

Briefing Paper

Modifications to the Distribution of Deceased Donor Lungs

OPTN/UNOS Thoracic Organ Transplantation Committee

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Modifications to the Distribution of Deceased Donor Lungs

<i>Affected Policies:</i>	<i>1.2: Definitions; 6.6.F: Allocation of Heart-Lungs; 10.2.A: Allocation Exception for Sensitized Patients; and 10.4: Lung Allocation Classifications and Rankings</i>
<i>Sponsoring Committee:</i>	<i>Thoracic Organ Transplantation Committee</i>
<i>Public Comment Period:</i>	<i>January 22, 2018 – March 23, 2018</i>
<i>Board of Director's Date:</i>	<i>June 11-12, 2018</i>

Executive Summary

On November 24, 2017, the OPTN/UNOS Executive Committee approved an emergency change to lung allocation policy to remove the donation service area (DSA) as a unit of distribution and instead distribute lungs from adult donors to all lung candidates within 250 nautical miles of the donor. DSA level allocation was also removed from the pediatric donor sequence. These changes to policy were implemented immediately. Because this change was made on an emergency basis, it was distributed for public comment. By November 24, 2018, the OPTN Board of Directors, upon review of lung allocation policy in light of the requirements of the OPTN final rule, and in consideration of the public comments and feedback received, must take a final action to either: (1) approve this interim policy as a non-interim policy; or (2) approve any other changes to the OPTN lung allocation policy the OPTN Board believes to be more consistent with the requirements of the OPTN final rule.

The Thoracic Organ Transplantation Committee is sponsoring this retrospective proposal, which also includes two additional changes to policy that are required as a consequence of removing the DSA as a unit of distribution from lung allocation policy:

1. Modifications to Board-approved heart-lung allocation policy that will be implemented fall 2018
2. Modifications to policy for sensitized lung candidates

The goal of these changes is to make lung allocation policy more consistent with the OPTN Final Rule and provide more equity in access to transplantation regardless of a candidate's geography. These changes also address how implementation of the new lung allocation policy impacts heart-lung allocation policy and policy addressing sensitized lung candidates.

What problems will this proposal address?

This proposal stems from emergency changes to OPTN policy approved by the OPTN/UNOS Executive Committee on November 24, 2017, to remove the donation service area (DSA) as a unit of distribution for lung allocation.¹ This proposal also addresses other sections of policy that must be modified to align with the removal of the DSA as a unit of distribution for lungs. The proposal therefore addresses three problems:

1. The use of the DSA as a unit of distribution in lung allocation is not consistent with the OPTN Final Rule
2. The removal of the DSA as a unit of distribution in lung allocation complicates Board-approved heart-lung allocation policy that has not yet been implemented
3. The removal of the DSA as a unit of distribution in lung allocation makes current policy for sensitized lung candidates impractical

¹ OPTN Mini Brief: Broader Sharing of Adult Donor Lungs. November 26, 2017. Accessed January 2, 2018. https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf

The history of the emergency change to lung allocation policy, as well as the background on the unintended consequences the change has on current policy for heart-lung allocation and sensitized lung candidates, is detailed below.

Use of the DSA as a unit of distribution in lung allocation is not consistent with the OPTN Final Rule

Before the emergency change on November 24, 2017, lung candidates at least 12 years old were prioritized for offers from donors within their DSA according to their lung allocation score (LAS), which is calculated using estimates of the candidate's medical urgency and likelihood of post-transplant success.² Offers from adult donors were sent to all candidates in the DSA before any offers were sent to candidates in Zone A, which at the time encompassed all candidates within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.³ Under this distribution scheme for lungs, a candidate with a very high LAS in Zone A would not receive a lung offer from this donor until after all candidates in the local DSA, including those with a relatively low severity of illness, were first offered the lungs.

The OPTN Final Rule permits individuals to submit critical comments to the Secretary of the U.S. Department of Health and Human Services (HHS), and outlines the Secretary's obligations in response to such comments:

"(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under §121.12. After this review, the Secretary may:

- 1) Reject the comments;
- 2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
- 3) Take such other action as the Secretary determines appropriate."⁴

On November 16, 2017, the U.S. Department of Health and Human Services (HHS) received a critical comment requesting that HHS "take immediate action and direct the Organ Procurement and Transplantation Network (OPTN) to set aside those portions of the OPTN Lung Allocation Policy, Policy 10, "that require donor lungs to first be made available to candidates within...DSAs irrespective of a candidate's medical priority."⁵ On November 21, 2017, on behalf of HHS, Health Resources and Services Administration (HRSA) directed the OPTN to conduct an emergency "review of the use of DSAs [donation service areas] in Lung Allocation Policy in accordance with the requirements of the OPTN final rule" and "inform HHS whether the use of DSAs in Lung Allocation Policy is consistent with the requirements of the OPTN final rule."⁶

Specifically, the OPTN was asked to explain whether the current adult donor allocation sequence allocating lungs to candidates in the DSA in the first six allocation classifications is more consistent with the Final Rule than an allocation policy that instead initially allocates lungs to all candidates within 500 nautical miles of the donor hospital.

The National Organ and Transplant Act (NOTA) and the OPTN Final Rule stress utility and equity in allocation policies. The letter from the HRSA Administrator made specific reference to sections of the Final Rule that require broad sharing when possible in allocation performance goals: "Distributing organs

² OPTN/UNOS Policies. *10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old*. (11/23/2017). Accessed November 20, 2017. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10

³ OPTN/UNOS Policies. *1.2: Definitions*. (11/23/2017). Accessed on November 20, 2017. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01

⁴ 42 C.F.R. § 121.4(d), available at [Electronic Code of Federal Regulations](#)

⁵ Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.

⁶ *Id.*

over as broad a geographic area as feasible...and in order of decreasing medical urgency," and states that organ allocation policies "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)...", which include that 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.⁷

The OPTN/UNOS Executive Committee convened on November 22 and 24, 2017, to consider HRSA's questions. The Executive Committee concluded that geography impacts cold ischemic times, which affect patient outcomes post-transplant. Geography also impacts the timing and costs of the organ recovery and matching processes. The Committee concluded that because of these factors, and because the Final Rule requires the OPTN to consider and balance these factors, geographic considerations are not inherently in conflict with the Final Rule. However, they must be rationally determined, consistently applied, and must not create inequalities in candidates' access to organ transplantation. The Executive Committee acknowledged that, as an allocation unit for lungs, DSAs might not be the best proxy for geography, as DSAs have disparate sizes, shapes, and populations.⁸ See **Figure 1** below.

Figure 1: Comparison of Smaller DSAs with Larger DSAs by Population and Land Area Served

OPO	Population	Land Area (Sq. Miles)
Legacy of Life Hawaii	1,419,561	6,423
Lifelink of Puerto Rico	3,615,086	3,557
LifeCenter Northwest	8,534,901	808,360
OneLegacy	19,865,545	44,822

DSAs do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates. A policy change to replace DSA-first sharing with sharing to a consistent size circle would begin to minimize the effect of geography on a candidate's access to donors in a manner more consistent with the requirements of the Final Rule. Providing medically urgent candidates access to a broader range of donors across DSA, and sometimes even across regional, borders would better address the relative importance of medical factors in allocation.

Removing the DSA as a unit of distribution in lung allocation complicates approved but not yet implemented heart-lung policy

Current heart-lung allocation policy is vague and does not specifically reference the DSA, so it is possible for current heart-lung allocation policy to operate in conjunction with the changes to lung distribution.⁹ However, removing the DSA as a unit of distribution in lung allocation impacts heart-lung allocation policy that was Board-approved in December 2016 but will be implemented fall 2018.¹⁰ **Figure 2**, below, demonstrates how the 2016 proposal attempted to equate geographic distribution for heart allocation and lung allocation when an OPO is making heart-lung offers off the lung match, and specifically refers to the DSA:

⁷ 42 C.F.R. § 121.8 available at [Electronic Code of Federal Regulations](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-B/part-121/subpart-1/section-121.8)

⁸ SRTR: OPO Statistics. <https://www.srtr.org/reports-tools/opo-specific-reports/>. Accessed on January 4, 2018.

⁹ OPTN/UNOS Policy 6.5.F: Allocation of Heart-Lungs. Accessed on January 2, 2018.

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_06

¹⁰ OPTN/UNOS Policy Notice: Proposal to Modify the Adult Heart Allocation System. Accessed on January 2, 2018.

https://optn.transplant.hrsa.gov/media/2028/thoracic_policynotice_201612.pdf

Figure 2: Approved but not yet implemented Heart-Lung Allocation Policy for allocating off the Lung Match:

When a heart-lung PTR in this geographic area is offered a lung:	The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:	Within this geographic area:
OPO's DSA or Zone A	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	OPO's DSA or Zone A
Zone B	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone B
Zone C	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone C
Zone D	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone D
Zone E	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone E

According to this table, if an OPO is offering a heart-lung, and has identified a lung candidate that is also registered for a heart, the OPO is not able to offer the heart to the lung candidate until the heart has been offered to all isolated pediatric status 1A or 1B and adult status 1, 2, or 3 heart candidates within the same geographic zone as the lung candidate. This policy largely relies on the geographic distances for distributing hearts and lungs being equal to each other. However, once the Executive Committee approved the changes to the distances by which lungs are distributed, it complicated the not-yet-implemented heart-lung policy. This policy is also complicated by other factors, such as including a priority for urgent heart candidates to permit those candidates to receive heart-alone offers prior to heart-lung candidates. The group of heart candidates that receive priority over heart-lung candidates may be over-inclusive, as all of these candidates may not have waitlist mortality rates comparable to heart-lung candidates. Heart-lung allocation policy is therefore problematic, and the changes to lung allocation exacerbate the problem.

Removing the DSA as a unit of distribution in lung allocation makes current policy for sensitized lung candidates impractical. Current policy permits a transplant program to make an agreement with all transplant programs and the OPO in a DSA to allocate lungs to a candidate out of sequence if all parties agree that the candidate is highly sensitized and in need of such prioritization.¹¹ However, once the DSA is removed as a unit of distribution, it no longer makes sense to leave this policy intact. Doing so would

¹¹ OPTN/UNOS Policy 10.2.A: Allocation Exception for Sensitized Patients. Accessed on January 2, 2018. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10

have the effect of permitting certain parties to agree to prioritize a candidate when all parties that would be affected (all candidates in lung Zone A) would not have the opportunity to make such an agreement.

Why should you support this proposal?

The proposal makes lung allocation policy more consistent with the requirements of the OPTN Final Rule. It removes the DSA, an inconsistently shaped geographic area, as a unit of distribution for lung allocation and replaces it with a consistently applied circle. The proposed changes to heart-lung allocation and sensitization policy make all of lung allocation policy internally consistent, and provide clarity and transparency to policies that are historically unclear and under-utilized.

How was this proposal developed?

These policy changes were developed in a rapid fashion as a result of an emergent order from HRSA. The Executive Committee developed the changes to lung allocation to remove the DSA as a unit of distribution for lungs, while the Thoracic Committee developed the changes to heart-lung and sensitization policy.

Executive Committee Changes

HRSA requested the OPTN to determine whether distributing lungs to Zone A (all candidates within 500 nautical miles of the donor hospital) was more equitable than using the DSA as the first unit of distribution. The Executive Committee sought the advice of the Thoracic Committee and reviewed OPTN data and literature to address HRSA's question. The Thoracic Committee, in considering whether to recommend making an immediate change to policy, concluded "there is value in exploring the removal of the DSA as a unit of allocation, but was reluctant to recommend doing so without the ability to perform analysis on the impact of such a change."¹² The Thoracic Committee's hesitation to make such a recommendation without updated analyses was partly due to its review of modeling performed for the Committee in 2009 that suggested broader distribution may result in increased discard rates for donated lungs.¹³

However, the Executive Committee reviewed several studies using OPTN/UNOS data that suggest that removing DSA as a unit of allocation may better align OPTN/UNOS policy with the requirements of the Final Rule and improve the overall allocation system.^{14,15,16,17,18} Under current policy, most lung transplant recipients in the U.S. receive a donated lung from within 250 nautical miles of their transplant hospital. See **Figures 3** below.

¹² OPTN/UNOS Thoracic Organ Transplantation Committee Memorandum: Removal of the Donation Service Area (DSA) As a Unit of Allocation for Lung Candidates. Distributed to the OPTN/UNOS Executive Committee on November 22, 2017.

¹³ SRTR, "Final Analysis for Data Request from the OPTN Thoracic Committee Meeting 11/21/08, Request 3: TSAM Analyses for Lung Allocation (II) - Geography." March 10, 2009. Presented to the Thoracic Committee on March 27, 2009.

¹⁴ Russo, et.al. Local Allocation of Lung Donors Results in Transplanting Lungs in Lower Priority Transplant Recipients. *Ann Thorac Surg* 2013;95:1231-5. DOI: 10.1016/j.athoracsur.2012.11.070

¹⁵ 42 C.F.R. § 121.8, available at [Electronic Code of Federal Regulations](#)

¹⁶ Mooney, et. al. Effect of Broader Geographic Sharing of Donor Lungs on Regional Waitlist (WL) Mortality and Transplant Center Volume. *The Journal of Heart and Lung Transplantation*, Volume 36, Issue 4, S206 - S207. DOI: <http://dx.doi.org/10.1016/j.healun.2017.01.541>

¹⁷ Iribarne, et. al. Distribution of donor lungs in the United States: a case for broader geographic sharing. *Clin Transplant*. 2016 Jun;30(6):688-93. doi: 10.1111/ctr.12735

¹⁸ Iribarne, et.al. Distribution of donor lungs in the United States: a case for broader geographic sharing. *Clin Transplant* 2016; 30: 688-693 DOI: 10.1111/ctr.12735

Figure 3: Average Distance from Donor Hospital to Transplant Center for Lung Transplants

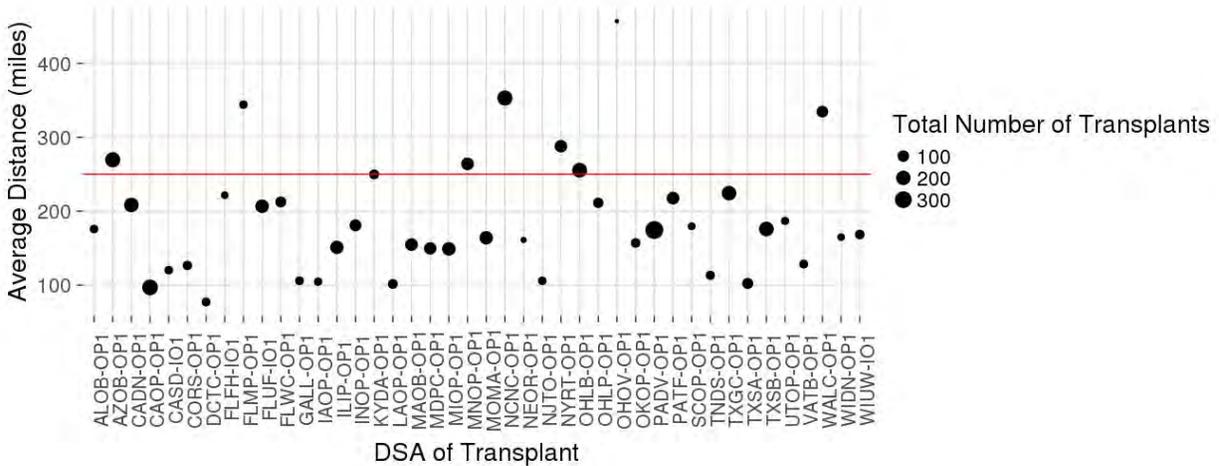


Figure 3 summarizes the average distance from the donor hospital to the transplant center by DSA for all lung transplants performed between January 1, 2015 and December 31, 2016, where the recipient was at least 12 years of age. The red line indicates an average of 250 nautical miles between the donor hospital and the transplant center.

The Executive Committee determined it was too risky to adopt a policy distributing lungs to a 500 nautical mile radius without the ability to perform analysis on the impact of such a sweeping change. Therefore, the Executive Committee concluded that the lung allocation policy should be revised to replace the use of DSA as the first unit of lung allocation with a 250 nautical mile circle around the donor hospital. The change took effect immediately on November 24, 2017, as permitted by HRSA.

Consistent with HRSA’s direction, by November 24, 2018, the OPTN Board of Directors, upon review of the Lung Allocation Policy in light of the requirements of the OPTN final rule, and in consideration of the public comments and feedback received, must take a final action to either: (1) approve this interim as a non-interim policy; or (2) approve any other changes to the OPTN Lung Allocation Policy the OPTN Board believes to be more consistent with the requirements of the OPTN final rule.”

Thoracic Committee Changes

To meet the six-month requirement, and to make the best use of the already-scheduled public comment period, the Thoracic Committee met multiple times throughout the month of December, 2017, to analyze the remaining lung allocation policy to determine whether additional changes were necessary. The Thoracic Committee also invited members of the OPTN/UNOS Organ Procurement Organization (OPO) Committee onto its conference calls to ensure input from parties that are most likely to be affected by these policy changes.

The Thoracic Committee’s discussions included three significant aspects of policy:

1. The removal of the DSA as a unit of distribution for lungs
2. Heart-lung allocation policy
3. Sensitization policy for lung candidates

The Thoracic Committee’s discussions about these aspects of policy are summarized below.

1. The removal of the DSA as a unit of distribution for lungs

The Thoracic Committee previously expressed to the Executive Committee that it did not recommend removing the DSA as a unit of distribution for lungs without the ability to perform analysis to understand the potential impact of such a change. However, for the reasons detailed above, the Executive Committee proceeded with the emergency changes. The Thoracic Committee subsequently discussed whether 250 nautical miles from the donor hospital is appropriate for the first unit of distribution for lungs.

The Committee determined that it will be difficult to discern the “correct” distance without modeling different potential changes to distribution. The Committee asserted that the ideal policy would result in:

- More transplants
- Lower waitlist mortality
- Higher utilization

It submitted a request to the Scientific Registry of Transplant Recipients (SRTR) to provide thoracic simulation allocation modeling (TSAM) comparing “old” policy (distributing lungs to the DSA first) to “new” policy (distributing lungs to a 250 nautical mile radius around the donor hospital), and to distributing lungs to a 500 nautical mile radius around the donor hospital.¹⁹ The Committee also discussed whether to model additional distances to determine whether 250 nautical miles is appropriate. Specifically, the Committee considered whether to request modeling for 75 nautical miles from the donor hospital, and 150 nautical miles from the donor hospital. However, due to the emergent nature of the proposal and the desire to at least learn about the impact of the change that already occurred, the Thoracic Committee limited its request.

2. Heart-Lung Allocation Policy

The Thoracic Committee next analyzed heart-lung allocation. To understand heart-lung allocation policy it is important to understand how the system is programmed.

a. Heart-Lung Programming

To register a candidate for a heart-lung transplant, the transplant program should register that candidate on the heart, lung, and heart-lung transplant waiting lists in UNetSM. When registering a candidate for a heart, the transplant program can indicate within the heart registration form that the candidate is registered for an additional organ, and can specify the other organ type as “lung” and/or “heart-lung.” The same is true for registering a lung candidate. There is a third separate registration for “heart-lung” as an organ type as well.

The OPTN previously advised transplant programs to register candidates in need of a heart and lung on all three waiting lists to ensure that they appear regardless of which match run the OPO generates.²⁰ An OPO can request that a match be generated for a single organ type or for multiple organ types simultaneously. All requests submitted at the same time are referred to as a batch.

In UNet the phrase “lung match” is used to refer to two different results: a match that includes only lung candidates and a match that includes both lung candidates and heart-lung candidates. In **Figure 4** below, the latter type of match is referenced as a lung* match.

Figure 4: Thoracic Organ Match Runs

Match organs requested in the batch	Match(es) generated	Candidates included on match	Policy for sorting candidates
Heart	Heart	Heart	Heart allocation policy
Lung	Lung	Lung	Lung allocation policy
Heart and lung	Heart-lung	Heart and heart-lung	Heart allocation policy
	Lung*	Lung and heart-lung	Lung allocation policy

When an OPO runs a heart match run, candidates will appear in order according to heart allocation policy. The match run will display that the heart candidate also needs a lung and/or a heart-lung if the candidate’s transplant program has indicated on the candidate’s heart registration that the candidate needs an “additional organ.” Similarly, when an OPO runs a lung match run, candidates will appear in order according to lung allocation policy. The match run will display that the lung candidate also needs a

¹⁹ SRTR Analysis Report. Data Request ID#: LU2017_02. January 12, 2018.

²⁰ OPTN/UNOS Thoracic Organ Transplantation Committee Memorandum: “Adding Heart-Lung Candidates to and Removing them from the Waiting List.” Distributed to Thoracic Transplant Clinicians on January 27, 2011.

heart and/or a heart-lung if the candidate's transplant program has indicated on the candidate's lung registration that the candidate needs an "additional organ." The "additional organ" indication does not affect a candidate's position on the match run.

b. Heart-Lung Policy

Under current policy, when a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate. When the heart-lung candidate is allocated a lung, the heart from the same deceased donor may only be allocated to the heart-lung candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart.²¹ A heart-lung guidance document was released previously to aid in the execution of heart-lung policy under the DSA system.²²

The Committee determined current policy is practical even with the removal of the DSA as a unit of distribution for lungs, because the policy is vaguely written and does not include references to any particular geographic areas. The Committee therefore considered retaining this vague policy. However, this policy is very difficult for members to understand and is inconsistently applied, despite the guidance document. And, if the Committee opted to retain current policy, it would have to update the guidance document. However, the guidance document does reference specific geographic areas, including the DSA, and cannot be updated easily. Therefore, the Committee determined that it does not recommend retaining current policy, and also recommends retracting the previously issued guidance. The guidance was rescinded March 8, 2018 and retrospectively approved by the OPTN/UNOS Executive Committee on March 19, 2018.

Next, the Thoracic Committee considered how to change the 2016 Board-approved but not-yet-implemented heart-lung allocation policy. Importantly, heart-lung allocation provides OPOs with some discretion. The OPO can allocate heart-lungs off the heart match or heart-lung match, which means potential transplant recipients (PTRs) appear on the match run according to the sorting dictated by heart allocation policy. The OPO can also offer lungs off the lung match, which means PTRs appear on the match run according to the sorting dictated by lung allocation policy. When an OPO opts to allocate off the heart sorting, approved policy is very simple: if the heart or heart-lung candidate requires a lung, the OPO can allocate the heart-lung to that candidate. If the OPO allocates off the lung sorting, the approved policy permits the OPO to allocate the heart to the lung candidate in need of a heart in Zone A (which previously for lungs was 500 nautical miles around the donor hospital but is now 250 nautical miles around the donor hospital) only if the OPO has already offered the heart to isolated adult status 1, 2 and 3 and pediatric status 1A and 1B heart PTRs within the DSA or heart Zone A (500 nautical miles around the donor hospital). See **Figure 2** above.

The approved version is not practical in light of the changes to lung distribution because it was written under the notion that heart allocation and lung allocation used the same zonal distribution distances and patterns. Furthermore, the policy does not account for the specifics of heart allocation: it over-generalizes the way in which heart candidates are sorted by urgency geographically. The unintended effect of this over-generalization is that the policy results in different prioritization of a heart candidate depending on whether the lung is allocated to a heart-lung candidate or not.²³

The Committee considered whether to eliminate offering heart-lungs according to the lung match from heart-lung policy altogether for the sake of simplicity, and thus require OPOs to allocate heart-lungs according to the heart match. However, there are instances in which a heart-lung candidate is allocated the heart from the same deceased donor after being allocated the lung, rather than being allocated the

²¹ OPTN/UNOS Policy 6.5.F: Allocation of Heart-Lungs.

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_06 (Accessed on January 4, 2018).

²² Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks. Rescinded March 8, 2018. Retrospectively approved by the OPTN/UNOS Executive Committee March 19, 2018.

²³ For example, the policy suggests that the while a heart-lung candidate in Zone A should not be allocated a heart before a status 3 candidate in Zone A, it could be offered the heart prior to a status 1 candidate in Zone B or a status 4 candidate in the DSA. This would occur despite the fact that both of these latter candidates would be higher on the heart allocation list than the status 3 candidate in Zone A.

lung from the same deceased donor after being allocated the heart, and therefore determined it would be inequitable to prevent such a situation in the future.

Heart-lung is a complicated issue and in the short timeframe provided for development of this policy, the Committee determined that it should adhere as closely as possible to the goals of the approved but not yet implemented policy: (1) that heart-lung candidates allocated a heart should be offered the lung from the same donor, and (2) that urgent heart candidates should be prioritized for heart offers prior to heart-lung candidates if the OPO is allocating the organs according to the lung match.

Although the Committee discussed the risk that in some circumstances that a lung candidate at higher risk of waitlist mortality might “lose” the lung offer to a lower risk heart-lung candidate, altering this aspect of the policy would be beyond the scope this emergency policy change. However, the Committee clearly recognizes that a more thorough analysis and comprehensive policy regarding allocation of multi-organ blocs based on the likelihood of waitlist mortality for both isolated and combined organ candidates would be beneficial in the future. Thus, the first aspect of the policy was left largely unchanged, allowing a heart-lung candidate allocated a heart to “pull” the lung from the same donor.

The second aspect, identifying which heart candidates should be prioritized over heart-lung candidates allocated a lung from the same donor, occupied significantly more of the Committee’s time. The Committee focused on defining which heart candidates are in more urgent need of transplant than a heart-lung candidate that pulls from the lung match, and how to equate the geographies between heart allocation and lung allocation in this new allocation schema.

The Committee realized that attempting to broadly equate geography on the heart match and lung match would be extremely difficult because the zones are now defined differently. In addition, while the new lung allocation policy allows all candidates in a particular zone access to an organ prior to candidates in the next zone, heart policy offers high risk candidates broader distribution prior to local sharing for lower risk candidates. Thus, defining allocation of heart-lung blocs based primarily on zones resulted in allocation priorities very different from heart allocation. The Committee therefore decided to remove references to zones from heart-lung policy altogether. It debated whether to instead refer to distances (i.e. “all candidates within 500 nautical miles of the donor”) but thought that may be complicated because the urgent heart candidates that receive priority over heart-lung candidates are not all subject to the same geographic distribution in heart policy. The Committee determined the most transparent and clear solution is to reference the heart, lung and heart-lung candidates by the classifications defined in the heart and lung allocation classification tables. Because heart and lung classification tables are divided by donor age (adult donors are 18 years or older; pediatric donors are less than 18 years old), heart-lung allocation policy must also be specific regarding adult donors vs. pediatric donors.

The Committee began by defining high priority heart-lung candidates on the lung allocation list as those in classifications 1-12. Classifications 1-12 include all lung candidates through lung Zone B (all candidates within 500 nautical miles of the donor hospital). See **Figure 5** below.

Figure 5: Allocation of Adult Donor Hearts versus Adult Donor Lungs

In this geographic area...	Adult donor hearts are allocated to these candidates...	Classification	In this geographic area...	Adult donor lungs are candidates...
OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and primary blood type match with the donor	1	Zone A	At least 12 years old, blood type identical to the donor
OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	2	Zone A	At least 12 years old, blood type compatible with the donor
OPO's DSA or Zone A	Adult status 2 and primary blood type match with the donor	3	Zone A	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
OPO's DSA or Zone A	Adult status 2 and secondary blood type match with the donor	4	Zone A	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
		5	Zone A	Priority 2, blood type identical to the donor
		6	Zone A	Priority 2, blood type compatible with the donor
		7	Zone B	At least 12 years old, blood type identical to the donor

In this geographic area...	Adult donor hearts are allocated to these candidates...	Classification	In this geographic area...	Adult donor lungs are candidates...
		8	Zone B	At least 12 years old, blood type compatible with the donor
		9	Zone B	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
		10	Zone B	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
		11	Zone B	Priority 2, blood type identical to the donor
		12	Zone B	Priority 2, blood type compatible with the donor

For pediatric donors, current lung policy distributes lungs to all candidates less than 18 years old through lung Zone C (1,000 nautical miles of the donor hospital). To remain consistent with proposed adult heart-

lung allocation policy by including as many of the same type of candidates in the policy as possible, the Committee proposes applying it to all lung candidates through lung classification 10. See **Figure 6** below.

Figure 6: Allocation of Pediatric Donor Hearts versus Pediatric Donor Lungs

In this geographic area...	Pediatric donor hearts are allocated to these candidates...	Classification	In this geographic area...	Pediatric donor lungs are allocated to these candidates...
OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor	1	Zone A, Zone B, or Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor	2	Zone A, Zone B, or Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
OPO's DSA	Adult status 1 and primary blood type match with the donor	3	Zone A, Zone B, or Zone C	Priority 2, blood type identical to the donor
OPO's DSA	Adult status 1 and secondary blood type match with the donor	4	Zone A, Zone B, or Zone C	Priority 2, blood type compatible with the donor
OPO's DSA	Adult status 2 and primary blood type match with the donor	5	Zone A, Zone B, or Zone C	12 to less than 18 years old, blood type identical to the donor
OPO's DSA	Adult status 2 and secondary blood type match with the donor	6	Zone A, Zone B, or Zone C	12 to less than 18 years old, blood type compatible with the donor
OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor	7	Zone A	At least 18 years old, blood type identical to the donor

In this geographic area...	Pediatric donor hearts are allocated to these candidates...	Classification	In this geographic area...	Pediatric donor lungs are allocated to these candidates...
OPO's DSA or Zone A	Pediatric status 1B and secondary blood type match with the donor	8	Zone A	At least 18 years old, blood type compatible with the donor
Zone A	Adult status 1 and primary blood type match with the donor	9	Zone B	At least 18 years old, blood type identical to the donor
Zone A	Adult status 1 and secondary blood type match with the donor	10	Zone B	At least 18 years old, blood type compatible with the donor
Zone A	Adult status 2 and primary blood type match with the donor	11		
Zone A	Adult status 2 and secondary blood type match with the donor	12		

In plain terms, a lung or heart-lung candidate in lung classifications 1-12 (for adult donors) or 1-10 (for pediatric donors) can be offered the heart from the same donor unless there is an urgent heart candidate that needs the heart.

The Committee next defined how urgent a heart candidate must be in order to be allocated the heart before the heart-lung candidate who has been allocated the lungs. In approved but not yet implemented policy, the limits are all pediatric status 1A and 1B candidates, and all adult status 1, 2 and 3 candidates in the DSA or Zone A. The Committee sought to mirror this policy as closely as possible. However, granting priority to pediatric status 1B and adult status 3 candidates in Zone A and adult status 3 candidates in Zone A would require the OPO to skip a number of candidates on the heart match run in the new adult heart allocation policy.²⁴ Importantly, the Committee was not confident that adult status 3 and pediatric status 1B candidates have a waitlist mortality rate that justifies granting these candidates priority over heart-lung candidates.

The Committee reviewed OPTN data and SRTR modeling to determine that pediatric status 1A candidates and adult status 1 or 2 candidates are most likely to demonstrate an urgency justifying a priority higher than heart-lung candidates (See "How well does this proposal address the problem statement?"). However, based on relative waitlist mortality, that priority should not extend to adult status 3 or pediatric status 1B heart candidates.

The Committee therefore proposes that, for allocation of heart-lungs from adult donors, candidates in heart classifications 1-4 should receive priority over lung and heart-lung candidates in lung classifications

²⁴ Adult status 1, pediatric status 1A, adult status 2 candidates in Zone B, and adult status 4 candidates in the DSA are prioritized on the heart match before adult status 3 and pediatric status 1B candidates in Zone A in approved but not yet implemented adult heart allocation policy.

1-12 (See Figure 6 above). For allocation of heart-lungs from pediatric donors, candidates in heart classifications 1-12 should receive priority over lung and heart-lung candidates in lung classifications 1-10.

The Committee recognized another point of confusion in current policy and approved but not yet implemented policy. Both versions of policy only prioritize “isolated” heart candidates over heart-lung candidates when allocating according to the lung match run. In effect, if a heart-lung candidate appeared in classifications 1-4 on the heart match run, that candidate would not be prioritized for the heart-lung offer over a heart-lung candidate on the lung match, even though a candidate only in need of a heart in classifications 1-4 would be. The policy would require the OPO to skip a heart-lung candidate on the heart or heart-lung match run, even though that heart-lung candidate’s heart urgency qualifies that candidate to appear there. There is no rationale for this. Therefore, the Committee proposes removing references to “heart alone” and instead replacing such references with “heart or heart-lung.”

The Committee discussed whether to create an urgency cut-off for lung candidates similar to the urgency cut-off for heart candidates. The Committee agrees in the future this may be appropriate. However, due to the exigent circumstances, there was not ample time to perform analyses that would inform the appropriate LAS cut-off. The Committee nevertheless believes this policy clarifies heart-lung allocation policy.

Finally, the Committee discussed whether to include additional policy language regarding what should happen after the OPO makes offers through the classifications mentioned above. Between 2015 and 2016, only 12 percent of offers for candidates waiting for a heart and lung were made to candidates greater than 500 nautical miles from the donor hospital.²⁵ It is even rarer for a heart-lung transplant to occur greater than 500 nautical miles away from the donor hospital. See **Figure 7** below.

Figure 7: Heart-Lung Transplants by Distance in Nautical Miles from Donor Hospital 2015-2016

Age Group	<100 NM	100-200 NM	200-300 NM	300-400 NM	400-500 NM	500+ NM
<18	1	1	0	1	1	0
≥ 18	16	3	6	1	2	1

Between 2015 and 2016, only one heart-lung transplant (for a recipient at least 18 years of age) occurred where the distance from donor hospital to transplant center was greater than 500 nautical miles. Even without including additional policy, if an OPO were to allocate heart-lungs beyond those classifications, it would still be bound by two policies: 1) the first part of heart-lung allocation policy that simply states that a lung must be allocated to a heart candidate if the OPO is making offers according to the heart classifications; and 2) lung allocation policy, if the OPO continued to allocate the heart-lung off the lung match. Because the proposed policy will address the vast majority of heart-lung allocations, the Committee declined to propose additional rules for how to allocate beyond the classifications explicitly included.

Practically, to adhere to the proposed policy an OPO should run the heart or heart-lung and lung match runs simultaneously. It should then look at the lung match run to see whether there are any candidates in classifications 1-12 that also require a heart (or 1-10, if the donor is less than 18 years old). If so, the OPO should make all offers to heart and heart-lung candidates in classifications 1-4 on the heart or heart-lung match run (or 1-12, if the donor is less than 18 years old). If those offers are turned down, it can then make offers down the lung match run through classification 12 (or through classification 10, if the donor is less than 18 years old), including to candidates that also require a heart.

c. Changes to Sensitization Policy

Current policy permits all transplant programs and the OPO in a DSA to agree that the OPO can offer lungs out of sequence to a highly sensitized lung candidate. Because this provision of policy is heavily reliant on parties in a DSA, and because the first unit of distribution for lungs now extends beyond the DSA, this policy must be modified. The Committee noted that the remedy a sensitized candidate needs is

²⁵ Data obtained from the OPTN database on December 12, 2017.

access to a broader range of donors, which the removal of the DSA in favor of a 250 nautical mile zone may accomplish.

With that in mind, it evaluated three potential options for changing sensitization policy:

1. Remove the policy altogether
2. Permit transplant programs to request an exception from the Lung Review Board (LRB) to prioritize the sensitized candidate
3. Modify it to permit all transplant programs and OPOs in any geographic area in which the candidate would appear in lung Zone A to agree to permit the OPO to allocate lungs to the sensitized candidate out of sequence

The first option the Committee considered was removing the policy altogether and not providing a pathway for sensitized candidates. The Committee noted that removing the policy carries some risk because there would be no options for sensitized candidates. However, the Committee believes the risk is only theoretical, as no Committee members attested to ever using this provision and UNOS staff could not recall any instances in which it has been used. This is the option the Committee proposed during public comment.

The second option is a simple solution that would centralize exception requests for sensitized candidates through the LRB. Policy currently prohibits this type of request from LRB consideration. This centralization would raise the fundamental issue of how to define a sensitized patient, which would include a threshold number of failed allocation attempts as a result of sensitization. Furthermore, the Committee was concerned that the LRB would not have ample guidance to determine whether to grant the request, which would lead to variability in approvals. The Committee noted it would not feel comfortable with this policy unless it provided the LRB with guidance, but providing guidance would require the same amount of analysis that would be required to create an ideal sensitization policy. However, the data to create an ideal policy do not currently exist in the OPTN database, because lung transplant programs are not required to report unacceptable antigens to the OPTN. The Committee expressed interest in working with the Histocompatibility Committee in the future to create an optimal policy.

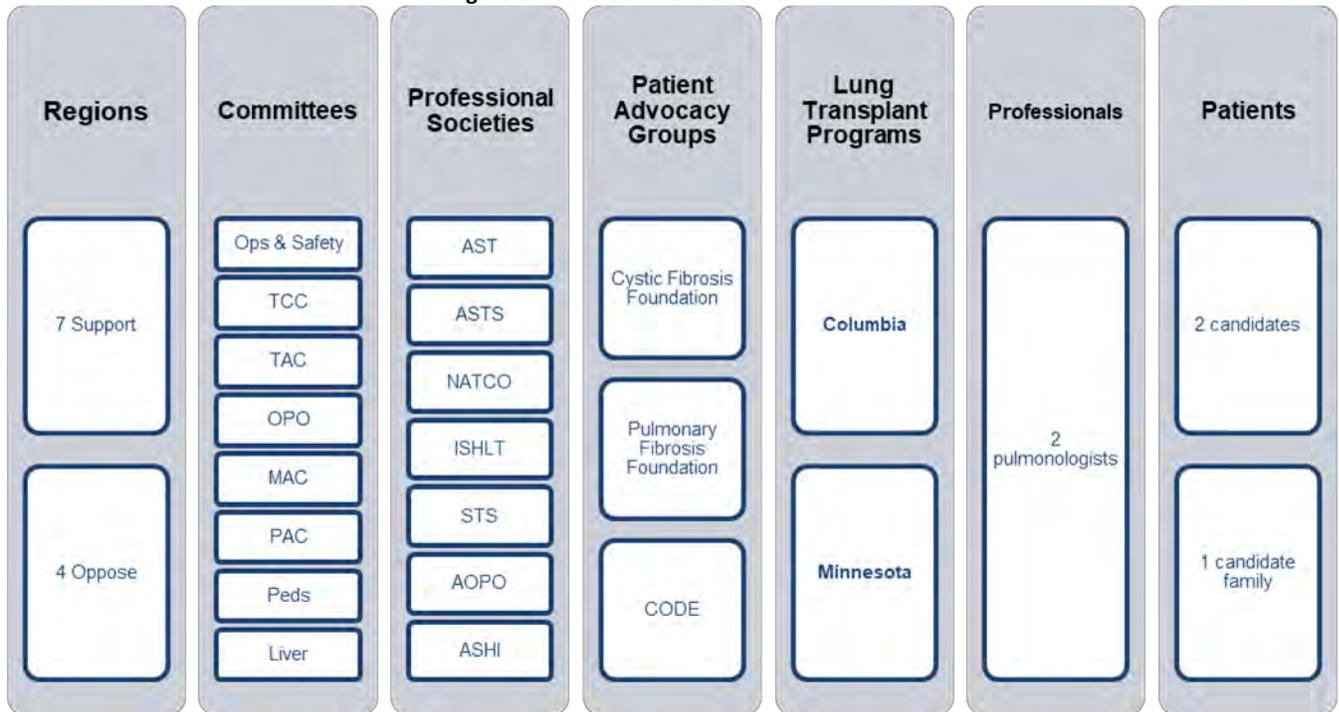
The final option most closely mirrors current policy and provides a pathway for prioritizing sensitized candidates. It would also permit any party that has the potential to be skipped on the match run in favor of the sensitized candidate to agree ahead of time. However, this option is logistically very difficult, because the number of transplant programs and OPOs with which the sensitized candidate could possibly share lung Zone A is large. Because the 250 nautical mile radius around any given donor hospital is a constantly shifting zone, it would be very difficult to obtain full agreement to allow an out of sequence organ allocation in a time-sensitive nature. Ultimately, the Committee adopted a variation of this option, detailed in the “Was this proposal changed in response to public comment?” section, below.

Was this proposal changed in response to public comment?

The proposal garnered 34 comments. Overall, there was general support for the concept of broader distribution for lungs. Further, there was support for the Committee to be granted the opportunity to vet

alternative solutions through the normal policy development process, thus necessitating an extension of the sunset date.

Figure 8: Public Comment Overview



The Committee sought specific feedback regarding the following questions:

1. Is 250 nautical miles from the donor hospital the appropriate first zone of distribution for lungs procured from donors at least 18 years old?
2. Are the proposed changes to heart-lung allocation policy clear?
3. Which of the options the Committee considered for sensitized candidates do you prefer?

In addition, members were asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. Consequently, this feedback, among other comments, is reflected in the overarching themes, detailed below. The Committee's response and any subsequent changes made post-public comment are elaborated upon within each theme.

1. Feedback regarding whether 250 nautical miles from the donor hospital is the appropriate first zone of distribution for lungs procured from donors at least 18 years old

Feedback regarding whether or not 250 nautical mile was the ideal first unit of distribution varied. There was some consensus for the 250 nautical mile solution, but there was also a fair amount of opposition. Those who supported the interim policy change, including the International Society of Heart and Lung Transplantation (ISHLT), were comfortable because the effect of distributing to 250 nautical miles was similar to distributing to the DSA, and post-implementation data indicated no immediate adverse impact to patients.²⁶ In addition, supporters felt this change better aligned with the Final Rule than DSA. Those who opposed distributing to 250 nautical miles encouraged the Committee to take the time to consider and analyze other options; the implemented change may not be the optimal solution. This faction was more

²⁶ OPTN/UNOS. *Monitoring of the Lung Allocation Change, 4 Month Report Removal of DSA as a Unit of Allocation*. Descriptive Data Request prepared for the OPTN/UNOS Thoracic Organ Transplantation Committee. Presented April 19, 2018. https://optn.transplant.hrsa.gov/media/2463/20180412_thoracic_committee_report_lung.pdf

likely to support distributing lungs even more broadly. Indeed, even among the regions that supported the change, there was support for the Committee to have the time to vet other options.

Patient advocacy groups and the OPTN/UNOS Patient Affairs Committee supported distributing lungs to 500 nautical miles. However, several commenters noted that the implemented change, and any other model of broader distribution, may have unintended consequences (see concerns, cited below). There were several suggestions for alternative solutions, including 125 nautical miles + DSA, and population density models. The Committee noted the modeling indicated a decrease in waitlist mortality with 500 nautical mile sharing, however without the opportunity to evaluate the consequences of other models, the Committee was hesitant to change the first unit of distribution from 250 nautical miles to 500 nautical miles.

In light of the public comment feedback, the Committee considered maintaining the 250 nautical mile solution, increasing the first unit of distribution to 500 nautical mile, or distributing based on some other model, either permanently or as a placeholder while the Committee explored other options (thus extending the sunset date). They reaffirmed that the 250 nautical mile interim policy should not be made permanent as there has not been sufficient time to vet an optimal geographic solution via analyses. In addition, the Committee has not yet had the opportunity to evaluate unintended consequences of the current change, let alone other models. Further, the Committee did not feel it prudent to finalize its policy proposal prior to the complimentary work being completed by the Ad Hoc Committee on Geography.²⁷ Indeed, it is likely their recommendations would inform future lung distribution policy. Therefore, they opted not to propose increasing the first unit of distribution to 500 nautical miles or some other model at this time.

The community also expressed other concerns associated with broader distribution of lungs:

- Potential for increased travel to recover organs
- Potential for increased costs associated with increased travel and increased use of ex vivo lung perfusion
- Unknown long-term impact on post-transplant outcomes
- Unknown impact to low volume/small centers
- Unknown impact to specific diagnoses groups

The Committee acknowledged these concerns and will ensure they are considered, should the Committee be given the opportunity to continue work. Ultimately, the Committee voted unanimously to propose maintaining distribution to 250 nautical miles as interim policy and request a two-year extension to allow the Committee ample time to consider alternatives (16-approve, 0-oppose, 0-abstentions).

2. Feedback regarding heart-lung policy

A majority of public comment feedback indicated support for the policy as written. Other feedback included:

- Concern that the policy does not help heart-lung candidates whose need for lungs is more urgent than their need for a heart
- Policy should be revised under a larger multi-organ project
- Heart-lung allocation shouldn't be a manual process by the OPO; a "smart" system should be programmed
- The proposed policy is still too complex

The Committee considered the following options based on public comment feedback:

- No change
- Extend priority to heart-lung candidates/create an exception pathway for heart-lung candidates
- Address via a larger multi-organ project

²⁷ Ad Hoc Committee on Geography. March 20, 2018 Meeting Minutes. Meeting Minutes. https://optn.transplant.hrsa.gov/media/2477/20180320_geography_meetingsummary.pdf

They acknowledged that ideally, heart-lung policy would be considered under a multi-organ policy project, which might include the “smart” programing suggested by the OPTN/UNOS Operations and Safety Committee. However, making those changes now would be substantive and out of scope at this time. However, in light of the emergency lung policy changes, and in recognition of the work that was already completed by the Committee under the adult heart allocation policy changes, the group felt it was necessary to move forward with modifications to the policy. The group did feel the changes made to heart-lung policy from the approved-but-not-yet-implemented adult heart allocation policy were more clear and informed by data.²⁸ However, the Committee acknowledged it is still a manual process for OPOs and the variability in how OPOs run matches remains.

Therefore, the Committee felt without the opportunity to look at heart-lung as part of a more holistic multi-organ project or make substantive changes in the form of an exception pathway, they were comfortable with the policy language as it went out for public comment as an interim solution.

The Committee voted unanimously (16-approve, 0-oppose, 0-abstentions) to recommend the policy as written with minor language clarifications.

3. Feedback regarding sensitized candidate policy

Finally, the Committee transitioned to the sensitized candidate policy. During development of the proposal, the Subcommittee considered three options:

- Remove the policy altogether
- Permit transplant programs to request an exception from the LRB to prioritize the sensitized candidate
- Modify current policy to permit all transplant programs and OPOs in any geographic area in which the candidate would appear in Zone A to agree to permit the OPO to allocate lungs to the candidate out of sequence

There was limited substantive feedback regarding this portion of the proposal. All regions supported striking the policy. Conversely, The OPTN/UNOS Transplant Administrators Committee, ISHLT, the National Association for Transplant Coordinators (NATCO), an individual transplant coordinator and a candidate family supported the LRB pathway. The OPTN/UNOS Transplant Coordinators Committee supported the current policy with Zone A swapped in for DSA. The OPTN/UNOS Pediatric Transplantation Committee was split between striking the policy and providing access through an LRB pathway. Finally, the OPTN/UNOS Patient Affairs Committee supported providing some option to prioritize these candidates, versus no option.

The Committee considered the feedback. It recognized that sensitized candidates have potential to be disadvantaged because they are less likely to be able to accept offers from donors, and that ideally, the policy could be modified more extensively, based on evidence. However, conceding that a lack of data is a barrier to developing a more robust policy, the Committee debated which of the options initially considered would be most prudent in the short-term.

The group considered the proposed solution that went out for public comment: striking the policy altogether. Public comment was not largely opposed to this option and it is straightforward. There is no information to help define sensitized candidates and there is little evidence that the existing pathway was ever used. This solution might be unlikely to impact many patients. In addition, sensitization does not equate to urgency, so it perpetuates the LAS as the sole driver of prioritization. Striking the policy does not attempt to address a complicated issue without clear solutions. Finally, broader distribution should benefit sensitized candidates to some extent; what they need is access to a greater number of offers, not necessarily higher priority on the match. However, the Committee noted that removing the policy carries some risk because there would be no mechanism for prioritization for sensitized candidates. In addition, it

²⁸ OPTN Descriptive Data Request, “Heart-Lung Allocation: Death Rates for Heart-Lung, Heart, and Lung Candidates.” Prepared for the Thoracic Committee on December 21, 2017.

eliminates a pathway that previously existed for a group of candidates that are more challenging to match.

There was strong consensus amongst the Committee that the LRB pathway was not optimal. Although logistically it may be most practical solution, there is not consensus within the lung transplant community around the definition of a sensitized patient. Lung transplant programs have different thresholds of what they are willing to accept as a positive crossmatch, and how many mismatches they are willing to accept. Members also noted that there was variable confidence in virtual HLA crossmatches. In addition, the Committee recognized the need to develop guidelines to help assist the LRB in evaluating sensitized candidate exception requests. This in itself would present the same challenges as developing policy. Further, since guidelines would have to be developed post-implementation of the policy change, as they are required to go out for public comment, the Committee did not favor this option.

Finally, the Committee considered the final option: maintaining policy that would permit allocating lungs out of sequence if the sensitized candidate's transplant program was able to secure agreements with other lung transplant programs whose candidates might appear ahead of the highly sensitized candidate. They debated four options that met this intent:

Table 1: Sensitized Candidate Policy Options Considered

Option	Timing of agreement	Advantages	Disadvantages
Option 1: Permit transplant programs to get agreements from any program above their candidate on the list to agree to be bypassed, no geographic limitation	At time of match	<ul style="list-style-type: none"> Provides a pathway for sensitized candidates Does not prescribe how far down the match run the sensitized candidate appears 	<ul style="list-style-type: none"> Not practical unless there are only a few candidates ahead of the sensitized candidate on the match run Difficult to achieve unless the transplant program knows the OPO and the other transplant programs ahead of it pretty well
Option 2: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs in Zone A	At time of match	<ul style="list-style-type: none"> Provides a pathway for sensitized candidates Most similar to current policy, except replaces DSA with Zone A Limits the benefit only to candidates in Zone A 	<ul style="list-style-type: none"> Constantly shifting geography Difficult to achieve in a timely manner because this would have to happen after the match is generated
Option 3: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs within 500 nautical mile of the candidate	Advanced agreement	<ul style="list-style-type: none"> Provides a pathway for sensitized candidates Similar concept to current policy Limits the benefit only to candidates in Zone A Alleviates the time-sensitive nature of the match by allowing the program to get these agreements in advance 	<ul style="list-style-type: none"> Difficult to achieve unless the transplant program knows the OPO and the other transplant programs within 500 nautical mile pretty well
Option 4: Policy modeled after kidney medical urgency policy ²⁹	At time of match	<ul style="list-style-type: none"> Provides a pathway for sensitized candidates Based on medical judgement Not complicated by securing agreements based on set geography Does not prescribe how far down the match run the sensitized candidate appears 	<ul style="list-style-type: none"> Not practical unless there are only a few ahead of the candidate on the match run

In addition to the disadvantages outlined in **Table 1**, sensitization does not equate to urgency, so allowing candidates with a lower LAS to receive a lung allograft before those who are listed at greater urgency may not be appropriate. In addition, it gives the OPO discretion, which they typically do not want. Finally, all of these options are difficult to monitor.

The Committee debated these concepts. They quickly eliminated options 2 and 3, as the logistic limitations made the solutions impractical. Options 1 and 4 are similar, but the Committee favored broader

²⁹ Policy 8.2.A Exceptions Due to Medical Urgency. Policy 8 Allocation of Kidneys. Organ Procurement and Transplant Network Policy. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08

policy language rather than a very specific policy that prescribes when it is permissible to bypass other candidates on the match. Option 4 is also most similar to *Policy 8.2.A: Exceptions Due to Medical Urgency* for kidneys. The Committee appreciated the importance of modeling its proposed sensitization policy off of concepts and precedent in other OPTN policies. Rather than striking the policy altogether, the Committee ultimately voted on option 4 (8-approve, 3-oppose, 2-abstentions).

The Committee voted to send the proposal to the Board of Directors in June for consideration (16-approve, 0-oppose, 0-abstentions).

How well does this proposal address the problem statement?

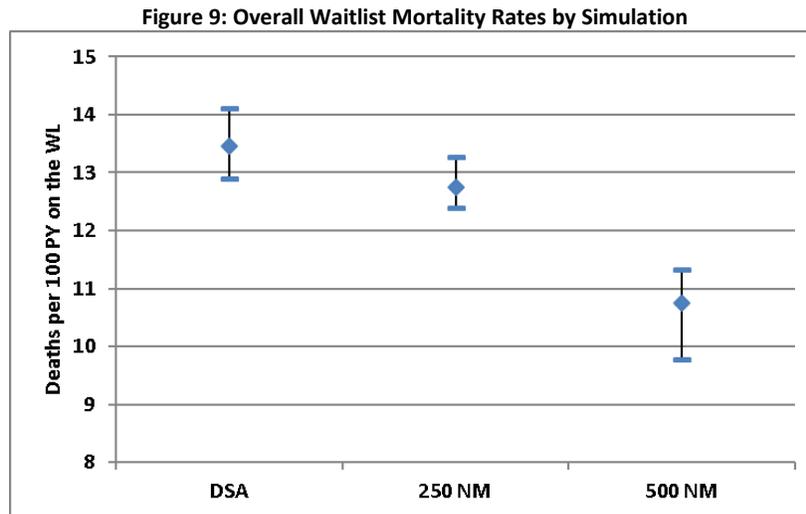
The Committee reviewed OPTN data and SRTR modeling to evaluate the proposed changes to policy.

1. Removal of DSA as a Unit of Distribution for Lungs

The SRTR provided a TSAM analysis to the Committee regarding the results of modeling distributing adult donor lungs to the DSA first, as compared to distributing adult donor lungs to all candidates within 250 nautical miles of the donor hospital, or 500 nautical miles of the donor hospital.³⁰ Graphs from simulations plot the average, minimum and maximum values of the data across 10 repetitions of the simulation.

Impact on Waitlist Mortality

Overall, the DSA and 250 nautical miles waitlist mortality rates were similar; the ranges (minimum to maximum) of these two simulations overlapped. When comparing DSA and 500 nautical miles simulations, however, more differences emerged. As shown in **Figure 9** below, deaths per 100 patient years on the waitlist declined to a greater degree at 500 nautical miles compared to 250 nautical miles or DSA.



When stratified by diagnosis, waitlist mortality rates did not change when comparing DSA and 250 nautical miles; however, with 500 nautical miles, waitlist mortality declined for candidates from diagnosis Group D.³¹

When stratified by OPTN region, the TSAM suggests that waitlist mortality rates are also not anticipated to increase in any region. In the 250 nautical mile simulation, average value for waitlist mortality rates tended to decline but overlapped the range of the DSA simulation's rates. In the 500 nautical mile

³⁰ SRTR Analysis Report. Data Request ID#: LU2017_02. January 12, 2018. The entire analysis report is attached to this proposal as Exhibit A.

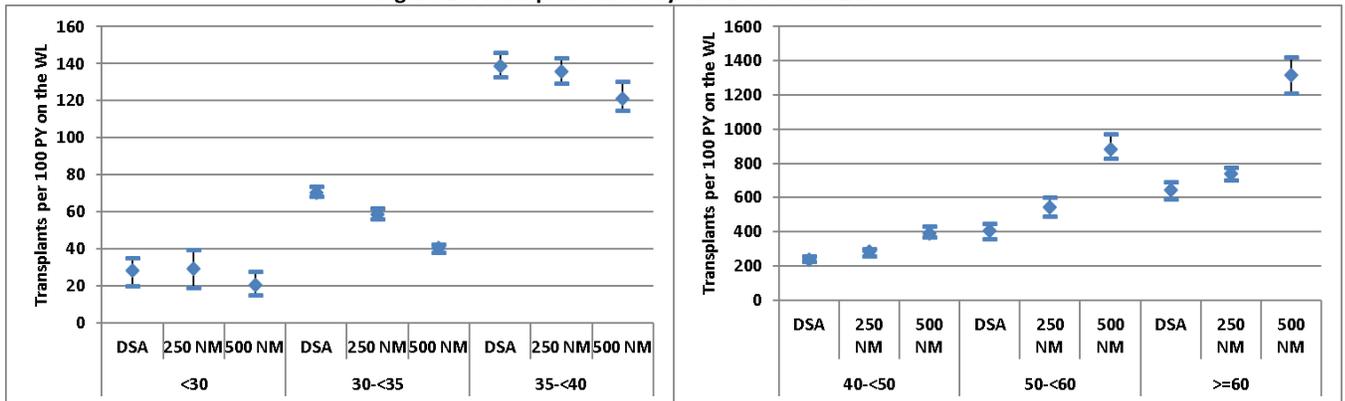
³¹ The LAS calculation uses Diagnosis Groups A, B, C, and D, as defined in OPTN/UNOS Policy 10.1.F.i: Lung Disease Diagnosis Groups. Reference policy for a complete list of the diagnoses that are categorized in each diagnosis group. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10. Accessed on January 18, 2018.

simulation, “waitlist mortality rates did not increase in any region; declined in regions 2, 3, 4, 9, and 10; and remained similar in regions 1, 5, 6, 7, 8 and 11, compared with the DSA simulation.”³² The SRTR explored whether regional changes by simulation could be explained by candidate severity of illness as demonstrated by higher LAS, and found, “The highest-LAS regions were 2, 3, 5, and 9. In regions 2, 3, and 9, first allocating to 500 nautical mile showed decreased waitlist mortality, suggesting that the sickest patients in these regions may have had increased opportunity to undergo transplant compared with the opportunity under prior rules favoring local DSA priority.”³³

Transplant Rates

Overall, transplant rates in the DSA and 250 nautical mile simulations differed slightly or not at all; however, in the 500 nautical mile simulation average rate declined, but remained within the range of the simulation.³⁴ Importantly, the transplant rates for candidates with LAS scores greater than or equal to 40 increased in both the 250 nautical mile and 500 nautical mile simulations. See **Figure 10** below.

Figure 10: Transplant Rates by Simulation and LAS



These simulations suggest that candidates that are more urgent, as demonstrated by higher LAS, are being prioritized for transplant in both of the modeled broader distribution simulations.

Impact on Post-Transplant Mortality

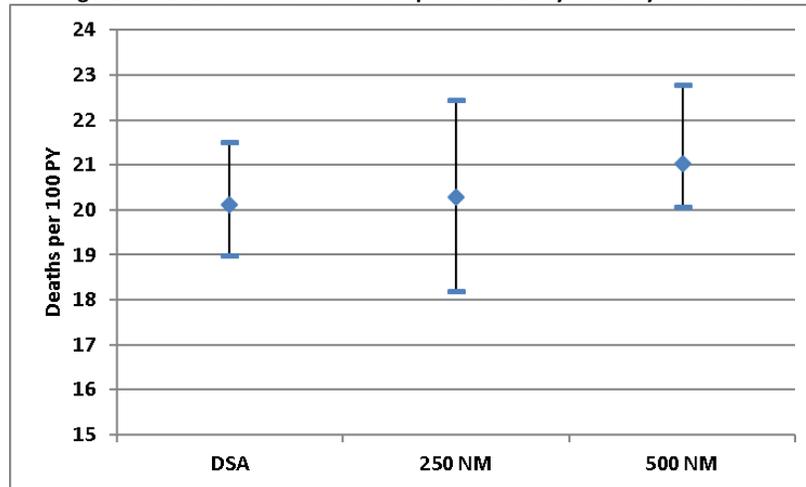
If more urgent candidates are being transplanted, it is important to examine whether these transplants are successful (as measured by increased post-transplant mortality). A system that shifts deaths on the waitlist to death post-transplant is one that results in only a minimal benefit to the transplant population. The TSAM demonstrates that overall one-year post-transplant mortality rates are not impacted dramatically by any of the modeled distances. See **Figure 11** below.

³² SRTR Analysis Report. Data Request ID#: LU2017_02 at page 9. January 12, 2018.

³³ *Id.* at 11.

³⁴ *Id.* at 5.

Figure 11: Overall 1-Year Post-Transplant Mortality Rates by Simulation



When stratified by diagnosis group, and when stratified by region, post-transplant mortality rates within a diagnosis group continued to be similar across all simulations.

In summary, the TSAM suggests that distributing adult donor lungs to all candidates within 250 nautical mile of the donor hospital will result in an effect that is similar to distributing first to the DSA. This suggests that the Executive Committee's change is unlikely to result in any immediate or unintended adverse impact. However, in order to realize the benefits of broader distribution, the TSAM suggests that it may be preferable to distribute first to a distance beyond 250 nautical mile, since patients with higher LAS scores will have a greater opportunity to receive a lung transplant.

Summary of the 4-Month Monitoring Impact of Removing DSA as a Unit of Allocation

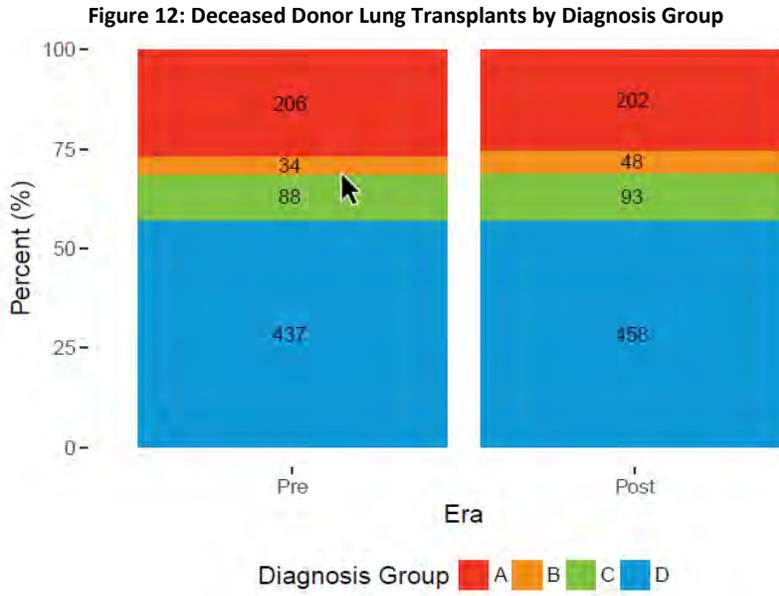
Monitoring began upon implementation of the emergency action lung policy change on November 24, 2017. Therefore, the Committee has had the opportunity to analyze short-term effects of the policy change: once at ten weeks post-implementation³⁵, and again at four months post-implementation.³⁶ The cohort for the four month analysis includes adults (age greater than or equal to 12) that received a lung alone transplant from November 25, 2016 through March 24, 2017 (pre era) and November 25, 2017 through March 24, 2018 (post era).

Transplant

There were a total of 765 deceased donor lung transplants for lung alone recipients (age greater than or equal to 12) in the pre (November 25, 2016 - March 24, 2017) era and a total of 801 deceased donor lung transplants for lung alone recipients (age greater than or equal to 12) in the post (November 25, 2017 - March 24, 2018) era. There were 4 pediatric (age <12) lung transplants in the pre era and 3 in the post era that are not included in the analysis cohort. **Figure 12** demonstrates the impact on deceased donor lung transplants by diagnosis group.

³⁵ OPTN/UNOS. Out-of-the-Gate Monitoring of Lung Allocation Removal of DSA as an Unit of Allocation. Prepared for the Thoracic Committee, Lung Subcommittee Meeting February 15, 2018.

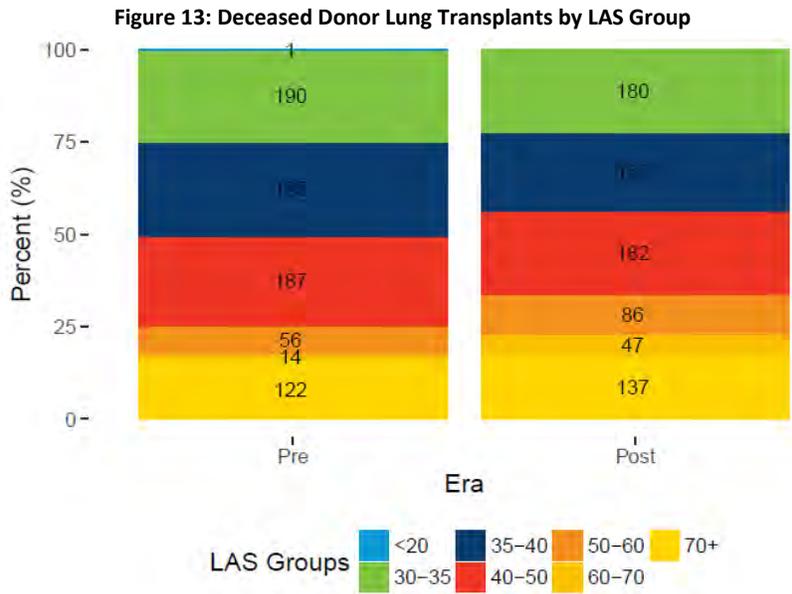
³⁶ OPTN/UNOS. *Monitoring of the Lung Allocation Change, 4 Month Report Removal of DSA as a Unit of Allocation.*



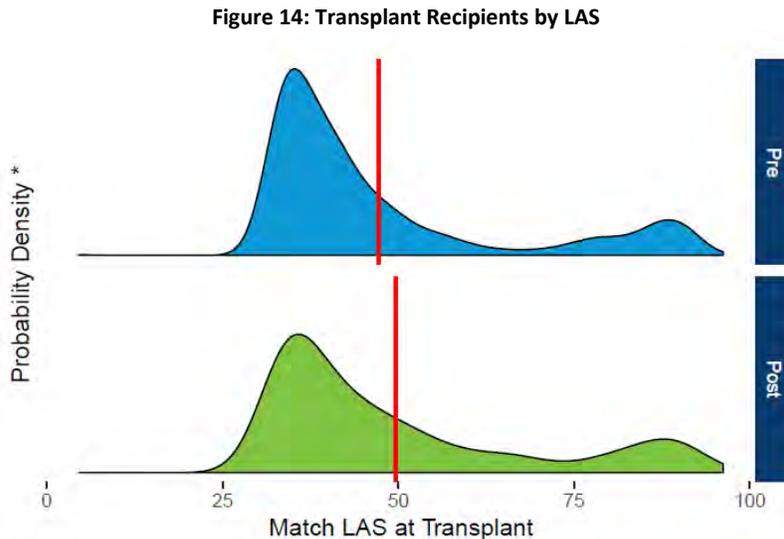
There was not a statistically significant difference in the diagnosis group of recipients of deceased donor lung transplants between the two eras. The majority of lung transplant recipients in both eras were in diagnosis group D- restrictive lung disease. There were approximately twice as many transplants for recipients in diagnosis group D than there were in the second largest diagnosis group, A- obstructive lung disease. The smallest transplant recipient diagnosis group in both eras is B- pulmonary vascular disease.

In **Figure 13**, deceased donor lung transplant recipients are summarized by LAS group.³⁷

³⁷ The LAS groups were defined as follows: <20, 20-30, 30-35, 35-40, 40-50, 50-60, 60-70, 70<, where higher LAS score represent clinically sicker patients.



There is evidence of a difference between proportion of recipients in each of the LAS groups when comparing the pre and post era. Similarly, the distribution of match LAS at transplant is depicted in **Figure 14**.³⁸

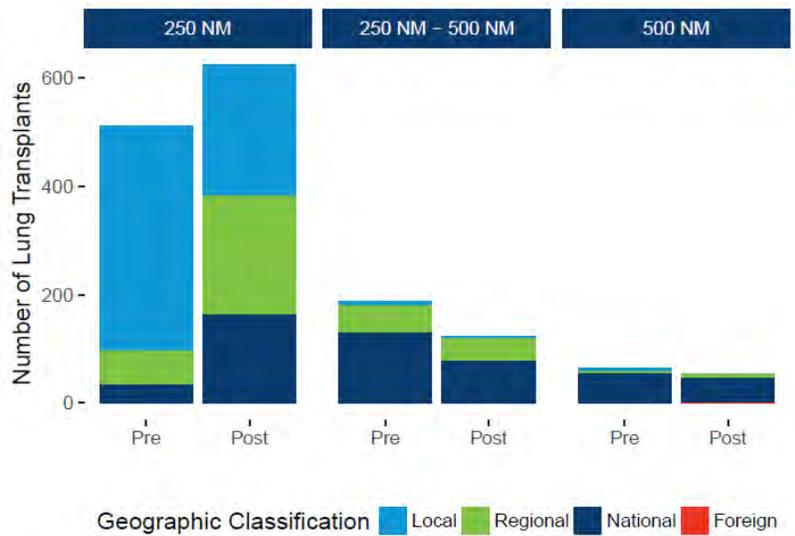


The average match LAS at time of transplant for the pre era was 47.23 and 49.61 for the post era. There was a statistically significant difference between the mean LAS in the pre era compared to the post era (p-value=0.009). Additionally, there were 112 recipients with a LAS of at least 75 in the pre era and 127 in the post era.

There was a 57.3% decrease in the number of transplants within the DSA. There was an increase in the number of regional transplants with the majority of that increase within the first unit of allocation (250 NM). There was also an overall increase in the number of nationally allocated lung transplants. **Figure 15** shows that 66.9% of lung transplants happened within the first unit of allocation (250 NM) in the post era.

³⁸ High probability density values mean that a high percentage of the population lies at or around the corresponding x-axis value, and vice versa. Red line indicates the mean in each corresponding era.

Figure 15: Transplants by Geographic Classification and Distance (NM)

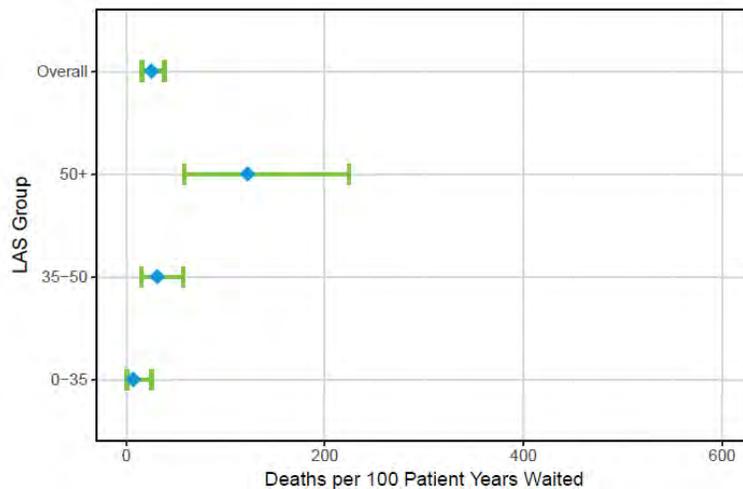


The Committee will continue to monitor the effect of the policy change, particularly with regard to how the change in distribution impacts waitlist and post-transplant outcomes.

2. Heart-Lung Allocation

The Committee requested OPTN data to evaluate the relative urgency of heart candidates compared to heart-lung candidates by comparing the death rate on the waiting list for heart-lung candidates based on their heart status and LAS.³⁹ **Figure 16** examines death rates for adult (age ≥ 18) heart-lung candidates ever waiting from January 1, 2015 to December 31, 2016, for a heart-lung, heart and heart-lung, lung and heart-lung, heart and lung, or heart, lung and heart-lung transplant stratified by LAS group. The LAS groups used to calculate death rates for heart-lung patients were based on the traditional LAS intervals studied by the Committee. However, some LAS groups were collapsed so that each LAS group represented at least 25 candidates.

Figure 16: Death Rates for Heart-Lung Candidates by LAS Group

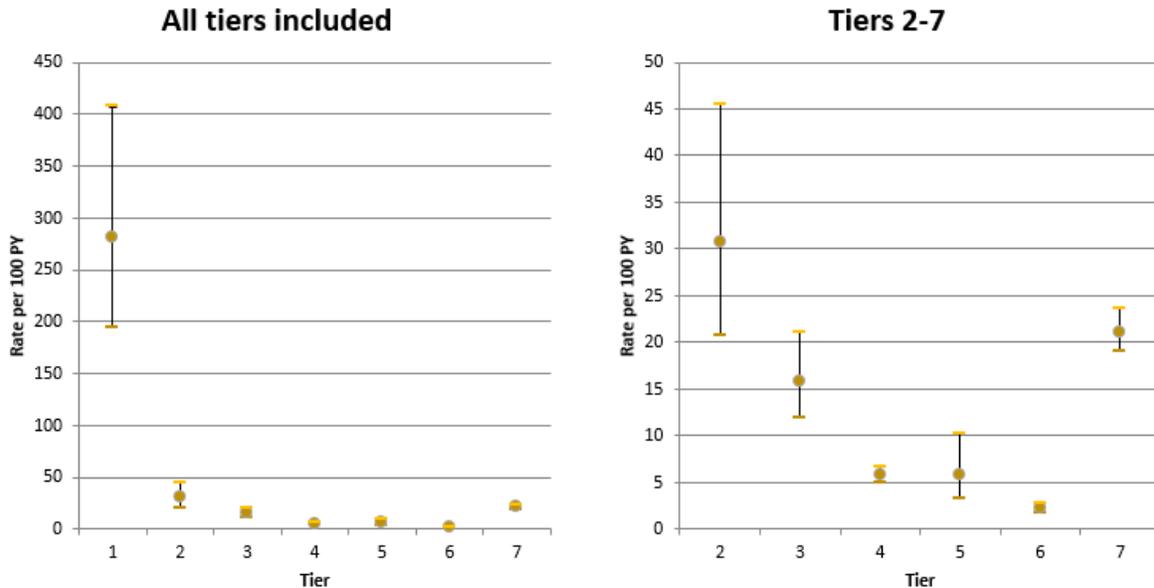


³⁹ OPTN Descriptive Data Request, "Heart-Lung Allocation: Death Rates for Heart-Lung, Heart, and Lung Candidates."

As a heart-lung candidate's LAS increase so does the waitlist death rate. The mean death rate for heart-lung candidates with an LAS greater than 50 is 122.07, for heart-lung candidates with an LAS between 35-50 is 31.24, and for candidates with an LAS 0-35 is 7.08.

The Committee then re-examined data previously prepared by the SRTR demonstrating projected waiting list mortality rates for candidates in the new adult heart allocation system, by tier (now referred to as statuses).⁴⁰ See **Figure 17** below.

Figure 17: Waiting List Mortality Rates by Tier in New Adult Heart Allocation System



The heart candidates projected to qualify for tier/status 2 in the new adult heart allocation system have a waitlist mortality rate close to 30 per 100 patient years, while the candidates that would qualify for status 3 demonstrate a projected waitlist mortality rate much lower; closer to 15. For this reason, the Committee proposes granting priority to heart or heart-lung candidates in heart classifications 1-4 for heart-lung offers prior to allocating heart-lungs to lung or heart-lung candidates in lung classifications 1-10 for offers from adult donors.

3. Sensitization Policy

Like adult heart allocation policy, there are no data to inform a more elaborate policy change because policy does not currently require transplant programs to report unacceptable antigens (UAs) for lung candidates. UAs are not reported for many lung candidates, and even if reported there is no way to determine whether all UAs have been reported for that candidate. However, even though no data exists, the Committee wanted to provide a pathway.

Which populations are impacted by this proposal?

This proposal is primarily intended to impact lung candidates greater than 12 years old, by providing them with access to donors in a broader geographic area. As of December 31, 2017, there were 1,355 candidates on the lung waiting list: 20 were 0-11 years old; 18 were 12-17 years old; and 1,317 were 18 years or older. This proposal will also impact heart-lung candidates. As of December 31, 2017, there were 43 candidates listed for a heart and a heart-lung or a heart and a lung or a lung and a heart-lung or a heart, lung, and heart-lung or a heart-lung. All of these candidates were 18 years or older.

⁴⁰ SRTR Data Request: Heart Allocation Request: Preliminary Data. Presented to the Thoracic Organ Transplantation Committee on February 19, 2014.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* These changes increase equity in access to transplants by ensuring candidates with greater medical urgency, regardless of their geographic location, have broader and more similar access to donor lungs.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* These changes may improve waitlist mortality by transplanting patients with higher LAS scores.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* These changes ensure that lung allocation policy as a whole is internally consistent and practical.

How will the OPTN implement this proposal?

The changes to lung distribution were programmed on November 24, 2017. Heart-lung allocation policy is not currently programmed and there is no need to program it if these changes are approved. If these changes are approved by the Board at its June 2018 meeting, then the changes to heart-lung policy will be effective at the time that the changes to adult heart allocation policy are implemented. This is currently scheduled for fourth quarter of 2018. There is no programming required for the proposed sensitization policy.

The OPTN/UNOS will follow normal processes to inform members and educate them on any policy changes through policy notices. The OPTN/UNOS will deliver communications to the membership to promote knowledge, awareness, and compliance related to policy and system changes in advance of implementation. UNOS Professional Education will monitor this proposal and determine whether education will be needed. In the likely event that education is needed, UNOS Professional Education will then determine the most effective way to educate members in the community.

How will members implement this proposal?

Transplant Hospitals

The changes to lung distribution may impact transplant program costs, as broader sharing may increase the number, distance, and time of additional lung fly outs and as some programs may need to hire more transplant surgeons to travel further to recover lungs from donors. Transplant programs may increase their use of ex vivo lung perfusion for lungs recovered from donors farther away. The changes to heart-lung allocation policy would not require transplant programs to change their behavior, and transplant programs with candidates in need of a heart and lung should continue to follow previous guidance distributed by the OPTN advising transplant programs to register those candidates for all three organs (heart, lung, and heart-lung).⁴¹

OPOs

These changes include modifications to the adult lung allocation sequence and may impact OPO practices and costs. Additionally, OPOs should become familiar with the changes to heart-lung allocation and sensitization policy. OPOs should follow previously-issued yet removed guidance advising OPOs to simultaneously generate a lung and heart-lung match run when allocating a heart-lung.

⁴¹ OPTN/UNOS Memorandum: Adding Heart-Lung Candidates to and Removing them from the Waiting List. Distributed via email to all thoracic transplant clinicians on January 27, 2011.

Histocompatibility Laboratories

There are no anticipated impacts on histocompatibility laboratories.

Will this proposal require members to submit additional data?

No, these changes do not require additional data collection.

How will members be evaluated for compliance with this proposal?

UNOS staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy and will continue to investigate potential policy violations. All policy requirements, as well as any data entered in UNetSM, may be subject to OPTN/UNOS review, and members are required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

Out-of-the-gate monitoring and a 4-month monitoring report was presented to the Thoracic Committee. Additional reports will be shared with the Committee within 12 months of the allocation change. This will focus on changes in the waiting list, transplants, and utilization and will encompass the following:

- Examine changes to the waiting list including the size, number of additions and/or removals, LAS, and population characteristics
- Evaluate the changes in the distribution of the LAS score at listing by geography, i.e. nationally/regionally/locally
- Examine changes in deceased donor lung transplants including recipient characteristics, LAS, and diagnosis
- Evaluate the geographic distribution of deceased donor lung transplants
- Evaluate changes in lung discard rate and rate of recovery of deceased donor lungs geographically
- Examine volume of candidates registered for both a heart and a lung, and volume of heart-lung transplants, and heart status and LAS of each

At least annually for three years, the Committee will review OPTN/UNOS data analyses to assess the efficacy of the LAS system. This will include waiting list and post-transplant outcomes for lung candidates and recipients, as well as the impact of distance on discard rates, acceptance rates and post-transplant survival rates – and whether these changes impacted various patient subpopulations including diagnosis groups, age, ethnicity, and others. Waiting list and post-transplant outcomes of heart-lung candidates and recipients will also be studied as part of monitoring the change to heart-lung allocation policy.

The OPTN and SRTR contractors will work with the committee to define the specific analyses requested for ongoing monitoring for each annual update.

Policy or Bylaws Language

New language is underlined (example) and language that is proposed for removal is struck through (~~example~~). The proposed language as shown below includes both the changes already approved by the Executive Committee on November 24, 2017 and the additional changes offered in this proposal.

1 **RESOLVED**, that the expiration date for Policies *1.2: Definitions; 10.4.C: Allocation of Lungs from*
2 *Deceased Donors at Least 18 Years Old; and 10.4.D: Allocation of Lungs from Deceased Donors Less*
3 *than 18 Years Old*, as set forth below, scheduled to expire on November 24, 2018, be extended to
4 November 24, 2020.

5
6 **FURTHER RESOLVED**, that changes to Policy *10.2.A: Allocation Exception for Sensitized Patients*, as
7 set forth below, are hereby approved, effective June 12, 2018.

8
9 **FURTHER RESOLVED**, that changes to Policy *6.6.F: Allocation of Heart-Lungs*, as set forth below, are
10 hereby approved, effective pending implementation and notice to members.

11 12 **1.2 Definitions**

13 **Zone**

14 A geographical area used in the allocation of certain organs.

15
16 The allocation of ~~thoracic organs~~ hearts uses the following five concentric bands:

17
18 Zone A Includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of
19 the donor hospital's DSA.

20 Zone B All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A
21 and the donor hospital's DSA.

22 Zone C All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone B
23 and the donor hospital's DSA.

24 Zone D All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone C.

25 Zone E All transplant hospitals more than 2,500 nautical miles from the donor hospital.

26
27 The allocation of lungs uses the following six concentric bands:

28
29 Zone A Includes all transplant hospitals within 250 nautical miles of the donor hospital.

30 Zone B All transplant hospitals within 500 nautical miles of the donor hospital but outside of Zone A.

31 Zone C All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone B.

32 Zone D All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone C.

33 Zone E All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone D.

34 Zone F All transplant hospitals more than 2,500 nautical miles from the donor hospital.

35 36 **6.6.F Allocation of Heart-Lungs**

37 ~~When a heart-lung potential transplant recipient (PTR) is offered a heart, the lung from the same~~
38 ~~deceased donor must be offered to the heart-lung PTR.~~

39
40 ~~When a heart-lung PTR is offered a lung, the heart from the same deceased donor must be~~
41 ~~offered to the heart-lung PTR according to *Table 6-9* below.~~

43

Table 6-9: Allocation of Heart-Lungs If PTR is Offered the Lung

When a heart-lung PTR in this geographic area is offered a lung:	The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:	Within this geographic area:
OPO's DSA or Zone A	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	OPO's DSA or Zone A
Zone B	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone B
Zone C	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone C
Zone D	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone D
Zone E	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone E

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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*.

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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* applies to heart-lung candidates when the candidates appear on the lung match run.

55

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

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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*.

61

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64

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

65 heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D:*
66 *Allocation of Hearts from Donors at Least 18 Years Old.*
67

68 **6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less**
69 **Than 18 Years Old**

70 If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO
71 must offer the lungs from the same deceased donor to the heart or heart-lung PTR
72 according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old.*
73

74 If a lung or heart-lung PTR in allocation classifications 1 through 10 according to
75 *Policy 10.4.D: Allocation of Lungs From Deceased Donors Less Than 18 Years Old*
76 requires a heart, the OPO cannot allocate the heart from the same deceased donor
77 to the lung or heart-lung PTR until after the heart has been offered to all heart and
78 heart-lung PTRs in allocation classifications 1 through 12 according to *Policy 6.6.E:*
79 *Allocation of Hearts from Donors Less Than 18 Years Old.*
80

81 **10.2.A Allocation Exception for Highly Sensitized Patients**

82 ~~Lungs may be allocated to sensitized candidates within a DSA out of the sequence required by~~
83 ~~the match run if:~~
84

- 85 ~~1. The candidate's transplant surgeon or physician determines that the candidate's antibodies~~
86 ~~would react adversely to certain human leukocyte antigens (HLA) antigens.~~
- 87 ~~2. All lung transplant programs and the OPO within the DSA agree to allocate the lung from a~~
88 ~~compatible deceased donor to the sensitized candidate because the results of a crossmatch~~
89 ~~between the blood serum of that the candidate and cells of the lung donor are negative.~~
- 90 ~~3. The candidate's transplant program, all lung transplant programs, and the OPO within a DSA~~
91 ~~agree upon the level of sensitization at which a candidate qualifies for the sensitization~~
92 ~~exception.~~

93
94 ~~Sensitization alone does not qualify a candidate to qualify for an exception as described in *Policy*~~
95 ~~*10.2.B: Lung Candidates with Exceptional Cases* below.~~
96

97 A lung candidate's transplant physician may use medical judgment to determine that a lung
98 candidate is highly sensitized.
99

100 If there is one or more lung transplant programs that have potential transplant recipients (PTRs)
101 who appear on the match run above the highly sensitized candidate, then the highly sensitized
102 candidate's transplant program may request that those transplant programs refuse the offer so
103 that the transplant program can accept the offer for the highly sensitized candidate.
104

105 If the only PTRs on the match run are registered at the same transplant program as the highly
106 sensitized candidate, the transplant physician may use medical judgment to accept the offer for
107 the highly sensitized candidate out of sequence.
108

109 **10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old**

110 Single and double lungs from deceased donors at least 18 years old are allocated according to
111 *Table 10-9* below.
112

113

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
4	OPO's DSA	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7₁	Zone A	At least 12 years old, blood type identical to the donor
8₂	Zone A	At least 12 years old, blood type compatible with the donor
9₃	Zone A	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
10₄	Zone A	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
11₅	Zone A	Priority 2, blood type identical to the donor
12₆	Zone A	Priority 2, blood type compatible with the donor
13₇	Zone B	At least 12 years old, blood type identical to the donor
14₈	Zone B	At least 12 years old, blood type compatible with the donor
15₉	Zone B	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor

Classification	Candidates that are included within the:	And are:
		<ul style="list-style-type: none"> • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
<u>4610</u>	Zone B	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
<u>4711</u>	Zone B	Priority 2, blood type identical to the donor
<u>4812</u>	Zone B	Priority 2, blood type compatible with the donor
<u>4913</u>	Zone C	At least 12 years old, blood type identical to the donor
<u>2014</u>	Zone C	At least 12 years old, blood type compatible with the donor
<u>2415</u>	Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
<u>2216</u>	Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
<u>2317</u>	Zone C	Priority 2, blood type identical to the donor
<u>2418</u>	Zone C	Priority 2, blood type compatible with the donor
<u>2519</u>	Zone D	At least 12 years old, blood type identical to the donor
<u>2620</u>	Zone D	At least 12 years old, blood type compatible with the donor
<u>2721</u>	Zone D	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
<u>2822</u>	Zone D	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
<u>2923</u>	Zone D	Priority 2, blood type identical to the donor
<u>3024</u>	Zone D	Priority 2, blood type compatible with the donor
<u>3125</u>	Zone E	At least 12 years old, blood type identical to the donor
<u>3226</u>	Zone E	At least 12 years old, blood type compatible with the donor
<u>3327</u>	Zone E	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for intended blood group incompatible offers</u>
<u>3428</u>	Zone E	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for intended blood group incompatible offers</u>
<u>3529</u>	Zone E	Priority 2, blood type identical to the donor
<u>3630</u>	Zone E	Priority 2, blood type compatible with the donor
<u>31</u>	<u>Zone F</u>	<u>At least 12 years old, blood type identical to the donor</u>
<u>32</u>	<u>Zone F</u>	<u>At least 12 years old, blood type compatible with the donor</u>
<u>33</u>	<u>Zone F</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for intended blood group incompatible offers</u>
<u>34</u>	<u>Zone F</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for intended blood group incompatible offers</u>
<u>35</u>	<u>Zone F</u>	<u>Priority 2, blood type identical to the donor</u>
<u>36</u>	<u>Zone F</u>	<u>Priority 2, blood type compatible with the donor</u>

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10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old

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Single and double lungs from deceased donors less than 18 years old are allocated according to *Table 10-10* below.

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120**Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old**

Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, or Zone B, or Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
2	OPO's DSA, Zone A, or Zone B, or Zone C	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
3	OPO's DSA, Zone A, or Zone B, or Zone C	Priority 2, blood type identical to the donor
4	OPO's DSA, Zone A, or Zone B, or Zone C	Priority 2, blood type compatible with the donor
5	OPO's DSA, Zone A, or Zone B, or Zone C	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA, Zone A, or Zone B, or Zone C	12 to less than 18 years old, blood type compatible with the donor
7	OPO's DSA	At least 18 years, blood type identical to the donor
8	OPO's DSA	At least 18 years, blood type compatible with the donor
<u>97</u>	Zone A	At least 18 years old, blood type identical to the donor
<u>408</u>	Zone A	At least 18 years old, blood type compatible with the donor
<u>449</u>	Zone B	At least 18 years old, blood type identical to the donor
<u>4210</u>	Zone B	At least 18 years old, blood type compatible with the donor
<u>11</u>	<u>Zone C</u>	<u>At least 18 years old, blood type identical to the donor</u>
<u>12</u>	<u>Zone C</u>	<u>At least 18 years old, blood type compatible with the donor</u>
13	Zone <u>CD</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
14	Zone <u>CD</u>	Priority 1 and <i>one</i> of the following:

Classification	Candidates that are included within the:	And are:
		<ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
15	Zone <u>GD</u>	Priority 2, blood type identical to the donor
16	Zone <u>GD</u>	Priority 2, blood type compatible with the donor
17	Zone <u>GD</u>	12 to less than 18 years old, blood type identical to the donor
18	Zone <u>GD</u>	12 to less than 18 years old, blood type compatible with the donor
19	Zone <u>GD</u>	At least 18 years old, blood type identical to the donor
20	Zone <u>GD</u>	At least 18 years old, blood type compatible with the donor
21	Zone <u>DE</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone <u>DE</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
23	Zone <u>DE</u>	Priority 2, blood type identical to the donor
24	Zone <u>DE</u>	Priority 2, blood type compatible with the donor
25	Zone <u>DE</u>	12 to less than 18 years old, blood type identical to the donor
26	Zone <u>DE</u>	12 to less than 18 years old, blood type compatible with the donor
27	Zone <u>DE</u>	At least 18 years old, blood type identical to the donor
28	Zone <u>DE</u>	At least 18 years old, blood type compatible with the donor
29	Zone <u>EF</u>	Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
30	Zone <u>EF</u>	Priority 1 and <i>one</i> of the following:

Classification	Candidates that are included within the:	And are:
		<ul style="list-style-type: none"> • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
31	Zone <u>EF</u>	Priority 2, blood type identical to the donor
32	Zone <u>EF</u>	Priority 2, blood type compatible with the donor
33	Zone <u>EF</u>	12 to less than 18 years old, blood type identical to the donor
34	Zone <u>EF</u>	12 to less than 18 years old, blood type compatible with the donor
35	Zone <u>EF</u>	At least 18 years old, blood type identical to the donor
36	Zone <u>EF</u>	At least 18 years old, blood type compatible with the donor

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