Concept Paper

OPTN/UNOS Kidney and Pancreas Committees

Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution

Scott Castro M.P.P. and Abigail Fox M.P.A.
UNOS Policy & Community Relations Department

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Executive Summary

The Final Rule (hereafter "Final Rule") sets requirements for allocation polices developed by the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS), including the use of sound medical judgement, achieving the best use of organs, preserving the ability for centers to decide whether to accept an organ offer, avoiding wasting organs, avoiding futile transplants, promoting patient access to transplantation and promoting efficiency.[1] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of registration, except to the extent required" by the other requirements of the Final Rule.[2]

In the past year, the United States Secretary of Health and Human Services (HHS) received critical comments regarding the OPTN/UNOS's compliance with the National Organ Transplant Act (NOTA) and the Final Rule with respect to the geographic units used in lung and liver distribution.[3,4,5] The OPTN/UNOS made rapid changes to eliminate using donation service area (DSA) and OPTN/UNOS regions (regions) in lung and liver distribution, respectively.[6,7] Furthermore, the OPTN/UNOS Executive Committee directed the organ-specific committees to analyze their distribution systems and replace DSAs and regions with more rational units of distribution.[8]

Policy 8: Allocation of Kidney and *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets* currently use DSA and region as geographic units of distribution.[9] These are poor proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs and regions result in an inconsistent application for all candidates. As noted in Department of Health and Human Services Administrator Sigounas's letter to the OPTN/UNOS President, "DSAs and Regions have not and cannot be justified" under the regulatory requirements of the Final Rule.[10]

Members of the OPTN/UNOS Kidney Transplantation Committee, joined by members from the OPTN/UNOS Pancreas Transplantation Committee and the OPTN/UNOS Pediatric Transplantation Committee, created the Kidney/Pancreas Workgroup (hereafter "the Workgroup") in order to remove DSA and region from kidney and pancreas allocation policies. The Workgroup reviewed OPTN/UNOS data on current distribution practices, engaged Workgroup members on their collective clinical experience, and

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[1] 42 C.F.R. § 121.8(a).
[2] 42 C.F.R. § 121.8(a)(8).
[3] NOTA, 42 U.S.C. § 273 et. seq.
[4] Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.
[5] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.
[6] *OPTN/UNOS Policy Notice Modifications to the Distribution of Deceased Donor Lungs*, OPTN/UNOS Thoracic Organ Transplantation Committee, July 2018, https://optn.transplant.hrsa.gov/media/2539/thoracic_policynotice_201807_lung.pdf, (accessed December 27, 2018).
[7] *OPTN/UNOS Policy Notice Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf (accessed January 21, 2019).
[8] Meeting Summary for August 1, 2018 meeting, OPTN/UNOS Executive Committee, https://optn.transplant.hrsa.gov /media/2609/20180801_executive_meetingsummary.pdf (accessed January 3, 2019).
[9] OPTN/UNOS Policy 11, *Allocation of Pancreas, Kidney-Pancreas and Islets* (accessed January 3, 2019).
[10] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.

utilized the OPTN/UNOS Board of Directors' "Geographic Organ Distribution Principles and Models"[11] to develop five potential allocation options that would eliminate DSA and region from kidney and pancreas allocation policies.

The five variations that the Workgroup chose to model are:

1. A fixed concentric circle framework with a 150 nautical mile (NM) small circle and a 300 NM large circle
2. A fixed concentric circle framework with a 250 NM small circle and a 500 NM large circle
3. A fixed concentric circle framework with a single 500 NM circle
4. A hybrid framework with a single 500 NM circle that utilizes a small number of proximity points inside and outside of the circle, and
5. A hybrid framework with a single 500 NM circle that utilizes a large number of proximity points inside and outside of the circle.

These variations will be more comprehensively outlined in this paper's "**What Concepts Are Being Considered?"** section. The Workgroup is not limiting itself to consideration of solely these five variations, but rather used these variations as choices to model in the Kidney/Pancreas Simulated Allocation Model (KPSAM) in order to most strategically determine what could be the ideal variation. The Workgroup understands that, given community feedback and additional evidence gathered, it is possible that the framework and variation ultimately selected by the Workgroup may be a combination of these variations, or perhaps a new variation, such as a single-circle hybrid with a smaller concentric circle.

The Workgroup is currently considering these five variations for modifying kidney and pancreas allocation policy to be more consistent with the Final Rule and to provide more equity in access to transplantation regardless of a candidate's place of residence or registration, except to the extent required by §121.8 (a)(1)-(5) of the Final Rule. The Workgroup requests community feedback in order to better inform the evidence-gathering and decision-making processes.

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

The Workgroup encourages all interested individuals to comment on the proposal in its entirety. The Workgroup requests specific feedback on variations for modifying kidney and pancreas distribution that were modeled by the Scientific Registry of Transplant Recipients (SRTR) (for discussion of the SRTR modeling, see "What are the concepts being considered?"). These variations are:

1. 150 NM/300 NM circles: This would replace DSA with a 150 NM circle and region with a 300 NM circle in the allocation tables for kidney and pancreas.

2. 250 NM/500 NM circles: This would replace DSA with a 250 NM circle and region with a 500 NM circle in the allocation tables for kidney and pancreas.

3. 500 NM circle, no points: This would replace DSA with one 500 NM circle and remove region from kidney and pancreas allocation tables.

4. 500 NM circle, shallow points: This would replace DSA with one 500 NM circle and remove region from kidney and pancreas allocation tables. Candidates registered at transplant hospitals within 500 NM of the donor hospital would receive up to **one** point depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals further than 500 NM of the donor hospital (allocation classifications that are national) would receive up to **two** points depending on the transplant hospital's proximity to the donor hospital. Proximity points would add to scores awarded within current classification tables and affect candidate placement on an organ match run.

[11] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

5. 500 NM circle, steep points: This would replace DSA with one 500 NM circle and remove region from kidney and pancreas allocation tables. Candidates registered at transplant hospitals within 500 NM of the donor hospital would receive up to **two** points depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals farther than 500 NM of the donor hospital (allocation classifications that are national) would receive up to **four** points depending on the transplant hospital's proximity to the donor hospital.

Members of the community should indicate why one or more variations would be a better replacement of the current distribution system compared to the other options being considered. Specifically, the Workgroup appreciates feedback grounded in evidence tied to the Final Rule, such as the impact on efficiency in organ placement or on achieving the best use of donated organs. Furthermore, the community should indicate preferences between the two framework types (fixed concentric circle vs. hybrid) and comment on the defining characteristics of each, such as the size of circles and the number of proximity points that should be awarded.

It is important to note that the Workgroup intends to gather additional evidence through SRTR analysis, OPTN/UNOS data, and relevant literature while this concept paper is being reviewed by the community. This additional evidence, along with community feedback, will inform a policy proposal to modify kidney and pancreas geographic distribution that is compliant with the Final Rule and could result in a variation that has not yet been modeled by the Workgroup. Community feedback can help inform specifically which of the two framework types might best align with the Final Rule and how variables within those variations, such as circle size or number of proximity points, could be altered to achieve that end.

The Workgroup also seeks feedback from the community on whether the pancreas distribution system should be separate from the kidney distribution system. Most pancreata are distributed with kidneys as simultaneous pancreas-kidney transplants (SPKs),[12] and the kidney and pancreas allocation systems have long been intertwined. While it may be confusing and lead to inefficiencies to have different distribution systems for kidney and pancreas, there could be reasons that it may be necessary such as differing tolerance of ischemic times for the organs and conflicts with Final Rule requirements regarding best use of organs, avoiding organ wastage, and promoting efficiency.[13] The Workgroup asks the community for feedback, based on the Final Rule, regarding whether it would be reasonable to have a different distribution system for pancreas compared to kidney and why (see "**How was this concept developed?**" for discussion of the pancreas-specific concerns).

[12] 2018 OPTN/UNOS data (accessed January 3, 2019).
[13] 42 C.F.R. § 121.8(a).

Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution

Sponsoring Committees: OPTN/UNOS Kidney Transplantation Committee, OPTN/UNOS Pancreas Transplantation Committee

Public Comment Period: January 22 – March 22, 2019

What problem will this concept solve?

The Final Rule sets requirements for allocation polices developed by the OPTN/UNOS, including the use of sound medical judgement, achieving the best use of organs, avoiding wasting organs, avoiding futile transplants, promoting patient access to transplant, and promoting efficiency.[14] The Final Rule also requires that allocation policies "shall not be based on the candidate's place of residence or place of registration, except to the extent required" by the other requirements of Section 121.8(a)(1)-(5) of the Final Rule.[15] Finally, the Final Rule contains 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".[16]

The requirement to distribute over a broad geographic area reflects a consensus understanding 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."[17] The Institute of Medicine (IOM) made this same conclusion in 1999.[18] In 2012, the American Medical Association (AMA) Code of Medical Ethics stated that, "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."[19] The Department of Health and Human Services (HHS) has stated this same principle several times in public rulemaking.[20,21] Most recently, the OPTN/UNOS Board of Directors adopted new Principles of Organ Distribution. Those principles reaffirm that "deceased donor organs are a national resource to be distributed as broadly as feasible."[22] This paper proposes allocation framework variations

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[14] 42 C.F.R. §121.8(a).
[15] 42 C.F.R. §121.8(a)(8).
[16] 42 C.F.R. §121.8(b)(3).
[17] 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.
[18] National Academies Press, "Organ Procurement and Transplantation." (1999).
[19] American Medical Association, "Opinion 2.16. Organ Transplantation Guidelines." Journal of Ethics. March 2012, Volume 14, Number 3: 204-214. doi: 10.1001/virtualmentor.2012.14.3.coet1-1203.
[20] 98 FR 16490, June 22, 1988. Page 33863. "We know that hospitals, OPOs, and tissue and eye banks share our view that organs and tissues are a precious national resource and that only through the collaborative efforts of all parties can lives be saved." https://www.gpo.gov/fdsys/pkg/FR-1998-06-22/html/98-16490.htm (accessed January 3, 2019).
[21] 12 76 FR 78216. Dec. 16, 2011. Page 78218. "One of the major reasons NOTA was enacted and affirmed by several amendments was to establish an organ allocation system that functions equitably on a nationwide basis with provisions for outcomes reporting and evaluation. Prior to the enactment of NOTA, deceased donor organs were allocated regionally, based on relationships between transplant programs and donor hospitals.
[22] 13 Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

to address the removal of DSA and region from kidney and pancreas organ allocation policies specifically. Other OPTN/UNOS organ-specific committees are currently considering their own allocation policy changes based on these Board directives.

Each of the variations of the two frameworks relies on a rationale based on the Final Rule. Specifically, Workgroup members provided evidence and clinical experience throughout the process thus far to provide possible rationale for each of the variations in one or more of the following requirements set forth in Section 121.8, that organ allocation:

- **Shall be based on sound medical judgement** by basing the decisions of the Workgroup on evidence such as SRTR modeling, published literature, the clinical and operational experience of committee members and input from stakeholder committees
- **Shall seek to achieve the best use of donated organs** by monitoring in the SRTR modeling the impact on waitlist mortality and the volume of transplants
- **Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate** by selecting the distance points based upon the clinical limitations of each organ (i.e., when transportation methods change from driving to flying and cold ischemic time limitations)
- **Shall be designed to avoid wasting organs** by considering variaitons with distribution distances that reflect limits on clinical ischemic times when necessary and monitoring the impact on the number of organ transplants in the SRTR modeling.
- **Shall be designed to promote patient access to transplantation** by monitoring the impact on waitlist mortality and waiting time in the SRTR modeling by urbanicity, insurance type, on pediatric patients, and minority populations
- **Shall be designed to promote the efficient management of organ placement** by limiting travel distance based on data indicating when the distribution method shifts from driving to flying and reflecting the current distribution of kidneys and pancreata
- **Shall not be based on the candidate's place of residence or place of listing**, except to the extent required by the factors listed above[23] by monitoring the impact on waitlist mortality and waiting time in the SRTR modeling by geography

Although the framework variations outlined in this concept paper address certain aspects of the Final Rule listed above, Workgroup discussions and review of SRTR analysis 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 designed to avoid futile transplants,
- Shall be reviewed periodically and revised as appropriate;
- 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;

Policy 8: Allocation of Kidney and *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets* currently use DSA and region as geographic units of organ distribution. These are not good proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations result in an inconsistent application for all candidates. As noted in Department of Health and Human Services Administrator Sigounas's letter to the OPTN/UNOS President, "DSAs and Regions have not and cannot be justified" under the regulatory requirements of the Final Rule and the principle of distribution that organs are a national resource meant to be allocated based on patients' medical need.

[23] 42 C.F.R. §121.8(a).

What are the concepts being considered?

The Workgroup is currently considering several variations of two frameworks, each grounded on the principles of the Final Rule and based on sound medical judgement, evidence gathered from existing data, and results from simulation allocation modeling conducted by the SRTR. The Workgroup considered and rejected the option of a national allocation system with no limitations on geographic distribution for either kidney or pancreas. There are specific concerns with the impact that such a system would have on the efficiency of organ management, best use of organs and organ loss. While each of the variations considered constrain distribution in some way, the constraints account for the increase in inefficiency and travel costs that may result from a national system while still increasing distribution compared to the current system. Additionally, Workgroup members expressed concern about best use of organs and potential increases in organ loss due to increased ischemic time, which can impact graft outcomes. The five variations under consideration are:

1. <u>150 NM/300 NM circles:</u> This would replace DSA with a 150 NM circle and region with a 300 NM circle in the allocation tables for kidney and pancreas.
2. <u>250 NM/500 NM circles:</u> This would replace DSA with a 250 NM circle and region with a 500 NM circle in the allocation tables for kidney and pancreas.
3. <u>500 NM circle, no points:</u> This would replace DSA with one 500 NM circle and eliminate current regional allocation classifications.
4. <u>500 NM circle, shallow points:</u> This would replace DSA with one 500 NM circle and eliminate current regional allocation classifications. Candidates registered at transplant hospitals within 500 NM of the donor hospital would receive up to **one** point depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals further than 500 NM of the donor hospital (allocation classifications that are national) but within 2500 NM of the donor hospital would receive up to **two** points depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals further than 2500 NM from the donor hospital would receive **no** additional points.
5. <u>500 NM circle, steep points:</u> This would replace DSA with one 500 NM circle and eliminate current regional allocation classifications. Candidates registered at transplant hospitals within 500 NM of the donor hospital would receive up to **two** point depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals further than 500 NM of the donor hospital (allocation classifications that are national) but within 2500 NM of the donor hospital would receive up to **four** points depending on the transplant hospital's proximity to the donor hospital. Candidates registered at transplant hospitals further than 2500 NM from the donor hospital would receive **no** additional points.

Within these variations, organs will be allocated according to their current classification tables, which include mandatory national distribution exceptions, such as those for 100 percent Calculated Panel Reactive Antigens (CPRA) candidates.

In addition, the Workgroup considered the possibility of developing separate distribution frameworks for kidney and pancreas allocation. The rationale for pursuing separate policies centered on the inherent differences between pancreas and kidney transplantation, including better tolerance for longer ischemic time for kidney compared to pancreas, geographically , differing issues with supply and demand for pancreata compared to kidneys, differences in procurement practices, and fewer and more spread out pancreas programs. Although kidney and pancreas have long been intertwined and distributed as simultaneous pancreas-kidney (SPK), pancreata are more similar to livers than kidneys in the tolerance for ischemic time. This lower tolerance for longer cold ischemic time for pancreata presents a contrast to kidney transplantation and may impact potential acceptable travel distances. However, it is important to note that the distribution of pancreas transplants (for pancreas alone) is currently broader overall than kidney transplants and kidney-pancreas transplants, as is evidenced by Figure 9. Additionally, some Workgroup members expressed concerns that separate distribution systems could lead to inefficiencies and complications in the two allocation policies, especially for programs that perform SPK transplants.

The Workgroup recognizes that evidence gathered from current kidney and pancreas allocation practices presents limitations because it was collected from a system utilizing DSAs and regions as frameworks for geographic allocation. Additionally, modeling conducted by the SRTR presents limitations because the KPSAM is limited in its ability to predict changes in donor recovery or, transplant hospital offer acceptance that could occur with any change in kidney and pancreas allocation policy.

Finally, the OPTN/UNOS Kidney Transplantation Committee is considering the possibility of incorporating work on currently-paused projects regarding further prioritization of pediatric and prior living donor candidates within the Kidney Allocation System KAS) classification tables into the forthcoming proposal. This deliberation will continue in close collaboration with the OPTN/UNOS Pediatric and OPTN/UNOS Living Donor Committees and has unanimous support within the OPTN/UNOS Kidney Transplantation Committee.

1. Fixed Concentric Circles: 150 NM/300 NM Circles

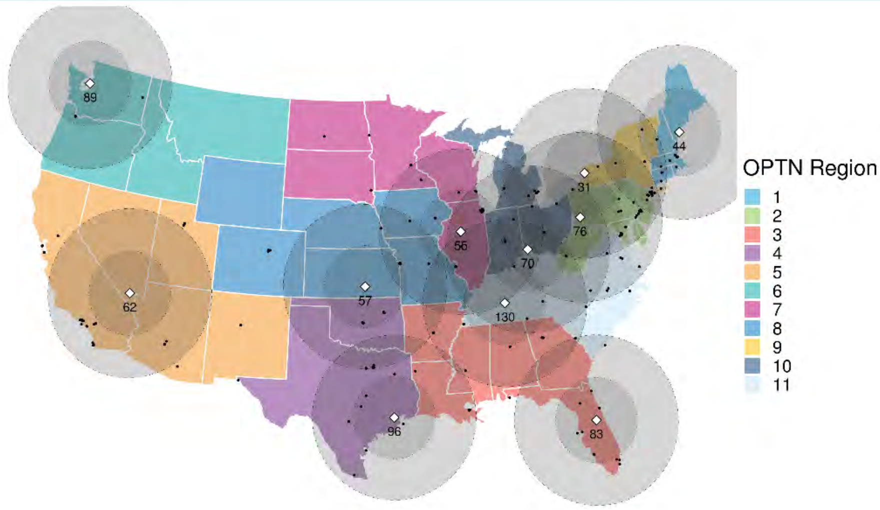
The first variation under consideration by the Workgroup is a variation of the "Organ Distribution Based on Fixed Distance from the Donor Hospital" framework presented to the OPTN/UNOS Board of Directors in the OPTN/UNOS Ad Hoc Geography Committee's Recommendations Report in June 2018.[24]

In this variation of the framework, "DSA" would be replaced in kidney and pancreas allocation policies with "a 150 NM circle from the donor hospital" and "region" would be replaced with "within a 300 NM circle from the donor hospital" before moving to national distribution.

Figure 1 below shows all kidney transplant hospitals with 150 NM and 300 NM circles around the top volume donor hospitals in each OPTN/UNOS region (in the contiguous United States) in order to illustrate how distribution would appear in different regions across the country, with darker circles representing a 150 NM radius and lighter circles representing a 300 NM radius. Numbers within the circles indicated the number of kidney donors recovered and transplanted at those donor hospitals between January 1, 2017 and November 30, 2018.The black dots represent all active kidney transplant programs during the same time period in the contiguous United States.

[24] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

Figure 1: Top Volume Donor Hospitals within each OPTN/UNOS Region with 150 NM and 300 NM Circles



Diamonds represent largest volume donor hosptial in each OPTN region in the contiguous US.

Numbers represent number of deceased kidney donors recovered and transplanted at largest volume donor hospital in each OPTN region in the contiguous US.

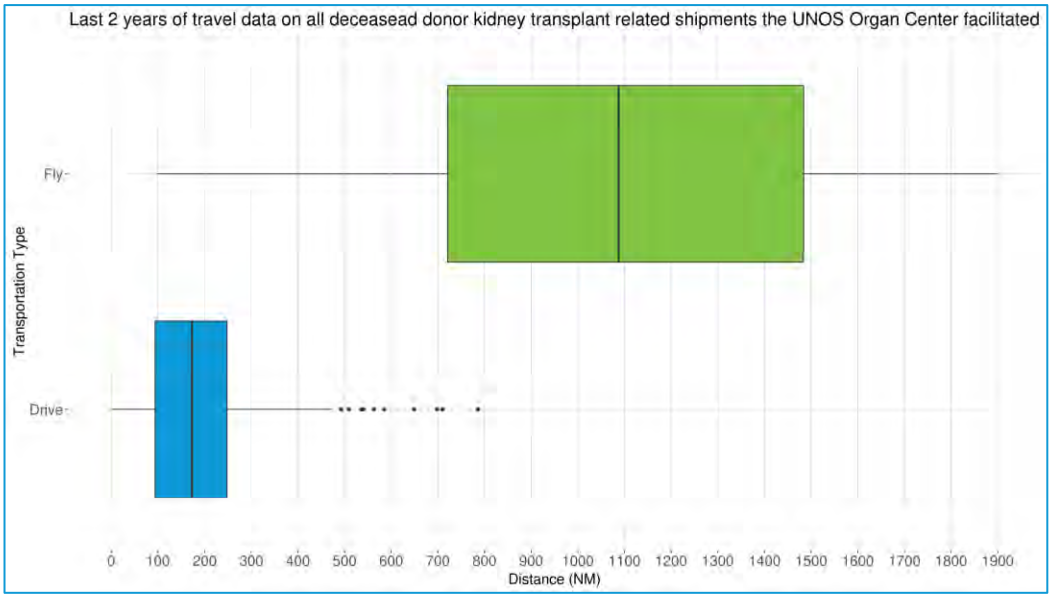
Dots represent active kidney transplant programs in the contiguous US.

Kidney and pancreas allocation would not be modified except to change geographic distribution: "DSA" and "region" would be removed and replaced with a 150 NM and 300 NM circle, respectively. Within each allocation classification, candidates within the 150 NM circles would receive organ offers before candidates in the 300 NM circle and candidates in the 300 NM circle would receive organ offers before candidates outside of the 300 NM circle (i.e. national), except for those exceptions outlined in current allocation policy, such as highly sensitized candidates. The classification tables within kidney and pancreas policies would still determine the order in which potential transplant recipients would appear on the match run.

These circles sizes were developed by the Workgroup based on clinical experience as well as data collected under the current allocation system.

Figure 2 below represents transportation type and distance for deceased donor kidney transplant related organ placements facilitated by the UNOS Organ Center. The KP Workgroup determined that this data illustrates how the 150 NM and 300 NM circles could represent points of interest in changes in transportation, from driving to flying. The lines represent the first and third quartiles, while the middle line in each box represents the median. Dots represent outliers.

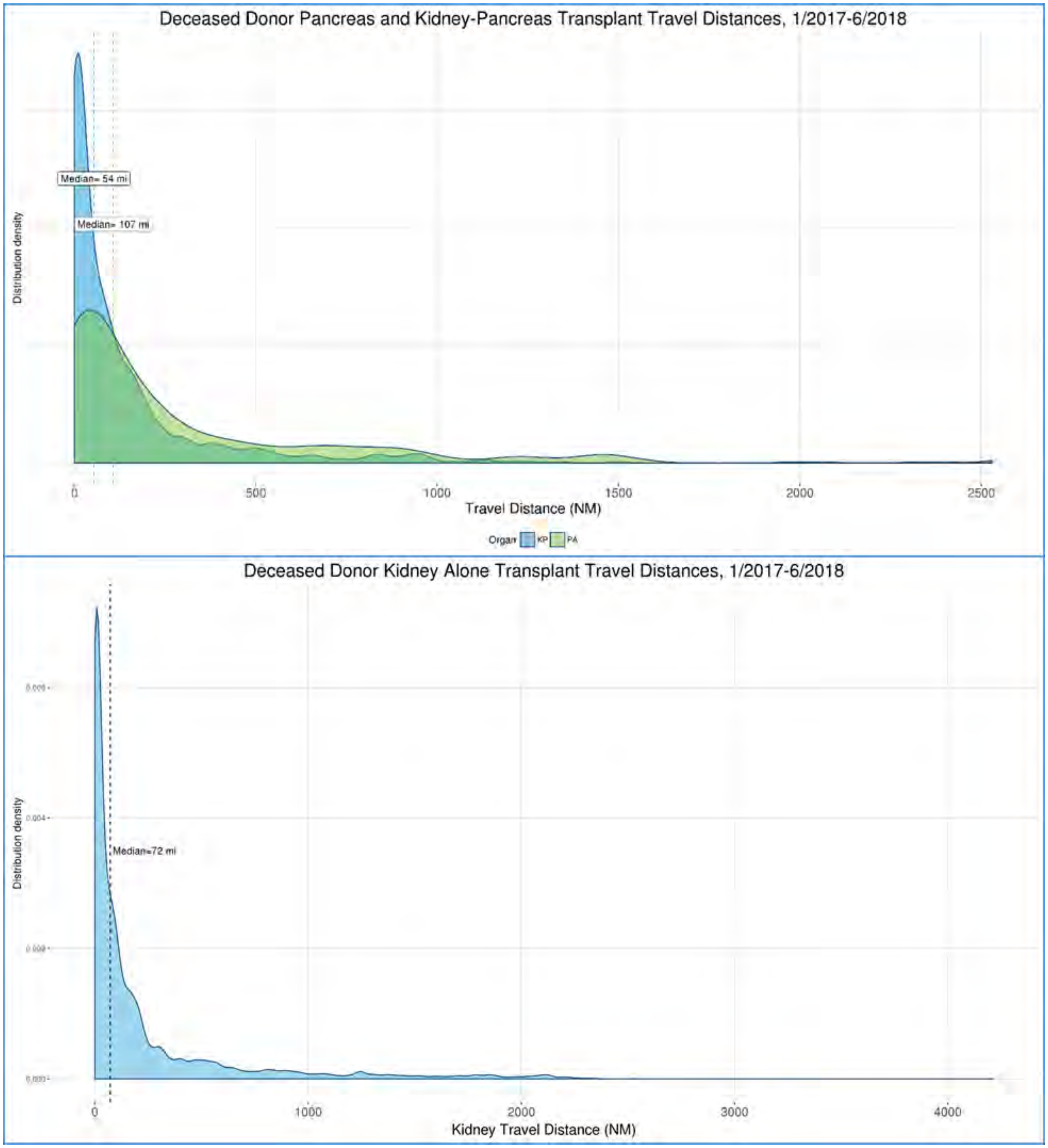
Figure 2: Travel Method and Distance for Deceased Donor Kidneys 06/2016 – 07/2018 (UNOS Organ Center)



The median driving distance for deceased donor kidney related transplants facilitated by the UNOS Organ Center is close to 150 NM. Some outliers lie beyond the typical range for driving these deceased donor kidneys; however, a 300 NM circle would encompass a large majority of the kidneys driven but does not limit the majority of kidneys that were flown (those kidneys saw a median travel distance of approximately 1100 NM). Thus the smaller 150 NM circle would reflect a distance that would promote efficiency of organ placement.

There is no UNOS organ center data on transportation type for kidney-pancreas (KP) and pancreas transplants. However, the Workgroup considered data that approximates the distance traveled for pancreata by calculating the straight-line distance between zip code centroids. Figure 3 shows that, on average, pancreata used for pancreas-alone traveled farther than for KP (this is also reflected in Figure 9: Distribution of Organ Travel Distance (SRTR)). The median distance is 54 NM for KP and 107 NM for pancreas. Figure 3 demonstrates that pancreata mostly travel a limited distance, with the number of KP and pancreas transplants traveling more than the range of 150 and 250 NM falling steeply. In this case, the smaller 150 NM circle would support the limited travel distances of KP transplants to promote efficiency in organ placement, in alignment with the Final Rule.

Figure 3: Travel Distance for Deceased Donor Pancreata, KP, and Kidneys (UNOS Research Department)



Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results in Figure 4 and Figure 5, below (see "**How was this concept developed?"** for discussion of the data request). Each model was run with 10 iterations to provide a measure of variability. The average results, along with the minimum and maximum, are provided. "BL" represents outcomes in baseline (current) policy, and modeled outcomes for the 150 NM/300 NM fixed concentric circles variation are represented on the row labeled "2CR_150," highlighted in yellow.

Figure 4: Outcomes Metrics for Five Proposed Framework Variations, Kidney (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.122 (0.121, 0.123)	13473 (13373, 13536)	0.048 (0.047, 0.048)	5262 (5247, 5279)	0.116 (0.109, 0.124)
1CR_nopts	0.105 (0.105, 0.106)	11727 (11665, 11839)	0.048 (0.048, 0.048)	5308 (5299, 5320)	0.12 (0.115, 0.124)
1CR_shallow	0.106 (0.105, 0.106)	11739 (11669, 11823)	0.048 (0.048, 0.048)	5312 (5300, 5326)	0.119 (0.113, 0.131)
1CR_steep	0.106 (0.105, 0.106)	11767 (11710, 11816)	0.048 (0.048, 0.048)	5305 (5298, 5317)	0.12 (0.113, 0.131)
2CR_150	0.112 (0.111, 0.113)	12399 (12319, 12486)	0.048 (0.047, 0.048)	5289 (5263, 5312)	0.118 (0.108, 0.129)
2CR_250	0.108 (0.107, 0.109)	11981 (11894, 12084)	0.048 (0.048, 0.048)	5300 (5292, 5309)	0.119 (0.113, 0.126)

Figure 5: Outcomes Metrics for Five Proposed Framework Variations, Kidney-Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.503 (0.49, 0.515)	944 (923, 961)	0.053 (0.05, 0.055)	99 (95, 103)	0.223 (0.195, 0.266)
1CR_nopts	0.599 (0.589, 0.608)	1081 (1074, 1089)	0.053 (0.051, 0.055)	96 (92, 99)	0.228 (0.203, 0.284)
1CR_shallow	0.599 (0.587, 0.605)	1081 (1071, 1089)	0.053 (0.051, 0.054)	95 (91, 98)	0.228 (0.198, 0.272)
1CR_steep	0.601 (0.592, 0.61)	1084 (1069, 1095)	0.052 (0.05, 0.054)	94 (91, 98)	0.215 (0.186, 0.276)
2CR_150	0.555 (0.549, 0.566)	1020 (1011, 1029)	0.052 (0.05, 0.055)	96 (92, 100)	0.219 (0.197, 0.236)
2CR_250	0.584 (0.577, 0.59)	1060 (1046, 1072)	0.053 (0.05, 0.055)	96 (91, 100)	0.227 (0.186, 0.261)

For kidney, each of the proposed variations shows a decrease in transplant rate and in transplant count, with minimal to no changes in waitlist mortality rate in patient years, waitlist mortality count in patient years, and graft failure rate in patient years. Modeling also projected a decrease in transplant count and rate for pancreas alone. For kidney-pancreas, an increase in transplant rates and counts was projected, but similar to kidney, waitlist mortality rate held steady across modeling options (Figure 5). According to the SRTR analysis report, “the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there's a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[25,26] It should be noted, however, that the 150 NM/300 NM fixed circles variation shows the smallest decreases in transplant rate and transplant count among the five proposed variations. The kidney post-transplant graft failure counts and rates shown in modeling of the 150 NM/300 NM fixed circles variation were slightly higher compared to the baseline, but did not show a significant increase.[27] For KP and pancreas, post-transplant graft failure was lower for the 150 NM/300 NM variation compared to the other modeling variations. It is important to note that the modeling could not incorporate data that reflected the new pancreas graft failure definition, which was implemented in 2018.[28]

Waitlist mortality was virtually identical across the runs.[29] SRTR modeling of transplant rates by insurance type showed an increase for Medicaid and Medicare compared to private insurance for KP transplants, a similar rate of Medicare and private transplant rate for kidney, and a transplant rate for pancreas that was similar across insurance type. SRTR modeling showed overlapping transplant rates for kidney and pancreas by urbanicity, with a slight increase across urbanicity subgroups for KP. The modeling showed a relatively higher transplant rate for candidates with higher cPRAs across kidney, pancreas and KP compared to lower cPRA candidates. The KPSAM demonstrated an increase in transplant rate across pediatric subgroups compared to adult populations. Additionally, the modeling showed relatively more kidney and pancreas transplants occurring in African-American recipients compared to white recipients. For KP, there was a similar increase across ethnicity categories. For kidney, there was a slight projected increase in transplant rate for candidates with more than 10 years of dialysis time. This evidence indicates that the options considered may not negatively impact patient access to transplant by increasing disparity, and could improve access for some subpopulations.[30]

The Workgroup determined that this 150 NM/300 NM fixed concentric circle framework variation aligns with the principles in the Final Rule and the corresponding Board-approved Principles of Distribution, as this framework considers a candidate's geographic location to the extent required to achieve allocation policies based on sound medical judgement and promote the best use of organs, as evidenced by limited impact on graft outcomes. Evidence of similar waitlist mortality and potential benefits to vulnerable subgroups including pediatric, highly sensitized, and African-American populations indicate that this variation would not have a negative impact on patient access to transplant. Furthermore, choosing 150NM and 300NM circles which indicate the median driving distance and inflection point between driving and flying, respectively, promotes the efficient management of the OPTN/UNOS, ensuring the variation is structured in a way that reduces travel costs compared to variations with much broader distribution.

It would be difficult to justify limiting kidney distribution to 150 NM when other organs tolerate shorter ischemic times to maintain organ quality but use an initial distribution circle of 250 NM.[31] While pancreas tolerance for longer ischemic time is significantly lower than kidney and a limiting factor for travel distance, it is similar to liver ischemic time, and liver distribution is being changed to reflect an initial distribution circle of 250 NM.[32]It is important to note that kidneys can tolerate cold ischemic times (CIT)

[25] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[26] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.
[27] Scientific Registry of Transplant Recipients, SRTR KI2018_01, December 7, 2018.
[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December, 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf, (accessed January 3, 2019).
[32] Ibid.

longer than other organs, some of which have already chosen distribution levels beyond 150 NM.[33] It may be difficult to rationalize limiting kidney distribution to 150 NM when other organs that can only tolerate shorter ischemic times to maintain organ quality but use an initial distribution circle of 250 NM.[34] While pancreas tolerance for longer ischemic time is significantly lower than kidney and a limiting factor for travel distance, it is similar to liver ischemic time, and liver distribution is being changed to reflect an initial distribution circle of 250 NM.[35]

Additionally, it should be considered that transportation method may reflect geography rather than the type of organ being distributed so it is relevant to consider evidence gathered by other organ-specific committees reviewing transportation methods. Specifically, the OPTN/UNOS Liver and Intestinal Committee collected evidence indicating a shift in transportation method from driving to flying around 200 NM.[36]

2. Fixed Concentric Circles: 250 NM/500 NM Circles

The second variation under consideration by the Workgroup is another variation of the "Organ Distribution Based on Fixed Distance from the Donor Hospital" framework as presented to the OPTN/UNOS Board of Directors in the OPTN/UNOS Ad Hoc Geography Committee's Recommendations Report in June 2018.[37]

In this variation of the framework, "DSA" and "region" would be removed and replaced with a 250 NM and 500 NM circle, respectively. Within each allocation classification, candidates within the 250 NM circles would receive organ offers before candidates in the 500 NM circle and candidates in the 500 NM circle would receive organ offers before candidates outside of the 500 NM circle (i.e. national), except for those exceptions outlined in current allocation policy, such as highly sensitized candidates. The classification tables within kidney and pancreas policies would still determine the order in which potential transplant recipients would appear on the match run.

Figure 6 below shows all kidney transplant hospitals with 250 NM and 500 NM circles around the top volume donor hospitals in each OPTN/UNOS region in order to illustrate how distribution would appear in different regions across the country. Numbers within the circles indicated the number of kidney donors recovered and transplanted at those donor hospitals between January 1, 2017 and November 30, 2018. The black dots represent all active kidney transplant programs during the same time period in the contiguous United States.

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[33] *Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution*, OPTN/UNOS Thoracic Organ Transplantation Committee, January, 2019.

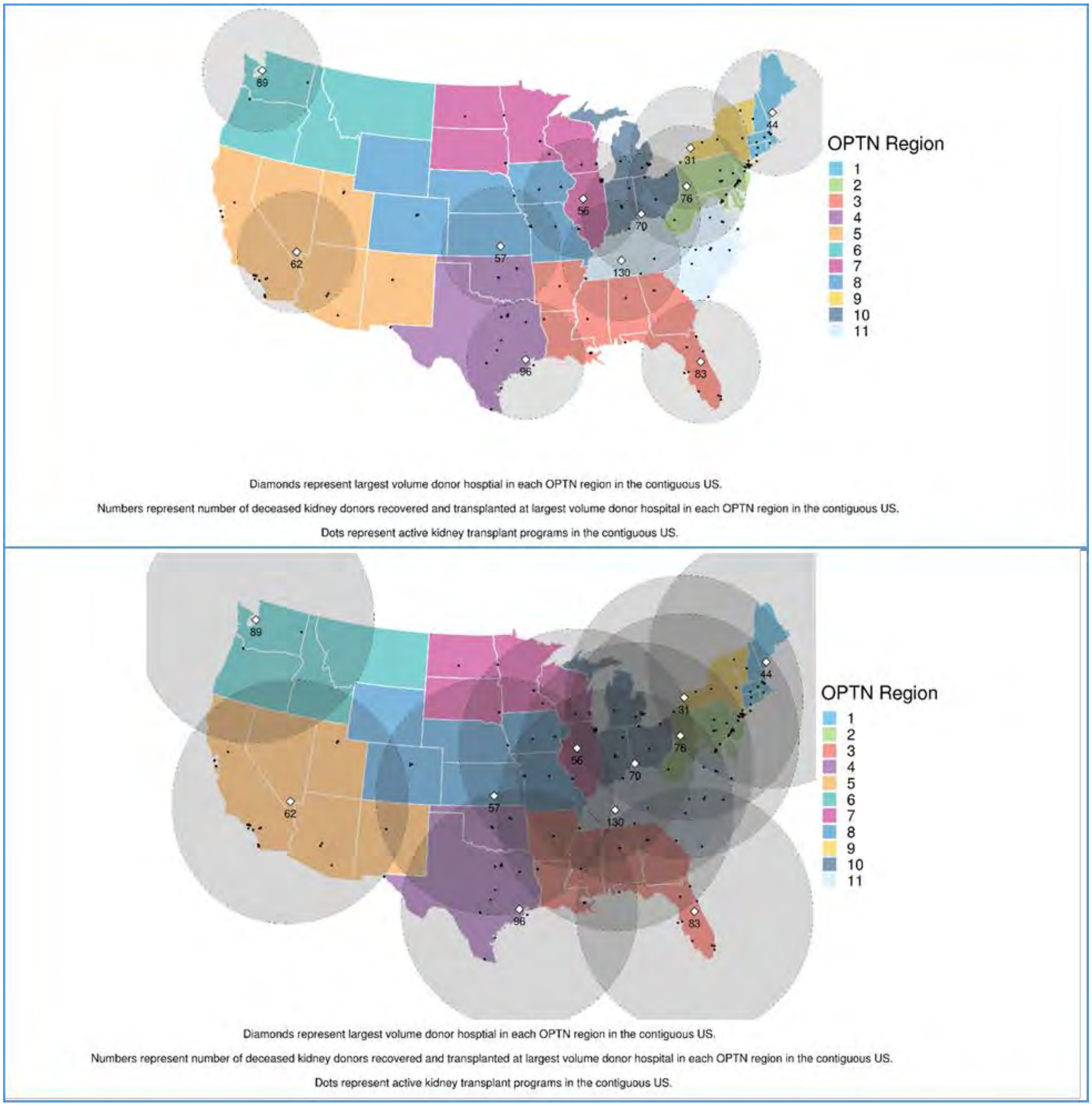
[34] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December, 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf, (accessed January 3, 2019).

[35] Ibid.

[36] *Executive Summary of OPTN/UNOS Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 13, 2018, https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf, (accessed January 3, 2019).

[37] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

Figure 6: Top Volume Donor Hospitals within each OPTN/UNOS Region with 250 NM and 500 NM Circles



These circles sizes were developed by the Workgroup based on clinical experience as well as data collected under the current allocation system. Most kidneys facilitated by the UNOS Organ Center are driven about 250 NM[38], while UNOS research data demonstrates that around 75 percent of kidneys and 80 percent of pancreata and KP are placed within 250 NM of the donor hospital. Figure 2 represents transportation type and distance for deceased donor kidney transplant related shipments facilitated by the UNOS Organ Center. It is important to note that transportation method may reflect geography rather than the type of organ being distributed so it is relevant to consider evidence gathered by other organ-specific committees reviewing transportation methods. Specifically, the OPTN/UNOS Liver and Intestinal Committee collected evidence indicating a shift in transportation method from driving to flying around 200

[38] 2018 OPTN/UNOS data (accessed January 4, 2019).

NM.[39] The UNOS Organ Center data, current distribution patterns, and evidence on liver distribution indicates that the smaller circle of 250 NM would reflect a distance that would promote efficiency of organ placement.

Figure 7 illustrates how deceased donor kidneys were transplanted between January 2017 and June 2018 were allocated by distance, with local, regional, and national distribution being depicted in blue, green and orange, respectively. Figure 8 illustrates how pancreata and KP transplanted between January 2017 and June 2018 were allocated by distance, with local, regional, and national distribution being depicted in blue, green, and orange, respectively.

Figure 7: Kidney Cold Ischemic Time vs. Travel Distance

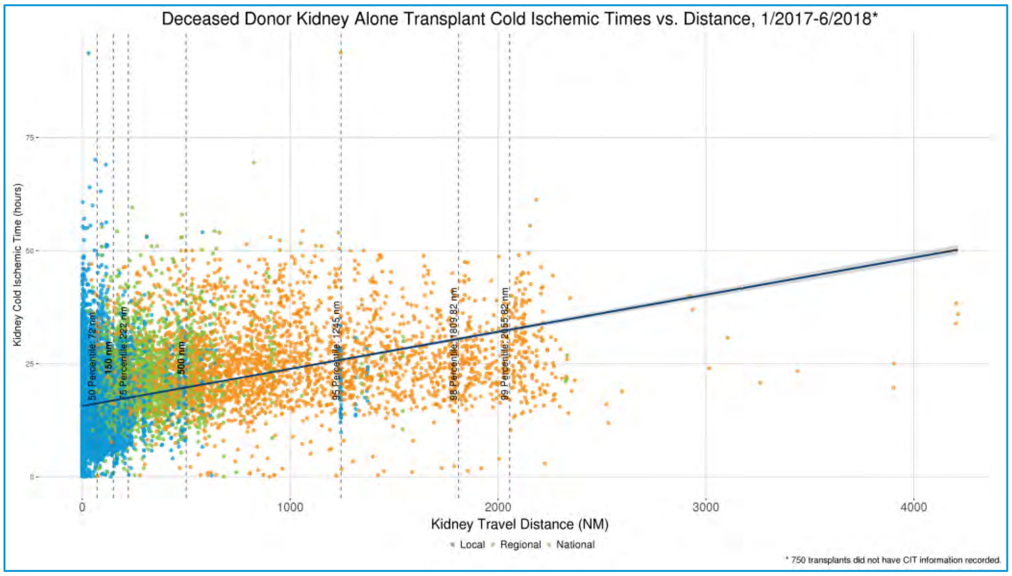
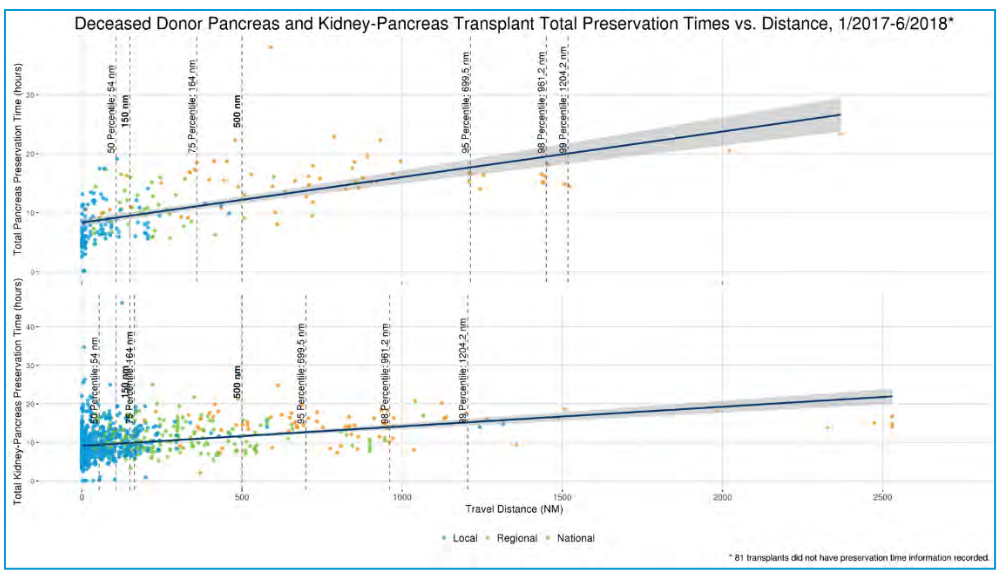


Figure 8: Pancreas and KP Cold Ischemic Time vs. Travel Distance



[39] *Executive Summary of OPTN/UNOS Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 13, 2018, https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf, (accessed January 3, 2019).

A large majority of kidneys are distributed locally and regionally, with 50 percent of kidneys being distributed within 75 NM, 75 percent of kidneys being distributed within 222 NM, and approximately 80 percent of kidneys being distributed within 500 NM. The majority of pancreata are also distributed locally and regionally, with 50 percent of pancreata distributed within 54 NM and 75 percent of pancreata being distributed within 164 NM. The Workgroup determined that a 500 NM circle would be a rational boundary to achieve the best use of organs and promote an efficient organ placement system by limiting travel distance for kidney transplantation based on this data collected under current allocation polices, because these data may support the notion that organs are more likely to be transplanted when allocated closer to the donor hospital, thus reducing travel costs unless based on other principles of the Final Rule, such as sound medical judgement or best use of organs. The Workgroup acknowledges that the data is limited by reflecting current allocation practices that are shaped by distribution using DSA and region. Therefore, the Workgroup supplemented its review of current data with SRTR modeling to demonstrate the potential impact of a distribution system, understanding that these data possess their own limitations, as previously stated.

Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results in Figure 4 and Figure 5. “BL” represents outcomes in baseline (current) policy, and modeled outcomes for the 250 NM/ 500 NM fixed concentric circles variation are represented on the row labeled “2CR_250” as seen in Figure 4 and Figure 5 (highlighted in yellow) and replicated below.

Figure 4: Outcomes Metrics for Five Proposed Framework Variations, Kidney (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.122 (0.121, 0.123)	13473 (13373, 13536)	0.048 (0.047, 0.048)	5262 (5247, 5279)	0.116 (0.109, 0.124)
1CR_nopts	0.105 (0.105, 0.106)	11727 (11665, 11839)	0.048 (0.048, 0.048)	5308 (5299, 5320)	0.12 (0.115, 0.124)
1CR_shallow	0.106 (0.105, 0.106)	11739 (11669, 11823)	0.048 (0.048, 0.048)	5312 (5300, 5326)	0.119 (0.113, 0.131)
1CR_steep	0.106 (0.105, 0.106)	11767 (11710, 11816)	0.048 (0.048, 0.048)	5305 (5298, 5317)	0.12 (0.113, 0.131)
2CR_150	0.112 (0.111, 0.113)	12399 (12319, 12486)	0.048 (0.047, 0.048)	5289 (5263, 5312)	0.118 (0.108, 0.129)
2CR_250	0.108 (0.107, 0.109)	11981 (11894, 12084)	0.048 (0.048, 0.048)	5300 (5292, 5309)	0.119 (0.113, 0.126)

Figure 5: Outcomes Metrics for Five Proposed Framework Variations, Kidney-Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.503 (0.49, 0.515)	944 (923, 961)	0.053 (0.05, 0.055)	99 (95, 103)	0.223 (0.195, 0.266)
1CR_nopts	0.599 (0.589, 0.608)	1081 (1074, 1089)	0.053 (0.051, 0.055)	96 (92, 99)	0.228 (0.203, 0.284)
1CR_shallow	0.599 (0.587, 0.605)	1081 (1071, 1089)	0.053 (0.051, 0.054)	95 (91, 98)	0.228 (0.198, 0.272)
1CR_steep	0.601 (0.592, 0.61)	1084 (1069, 1095)	0.052 (0.05, 0.054)	94 (91, 98)	0.215 (0.186, 0.276)
2CR_150	0.555 (0.549, 0.566)	1020 (1011, 1029)	0.052 (0.05, 0.055)	96 (92, 100)	0.219 (0.197, 0.236)
2CR_250	0.584 (0.577, 0.59)	1060 (1046, 1072)	0.053 (0.05, 0.055)	96 (91, 100)	0.227 (0.186, 0.261)

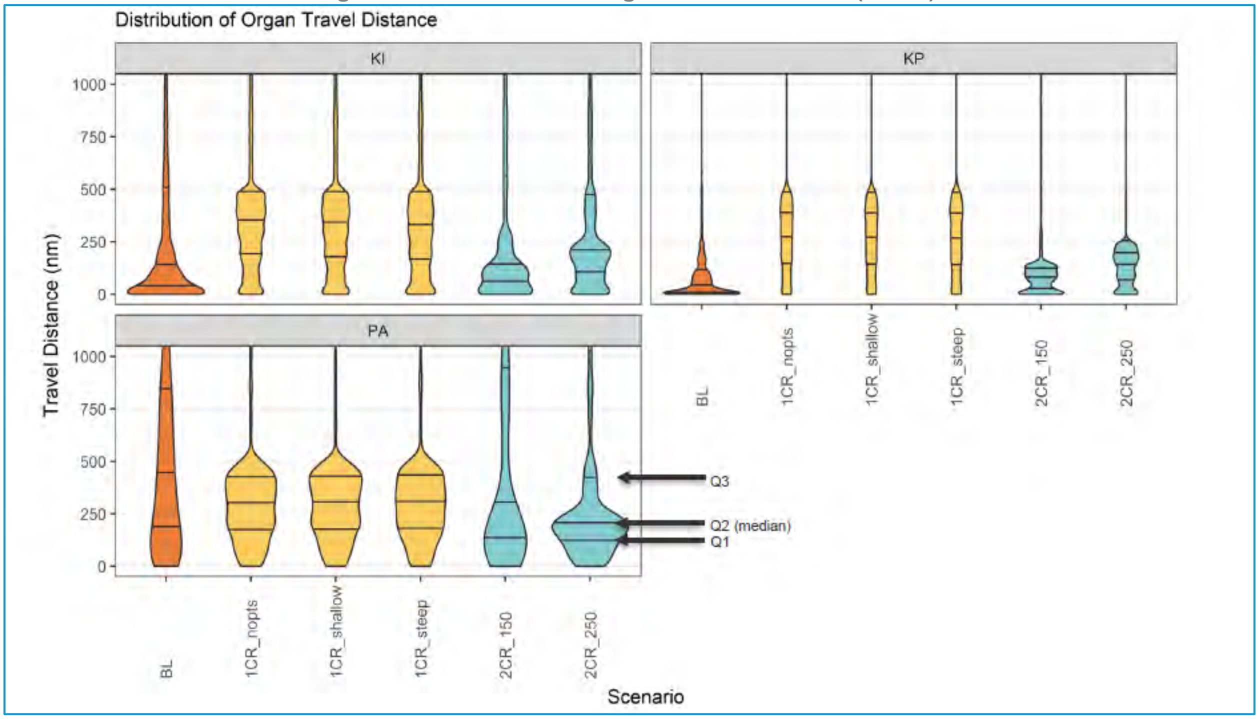
According to the SRTR analysis report, "the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there's a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[40,41]

The Workgroup determined that this 250 NM/500 NM fixed concentric circle framework variation aligns with the OPTN/UNOS Final Rule and the corresponding Board-approved Principles of Distribution. Specifically, a broader circle of 500 NM reflects an inflection point of kidney transplantation distances that aligns with sound medical judgment and promoting the best use of organs, while 250 NM represents a reasonable driving distance that serve to promote the efficient management of organ placement.

One of the key takeaways from the SRTR modeling requested by the Workgroup as it pertains to the fixed concentric circles modeling variations are the projected changes in the shape of distribution by distance. At their October 15, 2018 meeting, the majority of the OPTN/UNOS Kidney Committee agreed that broader distribution of kidneys is a value that they would like to see strengthened in whichever framework variation is selected.[42] The OPTN/UNOS Board of Directors, as evidenced by the Board-approved principle of distribution that "organs should be distributed as broadly as is feasible."[43] Figure 9, replicated below, illustrates how the shape of the distribution profile would be changed by each of the five framework variations for kidney, pancreas, and simultaneous kidney-pancreas allocations.

[40] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[41] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.
[42] Meeting Summary for October 15, 2018 meeting, OPTN/UNOS Kidney Committee, https://optn.transplant.hrsa.gov/media/2743/20181015_ kidney_committee _minutes.pdf (accessed January 3, 2019).
[43] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed November 16, 2018).

Figure 9: Distribution of Organ Travel Distance (SRTR)



In Figure 9, the top left square represents kidney allocation, the top-right square represents kidney-pancreas allocation, and the bottom-left square represents pancreas allocation. Each of the five proposed variations would broaden allocation of kidney and kidney-pancreas distribution when compared to the baseline, which represents allocation under the current policy. By contrast, pancreas alone allocation is projected to be distributed less broadly overall. As noted before, pancreas alone allocation represents a minority of all pancreas transplants, with a majority being comprised of KP transplants. Some members of the Workgroup expressed that the two fixed concentric circle variations represent the most viable options, as they most closely mirror the shape of distribution under current allocation policy. However, as stated at the December 2018 OPTN/UNOS Board meeting, the requirements outlined in the Final Rule are interpreted to mean that organ-specific committees and Workgroups would have to justify choosing a narrow distribution based on the Final Rule, and a lack of disruption from one allocation framework to another is not one of those requirements outlined therein.[44] The Workgroup intends to continue this dialogue after receiving community input.

3. 500 NM Circle, No Points

The third variation under consideration by the Workgroup is a fixed concentric circle framework variation with a single 500 NM circle.

This framework variation represents a hybrid between the fixed concentric circle framework and a continuous distribution framework as defined in the OPTN/UNOS Ad Hoc Geography Committee report, "Frameworks for Organ Distribution."[45]

[44] Executive Summary of OPTN/UNOS Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 13, 2018, https://optn.transplant.hrsa.gov/media/2787/ board_executivesummary_201812.pdf. (accessed January 3, 2019).

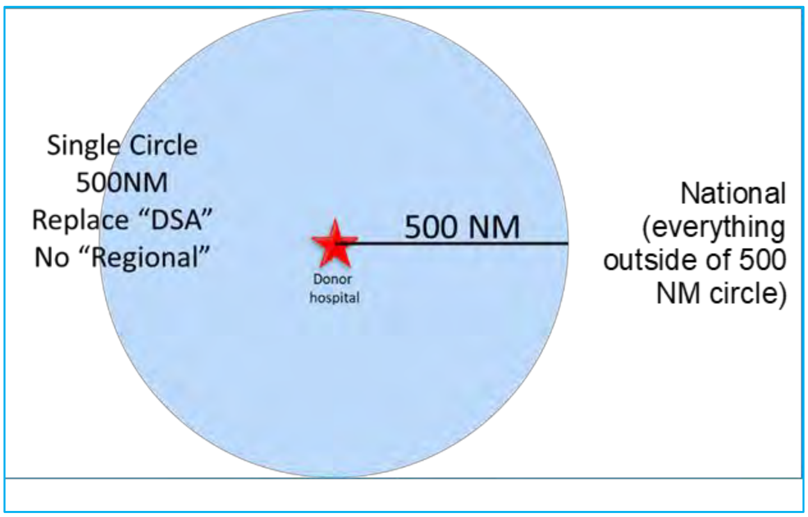
[45] *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Committee on Geography, August 2018, https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/ (accessed December 26, 2018).

Within the context of this framework, instances of DSA would be replaced with “a 500 NM fixed distance circle from the donor hospital” in both kidney and pancreas allocation policy, and regional classifications would be eliminated from allocation policies. Additionally, the Workgroup has considered removing regional 99 percent CPRA from the classification tables in kidney and pancreas allocation policies.[46] Candidates within the 500 NM circle would receive organ offers before candidates outside the 500 NM circle (except for those exceptions noted in polic0) and the classification tables within kidney and pancreas policies would still determine the order in which potential transplant recipients would appear on the match run.

Approximately 80 percent of deceased donor kidneys, KPs and pancreata transplanted between January 2017 and June 2018 occurred within a 500 NM distance from the donor hospital.

Figure 10 represents how the 500 NM No Points variation would operate in practice:

Figure 10: 500 NM Circle, No Points Variation



In this framework, kidneys would continue to be allocated based off current Kidney Allocation System (KAS) classification tables; specifically, ranking potential transplant recipients within classifications.[47]

Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results illustrated in Figure 4 for kidney and Figure 5 for kidney-pancreas. “BL” represents outcomes in baseline (current) policy, and modeled outcomes for the 500 NM fixed circle with no points variation is represented on the row labeled “1CR_nopts” as seen in Figure 4 and Figure 5 (highlighted in yellow) and replicated below.

[46] OPTN/UNOS Policy 11, *Allocation of Pancreas, Kidney-Pancreas and Islets* (accessed January 3, 2019).
[47] Ibid.

Figure 4: Outcomes Metrics for Five Proposed Framework Variations, Kidney (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.122 (0.121, 0.123)	13473 (13373, 13536)	0.048 (0.047, 0.048)	5262 (5247, 5279)	0.116 (0.109, 0.124)
1CR_nopts	0.105 (0.105, 0.106)	11727 (11665, 11839)	0.048 (0.048, 0.048)	5308 (5299, 5320)	0.12 (0.115, 0.124)
1CR_shallow	0.106 (0.105, 0.106)	11739 (11669, 11823)	0.048 (0.048, 0.048)	5312 (5300, 5326)	0.119 (0.113, 0.131)
1CR_steep	0.106 (0.105, 0.106)	11767 (11710, 11816)	0.048 (0.048, 0.048)	5305 (5298, 5317)	0.12 (0.113, 0.131)
2CR_150	0.112 (0.111, 0.113)	12399 (12319, 12486)	0.048 (0.047, 0.048)	5289 (5263, 5312)	0.118 (0.108, 0.129)
2CR_250	0.108 (0.107, 0.109)	11981 (11894, 12084)	0.048 (0.048, 0.048)	5300 (5292, 5309)	0.119 (0.113, 0.126)

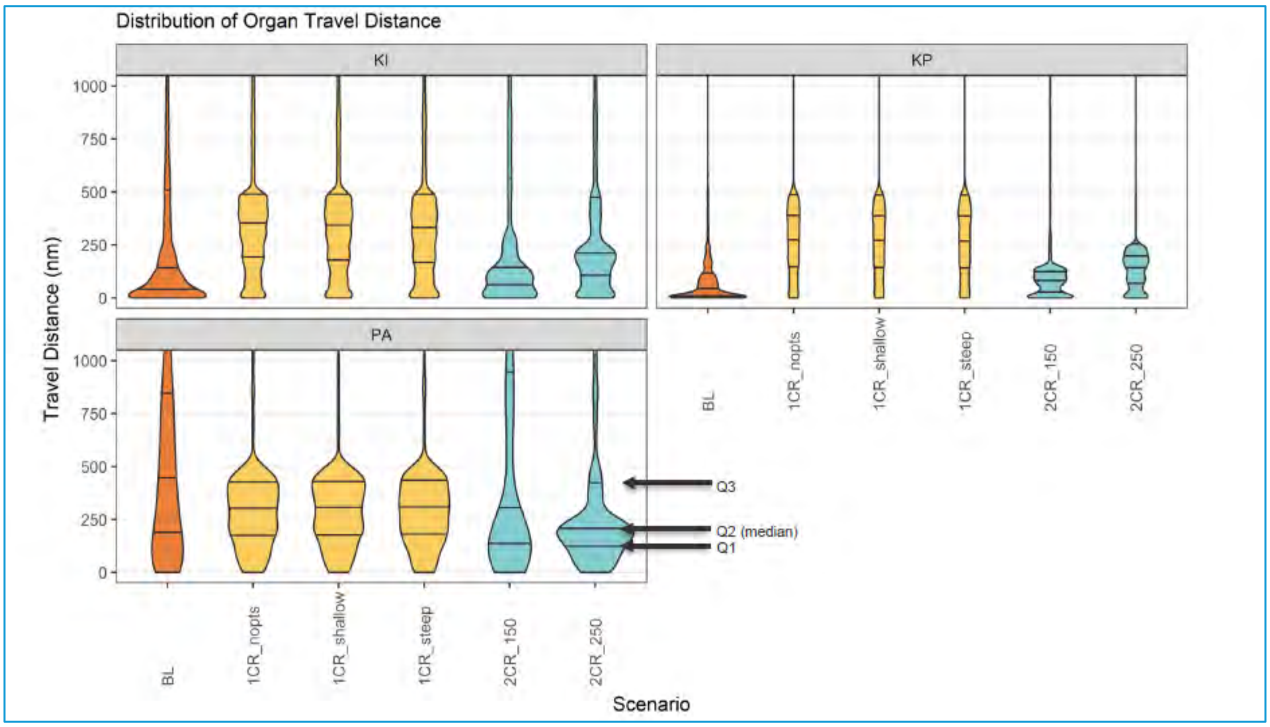
Figure 5: Outcomes Metrics for Five Proposed Framework Variations, Kidney-Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.503 (0.49, 0.515)	944 (923, 961)	0.053 (0.05, 0.055)	99 (95, 103)	0.223 (0.195, 0.266)
1CR_nopts	0.599 (0.589, 0.608)	1081 (1074, 1089)	0.053 (0.051, 0.055)	96 (92, 99)	0.228 (0.203, 0.284)
1CR_shallow	0.599 (0.587, 0.605)	1081 (1071, 1089)	0.053 (0.051, 0.054)	95 (91, 98)	0.228 (0.198, 0.272)
1CR_steep	0.601 (0.592, 0.61)	1084 (1069, 1095)	0.052 (0.05, 0.054)	94 (91, 98)	0.215 (0.186, 0.276)
2CR_150	0.555 (0.549, 0.566)	1020 (1011, 1029)	0.052 (0.05, 0.055)	96 (92, 100)	0.219 (0.197, 0.236)
2CR_250	0.584 (0.577, 0.59)	1060 (1046, 1072)	0.053 (0.05, 0.055)	96 (91, 100)	0.227 (0.186, 0.261)

For kidney, all variations of the hybrid framework also result in reductions in the transplant rate and transplant count and minimal to no changes in waitlist mortality rate in patient years, waitlist mortality count in patient years, and graft failure rate in patient years as compared to current policy. Modeling also projected a decrease in transplant count and rate for pancreas alone. For kidney-pancreas, an increase in transplant rates and counts was projected, but similar to kidney, waitlist mortality rate held steady across modeling options (Figure 5). Potential increases in graft failure rate and decreases in transplant rate may show a conflict with the best use of organs. According to the SRTR analysis report, “the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there’s a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes.”[48,49]

One of the key results from the SRTR modeling as it pertains to the hybrid modeling variations are the projected changes in the shape of distribution by distance. At their October 15, 2018 meeting, the majority of the OPTN/UNOS Kidney Committee agreed that broader distribution of kidneys is a value that they would like to see strengthened in whichever framework variation is selected.[50] The OPTN/UNOS Board of Directors, as evidenced by the Board-approved principle of distribution that “organs should be distributed as broadly as is feasible.”[51] Figure 9 illustrates how the shape of the distribution profile would be changed by each of the five framework variations for kidney, pancreas, and simultaneous kidney-pancreas allocations.

Figure 9: Distribution of Organ Travel Distance (SRTR)



In Figure 9, replicated above, the top left square represents kidney allocation, the top-right square represents kidney-pancreas allocation, and the bottom-left square represents pancreas allocation. Each of the five proposed variations would broaden allocation of kidney and kidney-pancreas distribution when compared to the baseline, which represents allocation under the current policy. By contrast, pancreas alone allocation is projected to be distributed less broadly overall. As noted before, pancreas alone

[48] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[49] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.
[50] Meeting Summary for October 15, 2018 meeting, OPTN/UNOS Kidney Committee, https://optn.transplant.hrsa.gov/media/2743/20181015_ kidney_committee _minutes.pdf (accessed January 3, 2019).
[51] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

allocation represents a minority of all pancreas transplants, with a majority being comprised of KP transplants.

The Workgroup determined that the three hybrid variations, represented in yellow, illustrate the principle of distributing organs as broadly as feasible. However, the Workgroup will continue to deliberate as to whether broader distribution via hybrid framework variations can be justified when these variations show larger decreases in transplant count and transplant rate compared to the baseline and to the fixed distance framework variations, even when considering the limitations of the KPSAM to project changes in behavior. Additionally, clinical research has shown that kidneys can withstand longer cold ischemic times compared to other organs without significant reductions in outcomes[52], and therefore the Workgroup determined that broader distribution, compared to current policy, provides possible rationale for this framework variation based on studies that represent sound medical judgement as outlined in the OPTN/UNOS Final Rule. It is important to note that pancreas ischemic times are more similar to liver than to kidney, so this may be a point of interest for the community to comment on regarding potential policies using the hybrid variations.

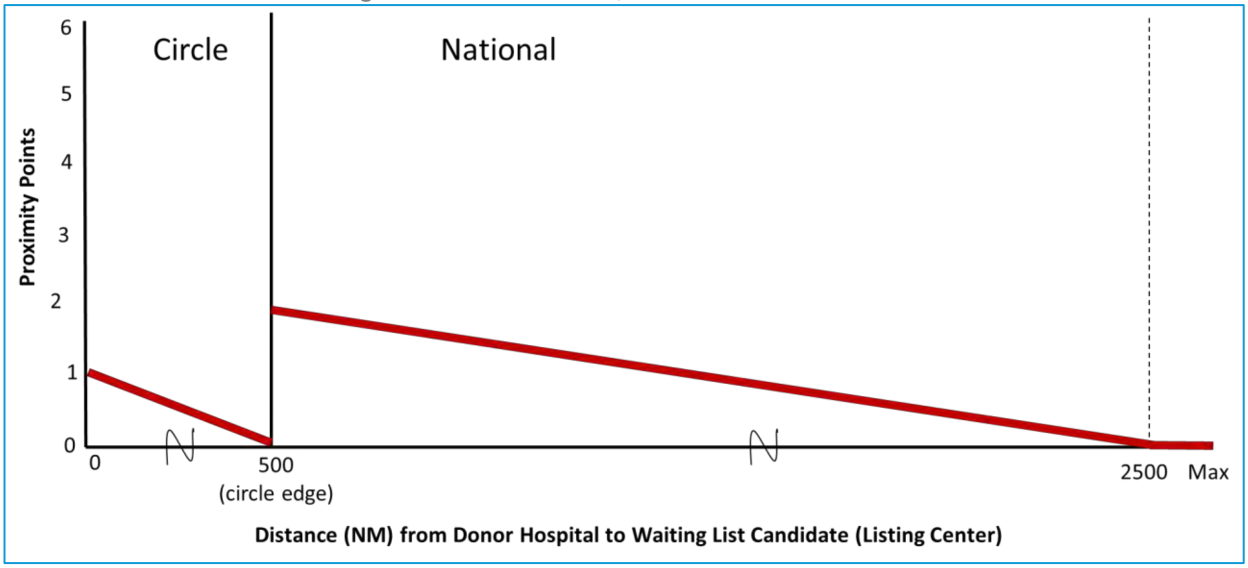
4. 500 NM Circle, Shallow Points

The fourth variation under consideration by the Workgroup is a hybrid framework variation with a single 500 NM circle and a shallow, linear proximity points line both inside and outside of the 500 NM circle.

This framework variation represents a hybrid between the fixed concentric circle framework and a continuous distribution framework as defined in the OPTN/UNOS Ad Hoc Geography Committee report, “Frameworks for Organ Distribution.”[53] The report defines a continuous distribution framework as, “a model of organ distribution without geographic boundaries” that “incorporates proximity of candidates to a donor through an algorithm designed to account for the principles above (e.g. outcomes, discards, efficiency), rather than their location inside or outside a boundary.”[54] The report states that, “by using this kind of calculation, there would not be absolute geographic boundaries, and candidates would be ranked on a match run based on a combination of their clinical characteristics and proximity to a donor.”[55] The number of points to be awarded based on distance are outlined in Figure 11, below:

[52] Gill, Jagbir Singh, Caren Rose, Yayuk Joffres, Matthew Kadatz and John S. Gill. “Cold ischemia time up to 16 hours has little impact on living donor kidney transplant outcomes in the era of kidney paired donation.” *Kidney international* 92 2 (2017): 490-496.
[53] *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Committee on Geography, August 2018, https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/ (accessed December 26, 2018).
[54] *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Committee on Geography, August 2018, https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/ (accessed December 26, 2018).
[55] *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Committee on Geography, August 2018, https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/ (accessed December 26, 2018).

Figure 11: 500 NM Circle, Shallow Points Variation



The Workgroup sees an opportunity with the hybrid framework to begin the process of eliminating fixed boundaries and determined that the allowance of the longest cold ischemic times afforded by kidneys[56] makes the organ and its associated OPTN/UNOS committee the ideal candidate to move towards a framework of continuous distribution. Whether this should apply to pancreas as well is question for which the Workgroup seeks feedback.

Within the context of this variation, instances of DSA would be replaced with "within a 500 NM fixed distance circle from the donor hospital" in both kidney and pancreas allocation policy. Regional distribution would be removed from allocation policies. Candidates within the 500 NM circle would receive organ offers before candidates outside the 500 NM circle (except for national mandatory shares outlined in policy such as 100 percent CPRA candidates) and the classification tables within kidney and pancreas policies would still determine placement on the organ offer list. In addition, a formula would be added to kidney and pancreas allocation tables to award points based on a candidate's proximity to the donor hospital. The formula for proximity points within the shallow points variation appears below:

Within the 500 NM circle: $y = 1 – (1/500)*x$, with "x" representing the distance in NM of the candidate's center of registration from the donor hospital and "y" representing the number of proximity points.

Outside of the 500 NM circle: $y = 2 – 1/(1000)*x$

Candidates within the 500 NM circle who are registered at the donor hospital would be awarded up to a single proximity point in addition to their scores based on current kidney and pancreas allocation tables. A candidate registered at a transplant hospital approximately 500 NM away from the donor hospital would receive no proximity points. Proximity points are awarded linearly between those two points, so a candidate registered at a hospital 250 NM from the donor hospital would be awarded 0.5 points. Again, candidates within the 500 NM circle receive organ offers before candidates outside the circle, except for those exceptions outlined in kidney and pancreas policies such as mandatory national distribution for 100 percent CPRA candidates. If no candidates within the 500 NM circle accept the organ offer, the organ moves out to national distribution. A candidate registered just outside the 500 NM circle would be awarded two proximity points and a candidate registered 2500 NM and beyond from the donor hospital would be awarded no proximity points. Proximity points are awarded linearly between those two points,

[56] Gill, Jagbir Singh, Caren Rose, Yayuk Joffres, Matthew Kadatz and John S. Gill. "Cold ischemia time up to 16 hours has little impact on living donor kidney transplant outcomes in the era of kidney paired donation." *Kidney international* 92 2 (2017): 490-496.

so a candidate registered at a hospital 1500 NM from the donor hospital would be awarded one proximity point.

The Workgroup selected these point values, both inside and outside of the 500 NM circle, after a lengthy discussion concerning the weight of proximity points as compared to other points awarded within the current KAS and associated classification tables.[57] The primary comparison within the Workgroup concerned proximity points versus wait time. In kidney and pancreas allocation, one proximity point would be equivalent to one year of waiting time. Hence, the two variations of hybrid frameworks that value proximity differently, with shallow and steep point allocation lines. The Workgroup decided on a proximity point endpoint at 2500 NM so as not to disadvantage geographically isolated hospitals and to maintain the efficient management of the OPTN/UNOS by limiting cross-country flights except in the most medically urgent cases.

SRTR modeling revealed that proximity points ultimately did not significantly alter the shape of organ distribution when compared to the 500 NM no points variation for kidney or kidney pancreas (Refer to Figure 9). Figure 12 provides numerical context to the distances illustrated in Figure 9 for kidney:

Figure 12: Allocation Distances (NM) for Kidneys across Framework Variations (SRTR)

Scenario	5^{th} percentile	Q1	Median	Mean	Q3	95^{th} percentile	Variance
BL	0.00	15.67	107.56	343.85	439.49	1592.12	522.89
1CR_nopts	11.54	188.82	354.29	485.21	487.56	1703.07	513.07
1CR_shallow	9.20	171.33	341.61	474.06	486.22	1683.09	510.76
1CR_steep	7.27	158.99	327.90	463.85	484.98	1670.79	509.84
2CR_150	0.51	43.23	128.83	389.15	495.65	1727.14	571.38
2CR_250	3.66	94.54	205.88	414.23	465.44	1704.28	539.95

Figure 12 shows that the shallow points variation, represented by the “1CR_shallow” label, only sees the median travel distance decrease by approximately 13 NM when compared to the 500 NM circle no points variation, represented by the “1CR_nopts” label. The Workgroup intends to continue deliberation as to how proximity points should be awarded to stabilize outcomes while broadening distribution and maintaining network efficiency.

Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results illustrated in Figure 4 for kidney and Figure 5 for kidney-pancreas. “BL” represents outcomes in baseline (current) policy, and modeled outcomes for the 500 NM fixed circle with shallow points variation is represented on the row labeled “1CR_shallow” as seen in Figure 4 and Figure 5 (highlighted in yellow) and replicated below.

[57] OPTN/UNOS Policy 8, *Allocation of Kidneys* (accessed January 3, 2018).

Figure 4: Outcomes Metrics for Five Proposed Framework Variations, Kidney (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.122 (0.121, 0.123)	13473 (13373, 13536)	0.048 (0.047, 0.048)	5262 (5247, 5279)	0.116 (0.109, 0.124)
1CR_nopts	0.105 (0.105, 0.106)	11727 (11665, 11839)	0.048 (0.048, 0.048)	5308 (5299, 5320)	0.12 (0.115, 0.124)
1CR_shallow	0.106 (0.105, 0.106)	11739 (11669, 11823)	0.048 (0.048, 0.048)	5312 (5300, 5326)	0.119 (0.113, 0.131)
1CR_steep	0.106 (0.105, 0.106)	11767 (11710, 11816)	0.048 (0.048, 0.048)	5305 (5298, 5317)	0.12 (0.113, 0.131)
2CR_150	0.112 (0.111, 0.113)	12399 (12319, 12486)	0.048 (0.047, 0.048)	5289 (5263, 5312)	0.118 (0.108, 0.129)
2CR_250	0.108 (0.107, 0.109)	11981 (11894, 12084)	0.048 (0.048, 0.048)	5300 (5292, 5309)	0.119 (0.113, 0.126)

Figure 5: Outcomes Metrics for Five Proposed Framework Variations, Kidney-Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.503 (0.49, 0.515)	944 (923, 961)	0.053 (0.05, 0.055)	99 (95, 103)	0.223 (0.195, 0.266)
1CR_nopts	0.599 (0.589, 0.608)	1081 (1074, 1089)	0.053 (0.051, 0.055)	96 (92, 99)	0.228 (0.203, 0.284)
1CR_shallow	0.599 (0.587, 0.605)	1081 (1071, 1089)	0.053 (0.051, 0.054)	95 (91, 98)	0.228 (0.198, 0.272)
1CR_steep	0.601 (0.592, 0.61)	1084 (1069, 1095)	0.052 (0.05, 0.054)	94 (91, 98)	0.215 (0.186, 0.276)
2CR_150	0.555 (0.549, 0.566)	1020 (1011, 1029)	0.052 (0.05, 0.055)	96 (92, 100)	0.219 (0.197, 0.236)
2CR_250	0.584 (0.577, 0.59)	1060 (1046, 1072)	0.053 (0.05, 0.055)	96 (91, 100)	0.227 (0.186, 0.261)

For kidney, ll variations of the hybrid framework also see reductions in the transplant rate and transplant count and minimal to no changes in waitlist mortality rate in patient years, waitlist mortality count in patient years, and graft failure rate in patient years. Modeling also projected a decrease in transplant count and rate for pancreas alone. For kidney-pancreas, an increase in transplant rates and counts was projected, but similar to kidney, waitlist mortality rate held steady across modeling options (Figure 5). According to the SRTR analysis report, “the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there's a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[58,59]

5. 500 NM Circle, Steep Points

The fifth variation under consideration by the Workgroup is a hybrid Framework variation with a single 500 NM circle and a steep, linear proximity points line both inside and outside of the 500 NM circle.

This steep points variation was chosen by the Workgroup to be modeled in an effort to see if distribution could be broadened as compared to baseline policy while possibly promoting more efficient management of organ placement by reducing median travel distances and thus travel costs (when compared to the no points and shallow points variations).

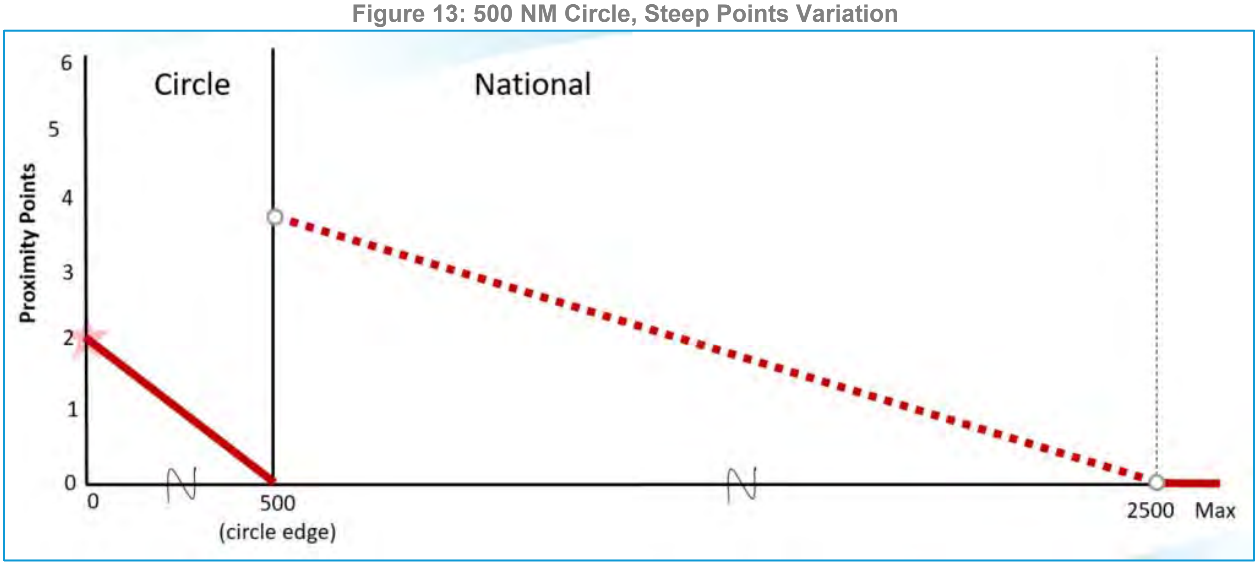
Within the context of this variation, instances of DSA would be replaced with "within a 500 NM fixed distance circle from the donor hospital" in both kidney and pancreas allocation policy. Regional distribution would be removed from allocation policies. Classification tables within kidney and pancreas policies would still determine placement on the organ offer list within these geographic boundaries. In addition, a formula would be added to kidney and pancreas allocation tables to award points based on a candidate's proximity to the donor hospital. The proposed formula for the steep variation of the hybrid framework appears below:

Within the 500 NM circle: y = 2 – (2/500)*x, with "x" representing the distance of the candidate's center of registration from the donor hospital and "y" representing the number of proximity points.

Outside of the 500 NM circle: y = 5 – (1/500)*x

The number of points to be awarded based on distance are outlined in the Figure 13.

Figure 13: 500 NM Circle, Steep Points Variation



Candidates within the 500 NM circle who are registered at the donor hospital would be awarded two proximity points in addition to their scores based on current kidney and pancreas allocation tables. A

[58] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[59] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.

candidate registered at a transplant hospital approximately 500 NM away from the donor hospital would receive no proximity points. Proximity points are awarded linearly between those two points, so a candidate registered at a hospital 250 NM from the donor hospital would be awarded one point. A candidate registered at a donor hospital just outside the 500 NM circle would be awarded four proximity points and a candidate registered 2500 NM and beyond from the donor hospital would be awarded no proximity points. Proximity points are awarded linearly between those two points, so a candidate registered at a hospital 1500 NM from the donor hospital would be awarded two proximity points.

Figure 12 shows that the steep points variation, represented by the "1CR_steep" label, sees the median travel distance decrease by approximately 30 NM when compared to the 500 NM circle no points variation, represented by the "1CR_nopts" label. The Workgroup intends to continue deliberation as to how proximity points should be awarded to stabilize outcomes while broadening distribution and maintaining network efficiency.

Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results illustrated in Figure 4 for kidney, and Figure 5 for kidney-pancreas, replicated below. "BL" represents outcomes in baseline (current) policy, and modeled outcomes for the 500 NM fixed circle with shallow points variation is represented on the row labeled "1CR_steep."

Figure 4: Outcomes Metrics for Five Proposed Framework Variations, Kidney (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.122 (0.121, 0.123)	13473 (13373, 13536)	0.048 (0.047, 0.048)	5262 (5247, 5279)	0.116 (0.109, 0.124)
1CR_nopts	0.105 (0.105, 0.106)	11727 (11665, 11839)	0.048 (0.048, 0.048)	5308 (5299, 5320)	0.12 (0.115, 0.124)
1CR_shallow	0.106 (0.105, 0.106)	11739 (11669, 11823)	0.048 (0.048, 0.048)	5312 (5300, 5326)	0.119 (0.113, 0.131)
1CR_steep	0.106 (0.105, 0.106)	11767 (11710, 11816)	0.048 (0.048, 0.048)	5305 (5298, 5317)	0.12 (0.113, 0.131)
2CR_150	0.112 (0.111, 0.113)	12399 (12319, 12486)	0.048 (0.047, 0.048)	5289 (5263, 5312)	0.118 (0.108, 0.129)
2CR_250	0.108 (0.107, 0.109)	11981 (11894, 12084)	0.048 (0.048, 0.048)	5300 (5292, 5309)	0.119 (0.113, 0.126)

Figure 5: Outcomes Metrics for Five Proposed Framework Variations, Kidney-Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.503 (0.49, 0.515)	944 (923, 961)	0.053 (0.05, 0.055)	99 (95, 103)	0.223 (0.195, 0.266)
1CR_nopts	0.599 (0.589, 0.608)	1081 (1074, 1089)	0.053 (0.051, 0.055)	96 (92, 99)	0.228 (0.203, 0.284)
1CR_shallow	0.599 (0.587, 0.605)	1081 (1071, 1089)	0.053 (0.051, 0.054)	95 (91, 98)	0.228 (0.198, 0.272)
1CR_steep	0.601 (0.592, 0.61)	1084 (1069, 1095)	0.052 (0.05, 0.054)	94 (91, 98)	0.215 (0.186, 0.276)
2CR_150	0.555 (0.549, 0.566)	1020 (1011, 1029)	0.052 (0.05, 0.055)	96 (92, 100)	0.219 (0.197, 0.236)
2CR_250	0.584 (0.577, 0.59)	1060 (1046, 1072)	0.053 (0.05, 0.055)	96 (91, 100)	0.227 (0.186, 0.261)

All variations of the hybrid framework also show potential reductions in the transplant rate and transplant count and minimal to no changes in in waitlist mortality rate in patient years, waitlist mortality count in patient years, and graft failure rate in patient years. According to the SRTR analysis report, "the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there's a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[60,61]

How were these concepts developed?

The OPTN/UNOS Kidney and Pancreas Committees were directed by the President of the OPTN/UNOS Board of Directors on June 25, 2018 to "propose revisions to [approved kidney & pancreas] policy that provide Final Rule compliant replacements for:

1) The use of region and DSA in kidney and pancreas allocation
2) The use of DSA in the awarding of points (when applicable)
3) The use of region and DSA in simultaneous kidney-pancreas (KP) allocation" [62]

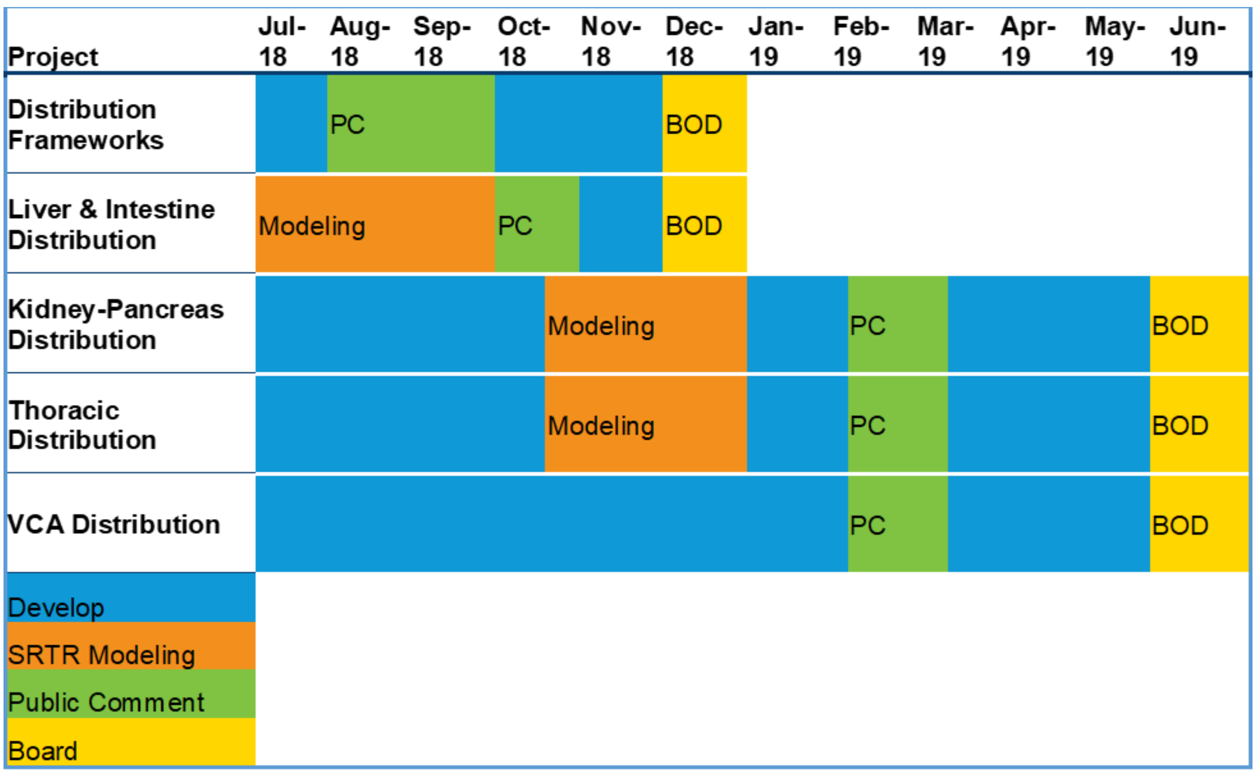
The Workgroup collaborated with multiple OPTN/UNOS committees representing particular patient groups and perspectives during the development of this proposal. Members of the OPTN/UNOS Pediatric Transplantation Committee provided input about the impact of each change considered on pediatric

[60] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[61] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.
[62] Yolanda Becker, OPTN/UNOS President, letter to the OPTN/UNOS Liver and Intestinal Organ Transplant Committee, June 25, 2018.

candidates. Members of the OPTN/UNOS Minority Affairs Committee reviewed proposed geographic framework variations and provided input on these vulnerable populations. The OPTN/UNOS Ad Hoc Geography Committee[63] received regular updates on the progress of the Workgroup and provided feedback about whether some of the solutions the Workgroup considered were consistent with the principles of geography.

While the Workgroup began work to remove DSAs and regions from kidney and pancreas distribution, the OPTN/UNOS Executive Committee charged several other committees to begin similar work, requiring the OPTN/UNOS Liver and Intestinal Transplantation Committee, the OPTN/UNOS Thoracic Organ Transplantation Committee, and the OPTN/UNOS Vascular Composite Allograft (VCA) Transplant Committee to remove DSA and regions from their distribution system (where applicable). Additionally, the OPTN/UNOS Ad Hoc Geography Committee was charged with ensuring that the committees maintained rapid progress on these projects with consistent interpretation and application of the requirements under NOTA, the Final Rule, and the Principles of Organ Distribution. Figure 14 shows the initial timeline for the committees to make these changes.

Figure 14: Timeline Overview of the Geography Projects



The primary goal of the Workgroup is to remove DSA and regions from allocation policy, and select a distribution policy consistent with NOTA and the OPTN/UNOS Final Rule.

[63] The OPTN/UNOS Ad Hoc Committee on Geography (the Geography Committee) was formed in December 2017 to examine the principles of geographic distribution of organs. The Geography Committee was charged with establishing guiding principles for the use of geographic constraints in organ allocation, reviewing and recommending models for incorporating geographic principles into allocation policies, and identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN/UNOS Final Rule.

Framework Development

In response to the Board directive, the Workgroup began considering the basic framework for the revised distribution system. The OPTN/UNOS Ad Hoc Geography Committee recently sponsored a public comment proposal to identify a single distribution framework for all organs.[64] Because that project is a long-term efficiency project for the OPTN/UNOS, it was not necessary to choose a single distribution framework for all organs first; however, the Workgroup was instructed by the OPTN/UNOS Executive Committee to develop their revised framework consistent with one of the frameworks being considered by the OPTN/UNOS Ad Hoc Geography Committee.

It was determined based on the timeline and constraints of the KPSAM that the concentric circles framework and a hybrid framework that utilized fixed distance circles and elements of continuous distribution (by incorporating proximity points) would be the frameworks with the most rationale to pursue potential policy changes.

While Workgroup members wanted to pursue the continuous allocation framework, they recognized the difficulty of implementation within the short timeline and agreed that developing a modeling request for concentric circles and a fully continuous framework was not feasible. Therefore, the Workgroup introduced a plan to develop a fixed-distance concentric circles framework as the first part of improving geographic allocation and working towards developing a hybrid framework incorporating elements of a fixed distance and continuous distribution frameworks.

In order to determine potential circle sizes for a new allocation system the Workgroup reviewed preliminary research presented by UNOS staff on travel distance, cold ischemic times and current distribution based on kidney and pancreas allocation. It was noted that there were several caveats to the data as it is based on the current system. Data included cold ischemic time (CIT) by KDPI, travel distances, travel distances vs. CIT and others. Based on this discussion, the Workgroup discussed modeling two circles representative of local and regional distances with possible distances around 150 NM or 300 NM for the smaller circle and 500 NM or 800 NM for the larger circle. During the discussion members noted that there could be possible disparities specifically for mid-western and western regions, as well as the state of Alaska, due to the increased distances between transplant programs. At the end of discussion three preliminary small circle sizes 75 NM, 150 NM, and 350 NM and three large circle sizes 350 NM, 500 NM, and 800 NM were proposed.

In early August, members of the Workgroup who sit on the OPTN/UNOS Pancreas Transplantation Committee discussed whether kidney and pancreas distribution should be designed separately based on several factors. These factors included longer tolerable CIT for kidney compared to pancreas and the related impact on travel time, pancreas programs that are fewer in number and more spread out, preventing organ wastage due to differing issues with supply and demand for pancreata compared to kidneys, and procurement practices are more like liver than kidney. The Workgroup members reviewed KP, pancreas, and kidney alone data as part of their discussion. Workgroup members expressed interest in modeling a smaller circle due to lower tolerance to CIT for pancreas. Workgroup members also agreed that procurement practices could impact methods of transportation for pancreas procurement teams, which could impact the distribution circle sizes. Due to these factors, Workgroup members agreed that pancreas distribution circles may need to differ. However, Workgroup members want to see additional data and SRTR modeling results to analyze the effects of various proposed circles on kidney and pancreas would be necessary to make a formative decision on separating the allocation proposals. Members also agreed that a priority was to ensure that the kidney still follows the pancreas.

Some concerns were raised that some of the proposed circle sizes were too small to be justified according to the Final Rule for kidney allocation considering the lower tolerance to ischemic time and subsequent ability to distribute more broadly. While the UNOS Research Department shared some basic scatter plot (see Figures 7 and 8), the Workgroup felt the data was too limited to narrow down the

[64] *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Committee on Geography, August 2018, https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/ (accessed October 1, 2018).

selected choices. At this point the Workgroup identified the top three options for a small and large circle respectively; 75 NM, 150 NM, or 250 NM and 250 NM, 500 NM, or 800 NM.

Concentric Circle Variations

The Workgroup members had many lengthy discussions regarding the proposed circle sizes based on preliminary OPTN/UNOS data as well as their professional experience. An informal poll determined that 150 NM and 500 NM had the most support. Workgroup members ultimately decided that they would request two variations of the concentric circles framework, one with 150 NM and 300 NM circles and the other with 250 NM and 500 NM circle. The Workgroup also decided to request modeling for a basic 500 NM single circle variation in order to gauge modeling result for removing regional allocation from kidney and pancreas policies altogether. However, the Workgroup expressed the need to evaluate SRTR modeling in order to fine-tune the circle sizes.

Hybrid Variations

Workgroup members also debated the merits of hybrid framework variations. The Workgroup determined that a hybrid framework utilizing circles and points could be an ideal solution that provides a transition to continuous distribution while still preserving KAS classification criteria with the addition of proximity points. Therefore, the Workgroup decided to additionally request SRTR modeling of two hybrid variations as well as the concentric circles variations. The Workgroup determined that requesting hybrid variations containing only one circle made the most sense given the mechanisms of the hybrid framework, while also providing an opportunity for the most modeling diversity. Kidney leadership initially considered giving maximum points out around 250 NM. The Workgroup as well as additional Pancreas Committee members compromised on linear proximity points in a 500 NM radius. The Workgroup decided to pursue a steep curve to maximize efficiency in cases where outcomes and other candidate characteristics might be similar, although the Workgroup decided to model one variation with a shallow curve to compare.

SRTR Modeling

The Workgroup requested a total of five different models:

- Simulation BL: baseline using current allocation systems
- Simulation 2CR_150: uses distances of 150 NM and 300 NM replacing local and regional designations
- Simulation 2CR_250: uses distances of 250 NM and 500 NM replacing local and regional designations
- Simulations 1CR_nopts, 1CR_shallow & 1CR_steep: uses distance of 500 NM in place of the local designation and regional distribution is eliminated. Instead organs are distributed nationally when beyond the 500 NM border

The Workgroup requested the following metrics from SRTR modeling: count of transplants, transplant rates, counts of waiting list deaths, waiting list mortality rates, total life years from transplant, total graft years from transplant, average median years of survival from transplant, post-transplant patient survival rates and post-transplant graft survival rates. These metrics were selected as they were the same ones used to modify and design KAS and were available under the current variation of the KPSAM. Certain metrics were not requested as they cannot be provided by SRTR, such as discard rates and travel costs.

The Workgroup put in a request to SRTR on September 4, 2018 and the results came back on December 7, 2018. SRTR was not able to provide all the requested metrics, specifically total graft years from transplant and average median years of survival from transplant.

All the simulations proposed have broader distribution than current allocation systems. During the results presentation by SRTR, it was heavily emphasized that the KPSAM modeling is not a precise predictor for concrete metrics such as total transplant count, transplant rates, and waitlist mortality, unlike metrics for changes in characteristics of recipients. According to the SRTR analysis report, “the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there’s a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[65,66] However, the KPSAM can estimate relative direction of possible effect of policy change.

Workgroup discussions

The Workgroup noted that the data report indicated a potential decrease in overall transplant count and rates across all variations for both organs individually. The Workgroup expressed concern about drawing implications from the SRTR data results regarding crucial metrics such as transplant counts, transplant rates, and waitlist mortality counts, given the limitations of the KPSAM in modeling changes in behavior. There were two main ideological differences that emerged amongst Workgroup members: one was whether to minimize issues in allocation policy transition from current allocation or opt for a variation with the broadest distribution and the other was a divide between pancreas members in favor of smaller circles and kidney members in favor of larger circles. UNOS staff emphasized to Workgroup members that each of these decisions would have to be grounded in the Final Rule.

The Workgroup discussed at length the possibility of developing separate allocation policies for kidney and pancreas allocation. The Pancreas Chair recommended that the pancreas allocation framework be determined separately as the tolerated ischemic time is lower for pancreata than kidneys. Pancreas Committee members indicated that lower tolerated ischemic time could impact acceptable travel distance, procurement process and the post-recovery organ utilization. Concerns about separating pancreas and kidney distribution methods had previously been discussed by the Workgroup, which decided to re-evaluate their concerns once they had received more substantial SRTR data. In light of the SRTR results, the OPTN/UNOS Pancreas Committee members felt that the data demonstrated a greater benefit to separating pancreas transplantation distribution because of the differing results seen in particular for kidney and KP metrics (kidney and pancreas metrics, overall, were more closely aligned). It is important to note, however, that current data indicates pancreata have longer observed travel distances than kidneys or KPs (see Figure 9). This undermines the implication that pancreas ischemic time should limit pancreas distribution to a smaller distance than kidney distribution. The Work Group and Pancreas Committee will continue to investigate the validity of concerns about ischemic time, procurement process and post-recovery utilization to identify if additional evidence could supplement committee discussions.

Based on the robust discussion and the Workgroup's desire to collect more evidence and community feedback before deciding on a new allocation framework for kidney and pancreas allocation, OPTN/UNOS staff suggested that the Workgroup submit a concept paper for the spring 2019 Public Comment period discussing their findings. Both full committees, Kidney and Pancreas respectively, met separately to discuss submitting a concept paper and moved forward. By providing the community with an opportunity to provide feedback before pursuing a policy solution, the Workgroup hopes to ensure the most reasonable framework variation with a rationale grounded in the Final Rule will be utilized. Additionally, pursuing a concept paper allows the Workgroup to gather more evidence before pursuing a policy change.

How does this concept support the OPTN/UNOS Strategic Plan?

1. *Increase the number of transplants:* As indicated in the SRTR modeling results, the options being considered by the Workgroup *could* decrease the number of transplants, but would ultimately depend on changes in center behavior in a new system. It is important to note that SRTR modeling is unable to predict changes in behavior under alternate allocation systems, and

[65] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774.
[66] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.

comparisons of previous modeling to actual behavior with KAS indicated the SRTR underestimated the transplant rate by about eight percent.[67] The Workgroup is considering more modeling and evidence gathering to better assess the potential impact on this goal before going forward with a policy proposal.

2. *Improve equity in access to transplants:* Patient access is an important consideration in pursuing changes in geography. Based on SRTR modeling, the framework variations may avoid an increase in waitlist mortality and could potentially benefit certain vulnerable populations, including pediatrics, African Americans, and highly sensitized candidates. Additionally, the options considered in this concept paper could decrease the variance in travel distance across the country.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact on this goal.

4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.

5. *Promote the efficient management of the OPTN:* This proposal is a first step to alleviate risk to the OPTN/UNOS regarding the use of DSAs and regions, which is an important and time sensitive issue regarding the management of the OPTN. The options presented in this concept paper could also impact the percentage of kidney and pancreas transplants that require air transportation and thereby impact costs and affect recovery team safety. It is important to note, however, that the OPTN/UNOS currently does not collect transportation mode nor can the KPSAM simulate it.

[67] OPTN/UNOS Descriptive Data Request. "Two Year Evaluation of the New, National Kidney Allocation System (KAS)." Prepared for OPTN/UNOS Kidney Transplantation Committee Teleconference, April 19, 2017.