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Public Comment Proposal

Eliminate the Use of DSAs in Thoracic Distribution

OPTN/UNOS Thoracic Organ Transplantation Committee

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Contents

Eliminate the Use of DSAs in Thoracic Distribution

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Sponsoring Committee:	*Thoracic Organ Transplantation Committee*
Public Comment Period:	*January 22, 2019 – March 22, 2019*

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) Final Rule (hereafter, Final Rule) sets requirements for allocation policies developed by the OPTN/UNOS, including sound medical judgement, best use of organs, ability for transplant hospitals to decide whether to accept an organ offer, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency. The Final Rule also includes a requirement that allocation policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements of the Final Rule listed above.[1]

In the past year, the United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA) and associated regulations under the Final Rule with respect to the geographic units used in lung and liver distribution.[2,3,4] The OPTN/UNOS made rapid changes to resolve using donation service area (DSA) and OPTN/UNOS regions (Regions) in lung and liver distribution, respectively.[5,6] Furthermore, the OPTN/UNOS Executive Committee directed the organ-specific committees to analyze those distribution systems and replace DSAs and OPTN/UNOS regions with a more rational and defensible unit of distribution.[7]

Policy 6: Allocation of Hearts and Heart-Lungs currently uses DSAs as a geographic unit of distribution. These are poor proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule.

The OPTN/UNOS Thoracic Organ Transplantation Committee (hereafter, the Committee) proposes replacing DSAs with a 250 nautical mile (NM) distance from the donor hospital. The goal of this change is to make heart allocation policy more consistent with the Final Rule and provide more equity in access to

[1]42 C.F.R. § 121.
[2]NOTA, 42 U.S.C. § 273 et. seq.
[3]Motty Shulman, letter [*Critical comment*] to The Honorable Eric D. Hargan, Acting Secretary, U.S. Department of Health and Human Services, November 16, 2017.
[4]Motty Shulman, letter [*Critical comment*] to the Honorable Alex M. Azar II, Secretary of the U.S, Department of Health and Human Services, May 30, 2018.
[5]OPTN/UNOS Policy Notice, *Modifications to the Distribution of Deceased Donor Lungs,* OPTN/UNOS Thoracic Organ Transplantation Committee, June 12, 2018, https://optn.transplant.hrsa.gov/media/2539/thoracic_policynotice_201807_lung.pdf. (accessed December 27, 2018).
[6]OPTN/UNOS online communication, *Board approves updated liver distribution system*, https://optn.transplant.hrsa.gov/news/optnunos-board-approves-updated-liver-distribution-system/, (accessed December 26, 2018).
[7] Meeting Summary for August 1, 2018 meeting, OPTN/UNOS Executive Committee, https://optn.transplant.hrsa.gov/media/2609/20180801_executive_meetingsummary.pdf. (accessed December 26, 2018).

transplantation regardless of a candidate's place of listing. In addition, this proposal realigns the first units of distribution for heart and lung allocation, addresses the limited utility of the exception for sensitized heart candidates, and finally, resolves several clerical artifacts that remain as a consequence of removing DSA as a unit of distribution from heart allocation policy.

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

The Committee encourages all interested individuals to comment on the proposal in its entirety. Members are 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. The Committee requests specific feedback on the following item:

1. Members are asked if they would recommend an alternative distance for thoracic distribution, versus the proposed distance of 250 NM? If so, what distance do you recommend and what evidence justifies this distance?

What problem will this proposal address?

Policy 6: Allocation of Hearts and Heart-Lungs currently uses DSAs as a geographic unit of distribution. These are poor proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs and regions result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule. Therefore, this proposal addresses four problems:

1. Use of the DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule
2. Removal of the DSA as a unit of distribution in heart allocation makes current policy for sensitized heart candidates impractical
3. Terminology describing geographic units across organ-specific allocation policies is increasingly inconsistent
4. Removing DSA as a unit of distribution from OPTN/UNOS policy would result in clerical artifacts remaining in the policies

1. Use of the DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule

The Final Rule sets requirements for allocation polices developed by the OPTN/UNOS, including: sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency.[8] The Final Rule also stipulates that allocation policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements of Section 121.8 of the Final Rule.[9] Finally, the Final Rule includes a performance goal for allocation policies of “Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.”[10]

The requirement to distribute over a broad geographic area reflects professional consensus that organs are a national resource meant to be allocated based on patients’ medical need. Specifically, the 1986 Task Force stated that:

> “The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.”[11]

The Institute of Medicine made this same conclusion in 1999.[12]

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[8]42 C.F.R. §121.8(a).
[9]42 C.F.R. §121.8(a)(8).
[10]42 C.F.R. §121.8(b)(3).
[11]U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, “Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation.” Rockville, MD., p. 91, 1987, quoting Hunsicker, LG.
[12]National Academies Press, “Organ Procurement and Transplantation.” (1999).

In 2012, the American Medical Association's Code of Medical Ethics stated that, "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."[13]

Despite these positions and recommendations, OPTN/UNOS policy development has historically emphasized consensus and compromise within the medical community to help inform OPTN/UNOS allocation policy. In addition, OPO and transplant program relationships have been derived from the DSA and regional structure, so the medical community naturally considers these relationships when considering proposals.[14] However, while the Health Resources and Services Administration (HRSA) recognizes that transplant policy development is optimally left to the expertise of the "OPTN and its members, which includes stakeholders that are part of the transplant community and other interested members of the public" it advised that "…consensus is not required under the OPTN final rule and should not be a barrier to adopting…allocation policy that complies with the OPTN final rule."[15]

During 2018, HHS received critical comments regarding compliance with NOTA and associated regulations under the Final Rule with respect to use of DSA and regions in lung and liver distribution.[16,17] Subsequently, the OPTN/UNOS made rapid policy changes to resolve using DSA and regions in lung and liver distribution. [18,19] This directive was made on the grounds that DSAs and regions, as allocation units, cannot be rationally determined, consistently applied, and thus may create inequalities in candidates' access to organ transplantation.[20,21] A policy change to replace DSA-first distribution with distribution to a consistent size circle, congruent with the "zone" distribution system already utilized in thoracic distribution, 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 borders would more appropriately prioritize medical urgency in allocation.

Currently, DSAs are used as a geographic unit of distribution in heart allocation.[22] While there is broader distribution for the most medically urgent heart candidates, hearts are allocated to less medically urgent candidates within the DSA before they are offered to more medically acute candidates further away from the donor hospital (**Table 1**).[23] This allocation pattern alternates through all six heart statuses, prioritizing less medically urgent candidates within the DSA over more medically urgent candidates less proximate to the donor hospital. For example, under this distribution pattern for hearts, and after broader distribution for adult status 1 and 2 heart candidates, an adult status 3 heart candidate or pediatric status 1B candidate in the organ procurement organization's (OPO) DSA would receive heart offers before adult status 1 or pediatric status 1A and adult status 2 in Zone B, which is currently defined as "All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA."[24]

[13] American Medical Association. "Opinion 2.16 – Organ Transplantation Guidelines." *AMA Journal of Ethics* 14(3) (2012); 204-214, https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-organ-transplantation/2012-03 (accessed December 26, 2018).
[14] Meeting summary for August 27, 2018 meeting, OPTN/UNOS Patient Affairs Committee, https://optn.transplant.hrsa.gov/media/2695/20180827_pac_meetingsummary.pdf. (accessed December 27, 2018).
[15] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.
[16] Critical comment, November 16, 2017.
[17] Critical comment, May 30, 2018.
[18] OPTN/UNOS Policy Notice, Modifications to the Distribution of Deceased Donor Lungs.
[19] OPTN/UNOS Online Communication, Board approves updated liver distribution system.
[20] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[21] OPTN/UNOS Board Briefing. *Liver and Intestine Distribution Using Distance from Donor Hospital,* OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf. (accessed December 26, 2018).
[22] OPTN/UNOS Policy 6, *Allocation of Hearts and Heart-Lungs*, October 18, 2018. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_06. (accessed December 26, 2018).
[23] OPTN/UNOS Policy 6.
[24] OPTN/UNOS Policy 1.2, *Definitions*, May 2, 2018. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. (accessed December 26, 2018).

Table 1: Heart distribution system under current policy[25]

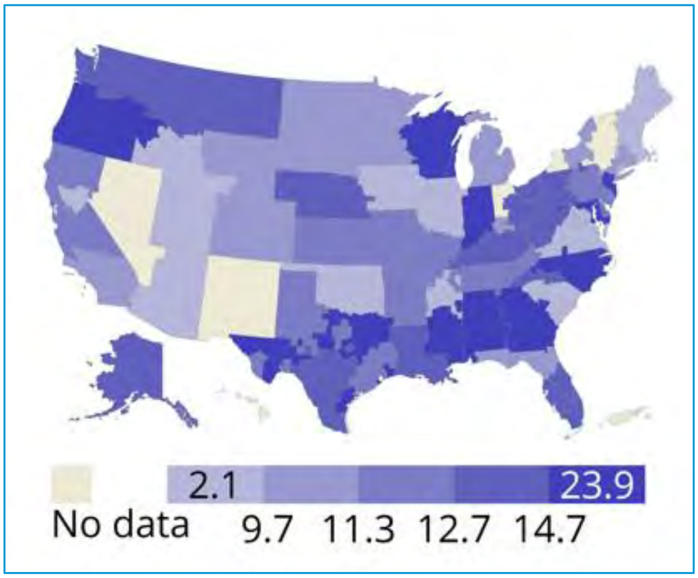
Classification	Candidates who are within the:	And are:
1-2	OPO's DSA or Zone A	Adult status 1 or pediatric status 1A
3-4	OPO's DSA or Zone A	Adult status 2
5-6	OPO's DSA	Adult status 3 or pediatric status 1B
7-8	Zone B	Adult status 1 or pediatric status 1A
9-10	Zone B	Adult status 2
11-12	OPO's DSA	Adult status 4
13-14	Zone A	Adult status 3 or pediatric status 1B
15-16	OPO's DSA	Adult status 5
17-18	Zone B	Adult status 3 or pediatric status 1B
19-20	OPO's DSA	Adult status 6 or pediatric status 2
21-22	Zone C	Adult status 1 or pediatric status 1A

As noted previously, DSAs have been determined to be an arbitrary geographic area with regard to allocation policy.[26] While concerns regarding system efficiency and patient access are appropriate considerations in policy development, there is no evidence that the use of DSAs provides the appropriate unit of geographic allocation to address these considerations. Therefore, DSAs do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates.[27] This presents a potential conflict with the Final Rule.

In addition, there are disparate waitlist mortality rates across DSAs. **Figure 1** shows wide variation in waitlist mortality by DSA, ranging from 2.1 to 23.9 deaths per 100 waitlist-years.[28,29] This is relevant as this metric is used as the measure for equity in thoracic organ transplantation.[30] This variation may not be exclusively due to geography, but a variety of factors, including utilization of mechanical circulatory support devices, trends in use of inotropes and other medicinal therapies, varying acceptance practices among heart transplant programs, and regional variation in disease-process.[31]

[25]Truncated version of heart allocation table from *Policy 6.6.D Allocation of Hearts from Donors at Least 18 years Old.* Offers go to primary blood type match with the donor before secondary blood type match with the donor.
[26]George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.
[27]Ibid.
[28]Colvin, Smith, Hadley, Skeans, Uccellini, Lehman, Robinson, Israni, Snyder, and Kasiske. "OPTN/SRTR 2017 Annual Data Report: Heart." Publication anticipated January 2019, *American Journal of Transplantation*.
[29]The Committee previously selected waitlist mortality as the best measure of equity for thoracic transplantation. See "How was this proposal developed?", page 12.
[30]See page 14, "Criteria" for detailed discussion
[31]Schulze, Kitada, Clerkin, Jin, and Mancini. "Regional Differences in Recipient Waitlist Time and Pre- and Post-Transplant Mortality After the 2006 United Network for Organ Distribution Policy Changes in the Donor Heart Allocation Algorithm." *JACC: Heart Failure* 2, no. 2 (2014): 166-77.

Figure 1: Waitlist mortality rates among adults waitlisted for heart transplant in 2016-2017, by DSA



2. Removal of the DSA as a unit of distribution in heart allocation makes current policy for sensitized heart candidates impractical

Current *Policy 6.4.B* permits a transplant program to make an agreement with all transplant programs and the OPO within a DSA to allocate hearts to a candidate out of sequence if all parties agree that the candidate is highly sensitized and in need of such prioritization. However, once DSA is removed as a unit of distribution, it is not logical to leave this policy intact. Doing so would have the effect of permitting certain parties to agree to prioritize a candidate when all affected parties would not have the opportunity to make such an agreement. Eliminating policy language permitting agreements limited to DSAs will remove inconsistency between heart and lung policy and avoids creating policy unsupported by evidence.[32]

3. Terminology describing geographic units across organ-specific allocation policies is increasingly inconsistent

Given the expedited timeline within which each organ-specific committee was directed to remove DSA and regions from their respective distribution systems, the Kidney Committee, working with Pancreas, and Vascularized Composite Allograft (VCA) Committees opted to adopt a concentric circle, "fixed distance" distribution framework.[33] This framework was previously vetted by the Ad Hoc Committee on Geography (Geography Committee).[34,35] The thoracic organ distribution system already utilizes a fixed distance framework.[36,37] As the other organ-specific committees considered what size "circles" would replace DSA

[32] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[33] The OPTN/UNOS Kidney and Pancreas Committees are also considering a "hybrid" distribution model hybrid model that is part continuous distribution and part fixed distance. A framework has not been decided upon, and they opted to issue a concept paper during the spring 2019 public comment cycle.
[34] OPTN/UNOS Board Briefing, *Frameworks for Organ Distribution,* OPTN/UNOS Ad Hoc Committee on Geography, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf. (accessed December 26, 2018).
[35] Not only was this framework deemed consistent with NOTA and the OPTN/UNOS Final Rule, the OPTN/UNOS determined it may be easier to implement in an expeditious manner.
[36] OPTN/UNOS Policy 6.
[37] OPTN/UNOS Policy 10, *Allocation of Lungs* (November 24, 2017).

and regions in their distribution systems within this framework, terminology became inconsistent between the abdominal, VCA and thoracic policies.[38,39,40]

Removing the term “zone” from OPTN/UNOS policy and replacing it with the actual distances in the allocation tables should minimize confusion, increase consistency and may make transition to a continuous distribution framework less cumbersome.[41] There are also several instances where zone occurs elsewhere in policy; these occurrences would also be stricken.

4. Removing DSA as a unit of distribution from OPTN/UNOS policy would result in clerical artifacts remaining in the policies

There are instances relevant to heart elsewhere in OPTN/UNOS policy that the term DSA needs to be removed as a result of replacing DSA within heart allocation policy.

Why should you support this proposal?

The proposed distance of 250 NM removes DSAs from heart allocation policy while striking an appropriate balance with the Final Rule requirements. This distance has a neutral effect on waitlist mortality and distributes hearts as broadly as feasible while minimizing the potential for organ wastage and the deleterious effect of long ischemic times on post-transplant mortality. In addition, it seeks to mitigate system inefficiency of longer donor-recipient distances and both the administrative and financial impediments on OPOs and transplant programs. Likewise, removing the term “zone” will not only make thoracic allocation policy internally consistent, but will ensure language consistency across all organ-specific policies. Finally, changes to the sensitization policy, and additional clerical changes, will provide clarity and transparency to policies that are historically under-utilized.

The proposed policy represents an improvement in heart allocation, making it more consistent with the Final Rule and potentially benefitting the most medically urgent candidates. However, it is also an opportunity to reinforce the importance of *who* should make decisions regarding organ distribution policies. The Final Rule permits individuals to submit critical comments to the HHS Secretary and outlines the Secretary’s obligations in response to such comments:

> “(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under §121.12. After this review, the Secretary may:
>
> 1) Reject the comments;
> 2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
> 3) Take such other action as the Secretary determines appropriate.”[42]

[38]OPTN/UNOS Board Briefing, *Enhancing Liver Distribution,* OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/2329/liver_boardreport_201712.pdf. (accessed December 26, 2018).
[39]OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.
[40]Meeting summary for July 16, 2018 meeting, OPTN/UNOS Kidney Committee, https://optn.transplant.hrsa.gov/media/2635/20180716_kidney_meetingsummary.pdf. (accessed January 2, 2019).
[41]OPTN/UNOS Board Briefing, Frameworks for Organ Distribution.
[42]42 C.F.R. § 121.4(d), available at Electronic Code of Federal Regulations

The July 2018 HHS letter regarding the litigation around liver distribution was more explicit, stating that "If the OPTN/UNOS Board fails to adopt a liver allocation policy that eliminates DSAs and regions and that is otherwise consistent with the requirements of the Final Rule, the Secretary may exercise further options or direct further action consistent with his authority under 42 C.F.R §121.4(d)."[43] Therefore, by supporting the proposal, the Committee will demonstrate the OPTN/UNOS's long-held view that organ allocation and distribution decisions are best decided by key stakeholders in the transplant community. In the alternative, the transplant community risks having these decisions made by the legislature, the judiciary, or HHS, as demonstrated by the recent HHS directives regarding lung and liver allocation.[44,45]

How was this proposal developed?

During the summer of 2018, the OPTN/UNOS Executive Committee directed the organ-specific committees to remove DSA and regions from their allocation systems and replace them with a rationally determined substitute that could be consistently applied and was legally defensible by way of better alignment with the Final Rule.[46] **Table 2** shows the timeline for the committees to make these changes. With this charge in mind, the Committee attempted to develop a policy which distributes organs as broadly as possible, where geographic limitations to allocation are based specifically on requirements of the referenced sections of the Final Rule.

Table 2: Timeline Overview of the Geography Projects

Project	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Distribution Frameworks		PC				BOD						
Liver & Intestine Distribution	Modeling			PC		BOD						
Kidney-Pancreas Distribution				Modeling				PC				BOD
Thoracic Distribution				Modeling				PC				BOD
VCA Distribution								PC				BOD

Legend
Develop
SRTR Modeling
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The Committee is comprised of representatives of transplant hospitals, OPOs, transplant coordinators, and transplant patients from each OPTN/UNOS region.[47] Members were selected for their expertise in the field of thoracic transplantation, and have decades of collective experience in transplantation. When evaluating the data available, members used experiential expertise to assess and interpret it. In addition, Committee members relied on each other's understanding of the differences in practice and the different challenges faced by the patient population and the transplant communities across the country.

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[43] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.
[44] For example, *see* H.R. 6458, 115th Congress, (2018) and H.R. 6517, 155th Congress (2018).
[45] For example, *see* Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371) and Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).
[46] Meeting Summary for August 1, 2018 meeting, OPTN/UNOS Executive Committee.
[47] As required by OPTN/UNOS Bylaws Article VII, 7.1: *Composition of Standing Committees.*

The Committee also collaborated with multiple other OPTN/UNOS committees representing particular patient groups or perspectives during the development of this proposal. For example, members of the OPTN/UNOS Pediatric Transplantation Committee joined committee meetings to bolster the existing pediatric specialist representation, and assess the impact of each change considered on pediatric candidates. The Patient Affairs Constituent Council offered feedback prior to public comment.[48]

The Ad Hoc Geography Committee received regular updates on the work of the Committee, and provided feedback about whether some of the solutions the Committee considered were compliant with the principles of geography and provided feedback on issues that were applicable to other organs as well, such as the treatment of non-contiguous states.[49,50] Additionally, the Geography Committee was charged with ensuring that the committees maintained rapid progress on these projects with consistent interpretation and application of the requirements under NOTA, the Final Rule, and the new OPTN/UNOS Principles of Organ Distribution.

The Committee agreed to a scope of work which included evaluation of the following:[51]

- What geographic framework should be used to remove DSA from heart distribution?
- If concentric circles are retained, what distance should replace DSA in heart distribution (adult and pediatric distribution)?
- Should lung distribution be re-evaluated or changed at all within this proposal?
- In particular, should lung allocation score (LAS) thresholds be established to distribute lungs more broadly to some candidates?[52,53]

1. Use of the DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule

Geographic Framework

The Ad Hoc Geography Committee distributed for public comment three frameworks for geographic distribution went out for public comment during the fall of 2018.[54,55] Early Committee discussions revolved around identifying a feasible and compliant geographic distribution framework for heart allocation, with the goal of developing a heart distribution policy proposal that reduces as much as possible the role of a candidate's place of listing in heart allocation while considering the best use of organs, organ wastage, patient access, and the efficient management of organ placement. The Committee based their decision in sound medical judgement through the use of OPTN/UNOS descriptive data reports, inferential modeling performed by the Scientific Registry of Transplant Recipients (SRTR), and published literature. There would be opportunity to further optimize thoracic organ distribution in the near future, but that was not the Committee's immediate task.

[48] Meeting summary for September 18th meeting, OPTN/UNOS Patient Affairs Committee, https://optn.transplant.hrsa.gov/media/2720/20180918_pac_meeting_minutes.pdf. (accessed December 26, 2018).
[49] The Ad Hoc Committee on Geography was comprised of current OPTN/UNOS Committee and Board leadership, in addition to representation from AST and ASTS.
[50] The Ad Hoc Committee on Geography (the Geography Committee) was formed in December 2017 to examine the principles of geographic distribution of organs and to establish guiding principles for the use of geographic constraints in organ allocation, reviewing and recommending models for incorporating geographic principles into allocation policies, and identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule.
[51] Meeting summary for July 19, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2616/20180719_thoracic_meetingsummary.pdf. (accessed December 26, 2018).
[52] The lung allocation score (LAS) is a calculated value used to stratify lung candidates that is based 2/3 on waitlist mortality and 1/3 on post-transplant survival.
[53] OPTN/UNOS Board Briefing, Lung public comment indicated some support of addressing broader distribution and establishing LAS thresholds for broader distribution, but those changes would have been too substantive to make post-public comment and within the timeframe provided.
[54] OPTN/UNOS Public Comment Proposal, *Frameworks for Organ Distribution,* OPTN/UNOS Ad Hoc Committee on Geography, August 2, 2018, https://optn.transplant.hrsa.gov/media/2565/geography_publiccomment_201808.pdf. (accessed December 26, 2018).
[55] The OPTN/UNOS Board of Directors approved the "continuous distribution" framework during the December 2018 meeting.

The Committee considered both retaining a fixed distance distribution approach or undertaking a more fundamental restructuring of the heart distribution policy.[56] The OPTN/UNOS Board tasked the Committee with removing DSA from thoracic distribution following the approval of, but prior to, implementation of the new policy changes to the adult heart allocation system.[57,58] The new adult heart allocation system is complex.[59] The most recent policy changes required more than 5 years of policy development prior to an 18-month implementation period. Therefore, the Committee opted to retain the current framework for heart distribution based on the following rationale:

1. *Complete analysis of extensive changes to policy is not possible within the prescribed time frame.*

There was insufficient time to adequately model and assess the impact of large-scale changes to the new adult heart allocation system.

2. *The use of concentric circles as consistent with the Final Rule has been validated by its use in lung allocation, and endorsed by the Geography Committee.*[60]

The use of concentric circles retained in the new adult heart allocation policy was based on sound medical judgment regarding balancing the ability for the most urgent patients to achieve access to donors over a broader geographic area, with concerns related to the impact of increasing cold ischemic times (and resultant worsening of post-transplant outcomes) and perceived increase in system costs resulting from longer travel distances.[61]

3. *As a matter of efficiency, the heart transplant community contributed significant resources on developing the policy and preparing for its impact.*

Replacing the system now would require another outlay of significant resources.

Overall, the Committee believed that the new allocation rules, particularly with broader distribution out to 500 NM for the sickest patients, were an important step in improving access to potential heart recipients beyond the boundaries of their local DSA.[62] Therefore, consistent with the directive of the OPTN/UNOS Board of Directors and the Final Rule, the Committee sought to eliminate DSA while leaving the preponderance of the not-yet-implemented policy changes in place, including the retention of the existing fixed distance framework.[63,64]

Considerations

Consideration of Making Further Changes to Distribution of Lungs

Based upon limited support for distributing donor lungs more broadly than the 250 NM distance implemented emergently, and made permanent by the OPTN/UNOS Board of Directors in June 2018, the Committee considered modifying lung distribution again.[65] During January 2018 public comment, patient advocacy groups and the OPTN/UNOS Patient Affairs Committee supported distributing lungs to 500 NM. The Committee noted the modeling indicated a decrease in waitlist mortality with 500 NM distribution, however without the opportunity to evaluate the consequences of distributing more broadly, the

[56] Meeting summary for July 19, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[57] Discussions regarding removing DSA from heart distribution began prior to implementation of the adult heart allocation system, which was implemented October 18, 2018.
[58] OPTN/UNOS UNet System Notice, October 18, 2018.
[59] OPTN/UNOS Policy 6.
[60] OPTN/UNOS Board Briefing, Frameworks for Organ Distribution.
[61] *Cold ischemic time:* In surgery, the time between the chilling of a tissue, organ, or body part after its blood supply has been reduced or cut off and the time it is warmed by having its blood supply restored. This can occur while the organ is still in the body or after it is removed from the body if the organ is to be used for transplantation. *National Cancer Institute*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cold-ischemia-time. (accessed December 26, 2018).
[62] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System.
[63] 6/28 meeting minutes
[64] Meeting summary for July 19, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[65] Meeting summary for August 23, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2650/20180823_thoracic_meetingsummary.pdf. (accessed December 26, 2018).

Committee was hesitant to increase the first unit of distribution from 250 NM to 500 NM.[66] Those who supported 250 NM, including the International Society of Heart and Lung Transplantation (ISHLT), were comfortable with this distance because post-implementation OPTN/UNOS data indicated no immediate adverse impact to patients.[67] In addition, there were several comments encouraging the Committee to consider establishing LAS thresholds for broader distribution. The Committee was not able to accommodate these suggestions based on the timeframe, substantive nature and complexity of making such changes post-public comment. These same issues made it unfeasible to reconsider further alterations to lung distribution policy within this project's scope. Therefore, the Committee opted to make no changes to the distances or other factors for lung distribution, and this proposal focuses exclusively on heart distribution.

The Impact of Broader Distribution on System Efficiency

Financial Costs

Costs are a relevant consideration within the context of broader distribution of organs because the Final Rule permits geographic limitations to the extent required by the consideration of the "efficient management of organ placement."[68,69] The Committee noted that concerns regarding cost were brought forth during public comment for the changes to the adult heart allocation system, the emergent changes to lung distribution, and most recently, the modifications to the liver distribution system.[70,71,72] A 9-month pre- vs. post- analysis of the impact of broader distribution of lungs only show an approximately 50 NM increase in median distance lungs travel from donor hospital to transplant hospital, yet anecdotally, Committee members cited a significant increase in travel and associated costs.[73,74]

While flying influences organ recovery in a variety of ways (see below), there is a significant jump in the costs associated with transportation for transplant; increased costs make the process less efficient.[75] In addition, costs related to the efficient management of organ placement (acquiring, preserving and transporting a donated organ) are a subset of the total cost to care for end stage organ failure patients or organ transplantation.[76] Unfortunately, while there is a dearth of definitive data regarding the financial impact of distributing thoracic organs more broadly, it remains a central concern to the community.[77,78] Therefore, the Committee emphasized cost be considered as a metric of efficient organ placement when determining a distance with which to replace DSA.

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[66] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[67] Ibid.
[68] 42 C.F.R. §121.8(a)(5).
[69] In evaluating the efficiency of the transplantation system, it is important to consider both the financial cost and the quality outcomes for the system. For this reason, the committee has focused on the below metrics which are a combination of financial cost and quality outcome metrics. This is consistent with current practices in evaluating healthcare efficiency. "The AQA, a consortium of physician professional groups, insurance plans, and others, has adopted a principle that measures can only be labeled "efficiency of care" if they incorporate a quality metric; those without quality incorporated are labeled "cost of care" measures."
Hussey PS, de Vries H, Romley J, et al. A Systematic Review of Health Care Efficiency Measures. *Health Services Research.* 2009;44(3):784-805. doi:10.1111/j.1475-6773.2008.00942.x. citing AQA, "AQA Principles of 'Efficiency' Measures." (2009).
[70] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System.
[71] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[72] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.
[73] OPTN/UNOS Descriptive Data Report. "Monitoring of the Lung Allocation Change, 9-Month Report Removal of DSA as a Unit of Allocation." Prepared for the OPTN/UNOS Thoracic Organ Transplantation Committee Meeting, November 1, 2018.
[74] Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2774/20181101_thoracic_committee_minutes.pdf. (accessed December 26, 2018).
[75] DuBay, MacLennan, Reed, Fouad, Martin, Meeks, Taylor, Kilgore, Tankersley, Gray, White, Eckhoff, and Locke. "The Impact of Proposed Changes in Liver Allocation Policy on Cold Ischemia Times and Organ Transportation Costs." *American Journal of Transplantation* 15, no. 2 (2015): 541-46. "The median transportation cost of a local donor within driving distance was only $101 while the median transportation cost of a local donor requiring air travel was $1993. The composite median cost of a local donor (including all local driving and local flying transportation episodes) was $548.Median liver procurement transportation costs increased significantly for regional flight travel, ranging from $8324 for flights less than 3 h to $27810 for flights longer than 3 h."
[76] Institute of Medicine, Committee on Organ Procurement and Transplantation Policy, "Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule", 1999, https://www.nap.edu/catalog/9628/organ-procurement-and-transplantation-assessing-current-policies-and-the-potential. (accessed December 26, 2018).
[77] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital, page 15.
[78] The OPTN/UNOS does not collect cost data.

Use of Air Transportation

In addition to the direct increase in financial costs associated with flying, the Committee expressed concern regarding the efficiency and safety of air transportation of thoracic organs. The availability of pilots, planes, and flights may impact the efficiency of organ placement if the number of flights needed to transport organs increases dramatically. This is especially problematic for the thoracic community, as thoracic surgical teams rely heavily on air travel in an attempt to mitigate cold ischemic time.[79] This may be in part because of a lack of available pilots as the number of pilots decrease. The Federal Aviation Administration concludes "both private and commercial pilot certificates are projected to decrease at an average annual rate of 0.8 and 0.5 percent, respectively until 2038."[80] "The [pilot] shortage has been caused by a recent increase in the flying hours required for commercial pilots, the aging pilot workforce, fewer new pilots coming out of the military, and a general decline of interest in the career." [81,82,83,84,85] In addition, the transplant community has noted additional transportation challenges resulting from new regulations governing crew duty and rest times.[86,87]

In addition, the Committee members agreed that the efficient functioning of the organ allocation system requires that teams accepting an organ be available and able to participate in the organ recovery in a relatively short timeframe. Committee members agreed that if flights are unavailable, the time between organ offer and cross-clamp may be extended, making the organ less viable, or candidates may lose the opportunity to receive an allocated donor allograft. Longer travel times also have the potential to limit transplant team availability. During organ recovery, transplant centers often do not have sufficient personnel to perform simultaneous recoveries. Committee members were concerned that an increasing percentage of recoveries requiring air travel would result in a longer periods of time when a center did not have a recovery team available, either resulting in the inability to accept an offered organ, or furthering delays in recovery.

Committee members felt that allocation should be constrained in order to mitigate logistical impracticalities, such as organs crossing in the air if being shipped to candidates on opposite coasts. For example, it would not be efficient (or cost-effective) for a surgical team from Seattle, Washington, to fly to Miami, Florida, to procure an organ for a medically urgent candidate on the waiting list in Seattle while a team from Jacksonville, Florida, was flying to Portland, Oregon to pick up an organ for a patient with a clinically inconsequential difference in degree of illness and/or priority on the waiting list in Jacksonville.[88] The organ distribution principle of promoting efficiencies of donation and transplant system resources organ placement supports limiting distribution to avoid this type of scenario.[89,90]

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[79]Lund, Khush, Cherikh, Goldfarb, Kucheryavaya, Levvey, Meiser, Rossano, Chambers, Yusen, and Stehlik. "The Registry of the International Society for Heart and Lung Transplantation: Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time." *Journal of Heart and Lung Transplantation* 36, no. 10 (2017): 1037-046.

[80]Federal Aviation Administration, "FAA Aerospace Forecast: Fiscal Years 2018-2038," Accessed October 1, 2018, https://www.faa.gov/data_research/aviation/aerospace_forecasts/media/FY2018-38_FAA_Aerospace_Forecast.pdf

[81]Robert Silk, "How the 1,500-hour Rule Created a Pilot Shortage: Travel Weekly," *Travel Weekly- The Travel Industry's Trusted Voice*, (August 18, 2017), https://www.travelweekly.com/Robert-Silk/How-1500-hour-rule-created-pilot-shortage.

[82]See Air Safety Institute, "Aging and the General Aviation Pilot: Research and Recommendations," Accessed December 14, 2018, https://www.aopa.org/-/media/Files/AOPA/Home/Pilot-Resources/Safety-and-Proficiency/Accident-Analysis/Special-Reports/1302agingpilotreport.pdf

[83]Maria Garcia, Forbes, "Advocates Worry that Changes to GI Bill Will Make Pilot Crisis Worse," accessed October 5, 2018, https://www.forbes.com/sites/marisagarcia/2018/08/02/advocates-worry-that-changes-to-gi-bill-will-make-pilot-crisis-worse/#6ededdb7d524.

[84]Rachel Premack. "Airlines are 'desperate' for new pilots, and the shortage is contributing to canceled routes that are taking a toll on smaller cities," accessed October 5, 2018, https://www.businessinsider.com/airlines-pilot-shortage-cancelled-routes-2018-8.

[85]Clay Lacy Aviation, "The Pilot Shortage Is A Reality In Business Aviation," accessed October 1, 2018, https://www.claylacy.com/insights/pilotshortagebusinessaviation/.

[86]See generally 14 C.F.R. § 135. A RAND Corporation study of this regulation predicted higher labor costs for the airlines with more impact being felt on smaller, charter airlines. Michael McGee, "Air Transport Pilot Supply and Demand: Current State and Effects of Recent Legislation," RAND Corporation. P.81. (March 2015).

[87]The Impact of Pilot Shortages On Air Service To Smaller And Rural Markets, 106th Congress. (1999) (Statement of Robert Palmersheim, Director Of Flight Operations And Secretary-Treasurer, Lynch Flying Service, Inc.).

[88]Meeting summary for September 18th meeting, OPTN/UNOS Patient Affairs Committee.

[89]OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.

[90]42 C.F.R. §121.8(a)(5).

Finally, the thoracic community in particular is sensitive to the increased risk to the safety of surgical teams--and organs--that comes with air transport. There are several documented fatalities of thoracic surgical teams who were en route to procure a thoracic organ from a deceased donor [91,92,93] Organ procurement flights have fatality rates nearly 1,000 times higher than scheduled commercial aviation; indeed, thoracic surgeons are 2 times as likely to fly and 3 times as likely to use a helicopter, which has particularly high accident rates when compared to scheduled commercial fixed-wing aviation.[94]

Efficient Management of Organ Placement

Eliminating the use of DSA in lung allocation has resulted in an approximately 1 hour increase in the time from first electronic offer to cross-clamp, potentially because there are generally more candidates within the first allocation classification, and those candidates may be considering multiple offers.[95] The median sequence number of the final acceptor has increased from 5 to 6.[96] There is not clear data that longer time periods between declaration of brain death and completion of the allocation process discourage families and result in them backing-out of the donation, or donor deterioration resulting in an inability to successfully recover, although both of those concerns were raised by members of the Committee.[97] However, Committee members posited that the increase in time between offer and cross-clamp means that the OPO may have to maintain personnel on site longer; the resources required for each organ recovery and transplant are thereby increased; decreasing the efficiency of the system as a whole.

Cold Ischemic Time

The Final Rule allows for geographic limitations to organ allocation where required in order to achieve the best use of donated organs, avoid organ wastage, and to avoid futile transplants.[98] Committee members were concerned that the broader distribution of donor organs might result in increased cold ischemic times due to longer transport times. Multiple studies have shown a relationship between donor organ ischemic time and post-transplant outcomes.[99,100,101,102] Concerns regarding broader distribution's implications to increased cold ischemic time, potential increase in discards and organ wastage were raised during public comment for the previous adult heart allocation system changes, modifications to distribution of donor lungs and most recently, the changes to the liver allocation system.[103,104,105] In line with Final Rule §121.8(a) which states, "... allocation policies: (1) Shall be based on sound medical judgment; (5) Shall be designed to avoid wasting organs...", members found that any distance considered should be evaluated on whether there would be a "clinically significant effect on ischemic time and organ

[91] Associated Press "Mayo Clinic Workers Die in Fla. Helicopter Crash," Accessed November 9, 2018, https://www.cbsnews.com/news/mayo-clinic-workers-die-in-fla-helicopter-crash/ (accessed December 14, 2018).
[92] Englesbe, Michael J., and Robert M. Merion. "Authors' Response: The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel." *American Journal of Transplantation* 10, no. 5 (2010): 1335.
[93] Associated Press "Transplant Team Killed, Organ Lost in Plane Crash" http://www.washingtonpost.com/wp-dyn/content/article/2007/06/05/AR2007060500295.html?noredirect=on. (accessed December 14, 2018).
[94] Englesbe, M. J., and R. M. Merion. "The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel."
[95] OPTN/UNOS Descriptive Data Report. "Monitoring of the Lung Allocation Change, 9-Month Report Removal of DSA as a Unit of Allocation."
[96] Ibid.
[97] Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[98] 42 C.F.R. §121.8(a)(2,5).
[99] Nicoara, Alina, David Ruffin, Mary Cooter, et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." *American Journal of Transplantation* 18, no. 6 (2018): 1461-470.
[100] Ford, Almond, Gauvreau, Piercey, Blume, Smoot, Fynn-Thompson, and Singh. "Association of Graft Ischemic Time with Survival after Heart Transplant among Children in the United States." *Journal of Heart and Lung Transplantation* 30, no. 11 (2011): 1244-249.
[101] Del Rizzo, Menkis, Pflugfelder, Novick, Mckenzie, Boyd, and Kostuk. "The Role of *Donor Age and Ischemic Time on Survival following Orthotopic Heart Transplantation."* Journal of Heart and Lung Transplantation 18, no. 4 (1999): 310-19.
[102] Joyce, Li, Edwards, Kobashigawa, and Daly. "Predicting 1-year Cardiac Transplantation Survival Using a Donor–recipient Risk-assessment Tool." *The Journal of Thoracic and Cardiovascular Surgery* 155, no. 4 (2018): 1580-590.
[103] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System.
[104] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[105] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.

quality”.[106,107] While the available data varies, there does appear to be an inflection point, with worsened post-transplant outcomes among hearts with greater than 4 hours of ischemic time.[108]

Number of Transplants and Utilization

Increasing the number of transplants is the primary strategic goal of the OPTN/UNOS. It is consistent with several aspects of the Final Rule, including achieving best use of donated organs, decreasing avoiding organ wastage, and promoting patient access to transplantation. The Committee determined that they would be unlikely to support a distance where modeling showed a significant decrease in the number of transplants.

The Final Rule identifies reducing avoiding organ wastage as a goal of allocation policy.[109] The potential for an increase in discards and organ wastage was raised during public comment on previous changes to allocation resulting in broader distribution, including the adult heart allocation system changes, modifications to distribution of donor lungs and most recently, the changes to the liver allocation system.[110,111,112] However, the most recent monitoring report evaluating the changes to lung allocation has shown minimal changes in organ utilization rates.[113] These comparisons to lung are relevant because these organs tolerate relatively similar ischemic times and are considering identical distances for distribution. Furthermore, there is some evidence that an increased number of transplant centers with candidates eligible for an offer for donor organs (as would be expected to occur with broader distribution) may result in improved organ utilization.[114] However, there is limited data specifically regarding the impact of broader distribution in heart allocation on organ utilization. It is plausible that the increased financial costs of traveling longer distances for procurements may dissuade centers from accepting marginal organs which may be turned down after visualization. In addition, Committee members opined that marginal organs are often only successfully allocated as the result of the close relationship between the OPO and the recovering center. The relationship between broader distribution, longer allocation times, and donor quality contributing to organ discards remains uncertain. Therefore, the Committee remains concerned about these factors with regard to distributing hearts more broadly.

Criteria

The Committee determined that in addition to the aforementioned considerations, any distance considered to replace DSA should, ideally, result in a positive (or at least neutral) impact to waitlist mortality and vulnerable populations.

Waitlist Mortality

Achieving the best use of donated organs requires that allocation policy, to the extent feasible, should aim to maximize the life-years gained through each transplanted organ.[115] Waitlist mortality is one such metric used to measure this. During its November 2012 meeting, the Board approved a resolution recognizing that the existing geographic disparity in allocation of organs for transplant was unacceptably high, and directing the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013.[116] Subsequently, during the March 19, 2013 meeting, the

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[106] OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.
[107] 42 C.F.R. §121.8(a)(1)(2)
[108] Kilic, Ahmet, Sitaramesh Emani, Chittoor B Sai-Sudhakar, Robert S D Higgins, and Bryan A Whitson. "Donor Selection in Heart Transplantation." *Journal of Thoracic Disease* 6, no. 8 (2014): 1097-104.
[109] 42 C.F.R. §121.8(a)(5)
[110] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System.
[111] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[112] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.
[113] OPTN/UNOS Descriptive Data Report. “Monitoring of the Lung Allocation Change, 9-Month Report Removal of DSA as a Unit of Allocation.”
[114] Adler, Joel T., Heidi F. Yeh, James A. Markmann, and David Axelrod. "Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?" *Transplantation* 100, no. 6 (2016): 1349-355.
[115] In this context, generally speaking, a measure of the quality and quantity of life lived, which includes waitlist mortality and post-transplant mortality.
[116] Executive Summary of the Minutes for the November 12-13, 2012 OPTN/UNOS Board of Directors Meeting.

Committee noted the primary purpose of the resolution was to determine an objective measure that defines fairness.[117] The most immediate measures proposed by the Committee were waitlist mortality and median time to transplant. Historically, the Committee's policies have aimed to reduce waitlist mortality, and Committee members expressed opinions that waitlist mortality is still the best measure of fairness. But, they also noted there is a complex interaction between waitlist mortality and waitlist time. For example, if the Committee were to determine that long waitlist times are "unfair," then resolving those inequities may inadvertently affect waitlist mortality rates.

At that time, the Committee ultimately determined the best indicator of fairness in geographic allocation of thoracic organs is waitlist mortality. Waitlist time and post-transplant survival were identified as secondary factors. They also identified ischemic time as a potential constraint on broader geographic allocation of thoracic organs. The Committee determined that analysis of the model used for zonal distribution of thoracic organs would likely demonstrate that waitlist time and waitlist mortality continue to be the best indicators of equity. With this in mind, the Committee deemed waitlist mortality a primary indicator of best use of organs.[118]

Therefore, waitlist mortality was one of the metrics used by the Committee to assess whether transplant candidates have equal access to transplant. This is in line with section 121.8(a)(5) of the Final Rule, that the OPTN shall develop policies that… "promote patient access to transplantation" and section 121.8(a)(8), that policies "Shall not be based on the candidate's place of residence or place of listing…". In addition, decreasing waitlist mortality aligns with an initiative under the "Improve waitlisted patient, living donor, and transplant recipient outcomes" OPTN strategic goal.[119,120]

Vulnerable Populations

In addition, the Committee committed to ensuring pediatrics and other vulnerable populations were not negatively impacted. The Final Rule stipulates that the OPTN/UNOS shall develop "Policies that reduce inequities resulting from socioeconomic status, including…[the] reform of allocation policies…" [121]

Impact to Children

NOTA specifically recognizes the special status of children, and charges the OPTN/UNOS "to adopt criteria, policies and procedures that address the unique health care needs of children."[122] Based on this charge and supported by other Final Rule provisions, the OPTN/UNOS has determined that "there is a reasonable basis for giving preference to pediatric transplant candidates for allocation."[123] Accordingly, the Committee committed to ensuring that children were not negatively impacted by these allocation changes.

Promoting Access to Transplantation

The Final Rule acknowledges the importance of promoting patient access to transplantation. The Committee was concerned that elimination of DSAs with attendant broader geographic allocation of organs might alter the access to transplantation of various populations. Most directly, the Committee expressed concerns that transplant candidates listed in rural areas, states with low population densities, or states with fewer transplant centers might have a loss of access to transplantation as larger programs in urban areas may receive the preponderance of offers. In addition, the Committee wanted to ensure that

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https://optn.transplant.hrsa.gov/media/1801/executivesummary_1112.pdf. (Accessed December 19, 2018)

[117] Board report for the June 24-25, 2013 OPTN/UNOS Board of Directors, OPTN/UNOS Thoracic Organ Transplantation Committee.

[118] 42 C.F.R § 121.4(a)

[119] OPTN/UNOS Strategic Plan, https://optn.transplant.hrsa.gov/governance/strategic-plan/.

[120] While modeling of 250 and 500 NM as the first unit of allocation didn't show declines in WL mortality, much of that improvement had been achieved in moving from DSA-first allocation under old allocation rules to broader distribution available to sickest patients under recently implemented rules.

[121] 42 C.F.R § 121.4(a)(3)

[122] National Organ Transplantation Act (NOTA) 42 USC 273 et seq

[123] OPTN/UNOS White Paper, *Ethical Principles of Pediatric Organ Allocation,* November 2014, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/. (accessed December 27, 2018).

other populations including minorities and particular blood types would not be adversely affected by any changes. Accordingly, the Committee requested that the SRTR provide modeling on the anticipated impact of broader geographic distribution of hearts on various population types.

Distance

The Committee considered whether it would be possible to allocate hearts without any consideration for geography. This would fulfill the Final Rule requirement that allocation "not be based on the candidate's place of residence or place of listing, except to the extent required…" and "...through the following performance goals, (3) distributing organs over as broad a geographic area as feasible ...".[124] There was consensus that for (adult) hearts, national distribution was likely impractical due to cold ischemic time limitations; nevertheless, the Committee approached the problem with the philosophy to attempt to distribute hearts as broadly as feasible.

The Committee considered previous SRTR modeling data from the changes to the adult heart and lung distribution systems, as well as OPTN/UNOS descriptive data to inform the discussion around selecting potential distances to replace DSA.[125] First, they reviewed a comparison of a model most similar to the new geographic distribution method for hearts (distribute more broadly to adult status 1 and 2, abbreviated "Sh 1/2A") and another similar to a "DSA-free" model (no "local" [DSA] preference for any status, distribute to Zone B through each status, abbreviated "Sh All") (see **Table 3**).[126]

Table 3: Descriptions of Allocation Orderings from SRTR Data Request from the Heart Subcommittee of the OPTN/UNOS Thoracic Organ Transplantation Committee, June 11, 2015

Simulation Name	Description
CurRule	Current allocation rules by status 1A, 1B, and 2, as of July 1, 2015, and current geographic allocation rules as of July 1, 2015
By tier	Candidates classified by tier rather than status. Organs are offered to most severe tiers first, but generally follow ordering of current rules to allow for direct comparison. Uses an approximation to current geographic allocation rules as of July 1, 2015.
Sh 1/2A	Share to zone B for tier 1, then zone B to tier 2 before offers are made to tier 3.
Sh 1/2B	Similar to Sh 1/2A, but with distribution to zone A among tier 3 candidates before tier 4 offers are made.
Sh All	No local preference for any tier, with distribution to zone B for tier 1, then tier 2, and distribution to zone A for tier 3, then tier 4.
TierPr	No combined zones. Offers made sequentially locally, to zone A, then zone B for tier 1, locally, to zone A, then zone B for tier 2.

Note[1]: The term "tier" was replaced by the term "status" to describe the medical urgency categories in the adult heart allocation policy. The statuses stratify heart candidates by medical urgency, largely informed by relative waitlist mortality. A status 1 candidate is more medically urgent than a status 2 candidate, and so on.
Note[2]: For hearts, Zone B includes all transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA.

The previous modeling showed that compared with the allocation rules in the new adult heart allocation system, broader distribution simulations resulted in:

- Slightly lower transplant rates & counts
- Similar post-transplant death rates & counts
- Lower waitlist death rates & counts
- Fewer local transplants

Specifically, as compared with Sh 1/2A, Sh All resulted in:

[124] 42 C.F.R § 121.8(a)(8) and (b)(3).
[125] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2646/20180809_thoracic_meetingsummary.pdf. (accessed December 26, 2018).
[126] Scientific Registry of Transplant Recipients, *SRTR HR2015_01,* June 11, 2015.

- Similar transplant rates for status 1, 2, 5
- Higher transplant counts & rates for status 3
- Lower transplant counts & rates for status 4 & 5
- Similar waitlist mortality counts & rates in all statuses
- Similar post-transplant death rates in all status, but different counts due to different numbers transplanted at each status.

With these projections in mind, the Committee revisited modeling highlights from the changes to the lung distribution system. The Committee believed reviewing lung modeling would be informative because lung distribution historically used the same units of distribution as the heart system. Modeling of DSA, as compared to replacing DSA with either 250 NM or 500 NM revealed:[127]

- 250 NM vs. DSA-first, overall:
  - Similar transplant rates & counts, and post-transplant death rates & counts
  - 250 NM had slightly lower waitlist death rates & counts than DSA-first
- 500 NM vs. DSA-first, overall:
  - Similar transplant rates but potentially higher transplant counts, similar post-transplant death rates & counts
- In general:
  - Broader distribution prioritized access to highest-LAS candidates, by decreasing their death counts & rates, decreasing their transplant rates but not counts, and having little effect on their post-transplant outcomes. It also increased the proportion of non-local transplants
  - Effects more intense in 500 NM versus 250 NM simulations, as LAS drove allocation decision more so than geography

In addition, the Committee consulted OPTN/UNOS descriptive data showing how hearts are distributed under recent allocation rules to assess the current state of heart distribution.[128,129] Under the previous distribution system, the median distance hearts travelled from donor hospital to transplant center was 96 NM (**Figure 2**).[130] In comparing the distance adult recipient hearts travel versus pediatric recipient hearts, pediatric hearts traveled farther than adult hearts (**Figure 3**). The Committee acknowledged this was unsurprising, considering the rarity of pediatric donors and the seeming resiliency of pediatric donor hearts to sustain longer ischemic time.[131,132,133]

[127]Scientific Registry of Transplant Recipients, SRTR LU2017_02, https://optn.transplant.hrsa.gov/media/2432/thoracic_meetingsummary_20180116.pdf. (accessed December 26, 2018).
[128]Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[129]Heart allocation rules in effect prior to October 18, 2018.
[130]Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[131]Meeting summary for August 23, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[132]Russo, Chen, Sorabella, Martens, Garrido, Davies, George, Cheema, Mosca, Mital, Ascheim, Argenziano, Stewart, Oz, and Naka. "The Effect of Ischemic Time on Survival after Heart Transplantation Varies by Donor Age: An Analysis of the United Network for Organ Distribution Database." The Journal of Thoracic and Cardiovascular Surgery 133, no. 2 (2007): 554
[133]Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."

Figure 2: Deceased Donor Heart Transplants from 1/1/2017-06/30/2018, Travel Distance from Donor Hospital to Transplant Hospital

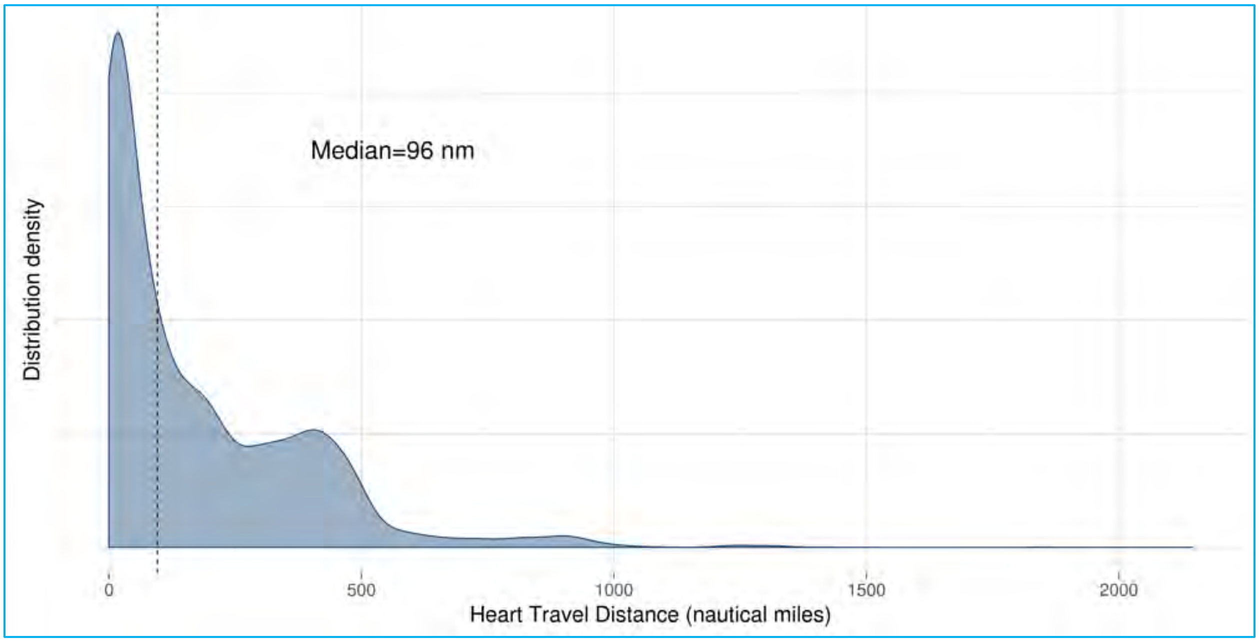
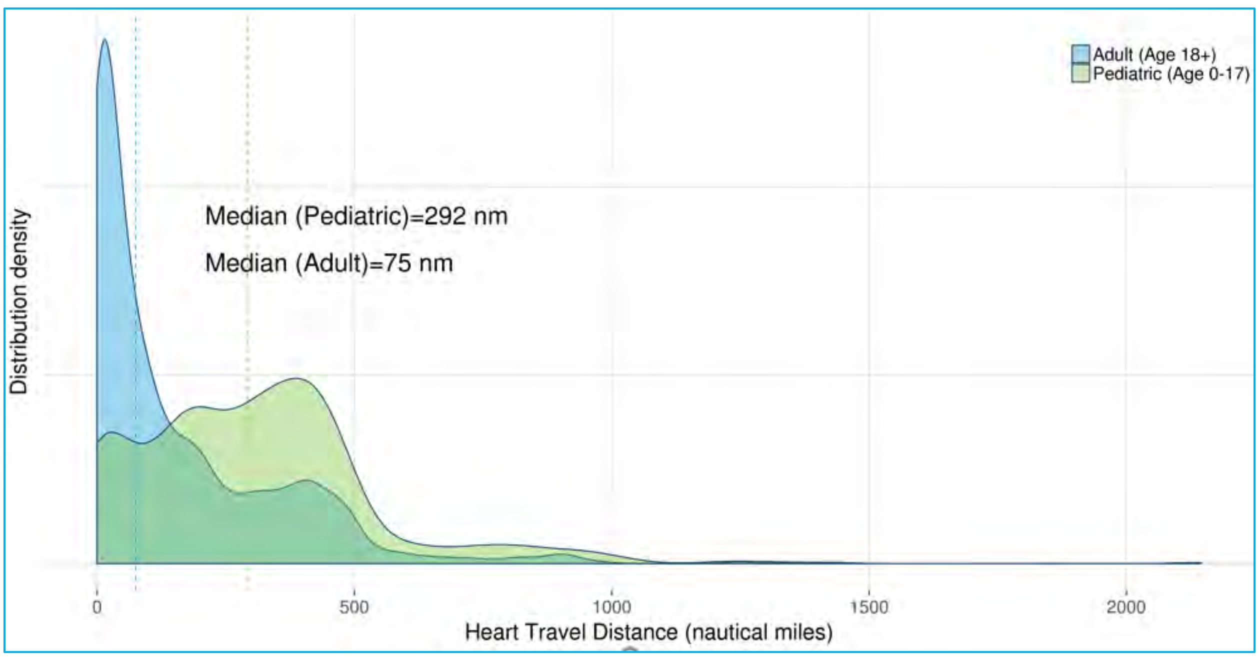


Figure 3: Deceased Donor Heart Transplants from 1/1/2017-06/30/2018, Travel Distance by Recipient Age



In examining OPTN/UNOS data for deceased donor heart transplants between 1/1/2017 and 6/30/2018, Committee members acknowledged that although there is not a direct correlation between distance and ischemic time, distance, in this discussion, is used as the best available, but an imperfect, proxy for time. Cold ischemic time is also a criterion in donor organ acceptance (**Figure 4**).[134,135] Any increase in distance has a potential impact due to corresponding increases in donor organ ischemic time.

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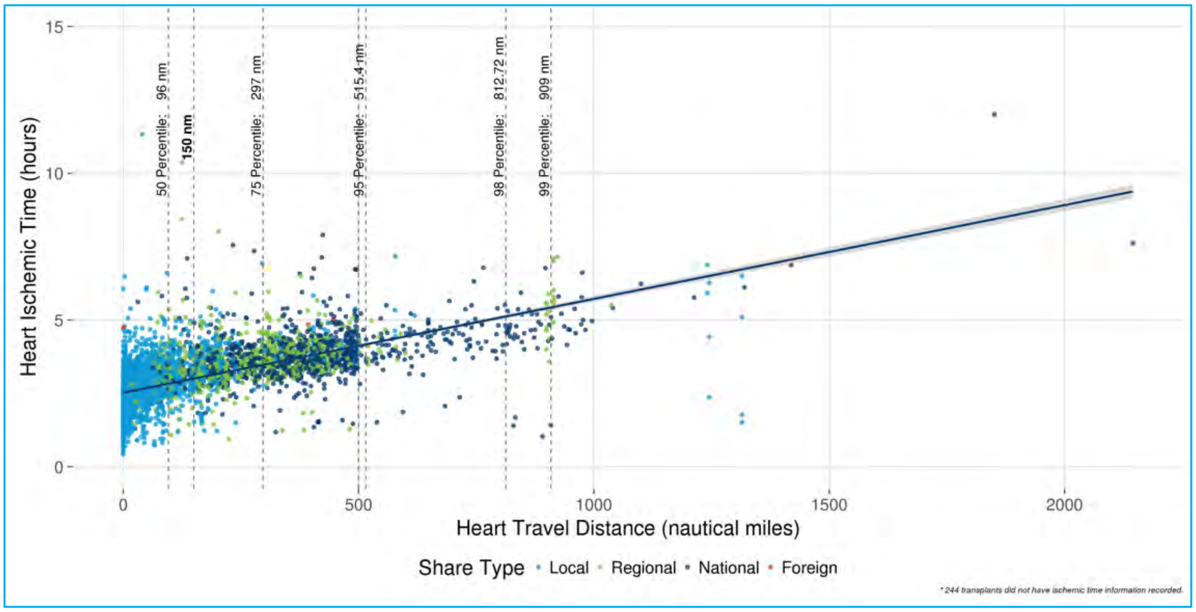
[134] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[135] Kilic et al. "Donor Selection in Heart Transplantation."

Figure 4: Deceased Donor Transplants from 1/1/2017-6/30/2018, Ischemic Times vs. Distance



Note: Local=within DSA, Regional=within OPTN/UNOS region.

With this information, the Committee discussed various distances that could replace DSA and on August 30, 2018, the Committee formally requested that SRTR model replacing DSA with 150 NM, 250 NM and 500 NM. The Committee's rationale for selecting these distances, and the results of the modeling presented to the Committee November 1, 2018, are detailed below.

500 NM

As previously described, the Committee first attempted to select a distance that would align with the broadest distribution feasible for hearts, per the Final Rule. In examining OPTN/UNOS data, members noted that most hearts were accepted within 500 NM (95th percentile: 514 NM, **Figure 4** on the previous page), and often, pediatric hearts were accepted at greater distances.[136] Given the limited number of transplants occurring beyond 500 NM and the fact that at that distance, nearly every donor heart likely would sustain an ischemic time beyond the 4 hour mark (**Figure 4**), the Committee did not feel that distances *beyond* 500 miles were feasible due to the potential impact on donor organ quality resulting from prolonged ischemic times, thereby negatively impacting the ability to transplant these organs and resulting in potential organ wastage and not making the best use of donated organs. Therefore, 500 NM was felt to be consistent with the Final Rule's performance goals, (3) distributing organs over as broad a geographic area as feasible ...".[137]

There was a brief discussion about acceptance criteria. Transplant programs enter the maximum distance they are willing to travel for a heart. There were a variety of distances noted by the Committee members, ranging from 1,500 to 2,000 NM. Although there was a suggestion to review these distance thresholds, UNOS staff noted that most transplant programs likely enter distances far greater than they are actually willing to travel. UNOS staff reminded the Committee that OPTN/UNOS data previously shared with the Committee illustrated that most hearts traveled within 500 NM with a few outliers.

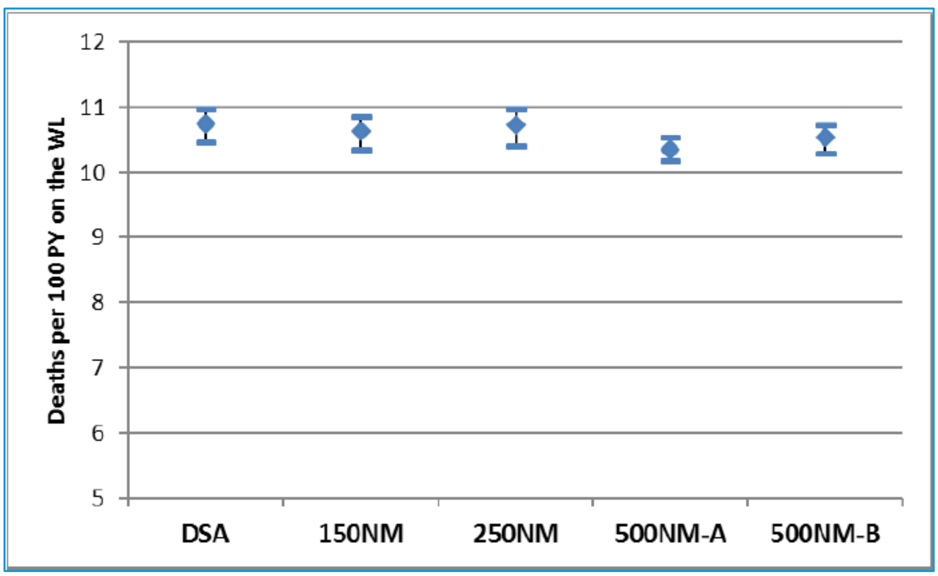
One important aspect of the heart allocation system implemented on October 18, 2018 includes the broadest distribution to the most urgent (status 1 and status 2) candidates. In this system, those status 1 and 2 candidates receive offers from any donors within the DSA or within 500 NM, while candidates in

[136]Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[137]42 C.F.R § 121.8(a) and (b)

statuses 3-6 receive offers first from any donors only within the DSA. The Committee noted that if 500 NM were the first unit of distribution to replace the DSA, then to retain broader distribution to status 1 and 2 candidates, the first unit of distance distribution shared would have to be even broader.[138] They briefly debated setting the broadest share distribution to 1,000 NM, which seemed logical based on the current zonal definitions. One member suggested 750 NM, but others agreed that seemed an arbitrary number. SRTR staff noted that as the allocation distances increase, the relationship without outcomes is often linear. Therefore, if the Committee chose to model 500 NM and extend distribution for the most medically urgent candidates to 1,000 NM, then the Committee could evaluate 750 NM by inference instead of running the TSAM for that particular distance. The Committee members expressed support for this approach. However, another member proposed 500 NM be the first unit of distribution for classifications 1, 2, and 3, which would effectively eliminate that broader distribution for the most medically acute status 1 and 2 candidates. Despite some discomfort expressed by some Committee members with the latter suggestion, the Committee agreed to have SRTR model two options for 500 NM as the first unit of distribution. 500 NM-A would retain broader distribution for status 1 and 2 candidates, and extend that distribution to 1,000 NM. 500 NM-B would remove broader distribution for these candidates, despite this approach being inconsistent with one of the primary goals of the recent changes to the adult heart allocation system.

The Committee reviewed SRTR modeling.[139,140,141] First, and potentially most importantly, modeling of both 500 NM-A and 500 NM-B allocation systems resulted in no measurable improvement in either waitlist or post-transplant outcomes (**Figure 5; Figure 6**).[142,143] Therefore, adoption of either the 500 NM-A or 500 NM-B would not be expected to achieve better use of donated organs (nor does it appear harmful).

Figure 5: Overall waitlist mortality rates by simulation



Note: 500 NM-A=500 NM as first unit of distribution, retaining broader distribution for status 1 and 2; 500 NM-B=500 NM as first unit of distribution, no broader distribution for status 1 and 2.

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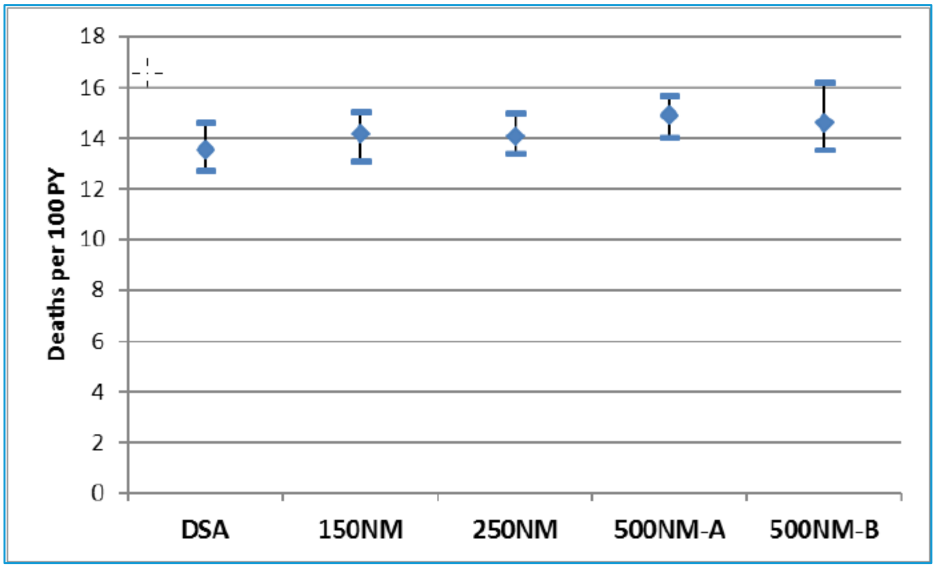
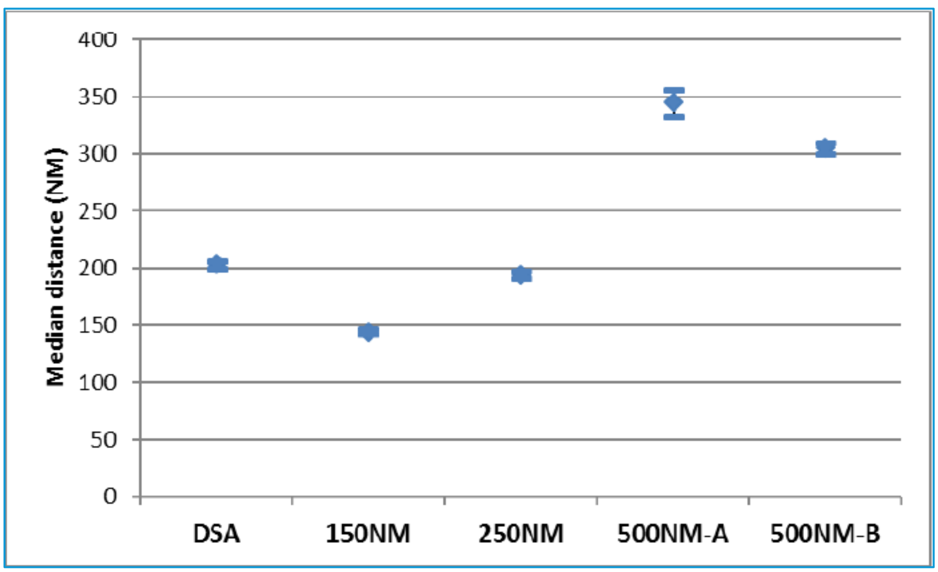
[138] Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2647/20180816_thoracic_meetingsummary.pdf. (accessed December 26, 2018).
[139] Although this modeling has limitations, it was noteworthy that the models used for revising lung allocation have been consistent with observable changes occurring post-implementation of those changes.
[140] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[141] Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[142] SRTR HR2018_01.
[143] SRTR simulation results (graphs) plot the average (point estimate), minimum, and maximum of the metric computed across the simulations, unless stated otherwise.

Figure 6: Overall 1-year post-transplant mortality rates by simulation



In addition, both models showed an increase in the median distance between the donor and transplant hospitals (from approximately 204 to 346 in 500 NM-A and 306 in 500 NM-B) (**Figure 7**).[144] This impacts travel and ischemic time. Median distance varied by circle size, and these differences in distance were expected.

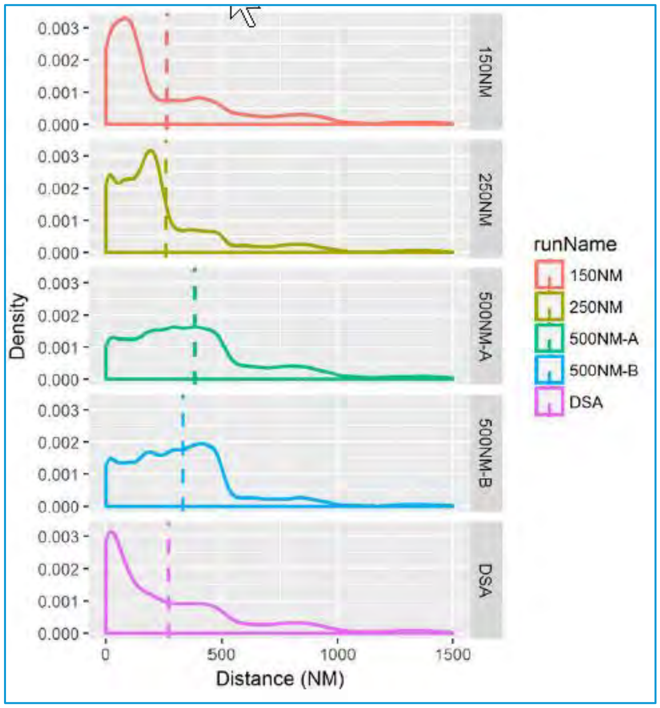
Figure 7: Median distance (NM) between donor and transplant hospital by simulation



In addition to changes in the median distance, this also results in a significant increase in the proportion of transplants occurring beyond 150 NM (from 55% under current allocation to 77%) (**Figure 8**). This distance is a relevant cut-off, because it is at this point that driving for thoracic organ recovery generally becomes infeasible.[145]

[144] SRTR HR2018_01.
[145] See discussion of 150 NM distance, pages 22-24.

Figure 8: Distribution of distance (NM) between donor and transplant hospital by simulation



As previously mentioned, the increase in distance also has a potential impact due to corresponding increases in donor organ ischemic time. In examining OPTN/UNOS data on deceased donor heart transplants between 1/1/2017 and 6/30/2018, there is not a direct correlation between distance and ischemic times (**Figure 4** found on page 18).[146] However, there are limits to the lower level of ischemic time with increasing distance. As seen in **Figure 4**, with distances between 250 and 500 nautical miles, ischemic times will rarely, if ever, be shorter than 3 hours. Ischemic time has been associated with increased incidence of primary graft dysfunction (itself associated with poor post-transplant outcomes and thus not making the best use of donated organs).[147]

Whether there is a specific point at which donor organ ischemic time results in worse outcomes has been difficult to determine (**Figure 9; Figure 10**).[148] In some analyses of adult donors, ischemic times as long as 5.5 hours have been tolerated (although clearly beyond that there was poorer survival).[149] However, other data has suggested that the more commonly accepted threshold of 3 to 4 hours may provide an inflection point at which post-transplant graft failure and death begin to increase, especially when evaluating older donors.[150,151,152] Furthermore, independent of effects on survival, morbidity and lengths of stay in the hospital post-transplant appear to be increased with prolonged donor organ ischemic time.[153] Based on these data, limiting ischemic time by encouraging transplant-recipient matches less likely to result in ischemic time exceeding 4 hours would be expected to improve post-transplant outcomes and achieve the best use of donated organs.

[146] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[147] Nicoara et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors."
[148] https://www.srtr.org/reports-tools/risk-adjustment-models-posttransplant-outcomes/
[149] Russo et al. "The Effect of Ischemic Time on Survival after Heart Transplantation Varies by Donor Age: An Analysis of the United Network for Organ Distribution Database."
[150] Ford, Almond, Gauvreau, Piercey, Blume, Smoot, Fynn-Thompson, and Singh. "Association of Graft Ischemic Time with Survival after Heart Transplant among Children in the United States." *Journal of Heart and Lung Transplantation* 30, no. 11 (2011): 1244-249.
[151] Del Rizzo, Menkis, Pflugfelder, Novick, Mckenzie, Boyd, and Kostuk. "The Role of Donor Age and Ischemic Time on Survival following Orthotopic Heart Transplantation." *Journal of Heart and Lung Transplantation* 18, no. 4 (1999): 310-19.
[152] Joyce, Li, Edwards, Kobashigawa, and Daly. "Predicting 1-year Cardiac Transplantation Survival Using a Donor–recipient Risk-assessment Tool." *The Journal of Thoracic and Cardiovascular Surgery* 155, no. 4 (2018): 1580-590.
[153] Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."

Figure 9: Association between Ischemic Time (in minutes) and Heart Graft Survival, October 2018

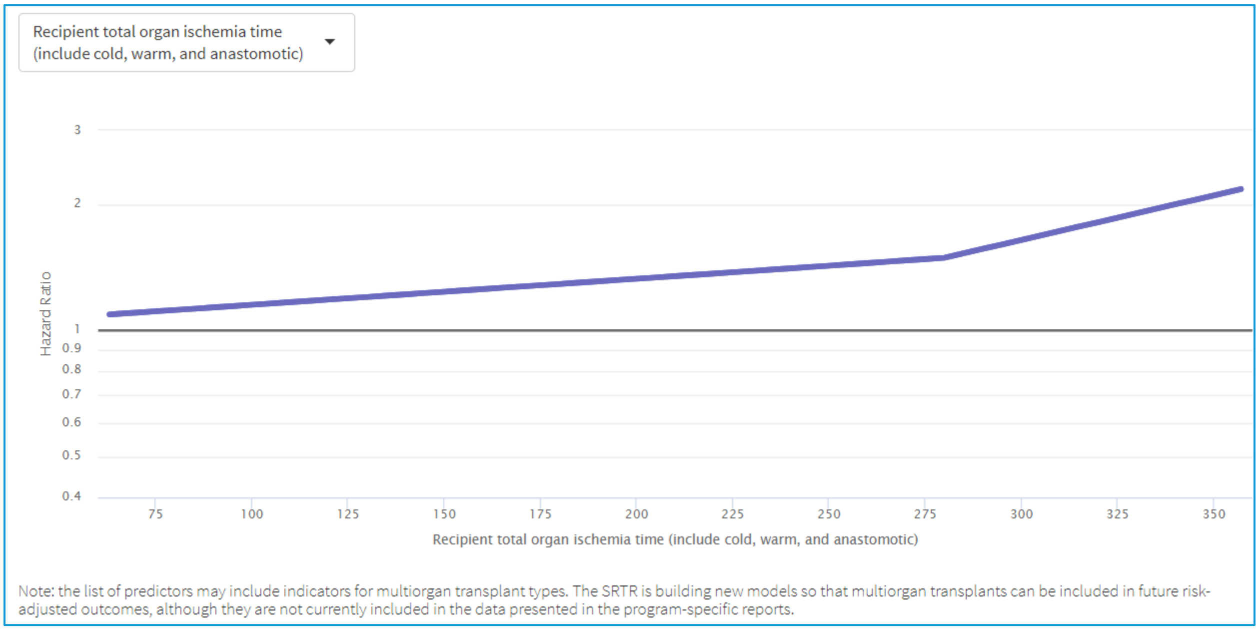
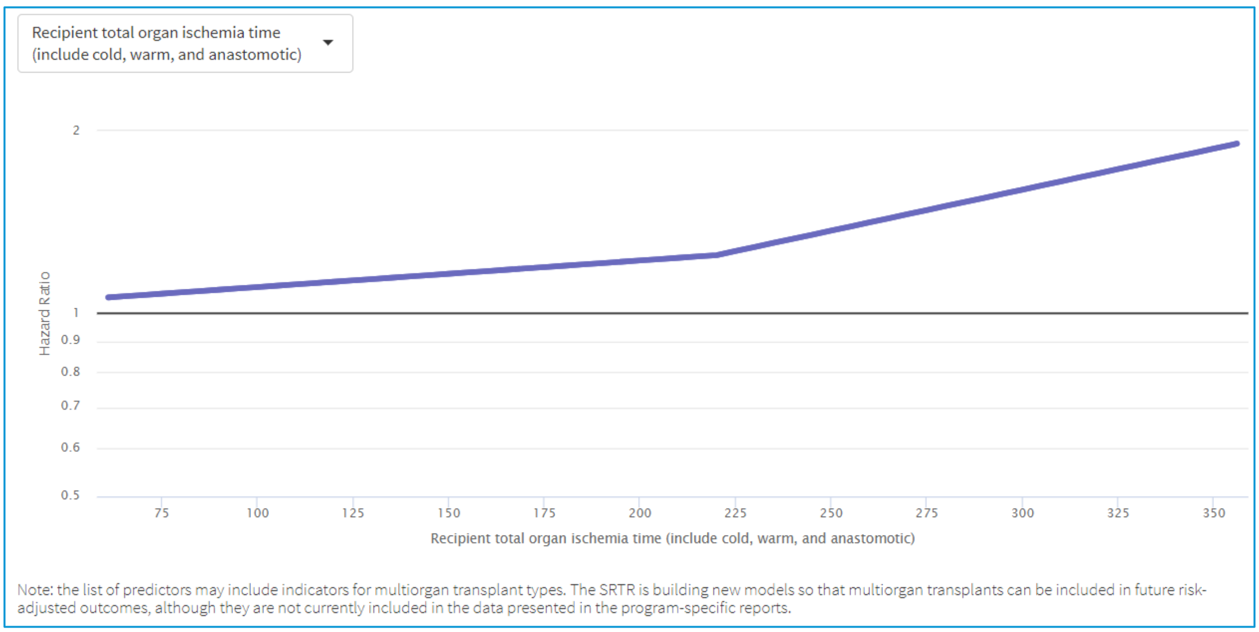


Figure 10: Association between Ischemic Time (in minutes) and Heart Patient Survival, October 2018



The Committee voiced concern that smaller centers, with smaller local donor populations, may be unable to absorb increased travel costs and loss of access may result. While the modeling provided by the SRTR did not demonstrate a systematic effect on any at-risk populations, the modeling does not account for the potential impact of costs on center viability, so can provide only limited predictive capability regarding long-term access to transplantation. Modeling did show a lower transplant rate in centers performing 25-50 heart transplants a year in the 500 NM-A and 500 NM-B simulations.[154]

[154] SRTR HR2018_01.

Another associated impact of switching from driving to flying concerns the transportation of surgical teams. The fatality rate for organ procurement air travel has been estimated at 1000 times higher than that for commercial air travel.[155] Increasing the frequency and duration of air travel may increase the risk of fatalities. Expecting surgeons and surgical teams to make a decision between their own safety and the best interests of their patients in obtaining a donor organ may be a fraught decision. While long-term changes, including the use of donor recovery centers, procurement by local surgeons, ex-vivo organ perfusion, and improved organ transportation may mitigate some of these risks, these are not yet extensively present and will not have a significant impact on surgical team transportation for many years to come.[156] Finally, by having donor recovery teams (including the transplant surgeon) traveling farther distances by air transport and therefore unavailable for longer time periods, it is likely that centers will be unable to effectively perform the same number of transplants due to surgeon unavailability.[157] This could result in loss of system organ placement efficiency and potential loss of geographically proximate donor organs appropriate for center recipients.

However, the 500 NM-A and 500 NM-B simulations did show some positive results. The transplant rate for blood type O increased on both the 500 NM simulations.[158]

In summary, the effects of using 500 NM as a unit of allocation to replace DSA include: longer median travel times, an increased need for air transportation of organs and teams, and a higher likelihood of ischemic times exceeding 4 hours. These would result in decreased system organ placement efficiency, the potential for decreased utilization of donated organs and increased organ wastage,discards, and the poorer use of the donated organs in terms of optimizing post-transplant outcomes. For these reasons, the Committee came to consensus that 500 NM (neither model A nor B) as a replacement for DSA did not represent the optimal distance meeting the requirements of the Final Rule.

150 NM vs. 250 NM

250 NM

The Committee then considered a more abbreviated distance to distribute hearts. Although one Committee member suggested modeling 300 NM (approximate 75th percentile, according to **Figure 3** found on page 18), a majority of Committee members agreed that 250 NM should be modeled (see Appendix B). This distance seeks to reduce travel time expected to have a clinically significant effect on ischemic time and organ quality.[159,160] In addition, members felt this distance would better balance distributing hearts more broadly while mitigating any negative impact to organ utilization.[161,162]

Advocates for a 250 NM radius argued that although still smaller than some DSAs, it was comparable or larger than many, and thus met the intent of distribution distributing organs more broadly.[163] It also is projected to increase the transplant rate for status 3 adult candidates.[164] Some in the heart transplant community felt that under the new allocation system, status 3 candidates may be disadvantaged relative to the old allocation system (some of these patients were status 1A).[165]

According to the TSAM modeling consulted during the development of the revised adult heart allocation system, status 1 and& 2 transplant rates were 4 to 10 times higher than status 3. Therefore, 250 NM could provide an advantage for status 3 candidates that they may have lost during the transition to the

[155]Englesbe, "The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel."
[156]Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[157]Ibid.
[158]SRTR HR2018_01.
[159]OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.
[160]42 C.F.R § 121.8(a)
[161]OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.
[162]42 C.F.R § 121.8(a)
[163]Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[164]SRTR HR2018_01.
[165]However, one of the goals of the *Modifications to the Adult Heart Allocation System* was to better stratify candidates by medical urgency (waitlist mortality).

new allocation system. Further, there was one additional efficiency argument for using 250 NM, which is that it would synchronize with the smallest allocation circle used in with the allocation system in lung transplantation. This has potential advantages from a policy perspective because of the desire to develop common policies for allocation of heart-lung blocs.[166]

Opponents of 250 NM argued that this distance would still result in an undesirable cold ischemic time to the organ and would result in increased costs as surgical teams most certainly would be relying on air travel to procure the organ. Further, in the modeling 250 NM did not result in an improvement in either waitlist or post-transplant outcomes (**Figure 5; Figure 6** found on page 20).[167] However, 250 NM also did not increase waitlist mortality.

150 NM

Finally, the Committee debated a more proximate distance to the donor hospital, such as 100 or 150 NM. Both distances were greater than the average median distance donor hearts were traveling, but places more emphasis on reducing ischemic time, cost, travel and efficiency in organ placement, all potentially valid reasons to limit distribution according to the Final Rule and Principles of Organ Distribution.[168,169] Further, Committee members approximated the average distance their programs switched from ground transport to air travel. Distances ranged from 80 NM to 120 NM. Members noted that geography and hospital/transplant program density plays a role in that decision; as does each program's individual comfort level with and desire to mitigate cold ischemic time.[170] Based on information gathered via interviews of OPO and transplant hospital employees, as conducted by the OPTN/UNOS Operations and Safety Committee members, there is evidence that across all regions, the median furthest distance traveled on the ground for transportation of a heart is no more than 100 miles.[171] Committee members agreed that at 150 NM, most programs were likely flying.[172]

However, several Committee members opposed modeling a distance shorter than 250 NM. They did not feel this distance better met the requirements set forth in the Final Rule of distributing organs as broadly as feasible, and may not be legally defensible.[173] This cohort noted that 150 NM radius is smaller than several DSAs. Others defended the recommendation, stating that of all the solid organs, hearts could justify a shorter distribution distance due to cold ischemic time's impact to outcomes.[174] After some debate between 100 and 150 NM, the Committee agreed to have SRTR model 150 NM as the shortest potential distribution unit.

In analyzing the modeling, the distinction between 150 NM and 250 NM was more nuanced, and the Committee was split as to which represented the most appropriate distance with which to replace DSA. After much debate during the November 1st meeting, an unofficial straw vote was taken in an attempt to determine where members stood, and pare down unsupported options (**Table 4**). The Chair abstained.

Table 4: Straw Poll Vote, November 1, 2018 Committee meeting

Model	Support
500 NM-A	1
500 NM-B	0
250 NM	7
150 NM	8

[166]OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[167]HR2018_01
[168]42 C.F.R § 121.8(a)
[169]OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.
[170]Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[171]See Appendix A: Operations and Safety Committee Transportation Report.
[172]Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[173]Meeting summary for July 26 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2617/20180726_thoracic_meetingsummary.pdf. (accessed December 26, 2018).
[174]Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."

As with the 500 NM system, there were no differences between the models in terms of waitlist or post-transplant outcomes.[175] Therefore, this suggested to the Committee that other considerations related to system efficiency, maximizing organ utility and avoiding organ wastage should guide committee decisions.

For 250 NM, the median distance remained similar to current allocation. However, for 150 NM, the median distance was lower. As noted above, this would have an important impact on minimizing system inefficiencies related to the use of air travel. However, in contrast to the 500 NM models, ischemic time would be unlikely to play a significant role, because between 150-250 NM, there is little correlation between distance and ischemic time and in that range a significant number of transplants continue to occur with ischemic times under 4 hours. Other outcomes were largely similar between the two distances.

The plurality of the Committee preferred the 250 NM distance primarily because it struck the most appropriate balance between equitable access and efficiency, and met the Final Rule requirement to distribute hearts as broadly as feasible. The final vote: 250 NM (10-Support, 0-Oppose, 0-Abstain); 150 NM (7-Support, 0-Oppose, 0-Abstain); 500 NM-A (0-Support, 0-Oppose, 0-Abstain); 500 NM-B (0-Support, 0-Oppose, 0-Abstain). The Committee noted that due to the close vote, it would pose the question to the community, which distance would they support during public comment.

2. Removal of the DSA as a unit of distribution in heart allocation makes current policy for sensitized heart candidates impractical

As a consequence of removing DSA from lung allocation policy, the Committee debated several options for addressing how to prioritize highly sensitized candidates.[176] Previous sensitized lung policy permitted 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. Since this provision of policy was heavily reliant on agreements between the parties in a DSA, and because the first unit of distribution for lungs now extends beyond the DSA, the policy had to be modified.[177] As the two policies were identical, the Committee now had to address the same issue with sensitized heart candidate policy.[178] The Committee considered similar options for the heart policy as it had for the lung policy:

Strike Policy

The Committee noted that removing the policy carries some risk because there would be no options for sensitized candidates. However, the Committee believes the risks are 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. The data to create an ideal policy do not currently exist in the OPTN/UNOS database, because thoracic transplant programs are not required to report unacceptable antigens to the OPTN/UNOS. The Committee expressed interest in working with the Histocompatibility Committee in the future to create an optimal policy.

Create Exception Pathway for Sensitized Candidates/Develop Guidance for HRB

The Committee quickly dismissed this option. Not only would the Committee have to define sensitization, but there is not a pathway in heart policy permitting heart review boards to grant a higher status for a candidate being sensitized alone.[179]

[175] SRTR HR2018_01.
[176] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[177] Ibid.
[178] Meeting summary for September 13, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2716/20180913_thoracic_committee_minutes.pdf. (accessed December 26, 2018).
[179] OPTN/UNOS Policy 6.4.B, *Exceptions to Allocation for Sensitized Patients*. Sensitization alone does not qualify a candidate to be assigned any status exception as described in Policy 6.4: Adult and Pediatric Status Exceptions above.

Replicate Board-Approved Sensitized Lung Candidate Policy

Although they initially proposed striking the sensitized lung candidate policy, the Committee heeded public comment feedback and adopted a modified version of the previous sensitized lung candidate policy, modeled after *Policy 8.2.A Exceptions Due to Medical Urgency* in kidney policy.[180] While it adopted the policy, the Committee still felt strongly that policies should be evidence-based.

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 NM may accomplish. Ultimately, the Committee opted to strike the policy for sensitized heart candidates for the same reasons it initially proposed striking the lung policy: predominantly that the other solutions were too cumbersome to provide any meaningful use.[181] Should public comment return similar sentiment, the Committee will mimic the approved policy language for sensitized lung candidates.

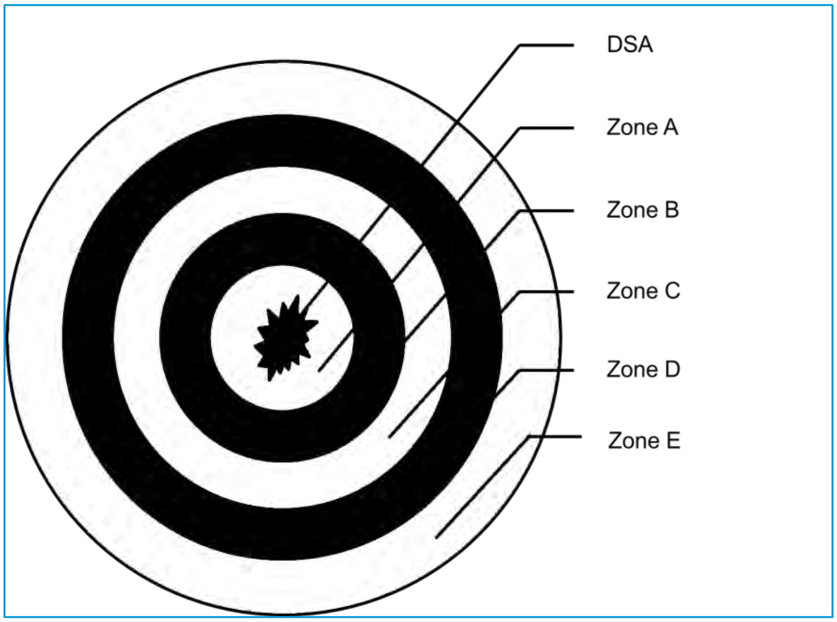
3. Terminology describing geographic units across organ-specific allocation policies is increasingly inconsistent

The Committee considered UNOS staff's recommendation to eliminate the term "zone" from OPTN/UNOS policy. As the other organ-specific committees considered what size "circles" would replace DSA and regions in their distribution systems within this framework, terminology became inconsistent between the abdominal, VCA and thoracic policies.[182,183,184] UNOS staff took time to explain the proposal to eliminate the term "zone", which is the geographic unit thoracic organ policies use. Geographic allocation depends on the location of the donor. **Figure 11** demonstrates the zonal structure for allocation of thoracic organs. The donation service area (DSA) is the starting point, and is the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals.[185] The 58 DSAs are not uniformly shaped and differ substantially in terms of land mass, area, population, and number of transplant programs.

"Zones" are not exactly equivalent to the concentric circle models being considered by the abdominal organ committees. "Zones" are exclusive of smaller geographic area immediately preceding. For hearts, Zone A includes all transplant hospitals within 500 miles of the donor hospital but outside of the donor hospital's DSA; Zone B includes all transplant hospitals within 1,000 miles of the donor hospital but outside of Zone A and the donor hospital's DSA; Zone C includes all transplant hospitals within 1,500 miles of the donor hospital but outside of Zone B and the donor hospital's DSA; Zone D includes all transplant hospitals within 2,500 miles of the donor hospital but outside of Zone C; and finally Zone E includes all transplant hospitals more than 2,500 miles from the donor hospital. In essence, this creates a distribution shape more similar to a "donut".

[180] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[181] Ibid.
[182] OPTN/UNOS Board Briefing, *Enhancing Liver Distribution*.
[183] OPTN/UNOS Board Briefing. Liver and Intestine Distribution Using Distance from Donor Hospital.
[184] Meeting summary from July 16th, 2018 meeting, OPTN/UNOS Kidney Committee.
[185] Policy 1.2 *Definitions*.

Figure 11: Visual representation of thoracic "Zone" definition[186]



As UNOS staff recommended striking the term "zone" from OPTN/UNOS policy language for consistency across organ policies, the Committee was asked if they could foresee any unintended consequences. For example, theoretically, candidates could appear in multiple classifications. However, these candidates will only be offered an organ based on the highest classification within which they could appear. Thus, the match is programmed so that a candidate would not appear in any lower classification. Committee leadership felt that this scenario may be internally transparent and understood within UNOS, but it may not be so in the greater transplant community and general public. The Chair stated that OPTN/UNOS policy should include verbiage explaining this. UNOS staff advised that language specific to this scenario is not currently in the proposed policy language for the current proposal, and this is not be unique to thoracic organs. UNOS staff advised this policy clarification could be incorporated at a future time.

Since the term "zone" will be stricken from OPTN/UNOS policy, this will impact lung allocation policy; specifically, the lung classification tables. UNOS staff explained that by striking the term "zone", the lung classification tables will also use distances rather than zones for consistency. There were also several other instances whereby OPTN/UNOS policy used the term "zone"; those will also be stricken. There were no objections from Committee members.

4. Removing DSA as a unit of distribution from OPTN/UNOS policy would result in clerical artifacts remaining in the policies

DSA will be removed from the recently revised *Policy 5.10.C Other Multi-Organ Combinations* and replaced with 250 NM.[187]

On November 29th, the Committee voted unanimously in support of the changes to the heart and associated policy language; a majority supported the changes to *Policy 10.4.C Allocation of Lungs from Deceased Donors at Least 18 years old* (replacing zones with distances); and a majority recommended the proposal go out for public comment during spring 2019 cycle.

[186] Policy 1.2 *Definitions.*
[187] OPTN/UNOS Board Briefing. Liver and Intestine Distribution Using Distance from Donor Hospital.

How well does this proposal address the problem statement?

This proposal is informed by SRTR modeling, OPTN/UNOS descriptive analyses, peer reviewed literature and, in matters of behavior, expert opinion. The solutions described herein address the aforementioned problems as described below:

1. Use of the DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule

Figure 12 on the following page shows the waitlist mortality rates by DSA and the previously discussed simulations. With broader distribution of donor organs, the number of dark-colored DSAs (those with the highest waitlist mortality rates) declined as the most urgent candidates received transplant offers within a given distance radius. This proposal replaces DSA with a 250 NM circle from the donor hospital. As previously outlined, 250 NM balances equitable access (as defined by waitlist mortality) and achieving the best use of donor organs with efficiency in organ placement.

2. Removal of the DSA as a unit of distribution in heart allocation makes current policy for sensitized heart candidates impractical

Removing the sensitized heart candidate policy removes an underutilized policy which was not grounded in evidence.

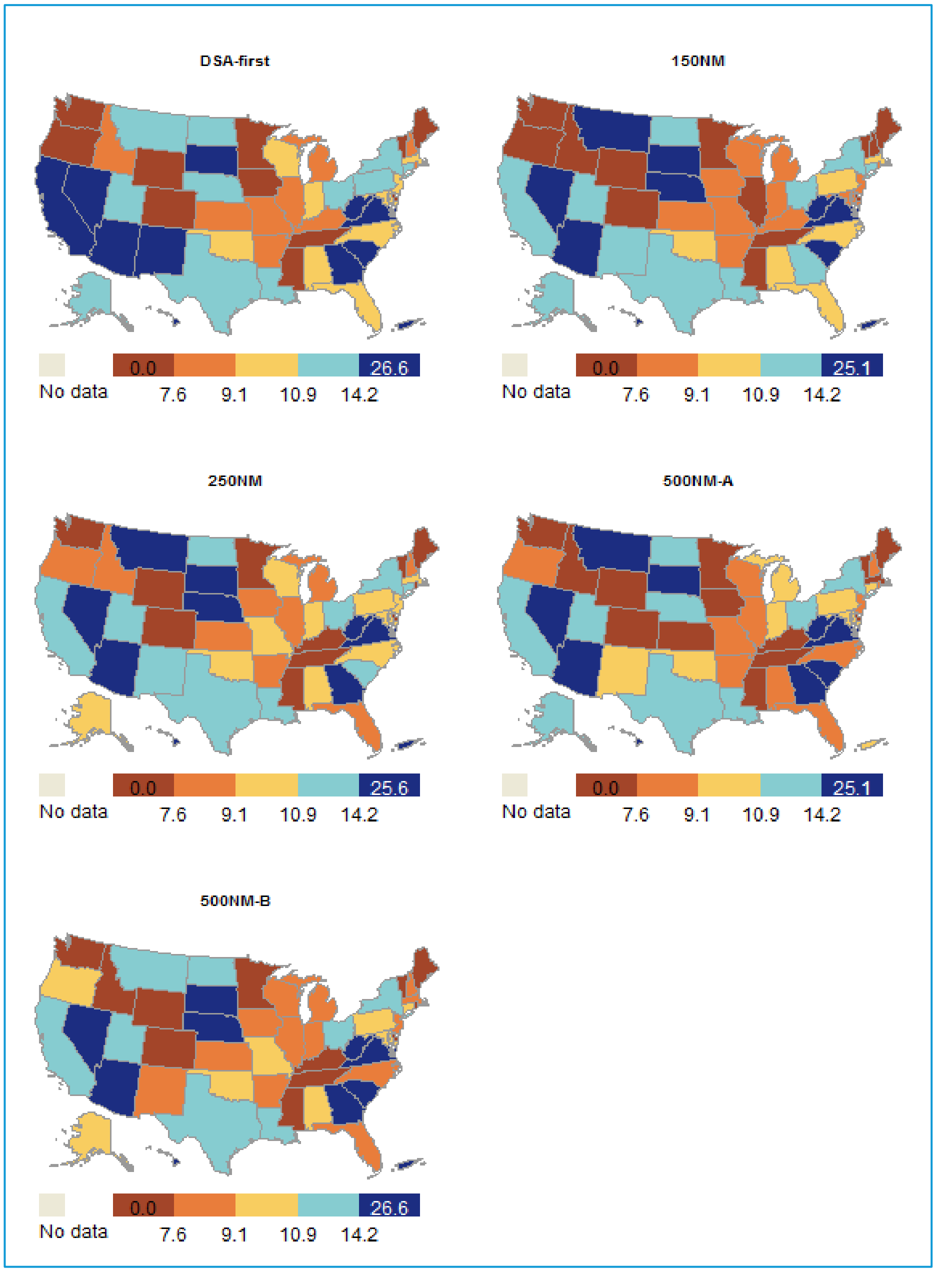
3. Terminology describing geographic units across organ-specific allocation policies in increasingly inconsistent

Removing the term “zone” from OPTN/UNOS policy and replacing with the actual distances in the allocation tables should minimize confusion, increase consistency and may make transition to a continuous distribution framework less cumbersome.

4. Removing DSA as a unit of distribution from OPTN/UNOS policy would result in clerical artifacts remaining in the policies

Addressing outstanding use of DSA elsewhere in policy will resolve inconsistencies that remain after ongoing revisions to OPTN/UNOS policy.

Figure 12: Waitlist mortality rates by DSA and simulation



Which populations are impacted by this proposal?

This proposal impacts adult and pediatric heart candidates by providing access to donors in a broader geographic area. Based on OPTN/UNOS data as of December 16, 2018, there were 3,486 adult candidates and 336 pediatric candidates on the heart waiting list.

Overall, there was no differential impact of any of the distance options considered based on gender, race/ethnicity, urbanicity, insurance status, or transplant center's location.[188]

[188] SRTR HR2018_01.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* As indicated in the SRTR modeling results, this proposal should neither significantly increase nor decrease the number of transplants.
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 hearts.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* These changes neither significantly improves nor worsens waitlist mortality or post-transplant mortality rates.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This proposal will reduce the legal risk to the OPTN/UNOS regarding the use of DSAs in the distribution of hearts, which is an important and time sensitive issue regarding the management of the OPTN/UNOS.

How will the OPTN/UNOS implement this proposal?

OPTN/UNOS IT programming changes are required and reflects the bulk of hours on this proposal. The OPTN/UNOS estimates the proposed solution to be a "Medium" size effort in terms of IT implementation. Changes will be made to the adult and pediatric heart match allocations to replace DSA with a 250 NM circle. In addition to that, classification titles in lung allocation will also be changed to remove references to "Zone". The distance in nautical miles will be referenced in lieu of "zone" for both heart and lung allocation. There will be no changes to the lung allocation itself. Updating the lung classifications is considered a clerical change for the purpose of consistency across heart and lung classification labels. There is no programming required for the proposed sensitization policy or other minor policy language changes.

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. This proposal may require instructional support. UNOS staff will continue to monitor this need throughout the development and discussion of the proposal. Instructional support for this proposal may be a part of a larger educational effort related to the elimination of DSAs and regions for the distribution of all organs.

How will members implement this proposal?

Transplant Hospitals

The changes to heart distribution may impact transplant program costs, as broader distribution may increase the number, distance, and time of additional heart fly outs. Some programs may need to hire more transplant surgeons to travel further to recover hearts from donors.

OPOs

These changes include modifications to the adult and pediatric heart allocation sequences and may impact OPO practices and costs.

Histocompatibility Laboratories

There are no anticipated impacts on histocompatibility laboratories.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

This proposal will not change the current routine monitoring of members. OPTN/UNOS contractor 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/UNOS policy, and staff 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?

The OPTN/UNOS Thoracic Committee will continue to monitor Adult Heart Allocation changes implemented on October 18, 2018 as outlined and scheduled in the corresponding briefing paper. In addition to those metrics, the Committee will monitor additional metrics as they relate to the proposed geographic changes regarding the removal of DSA from heart allocation. This includes, but is not limited to:

- The number/% of transplants stratified by distance (NM) between donor hospital and transplant center
- Unadjusted post-transplant patient survival stratified by distance (NM) between donor hospital and transplant center
- Volume of transplants by de-identified heart transplant centers
- Distribution of the distance (NM) between donor hospital and transplant center, including range, IQR, mean, and median
- Number and percent of transplants by geographic classification (local, regional, national) and distance (NM) between donor hospital and transplant center
- Distribution of ischemic time (hours) for heart transplants, including range, IQR, mean, and median

These reports will be presented to the Thoracic Committee as appropriate post implementation at 3-months, 6-months, and annually thereafter for two years.

Policy or Bylaws Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~).

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Policy 1: Administrative Rules and Definitions

1.2 Definitions

~~**Zone**~~

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

~~The allocation of 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~~.

5.10 Allocation of Multi-Organ Combinations

5.10.C Other Multi-Organ Combinations

When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to *Table 5-4* below:

Table 5-4: Allocation of Multi-Organ Combinations

Organ	Candidate is registered within the following geographical area:
Heart	~~Same DSA as~~ <u>250 nautical miles from</u> the donor hospital
Liver	150 nautical miles from the donor hospital
Lung	250 nautical miles from the donor hospital

If the multi-organ candidate is on a waiting list outside the geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

6.4.A. RRB and Committee Review of Status Exceptions

6.4.A.ii Committee Appeals

If the RRB denies the appeal, the candidate's transplant program must within 1 day of receiving notification of the denied ~~Zone~~ appeal either appeal to the Thoracic Organ Transplantation Committee or assign the candidate to the status for which the candidate qualifies. If the Thoracic Committee agrees with the RRB's decision, the candidate's transplant program must assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If the transplant program does not assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal, then the Committee will refer the case to the MPSC.

6.6.A Allocation of Hearts by Blood Type

Within each ~~heart status and geographical zone~~ classification, hearts are first allocated to primary blood type candidates then to secondary blood type candidates according to the blood type matching requirements in *Table 6-4* below.

Table 6-4: Blood Type Matching Prioritization for Heart Allocation

Hearts from Deceased Donors with:	Are Allocated to Primary Candidates defined as:	Then to Secondary Candidates, defined as:
Blood Type O	**Blood type O or blood type B**	**Blood type A or blood type AB**
Blood Type A	**Blood type A or blood type AB**	**Not applicable**
Blood Type B	**Blood type B or blood type AB**	**Not applicable**
Blood Type AB	**Blood type AB**	**Not applicable**

Pediatric candidates that are less than one year old at the time of the match run, including candidates eligible to receive a heart from an intended blood group incompatible deceased donor, will be classified as a primary blood type match candidate.

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from an intended blood group incompatible deceased donor will be classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to *Table 6-4*.

6.4.B Exceptions to Allocation for Sensitized Patients

~~An OPO may allocate a heart to sensitized candidates within a DSA out of sequence within a status as defined in *Policy 6.6: Heart Allocation Classifications and Rankings* if *all* of the following are true:~~

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

~~The sensitized candidate can only be prioritized ahead of candidates with the same status and within the same DSA. Sensitization alone does not qualify a candidate to be assigned any status exception as described in *Policy 6.4: Adult and Pediatric Status Exceptions* above.~~

6.6.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-7* below.

Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
1	Adult status 1 or pediatric status 1A and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
2	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
3	Adult status 2 and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
4	Adult status 2 and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
5	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~OPO's DSA~~ 250NM
6	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
7	Adult status 1 or pediatric status 1A and primary blood type match with the donor	~~Zone B~~ 1000NM
8	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	~~Zone B~~ 1000NM
9	Adult status 2 and primary blood type match with the donor	~~Zone B~~ 1000NM
10	Adult status 2 and secondary blood type match with the donor	~~Zone B~~ 1000NM
11	Adult status 4 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
12	Adult status 4 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
13	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~Zone A~~ 500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
14	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~Zone A~~ 500NM
15	Adult status 5 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
16	Adult status 5 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
17	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~Zone B~~ 1000NM
18	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~Zone B~~ 1000NM
19	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
20	Adult status 6 and pediatric status 2 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
21	Adult status 1 or pediatric status 1A and primary blood type match with the donor	~~Zone C~~ 1500NM
22	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	~~Zone C~~ 1500NM
23	Adult status 2 and primary blood type match with the donor	~~Zone C~~ 1500NM
24	Adult status 2 and secondary blood type match with the donor	~~Zone C~~ 1500NM
25	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~Zone C~~ 1500NM
26	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~Zone C~~ 1500NM
27	Adult status 4 and primary blood type match with the donor	~~Zone A~~ 500NM
28	Adult status 4 and secondary blood type match with the donor	~~Zone A~~ 500NM
29	Adult status 5 and primary blood type match with the donor	~~Zone A~~ 500NM
30	Adult status 5 and secondary blood type match with the donor	~~Zone A~~ 500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
31	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~Zone A~~ 500NM
32	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	~~Zone A~~ 500NM
33	Adult status 1 or pediatric status 1A and primary blood type match with the donor	~~Zone D~~ 2500NM
34	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	~~Zone D~~ 2500NM
35	Adult status 2 and primary blood type match with the donor	~~Zone D~~ 2500NM
36	Adult status 2 and secondary blood type match with the donor	~~Zone D~~ 2500NM
37	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~Zone D~~ 2500NM
38	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~Zone D~~ 2500NM
39	Adult status 4 and primary blood type match with the donor	~~Zone B~~ 1000NM
40	Adult status 4 and secondary blood type match with the donor	~~Zone B~~ 1000NM
41	Adult status 5 and primary blood type match with the donor	~~Zone B~~ 1000NM
42	Adult status 5 and secondary blood type match with the donor	~~Zone B~~ 1000NM
43	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~Zone B~~ 1000NM
44	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	~~Zone B~~ 1000NM
45	Adult status 1 or pediatric status 1A and primary blood type match with the donor	~~Zone E~~ Nation
46	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	~~Zone E~~ Nation
47	Adult status 2 and primary blood type match with the donor	~~Zone E~~ Nation

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
48	Adult status 2 and secondary blood type match with the donor	~~Zone E~~ Nation
49	Adult status 3 or pediatric status 1B and primary blood type match with the donor	~~Zone E~~ Nation
50	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	~~Zone E~~ Nation
51	Adult status 4 and primary blood type match with the donor	~~Zone C~~ 1500NM
52	Adult status 4 and secondary blood type match with the donor	~~Zone C~~ 1500NM
53	Adult status 5 and primary blood type match with the donor	~~Zone C~~ 1500NM
54	Adult status 5 and secondary blood type match with the donor	~~Zone C~~ 1500NM
55	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~Zone C~~ 1500NM
56	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	~~Zone C~~ 1500NM
57	Adult status 4 and primary blood type match with the donor	~~Zone D~~ 2500NM
58	Adult status 4 and secondary blood type match with the donor	~~Zone D~~ 2500NM
59	Adult status 5 and primary blood type match with the donor	~~Zone D~~ 2500NM
60	Adult status 5 and secondary blood type match with the donor	~~Zone D~~ 2500NM
61	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~Zone D~~ 2500NM
62	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	~~Zone D~~ 2500NM
63	Adult status 4 and primary blood type match with the donor	~~Zone E~~ Nation
64	Adult status 4 and secondary blood type match with the donor	~~Zone E~~ Nation
65	Adult status 5 and primary blood type match with the donor	~~Zone E~~ Nation
66	Adult status 5 and secondary blood type match with the donor	~~Zone E~~ Nation

Classification	Candidates that are ~~within the~~	And ~~are:~~ **registered at a transplant hospital that is within this distance from the donor hospital**
67	Adult status 6 or pediatric status 2 and primary blood type match with the donor	~~Zone E~~ Nation
68	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	~~Zone E~~ Nation

6.6.E Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-8* below.

Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are ~~within the~~	And ~~are:~~ **registered at a transplant hospital that is within this distance from the donor hospital**
1	Pediatric status 1A and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
2	Pediatric status 1A and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
3	Adult status 1 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
4	Adult status 1 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
5	Adult status 2 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
6	Adult status 2 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
7	Pediatric status 1B and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
8	Pediatric status 1B and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
9	Adult status 1 and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
10	Adult status 1 and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
11	Adult status 2 and primary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM
12	Adult status 2 and secondary blood type match with the donor	~~OPO's DSA or Zone A~~ 500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ <u>registered at a transplant hospital that is within this distance from the donor hospital</u>
13	Adult status 3 and primary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
14	Adult status 3 and secondary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
15	Adult status 4 and primary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
16	Adult status 4 and secondary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
17	Adult status 5 and primary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
18	Adult status 5 and secondary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
19	Adult status 3 and primary blood type match with the donor	~~Zone A~~ <u>500NM</u>
20	Adult status 3 and secondary blood type match with the donor	~~Zone A~~ <u>500NM</u>
21	Adult status 4 and primary blood type match with the donor	~~Zone A~~ <u>500NM</u>
22	Adult status 4 and secondary blood type match with the donor	~~Zone A~~ <u>500NM</u>
23	Adult status 5 and primary blood type match with the donor	~~Zone A~~ <u>500NM</u>
24	Adult Status 5 and secondary blood type match with the donor	~~Zone A~~ <u>500NM</u>
25	Pediatric status 2 and primary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
26	Pediatric status 2 and secondary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
27	Adult status 6 and primary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
28	Adult status 6 and secondary blood type match with the donor	~~OPO's DSA~~ <u>250NM</u>
29	Pediatric status 1A and primary blood type match with the donor	~~Zone B~~ <u>1000NM</u>
30	Pediatric status 1A and secondary blood type match with the donor	~~Zone B~~ <u>1000NM</u>
31	Adult status 1 and primary blood type match with the donor	~~Zone B~~ <u>1000NM</u>

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
32	Adult status 1 and secondary blood type match with the donor	~~Zone B~~ 1000NM
33	Adult status 2 and primary blood type match with the donor	~~Zone B~~ 1000NM
34	Adult status 2 and secondary blood type match with the donor	~~Zone B~~ 1000NM
35	Pediatric status 1B and primary blood type match with the donor	~~Zone B~~ 1000NM
36	Pediatric status 1B and secondary blood type match with the donor	~~Zone B~~ 1000NM
37	Adult status 3 and primary blood type match with the donor	~~Zone B~~ 1000NM
38	Adult status 3 and secondary blood type match with the donor	~~Zone B~~ 1000NM
39	Adult status 4 and primary blood type match with the donor	~~Zone B~~ 1000NM
40	Adult status 4 and secondary blood type match with the donor	~~Zone B~~ 1000NM
41	Adult status 5 and primary blood type match with the donor	~~Zone B~~ 1000NM
42	Adult status 5 and secondary blood type match with the donor	~~Zone B~~ 1000NM
43	Pediatric status 2 and primary blood type match with the donor	~~Zone A~~ 500NM
44	Pediatric status 2 and secondary blood type match with the donor	~~Zone A~~ 500NM
45	Adult status 6 and primary blood type match with the donor	~~Zone A~~ 500NM
46	Adult status 6 and secondary blood type match with the donor	~~Zone A~~ 500NM
47	Pediatric status 2 and primary blood type match with the donor	~~Zone B~~ 1000NM
48	Pediatric status 2 and secondary blood type match with the donor	~~Zone B~~ 1000NM
49	Adult status 6 and primary blood type match with the donor	~~Zone B~~ 1000NM
50	Adult status 6 and secondary blood type match with the donor	~~Zone B~~ 1000NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ <u>registered at a transplant hospital that is within this distance from the donor hospital</u>
51	Pediatric status 1A and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
52	Pediatric status 1A and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
53	Adult status 1 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
54	Adult status 1 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
55	Adult status 2 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
56	Adult status 2 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
57	Pediatric status 1B and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
58	Pediatric status 1B and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
59	Adult status 3 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
60	Adult status 3 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
61	Adult status 4 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
62	Adult status 4 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
63	Adult status 5 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
64	Adult status 5 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
65	Pediatric status 2 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
66	Pediatric status 2 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
67	Adult status 6 and primary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
68	Adult status 6 and secondary blood type match with the donor	~~Zone C~~ <u>1500NM</u>
69	Pediatric status 1A and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
70	Pediatric status 1A and secondary blood type match with the donor	~~Zone D~~ 2500NM
71	Adult status 1 and primary blood type match with the donor	~~Zone D~~ 2500NM
72	Adult status 1 and secondary blood type match with the donor	~~Zone D~~ 2500NM
73	Adult status 2 and primary blood type match with the donor	~~Zone D~~ 2500NM
74	Adult status 2 and secondary blood type match with the donor	~~Zone D~~ 2500NM
75	Pediatric status 1B and primary blood type match with the donor	~~Zone D~~ 2500NM
76	Pediatric status 1B and secondary blood type match with the donor	~~Zone D~~ 2500NM
77	Adult status 3 and primary blood type match with the donor	~~Zone D~~ 2500NM
78	Adult status 3 and secondary blood type match with the donor	~~Zone D~~ 2500NM
79	Adult status 4 and primary blood type match with the donor	~~Zone D~~ 2500NM
80	Adult status 4 and secondary blood type match with the donor	~~Zone D~~ 2500NM
81	Adult status 5 and primary blood type match with the donor	~~Zone D~~ 2500NM
82	Adult status 5 and secondary blood type match with the donor	~~Zone D~~ 2500NM
83	Pediatric status 2 and primary blood type match with the donor	~~Zone D~~ 2500NM
84	Pediatric status 2 and secondary blood type match with the donor	~~Zone D~~ 2500NM
85	Adult status 6 and primary blood type match with the donor	~~Zone D~~ 2500NM
86	Adult status 6 and secondary blood type match with the donor	~~Zone D~~ 2500NM
87	Pediatric status 1A and primary blood type match with the donor	~~Zone E~~ Nation
88	Pediatric status 1A and secondary blood type match with the donor	~~Zone E~~ Nation

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
89	Adult status 1 and primary blood type match with the donor	~~Zone E~~ Nation
90	Adult status 1 and secondary blood type match with the donor	~~Zone E~~ Nation
91	Adult status 2 and primary blood type match with the donor	~~Zone E~~ Nation
92	Adult status 2 and secondary blood type match with the donor	~~Zone E~~ Nation
93	Pediatric status 1B and primary blood type match with the donor	~~Zone E~~ Nation
94	Pediatric status 1B and secondary blood type match with the donor	~~Zone E~~ Nation
95	Adult status 3 and primary blood type match with the donor	~~Zone E~~ Nation
96	Adult status 3 and secondary blood type match with the donor	~~Zone E~~ Nation
97	Adult status 4 and primary blood type match with the donor	~~Zone E~~ Nation
98	Adult status 4 and secondary blood type match with the donor	~~Zone E~~ Nation
99	Adult status 5 and primary blood type match with the donor	~~Zone E~~ Nation
100	Adult status 5 and secondary blood type match with the donor	~~Zone E~~ Nation
101	Pediatric status 2 and primary blood type match with the donor	~~Zone E~~ Nation
102	Pediatric status 2 and secondary blood type match with the donor	~~Zone E~~ Nation
103	Adult status 6 and primary blood type match with the donor	~~Zone E~~ Nation
104	Adult status 6 and secondary blood type match with the donor	~~Zone E~~ Nation

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 ~~within the~~**	**And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital**
1	At least 12 years old, blood type identical to the donor	~~Zone A~~ 250NM
2	At least 12 years old, blood type compatible with the donor	~~Zone A~~ 250NM
3	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	~~Zone A~~ 250NM
4	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	~~Zone A~~ 250NM
5	Priority 2, blood type identical to the donor	~~Zone A~~ 250NM
6	Priority 2, blood type compatible with the donor	~~Zone A~~ 250NM
7	At least 12 years old, blood type identical to the donor	~~Zone B~~ 500NM
8	At least 12 years old, blood type compatible with the donor	~~Zone B~~ 500NM
9	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	~~Zone B~~ 500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
10	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	~~Zone B~~ 500NM
11	Priority 2, blood type identical to the donor	~~Zone B~~ 500NM
12	Priority 2, blood type compatible with the donor	~~Zone B~~ 500NM
13	At least 12 years old, blood type identical to the donor	~~Zone C~~ 1000NM
14	At least 12 years old, blood type compatible with the donor	~~Zone C~~ 1000NM
15	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	~~Zone C~~ 1000NM
16	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	~~Zone C~~ 1000NM
17	Priority 2, blood type identical to the donor	~~Zone C~~ 1000NM
18	Priority 2, blood type compatible with the donor	~~Zone C~~ 1000NM
19	At least 12 years old, blood type identical to the donor	~~Zone D~~ 1500NM
20	At least 12 years old, blood type compatible with the donor	~~Zone D~~ 1500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
21	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	~~Zone D~~ 1500NM
22	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	~~Zone D~~ 1500NM
23	Priority 2, blood type identical to the donor	~~Zone D~~ 1500NM
24	Priority 2, blood type compatible with the donor	~~Zone D~~ 1500NM
25	At least 12 years old, blood type identical to the donor	~~Zone E~~ 2500NM
26	At least 12 years old, blood type compatible with the donor	~~Zone E~~ 2500NM
27	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	~~Zone E~~ 2500NM
28	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	~~Zone E~~ 2500NM
29	Priority 2, blood type identical to the donor	~~Zone E~~ 2500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
30	Priority 2, blood type compatible with the donor	~~Zone E~~ 2500NM
31	At least 12 years old, blood type identical to the donor	~~Zone F~~ Nation
32	At least 12 years old, blood type compatible with the donor	~~Zone F~~ Nation
33	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	~~Zone F~~ Nation
34	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	~~Zone F~~ Nation
35	Priority 2, blood type identical to the donor	~~Zone F~~ Nation
36	Priority 2, blood type compatible with the donor	~~Zone F~~ Nation

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.

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

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
1	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	~~Zone A, Zone B, or Zone C~~ 1000NM
2	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	~~Zone A, Zone B, or Zone C~~ 1000NM
3	Priority 2, blood type identical to the donor	~~Zone A, Zone B, or Zone C~~ 1000NM
4	Priority 2, blood type compatible with the donor	~~Zone A, Zone B, or Zone C~~ 1000NM
5	12 to less than 18 years old, blood type identical to the donor	~~Zone A, Zone B, or Zone C~~ 1000NM
6	12 to less than 18 years old, blood type compatible with the donor	~~Zone A, Zone B, or Zone C~~ 1000NM
7	At least 18 years old, blood type identical to the donor	~~Zone A~~ 250NM
8	At least 18 years old, blood type compatible with the donor	~~Zone A~~ 250NM
9	At least 18 years old, blood type identical to the donor	~~Zone B~~ 500NM
10	At least 18 years old, blood type compatible with the donor	~~Zone B~~ 500NM
11	At least 18 years old, blood type identical to the donor	~~Zone C~~ 1000NM
12	At least 18 years old, blood type compatible with the donor	~~Zone C~~ 1000NM
13	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	~~Zone D~~ 1500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
14	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	~~Zone D~~ 1500NM
15	Priority 2, blood type identical to the donor	~~Zone D~~ 1500NM
16	Priority 2, blood type compatible with the donor	~~Zone D~~ 1500NM
17	12 to less than 18 years old, blood type identical to the donor	~~Zone D~~ 1500NM
18	12 to less than 18 years old, blood type compatible with the donor	~~Zone D~~ 1500NM
19	At least 18 years old, blood type identical to the donor	~~Zone D~~ 1500NM
20	At least 18 years old, blood type compatible with the donor	~~Zone D~~ 1500NM
21	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	~~Zone E~~ 2500NM
22	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	~~Zone E~~ 2500NM
23	Priority 2, blood type identical to the donor	~~Zone E~~ 2500NM
24	Priority 2, blood type compatible with the donor	~~Zone E~~ 2500NM
25	12 to less than 18 years old, blood type identical to the donor	~~Zone E~~ 2500NM
26	12 to less than 18 years old, blood type compatible with the donor	~~Zone E~~ 2500NM
27	At least 18 years old, blood type identical to the donor	~~Zone E~~ 2500NM
28	At least 18 years old, blood type compatible with the donor	~~Zone E~~ 2500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
29	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	~~Zone F~~ Nation
30	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	~~Zone F~~ Nation
31	Priority 2, blood type identical to the donor	~~Zone F~~ Nation
32	Priority 2, blood type compatible with the donor	~~Zone F~~ Nation
33	12 to less than 18 years old, blood type identical to the donor	~~Zone F~~ Nation
34	12 to less than 18 years old, blood type compatible with the donor	~~Zone F~~ Nation
35	At least 18 years old, blood type identical to the donor	~~Zone F~~ Nation
36	At least 18 years old, blood type compatible with the donor	~~Zone F~~ Nation

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Appendix A: OPTN/UNOS Operations and Safety Committee Transportation Report

Introduction:

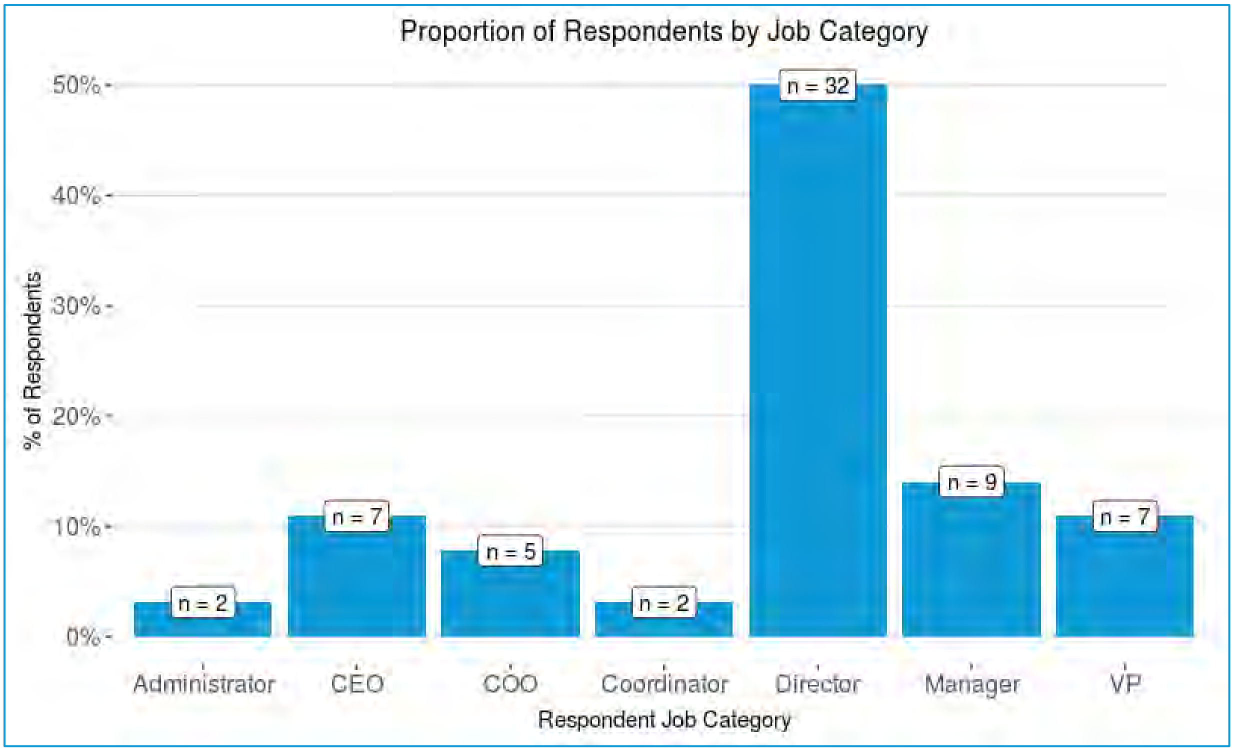
The OPTN/UNOS Operations and Safety Committee developed a questionnaire intended to assist the Ad Hoc Geography Committee and Organ-specific committees in their efforts to comply with the Department of Health and Human Services (HHS) directive[189] to eliminate DSA and Region as units of organ allocation. A major focus of the discussions regarding broader distribution is the likely increase in air travel that would be required if organs and surgical teams are travelling beyond "drivable" distances. To that end, our committee created a series of questions that focused on the operational aspects of broader distribution with a focus on ground and air travel logistics. Members of the committee then reached out to leadership in all 58 OPOs to determine the best individual(s) to answer the questions. For those OPOs that did not handle transportation for organ recovery, individual transplant centers were contacted to complete the questionnaire. The questionnaires were completed via a direct phone call with leadership of the OPO/Transplant Centers which allowed for both quantitative and qualitative data gathering. Once the questionnaires were completed, some of the questions were deemed "uninformative" by the committee and are not included in this document. Only those questions that the committee felt might be informative are included and focus on the issues that were included in the public comment proposal and some of the criteria used for SRTR modeling of allocation options (i.e. setting transition from driving to flying for liver at 200NM). The full questionnaire is included in the appendix. Answers were analyzed nationally and by region as it was determined that significant regional variations in the answers to the questions was revealed.

Rationale for Study Questions:

1. Driving distance questions were included to determine the current state for decision making between when organ/team travel exceeded driving times/distances
2. Questions regarding requirements for teams vs organs flown were meant to determine if more local recovery efforts might influence needs for aircraft/pilots
3. Questions related to ability to find pilots/planes were included to determine if increasing the need for flying might delay donor recovery procedures thus increasing pre-donation hospital stays and/or increasing cold time in the event that delivery of organs is delayed due to pilot/plane availability

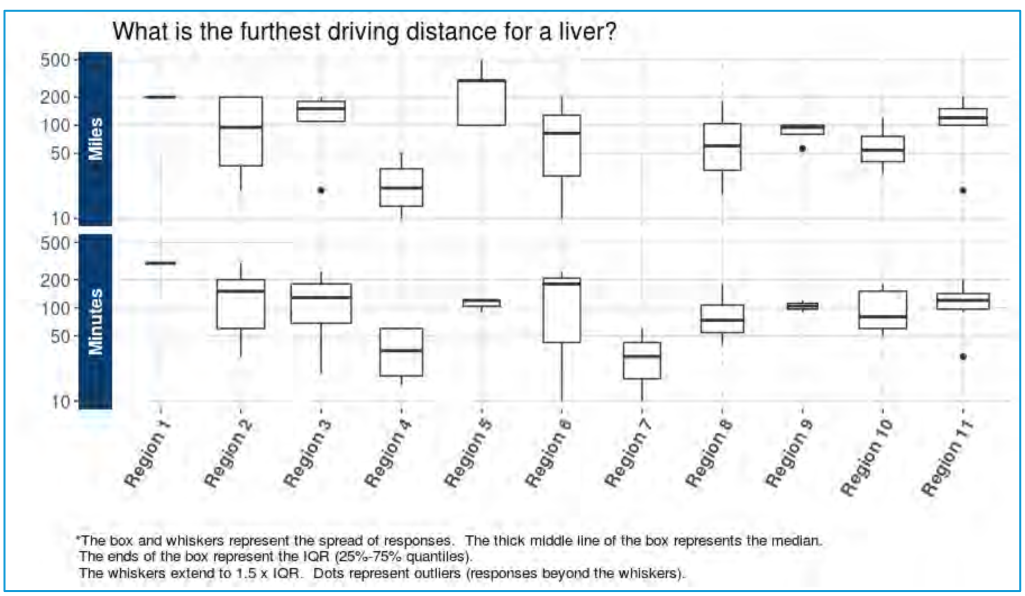
Contacts: Operations and Safety Committee members were able to complete questionnaires from 54 of the 58 OPOs and 10 transplant hospitals (where the transplant hospitals managed donor recovery transportation). The job roles of the respondents are depicted below:

[189]https://transplantpro.org/wp-content/uploads/sites/3/OPTN_letter_6.8.2018.pdf



Results:

Transition from driving to flying: Two hundred nautical miles was selected as the distance for modeling transition from driving to flying for liver allocation modeling. The graphic below supports the utilization of this distance.



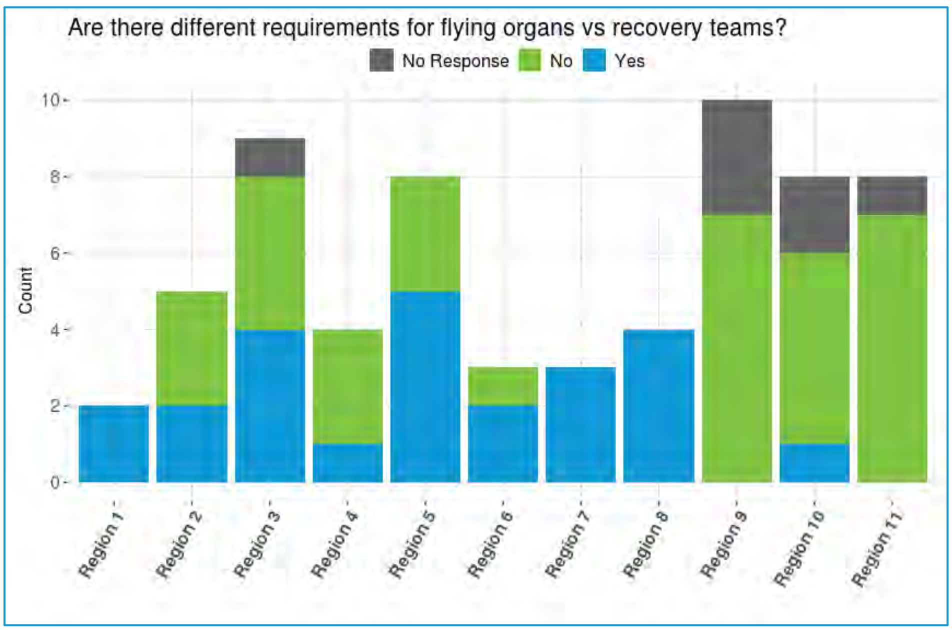
Selected comments from respondents:

- *“Highly dependent upon traffic conditions”*
- *Often determined by “time of day”*
- *“Weather and surgeon preference drive this cut-off”*
- *“More a time factor than mileage”*
- *“Nothing defined in policy….case by case basis”*
- *“Varies with organ”*

Equipment requirements for flying teams vs organs: The graphics below depict the number/percentage of respondents who indicated a difference between requirements for airplane type and pilot staffing between flying surgical teams vs organs. Nearly 40% (37.5%) of respondents indicated a difference. The answers differed by region.

Table 1. Are there different requirements for flying organs vs recovery teams?

	N	Percent
No	33	51.6%
Yes	24	37.5%
No Response	7	10.9%



Selected comments from respondents:

- *“Double pilots for people only, not organs”*
- *“Jets must have 2 pilots”*
- *“Always have 2 pilots when people on board, permit single pilot when only flying organs”*
- *“Prop is used to fly staff to cases. Jet is used for organs/surgeons”*
- *“Always 2 pilots and always a jet”*
- *“Single pilot for organs – always double pilots for moving people”*

Availability of Planes/Pilots: The availability of planes/pilots is depicted below. There are differences if recovery teams vs organs are flying and indicate that at times, planes may be available and pilots are not, and vice versa.

Table 2. Are you ever unable to find a plane/pilot for recovery team/organ?

Are you ever unable to find	No	Yes	No Response
Pilot for recovery team?	40 (56.3%)	24 (33.8%)	7 (9.9%)
Pilot for organ?	47 (66.2%)	15 (21.1%)	9 (12.7%)
Plane for recovery team?	40 (56.3%)	25 (35.2%)	6 (8.5%)
Plane for organ?	48 (67.6%)	17 (23.9%)	6 (8.5%)

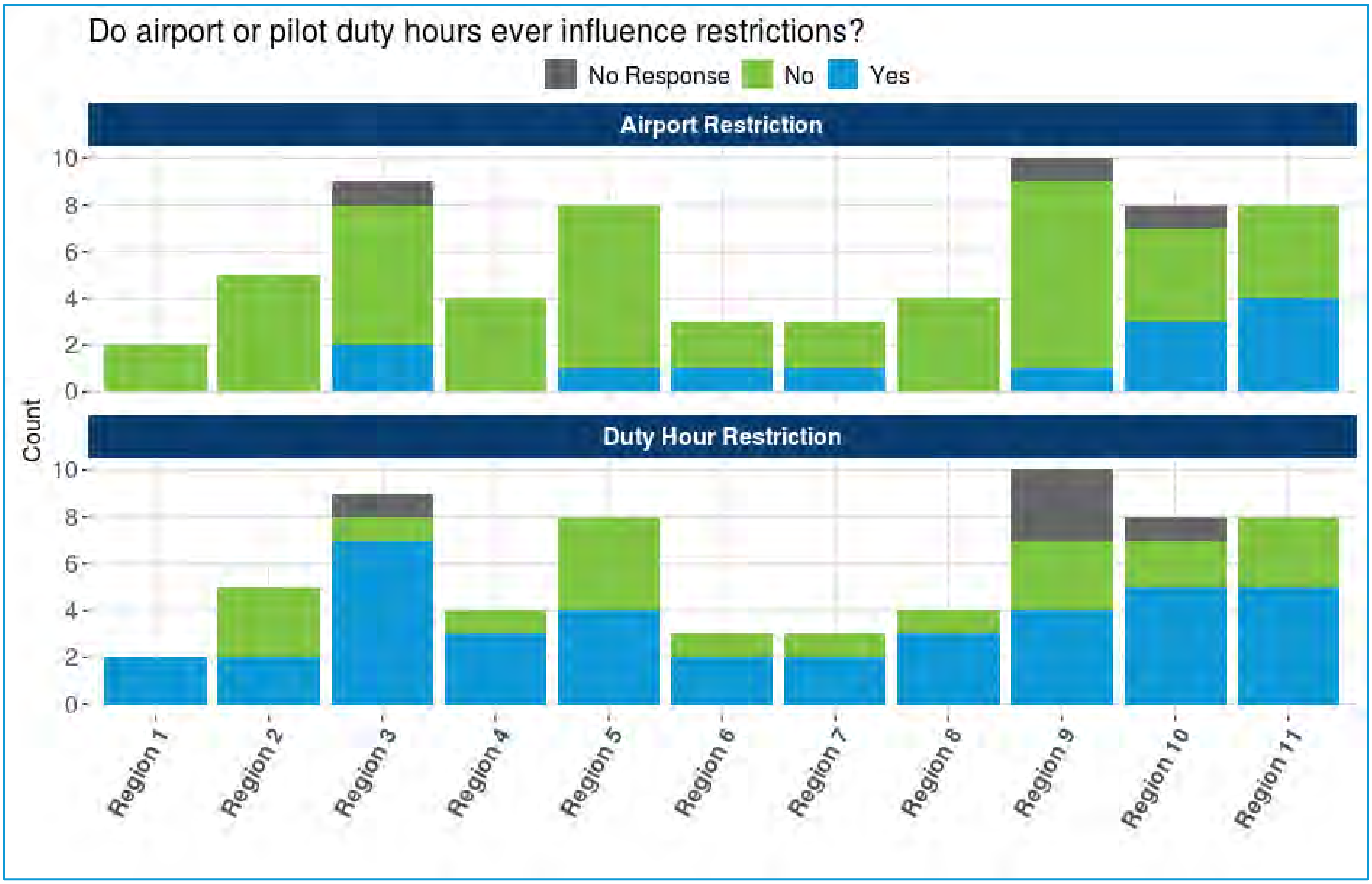
Selected comments from respondents:

- *“Rare, but charter company is expanding their fleet”*
- *“No planes/pilots are available on rare occasions”*
- *“Weather is always a factor. Large events in the state decrease the availability”*
- *“Always been able to find a plane but sometimes this causes delays”*
- *“Primarily during case reallocation with intra-op decline and time sensitive acceptance; several cases this year, at least one case this year when secondary charter choice at extreme expense for surgical team”*
- *”On rare occasions when a hospital plane not available, will charter”*
- *“Planes are ultimately located but there have been delays”*
- *“There has not been a time when we absolutely could not find a plane or team, but we have had delays”*
- *“Not unusual to delay OR for teams having trouble finding flight”*

Pilot duty hour restrictions: Pilot duty hour limitations are an additional variable that influences ability to fly organs/teams. OR delays could lead to need for additional teams to fly out to donor airports in the event that pilots time out.

Table 3. Do airport or pilot duty hour restrictions ever influence recovery?

	No	Yes	No Response
Airport restrictions	53 (74.6%)	14 (19.7%)	4 (5.6%)
Pilot duty hour restrictions	23 (32.4%)	42 (59.2%)	6 (8.5%)

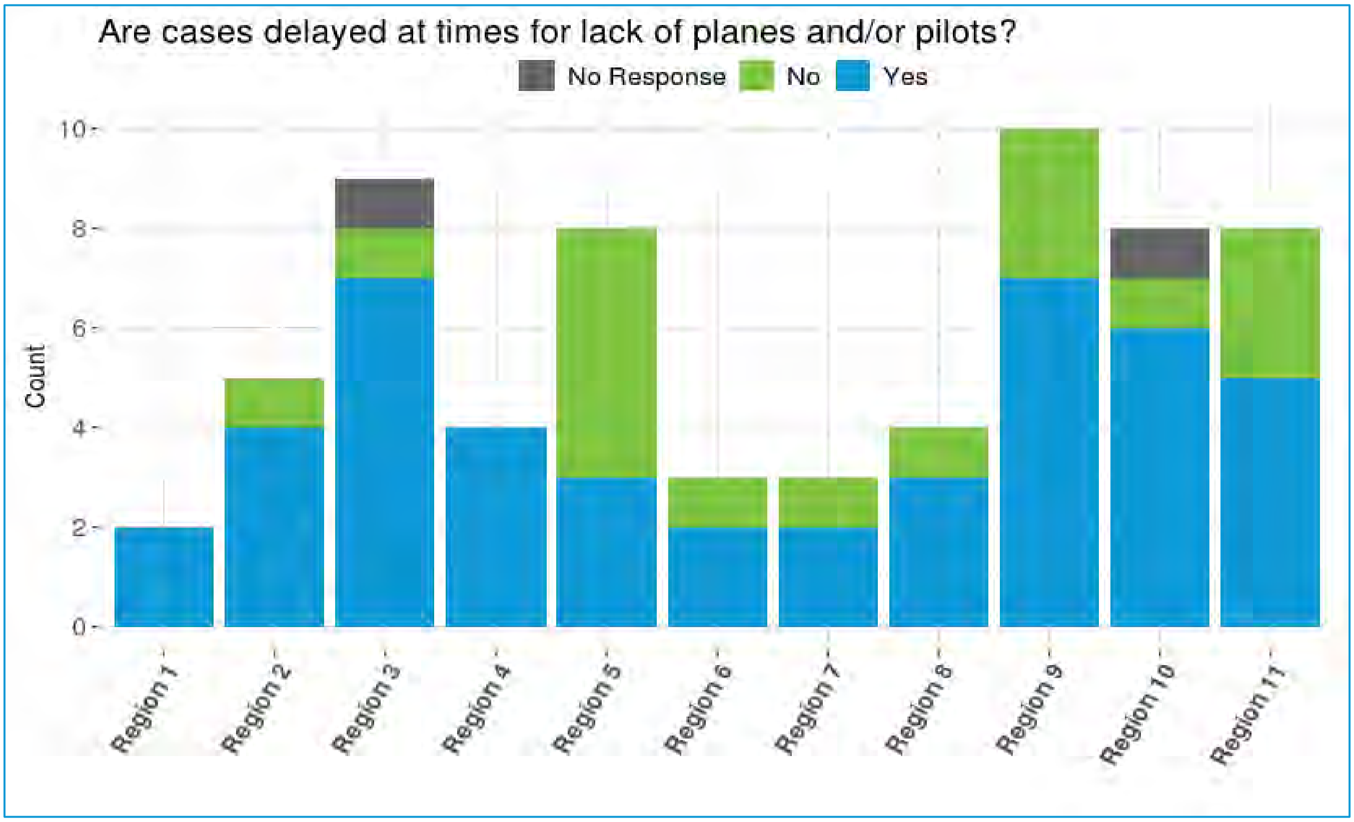


Selected comments from respondents:

- *"Pilot will "time out" if put on standby too soon or on the ground during organ recovery"*
- *Problems "due to pilot time restrictions"*
- *"…unable to distinguish source of unavailability (plane or pilot); may be pilot availability as rate limiting…pilot time out while on site has been an close call this year several times"*
- *"Sometimes need to delay the flight due to duty hours restrictions (relatively rare) or swap crews during procurement if duty hours are going to run out."*
- *"….pilots have timed out when flying very far - to the coasts to import organs…"*
- *"have had pilot time-out but not unable to find one"*
- *"pilots time out and sometimes needs another crew and one may not always be available"*
- *"Due to time out schedules of pilots, i.e. one pilot may time out in 2 hours, but the next pilot is not available for 5 hours"*
- *"…pilot timed out while waiting for recovery team-new pilots and plane had to be sent to recovery hospital to pick up team"*
- *"pilots/team times out frequently"*
- *"OR delay/bump resulted in pilot timing out....resulted in having to cancel recovery and delay 24hrs"*
- *"Seems to be happening more consistently"*
- *"never heard of this issue"*
- *"Case times adjusted due to pilot times"*
- *"If pilot availability or duty time is a concern we may strategically set the OR time based on those circumstances"*
- *"Can sometimes require additional plane when cases are delayed"*

- *"Experience a lot of time-out issues with pilots"*
- *"Typically because the recovery gets bumped due to trauma and pilots have to wait, gets bumped and have to fly in additional team"*
- *"definite impact on setting the OR time; safety concerns have led companies to be very strict about restriction"*
- *"Will flip teams when necessary and can add cost"*
- *Center "…has occasionally needed to secure a second plane/team when delays at donor site occurs or team times out"*
- *"Leads to delays in clamp times because pilot duty hours run out. NOT AN INSIGNIFANT PROBLEM! HAPPENS FREQUENTLY."*

Timing of donor OR times:



Selected comments from respondents:

- *"rarely, heart/lung teams will delay typically by 1-2hrs when planes take a while to find"*
- *"Prior to hiring broker in 2016, 45% of case were delayed due to flight arrangement problems"*
- *"Weather restrictions can be challenge"*
- *"The percent of cases delayed is very low"*
- *"Delays related to availability of surgeons (locally) and surgeons from outside teams (may be a surgeon or transportation issue)"*
- *"…Any time when aircraft are needed for use that are not our aircraft it takes additional time to get them into placed and can cause a delay. "*
- *"Need 5 hour heads up. Often leaves to delays. All charter companies need 5-6 hours of lead time. Some centers are demanding jets. Delays also occur because of lack of staff"*
- *"Usually, the delays are from teams to outside of the state. Especially heart and lung teams."*

- *"…when it is our donor, we can try to influence the timing of the cases in order to use our own plane…can go to OR sooner/later for weather. Also because we have our own plan we can get to donor hospitals faster and potentially get the unstable donor and utilize those organs"*
- *"Never had to turn down an organ but have had some delays"*
- *"Usually because Lung teams cannot find planes"*
- *"OR time regularly adjusted due to teams arriving from outside OPOs (OR start may not be delayed but more frequently setting of the OR time delayed based on flight availability)"*
- *"Delays are only due to surgical team availability"*
- *"Delays to start OR due to teams coming in"*
- *"…sometimes the delays are because the incoming team can't get a plane"*
- *"Delays in setting OR time. More often delays with last minute changes"*
- *"30% of cases experience some delay"*

Issues to Consider: Respondents conveyed that flying teams for organ recovery influences timing of the donor OR. Issues raised included:

1. Donor instability with longer pre-recovery times
2. Potential loss of organs due to logistics (e.g. lung)
3. Influence of case duration on OPO staffing requirements (inability to staff other cases if still managing existing cases due to time delays)
4. Concerns about pilot duty hours once activated if flight does not occur in timely fashion
5. Concerns about need for simultaneous fly-outs with broader distribution
6. Potential revocation of authorization with longer case times
7. Increased hospital costs related to longer case times
8. Airplane/pilot availability issues due to local sporting events or concerts where all private planes are committed to others
9. Pilot duty hour restrictions leading to need for additional pilots/planes to be flown into donor airports
10. Weather influence (need for strong local backup in the event of weather events that preclude flying)

Limitations: Obvious limitations to this report include the somewhat "anecdotal" nature of the questionnaire and the knowledge level of the respondents. We attempted to reach leadership at the OPOs and transplant centers as is indicated above in order to lessen these concerns.

Conclusions: The Operations and Safety Committee's goal in developing and executing this questionnaire was to assist the relevant OPTN/UNOS committees in their work towards eliminating DSAs and Region as units of allocation. We believe that the issues related to increased air travel and potential OR delays and costs are important issues for the committees to consider and hope that our work will help this process.

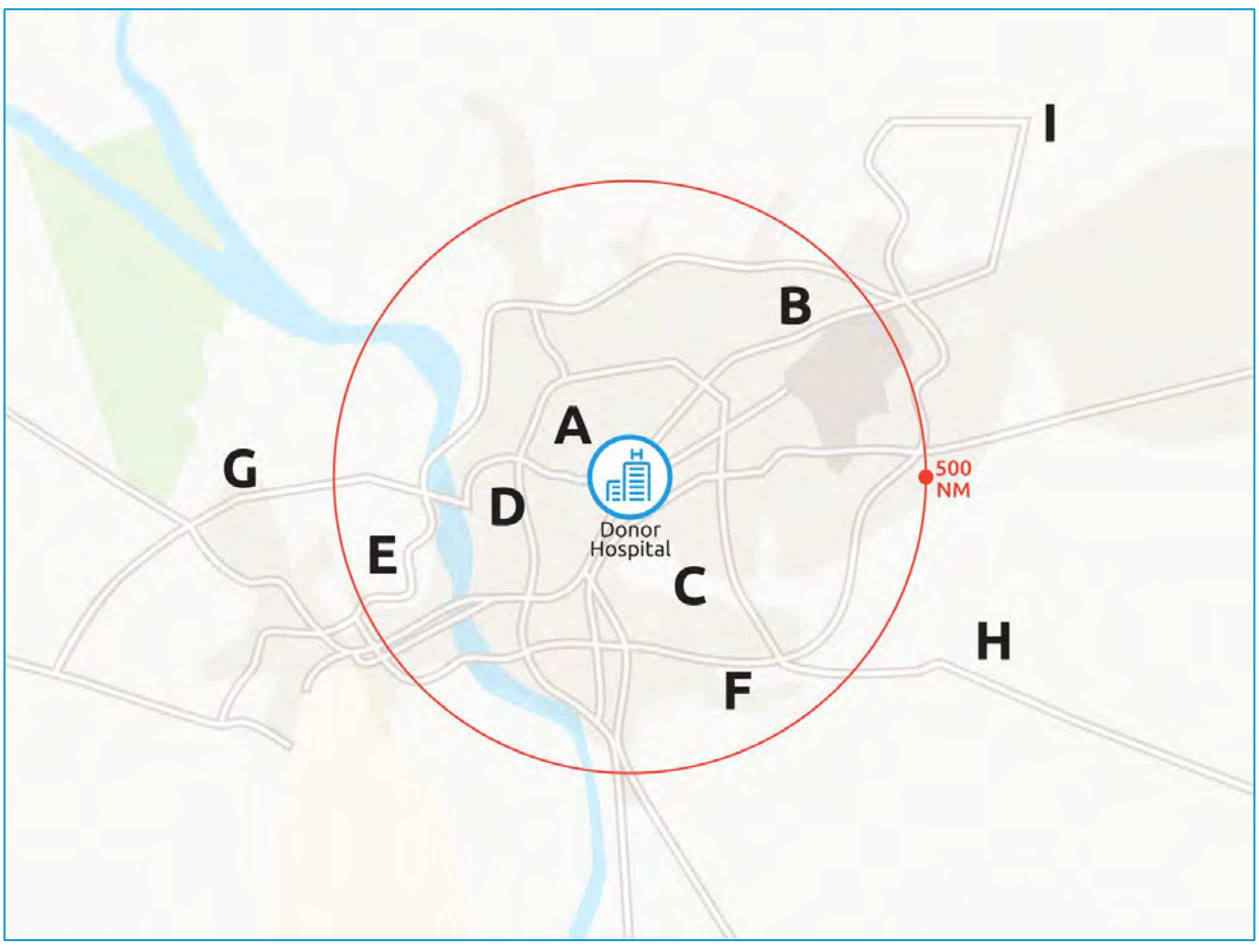
Appendix B: Description of Heart Allocation Sequences Under Modeling of 250 Nautical Mile Distance From Donor Hospital

Hearts from adult deceased donors will first be offered to adult Status 1 or pediatric Status 1A candidates listed at hospitals within 500 nautical miles of the donor hospital, then to adult Status 2 candidates within 500 nautical miles. For each status, candidates who are a primary blood type match with the donor would appear before those who are a secondary match.

In the following example and graphic:

- Transplant Hospital B has a pediatric Status 1A candidate.
- Hospitals A and C both have adult Status 2 candidates. The candidate at Hospital C is the same blood type as the donor; the candidate at Hospital A has a compatible but non-identical blood type.
- Transplant hospitals D, E and F are within 500 nautical miles, but they have no candidates who match in both priority and blood type compatibility.

The Status 1A candidate at Hospital B would be offered the heart first, followed by the Hospital C Status 2 (blood type identical) candidate and then the Hospital A Status 2 (blood type compatible) candidate.



After that initial distribution, hearts will be offered in the following sequence:

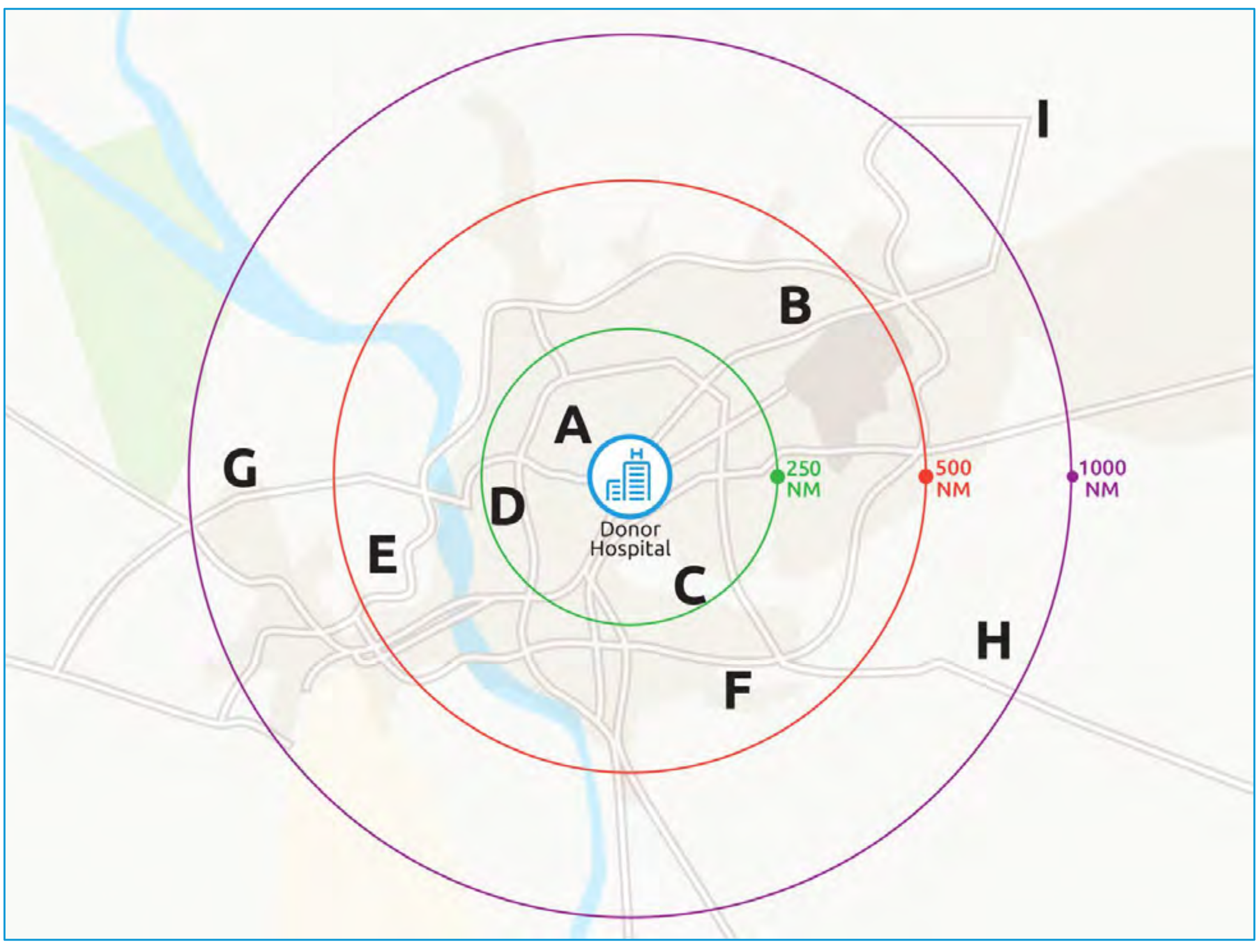
- Adult Status 3 or pediatric Status 1B candidates at hospitals within 250 nautical miles of the donor hospital
- Adult Status 1 or pediatric Status 1A candidates at hospitals within 1,000 nautical miles of the donor hospital
- Adult Status 2 candidates within 1,000 miles of the donor hospital

At each of these levels, candidates who are a primary blood type match with the donor will appear before candidates who are a secondary blood type match.

In the example below:

- Transplant Hospitals B and D each have an adult Status 3 candidate.
- Hospitals H and I both have adult Status 1 candidates.
- Hospital G has an adult Status 2 candidate.

The Status 3 candidate at Hospital D would be offered the heart first, as the transplant hospital is within 250 nautical miles of the donor hospital. (The candidate at Hospital B would be in a later offer sequence, as the hospital is beyond 250 nautical miles.) The next candidate considered is the Status 1 at Hospital H, as the hospital is within 1,000 nautical miles of the donor hospital. (Hospital I is beyond a 1,000-mile radius and would be considered in a later offer sequence.) Then the heart would be considered for the Status 2 Hospital G candidate, as the hospital is within the 1,000 nautical mile radius.



Following that, hearts will be offered in the following sequence:

- Adult Status 4 candidates at hospitals within 250 nautical miles of the donor hospital
- Adult Status 3 or pediatric Status 1B candidates at hospitals within 500 nautical miles of the donor hospital
- Adult Status 5 candidates within 250 nautical miles of the donor hospital
- Adult Status 3 or pediatric Status 1B candidates within 1,000 nautical miles of the donor hospital
- Adult Status 6 or pediatric Status 2 candidates within 250 nautical miles of the donor hospital

At each of these levels, candidates who are a primary blood type match with the donor will appear before candidates who are a secondary blood type match.

In the example below:

- Transplant Hospital A has an adult Status 4 candidate.
- Hospitals B and E each have a pediatric Status 1B candidate.
- Hospital C has an adult Status 5 candidate.
- Hospital D has an adult Status 6 candidate.
- Hospitals G, H, and I each have an adult Status 3 candidate.
- Hospital F does not have candidates meeting any of the criteria.

The Status 4 candidate at Hospital A would be first to receive an offer. The pediatric Status 1B candidates at Hospital B and E would be next, followed by the Status 5 candidate at Hospital C and the Status 3 candidates at Hospitals G and H. While there is a Status 3 candidate at Hospital I, this hospital is beyond a 1,000 nautical mile radius and would be considered in a later sequence.