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Public Comment Proposal

Modifications to the Distribution of Deceased Donor Lungs

OPTN/UNOS Thoracic Organ Transplantation Committee

Prepared by: Liz Robbins Callahan, Esq.
UNOS Policy Department

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Modifications to the Distribution of Deceased Donor Lungs

Affected Policies: *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*
Sponsoring Committee: *Thoracic Organ Transplantation Committee*
Public Comment Period: *January 22, 2018 – March 23, 2018*

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 is now being 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 public comment 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 has not yet been implemented
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, provide more equity in access to transplantation regardless of a candidate's geography, and to clarify and make more transparent the heart-lung allocation policy. These changes also address how implementation of the new lung allocation policy impacts heart-lung allocation policy and policy addressing sensitized lung candidates.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee appreciates feedback from the community on the entire proposal, and specifically requests that the community consider the interim policy and alternative policies in light of the requirements of the OPTN Final Rule. Additional questions include:

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?

Members are also asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

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

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.

1. 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

[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
[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

(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 Organ Procurement and Transplantation Network (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 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

[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.*
[7] 42 C.F.R. § 121.8 available at Electronic Code of Federal Regulations
[8] SRTR: OPO Statistics. https://www.srtr.org/reports-tools/opo-specific-reports/ Accessed on January 4, 2018.

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.

2. 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 is awaiting implementation. [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:

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

[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

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.

3. 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 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 the 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]

[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

[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

However, the Executive Committee considered multiple studies using OPTN/UNOS data suggest 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 and 4** below.

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

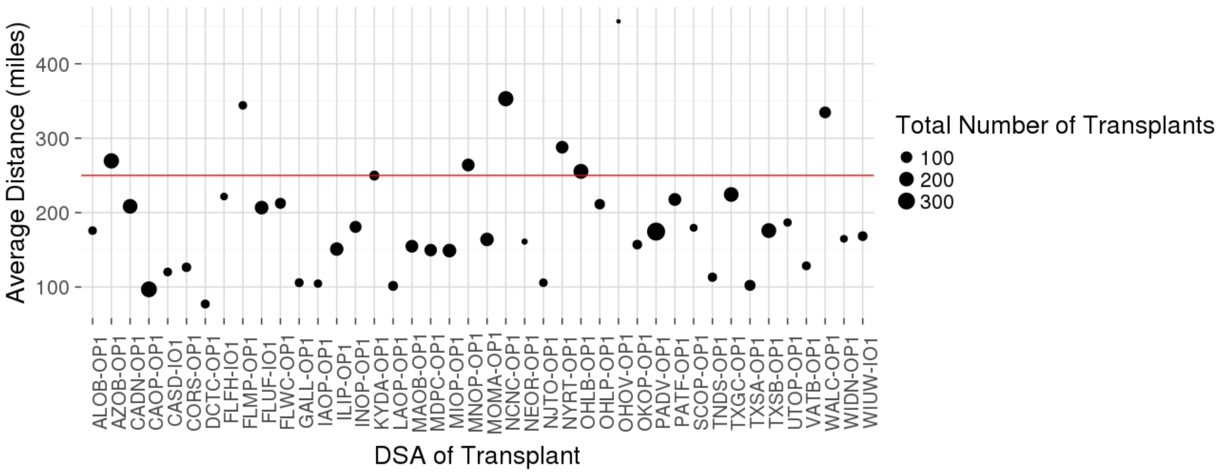


Figure 3 summarizes the average distance from the donor hospital to the transplant center by DSA for all lung transplants performed between January 1, 2015 and December 31, 2016 where the recipient was at least 12 years of age. The red line indicates an average of 250 nautical miles between the donor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

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 4: Percentage of Lung Transplants that Travelled Further than 250 miles by DSA

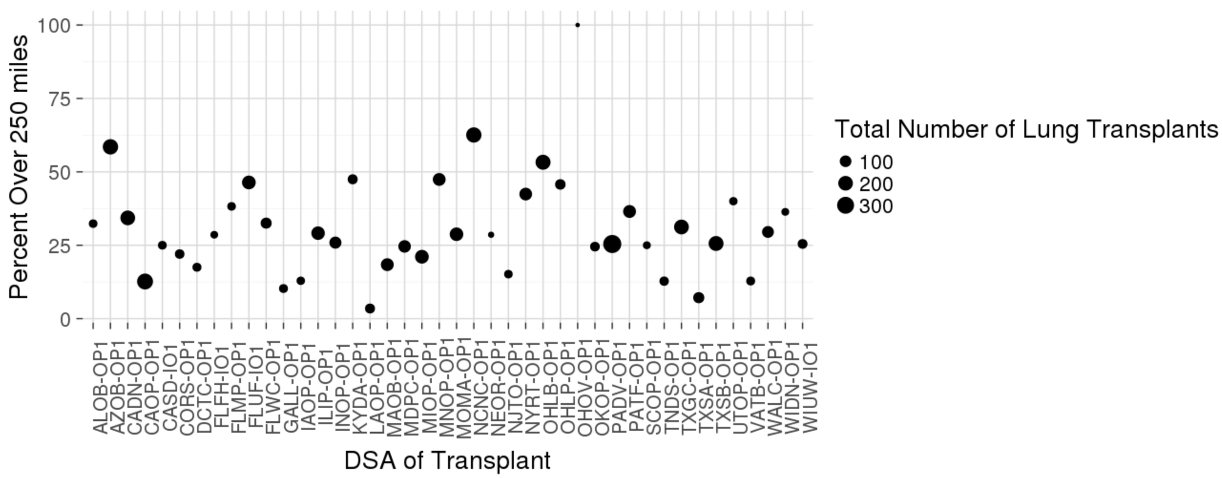


Figure 4 summarizes the percentage of lung transplants for the same cohort that travelled further than 250 nautical miles by DSA.

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) with "new" policy (distributing lungs to a 250 nautical mile radius around the donor hospital), and with 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.

During and following the public comment period, the Thoracic Committee will request additional modeling reflecting the other distances while continuing to develop lung allocation policy. The Committee's ongoing discussions will include whether 250 nautical miles is the optimal first unit of distribution for adult donor lungs, whether it makes sense - at least in areas with fewer donor hospitals that are further apart or where the DSA boundaries are bigger than the first zone - to distribute to the first zone and to the DSA, or whether more novel approaches, such as those based on population density, will result in optimal lung allocation.

1. 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 UNet℠. 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. 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 5 below, the latter type of match is referenced as a lung* match.

Figure 5: 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

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

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 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.[20] A heart-lung guidance document was released previously to aid in the execution of heart-lung policy under the DSA system.[21]

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.

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.[22]

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, Committee members cited instances from experience in which a heart-lung candidate is allocated the heart from the same deceased donor after being allocated the lung,

[20] 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).
[21] https://optn.transplant.hrsa.gov/media/1139/heart_lung_allocation_guidance.pdf
[22] 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

rather than being allocated the 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 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.

Therefore, 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 sharing prior to local sharing for low risk candidates. Thus, defining allocation of heart-lung blocs based primarily on zones resulted in allocation priorities very different from the 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 sharing 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 6 below.

Figure 6: 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

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 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 *one* of the following: • 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 *one* of the following: • 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
		8	Zone B	At least 12 years old, blood type compatible with the donor

In this geographic area…	Adult donor hearts are allocated to these candidates…	Classification	In this geographic area…	Adult donor lungs are candidates…
		9	Zone B	Priority 1 and *one* of the following: • 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 *one* of the following: • 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 7 below.

Figure 7: 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 *one* of the following: • Less than 12 years old and 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…
				• 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 *one* of the following: • 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
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

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…
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.[23] 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 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

[23] 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.

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.[24] It is even rarer for a heart-lung transplant to occur greater than 500 nautical miles away from the donor hospital. See **Figure 8** below.

Figure 8: Heart-Lung Transplants by Distance in Nautical Miles (NM) 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.

2. 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 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:

[24] Data obtained from the OPTN database on December 12, 2017.

2. 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;
3. permit transplant programs to request an exception from the Lung Review Board (LRB) to prioritize the sensitized candidate; or
4. remove the policy altogether.

The first 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.

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.

Finally, the Committee considered 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 ultimately proposes.

How well does this proposal address the problem statement?

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

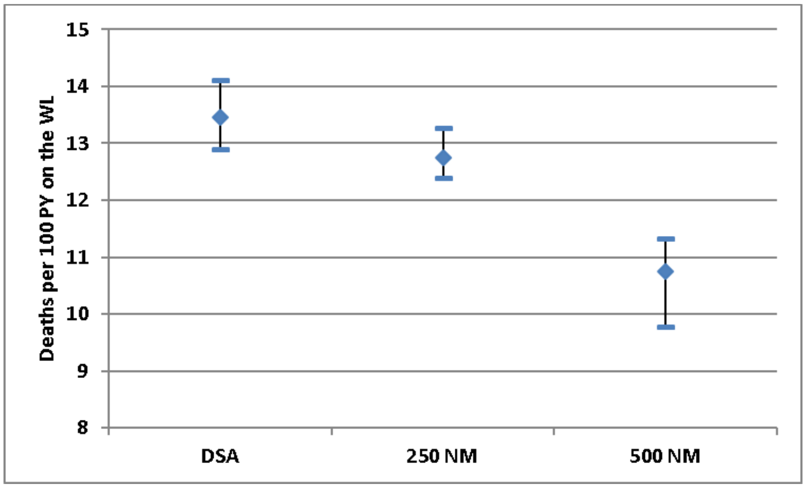
1. Removal of DSA as a Unit of Distribution for Lungs

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 (NM) of the donor hospital, or 500 NM of the donor hospital.[25] Graphs from simulations plot the average, minimum and maximum values of the data across 10 repetitions of the simulation.

<u>*Impact on Waitlist Mortality*</u>
Overall, the DSA and 250 NM waitlist mortality rates were similar; the ranges (minimum to maximum) of these two simulations overlapped. When comparing DSA and 500 NM 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 NM compared to 250 NM or DSA.

Figure 9: Overall Waitlist Mortality Rates by Simulation

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



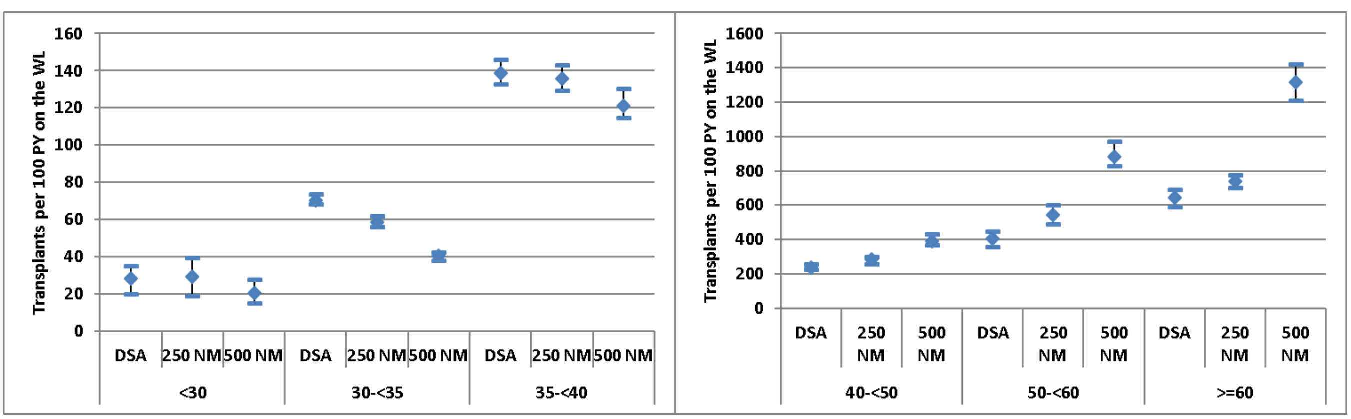
When stratified by diagnosis, waitlist mortality rates did not change when comparing DSA and 250 NM; however, with 500NM waitlist mortality declined for candidates from diagnosis Group D.[26]

When stratified by OPTN region, the TSAM suggests that waitlist mortality rates are also not anticipated to increase in any region. In the 250 NM simulation, average value for waitlist mortality rates tended to decline but overlapped the range of the DSA simulation's rates. In the 500 NM 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."[27] 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 NM 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."[28]

Transplant Rates

Overall, transplant rates in the DSA and 250 NM simulations differed slightly or not at all; however, in the 500 NM simulation average rate declined, but remained within the range of the simulation.[29] Importantly, the transplant rates for candidates with LAS scores greater than or equal to 40 increased in both the 250 NM and 500 NM simulations. See **Figure 10** below.

Figure 10: Transplant Rates by Simulation and LAS

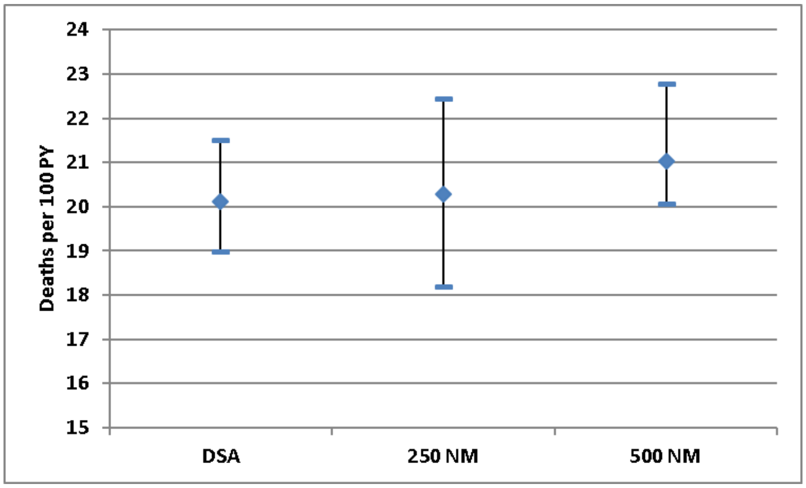


[26] The LAS calculation uses Diagnosis Groups A, B, C, and D, as defined in OPTN/UNOS Policy 10.1.F.i: Lung Disease Diagnosis Groups. Reference policy for a complete list of the diagnoses that are categorized in each diagnosis group. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10. Accessed on January 18, 2018.
[27] SRTR Analysis Report. Data Request ID#: LU2017_02 at page 9. January 12, 2018.
[28] *Id.* at 11.
[29] *Id.* at 5.

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.

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.

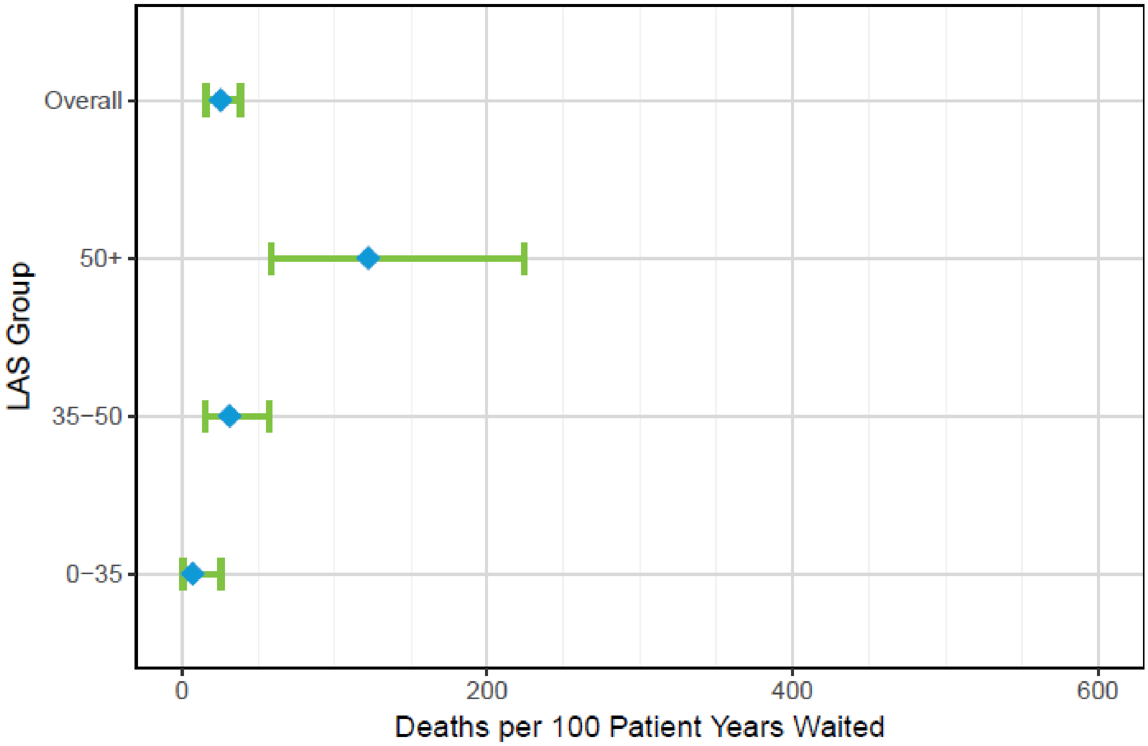
In summary, the TSAM suggests that distributing adult donor lungs to all candidates within 250 NM of the donor hospital will result in an effect that is similar to distributing first to the DSA. This suggests that the Executive Committee's change is unlikely to result in any immediate or alarming unintended 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 NM, since patients with higher LAS scores will have a greater opportunity to receive a lung transplant.

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.[30] **Figure 12** examines death rates for adult (age $\geq$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.

[30] 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.

Figure 12: Death Rates for Heart-Lung Candidates by LAS Group

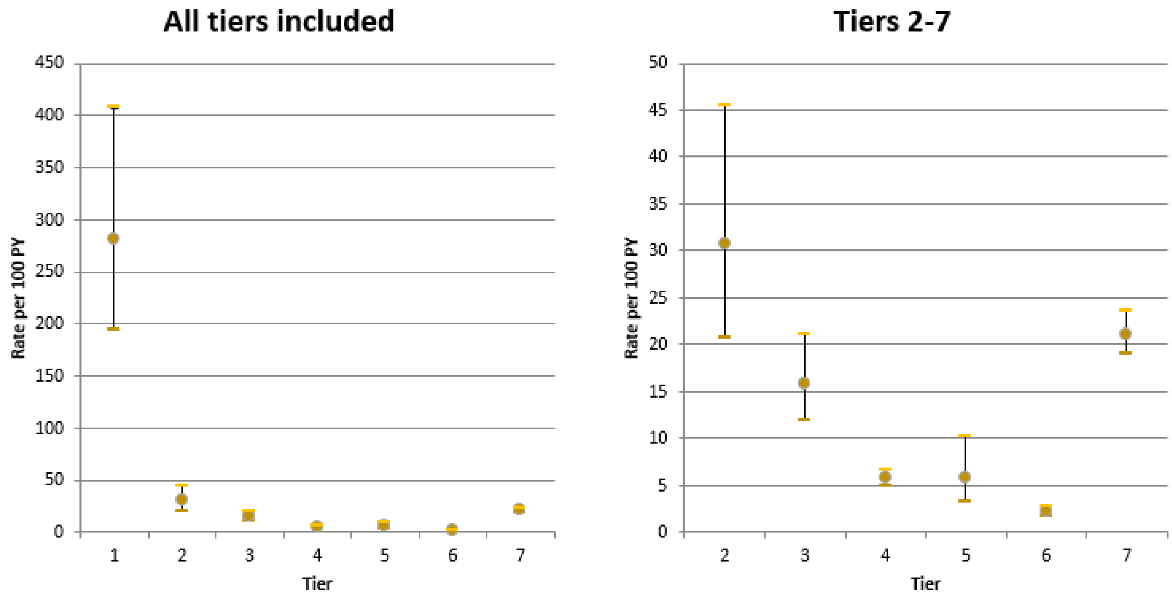


As a heart-lung candidate's LAS increase so does the waitlist death rate. The mean death rate for heart-lung candidates with an LAS greater than 50 is 122.07, for heart-lung candidates with an LAS between 35-50 is 31.24, and for candidates with an LAS 0-35 is 7.08.

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).[31] See **Figure 13** below.

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

Figure 13: 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. As mentioned previously, UNOS staff could not recall a time in which current sensitization policy has been used for a lung candidate, and there were no Committee members who have ever used this provision on behalf of their patients.

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.

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 will improve waitlist mortality by transplanting patients with high LAS scores, without dramatically impacting post-transplant mortality.
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 in 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 some time in the third 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. Instructional Innovations will monitor this proposal and determine whether education will be needed. In the likely event that education is needed, Instructional Innovations 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. 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).[32]

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. 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.

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.

[32] 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.

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 UNet℠, 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 of the system will be completed and presented to the Thoracic Committee within 6 and 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.

1.2 Definitions

Zone

A geographical area used in the allocation of certain organs.

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

Zone A	Includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.
Zone B	All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA.
Zone C	All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone B and the donor hospital's DSA.
Zone D	All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone C.
Zone E	All transplant hospitals more than 2,500 nautical miles from the donor hospital.

The allocation of lungs uses the following six concentric bands:

Zone A	Includes all transplant hospitals within 250 nautical miles of the donor hospital.
Zone B	All transplant hospitals within 500 nautical miles of the donor hospital but outside of Zone A.
Zone C	All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone B.
Zone D	All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone C.
Zone E	All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone D.
Zone F	All transplant hospitals more than 2,500 nautical miles from the donor hospital.

6.6.F Allocation of Heart-Lungs

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

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

~~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~~

~~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:~~
~~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~~

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

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

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

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

If a lung PTR in allocation classification 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 that lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.*

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

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

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

~~10.2.A Allocation Exception for Sensitized Patients~~

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

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

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

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

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

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 *one* of the following:~~ • ~~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~~

Classification	Candidates that are included within ~~the~~:	And are:
~~4~~	~~OPO's DSA~~	~~Priority 1 and *one* of the following:~~ • ~~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~~
~~7~~1	Zone A	At least 12 years old, blood type identical to the donor
~~8~~2	Zone A	At least 12 years old, blood type compatible with the donor
~~9~~3	Zone A	Priority 1 and *one* of the following: • 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~~4	Zone A	Priority 1 and *one* of the following: • 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~~5	Zone A	Priority 2, blood type identical to the donor
~~12~~6	Zone A	Priority 2, blood type compatible with the donor
~~13~~7	Zone B	At least 12 years old, blood type identical to the donor
~~14~~8	Zone B	At least 12 years old, blood type compatible with the donor
~~15~~9	Zone B	Priority 1 and *one* of the following: • 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
~~16~~10	Zone B	Priority 1 and *one* of the following: • 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
~~17~~11	Zone B	Priority 2, blood type identical to the donor
~~18~~12	Zone B	Priority 2, blood type compatible with the donor

Classification	Candidates that are included within ~~the~~:	And are:
~~19~~13	Zone C	At least 12 years old, blood type identical to the donor
~~20~~14	Zone C	At least 12 years old, blood type compatible with the donor
~~21~~15	Zone C	Priority 1 and *one* of the following: • 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~~16	Zone C	Priority 1 and *one* of the following: • 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~~17	Zone C	Priority 2, blood type identical to the donor
~~24~~18	Zone C	Priority 2, blood type compatible with the donor
~~25~~19	Zone D	At least 12 years old, blood type identical to the donor
~~26~~20	Zone D	At least 12 years old, blood type compatible with the donor
~~27~~21	Zone D	Priority 1 and *one* of the following: • 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
~~28~~22	Zone D	Priority 1 and *one* of the following: • 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
~~29~~23	Zone D	Priority 2, blood type identical to the donor
~~30~~24	Zone D	Priority 2, blood type compatible with the donor
~~31~~25	Zone E	At least 12 years old, blood type identical to the donor
~~32~~26	Zone E	At least 12 years old, blood type compatible with the donor

Classification	Candidates that are included within ~~the~~:	And are:
~~33~~27	Zone E	Priority 1 and *one* of the following: • 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
~~34~~28	Zone E	Priority 1 and *one* of the following: • 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
~~35~~29	Zone E	Priority 2, blood type identical to the donor
~~36~~30	Zone E	Priority 2, blood type compatible with the donor
31	Zone F	At least 12 years old, blood type identical to the donor
32	Zone F	At least 12 years old, blood type compatible with the donor
33	Zone F	Priority 1 and *one* of the following: • 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
34	Zone F	Priority 1 and *one* of the following: • 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
35	Zone F	Priority 2, blood type identical to the donor
36	Zone F	Priority 2, blood type compatible with the donor

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

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

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 *one* of the following: • 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 *one* of the following: • 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~~
~~9~~7	Zone A	At least 18 years old, blood type identical to the donor
~~10~~8	Zone A	At least 18 years old, blood type compatible with the donor
~~11~~9	Zone B	At least 18 years old, blood type identical to the donor
~~12~~10	Zone B	At least 18 years old, blood type compatible with the donor
11	Zone C	At least 18 years old, blood type identical to the donor
12	Zone C	At least 18 years old, blood type compatible with the donor
13	Zone ~~C~~D	Priority 1 and *one* of the following: • 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

Classification	Candidates that are included within the:	And are:
14	Zone ~~C~~D	Priority 1 and *one* of the following: • 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 ~~C~~D	Priority 2, blood type identical to the donor
16	Zone ~~C~~D	Priority 2, blood type compatible with the donor
17	Zone ~~C~~D	12 to less than 18 years old, blood type identical to the donor
18	Zone ~~C~~D	12 to less than 18 years old, blood type compatible with the donor
19	Zone ~~C~~D	At least 18 years old, blood type identical to the donor
20	Zone ~~C~~D	At least 18 years old, blood type compatible with the donor
21	Zone ~~D~~E	Priority 1 and *one* of the following: • 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 ~~D~~E	Priority 1 and *one* of the following: • 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 ~~D~~E	Priority 2, blood type identical to the donor
24	Zone ~~D~~E	Priority 2, blood type compatible with the donor
25	Zone ~~D~~E	12 to less than 18 years old, blood type identical to the donor
26	Zone ~~D~~E	12 to less than 18 years old, blood type compatible with the donor
27	Zone ~~D~~E	At least 18 years old, blood type identical to the donor
28	Zone ~~D~~E	At least 18 years old, blood type compatible with the donor
29	Zone ~~E~~F	Priority 1 and *one* of the following: • 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

Classification	Candidates that are included within the:	And are:
30	Zone ~~E~~F	Priority 1 and *one* of the following: • 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 ~~E~~F	Priority 2, blood type identical to the donor
32	Zone ~~E~~F	Priority 2, blood type compatible with the donor
33	Zone ~~E~~F	12 to less than 18 years old, blood type identical to the donor
34	Zone ~~E~~F	12 to less than 18 years old, blood type compatible with the donor
35	Zone ~~E~~F	At least 18 years old, blood type identical to the donor
36	Zone ~~E~~F	At least 18 years old, blood type compatible with the donor

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Analysis Report

Data Request from the Lung Sub-Committee of the OPTN Thoracic Committee

January 12, 2018

This report was provided to HRSA by SRTR in support of ongoing policy consideration by the OPTN Lung Subcommittee of the Thoracic Organ Transplantation Committee. The analysis described herein was conducted at the specific request of the OPTN Committee and does not represent a full or final analysis related to the policy issue under consideration.

Prepared by: Melissa Skeans, MS; Maryam Valapour, MD, MPP; Katie Audette, MS; Josh Pyke, PhD

Data Request ID#: LU2017_02

Timeline:

Request made	December 19, 2017
Analysis plan submitted	December 28, 2017
Analysis submitted	January 12, 2018
Next Committee meeting	January 16, 2018

Contents

Data request: Provide Thoracic Simulated Allocation Model (TSAM) results for models of 250 nautical miles (NM) compared with DSA as first unit of allocation of donor lungs

Background:

On November 24, 2017, an emergency action policy change was enacted by the Executive Committee for lung transplantation, removing donation service area (DSA) as the first unit of allocation. To achieve greater consistency with the Final Rule, the first unit of allocation was changed to allocate lungs to all candidates within 250 nautical miles (Zone A) of the donor hospital. Subsequent concentric bands defining units of allocation were changed to 500 nautical miles (Zone B), 1000 nautical miles (Zone C), 1500 nautical miles (Zone D), 2500 nautical miles (Zone E), and more than 2500 nautical miles (Zone F). After the emergency action policy change, the Thoracic Committee reconvened and decided it would be worthwhile to investigate the possible effect of various nautical mile distances as the first unit of allocation for donor lungs.

Strategic Goal or Committee Project Addressed:

Evaluate outcomes associated with the removal of DSA as the first unit of allocation. This project is in alignment with the strategic goal to improve equity in access to transplant.

Request:

The SRTR contractor will be responsible for running the TSAM to determine the potential impact of various nautical miles as the first unit of allocation for donor lungs. All analyses presented below will contain subgroup analyses to determine if specific diagnosis groups, OPTN regions, ethnicities, age groups, or blood types would be disadvantaged with the allocation change. SRTR will also evaluate simulated transplant rate and waitlist and post-transplant outcome differences that are coincidental with these allocation scenarios.

Study Population

The current TSAM uses a cohort of transplant candidates listed on the lung and heart-lung waiting lists on June 30, 2009, and candidates added to those waiting lists from July 1, 2009, through June 30, 2011, as well as all hearts and lungs offered for transplant between July 1, 2009, and June 30, 2011. Results for heart transplant candidates are not included in the report.

Analytic Approach

SRTR used TSAM output files (from data request LU2017_02) produced to compare policy prior to November 24, 2017, with the emergency policy enacted on November 24, 2017. The former policy used DSA as the first unit of allocation of adult donor lungs, and is referred to as the “DSA” simulation. The new policy first offers lungs to candidates within 250 NM of the donor hospital, and is referred to as the “250 NM” simulation. In addition, we provided a simulation of 500 NM as the first unit of allocation because in some large DSAs, use of 250 NM reduces rather than broadens organ sharing. We refer to this as the “500 NM” simulation.

We show results by lung diagnosis groups, demographic groups, blood groups, LAS, and OPTN regions.

Each simulation was repeated 10 times with different orderings of organ arrivals to provide a measure of variability. The average, minimum, and maximum of outcomes below were calculated overall and by subgroups.

1. Waitlist candidate counts.
2. Waitlist death counts and waitlist mortality rates (per 100 person-years of observation).
3. Transplant counts and transplant rates (per 100 person-years of observation).
4. Post-transplant death counts and mortality rates.

We also show changes in the numbers of simulated transplants and waitlist deaths by DSA, and transplant counts and post-transplant outcomes by distances between donor and recipient. Due to small sample sizes and relatively large variability, detailed metrics by DSA are not given.

We do not show center-level data. As TSAM results are subdivided into smaller populations, the impact of random variation increases and the range of TSAM estimates across iterations increases, making results by center difficult to interpret. TSAM also uses statistical models for offer acceptance and post-transplant outcomes, which are based the average observed outcomes across the country. This approach has good predictive power for the system as a whole, without relying on the unique circumstances at any given center in any given year. This is important, especially given the fact that TSAM is used to predict the effects of changes in national allocation policy, to which different centers can be expected to respond differently. However, simulated effects at individual centers would be more poorly predicted than the average effects across the country or other larger groups.

Finally, because definitions of zones changed with each set of allocation rules, we report allocation orderings and results by distances in nautical miles, making them comparable across simulations.

Find allocation rules in Appendix 2.

Summary

- In general, the 250 NM simulation was similar to the DSA simulation, overall and for most subgroups, and the 500 NM simulation produced results more consistent with prior "broader sharing" simulations, in which transplants increased and waitlist deaths decreased among groups known to have higher waitlist mortality.

- With larger radii for the first unit of allocation, the number of local transplants declined considerably, but the number of transplants beyond 1000 NM remained low and unchanged.
- While results of the 250 NM and DSA simulations were largely similar, some differences occurred.
  - We observed increased transplant rates in some subgroups, most of which were characterized by high LAS. These include diagnosis group D, LAS ≥ 40 (with greater increases for higher LAS groups), OPTN region 9, and centers that performed > 100 transplants in the TSAM 2-year time frame.
  - We observed decreased transplant rates in some subgroups, most of which were characterized by low LAS. These include diagnosis group A, LAS < 40, OPTN region 2, and centers that performed 36-75 transplants in the TSAM 2-year time frame.
  - Waitlist mortality rates did not increase among any subgroups, and deceased among adults, especially those aged 50-64 years. The number of waitlist deaths stayed the same or declined for all subgroups.
  - Post-transplant mortality rates were similar to rates in the DSA simulation.
- The 500 NM simulation differed more from the DSA simulation than the 250 NM simulation did, as it increased priority for a larger number of high-LAS candidates.
  - We observed increased transplant rates among Hispanic candidates, diagnosis groups B and D, LAS ≥ 40, OPTN region 9, ABO blood group O, and centers with > 100 transplants in the TSAM 2-year time frame.
  - We observed decreased transplant rates among diagnosis group A, LAS 30-< 40, OPTN regions 8 and 11, ABO blood group A, and centers with 36-75 transplants in the TSAM 2-year time frame.
  - Waitlist mortality rates did not increase for any subgroup, and deceased for adults, especially those aged 50 years or older, all diagnosis groups (with greater declines in high-LAS groups), OPTN regions 2, 5, 6, 8, and 11 (the mid-Atlantic, west, and upper Midwest), ABO blood groups A and O, and mid-volume centers.
  - The number of waitlist deaths remained stable or declined for all subgroups.
  - Post-transplant mortality rates were similar to rates in the DSA simulation.

Interpreting TSAM results

Unless stated otherwise, most graphs plot the average (point estimate), minimum and maximum of the metric computed across the simulations. See Figure 1 as an example. The blue diamond is the average transplant rate across 10 simulations, the top flat bar is the maximum transplant rate, and the bottom flat bar is the minimum transplant rate. Graphs of most TSAM results look as though they have 95% confidence limits, but they do not. TSAM uses the same candidates and donors in all simulation runs, but in different order, and the 10 TSAM runs are not independent samples, which means we cannot compute standard errors and 95% confidence limits.

Limitations of this analysis

The TSAM models and input files used for this analysis precede the February 19, 2015, change in the LAS calculation. Some of the reasons for this are technical, and are described in Appendix 3. Primarily, however, the analysis timeline required using the existing version of the software, which was ready to run immediately.

We believe the data given below are useful in spite of this limitation. We know that diagnosis group B candidates have increased access to donor lungs under the revised LAS. The exact rates computed from current TSAM output might be inaccurate under the more recent LAS equation. However, we don't expect that the relative effects of the 250 NM and 500 NM rules compared with DSA-favored allocation rules will differ greatly.

Discard data are not provided in this report. TSAM uses a straightforward rule under which any organ offered 200 times is discarded. This rule is a historical coding convenience that is unrelated to clinical decision-making from which real discards may result. Thus, we do not believe simulated discard rates would be an accurate enough data point for describing the effects of different allocation rules.

Results

Overall

Overall, the DSA and 250 NM simulations differed slightly or not at all. Transplant rates (Figure 1), waitlist mortality rates (Figure 2), and post-transplant mortality rates (Figure 3) were similar, as were numbers of transplants, waitlist deaths, removals from the waiting list, and post-transplant deaths (Table 1). Waitlist mortality point estimates declined slightly, but the min-max bars overlapped considerably.

When comparing DSA and 500 NM simulations, however, more differences emerged. Transplant rate point estimates declined somewhat, but remained within the range of the simulation. Waitlist mortality rates and death counts declined.

Figure 1. Overall transplant rates by simulation

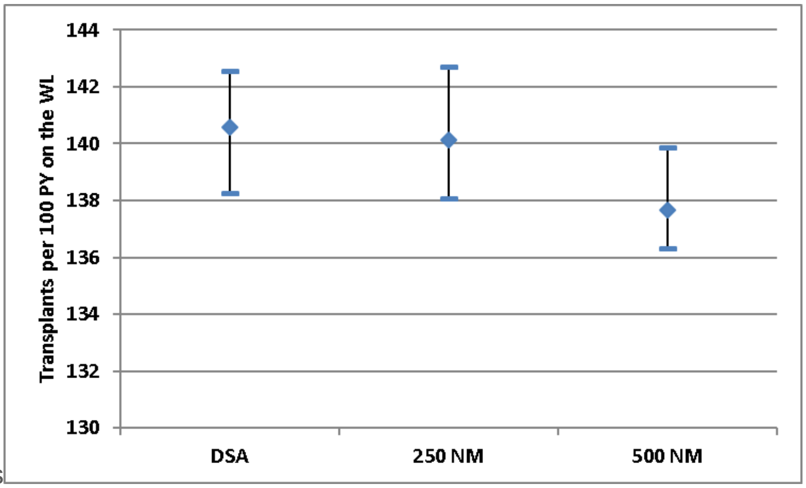

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Figure 2. Overall waitlist mortality rates by simulation

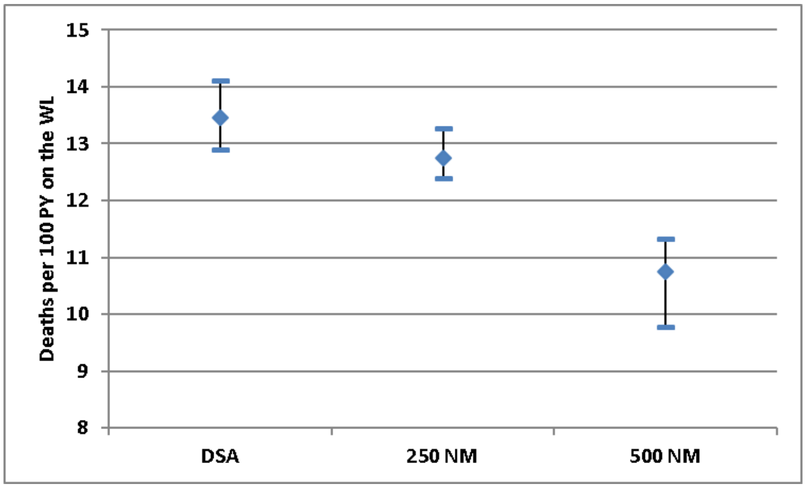


Figure 3. Overall 1-year post-transplant mortality rates by simulation

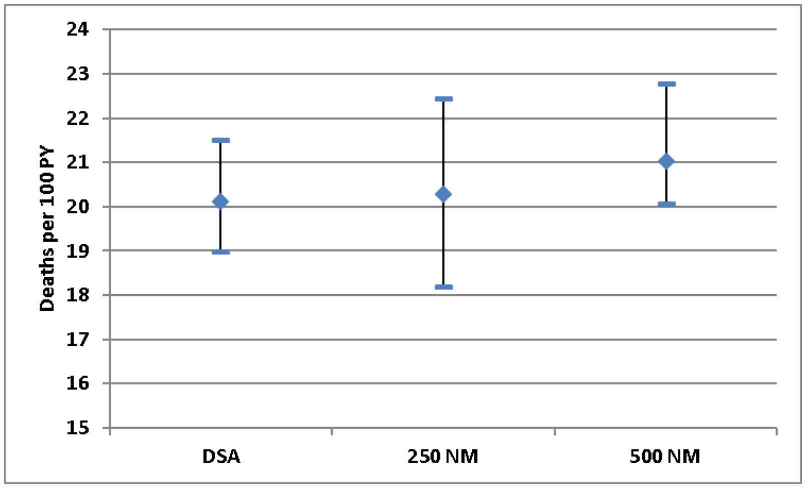


Table 1. Overall TSAM metrics by simulation

Metric	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	6732	6732	6732	6732	6732	6732	6732	6732	6732
TX count	3486	3470	3496	3497	3479	3518	3504	3495	3513
TX rates	140.6	138.3	142.6	140.1	138.1	142.7	137.7	136.3	139.9
WL death counts	487	469	506	464	452	481	397	363	420
WL morality rates	13.5	12.9	14.1	12.7	12.4	13.3	10.7	9.8	11.3
WL Removals	728	715	748	722	705	728	713	687	729
1Y PT deaths	620	592	656	626	568	685	647	621	694
1Y PT death rate	20.1	19.0	21.5	20.3	18.2	22.4	21.0	20.1	22.8

By diagnosis group

The 250 NM simulation showed lower transplant rates in diagnosis group A candidates, similar rates in diagnosis group B and C candidates, and increased rates in diagnosis D candidates compared with the DSA simulation (Figure 4). Waitlist mortality rates (Figure 5) and post-transplant mortality rates (Figure 6) were similar.

The 500 NM simulation showed even lower transplant rates for group A candidates and even higher rates for group D candidates, as larger numbers of high-LAS candidates received priority. Post-transplant mortality rates were similar.

Changes in transplant and waitlist mortality rates can be explained in part by differences in LAS by diagnosis group. As shown in Figure 7diagnosis group A had the lowest and group D the highest median LAS (last reported LAS per candidate). When allocating to a wider geographic area primarily by LAS, the organs will be offered to the most severely ill patients, who fall largely into diagnosis group D.

In all simulations, counts of waitlist deaths never increased with elimination of DSA as the first unit of allocation, and dropped considerably for group D (Table 4).

Figure 4. Transplant rates by simulation and diagnosis group

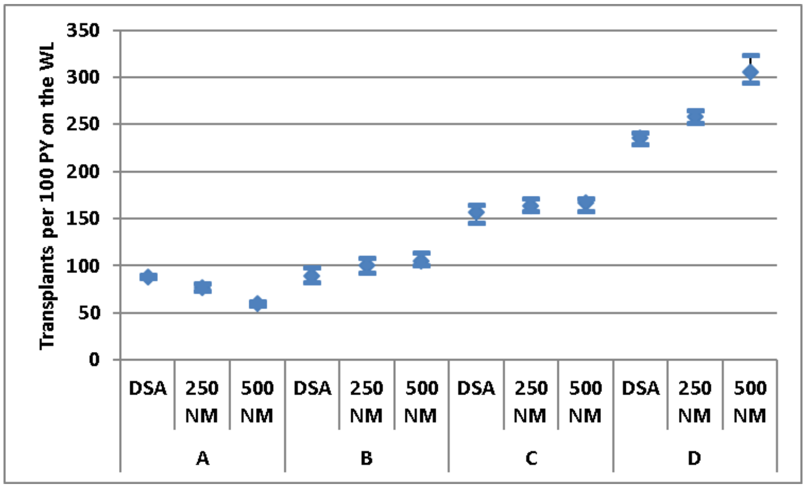


Figure 5. Waitlist mortality rates by simulation and diagnosis group

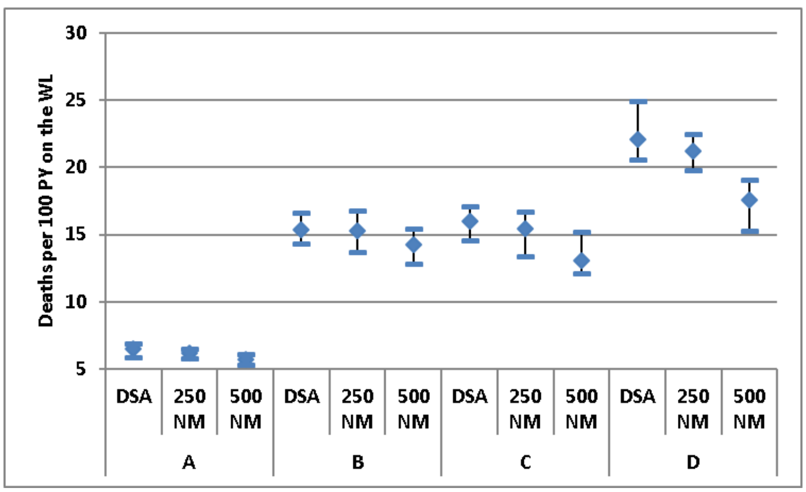


Figure 6. One-year post-transplant mortality rates by simulation and diagnosis group

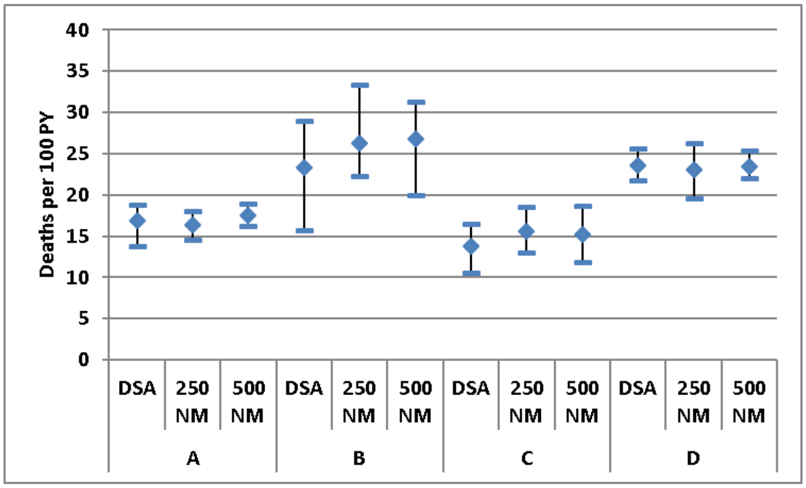
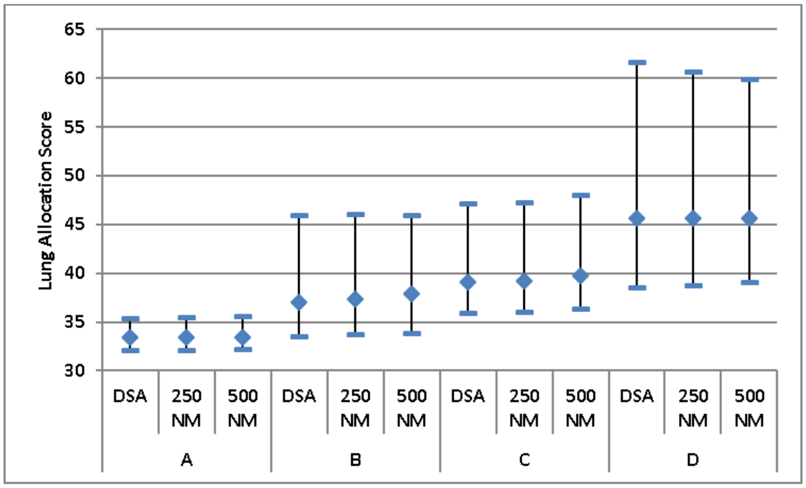


Figure 7. Median, 25th and 75th percentile of LAS by simulation and diagnosis group



By OPTN region

Compared with the DSA simulation, the 250 NM simulation showed similar transplant rates in most OPTN regions, although rates declined in region 2 and increased considerably in region 9 (Figure 8). Point estimates for waitlist mortality rates tended to decline but overlapped the range of the DSA simulation's rates (Figure 9).

The 500 NM simulation showed even higher transplant rates for region 9 and lower transplant rates for regions 8 and 11 compared with the DSA simulation. These regions had the highest transplant rates of all regions in the DSA 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.

Post-transplant mortality rates were similar across regions and simulations (Figure 10). Detailed data for all metric are in Table 5.

Figure 8. Transplant rates by simulation and OPTN region

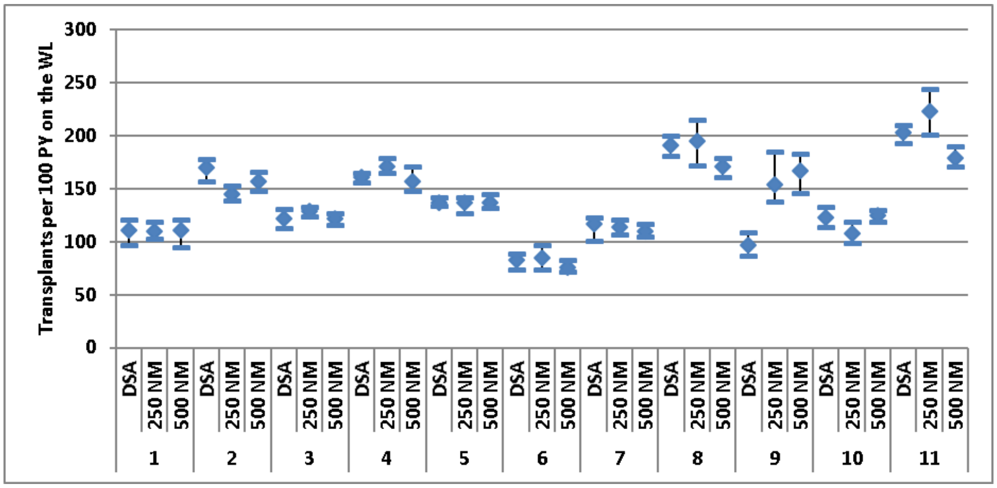


Figure 9. Waitlist mortality rates by simulation and OPTN region

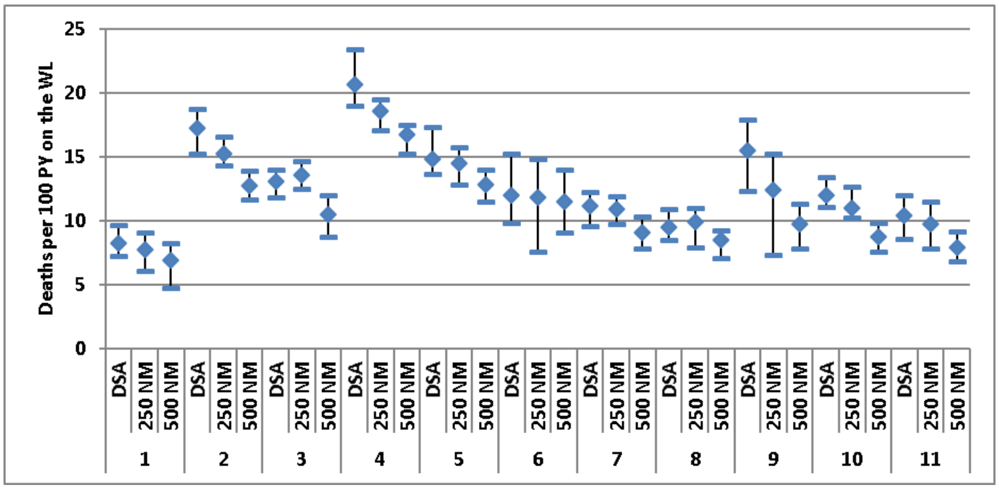
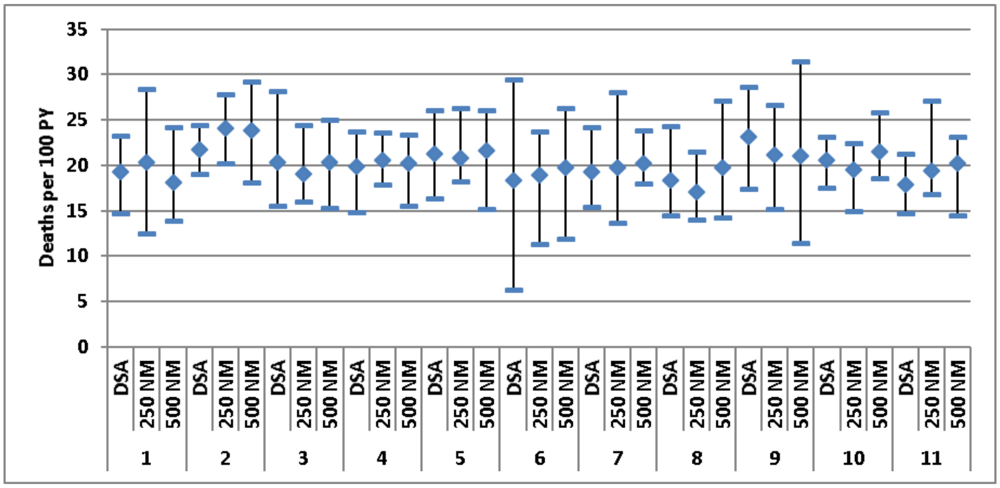
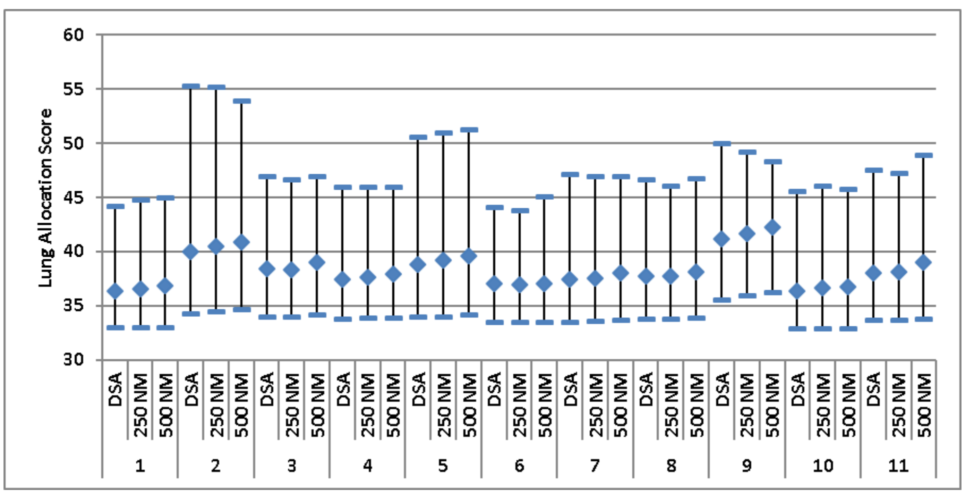


Figure 10. One-year post-transplant mortality rates by simulation and OPTN region



We examined LAS by OPTN region to determine whether regional changes by simulation could be explained by candidate severity of illness. The highest-LAS regions were 2, 3, 5, and 9. In regions 2, 3, and 9, first allocating to 500 NM 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.

Figure 11. Median, 25th and 75th percentiles of LAS by simulation and OPTN region



By race and ethnicity

Compared with the DSA simulation, the 250 NM simulation showed similar transplant rates in most race and ethnicity categories (Figure 12). Point estimates for transplant rates increased for Hispanics, Asians, and other race/ethnicity groups, but ranges of the simulations overlapped. Waitlist mortality rates were similar (Figure 13), as were post-transplant rates (Figure 14).

In the 500 NM simulation, more difference from the DSA simulation emerged. Transplant rates declined for white candidates and increased for Hispanic candidates. Point estimates for waitlist mortality declined for all groups, although the range of the simulations overlapped for all groups except white candidates. The average number of candidates who died awaiting transplant declined for all groups except other, in which three candidates died in each simulation (Table 6). Post-transplant rates were similar.

Detailed data for all metrics are in Table 6.

Figure 12. Transplant rates by simulation and race/ethnicity

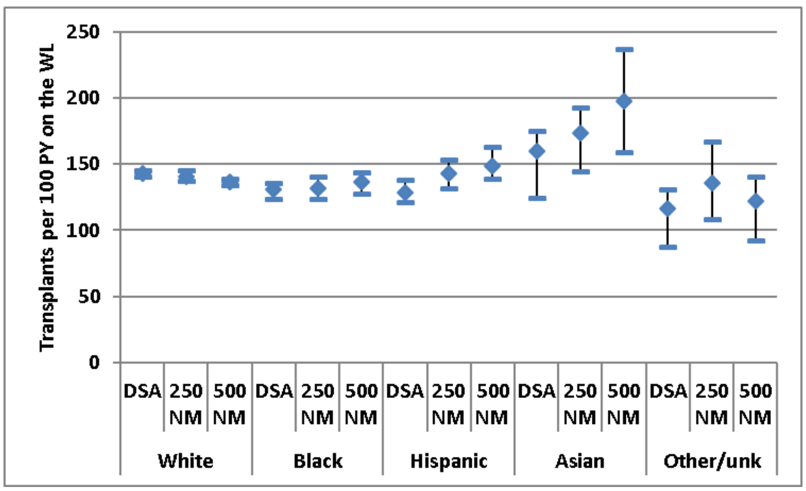


Figure 13. Waitlist mortality rates by simulation and race/ethnicity

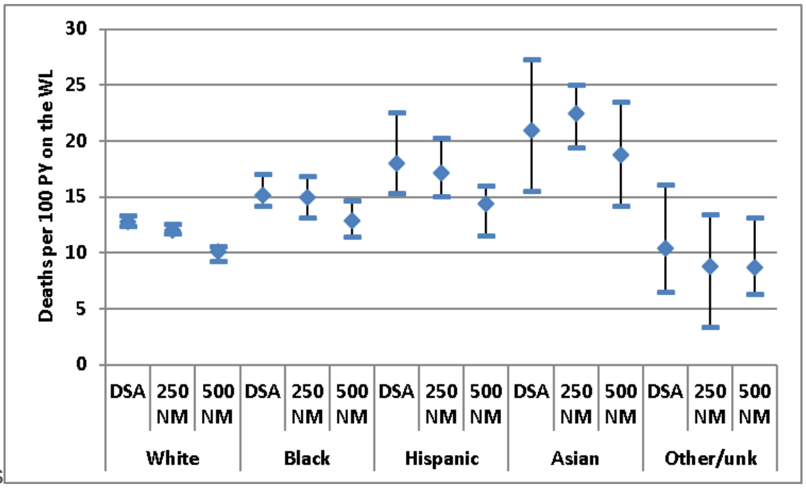


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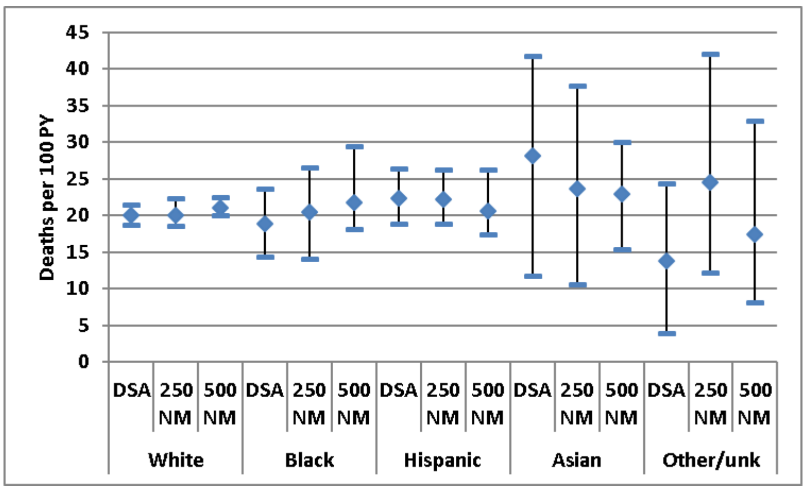
Figure 14. One-year post-transplant mortality rates by simulation and race/ethnicity



BY AGE

Among children, all simulations yielded similar transplant rates (Figure 15), waitlist mortality rates (Figure 16), and post-transplant mortality rates (Figure 17). This similarity was expected. Allocation of pediatric organs to pediatric recipients includes sharing 1000 NM, and this sharing continued as allocation of adult organs changed with each simulation.

Compared with the DSA simulation, the 250 NM simulation showed similar transplant rates (Figure 15), decreased waitlist mortality rates (Figure 16), and similar post-transplant mortality rates (Figure 17) among adult candidates. When adult candidates were divided by age groups, the largest reductions in waitlist mortality were among those aged 50-64 years.

In the 500 NM simulation, transplant rates among adults were similar to rates in the DSA simulation, and the drop in waitlist mortality was even larger than in the 250 NM simulation, especially among candidates aged 50 years or older, and post-transplant mortality rates were similar.

Detailed data for all metrics are in Table 7 and Table 8.

Figure 15. Transplant rates by simulation and age groups

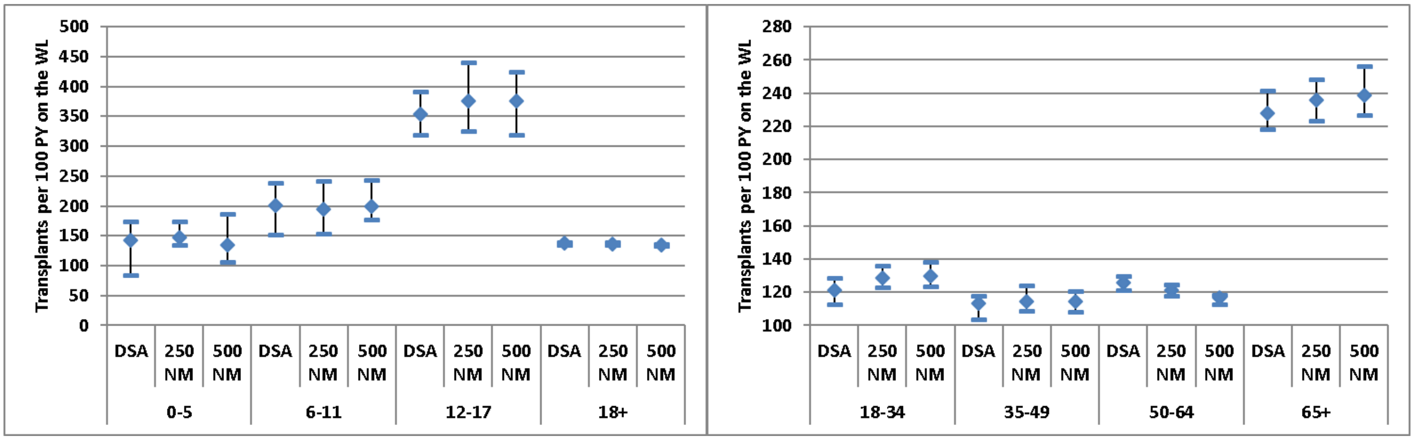


Figure 16. Waitlist mortality rates by simulation and age groups

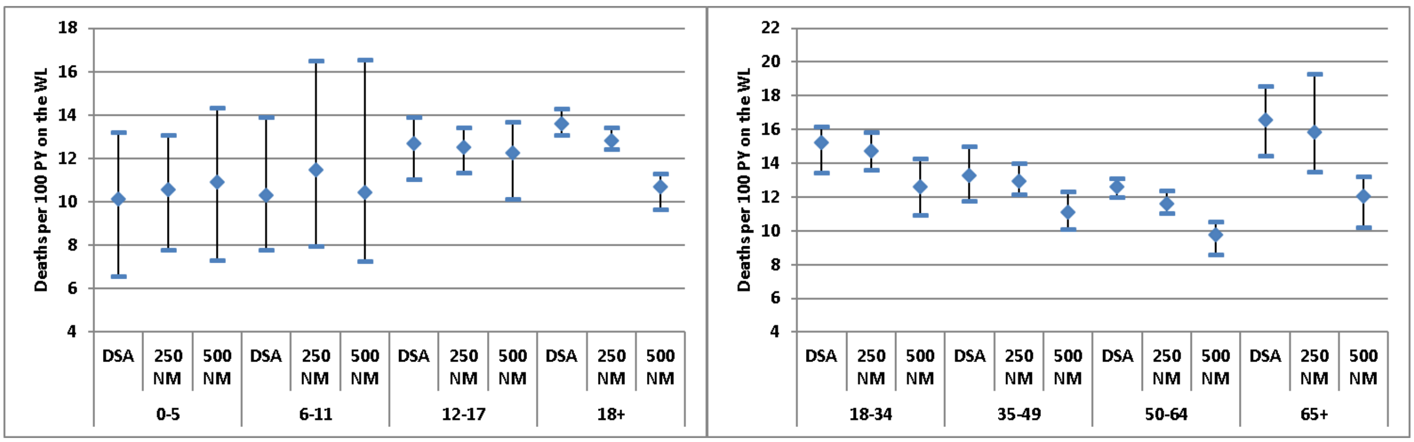
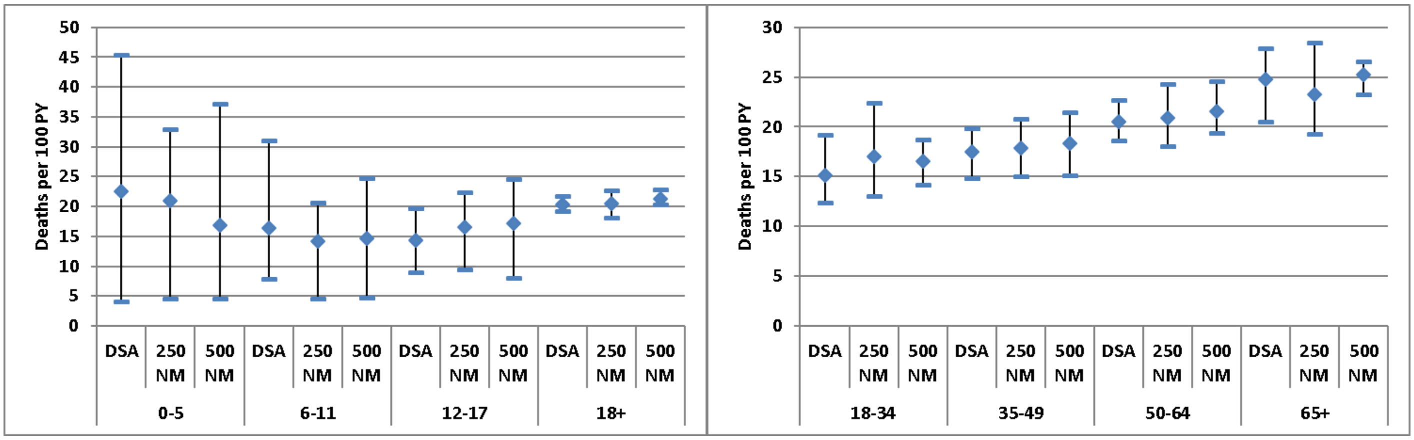


Figure 17. One-year post-transplant mortality rates by simulation and age groups



BY SEX

Simulation results by sex mirrored overall results. See transplant rates in Figure 18, waitlist mortality rates in Figure 19, post-transplant mortality rates in Figure 20, and detailed TSAM metrics in Table 9.

Figure 18. Transplant rates by simulation and sex

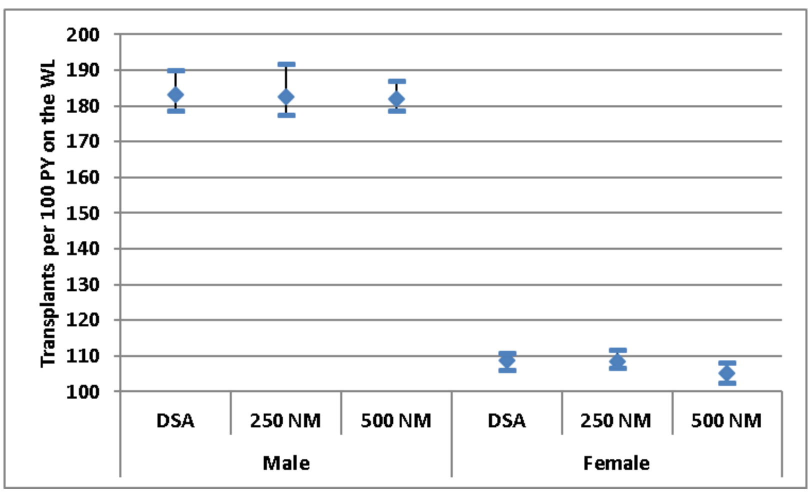


Figure 19. Waitlist mortality rates by simulation and sex

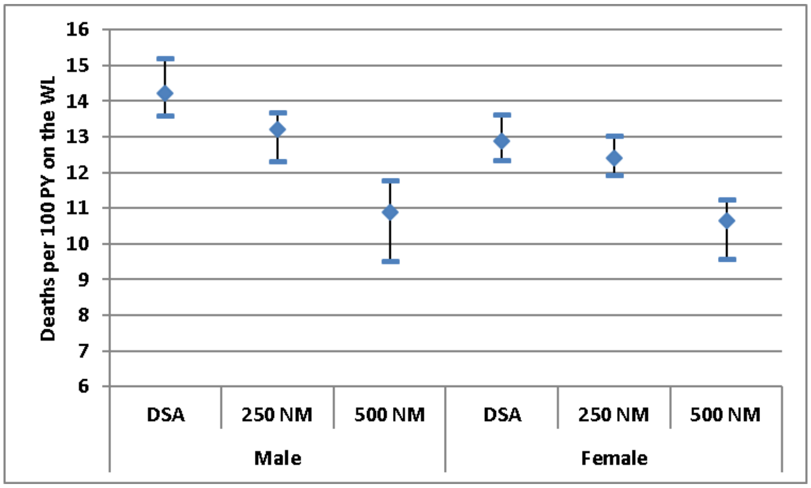
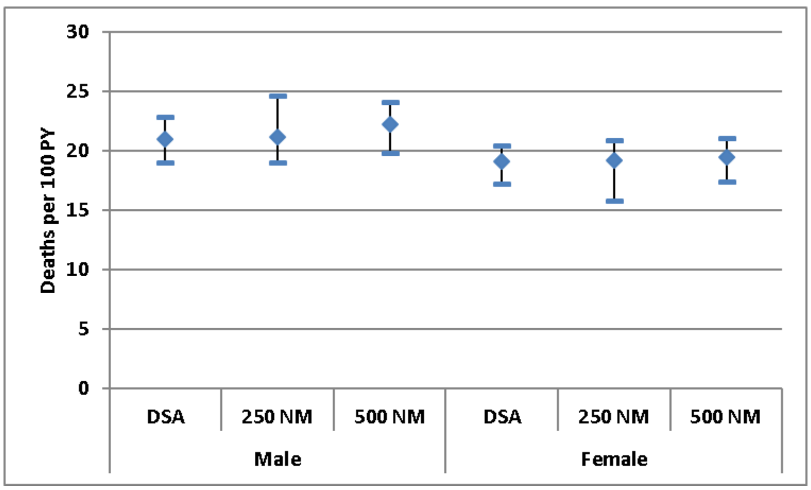


Figure 20. One-year post-transplant mortality rates by simulation and sex



By ABO blood group

Compared with the DSA simulation, the 250 NM simulation showed similar transplant rates (Figure 21), waitlist mortality rates (Figure 22), and post-transplant mortality rates in candidates of all ABO blood groups (Figure 23).

The 500 NM simulation showed lower transplant rates for candidates in blood group A, borderline lower rates for blood group AB, and increased rates for blood group O. Waitlist mortality rates declined for blood groups A and O, but not B and AB. Post-transplant mortality rates were similar.

Detailed data for all metrics are in Table 10.

Figure 21. Transplant rates by simulation and ABO blood group

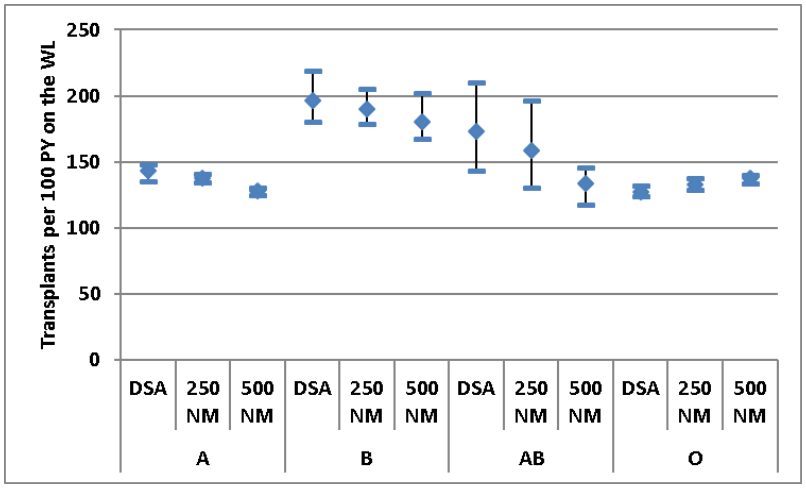


Figure 22. Waitlist mortality rates by simulation and ABO blood group

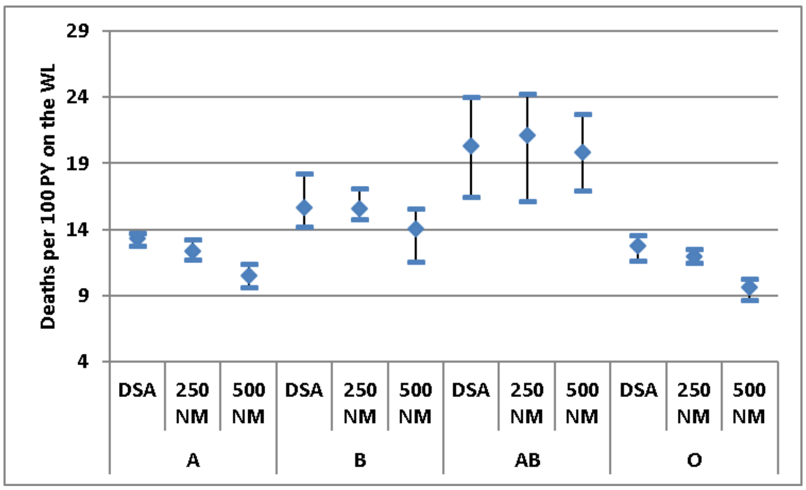
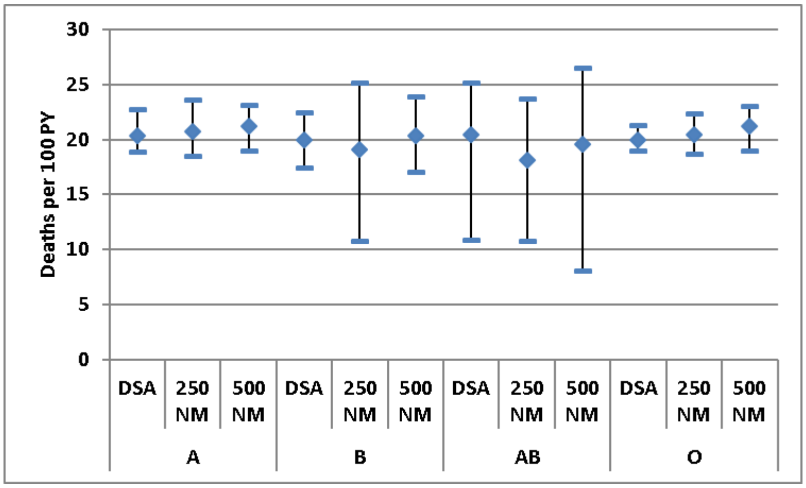


Figure 23. One-year post-transplant mortality rates by simulation and ABO blood group



By LAS

Compared with the DSA simulation, the 250 NM simulation showed increased transplant rates for candidates with LAS of 40 or above, lower rates for those with LAS of 30-< 35, and similar rates for those with LAS < 30 (Figure 24). Waitlist mortality rates were similar within each LAS group (Figure 25). Point estimates for the number of deaths declined in the 250 NM simulation for candidates with LAS ≥ 40, although the ranges of the simulations overlapped (Table 11). Post-transplant mortality rates were similar (Figure 26).

In the 500 NM simulation, transplant rates were higher still for candidates with LAS ≥ 40, and lower for those with LAS < 40. Waitlist mortality rates were similar in each LAS group, although point estimates for the number of waitlist deaths declined, particularly for candidates with LAS ≥ 50. Post-transplant mortality rates were similar.

Detailed data for all metrics are in Table 11.

Figure 24. Transplant rates by simulation and LAS

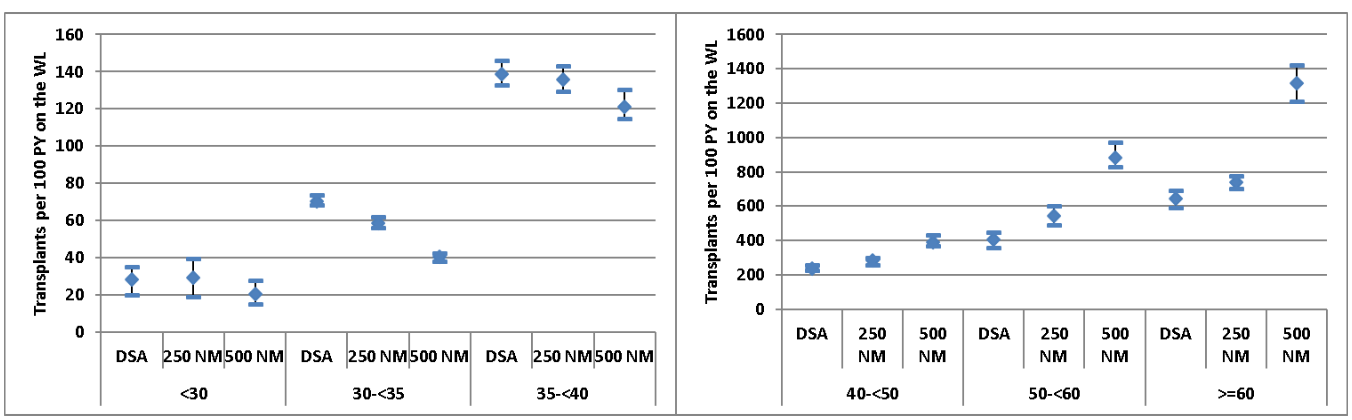


Figure 25. Waitlist mortality rates by simulation and LAS

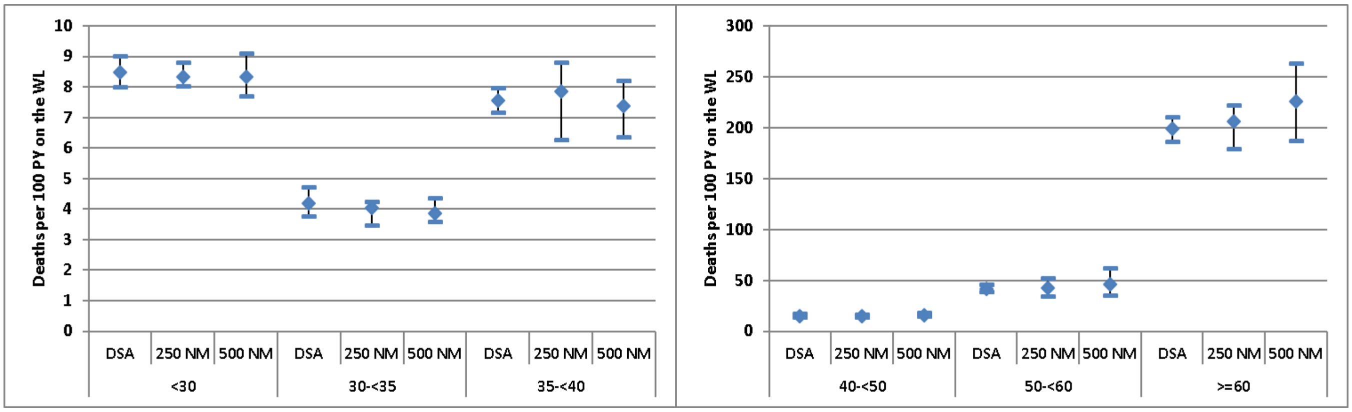
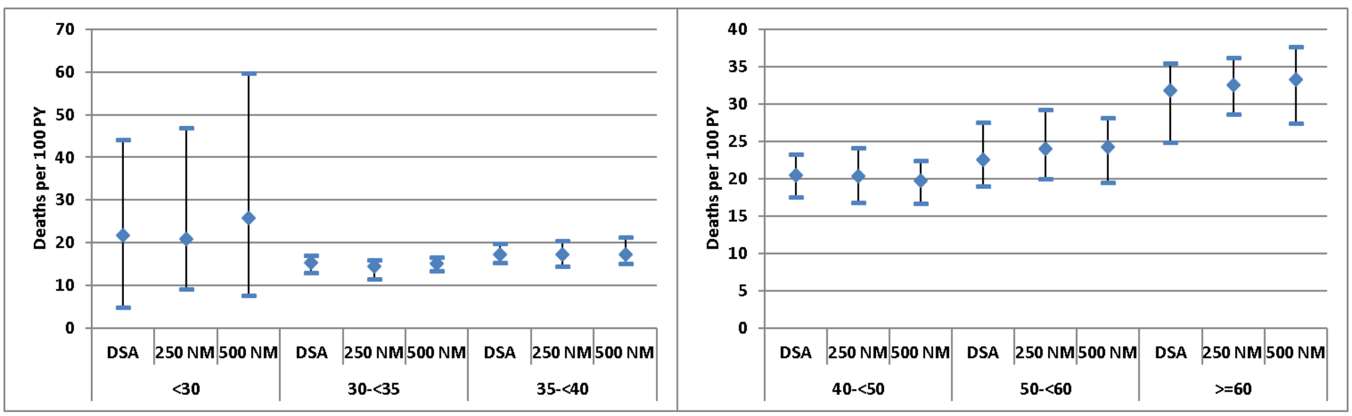


Figure 26. One-year post-transplant mortality rates by simulation and LAS



By center volume

For each simulation run, we categorized each transplant center by the number of transplants it performed over the 2-year period that defined the TSAM cohort, July 1, 2009–June 30, 2011. We then summarized waitlist and transplant outcomes by categories of center volume.

Compared with the DSA simulation, the 250 NM simulation showed lower transplant rates at centers performing 36-75 transplants in 2 years, higher rates at centers performing more than 100 transplants, and similar rates otherwise (Figure 27). Waitlist mortality rates were similar within volume groups (Figure 28), as were post-transplant mortality rates (Figure 29).

In the 500 NM simulation, transplant rates were even lower at centers performing 36-75 transplants, even higher at centers performing more than 100 transplants, and similar otherwise. Point estimates for waitlist mortality rates declined for all groups, and the ranges of simulation failed to overlap (suggesting real difference) among centers performing 36-75 and > 100 transplants. Average number of waitlist deaths also declined in those groups (Table 12). Post-transplant mortality rates were similar.

Detailed data for all metrics are Table 12.

Figure 27. Transplant rates by simulation and center volume

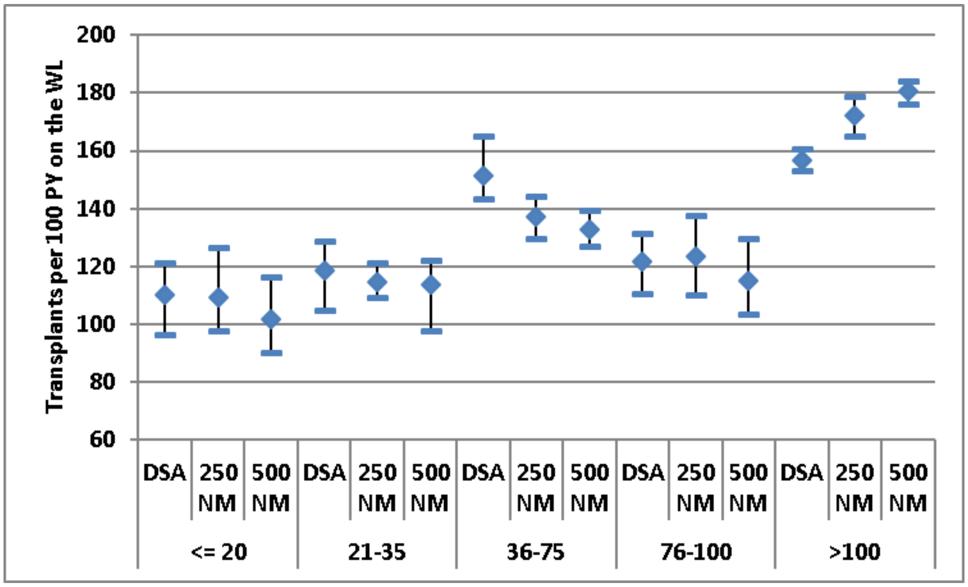


Figure 28. Waitlist mortality rates by simulation and center volume

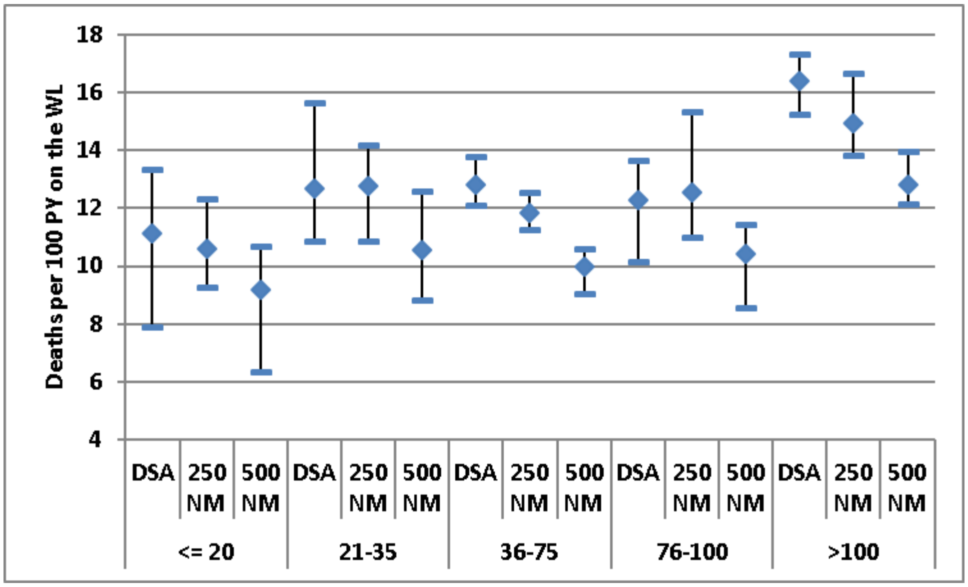
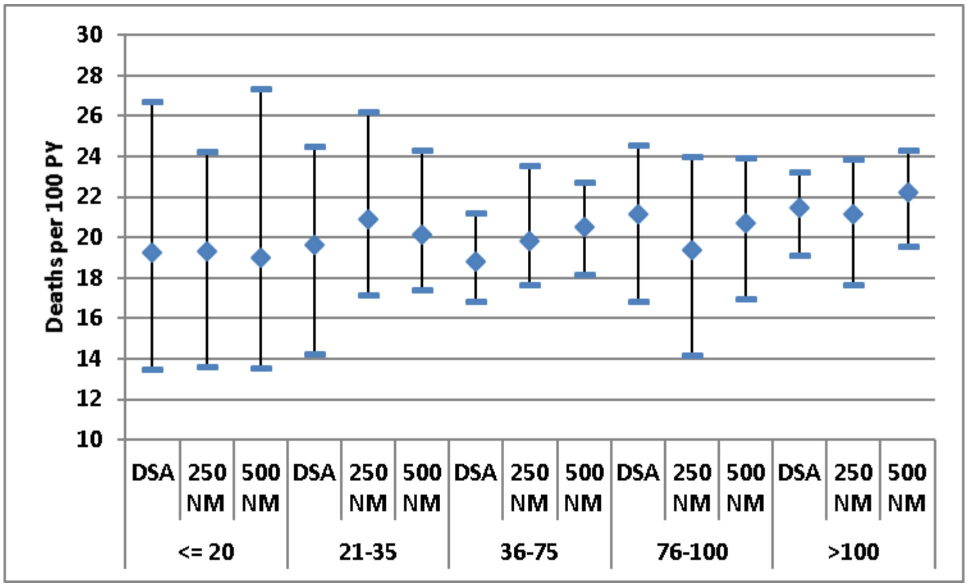


Figure 29. One-year post-transplant mortality rates by simulation and center volume



By zone and distance

Transplant rates and waitlist mortality rates by zone and distance do not exist because distance cannot be computed until a donor/recipient match has occurred. We computed transplant counts and post-transplant outcomes by zone and distance categories. Data by zone use the zone definition in place prior to the November 2017 policy change. That is, for "local" transplants, donor and recipient are in the same DSA. In some western DSAs, there are few lung transplant programs, and DSAs are large, so it is possible that a local transplant occurs at a distance of over 500 NM.

The 250 NM simulation showed half the number of local transplants as the DSA simulation, 808 vs. 1710, and 1.6 times the number of transplants outside the DSA but within 500 NM, 2283 vs. 1383 (Table 2). Table 3 shows similar data with more distance granularity for distances less than 500 NM. Transplants from donors within 75 NM declined by almost half (1283 to 704), while transplants from donors 75 to < 150 NM increased 62%, from 429 to 698. This suggests that several centers are relatively near a DSA border. The number of transplants from donors 150-< 250 NM away grew 3-fold, from 424 to 1299. The number of simulated donor organs that traveled 500 NM or more remained relatively small and little changed.

In the 500 NM simulation, the number of local transplants was about a quarter of the number resulting from the DSA simulation, while transplants within 500 NM increased from 1393 to 2658 (Table 2). When the first unit of allocation is 500 NM, the allocation system seeks the highest-LAS candidate who meets criteria, which nearly doubled the number of transplants in the 250-< 500 NM distance group (Table 3).

Table 2. Transplant counts and post-transplant mortality by simulation and former zone distances

Metric	Distance(NM)	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
TX count	Local	1710	1683	1764	808	776	833	444	419	489
	<500	1383	1352	1418	2283	2259	2315	2658	2618	2680
	<1000	302	280	319	312	292	337	312	274	350
	<1500	69	58	74	64	59	74	62	54	70
	>=1500	23	17	31	30	25	37	29	24	32
1Y PT deaths	Local	283	260	305	149	135	160	83	70	91
	<500	266	242	284	406	359	455	497	471	523
	<1000	52	40	66	54	45	61	51	35	61
	<1500	14	9	16	11	6	15	12	4	16
	>=1500	4	0	7	6	2	10	5	1	8
1Y PT death rates	Local	18.6	17.2	20.3	21.0	18.8	22.4	21.2	17.8	23.8
	<500	22.0	20.1	23.4	20.1	17.4	22.9	21.3	20.1	22.9
	<1000	19.8	15.0	28.2	19.7	15.2	23.7	18.2	12.2	20.8
	<1500	23.4	14.0	34.5	19.7	10.2	29.4	22.5	6.8	29.3
	>=1500	22.8	0.0	42.6	24.3	8.5	44.2	18.8	4.3	30.8

Table 3. Transplant counts and post-transplant mortality by simulation and distance

Metric	Distance (NM)	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
TX count	<75	1283	1251	1310	704	671	725	395	369	431
	75-<150	429	415	453	698	681	728	336	314	362
	150-<250	424	391	457	1299	1262	1318	631	600	672
	250-<500	950	908	975	390	359	410	1740	1715	1761
	500-<1000	304	283	320	312	292	337	312	274	350
	1000-<1500	74	63	81	64	59	74	62	54	70
	>=1500	23	17	31	30	25	37	29	24	32
1Y PT deaths	<75	218	203	233	130	115	147	72	62	84
	75-<150	72	64	82	130	112	157	63	55	79
	150-<250	78	64	95	231	212	246	117	106	129
	250-<500	181	155	195	63	47	75	328	297	362
	500-<1000	53	40	66	54	45	61	51	35	61
	1000-<1500	14	9	18	11	6	15	12	4	16
	>=1500	4	0	7	6	2	10	5	1	8
1Y PT death rates	<75	19.1	17.2	20.8	21.1	18.5	24.6	20.9	17.9	24.2
	75-<150	19.0	16.6	21.9	21.2	17.9	25.4	21.4	18.2	30.0
	150-<250	20.9	16.3	26.6	20.1	18.3	21.4	21.1	18.6	22.8
	250-<500	21.8	18.6	23.3	18.2	13.5	21.0	21.5	19.5	23.6
	500-<1000	19.7	14.9	27.9	19.7	15.2	23.7	18.2	12.2	20.8
	1000-<1500	22.1	13.0	31.1	19.7	10.2	29.4	22.7	6.8	29.3
	>=1500	22.8	0.0	42.6	24.3	8.5	44.2	18.8	4.3	30.8

Post-transplant mortality rates were similar in all three simulations regardless of how distance was categorized (Figure 30 and Figure 31).

Figure 30. One-year post-transplant mortality rates by simulation and former zone distances (NM)

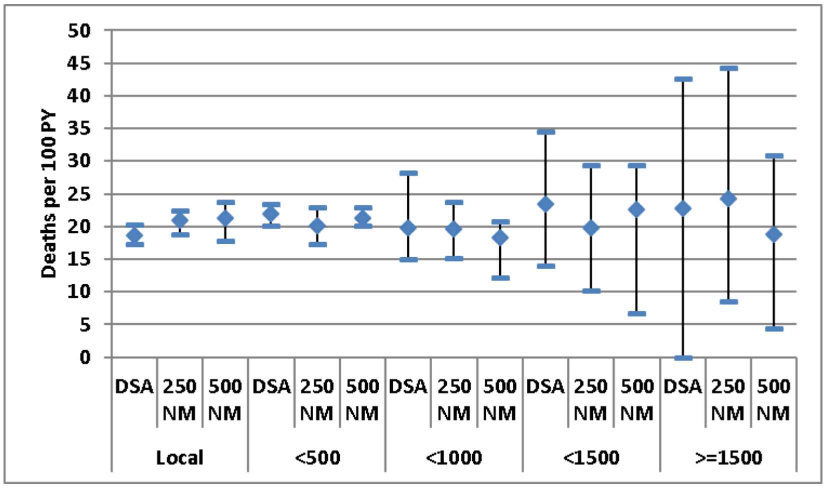
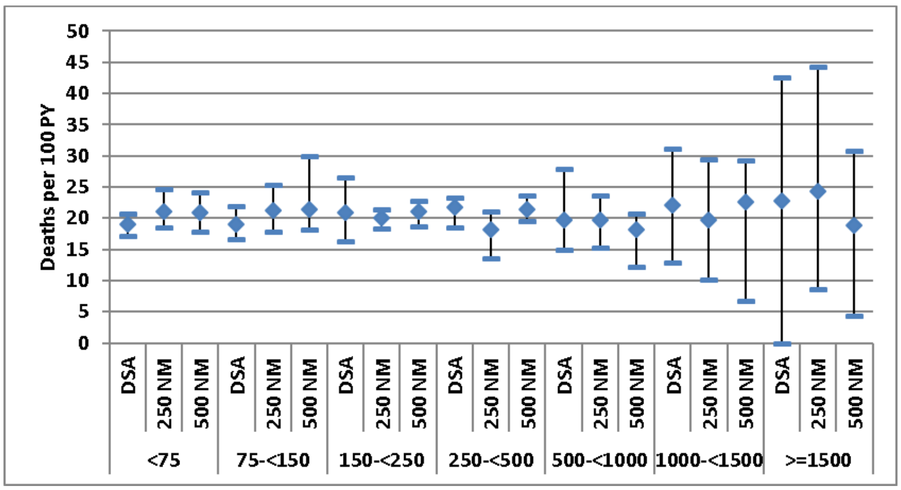


Figure 31. One-year post-transplant mortality rates by simulation and distance (NM)



By DSA

During the TSAM cohort timeframe, there were lung transplant programs in 40 DSAs. The geographic size and population densities of DSAs vary widely; the numbers of lung transplant candidates ranged from 4 to 400, and numbers of recipients ranged from 3 to 300. DSA-level rate metrics are difficult to interpret under such conditions. Nonetheless, we computed changes in numbers of transplants and waitlist deaths by DSA and examined some of these changes in greater detail.

Figure 32 shows the change in the number of transplants per DSA in the 250 NM and 500 NM simulations compared with the DSA simulation. Bars above the line at zero represent increased numbers of transplants compared with the DSA simulation; bars below 0 represent decreases. In DSA 1, for example, the 250 NM and 500 NM simulations showed 11 and 4 additional transplants, respectively, than the DSA simulation. In DSA 11, these simulations resulted in 11 and 19 fewer transplants, respectively.

Overall, we saw modest changes in transplant counts in most DSAs. In the 250 NM and 500 NM simulations, transplant counts changed by 10 or fewer at 31 (77%) and 28 (78%) DSAs, respectively. Moreover, in a given DSA, changes observed according to the 250 NM and 500 NM allocation rules occurred in the same direction (increase or decrease).

Some larger changes did occur, typically in DSAs with large centers or several centers, and nearby centers across a DSA border. In DSA 28, 43 fewer candidates underwent transplant in the 250 NM simulation, while in two nearby DSAs (24 and 29), 26 and 16 more, respectively, underwent transplant. Median LAS in DSA 28 was 37.9, compared with median LAS of 41.7 and 44.4 in DSAs 24 and 29, respectively.

Figure 32. Change in the average number of transplants by simulation and DSA

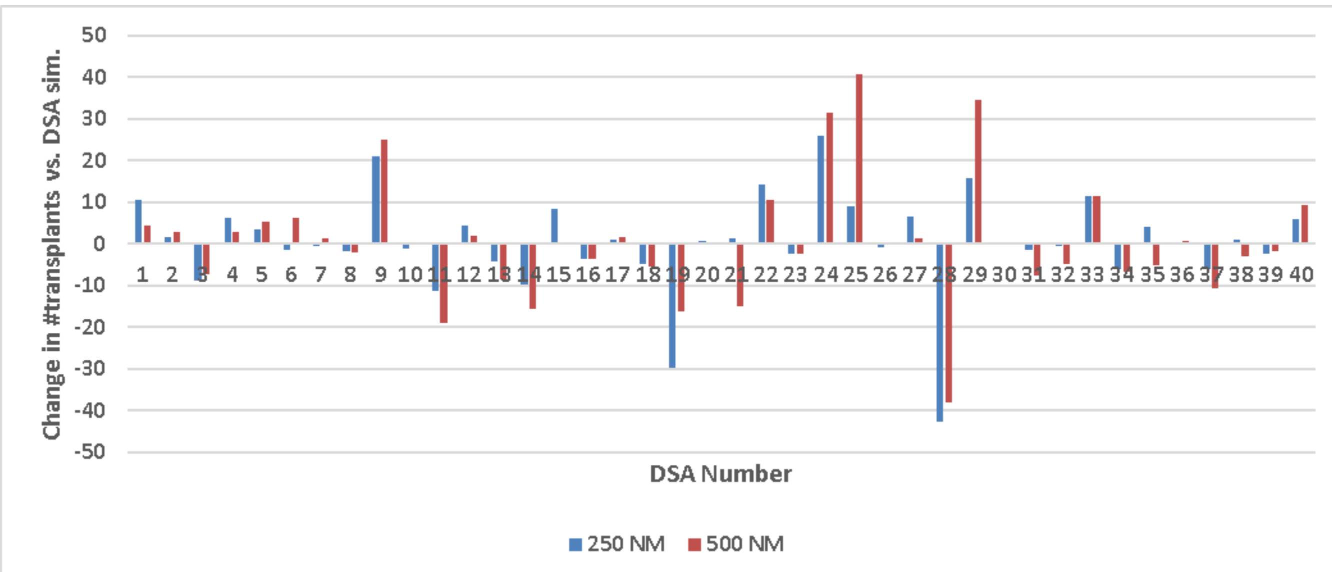
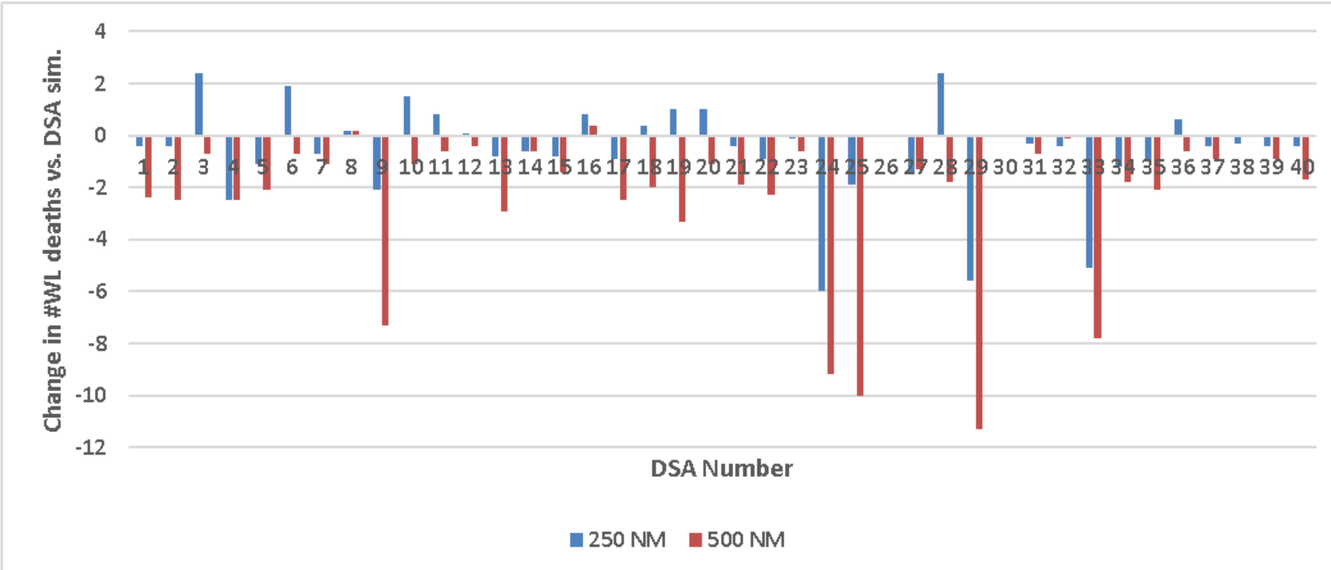


Figure 33 shows the change in the number of waitlist deaths per DSA. In most DSAs, the number of waitlist deaths declined in the 250 NM and 500 NM simulations compared with the DSA simulation. When increases occurred, they were small; the maximum increase was 2 in the 250 NM simulation and 0.4 in the 500 NM simulation, while the maximum decreases were 6 and 11, respectively. Larger decreases in waitlist deaths tended to occur in DSAs with large increases in transplant counts: DSAs 9, 24, 25, and 33.

Figure 33. Changes in the average number of waitlist deaths by simulation and DSA



Appendix 1: Detailed data tables of TSAM metrics by subgroups

Table 4. TSAM metrics by simulation and primary diagnosis groups

Metric	Diagnosis	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	A	2337	2337	2337	2337	2337	2337	2337	2337	2337
	B	666	666	666	666	666	666	666	666	666
	C	879	879	879	879	879	879	879	879	879
	D	2850	2850	2850	2850	2850	2850	2850	2850	2850
TX count	A	1063	1046	1082	978	945	1000	830	814	844
	B	213	203	227	228	215	239	235	227	247
	C	468	451	486	479	470	486	495	486	505
	D	1743	1713	1763	1812	1794	1836	1944	1930	1966
TX rates	A	88.4	86.4	90.4	76.9	72.9	80.9	59.8	57.6	61.6
	B	89.2	82.3	97.7	100.3	92.9	108.7	104.7	99.9	114.1
	C	156.5	145.8	164.7	163.3	157.7	171.8	167.4	158.1	171.4
	D	235.3	228.9	240.8	258.2	251.7	264.8	306.0	293.9	323.3
WL death counts	A	105	95	111	105	98	109	105	97	112
	B	75	70	81	73	66	80	67	60	73
	C	72	66	78	69	59	75	58	53	66
	D	236	219	262	218	204	233	167	145	182

Metric	Diagnosis	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
WL morality rates	A	6.5	5.8	6.9	6.2	5.7	6.5	5.7	5.3	6.1
	B	15.4	14.4	16.7	15.3	13.7	16.8	14.2	12.8	15.4
	C	16.0	14.6	17.1	15.4	13.3	16.7	13.1	12.1	15.2
	D	22.1	20.6	24.9	21.2	19.8	22.5	17.6	15.2	19.1
WL removals	A	296	287	305	308	294	321	324	310	332
	B	135	128	141	131	126	137	131	128	134
	C	97	94	103	93	85	99	90	86	94
	D	200	186	211	190	181	202	168	155	174
1Y PT deaths	A	161	136	180	144	132	152	130	122	140
	B	43	32	52	51	44	63	53	42	61
	C	59	46	69	68	57	77	68	54	84
	D	357	331	384	363	311	414	396	371	430
1Y PT death rates	A	16.8	13.8	18.8	16.3	14.6	18.0	17.5	16.3	19.0
	B	23.3	15.8	28.9	26.3	22.3	33.4	26.8	19.9	31.3
	C	13.8	10.6	16.4	15.6	13.0	18.6	15.2	11.9	18.6
	D	23.6	21.8	25.6	23.1	19.5	26.3	23.5	22.1	25.4

Table 5. TSAM metrics by simulation and OPTN region

Metric	OPTN region	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	1	273	273	273	273	273	273	273	273	273
	2	982	982	982	982	982	982	982	982	982
	3	794	794	794	794	794	794	794	794	794
	4	793	793	793	793	793	793	793	793	793
	5	879	879	879	879	879	879	879	879	879
	6	178	178	178	178	178	178	178	178	178
	7	553	553	553	553	553	553	553	553	553
	8	562	562	562	562	562	562	562	562	562
	9	256	256	256	256	256	256	256	256	256
	10	830	830	830	830	830	830	830	830	830
	11	632	632	632	632	632	632	632	632	632
TX count	1	110	100	118	111	105	117	111	102	119
	2	548	520	557	513	501	525	538	525	553
	3	412	402	425	425	411	435	417	405	428
	4	428	418	439	444	432	453	429	417	446
	5	472	455	484	474	461	487	476	468	483
	6	83	74	88	84	75	90	80	76	86
	7	272	254	277	271	265	281	270	263	280
	8	251	239	260	255	246	268	244	237	251
	9	88	83	93	114	107	124	119	113	126
	10	453	435	470	422	408	440	462	450	473
	11	370	357	378	384	370	397	357	350	366
TX rates	1	110.6	96.9	120.9	110.2	102.9	119.2	110.4	95.0	121.0
	2	170.2	156.7	178.0	145.3	139.3	152.7	157.1	148.0	166.5
	3	121.4	113.1	131.2	129.0	123.8	133.4	121.5	116.2	127.3
	4	161.3	155.6	165.5	171.1	164.6	179.3	156.9	147.8	171.4
	5	137.0	133.6	142.0	137.3	126.4	142.2	137.2	132.1	145.4
	6	82.7	74.3	88.8	85.1	73.5	97.2	76.0	71.3	83.3
	7	116.5	100.4	122.7	114.1	107.3	121.0	109.9	104.4	116.6
	8	191.0	180.9	200.4	195.1	172.1	215.1	170.7	161.2	179.3
	9	97.3	87.1	108.9	154.1	137.6	185.1	167.1	146.0	183.0
	10	122.5	113.5	132.7	107.7	98.7	118.7	124.5	119.3	129.7
	11	203.2	193.3	210.2	223.1	201.5	243.9	178.6	171.1	190.1
WL death counts	1	16	14	19	15	12	17	13	9	16

Metric	OPTN region	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
	2	74	64	82	70	65	76	57	51	64
	3	57	52	62	58	55	61	47	39	52
	4	76	70	86	68	62	72	63	58	67
	5	69	64	81	68	60	73	61	54	67
	6	15	12	18	15	9	19	15	12	18
	7	42	35	47	41	37	45	35	31	40
	8	37	33	42	39	30	42	34	28	37
	9	19	15	21	13	7	16	10	8	12
	10	53	49	57	51	46	60	39	33	44
	11	29	24	33	27	21	31	24	21	27
WL morality rates	1	8.2	7.2	9.7	7.8	6.0	9.1	6.9	4.7	8.3
	2	17.3	15.3	18.7	15.2	14.4	16.6	12.7	11.7	13.9
	3	13.1	11.8	14.0	13.6	12.5	14.7	10.5	8.8	12.0
	4	20.7	19.0	23.4	18.6	17.1	19.5	16.8	15.3	17.5
	5	14.8	13.7	17.3	14.5	12.8	15.8	12.9	11.5	14.0
	6	12.0	9.9	15.2	11.8	7.6	14.9	11.5	9.1	14.0
	7	11.2	9.6	12.3	10.9	9.7	12.0	9.1	7.9	10.3
	8	9.5	8.5	11.0	9.9	7.9	11.0	8.5	7.1	9.3
	9	15.5	12.4	18.0	12.4	7.3	15.3	9.8	7.8	11.3
	10	12.0	11.1	13.5	11.0	10.2	12.6	8.8	7.6	9.8
	11	10.4	8.6	12.0	9.7	7.8	11.5	7.9	6.8	9.1
WL removals	1	36	33	38	36	34	38	36	34	38
	2	98	93	106	105	102	108	102	100	104
	3	71	63	81	65	62	69	67	61	74
	4	78	73	82	76	73	80	76	67	82
	5	66	61	75	64	59	68	62	56	68
	6	6	3	6	5	3	8	5	3	7
	7	46	42	51	44	40	48	44	39	48
	8	103	101	105	101	100	105	102	100	103
	9	81	78	84	77	73	80	77	73	81
	10	64	56	68	69	63	74	63	57	68
	11	82	77	86	79	74	85	80	76	84
1Y PT deaths	1	19	15	22	20	13	27	18	14	22
	2	105	93	116	107	93	123	111	86	134
	3	74	57	98	72	61	90	74	56	89
	4	75	57	88	81	70	90	76	62	86
	5	88	70	103	87	77	106	90	65	105
	6	14	5	21	14	9	17	14	9	19
	7	47	38	58	47	33	63	48	43	57
	8	41	33	53	39	32	47	43	31	56
	9	18	14	21	21	15	28	22	13	30
	10	82	72	90	73	56	84	87	75	103
	11	59	51	70	66	58	89	64	47	72

Metric	OPTN region	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
1Y PT death rates	1	19.3	14.7	23.3	20.4	12.5	28.5	18.1	14.0	24.2
	2	21.7	19.0	24.4	24.1	20.2	27.8	23.9	18.1	29.2
	3	20.4	15.6	28.1	19.0	16.1	24.5	20.3	15.3	25.1
	4	19.9	14.8	23.7	20.6	17.9	23.6	20.3	15.5	23.4
	5	21	16	26	21	18	26	22	15	26
	6	18	6	29	19	11	24	20	12	26
	7	19	15	24	20	14	28	20	18	24
	8	18	15	24	17	14	21	20	14	27
	9	23.1	17.4	28.6	21.2	15.2	26.6	21.1	11.5	31.4
	10	20.6	17.6	23.1	19.5	15.0	22.5	21.5	18.5	25.8
	11	17.9	14.8	21.3	19.4	16.8	27.1	20.3	14.5	23.2

Table 6. TSAM metrics by simulation and race/ethnicity

Metric	Race/ethnicity	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	White	5453	5453	5453	5453	5453	5453	5453	5453	5453
	Black	663	663	663	663	663	663	663	663	663
	Hispanic	437	437	437	437	437	437	437	437	437
	Asian	132	132	132	132	132	132	132	132	132
	Other/unknown	47	47	47	47	47	47	47	47	47
TX count	White	2867	2854	2875	2863	2838	2902	2847	2828	2877
	Black	326	319	341	328	313	333	337	322	351
	Hispanic	208	199	214	220	208	238	228	220	236
	Asian	61	51	65	61	54	67	67	59	71
	Other/unknown	24	20	26	26	23	30	25	21	27
TX rates	White	142.7	140.9	145.1	140.4	137.7	145.7	136.2	134.2	138.7
	Black	130.8	124.1	135.6	132.0	123.6	140.4	136.8	127.9	143.5
	Hispanic	128.6	121.5	138.1	143.0	131.9	153.1	148.9	139.2	163.3
	Asian	160.1	124.2	175.3	173.8	144.4	192.7	197.4	159.4	237.1
	Other/unknown	116.3	87.6	130.8	135.9	108.4	167.3	122.1	92.0	140.4
WL death counts	White	374	361	392	355	346	373	305	280	321
	Black	54	51	61	54	48	59	46	41	53
	Hispanic	43	36	52	39	36	45	33	27	37
	Asian	13	9	16	13	11	15	11	8	14
	Other/unknown	3	2	5	3	1	4	3	2	4
WL morality rates	White	12.8	12.4	13.4	12.0	11.7	12.6	10.1	9.2	10.6
	Black	15.2	14.2	17.0	15.0	13.1	16.9	12.8	11.5	14.7
	Hispanic	18.0	15.3	22.6	17.2	15.1	20.2	14.4	11.5	16.0
	Asian	21.0	15.5	27.3	22.5	19.4	25.1	18.8	14.2	23.6
	Other/unknown	10.4	6.5	16.1	8.8	3.4	13.4	8.7	6.3	13.1
WL removals	White	560	552	572	556	539	566	553	533	564
	Black	85	79	91	84	79	88	81	77	85
	Hispanic	56	49	59	56	51	59	53	51	56
	Asian	20	18	22	20	18	23	19	17	22
	Other/unknown	7	6	8	6	4	7	6	5	8
1Y PT deaths	White	508	482	541	507	473	558	525	504	556
	Black	55	42	67	59	43	75	64	54	82
	Hispanic	41	36	47	43	35	47	41	35	50
	Asian	14	7	20	12	6	18	13	10	18
	Other/unknown	3	1	5	5	3	9	4	2	6
1Y PT death rates	White	20.0	18.7	21.5	20.0	18.5	22.4	21.0	20.0	22.5
	Black	18.8	14.4	23.7	20.5	14.1	26.6	21.8	18.1	29.4
	Hispanic	22.4	18.9	26.4	22.2	18.9	26.3	20.6	17.5	26.2
	Asian	28.1	11.7	41.7	23.6	10.6	37.7	23.0	15.5	30.1
	Other/unknown	13.8	3.9	24.4	24.6	12.2	42.1	17.4	8.2	32.9

Table 7. TSAM metrics by simulation and age group

Metric	Age group	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	0-5	88	88	88	88	88	88	88	88	88
	6-11	84	84	84	84	84	84	84	84	84
	12-17	174	174	174	174	174	174	174	174	174
	18+	6386	6386	6386	6386	6386	6386	6386	6386	6386
TX count	0-5	24	17	27	25	23	28	23	20	28
	6-11	43	38	47	43	38	46	44	40	48
	12-17	103	100	106	103	101	107	103	100	107
	18+	3316	3302	3325	3327	3310	3347	3334	3325	3343
TX rates	0-5	142.5	83.9	174.5	147.7	134.3	174.4	133.9	106.2	186.5
	6-11	200.2	152.6	238.0	194.6	153.3	241.6	199.8	176.6	243.2
	12-17	353.1	318.3	391.6	375.4	325.8	440.5	375.1	319.7	424.7
	18+	137.5	135.4	140.0	137.0	135.1	139.3	134.5	132.6	136.6
WL death counts	0-5	8	5	10	8	6	10	9	6	11
	6-11	5	4	8	6	4	9	5	4	8
	12-17	13	11	14	12	11	13	12	10	13
	18+	461	445	479	437	427	456	371	337	393
WL morality rates	0-5	10.1	6.6	13.2	10.5	7.8	13.1	10.9	7.3	14.3
	6-11	10.3	7.8	13.9	11.5	8.0	16.5	10.4	7.3	16.5
	12-17	12.7	11.1	13.9	12.5	11.3	13.4	12.3	10.1	13.7
	18+	13.6	13.1	14.3	12.8	12.4	13.4	10.7	9.6	11.3
WL removals	0-5	16	14	17	16	14	17	16	15	18
	6-11	12	10	14	12	11	15	12	11	14
	12-17	21	19	23	22	21	24	21	20	21
	18+	679	668	696	671	651	678	664	640	677
1Y PT deaths	0-5	4	1	8	4	1	7	3	1	6
	6-11	6	3	12	5	2	8	6	2	10
	12-17	14	9	18	15	9	20	16	8	21
	18+	596	566	631	601	537	659	622	598	665
1Y PT death rates	0-5	22.6	4.2	45.3	20.9	4.5	32.9	16.8	4.5	37.1
	6-11	16.4	7.9	31.1	14.1	4.6	20.7	14.6	4.8	24.7
	12-17	14.3	9.0	19.7	16.5	9.5	22.3	17.1	8.0	24.6
	18+	20.4	19.2	21.7	20.5	18.1	22.7	21.3	20.3	22.9

Table 8. TSAM metrics among adult candidates by simulation and age group

Metric	Age group	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	18-34	866	866	866	866	866	866	866	866	866
	35-49	1149	1149	1149	1149	1149	1149	1149	1149	1149
	50-64	3191	3191	3191	3191	3191	3191	3191	3191	3191
	65+	1180	1180	1180	1180	1180	1180	1180	1180	1180
TX count	18-34	389	372	401	403	389	418	415	398	430
	35-49	500	474	514	504	483	530	511	492	525
	50-64	1647	1611	1679	1624	1603	1648	1599	1578	1616
	65+	781	760	799	797	784	814	810	798	829
TX rates	18-34	121.1	112.9	128.8	128.8	123.0	135.9	130.0	123.4	138.1
	35-49	113.2	103.8	117.8	114.7	109.0	123.8	114.2	108.2	120.6
	50-64	126.1	121.1	129.5	121.3	118.0	124.6	116.5	112.7	118.6
	65+	228.0	218.2	241.7	236.0	223.2	248.2	238.8	226.9	256.3
WL death counts	18-34	77	68	83	73	68	78	63	55	72
	35-49	98	87	108	95	89	103	83	75	90
	50-64	221	214	233	208	199	223	179	159	194
	65+	65	57	73	61	53	72	47	40	52
WL morality rates	18-34	15.2	13.5	16.2	14.7	13.6	15.8	12.6	11.0	14.3
	35-49	13.3	11.8	15.0	13.0	12.2	14.0	11.1	10.1	12.4
	50-64	12.6	12.0	13.1	11.6	11.1	12.4	9.7	8.6	10.6
	65+	16.6	14.4	18.6	15.8	13.5	19.3	12.0	10.2	13.2
WL removals	18-34	144	138	150	139	135	143	136	133	138
	35-49	183	174	192	183	179	188	183	178	187
	50-64	290	282	298	290	279	296	288	268	300
	65+	62	59	67	60	55	64	57	51	65
1Y PT deaths	18-34	54	45	67	62	48	79	62	53	70
	35-49	79	64	88	80	71	94	83	72	95
	50-64	297	277	327	298	262	343	302	272	342
	65+	166	142	187	161	137	191	175	163	186
1Y PT death rates	18-34	15.2	12.4	19.2	17.0	13.1	22.4	16.6	14.2	18.7
	35-49	17.5	14.8	19.9	17.9	15.0	20.8	18.3	15.2	21.4
	50-64	20.5	18.7	22.7	20.9	18.0	24.3	21.6	19.4	24.6
	65+	24.8	20.5	27.9	23.2	19.3	28.5	25.2	23.3	26.6

Table 9. TSAM metrics by simulation and sex

Metric	Sex	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	Male	3357	3357	3357	3357	3357	3357	3357	3357	3357
	Female	3375	3375	3375	3375	3375	3375	3375	3375	3375
TX count	Male	1936	1912	1959	1942	1919	1965	1961	1937	1983
	Female	1550	1524	1575	1555	1540	1573	1542	1530	1558
TX rates	Male	183.3	178.7	190.0	182.7	177.4	191.8	181.9	178.6	187.0
	Female	108.9	106.0	110.9	108.6	106.7	111.6	105.2	102.5	108.2
WL death counts	Male	220	212	231	206	191	214	171	149	186
	Female	267	254	281	258	250	270	226	206	239
WL morality rates	Male	14.2	13.6	15.2	13.2	12.3	13.7	10.9	9.5	11.8
	Female	12.9	12.3	13.6	12.4	11.9	13.0	10.7	9.6	11.3
WL removals	Male	309	294	326	309	298	313	296	279	310
	Female	420	414	425	413	394	423	417	408	425
	Female	9.7	8.5	10.5	9.3	8.6	9.7	7.9	6.8	8.3
1Y PT deaths	Male	357	326	390	361	334	409	381	342	409
	Female	263	244	280	265	222	286	266	243	285
1Y PT death rates	Male	21.0	19.0	22.9	21.2	19.0	24.6	22.3	19.8	24.1
	Female	19.1	17.3	20.4	19.2	15.8	20.9	19.5	17.4	21.0

Table 10. TSAM metrics by simulation and blood type

Metric	Blood type	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	A	2622	2622	2622	2622	2622	2622	2622	2622	2622
	B	750	750	750	750	750	750	750	750	750
	AB	213	213	213	213	213	213	213	213	213
	O	3147	3147	3147	3147	3147	3147	3147	3147	3147
TX count	A	1388	1355	1406	1366	1346	1386	1330	1320	1337
	B	429	414	437	422	417	437	416	410	421
	AB	105	99	112	100	91	110	92	85	99
	O	1564	1540	1583	1610	1598	1623	1666	1650	1686
TX rates	A	143.5	135.4	147.8	137.3	134.5	141.0	128.3	124.6	130.1
	B	196.4	180.2	219.1	189.6	178.7	204.9	180.4	167.3	202.2
	AB	173.4	143.6	209.9	158.5	130.3	196.6	133.2	117.9	145.9
	O	126.9	123.8	131.7	132.6	128.6	137.7	137.9	133.9	140.2
WL death counts	A	186	180	193	176	166	189	155	140	169
	B	55	51	60	55	52	60	51	43	57
	AB	23	18	28	24	18	27	24	20	26
	O	224	207	240	209	200	217	168	153	178
WL morality rates	A	13.3	12.8	13.7	12.3	11.7	13.2	10.5	9.6	11.4
	B	15.7	14.2	18.2	15.6	14.7	17.1	14.1	11.5	15.6
	AB	20.3	16.5	24.0	21.1	16.2	24.3	19.8	17.0	22.8
	O	12.7	11.6	13.5	12.0	11.4	12.5	9.6	8.6	10.3
WL removals	A	256	249	265	255	248	265	260	252	268
	B	80	72	87	81	77	85	80	73	86
	AB	25	23	26	26	23	28	26	24	30
	O	367	356	378	361	348	368	347	337	355
1Y PT deaths	A	249	235	272	249	225	280	247	225	266
	B	76	68	85	72	42	91	74	64	86
	AB	19	10	23	16	10	19	16	7	22
	O	276	262	291	289	268	311	310	281	333
1Y PT death rates	A	20.4	18.9	22.7	20.7	18.5	23.6	21.2	19.0	23.1
	B	20.0	17.4	22.5	19.1	10.8	25.1	20.3	17.0	23.9
	AB	20.4	10.8	25.1	18.1	10.8	23.7	19.6	8.1	26.5
	O	19.9	18.9	21.3	20.4	18.7	22.3	21.2	19.0	23.1

Table 11. TSAM metrics by simulation and LAS

Metric	LAS group	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	<30	680	680	680	680	680	680	680	680	680
	<35	2399	2399	2399	2399	2399	2399	2399	2399	2399
	<40	1527	1527	1527	1527	1527	1527	1527	1527	1527
	<50	1081	1081	1081	1081	1081	1081	1081	1081	1081
	<60	325	325	325	325	325	325	325	325	325
	60+	548	548	548	548	548	548	548	548	548
TX count	<30	17	12	22	18	12	23	13	10	18
	<35	896	875	939	791	762	819	593	562	622
	<40	818	789	850	798	760	836	741	710	780
	<50	829	801	861	914	873	961	1050	1022	1090
	<60	329	318	351	371	343	401	420	392	440
	60+	530	497	549	539	511	564	619	594	635
TX rates	<30	28.4	19.8	35.3	29.1	18.9	39.6	20.7	15.3	27.7
	<35	70.2	68.2	73.8	58.9	56.3	62.0	40.5	38.3	42.6
	<40	138.8	132.8	146.1	135.9	129.4	143.1	121.3	114.8	130.3
	<50	236.0	225.4	255.7	282.7	258.8	300.4	387.7	368.9	432.3
	<60	404.9	360.6	447.4	540.9	488.8	601.3	880.1	827.7	972.2
	60+	644.7	588.3	689.1	738.7	704.3	774.3	1314.2	1209.5	1423.3
WL death counts	<30	66	62	70	65	62	68	65	60	71
	<35	62	56	70	63	55	67	65	60	74
	<40	50	47	52	52	41	57	50	42	56
	<50	58	51	64	53	50	58	48	43	54
	<60	38	35	44	32	26	37	24	19	30
	60+	201	189	223	185	173	194	130	113	144
WL morality rates	<30	8.5	8.0	9.0	8.3	8.0	8.8	8.3	7.7	9.1
	<35	4.2	3.8	4.7	4.0	3.5	4.3	3.9	3.6	4.4
	<40	7.6	7.2	8.0	7.9	6.3	8.8	7.4	6.4	8.2
	<50	15.1	13.5	17.1	15.1	14.3	16.6	16.2	14.7	18.0
	<60	42.0	38.7	46.4	42.4	34.4	52.0	45.8	35.8	62.2
	60+	199.0	186.8	211.0	206.4	178.9	222.3	226.2	186.9	263.2
WL removals	<30	358	354	364	357	353	365	364	359	369
	<35	153	141	158	161	155	169	171	162	178
	<40	75	69	81	75	69	82	76	71	81
	<50	52	43	59	46	40	51	40	32	47
	<60	11	9	13	10	6	13	5	3	8
	60+	51	44	57	43	35	49	29	23	32
1Y PT deaths	<30	3	1	6	3	1	8	3	1	5

Metric	LAS group	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
	<35	125.4	108.0	140.0	104.6	86.0	112.0	81.2	74.0	92.0
	<40	127.1	114.0	140.0	123.6	105.0	138.0	114.6	99.0	140.0
	<50	149.5	128.0	174.0	163.4	142.0	194.0	183.7	158.0	205.0
	<60	64.5	54.0	74.0	76.7	65.0	90.0	87.4	72.0	103.0
	60+	139.6	113.0	156.0	144.4	134.0	160.0	168.0	147.0	189.0
1Y PT death rates	<30	21.8	4.9	44.2	20.9	9.1	46.9	25.9	7.7	59.8
	<35	15.4	13.0	16.9	14.5	11.6	16.0	15.1	13.4	16.5
	<40	17	15	20	17	14	21	17	15	21
	<50	20	18	23	20	17	24	20	17	22
	<60	23	19	28	24	20	29	24	19	28
	60+	32	25	36	33	29	36	33	27	38

Table 12. TSAM metrics by simulation and center volume

Metric	Center volume	DSA Avg	DSA Min	DSA Max	250 NM Avg	250 NM Min	250 NM Max	500 NM Avg	500 NM Min	500 NM Max
Candidates	<= 20	418	371	463	394	327	501	408	371	498
	21-35	739	590	839	720	560	837	864	743	1027
	36-75	2508	2182	2870	2585	2361	2822	2407	2037	2649
	76-100	1126	859	1361	981	785	1258	1000	646	1386
	>100	1940	1809	1996	2052	2052	2052	2052	2052	2052
TX count	<= 20	191	178	206	179	147	210	181	166	212
	21-35	347	266	394	335	263	393	407	342	495
	36-75	1281	1087	1479	1268	1180	1383	1168	964	1304
	76-100	558	411	688	514	416	646	513	352	743
	>100	1109	1026	1150	1201	1184	1225	1236	1213	1249
TX rates	<= 20	110.2	96.5	121.2	109.5	97.8	126.5	101.8	90.2	116.4
	21-35	118.8	105.0	128.7	114.4	109.5	121.3	113.6	97.7	121.9
	36-75	151.4	143.4	165.0	137.1	129.6	144.5	132.6	127.1	139.6
	76-100	121.9	110.8	131.6	123.4	110.0	137.7	115.0	103.6	129.5
	>100	156.5	153.0	160.8	172.3	165.0	179.0	180.5	176.3	184.1
WL death counts	<= 20	28	20	33	25	22	29	24	18	36
	21-35	57	46	70	55	45	66	54	43	68
	36-75	180	164	218	177	153	195	144	123	163
	76-100	76	51	100	72	53	96	62	42	82
	>100	146	134	157	134	123	149	113	107	121
WL morality rates	<= 20	11.1	7.9	13.4	10.6	9.3	12.3	9.2	6.3	10.7
	21-35	12.7	10.9	15.7	12.8	10.9	14.2	10.6	8.8	12.6
	36-75	12.8	12.1	13.8	11.8	11.3	12.6	10.0	9.0	10.6
	76-100	12.3	10.1	13.7	12.5	11.0	15.3	10.4	8.6	11.4
	>100	16.4	15.2	17.3	14.9	13.8	16.7	12.8	12.1	13.9
WL removals	<= 20	71	58	91	68	57	95	71	58	112
	21-35	101	85	121	106	80	131	122	101	143
	36-75	307	276	335	306	288	333	283	261	303
	76-100	131	108	153	67	56	87	73	44	94
	>100	118	110	126	175	167	184	164	154	172
1Y PT deaths	<= 20	32	25	40	31	20	44	30	22	39
	21-35	60	43	74	61	41	71	72	56	86
	36-75	215	165	244	222	200	245	211	176	246
	76-100	104	75	136	88	54	112	94	62	140
	>100	208	190	231	223	189	247	239	215	260
1Y PT death rates	<= 20	19.2	13.5	26.7	19.3	13.6	24.3	19.0	13.6	27.4
	21-35	19.6	14.3	24.5	20.9	17.1	26.2	20.2	17.4	24.3
	36-75	18.8	16.9	21.2	19.8	17.7	23.6	20.5	18.2	22.8
	76-100	21.1	16.8	24.5	19.4	14.2	24.0	20.7	16.9	23.9
	>100	21.5	19.1	23.2	21.2	17.7	23.9	22.2	19.6	24.3

Appendix 2: Allocation rules per simulation

Table 13. Offer order: DSA simulation, donors aged 18 years or older

Order	Geography	Candidate group
1	DSA	Age 12 years or older, blood identical
2	DSA	Age 12 years or older, blood compatible
3	DSA	Age 0-11, priority 1, blood identical*
4	DSA	Age 0-11, priority 1, blood compatible
5	DSA	Age 0-11, priority 2, blood identical
6	DSA	Age 0-11, priority 2, blood compatible
7	500 nautical miles	Age 12 years or older, blood identical
8	500 nautical miles	Age 12 years or older, blood compatible
9	500 nautical miles	Age 0-11, priority 1, blood identical*
10	500 nautical miles	Age 0-11, priority 1, blood compatible
11	500 nautical miles	Age 0-11, priority 2, blood identical
12	500 nautical miles	Age 0-11, priority 2, blood compatible
13	1000 nautical miles	Age 12 years or older, blood identical
14	1000 nautical miles	Age 12 years or older, blood compatible
15	1000 nautical miles	Age 0-11, priority 1, blood identical*
16	1000 nautical miles	Age 0-11, priority 1, blood compatible
17	1000 nautical miles	Age 0-11, priority 2, blood identical
18	1000 nautical miles	Age 0-11, priority 2, blood compatible
19	1500 nautical miles	Age 12 years or older, blood identical
20	1500 nautical miles	Age 12 years or older, blood compatible
21	1500 nautical miles	Age 0-11, priority 1, blood identical*
22	1500 nautical miles	Age 0-11, priority 1, blood compatible
23	1500 nautical miles	Age 0-11, priority 2, blood identical
24	1500 nautical miles	Age 0-11, priority 2, blood compatible
25	2500 nautical miles	Age 12 years or older, blood identical
26	2500 nautical miles	Age 12 years or older, blood compatible
27	2500 nautical miles	Age 0-11, priority 1, blood identical*
28	2500 nautical miles	Age 0-11, priority 1, blood compatible
29	2500 nautical miles	Age 0-11, priority 2, blood identical
30	2500 nautical miles	Age 0-11, priority 2, blood compatible
31	> 2500 nautical miles	Age 12 years or older, blood identical
32	> 2500 nautical miles	Age 12 years or older, blood compatible
33	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
34	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
35	> 2500 nautical miles	Age 0-11, priority 2, blood identical
36	> 2500 nautical miles	Age 0-11, priority 2, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Table 14. Offer order: DSA simulation, donors aged 0-17 years

Order	Geography	Candidate group
1	DSA or 1000 nautical miles	Age 0-11, priority 1, blood identical*
2	DSA or 1000 nautical miles	Age 0-11, priority 1, blood compatible
3	DSA or 1000 nautical miles	Age 0-11, priority 2, blood identical
4	DSA or 1000 nautical miles	Age 0-11, priority 2, blood compatible
5	DSA or 1000 nautical miles	Age 12-17 years, blood identical
6	DSA or 1000 nautical miles	Age 12-17 years, blood compatible
7	DSA	Age 18 years or older, blood identical
8	DSA	Age 18 years or older, blood compatible
9	500 nautical miles	Age 18 years or older, blood identical
10	500 nautical miles	Age 18 years or older, blood compatible
11	1000 nautical miles	Age 18 years or older, blood identical
12	1000 nautical miles	Age 18 years or older, blood compatible
13	1500 nautical miles	Age 0-11, priority 1, blood identical*
14	1500 nautical miles	Age 0-11, priority 1, blood compatible
15	1500 nautical miles	Age 0-11, priority 2, blood identical
16	1500 nautical miles	Age 0-11, priority 2, blood compatible
17	1500 nautical miles	Age 12-17 years, blood identical
18	1500 nautical miles	Age 12-17 years, blood compatible
19	1500 nautical miles	Age 18 years or older, blood identical
20	1500 nautical miles	Age 18 years or older, blood compatible
21	2500 nautical miles	Age 0-11, priority 1, blood identical*
22	2500 nautical miles	Age 0-11, priority 1, blood compatible
23	2500 nautical miles	Age 0-11, priority 2, blood identical
24	2500 nautical miles	Age 0-11, priority 2, blood compatible
25	2500 nautical miles	Age 12-17 years, blood identical
26	2500 nautical miles	Age 12-17 years, blood compatible
27	2500 nautical miles	Age 18 years or older, blood identical
28	2500 nautical miles	Age 18 years or older, blood compatible
29	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
30	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
31	> 2500 nautical miles	Age 0-11, priority 2, blood identical
32	> 2500 nautical miles	Age 0-11, priority 2, blood compatible
33	> 2500 nautical miles	Age 12-17 years, blood identical
34	> 2500 nautical miles	Age 12-17 years, blood compatible
35	> 2500 nautical miles	Age 18 years or older, blood identical
36	> 2500 nautical miles	Age 18 years or older, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Table 15. Offer order: 250 NM simulation, donors aged 18 years or older

Order	Geography	Candidate group
1	250 nautical miles	Age 12 years or older, blood identical
2	250 nautical miles	Age 12 years or older, blood compatible
3	250 nautical miles	Age 0-11, priority 1, blood identical*
4	250 nautical miles	Age 0-11, priority 1, blood compatible
5	250 nautical miles	Age 0-11, priority 2, blood identical
6	250 nautical miles	Age 0-11, priority 2, blood compatible
7	500 nautical miles	Age 12 years or older, blood identical
8	500 nautical miles	Age 12 years or older, blood compatible
9	500 nautical miles	Age 0-11, priority 1, blood identical*
10	500 nautical miles	Age 0-11, priority 1, blood compatible
11	500 nautical miles	Age 0-11, priority 2, blood identical
12	500 nautical miles	Age 0-11, priority 2, blood compatible
13	1000 nautical miles	Age 12 years or older, blood identical
14	1000 nautical miles	Age 12 years or older, blood compatible
15	1000 nautical miles	Age 0-11, priority 1, blood identical*
16	1000 nautical miles	Age 0-11, priority 1, blood compatible
17	1000 nautical miles	Age 0-11, priority 2, blood identical
18	1000 nautical miles	Age 0-11, priority 2, blood compatible
19	1500 nautical miles	Age 12 years or older, blood identical
20	1500 nautical miles	Age 12 years or older, blood compatible
21	1500 nautical miles	Age 0-11, priority 1, blood identical*
22	1500 nautical miles	Age 0-11, priority 1, blood compatible
23	1500 nautical miles	Age 0-11, priority 2, blood identical
24	1500 nautical miles	Age 0-11, priority 2, blood compatible
25	2500 nautical miles	Age 12 years or older, blood identical
26	2500 nautical miles	Age 12 years or older, blood compatible
27	2500 nautical miles	Age 0-11, priority 1, blood identical*
28	2500 nautical miles	Age 0-11, priority 1, blood compatible
29	2500 nautical miles	Age 0-11, priority 2, blood identical
30	2500 nautical miles	Age 0-11, priority 2, blood compatible
31	> 2500 nautical miles	Age 12 years or older, blood identical
32	> 2500 nautical miles	Age 12 years or older, blood compatible
33	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
34	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
35	> 2500 nautical miles	Age 0-11, priority 2, blood identical
36	> 2500 nautical miles	Age 0-11, priority 2, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Table 16. Offer order: 250 NM simulation, donors aged 0-17 years

Order	Geography	Candidate group
1	1000 nautical miles	Age 0-11, priority 1, blood identical*
2	1000 nautical miles	Age 0-11, priority 1, blood compatible
3	1000 nautical miles	Age 0-11, priority 2, blood identical
4	1000 nautical miles	Age 0-11, priority 2, blood compatible
5	1000 nautical miles	Age 12-17 years, blood identical
6	1000 nautical miles	Age 12-17 years, blood compatible
7	250 nautical miles	Age 18 years or older, blood identical
8	250 nautical miles	Age 18 years or older, blood compatible
9	500 nautical miles	Age 18 years or older, blood identical
10	500 nautical miles	Age 18 years or older, blood compatible
11	1000 nautical miles	Age 18 years or older, blood identical
12	1000 nautical miles	Age 18 years or older, blood compatible
13	1500 nautical miles	Age 0-11, priority 1, blood identical*
14	1500 nautical miles	Age 0-11, priority 1, blood compatible
15	1500 nautical miles	Age 0-11, priority 2, blood identical
16	1500 nautical miles	Age 0-11, priority 2, blood compatible
17	1500 nautical miles	Age 12-17 years, blood identical
18	1500 nautical miles	Age 12-17 years, blood compatible
19	1500 nautical miles	Age 18 years or older, blood identical
20	1500 nautical miles	Age 18 years or older, blood compatible
21	2500 nautical miles	Age 0-11, priority 1, blood identical*
22	2500 nautical miles	Age 0-11, priority 1, blood compatible
23	2500 nautical miles	Age 0-11, priority 2, blood identical
24	2500 nautical miles	Age 0-11, priority 2, blood compatible
25	2500 nautical miles	Age 12-17 years, blood identical
26	2500 nautical miles	Age 12-17 years, blood compatible
27	2500 nautical miles	Age 18 years or older, blood identical
28	2500 nautical miles	Age 18 years or older, blood compatible
29	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
30	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
31	> 2500 nautical miles	Age 0-11, priority 2, blood identical
32	> 2500 nautical miles	Age 0-11, priority 2, blood compatible
33	> 2500 nautical miles	Age 12-17 years, blood identical
34	> 2500 nautical miles	Age 12-17 years, blood compatible
35	> 2500 nautical miles	Age 18 years or older, blood identical
36	> 2500 nautical miles	Age 18 years or older, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Table 17. Offer order: 500 NM simulation, donors aged 18 years or older

Order	Geography	Candidate group
1	500 nautical miles	Age 12 years or older, blood identical
2	500 nautical miles	Age 12 years or older, blood compatible
3	500 nautical miles	Age 0-11, priority 1, blood identical*
4	500 nautical miles	Age 0-11, priority 1, blood compatible
5	500 nautical miles	Age 0-11, priority 2, blood identical
6	500 nautical miles	Age 0-11, priority 2, blood compatible
7	1000 nautical miles	Age 12 years or older, blood identical
8	1000 nautical miles	Age 12 years or older, blood compatible
9	1000 nautical miles	Age 0-11, priority 1, blood identical*
10	1000 nautical miles	Age 0-11, priority 1, blood compatible
11	1000 nautical miles	Age 0-11, priority 2, blood identical
12	1000 nautical miles	Age 0-11, priority 2, blood compatible
13	1500 nautical miles	Age 12 years or older, blood identical
14	1500 nautical miles	Age 12 years or older, blood compatible
15	1500 nautical miles	Age 0-11, priority 1, blood identical*
16	1500 nautical miles	Age 0-11, priority 1, blood compatible
17	1500 nautical miles	Age 0-11, priority 2, blood identical
18	1500 nautical miles	Age 0-11, priority 2, blood compatible
19	2500 nautical miles	Age 12 years or older, blood identical
20	2500 nautical miles	Age 12 years or older, blood compatible
21	2500 nautical miles	Age 0-11, priority 1, blood identical*
22	2500 nautical miles	Age 0-11, priority 1, blood compatible
23	2500 nautical miles	Age 0-11, priority 2, blood identical
24	2500 nautical miles	Age 0-11, priority 2, blood compatible
25	> 2500 nautical miles	Age 12 years or older, blood identical
26	> 2500 nautical miles	Age 12 years or older, blood compatible
27	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
28	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
29	> 2500 nautical miles	Age 0-11, priority 2, blood identical
30	> 2500 nautical miles	Age 0-11, priority 2, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Table 18. Offer order: 500 NM simulation, donors aged 0-17 years

Order	Geography	Candidate group
1	1000 nautical miles	Age 0-11, priority 1, blood identical*
2	1000 nautical miles	Age 0-11, priority 1, blood compatible
3	1000 nautical miles	Age 0-11, priority 2, blood identical
4	1000 nautical miles	Age 0-11, priority 2, blood compatible
5	1000 nautical miles	Age 12-17 years, blood identical
6	1000 nautical miles	Age 12-17 years, blood compatible
7	500 nautical miles	Age 18 years or older, blood identical
8	500 nautical miles	Age 18 years or older, blood compatible
9	1000 nautical miles	Age 18 years or older, blood identical
10	1000 nautical miles	Age 18 years or older, blood compatible
11	1500 nautical miles	Age 0-11, priority 1, blood identical*
12	1500 nautical miles	Age 0-11, priority 1, blood compatible
13	1500 nautical miles	Age 0-11, priority 2, blood identical
14	1500 nautical miles	Age 0-11, priority 2, blood compatible
15	1500 nautical miles	Age 12-17 years, blood identical
16	1500 nautical miles	Age 12-17 years, blood compatible
17	1500 nautical miles	Age 18 years or older, blood identical
18	1500 nautical miles	Age 18 years or older, blood compatible
19	2500 nautical miles	Age 0-11, priority 1, blood identical*
20	2500 nautical miles	Age 0-11, priority 1, blood compatible
21	2500 nautical miles	Age 0-11, priority 2, blood identical
22	2500 nautical miles	Age 0-11, priority 2, blood compatible
23	2500 nautical miles	Age 12-17 years, blood identical
24	2500 nautical miles	Age 12-17 years, blood compatible
25	2500 nautical miles	Age 18 years or older, blood identical
26	2500 nautical miles	Age 18 years or older, blood compatible
27	> 2500 nautical miles	Age 0-11, priority 1, blood identical*
28	> 2500 nautical miles	Age 0-11, priority 1, blood compatible
29	> 2500 nautical miles	Age 0-11, priority 2, blood identical
30	> 2500 nautical miles	Age 0-11, priority 2, blood compatible
31	> 2500 nautical miles	Age 12-17 years, blood identical
32	> 2500 nautical miles	Age 12-17 years, blood compatible
33	> 2500 nautical miles	Age 18 years or older, blood identical
34	> 2500 nautical miles	Age 18 years or older, blood compatible

* TSAM does not have titer data for modeling infants eligible for ABO-incompatible offers.

Appendix 3: TSAM technical details

Models that underlie TSAM use historical data to predict future outcomes under different allocation rules. Acceptance models, which predict which organs will be accepted for which candidates, were built on a cohort of patients from July 2009 to June 2011.

TSAM also uses waitlist and post-transplant survival models. Waitlist survival models are used to give each candidate a complete history for the duration of the TSAM cohort period. In a given simulation run, a candidate may remain on the waiting list after undergoing transplant in real life. At the time of real-life transplant, a candidate ceases to have real waitlist data needed to participate in simulated allocation. We use waitlist survival models to create a history of appropriate clinical severity for these patients and append that history to their own. We use post-transplant survival models to predict survival in patients after they undergo simulated transplant.

To avoid over-fitting the models, we built these survival prediction models on a cohort of candidates and recipients from January 1, 2007, to June 30, 2009, the most recent cohort available prior to the cohort included in the TSAM runs. Thus, current results are based on pre-revision LAS. Updating the TSAM software was not feasible for this request, given the short timeline. Moreover, insufficient time has passed to allow enough follow-up for both acceptance models and TSAM survival models among candidates listed and recipients transplanted February 19, 2015 or later.