OPTN

Briefing Paper

Eliminate the Use of DSAs in Thoracic Distribution

OPTN Thoracic Organ Transplantation Committee

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Contents

Eliminate the Use of DSAs in Thoracic Distribution

Affected Policies:	*Policy 1.2: Definitions; Policy 5.10.C: Other Multi-Organ Combinations; 6.4.A.ii: Committee Appeals; Policy 6.4.B: Exceptions to Allocation for Sensitized Patients; Policy 6.6.A: Allocation of Hearts by Blood Type; Policy 6.6.D: Allocation of Hearts from Donors at Least 18 years Old; Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old; 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old; 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old*
Sponsoring Committee:	*Thoracic Organ Transplantation Committee*
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Executive Summary

The OPTN Final Rule (hereafter “Final Rule”) sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, and promoting efficient management of organ placement. 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.[1]

At its December 2018 meeting, the OPTN Board of Directors directed the organ-specific committees to pursue removal of DSA and regions from their allocation systems. This directive was made on the grounds that DSAs and regions, as allocation units, are not rationally determined or consistently applied, and thus may create inequalities in candidates’ access to organ transplantation. The Board directed the committees to replace their use with a rationally determined substitute that could be consistently applied and aligns with the Final Rule. With this charge in mind, the Committee sought to develop a policy which distributes organs as broadly as possible, with any geographic limitations to allocation based specifically on requirements of the Final Rule.

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 Thoracic Organ Transplantation Committee (hereafter, “Committee”) proposes replacing DSAs within allocation policy 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 transplantation regardless of where the candidate is listed. 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.

[1] 42 C.F.R. § 121.

What problem will this proposal address?

This proposal is intended to address the following four problems associated with using DSAs as a unit of distribution for hearts:

1. Using DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule
2. Removing 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 policy would result in clerical artifacts remaining in the policies

1. Using 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, 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.[2] 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.[3] 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."[4]

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."[5]

The Institute of Medicine made this same conclusion in 1999.[6] In 2012, the American Medical Association's Code of Medical Ethics stated that, "[o]rgans 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."[7]

Currently, DSAs are used as a geographic unit of distribution in heart allocation.[8] While there is broader distribution for the most medically urgent heart candidates within a 500 mile radius of the donor hospital,

[2] 42 C.F.R. §121.8(a).
[3] 42 C.F.R. §121.8(a)(8).
[4] 42 C.F.R. §121.8(b)(3).
[5] 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.
[6] National Academies Press, "Organ Procurement and Transplantation." (1999).
[7] 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).
[8] OPTN *Policy 6: Allocation of Hearts and Heart-Lungs*, October 18, 2018.

hearts are allocated to less medically urgent candidates within the DSA before they are offered to more medically acute candidates outside of the DSA (**Table 1**).[9] This allocation pattern alternates through all six heart statuses, prioritizing less medically urgent candidates within the DSA over more medically urgent candidates outside of the DSA. Notably, due to the arbitrary boundaries of DSAs, these more medically urgent candidates may actually be closer to the donor hospital than the prioritized candidates within the DSA. 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 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 (NM) of the donor hospital but outside of Zone A and the donor hospital's DSA."[10]

Table 1: Heart distribution system under current policy[11]

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 are an arbitrary geographic area with regard to allocation policy.[12] While concerns regarding system efficiency and patient access are appropriate considerations in policy development, there is no evidence that using 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.[13] 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.[14,15] This is relevant as this metric is used as the measure for equity in thoracic organ transplantation.[16] 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.[17]

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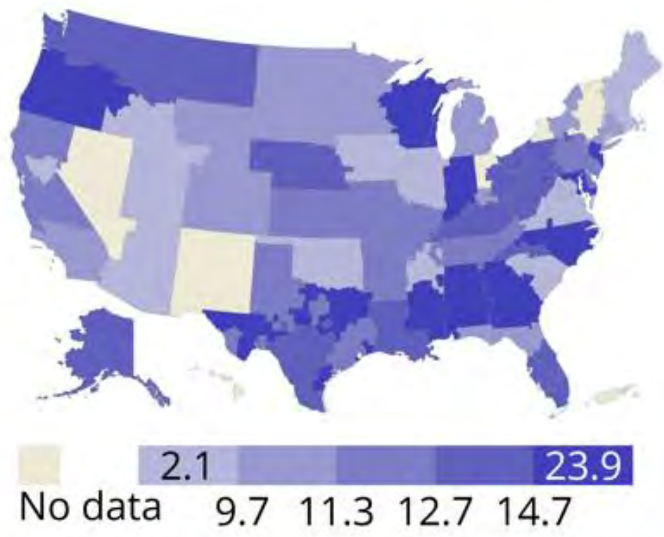
https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_06. (accessed December 26, 2018).
[9] OPTN Policy 6: Allocation of Hearts and Heart-Lungs.
[10] OPTN *Policy 1.2: Definitions*, May 2, 2018. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. (accessed December 26, 2018).
[11] 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.
[12] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.
[13] Ibid.
[14] 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*.
[15] The Committee previously selected waitlist mortality as the best measure of equity for thoracic transplantation. See "How was this proposal developed?", page 12.
[16] See page 14, "Criteria" for detailed discussion.
[17] 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. Removing DSA as a unit of distribution in heart allocation makes current policy for sensitized heart candidates impractical

Current *Policy 6.4.B Exceptions to Allocation for Sensitized Patients* 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.[18]

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 OPTN Kidney Transplantation Committee (hereafter "the Kidney Committee"), working with the OPTN Pancreas Transplantation Committee (hereafter "the Pancreas Committee"), and the Vascularized Composite Allograft Committee (hereafter "the VCA Committee") identified allocation options that include concentric circle and variations of fixed distance distribution frameworks.[19] This framework was previously vetted in 2018 by the Ad Hoc Committee on Geography (hereafter "the Ad Hoc Geography Committee").[20,21] The thoracic organ

[18] OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.

[19] 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.

[20] 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).

[21] Not only was this framework deemed consistent with NOTA and the OPTN Final Rule, the OPTN/UNOS determined it may be easier to implement in an expeditious manner.

distribution system already utilizes a fixed distance framework.[22,23] 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.[24,25,26] Most importantly, in current policy, Zone A for lung allocation is not the same as Zone A for heart allocation, increasing confusion within thoracic organ allocation policy.

Removing the term "zone" from OPTN 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.[27] 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 policy would result in clerical artifacts remaining in the policies

There are instances relevant to heart elsewhere in OPTN 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.

How was this proposal developed?

At its December 2018 meeting, the OPTN Board of Directors directed the organ-specific committees to pursue removal of DSA and regions from their allocation systems. This directive was made on the grounds that DSAs and regions, as allocation units, are not rationally determined or consistently applied, and thus may create inequalities in candidates' access to organ transplantation. The Board directed the committees to replace their use with a rationally determined substitute that could be consistently applied and aligns with the Final Rule. With this charge in mind, the Committee sought to develop a policy which distributes organs as broadly as possible, with any geographic limitations to allocation based specifically on requirements of the Final Rule.

The Committee is comprised of transplant hospital representatives, OPO representatives, transplant coordinators, and transplant patients from each OPTN region.[28] Committee members were selected for

[22] OPTN Policy 6: Allocation of Hearts and Heart-Lungs (April 12, 2019).
[23] OPTN Policy 10: Allocation of Lungs (November 24, 2017).
[24] 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).
[25] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.
[26] 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).
[27] OPTN/UNOS Board Briefing, *Frameworks for Organ Distribution*, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf.
[28] As required by OPTN/UNOS Bylaws Article VII, 7.1: *Composition of Standing Committees.*

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.

The Committee also collaborated with multiple other OPTN committees representing particular patient groups or perspectives during the development of this proposal. For example, members of the OPTN 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.[29] In addition, the Committee provided regular updates of its activities to the Ad Hoc Geography Committee.

As discussed previously discussed, the Committee addressed four primary problems in this proposal:

1. Using DSA as a unit of distribution in heart allocation is inconsistent with the Final Rule
2. Removing 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 policy would result in clerical artifacts remaining in the policies

The next sections describe how the Committee developed responses to each of the four issues.

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

When determining how to replace DSA in heart allocation policy, the Committee agreed to a scope of work which included evaluation of the following:[30]

1. Which geographic framework should be used to remove DSA from heart distribution?
2. If concentric circles are retained, which distance should replace DSA in heart distribution (adult and pediatric distribution)?
3. Should lung distribution be re-evaluated or changed at all within this proposal?
4. In particular, should lung allocation score (LAS) thresholds be established to distribute lungs more broadly to some candidates?[31,32]

Geographic Framework

The Committee, considering the Board's direction to move toward a continuous distribution framework, and considering the complications of the new heart allocation system, determined that a concentric circle model was an appropriate step in that direction for the Committee to take. Overall, the Committee believed that the new allocation rules, particularly with broader distribution out to 500 NM for the sickest

[29] 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).
[30] 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).
[31] The lung allocation score (LAS) is a calculated value used to stratify lung candidates. The LAS is weighted two-thirds on waitlist mortality and one-third on post-transplant survival.
[32] OPTN/UNOS Board Briefing, *Modifications to the Distribution of deceased Donor Lungs*, June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf. 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.

patients, could improve access to potential heart recipients beyond the boundaries of their local DSA.[33] Therefore, consistent with the directive of the Board and the Final Rule, the Committee sought to eliminate DSA while retaining the existing fixed distance framework. [34,35]

Considerations

Consideration of Making Further Changes to Distribution of Lungs

After making emergent, and then permanent, changes to lung distribution policy to replace DSA with 250 NM, the Committee considered whether to modify lung distribution again.[36] During January 2018 public comment, patient advocacy groups and the OPTN 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 more extensively evaluate the consequences of distributing more broadly, the Committee was hesitant to increase the first unit of distribution from 250 NM to 500 NM.[37] Those who supported 250 NM, including the International Society of Heart and Lung Transplantation (ISHLT), were comfortable with this distance because post-implementation OPTN data indicated no immediate adverse impact to patients.[38] 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. As a result, 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 to achieve other goals of the regulation, including the efficient management of organ placement."[39,40] 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

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[33] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.
[34] Meeting summary for June 28, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[35] Meeting summary for July 19, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[36] 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).
[37] OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
[38] Ibid.
[39] 42 C.F.R. §121.8(a)(5).
[40] 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).

distribution system.[41,42,43] A nine-month pre- vs. post- analysis of the impact of broader distribution of lungs reported 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.[44,45]

While flying influences organ recovery in a variety of ways (see “Use of Air Transportation” below), there is a significant jump in the costs associated with transportation for transplant; increased costs make the process less efficient.[46] 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.[47] 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.[48,49] Therefore, the Committee emphasized cost be considered as a metric of efficient organ placement when determining a distance with which to replace DSA.

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. Aviation experts and pilot organizations have both reported a pilot shortage is likely under current FAA training requirements and airline industry demand.[50] A lack 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.[51] 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.”[52] “The [pilot] shortage has been caused by a recent increase in the flying hours required for

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[41] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.
[42] OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
[43] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital, December 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.
[44] 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.
[45] 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).
[46] 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.”
[47] 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).
[48] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital, page 15.
[49] The OPTN/UNOS does not collect cost data.
[50] Green, Shannon, “The Future of Aviation,” *Orlando Sentinel*, April 4, 2019, p. A1.
[51] 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.
[52] 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

commercial pilots, the aging pilot workforce, fewer new pilots coming out of the military, and a general decline of interest in the career." [53,54,55,56,57] In addition, the transplant community has noted additional transportation challenges resulting from new regulations governing crew duty and rest times.[58,59]

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 longer periods of time when a hospital did not have a recovery team available, either resulting in the inability to accept an offered organ, or furthering delays in organ 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 of similar medical urgency 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.[60] The organ distribution principle of promoting efficiencies of donation and transplant system resources supports limiting distribution to avoid this type of scenario.[61,62]

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.[63,64,65] Organ procurement flights have fatality rates nearly 1,000 times higher than scheduled commercial

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[53] 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.

[54] 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

[55] 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.

[56] 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.

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

[58] 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).

[59]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.).

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

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

[62] 42 C.F.R. §121.8(a)(5).

[63] 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).

[64] 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.

[65] 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).

aviation; furthermore, 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.[66]

Efficient Management of Organ Placement

Eliminating the use of DSAs in lung allocation has resulted in an approximately 1 hour increase in the time from first electronic offer to cross-clamp, probably because there are generally more candidates within the first allocation classification, and those candidates may be considering multiple offers.[67] The median sequence number of the final acceptor has increased from 5 to 6.[68] There is no 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.[69] However, the increase in time between offer and cross-clamp means that the OPO will 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.[70] 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 demonstrated a relationship between donor organ ischemic time and post-transplant outcomes.[71,72,73,74] 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.[75,76,77] 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 quality".[78,79] 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.[80]

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66 Englesbe, M. J., and R. M. Merion. "The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel."

67 OPTN/UNOS Descriptive Data Report. "Monitoring of the Lung Allocation Change, 9-Month Report Removal of DSA as a Unit of Allocation," November 1, 2018.

68 Ibid.

69 Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.

70 42 C.F.R. §121.8(a)(2,5).

71 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.

72 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.

73 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.

74 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.

75 OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.

76 OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.

77 OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital, December 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.

78 OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution.

79 42 C.F.R. §121.8(a)(1)(2)

80 Kilic, Ahmet, Sitaramesh Emani, Chittoor B Sai-Sudhakar, Robert S D Higgins, and Bryan A Whitson. "Donor

Number of Transplants and Utilization

Increasing the number of transplants is the primary strategic goal of the OPTN. It is consistent with several aspects of the Final Rule, including achieving best use of donated organs, 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 avoiding organ wastage as a goal of allocation policy.[81] 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.[82,83,84] However, the most recent monitoring report evaluating the changes to lung allocation has shown minimal changes in organ utilization rates.[85] 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.[86] 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.[87] 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.[88] Subsequently, during the March 19, 2013 meeting, the Committee noted the primary purpose of the resolution was to determine an objective measure that

Selection in Heart Transplantation." *Journal of Thoracic Disease* 6, no. 8 (2014): 1097-104.
[81] 42 C.F.R. §121.8(a)(5)
[82] OPTN/UNOS Board Briefing, Proposal to Modify the Adult Heart Allocation System.
[83] OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
[84] OPTN/UNOS Board Briefing, Liver and Intestine Distribution Using Distance from Donor Hospital.
[85] OPTN/UNOS Descriptive Data Report. "Monitoring of the Lung Allocation Change, 9-Month Report Removal of DSA as a Unit of Allocation."
[86] 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.
[87] In this context, generally speaking, a measure of the quality and quantity of life lived, which includes waitlist mortality and post-transplant mortality.
[88] Executive Summary of the Minutes for the November 12-13, 2012 OPTN/UNOS Board of Directors Meeting. https://optn.transplant.hrsa.gov/media/1801/executivesummary_1112.pdf. (Accessed December 19, 2018)

defines fairness.[89] 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.[90]

Therefore, waitlist mortality was one of the metrics used by the Committee to assess whether transplant candidates have equitable 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.[91,92]

Vulnerable Populations

In addition, the Committee committed to ensuring pediatrics and other vulnerable populations were not negatively impacted.

Impact to Children

NOTA specifically recognizes the special status of children, and charges the OPTN "to adopt criteria, policies and procedures that address the unique health care needs of children."[93] Based on this charge and supported by other Final Rule provisions, the OPTN has determined that "there is a reasonable basis for giving preference to pediatric transplant candidates for allocation."[94] 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 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.

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[89] Board report for the June 24-25, 2013 OPTN/UNOS Board of Directors, OPTN/UNOS Thoracic Organ Transplantation Committee.
[90] 42 C.F.R § 121.4(a)
[91] OPTN/UNOS Strategic Plan, approved June 2018, https://optn.transplant.hrsa.gov/governance/strategic-plan/.
[92] 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.
[93] National Organ Transplantation Act (NOTA) 42 USC 273 et seq
[94] 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).

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 ...".[95] 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 descriptive data to inform the discussion around selecting potential distances to replace DSA.[96] 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 2**).[97]

Table 2: Descriptions of Allocation Orderings from SRTR Data Request from the Heart Subcommittee of the OPTN 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:

- Similar transplant rates for status 1, 2, 5
- Higher transplant counts & rates for status 3

[95] 42 C.F.R § 121.8(a)(8) and (b)(3).
[96] 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).
[97] Scientific Registry of Transplant Recipients, *SRTR HR2015_01,* June 11, 2015.

- 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:[98]

- 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 descriptive data showing how hearts are distributed under recent allocation rules to assess the current state of heart distribution.[99] Under the previous distribution system, the median distance hearts travelled from donor hospital to transplant center was 96 NM (**Figure 2**).[100] 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.[101,102,103]

[98] Scientific Registry of Transplant Recipients, SRTR LU2017_02, *https://optn.transplant.hrsa.gov/media/2432/thoracic_meetingsummary_20180116.pdf*. (accessed December 26, 2018).
[99] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee (Heart allocation rules in effect prior to October 18, 2018).
[100] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[101] Meeting summary for August 23, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[102] 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
[103] 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

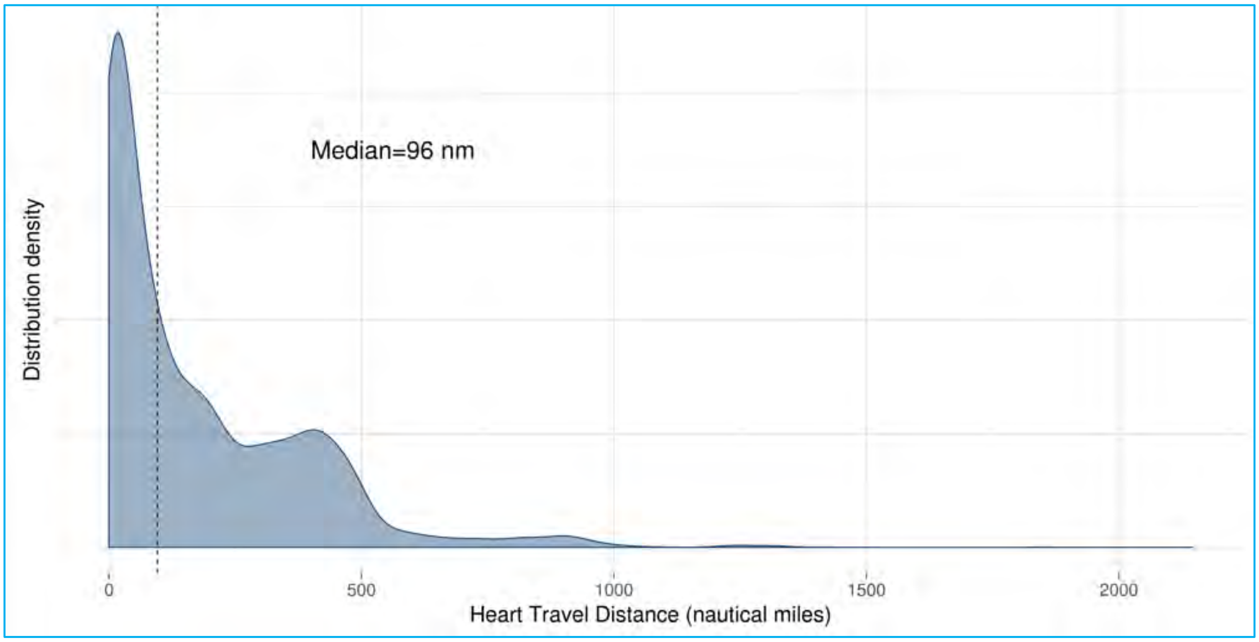
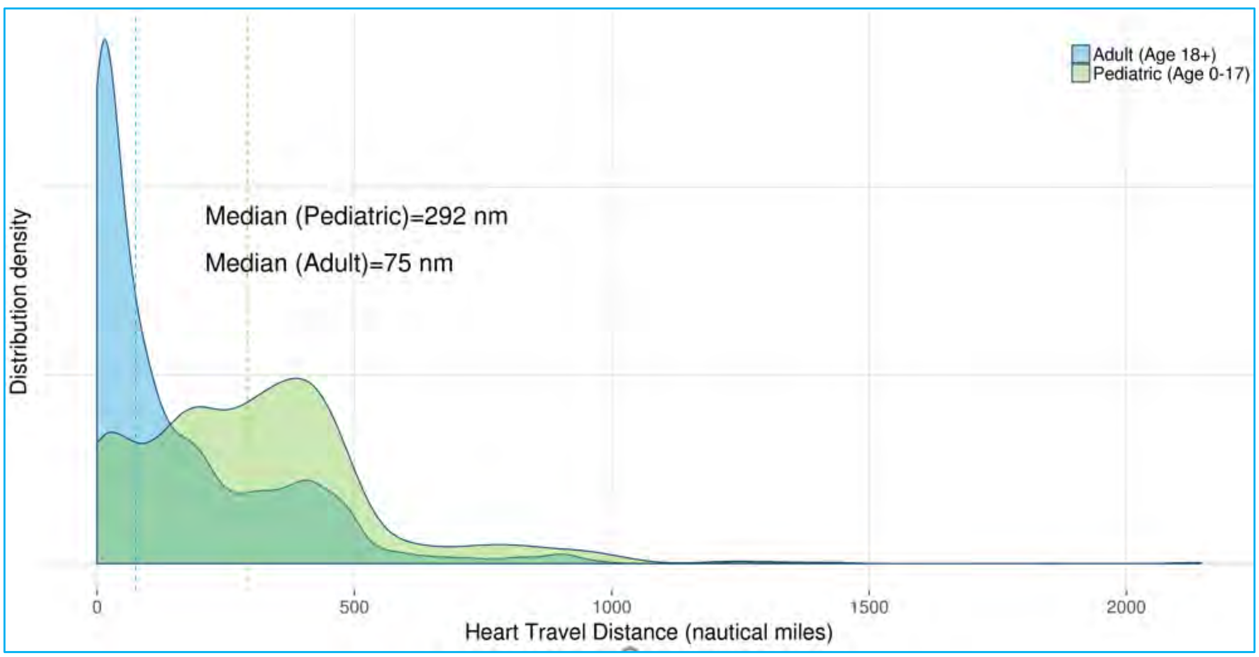


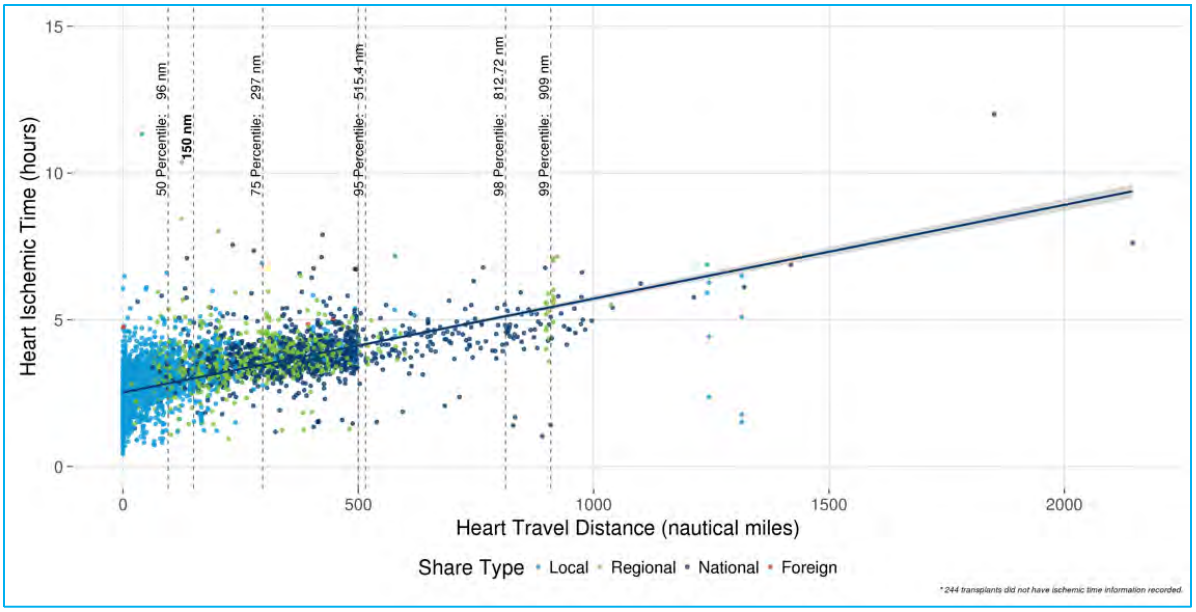
Figure 3: Deceased Donor Heart Transplants from 1/1/2017-06/30/2018, Travel Distance by Recipient Age



In examining OPTN 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 **(Figure 4)**. Cold ischemic time is also a criterion in donor organ acceptance.[104,105] Any increase in distance has a potential impact due to corresponding increases in donor organ ischemic time.

[104] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[105] 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 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 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.[106] 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 ...".[107]

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 data previously shared with the Committee illustrated that most hearts traveled within 500 NM with a few outliers.

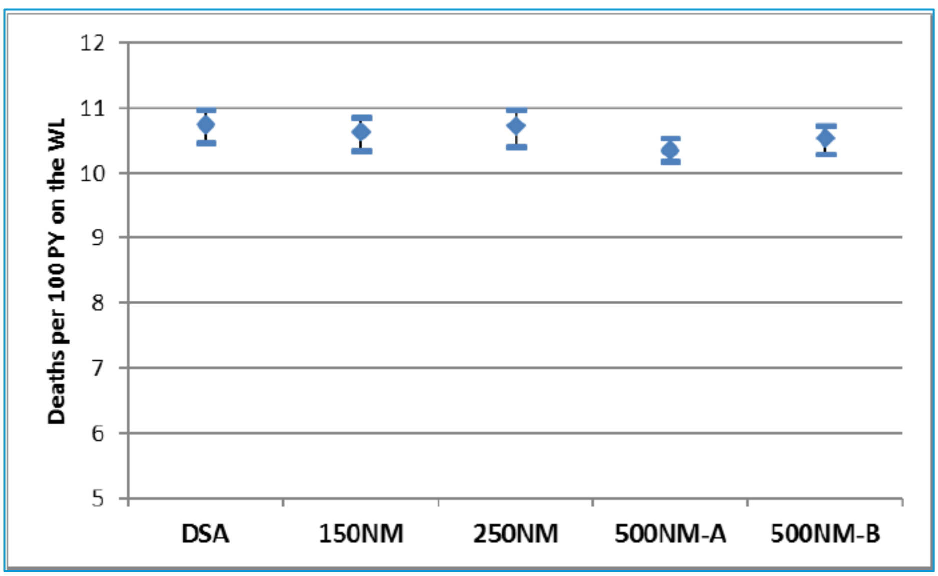
One important aspect of the heart allocation system implemented on October 18, 2018 includes the broadest distribution to the most urgent (status 1 and status 2) candidates. In this system, donor organs are first allocated to status 1 and 2 candidates within the DSA or within 500 NM (whichever is larger). The

[106] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[107] 42 C.F.R § 121.8(a) and (b)

next allocation classification is to higher status candidates within the same DSA as the donor. 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.[108] They briefly debated setting the broadest 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 with 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 Thoracic Simulated Allocation Model (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.[109,110,111] 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**).[112,113] 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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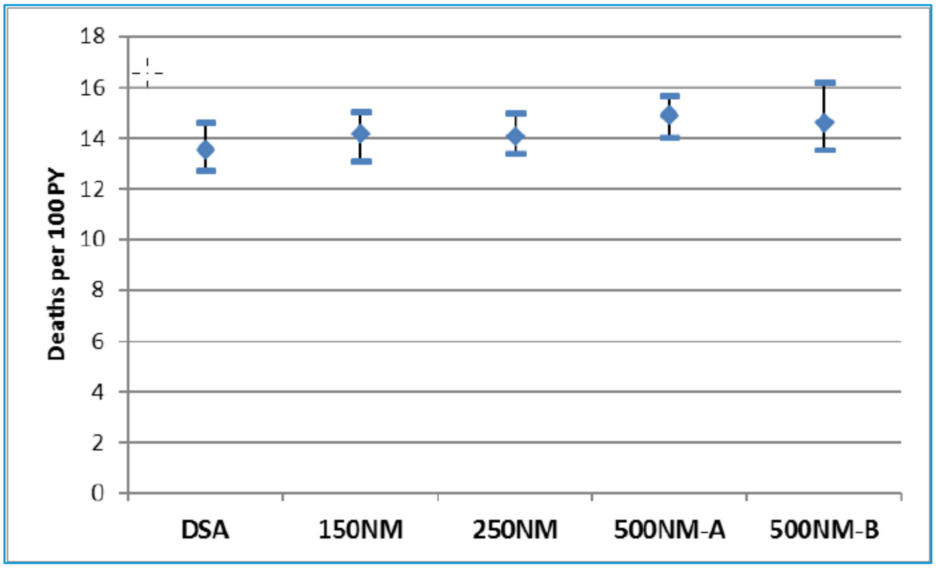
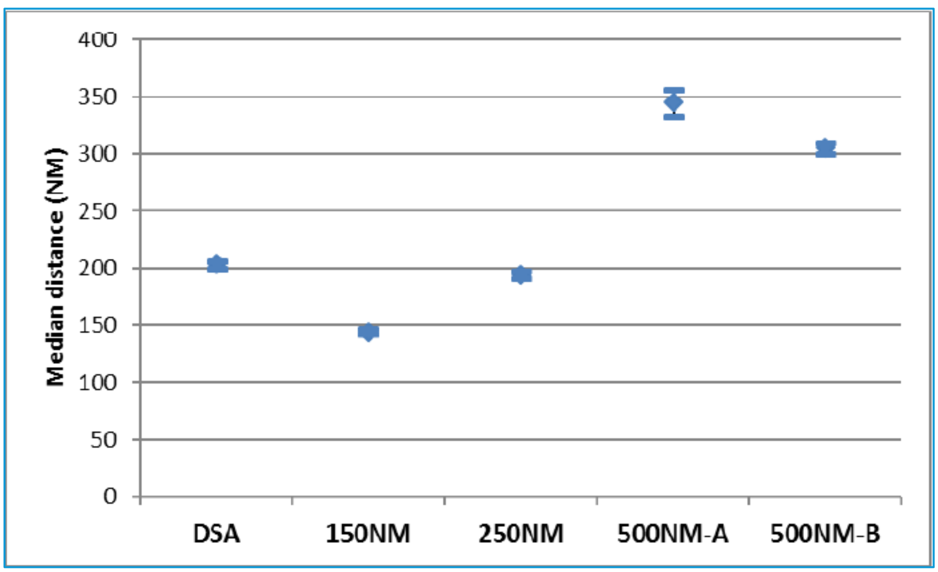
108 Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/2647/20180816_thoracic_meetingsummary.pdf. (accessed December 26, 2018).
109 Although this modeling has limitations, it was noteworthy that the models used for revising lung allocation have been consistent with observable changes occurring post-implementation of those changes.
110 Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
111 Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
112 Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.
113 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**).[114] This impacts travel and ischemic time. Median distance varied by circle size, and these differences in distance were expected.

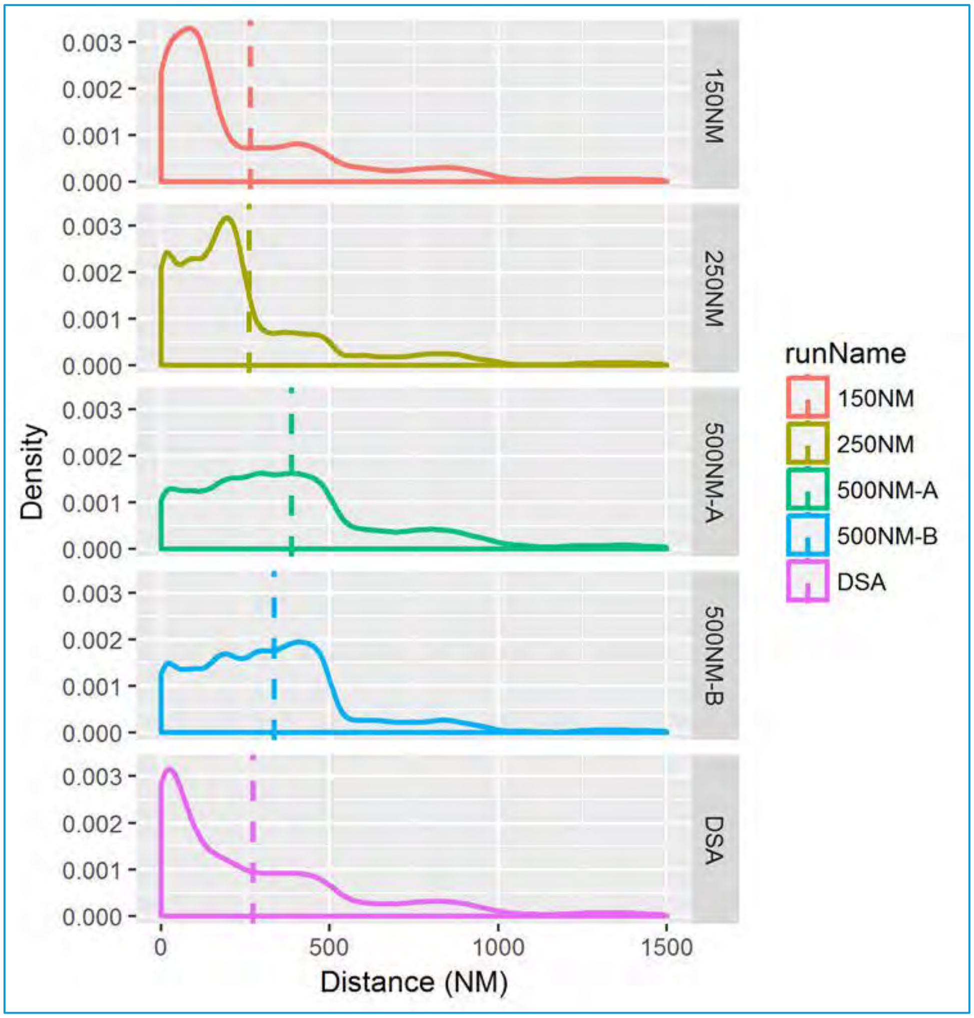
Figure 7: Median distance (NM) between donor and transplant hospital by simulation



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.[115]

[114] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.
[115] See discussion of 150 NM distance, pages 22-24.

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



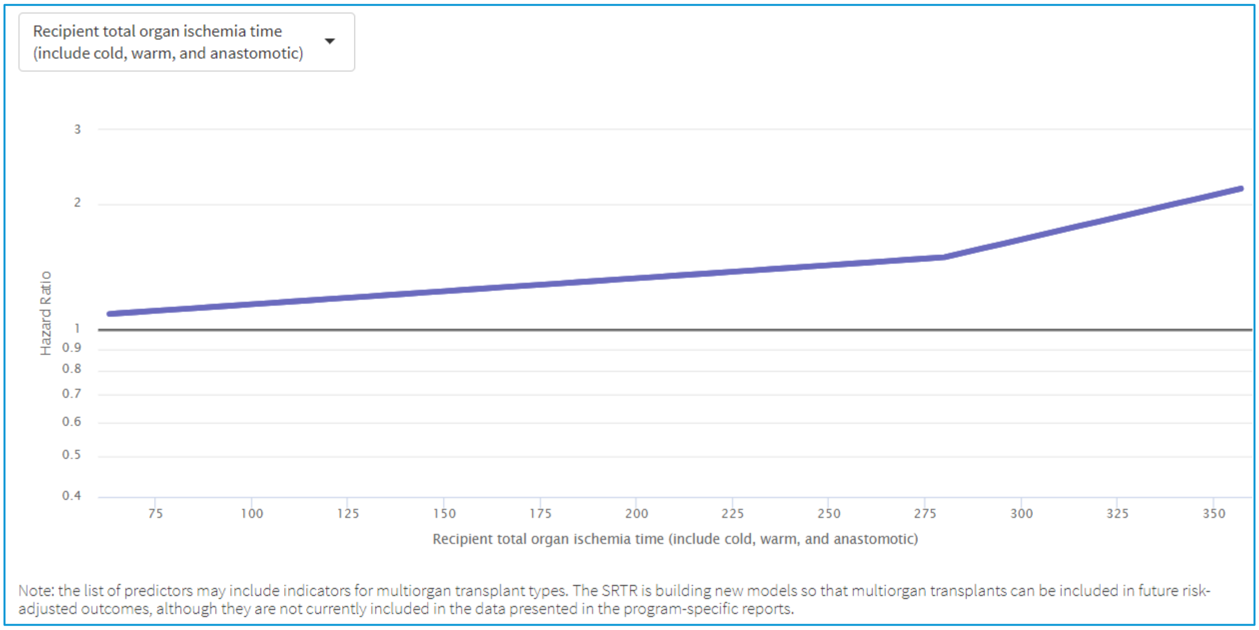
As previously mentioned, the increase in distance also has a potential impact due to corresponding increases in donor organ ischemic time. In examining OPTN data on deceased donor heart transplants between 1/1/2017 and 6/30/2018, there is not a direct correlation between distance and ischemic times (**Figure 4** found on page 18).[116] However, there are limits to the lower level of ischemic time with increasing distance. As seen in **Figure 4**, with distances between 250 NM and 500 NM, 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).[117]

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**).[118] 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).[119] However,

[116] Meeting summary for August 9, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[117] Nicoara et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors."
[118] https://www.srtr.org/reports-tools/risk-adjustment-models-posttransplant-outcomes/
[119] 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."

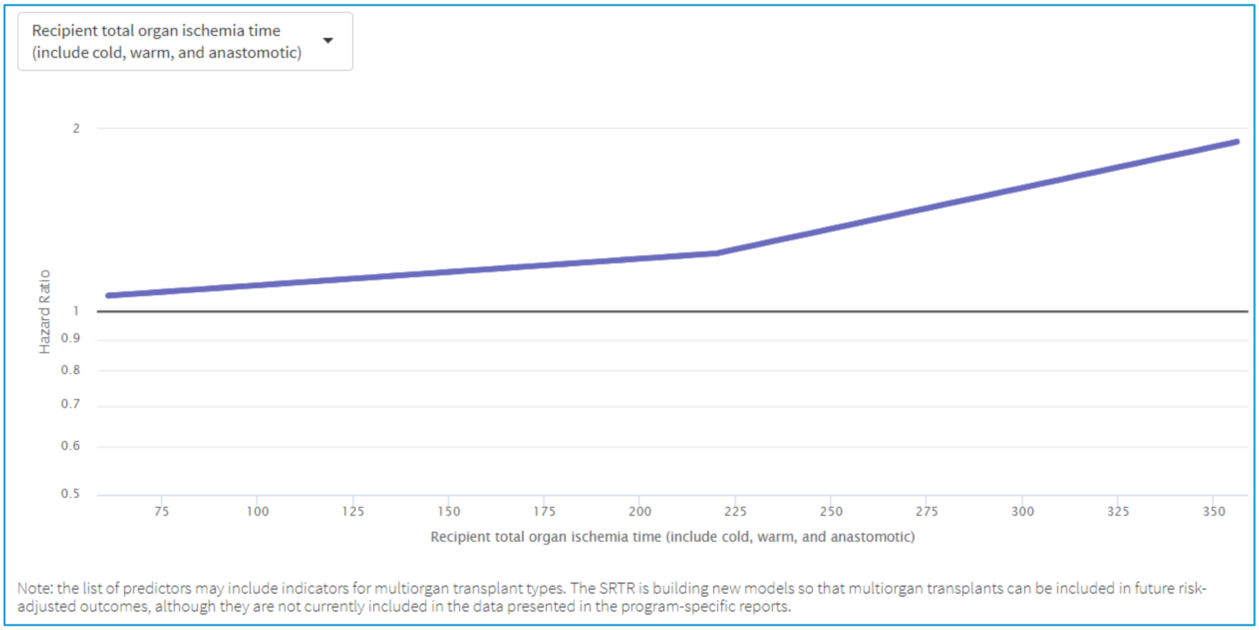
other data has suggested that the more commonly accepted threshold of 3 to 4 hours may provide an inflection point at which post-transplant graft failure and death begin to increase, especially when evaluating older donors.[120,121,122] Furthermore, independent of effects on survival, morbidity and lengths of stay in the hospital post-transplant appear to be increased with prolonged donor organ ischemic time.[123] 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.

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



[120] 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.
[121] 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.
[122] 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.
[123] Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."

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



The Committee voiced concern that smaller hospitals, with smaller local donor populations, may be unable to absorb increased travel costs and loss of access for the patients those hospitals serve 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.[124]

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.[125] 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.[126] 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.[127] 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 candidates increased on both the 500 NM simulations.[128]

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

[124] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.
[125] Englesbe, “The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel.”
[126] Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[127] Ibid.
[128] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.

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 A). This distance seeks to reduce travel time expected to have a clinically significant effect on ischemic time and organ quality.[129,130] In addition, members felt this distance would better balance distributing hearts more broadly while mitigating any negative impact to organ utilization.[131,132]

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.[133] It also is projected to increase the transplant rate for status 3 adult candidates.[134] 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).[135]

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 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.[136]

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).[137] 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 NM 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

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129 OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution, June 11, 2018, https://optn.transplant.hrsa.gov/news/optnunos-board-adopts-principles-of-geographic-organ-distribution/.
130 42 C.F.R § 121.8(a)
131 OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution, June 11, 2018, https://optn.transplant.hrsa.gov/news/optnunos-board-adopts-principles-of-geographic-organ-distribution/.
132 42 C.F.R § 121.8(a)
133 Meeting summary for November 1, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
134 Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.
135 However, one of the goals of the *Modifications to the Adult Heart Allocation System* was to better stratify candidates by medical urgency (waitlist mortality).
136 OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
137 Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.

Distribution.[138,139] 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.[140] Based on information gathered via interviews of OPO and transplant hospital employees, as conducted by the OPTN 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.[141] Committee members agreed that at 150 NM, most programs were likely flying.[142]

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.[143] 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.[144] After some debate between 100 NM 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 3**). The Chair abstained.

Table 3: Straw Poll Vote, November 1, 2018 Committee meeting

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

As with the 500 NM system, there were no differences between the models in terms of waitlist or post-transplant outcomes.[145] 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 donor organs traveled 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

[138] 42 C.F.R § 121.8(a)
[139] OPTN/UNOS Online Communication, OPTN/UNOS Board adopts principles of geographic organ distribution, June 11, 2018, https://optn.transplant.hrsa.gov/news/optnunos-board-adopts-principles-of-geographic-organ-distribution/.
[140] Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[141] OPTN, Operations and Safety Committee Transportation Report.
[142] Meeting summary from August 16, 2018 meeting, OPTN/UNOS Thoracic Organ Transplantation Committee.
[143] 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).
[144] Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."
[145] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.

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. Removing 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.[146] 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.[147] As the two policies were identical, the Committee now had to address the same issue with sensitized heart candidate policy.[148] The Committee considered similar options for the heart policy as it had for the lung policy:

Strike Policy

The data to create an ideal policy do not currently exist in the OPTN database, because thoracic transplant programs are not required to report unacceptable antigens to the OPTN. The Committee expressed interest in working with the Histocompatibility Committee in the future to create an optimal policy.

Create Exception Pathway for Sensitized Candidates/Develop Guidance for Heart Review Board

The Committee 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.[149]

Replicate Board-Approved Sensitized Lung Candidate Policy

Although the Committee recommended striking the sensitized lung candidate policy, the OPTN Board 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.[150] While it heeded the Board's opinion, the Committee felt strongly that policies should be evidence-based and should provide an actual remedy, rather than an inoperable one.

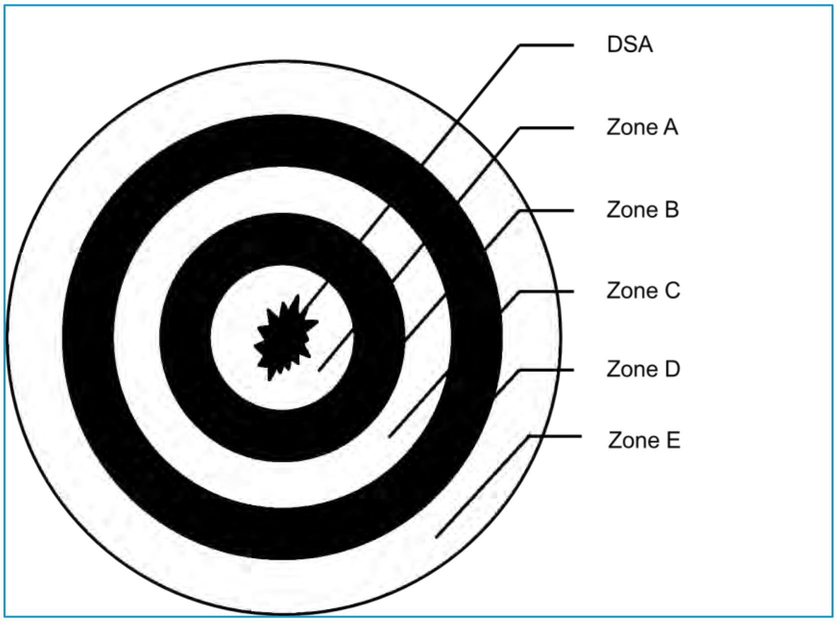
The Committee noted that the remedy a sensitized candidate needs is access to a broader range of donors, which the removal of the DSA in favor of a 250 NM may accomplish. Ultimately, the Committee opted to strike the policy for sensitized heart candidates for the same reasons it recommended striking the lung policy: predominantly that the other solutions were too cumbersome to provide any meaningful use.[151]

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

[146] OPTN/UNOS Board Briefing, *Modifications to the Distribution of Deceased Donor Lungs,* June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
[147] Ibid.
[148] 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).
[149] 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.
[150] OPTN/UNOS Board Briefing, Modifications to the Distribution of Deceased Donor Lungs.
[151] Ibid.

Zones are used as geographic units in thoracic organ policy. Zones are exclusive of smaller geographic area immediately preceding. **Figure 11** demonstrates the zonal structure for allocation of thoracic organs. The DSA is the starting point. For hearts, Zone A includes all transplant hospitals within 500 NM of the donor hospital but outside of the donor hospital's DSA; Zone B includes all transplant hospitals within 1,000 NM of the donor hospital but outside of Zone A and the donor hospital's DSA; Zone C includes all transplant hospitals within 1,500 NM of the donor hospital but outside of Zone B and the donor hospital's DSA; Zone D includes all transplant hospitals within 2,500 NM of the donor hospital but outside of Zone C; and finally Zone E includes all transplant hospitals more than 2,500 NM from the donor hospital. In essence, this creates a distribution shape more similar to a "donut".

Figure 11: Visual representation of thoracic "Zone" definition[152]



Currently, the term "zone" is only used in thoracic policy. The Committee decided to strike the term "zone" from OPTN policy language for consistency across organ policies. Because the term "zone" will be stricken from OPTN 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 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 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.[153]

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.

152 OPTN Policy 1.2 *Definitions*.
153 OPTN/UNOS Board Briefing. Liver and Intestine Distribution Using Distance from Donor Hospital, December 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.

How well does this proposal address the problem statement?

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

1. Using 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. Removing 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.

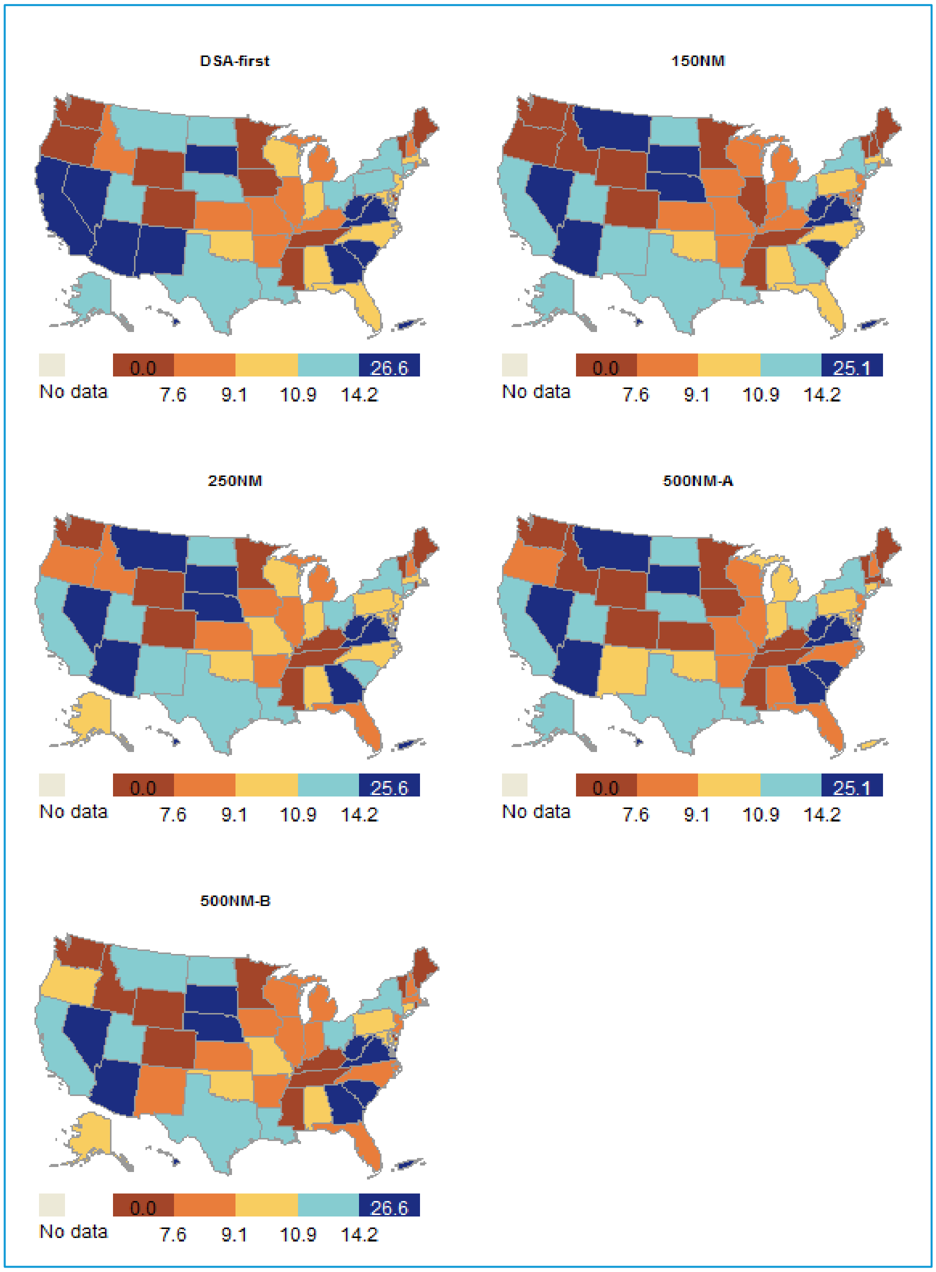
3. Terminology describing geographic units across organ-specific allocation policies in increasingly inconsistent

Removing the term “zone” from OPTN policy and replacing with the fixed 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 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 policy.

Figure 12: Waitlist mortality rates by DSA and simulation



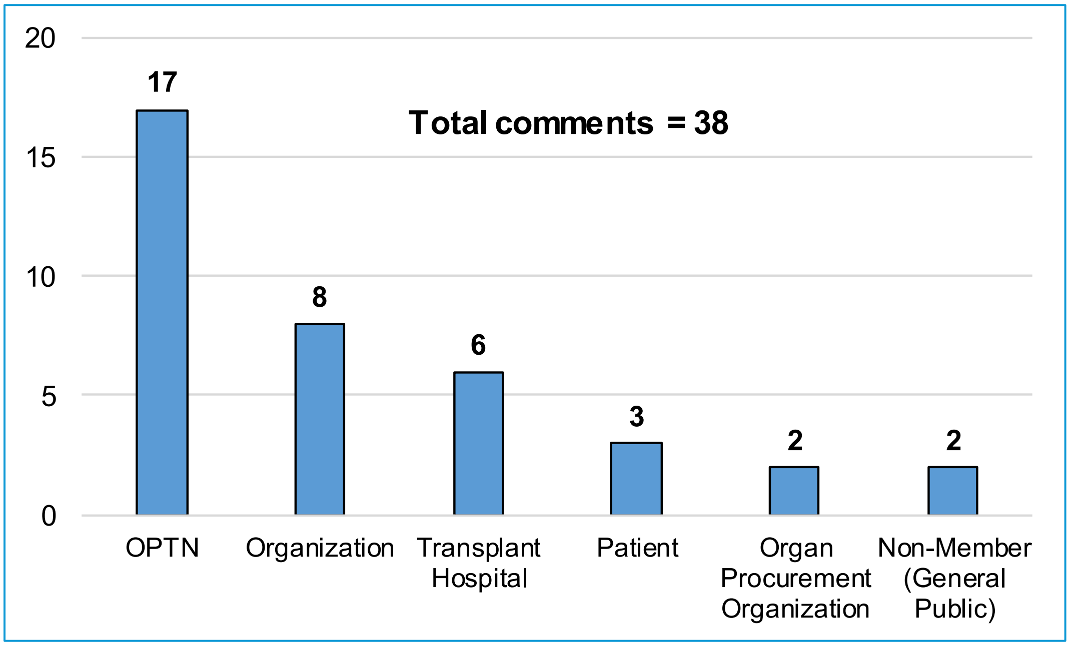
Was this proposal changed in response to public comment?

The Committee considered all of the information provided during public comment in support of the proposal and in opposition. Based on the comments, the Committee determined not to make any changes to the proposal.

The proposal was available for public comment on the OPTN website from January 22, 2019 through March 22, 2019. The Committee asked members and the public if they would recommend an alternative distance for thoracic distribution versus the proposed distance of 250 NM. If a different distance was recommended, members were also asked to provide a recommended distance and for information or evidence justifying the distance.

Thirty-eight comments were submitted to the OPTN website (**Figure 13**). OPTN comments include those submitted by the 11 regions and six committees. Three patients also submitted comments.

Figure 13: Types of Commenters



The proposal received support from 28 of the 38 comments submitted. The remainder of this section discusses the comments in more detail.

Eight of the 11 OPTN regions supported the proposal, two regions opposed it, and one region was split almost evenly. **Figure 14** identifies the level of support for the proposal by region. The value shown in the blue circle represents the average public sentiment score using a five-point Likert scale. A value of more than 3.0 indicates support for the proposal. Across all of the regions, the average sentiment score was 3.4. Five regions recorded sentiment scores of 4.0 or greater, including Region 7 which reported the highest average score of 4.3. Only Region 6 (2.8), Region 8 (2.2), and Region 11 (1.6) reported sentiment scores of 3.0 or less.

Figure 14: Sentiment Support for the Proposal, by Region

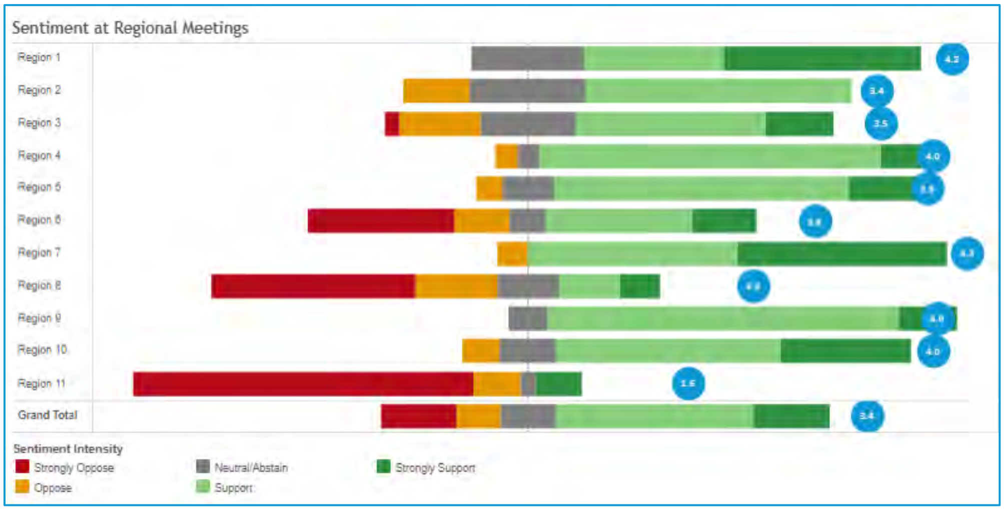


Figure 15 shows the overall levels of support and opposition to the proposal based on the regional voting. Among the 294 votes cast in the regional meetings, 180 votes (61%) strongly supported or supported the proposal. Another 58 votes (27%) opposed or strongly opposed the proposal. Finally, 36 votes (12%) abstained or were neutral to the proposal.

Figure 15: Proposal Support – All Regions

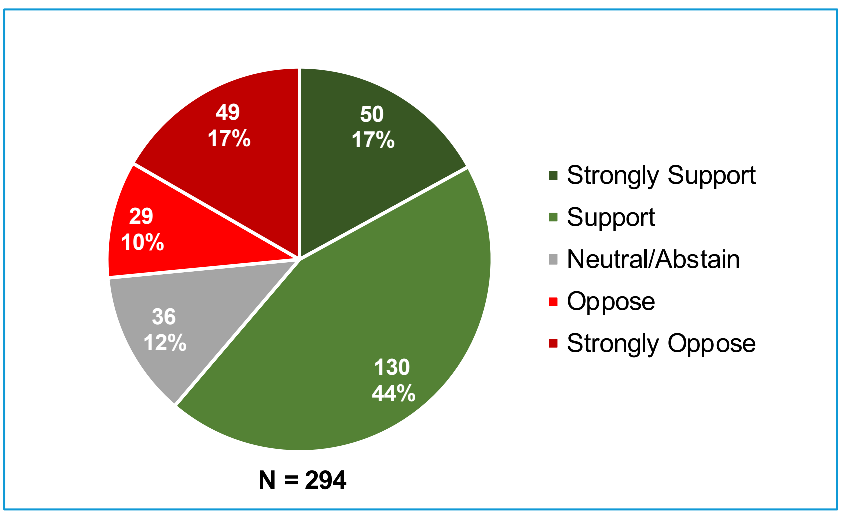
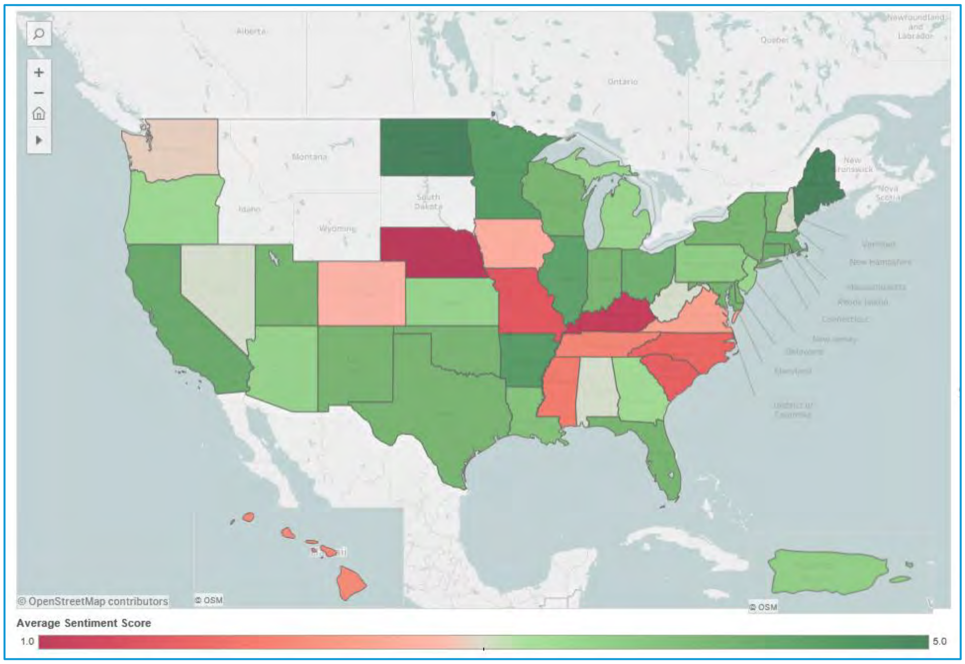


Figure 16 shows the average sentiment score for the proposal by state, including the District of Columbia and Puerto Rico. The darker green the color, the closer the average response is to strongly support. The closer an average score is to strongly oppose, the darker red the color. As the figure shows, a majority of commenters in most states showed some level of support for the proposal.

Figure 16: Support for the Proposal by State



In addition to the OPTN regions, the proposal was also presented to the following six OPTN committees for comment: Ethics, Minority Affairs, OPO, Pancreas Transplantation, Patient Affairs, and Pediatric Transplantation. All six committees expressed support for the proposal.

The proposal also received written comments from the following eight professional organizations:

- International Society for Heart and Lung Transplantation (ISHLT)
- Society of Thoracic Surgeons (STS)
- Heart Failure Society of America (HFSA)
- American College of Chest Physicians (CHEST)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Association of Organ Procurement Organizations (AOPO)

Seven of the organizations supported the proposal to varying degrees, while ASHI abstained from commenting.

Among the six comments associated with transplant hospitals, three were submitted by facilities in Missouri who opposed the proposal. All three patients' comments were in support of the proposal. Of the two OPO comments, one was in support and the other opposed. The same was true for the two non-member comments that were submitted: one was in support and the other opposed.

The general themes raised during public comment were:

- Changes are too soon following October 2018 *Modifications to the Adult Heart Allocation System* policy changes[154]
- 250 NM distance is too far
- 250 NM distance is not far enough and limits access to organs
- 250 NM is an appropriate distance

[154] OPTN website, Modify adult heart allocation 2016 2nd round, Phase 2, October 18, 2018, https://optn.transplant.hrsa.gov/governance/public-comment/modify-adult-heart-allocation-2016-2nd-round/.

In addition to the aforementioned general themes, some comments were submitted regarding the elimination of policy language for sensitized patients; most notably, from ISHLT.

Below is a summary of the key themes raised during the public comment period.

1. Changes Are Too Soon Following October 2018 *Modifications to the Adult Heart Allocation System* policy changes

Substantial changes to the adult heart allocation system were implemented in October 2018. The community has been waiting for comprehensive outcome data to be released analyzing the impact of the changes. In light of these changes, several commenters raised concerns about making any new changes regarding heart policy until the modifications implemented in October 2018 could be fully analyzed. The comments were made by individuals associated with transplant hospitals, regional meeting attendees, and by professional organizations. For example, in its response to the proposal, the Society of Thoracic Surgeons (STS) commented that while supporting the elimination of DSAs, the STS recommended delaying such a change until there is a better understanding of the October change, "particularly with regards to waitlist mortality, post-transplant survival, and cost." In addition to the factors just mentioned, others recommended waiting for outcome data to show the change in distance hearts were traveling after increasing the first offering from DSA to 500 NM. A commenter associated with a transplant hospital reported that since the October 2018 implementation, the hospital has received only one of 13 donor hearts that had become available within their local area.

Throughout the development of this proposal, the Committee acknowledged the importance of analyzing the outcome data associated with the policy changes implemented in October 2018. Those changes were part of a comprehensive overhaul of the heart allocation system. The established monitoring plan calls for the analysis of pre- and post-transplant outcome data on a six-month basis over a two to three year period. Moreover, some of the public comments appeared less specific to this proposal and more about the 2018 *Modifications*.

Nonetheless, both the HHS Secretary and the OPTN Executive Committee have notified the organ-specific committees to replace the use of DSAs and regions with more rational and defensible units of distribution. The Committee developed this proposal focusing on making heart allocation policy more consistent with the Final Rule and providing more equity in access to transplantation, regardless of a candidate's place of listing.

2. 250 NM Distance Is Too Far

Those opposed to the elimination of DSAs as a unit of distribution cited many of the same concerns that were expressed when modifications to the adult heart allocation were considered in 2016. The concerns addressed how extending beyond DSA could worsen outcomes and result in organ underutilization due to longer ischemic times associated with recovery teams having to go out to a 250 NM distance. Increased air travel was also cited as a disadvantage with changing the policy to 250 NM. As transplant programs are required to fly when traveling farther, they can expect their program costs to also increase. Some commenters also pointed out that increased air travel raises the risks of more frequent crashes and deaths among recovery team members.

Several of those who found 250 NM to be too far also questioned why 150 NM had not been chosen. For instance, commenters at a regional meeting asked if a 150 NM distance would accomplish the same goal of eliminating the use of DSAs, while also keeping organs in underserved rural areas. Other members of the community provided similar anecdotal comments regarding the export of "local" organs to more urban areas.

The Committee considered all of the public comments associated with eliminating DSAs and replacing them with a 250 NM distance from the donor hospital. As part of its discussions, the Committee relied on their medical experience, as well as all of the data analyses performed for the project, and the input of other OPTN committee whose constituencies could be impacted before making a final decision. For example, SRTR analysis found that simulated waitlist and post-transplant outcomes differed little nationally when comparing distances of 150 NM and 250 NM.[155] The simulations also analyzed urban versus rural outcomes based on candidate's home zip code. According to the analysis, for recipients living in rural areas, the ranges in travel distance for the 150 NM and 250 NM distances overlapped those in the DSA-first simulation, and the median distances were less than the DSA-first simulation. Furthermore, the median distances of the 150 NM and 250 NM distances were found to be very similar. As a result, it appears the 250 NM distance better achieves the Final Rule's mandate to distribute organs as geographically broad as possible.

After much deliberation, including a discussion of its decision to propose 250 NM instead of 150 NM, the Committee determined to keep the proposed geography-specific changes. The Committee indicated that the proposal is aligned with the Final Rule's mandates, including the requirement to share organs as broadly as feasible without negatively impacting cold ischemic time that would result in organ discards and negative post-transplant outcomes. Additionally, the Committee acknowledges that the continued use of DSAs are potentially in conflict with the Final Rule. The use of DSA as a proxy for geographic distance results in an inconsistent application of heart allocation policy for all candidates. While the Committee understands the increased distance will likely result in increased program costs, the members believed that the 250 NM distance was the best balance between equitable access and efficiency, while meeting the Final Rule requirement to distribute hearts as broadly as feasible.

3. 250 NM Is Not Far Enough and Limits Access to Organs

Multiple comments were received indicating that the use of a 250 NM distance from the donor hospital is too limiting. One commenter at a regional meeting reported that their offers would decline if 250 NM is implemented because many of their primary donor hospitals are just beyond that distance. Two commenters indicated that 250 NM may not be far enough as it applies to pediatric candidates. For example, a member of the Pediatric Committee asked if pediatric programs would benefit from having a larger distribution area as compared to the adult programs. Another commenter expressed a concern that the proposal does not appropriately account for the "scarcity" of pediatric trauma centers within 250 NM. The commenter also stated that the inclusion of adult status 1 and adult status 2 candidates in the allocation table of hearts from donors less than 18 years old would result in pediatric organs going to adult candidates.

As part of its post-public comment considerations, the Committee revisited its deliberations regarding several distances beyond 250 NM prior to submitting the proposal for public comment. As a result of those discussions, the Committee requested modeling of two 500 NM options. The Committee members also revisited their discussions of the policy changes' potential impact on pediatric members. At that time, the Committee reviewed the simulated waiting list analysis provided by SRTR. The results found that outcomes differed little by pediatric status group across all of the models. The exception was among pediatric status 1A candidates where the modeling indicated an increase in transplant rates in? 500 NM models when compared with the DSA-first approach. During development of the public comment proposal, the Committee also acknowledged that pediatric donor hearts have demonstrated resiliency in sustaining longer ischemic times than adult hearts (see Figures 2 and 3). Pediatric candidates in Status 1A also receive priority in the allocation of hearts from donors at least 18 years old within 500 NM. Additionally, pediatric candidates in Status 1A get broader distribution to 500 NM for donor hearts less than 18 years old, and then following consideration of adult statuses 1 and 2 at 250 NM, pediatric status 1B candidates get broader distribution to 500 NM. Based on the modeling results and the other factors discussed in the proposal, the Committee believed that maintaining the current distances is appropriate and meets the Final Rule's mandates concerning sound medical judgment.

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[155] SRTR, Analysis Report: Data Request from the Heart Sub-Committee of the OPTN Thoracic Committee, October 12, 2018, pp. 7-9.

4. 250 NM Is Appropriate

Public comments from individuals and professional organizations, along with regional feedback, endorsed the appropriateness of the 250 NM distance. Committee members confirmed that the comments helped support their decisions. The Committee's intention in proposing a 250 NM distance from the donor hospital was to mitigate travel time expected to have a clinically significant effect on ischemic time and organ quality. Furthermore, the Committee believed the distance would better balance distributing hearts more broadly while mitigating any negative impact to organ utilization.

Both the American Society of Transplant Surgeons (ASTS) and the Heart Failure Society of America (HFSA) supported the proposed distance. ASTS' support was based on the potential that replacing DSA with a 250 NM distance may balance access issues with cost and logistical challenges associated with the other modeled distances. HFSA' response cited how the different sizes, shapes, and populations within DSAs leads to the inconsistent application of allocation policy for all candidates. HFSA indicated that the proposal's intent of eliminating DSA as a geographic unit of distribution will lead to greater equity in access to transplant regardless of a candidate's place of residence. Several comments submitted by individuals also supported the proposed distance as means for prioritizing medical urgency above location or arbitrary DSA boundaries.

5. Consideration of Removal of Sensitized Candidates Policy

Although not rising to the level of a general theme, some comments were received about eliminating the policy for sensitized candidates. ISHLT was one of three commenters addressing the proposal's recommendation to eliminate *Policy 6.4.B Exceptions to Allocation for Sensitized Patients*. While stating that elimination of the policy is "reasonable due to its impracticality and lack of use," ISHLT's response also recommended that the Committee should begin collaborating with the Histocompatibility Committee immediately to develop an optimal solution for sensitized heart transplant candidates. The Committee considered the comments regarding the potential impact of the policy change on sensitized candidates, along with the other information collected and analyzed when making the recommendation. From the discussions, the Members still agreed to strike policy.

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 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.[156]

How does this proposal comply with the Final Rule?

A critical objective of the Final Rule is to achieve the most equitable and medically effective use of donated human organs.[157] Towards that goal, the Final Rule directs the OPTN to overcome as much as possible arbitrary geographic barriers that restrict the allocation of organs to patients with the greatest medical urgency.[158] In developing this proposal, the Committee considered the Final Rule's equitable allocation criteria as set forth in Section 121.8 as follows:

[156] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.
[157] Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,650 (October 20, 1999).
[158] Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,651 (October 20, 1999).

- **Shall be based on sound medical judgment:** The Committee based its decisions on evidence such as SRTR modeling[159], published literature,[160] and their collective experience in the field of thoracic transplantation. The Committee also collaborated with other OPTN committees representing particular patient groups or perspectives during development of the proposal.
- **Shall seek to achieve the best use of donated organs:** The Committee reviewed and discussed the results of the SRTR modeling on waiting list mortality as measured by the life-years gained through transplantation.[161] The Committee also identified waitlist time and post-transplant survival as secondary factors for consideration.
- **Shall be designed to avoid wasting organs:** The Committee members determined early in their deliberations that they would be unlikely to support a distance between donor and candidate where modeling showed a significant decrease in the number of transplants As part of their analysis, the Committee reviewed the findings of the lung allocation monitoring report, which showed minimal change in organ utilization rates, because of the similar ischemic times between hearts and lungs.
- **Shall be designed to avoid…futile transplants:** When considering geographic distance, the Committee used data analysis associating worsened post-transplant outcomes among heart transplant recipients with greater than four hours of ischemic time to help identify an appropriate distance that would limit futile transplants.[162]
- **Shall be designed to…promote patient access to transplantation:** The Committee used findings from SRTR modeling of waitlist mortality outcomes associated with removing DSA to help in its assessment of whether transplant candidates have equitable access to transplant.[163] The Committee also relied on SRTR modeling of the potential impact of broader sharing on various populations, including waiting list candidates living in rural areas, those who are minorities, and those with particular blood types.
- **Shall be designed to…promote the efficient management of organ placement:** The Committee relied on simulation modeling of potential travel distances and the available information about costs and transplant team availability to help it assess the efficiency of the proposals.
- **Shall not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** The Committee focused on methods to distribute hearts as broadly as geographically feasible. In doing so, the members considered previous SRTR modeling data from the changes to the adult heart and lung distribution systems, as well as OPTN descriptive data. They also relied on their collective medical experience with organ transplantation.

Although the framework variations outlined in this briefing paper address certain aspects of the Final Rule listed above, Committee discussions did not demonstrate impacts on the following aspects of the Final Rule:

- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
- Shall be reviewed periodically and revised as appropriate;

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[159]Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.

[160] See e.g. : Lund et al. Thirty-fourth Adult Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time."; 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; 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

[161] Scientific Registry of Transplant Recipients, SRTR HR2018_01, October 12, 2018.

[162] 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.

[163] Scientific Registry of Transplant Recipients, Analysis Report: Data Request from the Heart Sub-Committee of the OPTN Thoracic Committee, SRTR HR2018_01, October 12, 2018.

- Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.

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 regarding the use of DSAs in the distribution of hearts, which is an important and time sensitive issue regarding the management of the OPTN.

What are the potential costs associated with this proposal?

Member

Changing heart allocation could result in cost increases for organ recovery. While cost data are limited, some research findings indicate that transportation-related costs associated with more frequent and longer flights with recovery teams, will be the primary cost driver.[164] Accessibility of planes and pilots, use of either commercial or charter flights, and potential complications from additional organ ischemic time are variables that may impact transplant center cost. It is uncertain if additional costs beyond prepaid standard cases rate are reimbursable. Centers often negotiate contracts that may not allow for reimbursement for unexpected costs, such as chartered flights.

Additional staff hours or new positions may be needed to accommodate the greater length of time and complexity per transplant. Complexities from longer travel (ischemic time) may result. Positions with additional demands can include on-call procurement staff, and clinical staff, such as surgeons, nurse practitioners, or physician's assistants. Staff impact would vary depending on program size and location.

Some of the estimated cost increases may be offset by reduced costs for pre-transplant care, transplant episode, and post-transplant care. Additionally, if a local recovery team is used instead of a transplant hospital sending its own team, this may also reduce costs and complexity. On the other hand, if recipients experience longer lengths of stay, costs may increase.

There are other variables that may affect the cost per transplant. Transplant of local organs is usually more cost efficient than imported organs. Since each thoracic program may have a unique payer mix, including Medicare and commercial payers, the ability to be reimbursed for additional unexpected costs through commercial contracts may be challenging. Despite average cost per transplant decreasing or increasing due to change in volume, the ability to be reimbursed is paramount.

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[164] Puri et al., "Unintended Consequences of Changes to Lung Allocation Policy," *American Journal of Transplantation*, https://doi.org/10.1111/ajt.15307 (2019). Lehman and Chan, "Elimination of the Donor Service Area (DSA) from Lung Allocation: No Turning Back," *American Journal of Transplantation*, https://doi.org.10.1111/ajt.15413 (2019).

Implementation is estimated at 1-3 months to allow for OPO and transplant hospital staff education and planning.

UNOS

Modification to the heart allocation requires a high level of collaborative effort to develop, implement, and monitor changes. Research and Policy and Community Relations estimated about 400 hours in analysis and committee work in proposal development. The IT department requires just under 2,000 hours (Large Effort) to program modification of the donor match acceptance criteria to account for geographic changes for organs that are considered local and non-local. Communications will execute a comprehensive notification plan, including various notices, and education to inform the community of changes (less than 100 staff hours). Both Research and IT will continue to monitor the new allocation and analyze outcomes for OPTN committees and the public.

How will the OPTN implement this proposal?

UNet℠ programming changes are required. Changes will be made to the adult and pediatric heart match allocations to replace DSA with a 250 NM circle from the donor hospital. In addition, lung allocation classification titles will have "zone" references removed. The nautical mile distance will be referenced in policy and used for programming instead of "zone" for both heart and lung allocation. There will be no functional changes to lung allocation and updated language is considered a clerical change for consistency across heart and lung classification labels.

The OPTN will follow regular processes to inform members and educate them on any policy changes through policy notices. The OPTN will deliver communications to the membership to promote knowledge, awareness, and compliance related to policy and system changes in advance of implementation. Additionally, staff will develop an educational offering to further support this proposal. Instructional support for this proposal may be a part of a larger educational effort related to the elimination of DSAs and regions in all organ distribution systems.

How will members implement this proposal?

Transplant Hospitals

As a result of the increased distance, some transplant hospitals will receive offers from OPOs with whom they have not worked previously. Transplant hospitals may need to develop relationships with all OPOs within a travel distance the transplant hospital believes is realistic for obtaining an organ. Furthermore, under the broadened relationships, transplant hospitals may need to adjust their operations to account for the practices of their new OPO partners, including how they communicate with one another.

The changes to heart distribution may also impact overall transplantation 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. Transplants hospitals may want to establish a process for sharing organ acquisition cost information as part of their outreach to new OPOs.

OPOs

OPOs will continue allocating donor organs through the match runs. OPOs that will be working with transplant hospitals for the first time may want to consider developing working relationships to address issues such as sharing donor information and coordinating recoveries.

OPO practices may also be impacted by the modifications to the adult and pediatric heart allocation sequences that will be implemented. Such changes, may impact OPO costs, as well.

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 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 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 review, and members are required to provide documentation as requested.

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

The 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/percent of transplants stratified by distance (NM) between donor hospital and transplant hospital
- Unadjusted post-transplant patient survival stratified by distance (NM) between donor hospital and transplant hospital
- Volume of transplants by de-identified heart transplant hospitals
- Distribution of the distance (NM) between donor hospital and transplant hospital, 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 hospital
- Distribution of ischemic time (hours) for heart transplants, including range, IQR, mean, and median

These reports will be presented to the 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 (example) 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~~ 250 nautical miles from 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
14	Adult status 3 or pediatric status 1B and secondary blood type	~~Zone A~~ 500NM

	match with the donor	
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
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	~~Zone D~~ 2500NM

	1A and primary blood type match with the donor	
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
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	~~Zone C~~ 1500NM

	blood type match with the donor	
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
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
13	Adult status 3 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
14	Adult status 3 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
15	Adult status 4 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
16	Adult status 4 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM
17	Adult status 5 and primary blood type match with the donor	~~OPO's DSA~~ 250NM
18	Adult status 5 and secondary blood type match with the donor	~~OPO's DSA~~ 250NM

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

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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
51	Pediatric status 1A and primary blood type match with the donor	~~Zone C~~ 1500NM
52	Pediatric status 1A and secondary blood type match with the donor	~~Zone C~~ 1500NM
53	Adult status 1 and primary blood type match with the donor	~~Zone C~~ 1500NM
54	Adult status 1 and secondary blood type match with the donor	~~Zone C~~ 1500NM
55	Adult status 2 and primary blood type match with the donor	~~Zone C~~ 1500NM
56	Adult status 2 and secondary blood type match with the donor	~~Zone C~~ 1500NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ <u>registered at a transplant hospital that is within this distance from the donor hospital</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>
70	Pediatric status 1A and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
71	Adult status 1 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
72	Adult status 1 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
73	Adult status 2 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
74	Adult status 2 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
75	Pediatric status 1B and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>

Classification	Candidates that are ~~within the~~	And ~~are:~~ <u>registered at a transplant hospital that is within this distance from the donor hospital</u>
76	Pediatric status 1B and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
77	Adult status 3 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
78	Adult status 3 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
79	Adult status 4 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
80	Adult status 4 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
81	Adult status 5 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
82	Adult status 5 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
83	Pediatric status 2 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
84	Pediatric status 2 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
85	Adult status 6 and primary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
86	Adult status 6 and secondary blood type match with the donor	~~Zone D~~ <u>2500NM</u>
87	Pediatric status 1A and primary blood type match with the donor	~~Zone E~~ <u>Nation</u>
88	Pediatric status 1A and secondary blood type match with the donor	~~Zone E~~ <u>Nation</u>
89	Adult status 1 and primary blood type match with the donor	~~Zone E~~ <u>Nation</u>
90	Adult status 1 and secondary blood type match with the donor	~~Zone E~~ <u>Nation</u>
91	Adult status 2 and primary blood type match with the donor	~~Zone E~~ <u>Nation</u>
92	Adult status 2 and secondary blood type match with the donor	~~Zone E~~ <u>Nation</u>
93	Pediatric status 1B and primary blood type match with the donor	~~Zone E~~ <u>Nation</u>
94	Pediatric status 1B and secondary blood type match with the donor	~~Zone E~~ <u>Nation</u>

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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

Classification	Candidates that are ~~within the~~	And ~~are:~~ <u>registered at a transplant hospital that is within this distance from the donor hospital</u>
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~~ <u>250NM</u>
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~~ <u>250NM</u>
5	Priority 2, blood type identical to the donor	~~Zone A~~ <u>250NM</u>
6	Priority 2, blood type compatible with the donor	~~Zone A~~ <u>250NM</u>
7	At least 12 years old, blood type identical to the donor	~~Zone B~~ <u>500NM</u>
8	At least 12 years old, blood type compatible with the donor	~~Zone B~~ <u>500NM</u>
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~~ <u>500NM</u>
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~~ <u>500NM</u>
11	Priority 2, blood type identical to the donor	~~Zone B~~ <u>500NM</u>

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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
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

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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
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

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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.

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 compatible offers	~~Zone A, Zone B, or Zone C~~ 1000NM

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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
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

Classification	Candidates that are ~~within the~~	And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital
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
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

Classification	**Candidates that are ~~within the~~**	**And ~~are:~~ registered at a transplant hospital that is within this distance from the donor hospital**
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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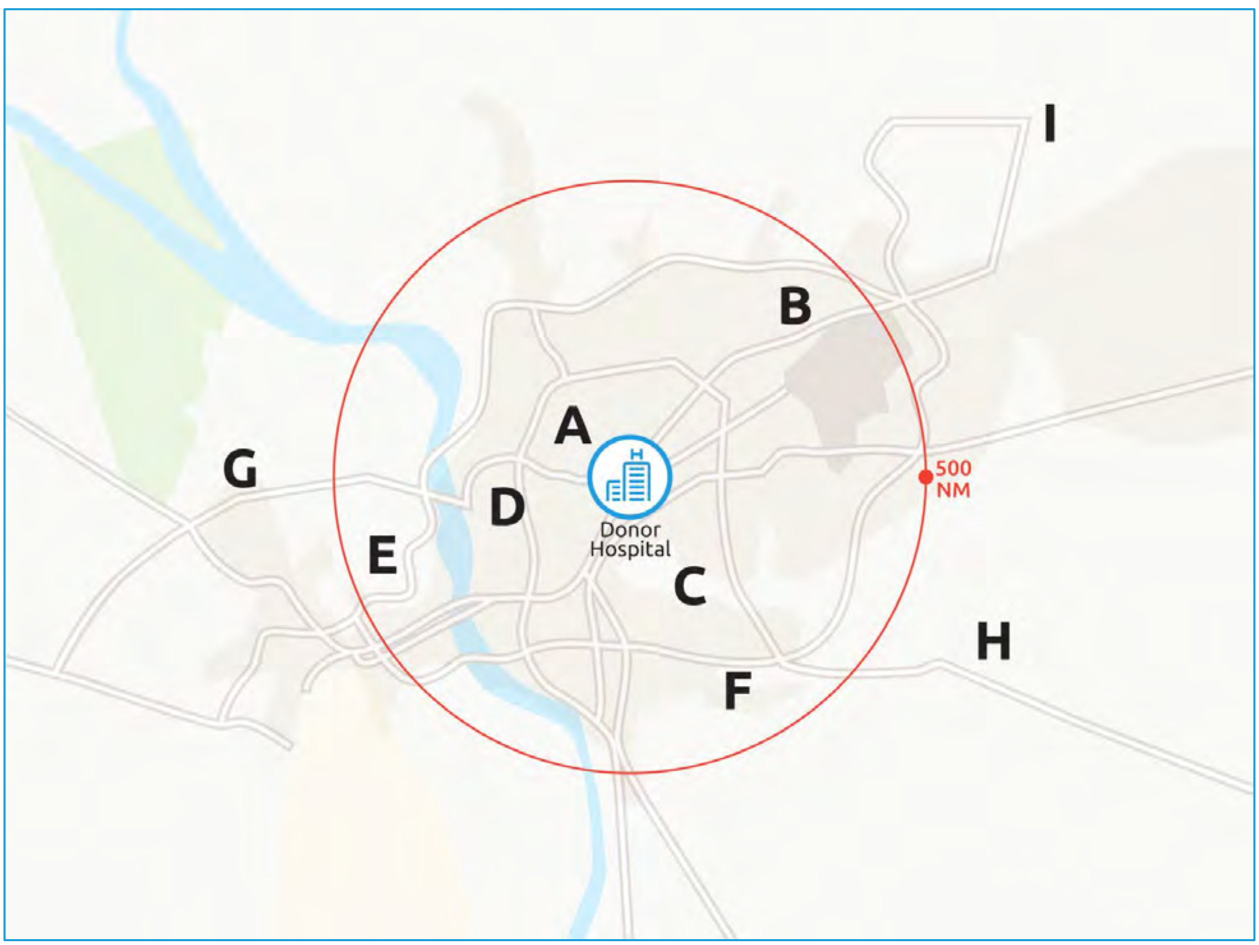
Appendix A: Description of Heart Allocation Sequences Under Modeling of 250 Nautical Mile Distance From Donor Hospital

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:

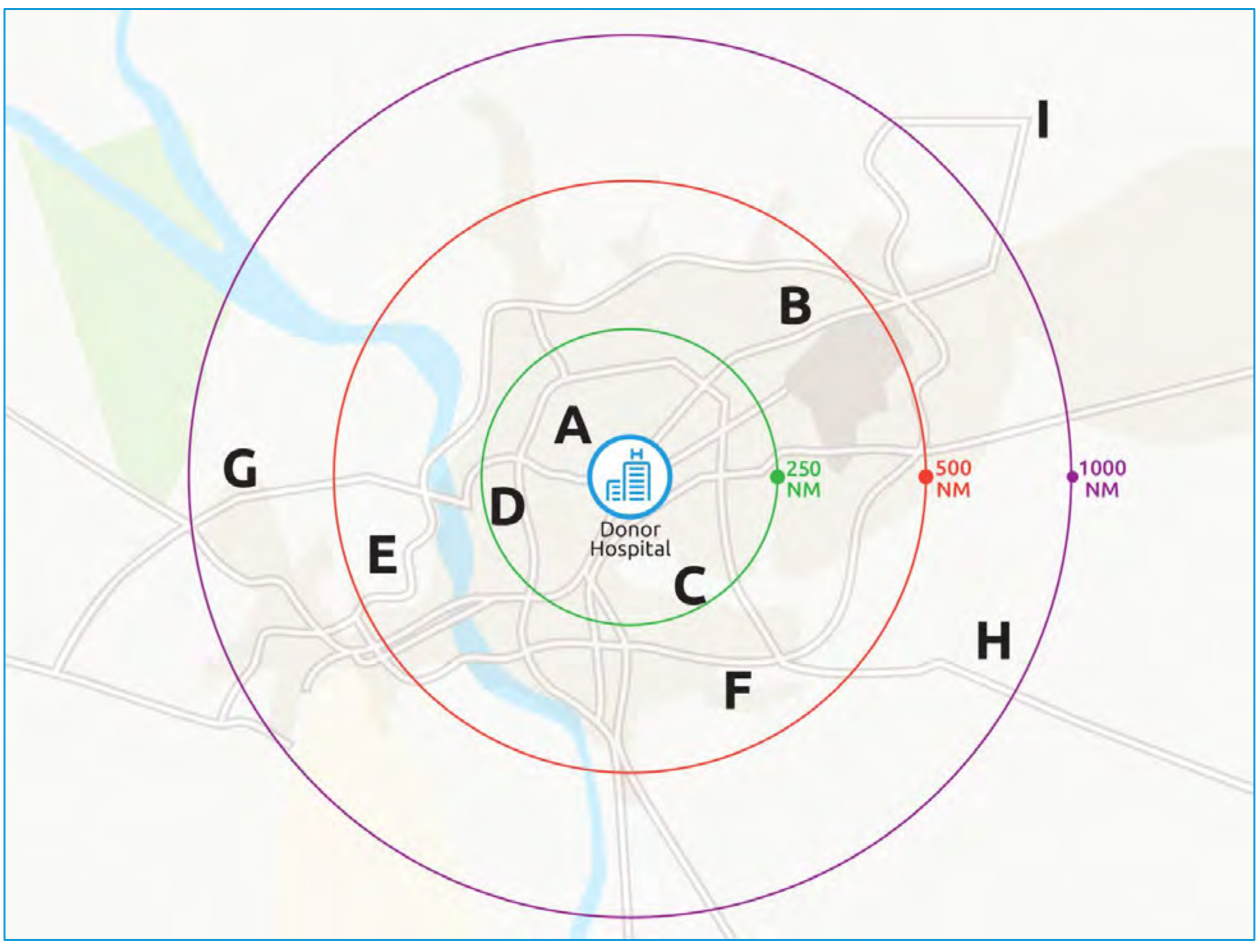
- Adult Status 3 or pediatric Status 1B candidates at hospitals within 250 nautical miles of the donor hospital
- Adult Status 1 or pediatric Status 1A candidates at hospitals within 1,000 nautical miles of the donor hospital
- Adult Status 2 candidates within 1,000 miles of the donor hospital

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.