.998665	97	0.998115	132	0.997584
28	0.999335	63	0.998665	98	0.998076	133	0.997577
29	0.999302	64	0.998660	99	0.998046	134	0.997570
30	0.999294	65	0.998630	100	0.998046	135	0.997570
31	0.999272	66	0.998617	101	0.998036	136	0.997561
32	0.999262	67	0.998575	102	0.998036	137	0.997552
33	0.999243	68	0.998570	103	0.998026	138	0.997540
34	0.999201	69	0.998567	104	0.997991	139	0.997540

T	$S_{TX}(t)$
140	0.997540
141	0.997540
142	0.997540
143	0.997534
144	0.997534
145	0.997534
146	0.997530
147	0.997515
148	0.997504
149	0.997499
150	0.997492
151	0.997477
152	0.997477
153	0.997455
154	0.997410
155	0.997335
156	0.997335
157	0.997327
158	0.997321
159	0.997315
160	0.997294
161	0.997294
162	0.997294
163	0.997273
164	0.997273
165	0.997273
166	0.997269
167	0.997223
168	0.997223
169	0.997218
170	0.997209
171	0.997209
172	0.997209
173	0.997209
174	0.997209
175	0.997183
176	0.997169
177	0.997169
178	0.997169
179	0.997169
180	0.997160
181	0.997160
182	0.997132

T	$S_{TX}(t)$
183	0.997113
184	0.997113
185	0.997109
186	0.997099
187	0.997099
188	0.997099
189	0.997099
190	0.997099
191	0.997099
192	0.997099
193	0.997099
194	0.997091
195	0.997067
196	0.996968
197	0.996968
198	0.996968
199	0.996959
200	0.996959
201	0.996945
202	0.996861
203	0.996838
204	0.996838
205	0.996825
206	0.996819
207	0.996819
208	0.996819
209	0.996819
210	0.996810
211	0.996796
212	0.996717
213	0.996636
214	0.996621
215	0.996621
216	0.996614
217	0.996602
218	0.996579
219	0.996579
220	0.996574
221	0.996524
222	0.996511
223	0.996439
224	0.996439
225	0.996423

T	$S_{TX}(t)$
226	0.996423
227	0.996412
228	0.996388
229	0.996388
230	0.996368
231	0.996368
232	0.996368
233	0.996368
234	0.996368
235	0.996368
236	0.996368
237	0.996368
238	0.996368
239	0.996368
240	0.996368
241	0.996258
242	0.996258
243	0.996195
244	0.996195
245	0.996195
246	0.996096
247	0.996044
248	0.996025
249	0.995988
250	0.995974
251	0.995974
252	0.995955
253	0.995955
254	0.995938
255	0.995938
256	0.995938
257	0.995938
258	0.995927
259	0.995927
260	0.995923
261	0.995923
262	0.995923
263	0.995923
264	0.995923
265	0.995923
266	0.995895
267	0.995794
268	0.995794

T	$S_{TX}(t)$
269	0.995778
270	0.995778
271	0.995778
272	0.995778
273	0.995778
274	0.995770
275	0.995764
276	0.995741
277	0.995726
278	0.995726
279	0.995726
280	0.995726
281	0.995691
282	0.995691
283	0.995691
284	0.995691
285	0.995680
286	0.995680
287	0.995680
288	0.995661
289	0.995661
290	0.995639
291	0.995639
292	0.995548
293	0.995548
294	0.995505
295	0.995498
296	0.995479
297	0.995464
298	0.995439
299	0.995439
300	0.995414
301	0.995414
302	0.995385
303	0.995358
304	0.995345
305	0.995345
306	0.995345
307	0.995309
308	0.995296
309	0.995296
310	0.995274
311	0.995274

T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$
312	0.995251	**326**	0.995080	**340**	0.994937	**354**	0.994585
313	0.995251	**327**	0.995080	**341**	0.994937	**355**	0.994585
314	0.995251	**328**	0.995080	**342**	0.994937	**356**	0.994572
315	0.995228	**329**	0.995080	**343**	0.994937	**357**	0.994527
316	0.995228	**330**	0.995080	**344**	0.994842	**358**	0.994527
317	0.995228	**331**	0.995080	**345**	0.994842	**359**	0.994527
318	0.995167	**332**	0.995067	**346**	0.994842	**360**	0.994477
319	0.995131	**333**	0.994986	**347**	0.994738	**361**	0.994477
320	0.995131	**334**	0.994951	**348**	0.994695	**362**	0.994477
321	0.995131	**335**	0.994951	**349**	0.994685	**363**	0.994477
322	0.995131	**336**	0.994951	**350**	0.994685	**364**	0.994390
323	0.995131	**337**	0.994937	**351**	0.994685		
324	0.995080	**338**	0.994937	**352**	0.994685		
325	0.995080	**339**	0.994937	**353**	0.994685		

21.2.B Values Used in the Calculation of Post-Transplant Outcomes

21.2.B.1 Coefficients Used in Calculating Lung Post-Transplant Outcomes

Table 21-6: Post-Transplant Outcomes Calculation: Covariates and Their Coefficients lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 21-6: Post-Transplant Outcomes Calculation: Covariates and Their Coefficients

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
Age at the time of the match run (fractional calendar year)	age is less than 20	0.0676308559079852 x (20 - age) + 0.78241832
	age is at least 20 and less than 30,	-0.0782418319259552 x (age - 20) + 0.78241832
	age is at least 30 and less than 40	0
	age is at least 40 and less than 50	0.0025908121347866 x (age - 40)
	age is at least 50 and less than 60	0.0167463361760962 x (age - 50) + 0.02590812
	age is at least 60 and less than 70	0.0227144625797883 x (age - 60) + 0.19337148
	age is at least 70	0.0612288624399672 x (age - 70) + 0.42051611

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
Creatinine (serum) (mg/dL) with the most recent test date and time	creatinine is less than 0.4 and candidate is at least 18 years old	-7.4016726145812200 x (0.4 - creatinine) + 0.41872820
	creatinine is at least 0.4 and less than 0.6 and candidate is at least 18 years old	-1.2584103289549000 x (creatinine - 0.4) + 0.41872820
	creatinine is at least 0.6 and less than 0.8 and candidate is at least 18 years old	0.3712348866558860 x (creatinine - 0.6) + 0.16704614
	creatinine is at least 0.8 and less than 1.4 and candidate is at least 18 years old	0.6844301806854400 x (creatinine - 0.8) + 0.24129311
	creatinine is at least 1.4 and candidate is at least 18 years old	0.6881894154264970 x (creatinine - 1.4) + 0.65195122
	Candidate is less than 18 years old	0
Cardiac index ($L/min/m^2$) at rest, prior to any exercise	Less than 2 $L/min/m^2$	-0.4837491139906200 x (2 – cardiac index) + 0.04030226
	At least 2 and less than 2.5 $L/min/m^2$	-0.0806045255202868 x (cardiac index - 2) + 0.04030226
	At least 2.5 and less than 3.5 $L/min/m^2$	0.0136169358319050 x (cardiac index - 2.5)
	At least 3.5 and less than 4.5 $L/min/m^2$	0.0808432592591954 x (cardiac index - 3.5) + 0.01361694
	At least 4.5 and less than 5 $L/min/m^2$	0.0696938839239190 x (cardiac index - 4.5) + 0.09446020
	At least 5 $L/min/m^2$	-0.0023264599609358 x (cardiac index - 5) + 0.12930714
Assisted ventilation	ECMO or continuous mechanical-hospitalized	0.267537018672253
	not ECMO or continuous mechanical-hospitalized	0
Diagnosis Group	A	-0.098901796
	B	0
	C	-0.167126401
	D	0

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
Detailed diagnosis within Group A	Bronchiectasis	-0.026706663
	Lymphangioleiomyomatosis	-0.271420386
	Sarcoidosis with PA mean pressure of 30 mm Hg or less	0.501743373724746
	Sarcoidosis with PA mean pressure missing	0.501743373724746
Detailed diagnosis within Group D	COVID-19: pulmonary fibrosis	0.046504644
	Obliterative bronchiolitis (non-retransplant)	-0.132634978
	Constrictive bronchiolitis	-0.132634978
	Sarcoidosis with PA mean pressure greater than 30 mm Hg	0.0561853179859775
	Pulmonary fibrosis, other	0.046504644
Functional Status	No assistance needed with activities of daily living	-0.005304128
	Some or total assistance needed with activities of daily living	0.074378407
Six-minute-walk distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	Less than 200 feet	-0.0002535116049789 x (200 - Six-minute-walk distance) + 0.11168755
	At least 200 feet and less than 600 feet	-0.0002841805913329 x (Six-minute-walk distance - 200) + 0.11168755
	At least 600 feet and less than 800 feet	-0.0000049617083362 x (Six-minute-walk distance - 600) - 0.00198468
	At least 800 feet and less than 1,200 feet	-0.0001950464256370 x (Six-minute-walk distance - 800) - 0.00297703
	At least 1,200 feet and less than 1,600 feet	-0.0007428583659073 x (Six-minute-walk distance - 1200) - 0.08099560

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
	At least 1,600 feet	0.0035374143842919 x (Six-minute-walk distance - 1600) - 0.37813894

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-4*, then the composite allocation score calculation will substitute normal or least beneficial values to calculate the candidate's post-transplant outcomes score. *Table 21-7: Values Substituted for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes Score* lists the normal and least beneficial values that will be substituted.

Table 21-7: Values Substituted for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes Score

If this covariate's value:	Is:	Then the post-transplant outcomes score calculation will use this substituted value:
Cardiac index	Missing, or greater than 5	5.0 L/min/m^2
Assisted ventilation	Missing or expired	Continuous mechanical ventilation while hospitalized
Creatinine (serum) (mg/dL)	Missing, expired or greater than 1.6	1.6 mg/dL
Functional status	Missing or expired	Total assistance needed
Six-minute-walk distance	Missing or expired	200 feet
	Greater than 1,600	1,600 feet

21.2.B.2 Probabilities Used in Calculating Lung Post-Transplant Survival

Table 21-8: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1	0.999154	11	0.992107	21	0.988086	31	0.984705
2	0.998058	12	0.991806	22	0.987633	32	0.984048
3	0.997111	13	0.991154	23	0.98738	33	0.983592
4	0.996312	14	0.990802	24	0.986977	34	0.98344
5	0.995562	15	0.99025	25	0.986574	35	0.983238
6	0.995162	16	0.989747	26	0.986473	36	0.982731
7	0.994562	17	0.989294	27	0.986069	37	0.982478
8	0.994011	18	0.988942	28	0.985917	38	0.982225
9	0.99336	19	0.98864	29	0.985463	39	0.981616
10	0.992859	20	0.988287	30	0.984907	40	0.981363

t	$S_{TX}(t)$
41	0.981007
42	0.980957
43	0.980652
44	0.980297
45	0.980144
46	0.980043
47	0.97989
48	0.979687
49	0.979484
50	0.979484
51	0.979179
52	0.978772
53	0.978772
54	0.978467
55	0.978162
56	0.977857
57	0.977653
58	0.977347
59	0.977195
60	0.977042
61	0.976634
62	0.976431
63	0.976125
64	0.976074
65	0.975921
66	0.975717
67	0.975666
68	0.975513
69	0.975411
70	0.975156
71	0.974748
72	0.974645
73	0.974441
74	0.974339
75	0.974339
76	0.974339
77	0.974288
78	0.974186
79	0.974083
80	0.973981
81	0.973879
82	0.973828

t	$S_{TX}(t)$
83	0.973726
84	0.973675
85	0.973572
86	0.97347
87	0.973214
88	0.972908
89	0.972703
90	0.972549
91	0.972549
92	0.972396
93	0.972396
94	0.972242
95	0.971884
96	0.971884
97	0.971782
98	0.971474
99	0.971423
100	0.971064
101	0.970808
102	0.970757
103	0.970552
104	0.970398
105	0.970398
106	0.970346
107	0.970193
108	0.969987
109	0.969885
110	0.969731
111	0.969474
112	0.969423
113	0.969269
114	0.969115
115	0.968755
116	0.968652
117	0.968395
118	0.968292
119	0.967984
120	0.967932
121	0.967675
122	0.967572
123	0.967469
124	0.967315

t	$S_{TX}(t)$
125	0.967161
126	0.967161
127	0.966955
128	0.966903
129	0.966852
130	0.966749
131	0.966697
132	0.966646
133	0.966543
134	0.966543
135	0.96644
136	0.966388
137	0.966131
138	0.965925
139	0.965925
140	0.965615
141	0.965461
142	0.965358
143	0.965254
144	0.965151
145	0.964842
146	0.96479
147	0.964481
148	0.964377
149	0.964223
150	0.964068
151	0.963913
152	0.963913
153	0.963655
154	0.963345
155	0.963241
156	0.963138
157	0.963035
158	0.96288
159	0.962724
160	0.962621
161	0.962518
162	0.962414
163	0.962311
164	0.962207
165	0.962052
166	0.961845

t	$S_{TX}(t)$
167	0.961741
168	0.961638
169	0.961586
170	0.961483
171	0.961275
172	0.961224
173	0.961017
174	0.960913
175	0.960706
176	0.96055
177	0.960447
178	0.960239
179	0.960187
180	0.960032
181	0.959928
182	0.959876
183	0.959565
184	0.959513
185	0.959358
186	0.95915
187	0.958994
188	0.958943
189	0.958839
190	0.958579
191	0.958475
192	0.958164
193	0.958008
194	0.957852
195	0.9578
196	0.9578
197	0.957644
198	0.957384
199	0.957176
200	0.957072
201	0.956864
202	0.956604
203	0.956396
204	0.95624
205	0.955928
206	0.955824
207	0.955772
208	0.955511

t	$S_{TX}(t)$
209	0.955303
210	0.955147
211	0.954886
212	0.95473
213	0.954678
214	0.954469
215	0.954313
216	0.954156
217	0.954052
218	0.954
219	0.953843
220	0.953739
221	0.953634
222	0.953478
223	0.953269
224	0.95306
225	0.952956
226	0.952799
227	0.952642
228	0.952329
229	0.952277
230	0.952016
231	0.951963
232	0.951702
233	0.95165
234	0.95144
235	0.951074
236	0.950813
237	0.950603
238	0.950446
239	0.950342
240	0.950342
241	0.950289
242	0.950185
243	0.950028
244	0.949923
245	0.949713
246	0.949713
247	0.949556
248	0.949556
249	0.949399
250	0.949137

t	$S_{TX}(t)$
251	0.949085
252	0.949032
253	0.94898
254	0.94877
255	0.948613
256	0.948193
257	0.947931
258	0.947826
259	0.947774
260	0.947616
261	0.947459
262	0.947406
263	0.947301
264	0.947196
265	0.946986
266	0.946881
267	0.946724
268	0.946566
269	0.946461
270	0.946198
271	0.945935
272	0.945935
273	0.94583
274	0.945778
275	0.945567
276	0.945462
277	0.94541
278	0.945199
279	0.945147
280	0.944989
281	0.944936
282	0.944831
283	0.94462
284	0.94462
285	0.944515
286	0.944357
287	0.944094
288	0.943936
289	0.943831
290	0.943673
291	0.943356
292	0.943198

t	$S_{TX}(t)$
293	0.942987
294	0.942882
295	0.942777
296	0.942777
297	0.942513
298	0.94246
299	0.942302
300	0.942196
301	0.941985
302	0.941985
303	0.941827
304	0.941774
305	0.94151
306	0.941405
307	0.941352
308	0.941193
309	0.940982
310	0.940876
311	0.940771
312	0.940559
313	0.9404
314	0.940295
315	0.940189
316	0.94003
317	0.939925
318	0.939766
319	0.939713
320	0.93966
321	0.939607
322	0.939501
323	0.939342
324	0.939342
325	0.939078
326	0.938972
327	0.938919
328	0.938707
329	0.938495
330	0.938389
331	0.938177
332	0.938124
333	0.937913
334	0.937701

t	$S_{TX}(t)$
335	0.937435
336	0.93717
337	0.936905
338	0.93664
339	0.936534
340	0.936428
341	0.936162
342	0.936056
343	0.936003
344	0.93595
345	0.935897
346	0.935737
347	0.935631
348	0.935578
349	0.935472
350	0.935259
351	0.935259
352	0.935047
353	0.934887
354	0.934728
355	0.934728
356	0.934675
357	0.934462
358	0.934196
359	0.934037
360	0.933877
361	0.933664
362	0.933664
363	0.933664
364	0.933664
365	0.933664
366	0.933505
367	0.933239
368	0.932866
369	0.932653
370	0.932546
371	0.93228
372	0.931854
373	0.931801
374	0.931747
375	0.931641
376	0.931481

t	$S_{TX}(t)$
377	0.931374
378	0.931267
379	0.930947
380	0.930947
381	0.930787
382	0.930627
383	0.930147
384	0.929987
385	0.929666
386	0.929506
387	0.929453
388	0.929292
389	0.929079
390	0.928865
391	0.928811
392	0.928704
393	0.928277
394	0.92817
395	0.927956
396	0.927849
397	0.927421
398	0.927368
399	0.927207
400	0.926993
401	0.926886
402	0.926725
403	0.926725
404	0.926618
405	0.926457
406	0.926189
407	0.926136
408	0.925975
409	0.925921
410	0.925868
411	0.925707
412	0.925439
413	0.925439
414	0.925332
415	0.925332
416	0.925117
417	0.925063
418	0.924956
419	0.924634
420	0.924634
421	0.924581
422	0.92442
423	0.924312
424	0.924205
425	0.923829
426	0.92356
427	0.923507
428	0.923292
429	0.923184
430	0.923184
431	0.92313
432	0.922969
433	0.922915
434	0.922646
435	0.922485
436	0.922377
437	0.922108
438	0.922001
439	0.921839
440	0.92157
441	0.921409
442	0.921355
443	0.921301
444	0.921247
445	0.921193
446	0.921139
447	0.920816
448	0.920708
449	0.920493
450	0.920277
451	0.920223
452	0.920062
453	0.9199
454	0.919846
455	0.919576
456	0.919361
457	0.919199
458	0.919091
459	0.918983
460	0.918821
461	0.918821
462	0.918659
463	0.918389
464	0.918173
465	0.918119
466	0.917795
467	0.917632
468	0.917416
469	0.917308
470	0.917254
471	0.917092
472	0.916875
473	0.916821
474	0.916659
475	0.916442
476	0.916442
477	0.916388
478	0.91628
479	0.916172
480	0.916117
481	0.916009
482	0.915955
483	0.915793
484	0.915522
485	0.915413
486	0.915413
487	0.915142
488	0.915088
489	0.91498
490	0.91498
491	0.91498
492	0.91498
493	0.914926
494	0.914709
495	0.914655
496	0.914492
497	0.914221
498	0.914112
499	0.914058
500	0.913949
501	0.913841
502	0.913732
503	0.913461
504	0.913352
505	0.913243
506	0.913026
507	0.912972
508	0.912809
509	0.912592
510	0.912429
511	0.912265
512	0.912157
513	0.911939
514	0.911776
515	0.911613
516	0.911232
517	0.911069
518	0.910797
519	0.910688
520	0.910525
521	0.910525
522	0.910471
523	0.910362
524	0.910253
525	0.910144
526	0.909926
527	0.909872
528	0.909817
529	0.909817
530	0.909599
531	0.90949
532	0.909436
533	0.909381
534	0.909381
535	0.909272
536	0.909163
537	0.908945
538	0.908836
539	0.908618
540	0.908618
541	0.908455
542	0.908291
543	0.908073
544	0.908018

t	$S_{TX}(t)$
545	0.9078
546	0.907745
547	0.907636
548	0.907527
549	0.907472
550	0.907254
551	0.907144
552	0.906926
553	0.906871
554	0.906817
555	0.906598
556	0.90627
557	0.906161
558	0.906161
559	0.906051
560	0.905723
561	0.905559
562	0.90534
563	0.905231
564	0.905121
565	0.905121
566	0.905121
567	0.904902
568	0.904738
569	0.904574
570	0.90441
571	0.904355
572	0.904245
573	0.904136
574	0.903971
575	0.903862
576	0.903643
577	0.903533
578	0.903259
579	0.903149
580	0.903094
581	0.902875
582	0.902875
583	0.902765
584	0.902655
585	0.90249
586	0.902269

t	$S_{TX}(t)$
587	0.902159
588	0.902104
589	0.902049
590	0.901938
591	0.901883
592	0.901773
593	0.901662
594	0.901607
595	0.901551
596	0.901496
597	0.901496
598	0.90133
599	0.90133
600	0.901274
601	0.901274
602	0.901051
603	0.900829
604	0.900773
605	0.900662
606	0.90055
607	0.900438
608	0.900326
609	0.90027
610	0.900103
611	0.900103
612	0.899934
613	0.89971
614	0.899654
615	0.899485
616	0.899317
617	0.899204
618	0.899148
619	0.899035
620	0.898979
621	0.898866
622	0.898866
623	0.89864
624	0.898527
625	0.898414
626	0.898414
627	0.898187
628	0.898017

t	$S_{TX}(t)$
629	0.897903
630	0.89779
631	0.897562
632	0.897505
633	0.897448
634	0.897277
635	0.897163
636	0.896992
637	0.896935
638	0.896878
639	0.89682
640	0.89682
641	0.896591
642	0.896534
643	0.896477
644	0.896247
645	0.896075
646	0.895845
647	0.895729
648	0.895556
649	0.895441
650	0.895268
651	0.89521
652	0.895152
653	0.895152
654	0.894978
655	0.894746
656	0.894688
657	0.894688
658	0.894572
659	0.894514
660	0.894455
661	0.894222
662	0.893988
663	0.893872
664	0.893638
665	0.893579
666	0.893404
667	0.893345
668	0.893287
669	0.893228
670	0.893052

t	$S_{TX}(t)$
671	0.892935
672	0.892641
673	0.892641
674	0.892523
675	0.892405
676	0.892346
677	0.89211
678	0.892051
679	0.891874
680	0.891756
681	0.891519
682	0.89146
683	0.89146
684	0.891341
685	0.891162
686	0.890805
687	0.890567
688	0.890507
689	0.890448
690	0.890448
691	0.890328
692	0.890268
693	0.890149
694	0.890089
695	0.890089
696	0.889669
697	0.889548
698	0.889368
699	0.889187
700	0.889067
701	0.888946
702	0.888946
703	0.888825
704	0.888705
705	0.888584
706	0.888341
707	0.88816
708	0.888038
709	0.887856
710	0.887735
711	0.887613
712	0.887309

t	$S_{TX}(t)$
713	0.887188
714	0.887188
715	0.887005
716	0.886883
717	0.886883
718	0.886883
719	0.886821
720	0.886821
721	0.886821
722	0.886637
723	0.886515
724	0.886453
725	0.886207
726	0.886146
727	0.886084
728	0.886084
729	0.886022
730	0.885961
731	0.885899
732	0.885775
733	0.885528
734	0.885528
735	0.885404
736	0.885404
737	0.885032
738	0.884845
739	0.884721
740	0.884597
741	0.884597
742	0.884285
743	0.884035
744	0.88366
745	0.883472
746	0.88316
747	0.883097
748	0.882721
749	0.882532
750	0.88247
751	0.882407
752	0.882344
753	0.882092
754	0.882029

t	$S_{TX}(t)$
755	0.881902
756	0.881839
757	0.881713
758	0.88165
759	0.881586
760	0.881333
761	0.881142
762	0.881015
763	0.880888
764	0.880825
765	0.880761
766	0.880634
767	0.880315
768	0.880187
769	0.880187
770	0.88006
771	0.879932
772	0.879676
773	0.87942
774	0.879356
775	0.879292
776	0.8791
777	0.878971
778	0.878779
779	0.878586
780	0.878457
781	0.878264
782	0.878199
783	0.878199
784	0.87807
785	0.87794
786	0.877811
787	0.877811
788	0.877681
789	0.877616
790	0.877551
791	0.877551
792	0.877291
793	0.877226
794	0.877161
795	0.877031
796	0.876835

t	$S_{TX}(t)$
797	0.876639
798	0.876443
799	0.876443
800	0.876312
801	0.876312
802	0.876246
803	0.876115
804	0.876049
805	0.875918
806	0.875786
807	0.875654
808	0.875522
809	0.87539
810	0.875192
811	0.874795
812	0.87453
813	0.874398
814	0.874332
815	0.874265
816	0.874265
817	0.874133
818	0.873933
819	0.873866
820	0.8736
821	0.8734
822	0.8734
823	0.873199
824	0.873066
825	0.872865
826	0.872664
827	0.872462
828	0.872395
829	0.872261
830	0.872193
831	0.872059
832	0.871856
833	0.871519
834	0.871384
835	0.871249
836	0.871046
837	0.870775
838	0.870707

t	$S_{TX}(t)$
839	0.870435
840	0.870367
841	0.870231
842	0.869755
843	0.869619
844	0.869482
845	0.869414
846	0.869209
847	0.869141
848	0.868936
849	0.868799
850	0.868593
851	0.868456
852	0.868319
853	0.86825
854	0.868112
855	0.868112
856	0.867768
857	0.867768
858	0.867768
859	0.867561
860	0.867422
861	0.867353
862	0.867215
863	0.867215
864	0.867215
865	0.867006
866	0.866937
867	0.866867
868	0.866797
869	0.866728
870	0.866588
871	0.866518
872	0.866518
873	0.866379
874	0.866169
875	0.865889
876	0.865748
877	0.865608
878	0.865467
879	0.865397
880	0.865397

t	$S_{TX}(t)$
881	0.865186
882	0.865044
883	0.865044
884	0.864974
885	0.864903
886	0.864832
887	0.86469
888	0.864619
889	0.864619
890	0.864477
891	0.864335
892	0.864335
893	0.864192
894	0.864121
895	0.864049
896	0.863978
897	0.863978
898	0.863978
899	0.863978
900	0.863691
901	0.863691
902	0.863691
903	0.863619
904	0.863474
905	0.863402
906	0.86333
907	0.863186
908	0.862896
909	0.862607
910	0.862317
911	0.8621
912	0.862027
913	0.862027
914	0.861881
915	0.861809
916	0.86159
917	0.861517
918	0.861444
919	0.861078
920	0.861078
921	0.860785
922	0.860712

t	$S_{TX}(t)$
923	0.860712
924	0.860492
925	0.860345
926	0.860197
927	0.860124
928	0.859976
929	0.859828
930	0.859828
931	0.85968
932	0.859606
933	0.859458
934	0.859384
935	0.859384
936	0.859235
937	0.859012
938	0.859012
939	0.858863
940	0.858863
941	0.858714
942	0.85849
943	0.85849
944	0.858266
945	0.858191
946	0.857966
947	0.857891
948	0.857665
949	0.85759
950	0.85759
951	0.85744
952	0.85744
953	0.857364
954	0.857063
955	0.856987
956	0.85676
957	0.856685
958	0.856305
959	0.856229
960	0.856229
961	0.856153
962	0.856077
963	0.855772
964	0.855619

t	$S_{TX}(t)$
965	0.855619
966	0.855543
967	0.855313
968	0.855313
969	0.85516
970	0.855083
971	0.85493
972	0.854699
973	0.854622
974	0.854622
975	0.854545
976	0.854468
977	0.854237
978	0.854159
979	0.854159
980	0.854082
981	0.854005
982	0.853927
983	0.853694
984	0.853616
985	0.853539
986	0.853539
987	0.853383
988	0.853305
989	0.853149
990	0.853071
991	0.852914
992	0.852836
993	0.852836
994	0.852758
995	0.852679
996	0.852601
997	0.852601
998	0.852286
999	0.852049
1000	0.852049
1001	0.852049
1002	0.851812
1003	0.851495
1004	0.851336
1005	0.851336
1006	0.851257

t	$S_{TX}(t)$
1007	0.851257
1008	0.851098
1009	0.851018
1010	0.851018
1011	0.851018
1012	0.850858
1013	0.850778
1014	0.850778
1015	0.850778
1016	0.850618
1017	0.850538
1018	0.850217
1019	0.849895
1020	0.849895
1021	0.849895
1022	0.849815
1023	0.849492
1024	0.849492
1025	0.849492
1026	0.849492
1027	0.84933
1028	0.84933
1029	0.84933
1030	0.849249
1031	0.849086
1032	0.848842
1033	0.848679
1034	0.848598
1035	0.848353
1036	0.848109
1037	0.848109
1038	0.847782
1039	0.847619
1040	0.847619
1041	0.847455
1042	0.847373
1043	0.84729
1044	0.847126
1045	0.846961
1046	0.846879
1047	0.846714
1048	0.846549

t	$S_{TX}(t)$
1049	0.846301
1050	0.84597
1051	0.845804
1052	0.845638
1053	0.845389
1054	0.845389
1055	0.845389
1056	0.845222
1057	0.845138
1058	0.845138
1059	0.845138
1060	0.844971
1061	0.844971
1062	0.844887
1063	0.844887
1064	0.844719
1065	0.844635
1066	0.844635
1067	0.84455
1068	0.844466
1069	0.844466
1070	0.844128
1071	0.844044
1072	0.844044
1073	0.843959
1074	0.843959
1075	0.843789
1076	0.84362
1077	0.84362
1078	0.843535
1079	0.843364
1080	0.843194
1081	0.843023
1082	0.843023
1083	0.843023
1084	0.842851
1085	0.842508
1086	0.842337
1087	0.842251
1088	0.841993
1089	0.841907
1090	0.841907

t	$S_{TX}(t)$
1091	0.841821
1092	0.841734
1093	0.841561
1094	0.841389
1095	0.841129
1096	0.841042
1097	0.840956
1098	0.840869
1099	0.840695
1100	0.840695
1101	0.840608
1102	0.840434
1103	0.840259
1104	0.839735
1105	0.839648
1106	0.839473
1107	0.839385
1108	0.839122
1109	0.839034
1110	0.838946
1111	0.838946
1112	0.838858
1113	0.838858
1114	0.838682
1115	0.838505
1116	0.838417
1117	0.838328
1118	0.838151
1119	0.838151
1120	0.837973
1121	0.837795
1122	0.837795
1123	0.837706
1124	0.837706
1125	0.837706
1126	0.837527
1127	0.837437
1128	0.837437
1129	0.837257
1130	0.836987
1131	0.836896
1132	0.836806

t	$S_{TX}(t)$
1133	0.836806
1134	0.836535
1135	0.836263
1136	0.835901
1137	0.835719
1138	0.835719
1139	0.835628
1140	0.835537
1141	0.835446
1142	0.835082
1143	0.835082
1144	0.834899
1145	0.834899
1146	0.834532
1147	0.834532
1148	0.834256
1149	0.834256
1150	0.834072
1151	0.834072
1152	0.834072
1153	0.833795
1154	0.83361
1155	0.833518
1156	0.833147
1157	0.833147
1158	0.833055
1159	0.832869
1160	0.832683
1161	0.832683
1162	0.83231
1163	0.832217
1164	0.832124
1165	0.832124
1166	0.831843
1167	0.831655
1168	0.831561
1169	0.831186
1170	0.831092
1171	0.830997
1172	0.830997
1173	0.830997
1174	0.830997

t	$S_{TX}(t)$
1175	0.830808
1176	0.830524
1177	0.830524
1178	0.830429
1179	0.830144
1180	0.830049
1181	0.830049
1182	0.829858
1183	0.829763
1184	0.829763
1185	0.829667
1186	0.829571
1187	0.829379
1188	0.829187
1189	0.82861
1190	0.82861
1191	0.828417
1192	0.828224
1193	0.827837
1194	0.827643
1195	0.827546
1196	0.827546
1197	0.827449
1198	0.827449
1199	0.827254
1200	0.827059
1201	0.826961
1202	0.826863
1203	0.826765
1204	0.826569
1205	0.826373
1206	0.826373
1207	0.826373
1208	0.826373
1209	0.826373
1210	0.826275
1211	0.826078
1212	0.825782
1213	0.825585
1214	0.825487
1215	0.825487
1216	0.825487

t	$S_{TX}(t)$
1217	0.825487
1218	0.825387
1219	0.825288
1220	0.824991
1221	0.824891
1222	0.824891
1223	0.824891
1224	0.824692
1225	0.824392
1226	0.824392
1227	0.824292
1228	0.823992
1229	0.823791
1230	0.823791
1231	0.823791
1232	0.823791
1233	0.82369
1234	0.823489
1235	0.823187
1236	0.822884
1237	0.822884
1238	0.822884
1239	0.822884
1240	0.822681
1241	0.822579
1242	0.822274
1243	0.822172
1244	0.82207
1245	0.82207
1246	0.821968
1247	0.821968
1248	0.821456
1249	0.821149
1250	0.821149
1251	0.821149
1252	0.821149
1253	0.82084
1254	0.820634
1255	0.82053
1256	0.82022
1257	0.82022
1258	0.82022
1259	0.820116
1260	0.819804
1261	0.819804
1262	0.8197
1263	0.819595
1264	0.819387
1265	0.819387
1266	0.819177
1267	0.818968
1268	0.818863
1269	0.818653
1270	0.818548
1271	0.818442
1272	0.818126
1273	0.818126
1274	0.818021
1275	0.817809
1276	0.817598
1277	0.817492
1278	0.817386
1279	0.817173
1280	0.817067
1281	0.817067
1282	0.817067
1283	0.817067
1284	0.816854
1285	0.81664
1286	0.81664
1287	0.81664
1288	0.816426
1289	0.816426
1290	0.816211
1291	0.816103
1292	0.816103
1293	0.815887
1294	0.81567
1295	0.815562
1296	0.815562
1297	0.815562
1298	0.815453
1299	0.815236
1300	0.815236
1301	0.815236
1302	0.815236
1303	0.815236
1304	0.815236
1305	0.814798
1306	0.814798
1307	0.814579
1308	0.814359
1309	0.814359
1310	0.814029
1311	0.814029
1312	0.813809
1313	0.813809
1314	0.813809
1315	0.813809
1316	0.813698
1317	0.813587
1318	0.813365
1319	0.813365
1320	0.813142
1321	0.813142
1322	0.813142
1323	0.813142
1324	0.812918
1325	0.812918
1326	0.812806
1327	0.812806
1328	0.812581
1329	0.812468
1330	0.812468
1331	0.812356
1332	0.812356
1333	0.812356
1334	0.812243
1335	0.812243
1336	0.81213
1337	0.811903
1338	0.811903
1339	0.811561
1340	0.811446
1341	0.811332
1342	0.811217
1343	0.810988
1344	0.810873
1345	0.810528
1346	0.810298
1347	0.810183
1348	0.810068
1349	0.809953
1350	0.809722
1351	0.809722
1352	0.809722
1353	0.809374
1354	0.809258
1355	0.809142
1356	0.809025
1357	0.808909
1358	0.808793
1359	0.808676
1360	0.808676
1361	0.808676
1362	0.808442
1363	0.80809
1364	0.80809
1365	0.807972
1366	0.807855
1367	0.807855
1368	0.807737
1369	0.807737
1370	0.807737
1371	0.807618
1372	0.807618
1373	0.807618
1374	0.8075
1375	0.807143
1376	0.807024
1377	0.806905
1378	0.806905
1379	0.806905
1380	0.806905
1381	0.806786
1382	0.806786
1383	0.806546
1384	0.806427

t	$S_{TX}(t)$
1385	0.806187
1386	0.806067
1387	0.805826
1388	0.805586
1389	0.805586
1390	0.805344
1391	0.805223
1392	0.805223
1393	0.805102
1394	0.805102
1395	0.805102
1396	0.804981
1397	0.804737
1398	0.804615
1399	0.804494
1400	0.804494
1401	0.804371
1402	0.804249
1403	0.804249
1404	0.804126
1405	0.803635
1406	0.803635
1407	0.803635
1408	0.803512
1409	0.803265
1410	0.803265
1411	0.803141
1412	0.803141
1413	0.803017
1414	0.802893
1415	0.802395
1416	0.802395
1417	0.802145
1418	0.801895
1419	0.801895
1420	0.801895
1421	0.801644
1422	0.801519
1423	0.801141
1424	0.801141
1425	0.801141
1426	0.801015
1427	0.800636
1428	0.800256
1429	0.800003
1430	0.800003
1431	0.800003
1432	0.800003
1433	0.800003
1434	0.799875
1435	0.79962
1436	0.799493
1437	0.799365
1438	0.799365
1439	0.799365
1440	0.799365
1441	0.799365
1442	0.799108
1443	0.799108
1444	0.799108
1445	0.798849
1446	0.79872
1447	0.79872
1448	0.798332
1449	0.798332
1450	0.798072
1451	0.797942
1452	0.797682
1453	0.797682
1454	0.79729
1455	0.79729
1456	0.796897
1457	0.796765
1458	0.796634
1459	0.796502
1460	0.796502
1461	0.796238
1462	0.796238
1463	0.796105
1464	0.795708
1465	0.795708
1466	0.795441
1467	0.795174
1468	0.795174
1469	0.795174
1470	0.79504
1471	0.794638
1472	0.794503
1473	0.794503
1474	0.794368
1475	0.794368
1476	0.794233
1477	0.793827
1478	0.793691
1479	0.793419
1480	0.793419
1481	0.793147
1482	0.79301
1483	0.792737
1484	0.792737
1485	0.792737
1486	0.792737
1487	0.792464
1488	0.792464
1489	0.792464
1490	0.792189
1491	0.792052
1492	0.791776
1493	0.791776
1494	0.791362
1495	0.791223
1496	0.791223
1497	0.791084
1498	0.791084
1499	0.791084
1500	0.791084
1501	0.790945
1502	0.790805
1503	0.790665
1504	0.790665
1505	0.790524
1506	0.790524
1507	0.790524
1508	0.790524
1509	0.790524
1510	0.790383
1511	0.790241
1512	0.790241
1513	0.790098
1514	0.790098
1515	0.790098
1516	0.789813
1517	0.789813
1518	0.789813
1519	0.789813
1520	0.789669
1521	0.789525
1522	0.789237
1523	0.789237
1524	0.789237
1525	0.789092
1526	0.788947
1527	0.788947
1528	0.788947
1529	0.788654
1530	0.788654
1531	0.788361
1532	0.788215
1533	0.787921
1534	0.787921
1535	0.787627
1536	0.787479
1537	0.787479
1538	0.787479
1539	0.787479
1540	0.787035
1541	0.787035
1542	0.787035
1543	0.787035
1544	0.787035
1545	0.786736
1546	0.786287
1547	0.786137
1548	0.786137
1549	0.785986
1550	0.785835
1551	0.785684
1552	0.785533

t	$S_{TX}(t)$
1553	0.785533
1554	0.785381
1555	0.785381
1556	0.785076
1557	0.785076
1558	0.784923
1559	0.784769
1560	0.784769
1561	0.784769
1562	0.784462
1563	0.784308
1564	0.784308
1565	0.784153
1566	0.784153
1567	0.784153
1568	0.784153
1569	0.784153
1570	0.784153
1571	0.784153
1572	0.783997
1573	0.783997
1574	0.783997
1575	0.783997
1576	0.783839
1577	0.783682
1578	0.783524
1579	0.783524
1580	0.783366
1581	0.783366
1582	0.783366
1583	0.783207
1584	0.783207
1585	0.783047
1586	0.783047
1587	0.783047
1588	0.783047
1589	0.782887
1590	0.782887
1591	0.782887
1592	0.782887
1593	0.782887
1594	0.782887

t	$S_{TX}(t)$
1595	0.782887
1596	0.782887
1597	0.782887
1598	0.782887
1599	0.782887
1600	0.782887
1601	0.782887
1602	0.782887
1603	0.782723
1604	0.782723
1605	0.782723
1606	0.782559
1607	0.782559
1608	0.782559
1609	0.782559
1610	0.782559
1611	0.782228
1612	0.782228
1613	0.782228
1614	0.782228
1615	0.781895
1616	0.781895
1617	0.781895
1618	0.781895
1619	0.781895
1620	0.781895
1621	0.781895
1622	0.781726
1623	0.781726
1624	0.781558
1625	0.781221
1626	0.781052
1627	0.781052
1628	0.780544
1629	0.780205
1630	0.780035
1631	0.780035
1632	0.780035
1633	0.780035
1634	0.780035
1635	0.780035
1636	0.780035

t	$S_{TX}(t)$
1637	0.779691
1638	0.779691
1639	0.779691
1640	0.779345
1641	0.779172
1642	0.778825
1643	0.778825
1644	0.778652
1645	0.778652
1646	0.778652
1647	0.778652
1648	0.778652
1649	0.778652
1650	0.778652
1651	0.778475
1652	0.778475
1653	0.778298
1654	0.777943
1655	0.777943
1656	0.777943
1657	0.777943
1658	0.777765
1659	0.777765
1660	0.777765
1661	0.777765
1662	0.777765
1663	0.777765
1664	0.777765
1665	0.777584
1666	0.777584
1667	0.777584
1668	0.777584
1669	0.777584
1670	0.777402
1671	0.777402
1672	0.777402
1673	0.777219
1674	0.777219
1675	0.776668
1676	0.776668
1677	0.776301
1678	0.776116

t	$S_{TX}(t)$
1679	0.776116
1680	0.775931
1681	0.775931
1682	0.77556
1683	0.77556
1684	0.77556
1685	0.775373
1686	0.774998
1687	0.774998
1688	0.774809
1689	0.774809
1690	0.77462
1691	0.77462
1692	0.77462
1693	0.77462
1694	0.77443
1695	0.774048
1696	0.774048
1697	0.773856
1698	0.773664
1699	0.773471
1700	0.773471
1701	0.773471
1702	0.773471
1703	0.773277
1704	0.773277
1705	0.773083
1706	0.773083
1707	0.772692
1708	0.772497
1709	0.772497
1710	0.772497
1711	0.772497
1712	0.772497
1713	0.772497
1714	0.7723
1715	0.7723
1716	0.7723
1717	0.772101
1718	0.771505
1719	0.771505
1720	0.770906

t	$S_{TX}(t)$
1721	0.770906
1722	0.770505
1723	0.770304
1724	0.770103
1725	0.769699
1726	0.769699
1727	0.769699
1728	0.769699
1729	0.769699
1730	0.769496
1731	0.769293
1732	0.769293
1733	0.769293
1734	0.769293
1735	0.769088
1736	0.768883
1737	0.768883
1738	0.768678
1739	0.768472
1740	0.768472
1741	0.768472
1742	0.768265
1743	0.768265
1744	0.76785
1745	0.76785
1746	0.767434
1747	0.766599
1748	0.766599
1749	0.766389
1750	0.765758
1751	0.765758
1752	0.765547
1753	0.765125
1754	0.764913
1755	0.764913
1756	0.764701
1757	0.764701
1758	0.764701
1759	0.764701
1760	0.764487
1761	0.764487
1762	0.764487

t	$S_{TX}(t)$
1763	0.764487
1764	0.764057
1765	0.763412
1766	0.763196
1767	0.763196
1768	0.763196
1769	0.763196
1770	0.763196
1771	0.763196
1772	0.76276
1773	0.762542
1774	0.762542
1775	0.762323
1776	0.761884
1777	0.761664
1778	0.761224
1779	0.761003
1780	0.760782
1781	0.760782
1782	0.760782
1783	0.760337
1784	0.760337 713
1785	0.760337
1786	0.760337
1787	0.760337
1788	0.759442
1789	0.759217
1790	0.759217
1791	0.759217
1792	0.759217
1793	0.759217
1794	0.759217
1795	0.758991
1796	0.758991
1797	0.758991
1798	0.758991
1799	0.758762
1800	0.758533
1801	0.758533
1802	0.758303
1803	0.758303
1804	0.758303

t	$S_{TX}(t)$
1805	0.758303
1806	0.758303
1807	0.758303
1808	0.75807
1809	0.757837
1810	0.757837
1811	0.757837
1812	0.757602
1813	0.757602
1814	0.757602
1815	0.757602
1816	0.757602
1817	0.757602
1818	0.757365
1819	0.757365
1820	0.757365
1821	0.756888
1822	0.756888
1823	0.756888
1824	0.756409
1825	0.756169

21.2.C Values Used in the Calculation of Biological Disadvantages

21.2.C.1 Probability of Incompatible Lung Donors Based on Height

Table 21-9 lists the proportion of incompatible donors based on the candidate's height and diagnosis group.

Table 21-9 Proportion of Incompatible Donors Based on Lung Height

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
63 or less	0.9949	0.9949	0.9949
64	0.9916	0.9949	0.9949
65	0.9916	0.9949	0.9949
66	0.9899	0.9949	0.9949
67	0.9882	0.9949	0.9949
68	0.9882	0.9949	0.9949
69	0.9882	0.9916	0.9949
70	0.9882	0.9916	0.9949
71	0.9866	0.9882	0.9916
72	0.9866	0.9882	0.9916
73	0.9849	0.9882	0.9899
74	0.9849	0.9882	0.9882
75	0.9849	0.9882	0.9882
76	0.9866	0.9866	0.9882
77	0.9849	0.9866	0.9882
78	0.9849	0.9849	0.9866
79	0.9849	0.9849	0.9866
80	0.9849	0.9866	0.9849
81	0.9849	0.9866	0.9849
82	0.9866	0.9849	0.9849
83	0.9866	0.9849	0.9849
84	0.9882	0.9849	0.9833
85	0.9882	0.9849	0.9849
86	0.9882	0.9866	0.9849
87	0.9849	0.9866	0.9849
88	0.9849	0.9882	0.9849

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
89	0.9849	0.9882	0.9849
90	0.9849	0.9882	0.9849
91	0.9849	0.9882	0.9866
92	0.9833	0.9849	0.9866
93	0.9833	0.9849	0.9882
94	0.9816	0.9849	0.9849
95	0.9816	0.9849	0.9849
96	0.9816	0.9849	0.9849
97	0.9816	0.9833	0.9849
98	0.9816	0.9833	0.9849
99	0.9799	0.9816	0.9833
100	0.9833	0.9816	0.9833
101	0.9833	0.9816	0.9816
102	0.9866	0.9816	0.9816
103	0.9866	0.9816	0.9816
104	0.9866	0.9833	0.9816
105	0.9866	0.9833	0.9816
106	0.9866	0.9849	0.9799
107	0.9866	0.9866	0.9799
108	0.9882	0.9866	0.9799
109	0.9882	0.9866	0.9833
110	0.9849	0.9866	0.9833
111	0.9849	0.9882	0.9849
112	0.9833	0.9866	0.9866
113	0.9833	0.9882	0.9866
114	0.9833	0.9882	0.9849
115	0.9799	0.9849	0.9849
116	0.9766	0.9849	0.9866
117	0.9701	0.9833	0.9833
118	0.9619	0.9833	0.9849
119	0.9603	0.9833	0.9833
120	0.9442	0.9799	0.9816
121	0.9394	0.9766	0.9816

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
122	0.9268	0.9652	0.9799
123	0.9206	0.9603	0.9766
124	0.9175	0.9603	0.9701
125	0.8825	0.9442	0.9619
126	0.8810	0.9394	0.9603
127	0.8247	0.9206	0.9442
128	0.7933	0.9206	0.9394
129	0.7879	0.9175	0.9268
130	0.7130	0.8825	0.9175
131	0.7118	0.8810	0.9144
132	0.6235	0.7986	0.8825
133	0.5776	0.7933	0.8810
134	0.5698	0.7892	0.8247
135	0.4756	0.7130	0.7919
136	0.4359	0.7105	0.7866
137	0.4220	0.6235	0.7118
138	0.3223	0.5776	0.7105
139	0.3129	0.5708	0.6235
140	0.2375	0.4435	0.5776
141	0.2106	0.4345	0.5698
142	0.2047	0.4220	0.4748
143	0.1359	0.3223	0.4352
144	0.1316	0.3129	0.4220
145	0.0998	0.2173	0.3223
146	0.0897	0.2091	0.3129
147	0.0865	0.2051	0.2375
148	0.0590	0.1359	0.2106
149	0.0576	0.1316	0.2047
150	0.0447	0.0910	0.1357
151	0.0388	0.0897	0.1314
152	0.0376	0.0869	0.0998
153	0.0226	0.0590	0.0893
154	0.0222	0.0576	0.0862

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
155	0.0161	0.0401	0.0587
156	0.0142	0.0390	0.0574
157	0.0134	0.0379	0.0447
158	0.0072	0.0227	0.0387
159	0.0070	0.0221	0.0373
160	0.0055	0.0143	0.0221
161	0.0051	0.0142	0.0217
162	0.0049	0.0137	0.0157
163	0.0045	0.0072	0.0137
164	0.0046	0.0070	0.0129
165	0.0046	0.0061	0.0067
166	0.0052	0.0051	0.0066
167	0.0052	0.0059	0.0053
168	0.0080	0.0046	0.0045
169	0.0082	0.0047	0.0043
170	0.0084	0.0061	0.0031
171	0.0133	0.0052	0.0031
172	0.0137	0.0073	0.0039
173	0.0163	0.0082	0.0036
174	0.0215	0.0084	0.0037
175	0.0224	0.0136	0.0049
176	0.0362	0.0136	0.0048
177	0.0378	0.0144	0.0068
178	0.0438	0.0215	0.0079
179	0.0617	0.0224	0.0081
180	0.0640	0.0361	0.0132
181	0.0939	0.0375	0.0135
182	0.0955	0.0388	0.0142
183	0.1090	0.0617	0.0215
184	0.1427	0.0639	0.0224
185	0.1458	0.0939	0.0359
186	0.2008	0.0953	0.0373
187	0.2084	0.0987	0.0386

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
188	0.2128	0.1427	0.0617
189	0.3189	0.1458	0.0639
190	0.3256	0.1823	0.0939
191	0.4397	0.2062	0.0953
192	0.4473	0.2124	0.0987
193	0.4589	0.3189	0.1427
194	0.6440	0.3250	0.1458
195	0.6539	0.4036	0.1823
196	0.7591	0.4435	0.2062
197	0.7668	0.4589	0.2124
198	0.7773	0.6440	0.3189
199	0.8795	0.6539	0.3250
200	0.8840	0.7154	0.4036
201	0.9021	0.7643	0.4435
202	0.9458	0.7773	0.4589
203	0.9458	0.8795	0.6440
204	0.9684	0.8825	0.6539
205	0.9750	0.8900	0.7154
206	0.9783	0.9458	0.7643
207	0.9882	0.9458	0.7773
208	0.9882	0.9684	0.8795
209	0.9949	0.9733	0.8825
210	0.9949	0.9750	0.8900
211	0.9949	0.9882	0.9458
212	0.9949	0.9882	0.9458
213	0.9966	0.9949	0.9684
214	1.0000	0.9949	0.9733
215	1.0000	0.9949	0.9750
216	1.0000	0.9949	0.9882
217	1.0000	0.9966	0.9882
218	1.0000	1.0000	0.9949
219	1.0000	1.0000	0.9949
220	1.0000	1.0000	0.9949

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
221	1.0000	1.0000	0.9949
222	1.0000	1.0000	0.9966
223 or more	1.0000	1.0000	1.0000

Repealed.

Lung Review Board Operational Guidelines

Overview

The purpose of the Lung Review Board (Review Board) is to provide fair, equitable, and prompt peer review of exception requests. The Review Board will review these exception requests and determine if the request is comparable to other candidates with the same score.

Representation

Policy 10.2 Lung Composite Score Exceptions sets the structure and composition of the Lung Review Board.

The membership of the Lung Review Board will be comprised of 12 individual lung transplant surgeons or lung transplant physicians. Each active lung transplant program shall have the opportunity to rotate onto the review board. Qualifications to serve on the Lung Review Board include:

- The review board representative must be employed at an active lung transplant program.
  - If a transplant hospital inactivates or withdraws its lung program, the review board representative from that hospital may not participate in the Review Board. The term of the transplant hospital's representative on the Review Board ends upon program's inactivation or withdrawal from the OPTN. Another eligible transplant program will be contacted at random and requested to put forth a representative and an alternate to replace the departed member. Should a transplant program reactivate, it may again have the opportunity to be represented on the LRB during future rotations.
  - It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the both the primary review board representative and the alternate from their program. Should a representative leave his transplant program, then the program's alternate representative will become the review board member and another alternate will be appointed. The departing member will be removed from the review board.
- Review board members serve a term of 2 years. Service terms will be staggered among the LRB members. This requirement is to preserve the continuity of the LRB and the efficiency of its operation. If additional LRB representatives are to be appointed to the LRB due to a change in the operational guidelines, the Chair of the OPTN Lung Transplantation Committee (Committee) will select the additional members and establish the terms of their initial appointment.
- At least 3 members represent active pediatric lung transplant programs.
- The Chair of the Committee will appoint a primary review board member to serve as the Review Board Chair for a 2-year term.

Representatives Responsibilities

Review board representatives must:

A. Vote within on all exception requests, and appeals according to the timelines set by policy.
B. Provide an explanation for the disapproval to the candidate's lung program when voting to not approve.
C. Notify the OPTN of any planned absences. Requests will not be assigned to representatives who are known to be unavailable to review requests.
D. Each review board member is required to appoint an alternate representative from his transplant program.

Voting Procedure

The OPTN Contractor will send the application or appeal to nine of the LRB members. If the assigned Review Board member has not voted within three days of when the OPTN Contractor sends the application or appeal to the LRB, then the OPTN Contractor will send the case to the alternate. Thereafter, the LRB alternate may vote on the application within two days of the OPTN Contractor sending the application to the LRB alternate.

The review board will review all exception requests prospectively. The candidate will not receive the exception score unless or until it is approved.

Review board representatives will have five days to vote and exception requests will be decided as follows:

If the vote is…	**The request is…**
Majority vote to approve	Approved
Majority vote to not approve	Denied
No majority met	Approved

A majority vote requires that more than half of the representatives who voted on the application agree.

Voting will close at the earliest of when:

- A majority of all eligible voters have voted to approve an exception request
- A majority of all eligible voters have voted not to approve an exception request
- The timeline elapses for the review board members to vote on the exception request.

Appeal Process

A candidate's lung program may appeal the review board's decision to deny an exception request within seven days of receiving the appeal denial notification. All representative comments of denied requests are provided to the lung program. The program must submit additional written information justifying or amending the requested exception and may include responses to the comments of dissenting review board representatives. This additional information will be provided to the review board representatives for further consideration.

Following a denial on an appeal to the Review Board, the candidate's lung program can appeal to the Committee. The lung program must appeal within 14 days of notification. The program can provide additional written information justifying the requested exception status to be sent to the Committee. The Committee will approve or not approve each appeal on the next scheduled Committee call following the request to the Committee

Appendix A: Glossary of Terms

The following terms are used throughout the proposal.

Attribute

Attributes are criteria we use to classify then sort and prioritize candidates. For example, in lung allocation, our criteria include medical urgency, travel mode, ischemic time, blood type compatibility, and others.

Classification-based framework

A classification-based framework groups similar candidates into classifications or groupings. We then sort candidates within those classifications. A candidate will only appear in the classification that is most beneficial to them. This is the framework currently used to allocate organs.

Cliff

Cliffs are an illustrative term to describe hard boundaries in the attributes used to prioritize candidates. For example, the zones used in concentric circles have hard boundaries at specific distances. Continuous distribution and the move to a points-based framework aim to smooth these hard boundaries.

Composite Allocation Score

The scoring system used to prioritize candidates on the match run. It ranges from 0-100 and is an aggregate of separate goal level scores.

Continuous Distribution

Continuous distribution was the phrase used in the 2018 Snyder article and by the Ad Hoc Geography Committee to describe a new framework for organ distribution. It utilizes points to prioritize candidates for organ transplant.

Distance

The distance between the donor hospital and transplant hospital is either the straight line or travel distance. Straight line distance is the current method for calculating distance and represents the shortest two points. Travel distance is the most likely distance that the organ would travel between two points. For example, a straight line distance would be the shortest distance between hospitals on either side of a body of water; whereas, the travel distance would be the distance that somebody might drive on the roads and bridges around the body of water.

Framework

A collection of policies and procedures used to distribute organs. Examples include concentric circles and continuous distribution.

Points

Points are awarded for each attribute. The total points within a single goal are equal to the score for that goal. The total points for all attributes are equal to the composite allocation score.

Points-based framework

A points-based framework gives each candidate a score or points. Organs are then offered in descending order based upon the candidate's score. This concept paper proposes a points-based framework for organ allocation.

Rating Scale

A rating scale describes how much preference is provided to candidates within each attribute. For example, if all else is equal, should a candidate with an LAS 80 receive twice as much priority as a candidate with an LAS 40? Applying the rating scale to each candidate's information and combining it with the weight of the attribute results in an overall composite score for prioritizing candidates.

Revealed Preference Analysis (RPA)

A revealed preference analysis looks at actual decisions to determine the implicit preferences of the decision maker. This is compared with a stated preference analysis (for example, AHP or DCE) that asks the decision maker to state their preferences in an experiment.

Score

A candidate is assigned a score for each goal. The score for a goal is equal to the total points for the attributes within that goal. The total of the scores for all goals is equal to the candidate's composite allocation score.

Stated Preference

A stated preference analysis asks participants to state their preferences in a pairwise comparison. AHP and DCE are examples of stated preference analysis.

Weight

Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. For example, should waitlist mortality be more or less important than post-transplant outcomes? Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.