Proposal at a glance

Public Comment Proposal: Eliminate the Use of DSA and Region in Pancreas Allocation Policy
Sponsoring Committee: OPTN Pancreas Transplantation Committee

You may be interested in this proposal if:

- You or your loved one needs a pancreas or kidney-pancreas (KP) transplant
- You are a healthcare professional who cares for patients with diabetes or pancreatic exocrine insufficiency
- You work for a pancreas transplant program or an Organ Procurement Organization (OPO)

Here's what we propose and why

The OPTN Pancreas Transplantation Committee proposes to remove the Donation Service Area (DSA) and regional boundaries used in the current system and allocate using a 500 nautical mile (NM) circle around the donor hospital. Points would be assigned based on how close the candidate's transplant hospital is to the hospital where the organ donation takes place. This is to prevent a pancreas or kidney-pancreas being transported further away when there is a candidate of similar priority closer to the donor hospital. The pancreas and kidney-pancreas would first be allocated to all eligible candidates inside the 500 NM circle. If the organ has not been accepted by those candidates, it would then be offered to other eligible candidates.

Location should not impact access to transplant except to promote efficient organ placement and to prevent unnecessary organ loss.

Why this may matter to you

The proposal aims to increase equity for U.S. pancreas and kidney-pancreas transplant candidates by reducing the impact that a patient's location has on their access to transplant. Certain areas of the country will see an increase in the number of transplants and other areas will experience a decrease. Some pancreata and kidney-pancreata will have to travel further than they do in the current system. This will result in new working relationships between OPOs and transplant centers.

Tell us what you think about

- What considerations should be taken into account to select a circle size that distributes pancreata broadly and efficiently?
- Proximity points are intended to contribute to efficiency in the broader distribution of pancreata. Should they be used inside the 500 NM circle? Should they be used outside the 500 NM circle?
- What operational concerns should the Committee consider as this policy is being prepared for OPTN board action and implementation?
- For import back up, should the initial distance from the transplant program be 150 NM or another distance, when considering the efficient reallocation of pancreas and kidney-pancreas? Should proximity points be included outside the initial import match run circle to limit travel

costs and preservation time, or should there be a secondary circle of 500 NM to address those concerns?

- Should programs qualify for facilitated placement if the program performs 2 or 5 transplants in 2 years from pancreata imported beyond 500 NM from the transplant program?

OPTN

Public Comment Proposal

Eliminate the Use of DSA and Region in Pancreas Allocation Policy

OPTN Pancreas Transplantation Committee

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Contents

Eliminate the Use of DSA and Region in Pancreas Allocation Policy

Affected Policies:	*Policy 11.3: Waiting Time; Policy 11.4.A: Kidney-Pancreas Allocation Order; Policy 11.4.B: Pancreas Allocation When a Kidney is Unavailable; Policy 11.4.C: Organ Offer Limits; Policy 11.4.D: Blood Type for Kidney-Pancreas Allocation; Policy 11.4.E: Sorting Within Each Classification; Policy 11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2; Policy 11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m^2; Policy 11.5: Reallocation of Unsuitable Islets; Policy 11.6: Facilitated Pancreas Allocation*
Sponsoring Committee:	*OPTN Pancreas Transplantation Committee*
Public Comment Period:	*August 2, 2019 – October 2, 2019*

Executive Summary

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

OPTN *Policy 11: Allocation of Pancreas, Kidney-Pancreas and Islets* currently uses DSA and region as geographic units of distribution. DSAs and regions are poor proxies for geographic distance between donors and transplant candidates due to variation in size, shapes and populations, resulting in an inconsistent application for all candidates. As a result, the use of DSAs and regions in pancreas distribution presents a potential conflict with the Final Rule. The use of DSAs and regions in pancreas distribution may also contribute to variation in pancreas utilization and discard rates geographically, potentially conflicting with the Final Rule requirement to promote patient access to transplant. Finally, most pancreas recipients are also kidney recipients, and DSA is the largest factor related to disparity in kidney allocation, which also indicates that DSAs and regions present a potential conflict with promoting patient access to transplant.

The OPTN Pancreas Transplantation Committee (hereafter, "Committee") proposes removing DSA within pancreas allocation policy in favor of a single fixed distance circle encompassing 500 nautical miles (NM) with the donor hospital at its center. Region as currently determined would be removed as a unit of distribution. The 500 NM circle would include proximity points that award candidates inside the single fixed circle a maximum of four points and award candidates outside of the fixed circle a maximum of eight points based on their distance from the donor hospital.

[1] 42 C.F.R. § 121.8(a).
[2] 42 C.F.R. § 121.8(a)(8).

To determine the proposed solution, the Committee used sound medical judgment, including review of kidney-pancreas simulated allocation model (KPSAM) and relevant literature, clinical and operational experience of Committee members, input from stakeholders and feedback from public comment. The Committee considered many options before deciding on the proposed solution – these options included multiple fixed distance circles with no points, multiple fixed distance circles with points, and single circles with no points. The Committee chose the proposed solution because it reflects the Final Rule's requirement that organ allocation not be based on a candidate's place of residence or place of listing except as necessary. Broader distribution would indicate that geography would play less of a role than it would if initial distribution were confined to a smaller circle. At the same time, the proposed solution also fulfills Final Rule requirements for avoiding unnecessary organ loss and promoting the efficient management of organ placement by including steep proximity points inside and outside the circle to avoid organs traveling unnecessarily and to promote efficiency.

The goal of the proposed changes is to make pancreas allocation policy more consistent with the Final Rule and to increase geographic equity in access to transplantation regardless of a candidate's place of listing, while limiting transportation costs and inefficiencies through the use of proximity points.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding:

What considerations should be taken into account to select a circle size that distributes pancreata broadly and efficiently?

Proximity points are intended to contribute to efficiency in the broader distribution of pancreata. Should they be used inside the 500NM circle? Should they be used outside the 500NM circle?

What operational concerns should the committee consider as this policy is being prepared for OPTN board action and implementation?

For import back up, should the initial distance from the transplant program be 150 NM or another distance, when considering the efficient reallocation of pancreas and kidney-pancreas? Should proximity points be included outside the initial import match run circle to limit travel costs and preservation time, or should there be a secondary circle of 500 NM to address those concerns?

Should programs qualify for facilitated placement if the program performs 2 or 5 transplants in 2 years from pancreata imported beyond 500 NM from the transplant program?

What is the Problem this Proposal will Address?

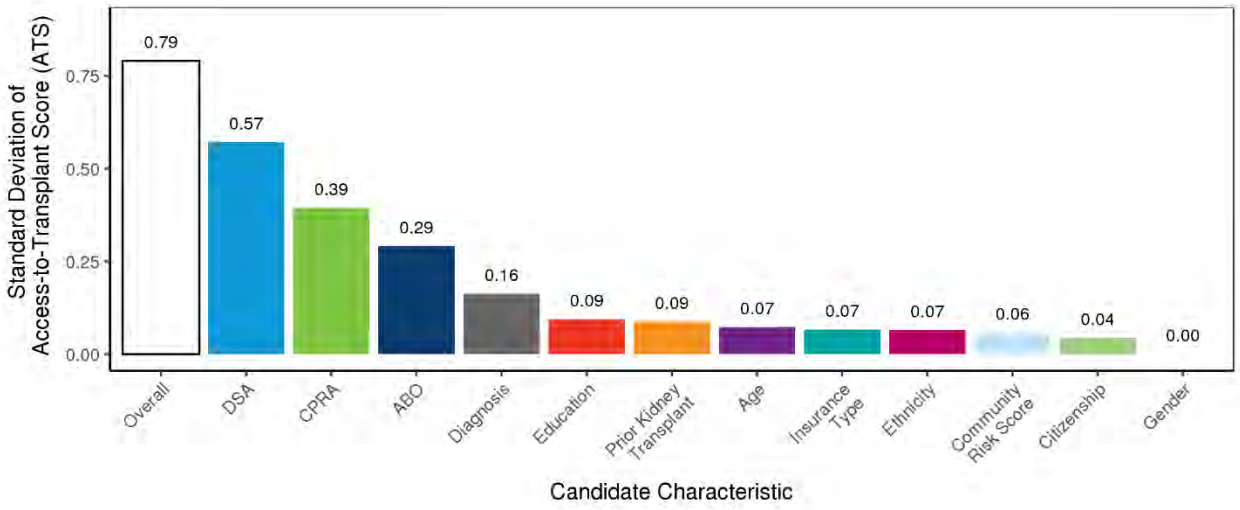
The OPTN is required to develop policies for the "equitable allocation of cadaveric organs among potential recipients."[3] The use of DSA and region as units of distribution for pancreas allocation results in disparities in access to transplant for waitlisted candidates, in potential conflict with the Final Rule. Specifically, access to transplant for pancreas candidates is impacted by DSA as a disparity metric in kidney allocation (most pancreas recipients are also kidney recipients).[4] Variance in pancreas utilization and offer acceptance practices mean that access to transplant may vary geographically depending on a candidate's access to a pancreas program that accepts and transplants more viable pancreata, which also may indicate a potential conflict with the Final Rule. The Committee considers that broader distribution could lead to increased competition between pancreas programs, which could spur programs to be more aggressive in their acceptance practices of viable pancreata. The proposal also addresses the problem that DSAs and regions were not optimized for purposes of organ distribution, which is a potential conflict with the Final Rule requirement that organ distribution not be limited except to the extent required.

DSA as Disparity Metric in Kidney Allocation

Under current allocation, research performed by the OPTN highlights DSA as the largest factor related to disparity in kidney allocation.[5] This is significant because a majority of pancreas transplants are simultaneous pancreas-kidney (SPKs).[6] Equity in access can be measured by examining the degree to which candidates' rates of transplant vary depending on patient characteristics.[7] The Access to Transplant Score (ATS) was developed to measure relative differences in candidates' access to transplant associated with patient characteristics such as blood type, cPRA, DSA of listing, age, ethnicity, and other factors considered to potentially impact a candidate's time-to-transplant and produces a score to measure how each factor affects variability in transplant access.[8] The variation in ATS among candidates on the waiting list (as measured by the standard deviation) is a reflection in the system-level degree of equity in access in kidney allocation. Among the candidate characteristics affecting ATS, the DSA where a candidate is listed has the strongest association with disparities (or highest variability) in access to transplantation (**Figure 1**).[9]

[3] 42 C.F.R. § 121.8(a).
[4] SPK transplants account for 81% of all pancreas transplants in 2018, indicating most candidates receiving a pancreas are also kidney recipients. 2019 OPTN data (accessed July 10, 2019).
[5] OPTN Descriptive Data Request. "Report on Equity in Access." Presented to the OPTN/UNOS Board of Directors Meeting, December 2016
[6] 2019 OPTN data (accessed June 28, 2019).
[7] Stewart DE, Wilk AR, Toll AE, Harper AM, Lehman RR, Robinson AM, Noreen SA, Edwards EB, Klassen DK. Measuring and monitoring equity in access to deceased donor kidney transplantation. American Journal of Transplantation. 2018 Aug;18(8):1924-35.
[8] OPTN Descriptive Data Request. "Report on Equity in Access." Presented to the OPTN/UNOS Board of Directors Meeting, December 2016.
[9] Ibid.

Figure 1: Standard Deviation of Transplant Score and DSA for Kidney Transplants



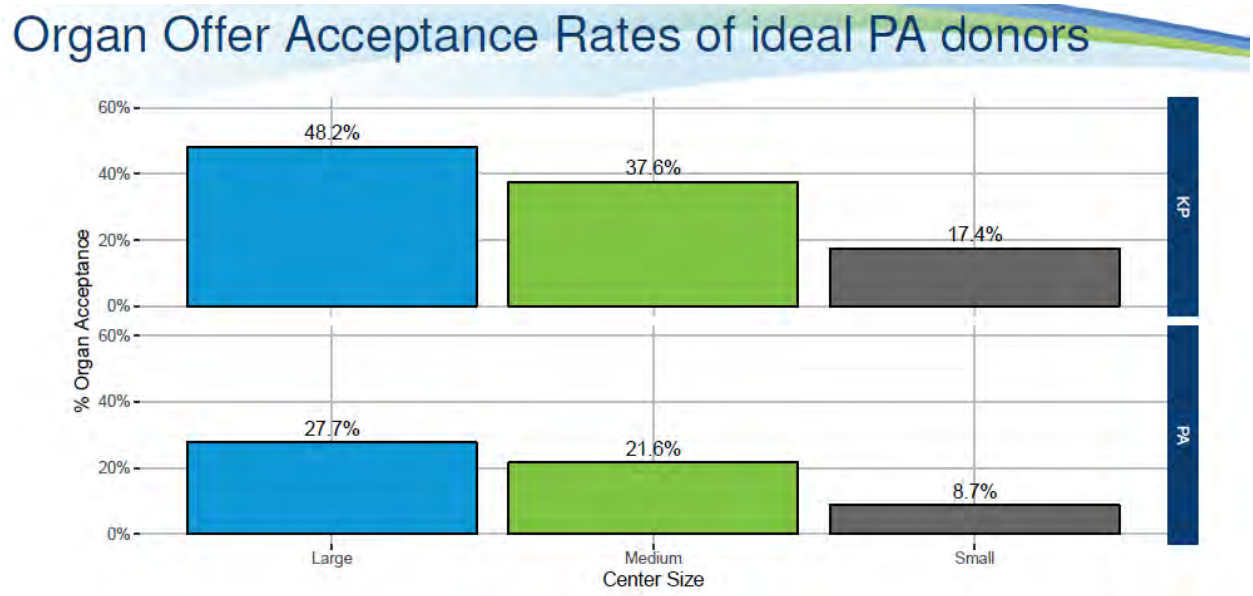
Kidney-pancreas candidates do have greater access than kidney-alone candidates overall, which reflects their increased priority in allocation above kidney-alone candidates. However, SPK transplants account for 81% of all pancreas transplants in 2018, meaning most pancreas recipients are also kidney recipients, and may be impacted by the disparity inherent in DSA boundaries.[10] The ATS evidence indicates that DSA specifically may violate the Final Rule requirement to promote patient access to transplant, and also the requirement that where a candidate is listed should not impact their access to transplant.

Variance in Pancreas Utilization and Offer Acceptance Practices

Another problem identified in the pancreas community that may affect equity is the underutilization of pancreata and variance in offer acceptance. In 2017, 23.6% of pancreata were discarded overall, and the rate of discard varied from 0% to 54.5% depending on DSA.[11] This variance of utilization implies a potential inequity in access to transplant depending on the DSA of the transplant program at which the candidate is listed. The Final Rule requires that organ allocation promote patient access to transplant. Anecdotally, the Committee has identified that organ acceptance behavior varies greatly within pancreas programs, and smaller volume programs may be more likely to decline viable pancreata.[12] **Figure 2** show how pancreas program volume may correlate with offer acceptance practices.

[10] 2019 OPTN data (accessed July 3, 2019).
[11] Urban, Read. UNOS Research, 2017 OPTN data.
[12] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.

Figure 2: Organ Offer Acceptance Rates of Ideal Pancreas-Alone (PA) Donors[13]



Because of the variance in transplant program offer acceptance and pancreas utilization, candidates may have a greater or lesser access to transplant depending on their DSA. There are fewer pancreas programs than kidney programs (126 compared to 234, respectively) and pancreas programs are more spread out.[14] The Committee considers that broader distribution could allow programs that are more aggressive in transplanting pancreata to receive and accept more offers, and this could impact acceptance behaviors of smaller volume programs that may not be accepting viable pancreata for their kidney-pancreas or pancreas-alone candidates.[15] The kidney-pancreas simulated allocation model (KPSAM) used by the Scientific Registry of Transplant Recipients (SRTR) cannot predict changes in approximate discard rate because of limitations with the input data and the difficulty of modeling changes in behavior.[16] However, the Committee considers that broader distribution could lead to increased competition between pancreas programs, which could spur programs to be more aggressive in their acceptance practices of viable pancreata.[17]

Candidates at programs that pass on viable pancreata may be impacted in their access to transplant by waiting unnecessarily long for a life-enhancing transplant. Broader and more consistent distribution with a 500 NM circle around the donor hospital may increase the competition between programs and encourage programs to accept offers they may not have otherwise. This could impact equity in access to transplant required by the Final Rule by decreasing the variance in offer acceptance practices and utilization of viable pancreata.

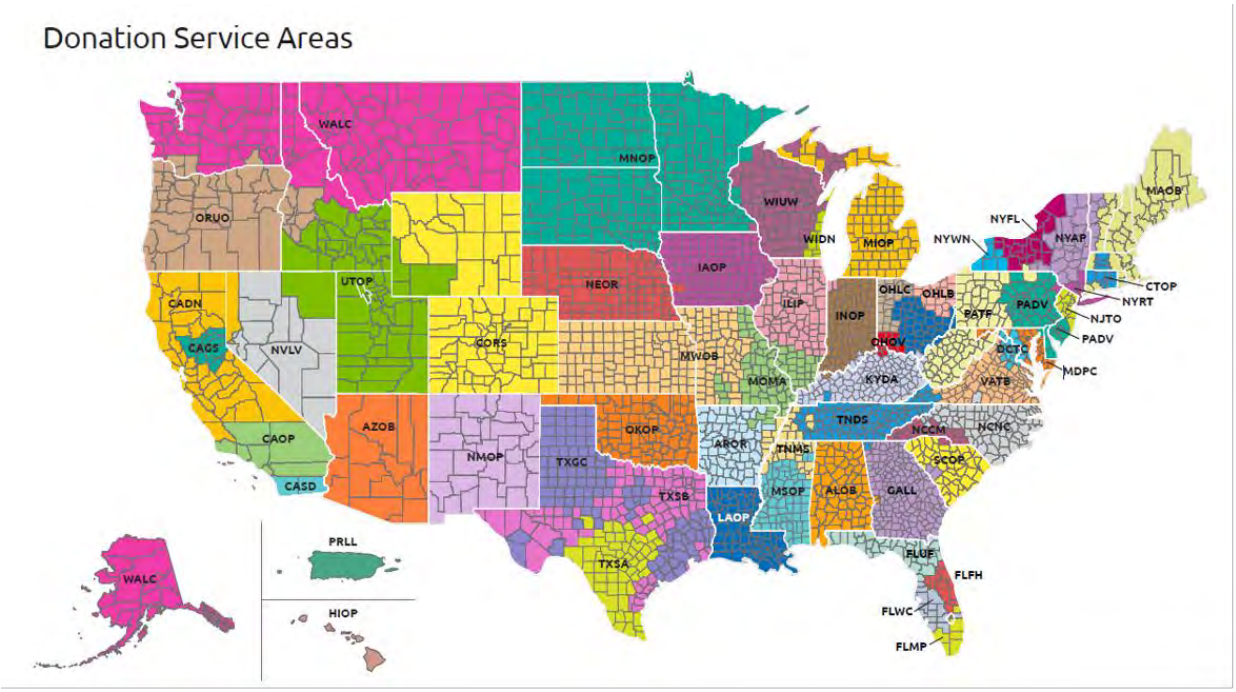
[13] OPTN/UNOS Descriptive Data Request. "Pancreas Functional Inactivity." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, September 27, 2018.
[14] Urban, Read. UNOS Research, 2019 OPTN data.
[15] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.
[16] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)
[17] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.

DSA and Region not optimized as Geographic Units of Allocation

DSAs and regional boundaries were not optimized as geographic units for the purposes of organ allocation. The DSA is the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one Organ Procurement Organization (OPO), one or more transplant programs, and one or more donor hospitals. DSA boundaries were drawn to define the boundaries in which an OPO is obligated to recover organs, not for equitable organ distribution purposes.

Regions are administrative boundaries used to facilitate OPTN governance activities. Each region is a collection of DSAs in which there were historical relationships between the OPOs and transplant hospitals. Regions vary in population, transplant volume, and geographic size. These regions are used for multiple purposes (collecting public comment, Board and committee representation, etc.) but were not designed to optimize organ distribution.[18] **Figure 3** and **Figure 4**[19] below illustrate the current geographic layout of DSAs and OPTN regions across the country.

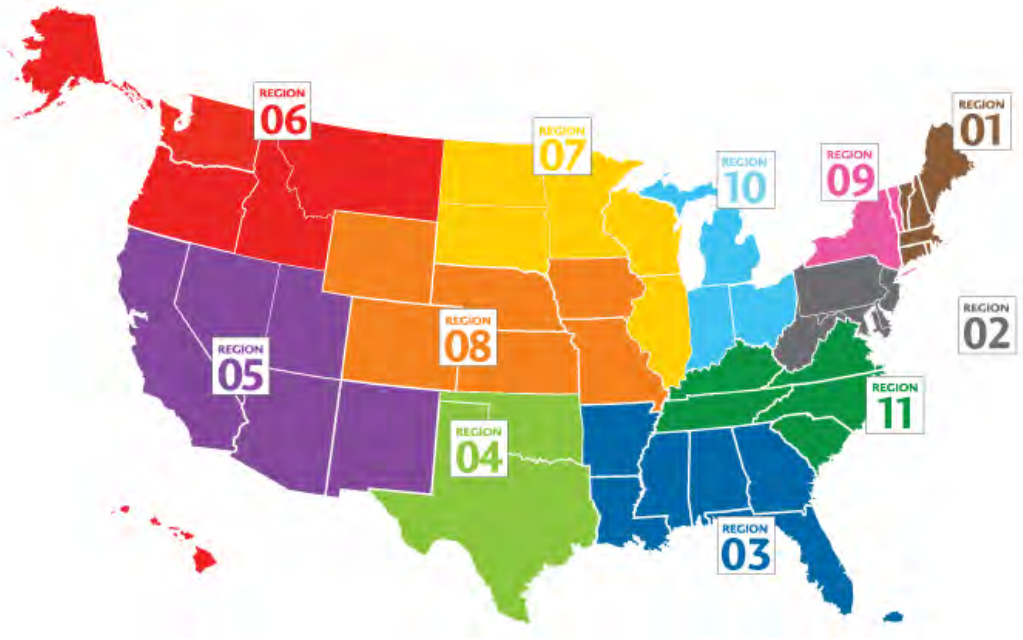
Figure 3: Geographic Layout of DSAs across the United States



[18] OPTN Bylaws Article IX: Regions. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Article_09 (accessed July 9, 2019).

[19] "Regions." Organ Procurement and Transplantation Network. https://optn.transplant.hrsa.gov/members/regions/. (accessed July 3, 2019).

Figure 4: Map of OPTN Regions across the United States



The requirement to distribute over a broad geographic area reflects professional consensus that organs are a national resource meant to be allocated based on patients' medical need. Alongside the passage of the National Organ Transplant Act (NOTA) in 1984, the Task Force on Organ Transplantation was formed within the U.S. Department of Health and Human Services to "conduct a comprehensive assessment of organ donation and procurement."[20] The final report of the 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."[21]

The Institute of Medicine made this same conclusion in 1999.[22] In 2012, the American Medical Association's Code of Medical Ethics stated that, "[o]rgans should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."[23]

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[21] 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.

[22] National Academies Press, "Organ Procurement and Transplantation." (1999).

[23] American Medical Association. "Opinion 2.16 – Organ Transplantation Guidelines." *AMA Journal of Ethics* 14(3) (2012); 204-214, https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-organ-transplantation/2012-03 (accessed December 26, 2018).

Additionally, a national survey conducted by the U.S. Department of Health and Human Services in 2012 showed that 81.7% of respondents would prefer for their "organs to go to more medically urgent patients regardless of where they live in the U.S."[24] The Advisory Committee on Transplantation (ACOT) recommended, "that the Secretary take steps to ensure the OPTN develops evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions and state boundaries."[25]

The OPTN Board of Directors has also concluded that organs are a national resource, as evidenced by the Principles of Geography composed and affirmed by a Board vote in December 2017.[26]

This proposal seeks to remove DSA and region from pancreas allocation policy and replace their use with geographic units that are rationally determined and consistently applied, in accordance with the Final Rule requirement that organ allocation not be based on a candidate's geography. The proposed changes seek to produce a more equitable allocation system for pancreas candidates.

Background

In July 2018, the Secretary of Health and Human Resources (HHS) directed the OPTN to identify a plan to eliminate the use of Donation Service Area (DSA) and region in non-liver organ policies with a rationally determined substitute that could be consistently applied and aligns with the regulatory requirements of the Final Rule.[27] In response to the Secretary of HHS letter, in August 2018 the OPTN Executive Committee directed the OPTN Kidney Transplantation and Pancreas Transplantation Committees to pursue removal of DSA and regions from their allocation systems.[28] This directive was made on the grounds that DSAs and regions, as distribution units, are not rationally determined or consistently applied, and thus may create inequities in candidates' access to organ transplantation.

A Kidney-Pancreas Workgroup ("Workgroup"), with members from the respective committees as well as the OPTN Pediatric Transplantation Committee, developed a modeling request based on Workgroup members' collective clinical experience, OPTN data on current distribution practices, and the OPTN "Geographic Organ Distribution Principles and Models."[29] When developing the modeling request, the Workgroup collaborated with relevant stakeholders, including the OPTN Minority Affairs Committee and Ad Hoc Geography Committee.[30]

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[24] U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, 2012 National Survey of Organ Donation Attitudes and Behaviors. Rockville, Maryland: U.S. Department of Health and Human Services, 2013.

[25] Advisory Committee on Organ Transplantation Recommendation 51, August 2010. https://www.organdonor.gov/about-dot/acot/acotrecs51.html (accessed July 9, 2019).

[26] Meeting Summary for December 4-5, 2017 meeting, OPTN/UNOS Executive Committee.

[27] George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

[28] Meeting Summary for August 1, 2018 meeting, OPTN/UNOS Executive Committee, https://optn.transplant.hrsa.gov/media/2609/20180801_executive_meetingsummary.pdf. (accessed December 26, 2018).

[29] 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)

[30] The OPTN 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 Final Rule.

The Kidney and Pancreas Committees submitted a concept paper for public comment in spring 2019 to garner feedback from the community on the modeling results and efforts of the Workgroup to remove DSA and region from kidney and pancreas allocation. Now including important stakeholder members from the OPTN Minority Affairs and Organ Procurement Organization (OPO) Committees, the Workgroup met throughout February and March to review public comment themes and consider future modeling requests. Workgroup discussions closely followed public comment feedback, including concerns about system efficiency, the potential impact on socioeconomically disadvantaged candidates, and support for pancreas and kidney pursuing separate solutions for their respective allocation policies.

Feedback received during the spring 2019 public comment period supported the OPTN Kidney and Pancreas Transplantation Committees composing separate policy proposals for fall 2019 public comment. The Workgroup voted unanimously that both committees (kidney and pancreas) utilize the same data request for KPSAM modeling to maximize the available bandwidth and thereby model the most framework variations. Furthermore, each committee (kidney and pancreas) wanted to consistently consider the effects on kidney-pancreas transplants across variations.

Based on the support indicated at OPTN regional meetings and input received on the OPTN public comment site as well as their clinical experience, the Workgroup members voted unanimously to move forward with modeling hybrid variations that included circle sizes of 150, 250, and 500 nautical miles. One nautical mile equals 1.151 miles.

The next sections (Hybrid Framework and Changes to the KPSAM Accept/Decline Model) detail the Committees' considerations of elements included in the second KPSAM request, reflecting that the recommendations for the second KPSAM request were thoroughly discussed and considered. Throughout the policy development process, Workgroup discussions were grounded in consideration of the impact of possible solutions on the Final Rule, in particular: avoiding unnecessary organ loss, promoting patient access to transplantation, promoting efficient management of organ placement, and not being based on a candidate's place of residence or listing except to the extent required.

Hybrid Framework

The "hybrid" framework favored by the Committee combines elements of fixed distance and continuous distribution frameworks by using both a fixed-distance circle and proximity points.[31] The Workgroup unanimously supported modeling only hybrid framework variations in the second KPSAM request because it considered that the "hybrid" framework will broaden distribution while retaining operational efficiency through the use of proximity points. This fulfills the Final Rule requirement that organ allocation not be based on a candidate's place of listing while not violating the Final Rule requirement that organ allocation shall be designed to promote the efficient management of organ placement. Also, the Workgroup agreed that utilizing a hybrid framework would represent a proactive step towards continuous distribution, which the OPTN Board of Directors directed all organ systems to eventually adopt at their December 2018 meeting.[32] Therefore, the Workgroup focused on potential solutions that utilized proximity points above those potential solutions that did not use proximity points.

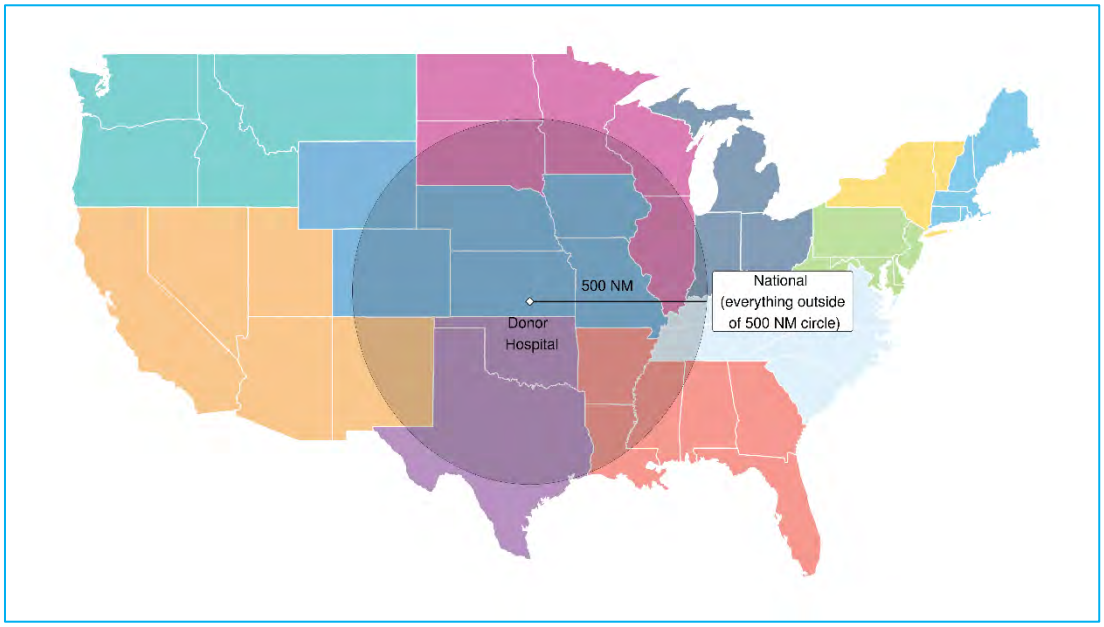
[31] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018)

[32] Executive Summary for December 4, 2018 meeting, OPTN/UNOS Board of Directors, https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf

Fixed-Distance Circle

The hybrid framework utilizes a single fixed-distance circle to replace DSA in allocation policies. The circle is a fixed geographic unit based on the distance from the donor hospital to the candidate's place of listing.[33] The hybrid framework removes regional classifications, so any organs that move beyond the single fixed-distance circle would be considered "national" organ offers. This method[34] is illustrated in **Figure 5** below, utilizing a 500 NM circle:

Figure 5: Visualization of Single Fixed-Distance 500 NM Circle for DSA



Proximity Points

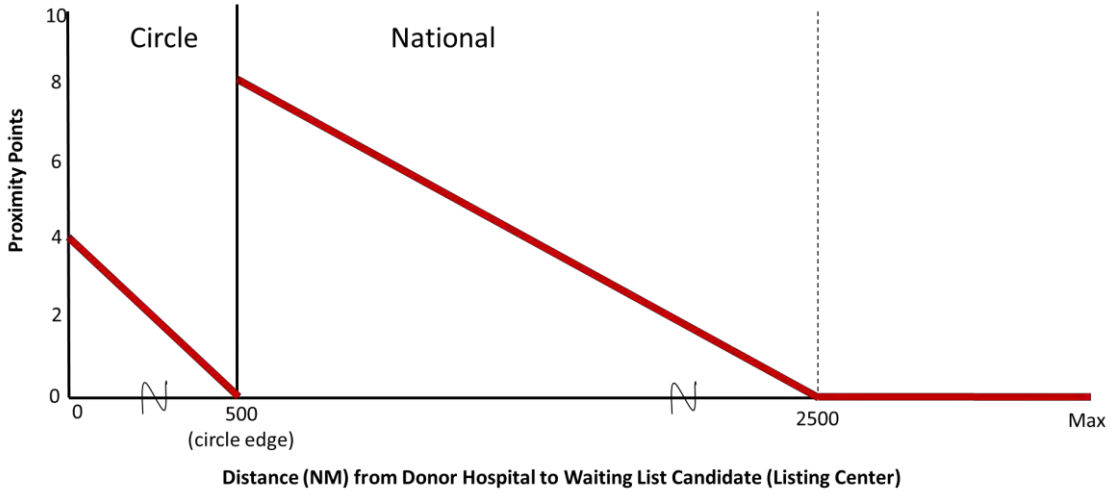
The hybrid framework awards proximity points to candidates based on the distance between the program where a candidate is registered and the donor hospital.[35] The intent of proximity points is to reflect requirements of the Final Rule to promote the efficient management of organ placement and avoid unnecessary organ loss by reducing unnecessary transportation time, cold ischemic time, cost, and the potential for higher offer refusal rates. The effect of proximity points imply that a pancreas would not travel substantially further for a candidate with only slightly higher waiting time compared to a nearby candidate.[36]

[33] *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf
[34] *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution,* OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).
[35] *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf
[36] *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution,* OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).

Candidates listed at centers closer to the donor hospital will receive more proximity points than those listed at centers further away. The current pancreas allocation system is still utilized to determine the order these candidates appear within each classification to receive organ offers on the match run. Proximity points would represent an additional value to the match run that could change the order of the match run based on a candidate's proximity to the donor hospital. Based on the current pancreas allocation tables, one proximity point can be thought of as equivalent to one year of waiting time.[37] Importantly, no matter how many proximity points are awarded, all candidates *inside the circle* will be prioritized ahead of all candidates *outside the circle*. In other words, proximity points only affect rank-ordering of candidates *within* classifications (e.g. "Inside circle EPTS <=20%"); they cannot cause candidates in a lower classification to be prioritized over candidates in a higher classification.

Points are awarded in a linear fashion, so a candidate listed at the donor hospital at the center of the fixed-distance circle would receive the maximum four points. The recommended solution utilizes a 500 NM fixed distance circle, so, a candidate listed at a transplant program located 320 NM from the donor hospital would be awarded 2.56 proximity points. If no candidate within the fixed-distance circle accepts the organ offer, allocation then moves outside of the fixed-distance circle. At this stage of allocation, a candidates can receive a maximum of eight proximity points. A candidate listed at a center 500.1 NM away from the donor hospital would be awarded that maximum number of proximity points. Points continue to be awarded linearly out to an endpoint of 2500 NM. Beyond 2500 NM, no proximity points are awarded. Therefore, a candidate listed at a transplant program located 1125 NM miles away from the donor hospital would be awarded 5.50 proximity points. **Figure 6** illustrates the linear nature in which proximity points are awarded first inside of the fixed-distance circle and then subsequently outside the fixed-distance circle.

Figure 6: Illustration of Proximity Points Allocation



The higher the maximum number proximity points awarded inside and/or outside of the fixed-distance circle, the greater the geography weighs when determining a candidates position on a match run compared to waiting time for pancreas candidates. Therefore, if the maximum number of points

[37] OPTN Policy 11.4 Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_11 (accessed July 7, 2019).

awarded is high, then points awarded for these candidate characteristics will have relatively less effect on candidate match run placement.

Regardless of the maximum number of proximity points utilized, a candidate cannot move from one classification to another on the match run. Proximity points simply "reorder" candidates against each other, in terms of identified characteristics as well as geography *within* their classification. This is illustrated in **Figure 7** below, which simulates a kidney match run with different maximum proximity point values.

Figure 7: Simulated Match Run with Various Maximum Proximity Point Values

Match Classification	Initial Allocation Pts	Initial Allocation Pts Breakdown	Distance (NM)	Current Seq #	New Allocation Pts (Including Proximity Points) and Sequence #							
					Up to 2	Seq #	Up to 4	Seq #	Up to 10	Seq #	Up to 20	Seq #
Inside Circle	9.128356	CPRA 1.09, Waiting Time 6.038356, HLAMM 2	100.097538	1	10.72796585	2	12.3275757	2	17.12640524	2	25.12445448	4
(Local)	9.065753	Waiting Time 7.065753, HLAMM 2	11.552598	2	11.01954261	1	12.97333222	1	18.83470104	1	28.60364908	1
	8.167808	CPRA 4.05, Waiting Time 3.117808, HLAMM 1	56.459213	3	9.941971148	3	11.7161343	3	17.03862374	3	25.90943948	2
	5.517808	CPRA 4.05, Waiting Time 0.458739, HLAMM 1	2.613756	4	7.507352976	4	9.496897952	4	15.46553288	4	25.41325776	3
	5.508739	CPRA 4.05, Waiting Time 3.117808, HLAMM 1	475.64834	5	5.60614564	7	5.70355228	8	5.9957722	10	6.4828054	10
	5.470726	CPRA 0.34, Waiting Time 4.139726, HLAMM 1	36.459213	6	7.324889148	5	9.179052296	5	14.74154174	5	24.01235748	5
	4.626234	CPRA 0.34, Waiting Time 3.286234, HLAMM 1	154.67954	7	6.00751584	6	7.38879768	6	11.5326432	6	18.4390524	7
	4.001367	CPRA 0.34, Waiting Time 1.661367, HLAMM 2	239.28946	8	5.04420916	8	6.08705132	7	9.2155778	8	14.4297886	8
	3.290411	Waiting Time 2.290411, HLAMM 1	351.964387	9	3.882553452	9	4.474695904	10	6.25112326	9	9.21183552	9
	1.096784	Waiting Time 0.96784, HLAMM 1	367.89551	10	1.62520196	11	2.15361992	11	3.7388738	11	6.3809636	11
	1.005479	Waiting Time 0.005479, HLAMM 1	16.459213	11	2.939642148	10	4.873805296	9	10.67629474	7	20.34711048	6
				Current Seq #	Up to 2	Seq #	Up to 4	Seq #	Up to 10	Seq #	Up to 20	Seq #
Outside Circle	204.1384	CPRA 202.1, Waiting Time 1.038356, HLAMM 1	1372.419474	12	205.2659365	12	206.3935171	12	209.7762586	12	215.4141613	12
(National)	58.91466	CPRA 50.09, Waiting Time 6.824658, HLAMM 2	1092.8594	13	60.3217986	13	61.7289392	13	65.950361	13	72.986064	13
	57.8626	CPRA 50.09, Waiting Time 6.772603, HLAMM 1	1982.5005	14	58.3801025	14	58.897602	16	60.4501005	16	63.037598	18
	57.40233	CPRA 50.09, Waiting Time 5.312329, HLAMM 2	1727.498212	15	58.17483079	16	58.94733258	15	61.26483794	15	65.12734688	16
	56.78315	CPRA 50.09, Waiting Time 4.693151, HLAMM 2	1091.3683	16	58.1917827	15	59.6004144	14	63.8263095	14	70.869468	14
	55.39137	CPRA 50.09, Waiting Time 3.301370, HLAMM 2	1534.9864	17	56.3563836	17	57.3213972	17	60.216438	17	65.041506	17
	51.18041	CPRA 50.09, Waiting Time 0.090411, HLAMM 1	1091.3683	18	52.5890427	18	53.9976744	18	58.2235695	18	65.266728	15
	41.41781	CPRA 17.3, Waiting Time 23.117808, HLAMM 1	1727.498212	19	42.19030979	19	42.96281158	19	45.28031694	19	49.14282588	19
	15.27945	Waiting Time 13.279452, HLAMM 2	1251.19039	20	16.52826161	20	17.77707122	21	21.52350005	21	27.7675481	21
	14.28562	CPRA 4.05, Waiting Time 9.235616, HLAMM 1	718.2672	21	16.0673488	21	17.8490816	20	23.19428	20	32.102944	20
	9.923288	Waiting Time 8.923288, HLAMM 1	828.87145	22	11.59441655	22	13.2655451	22	18.27893075	22	26.6345735	22
	9.70411	Waiting Time 7.704110, HLAMM 2	1251.19039	23	10.95291961	23	12.20172922	23	15.94815805	23	22.1922061	23
	9.70137	Waiting Time 7.701370, HLAMM 2	1511.6697	24	10.6897003	24	11.6780306	24	14.6430215	24	19.584673	25
	6.320548	Waiting Time 4.320548, HLAMM 2	1726.8535	25	7.0936945	25	7.866841	25	10.1862805	27	14.052013	28
	6.320548	Waiting Time 5.320548, HLAMM 1	2435.9697	26	6.3845783	26	6.4486086	27	6.6406995	29	6.960851	29
	1.679452	Waiting Time 0.679452, HLAMM 1	718.2672	27	3.4611848	28	5.2429176	28	10.588116	26	19.49678	26
	1.668493	Waiting Time 0.668493, HLAMM 1	505.567123	28	3.662925877	27	5.657358754	26	11.64065739	25	21.61282177	24
	1	HLAMM 1	869.2852	29	2.6307148	29	4.2614296	29	9.153574	28	17.307148	27
	1	HLAMM 1	3001.6792	30	1	30	1	30	1	30	1	30

Figure 7 illustrates how the rank ordering of candidates on a match run would change by awarding points based on shallower versus steeper proximity point functions. Candidates are shown rank ordered in column 2 by current total points awarded in the kidney allocation system (KAS). The current sequence number (column 5) shows how these candidates are rank-ordered under KAS. Note that distance (column 4) does not currently affect rank-ordering in KAS.

Column 6 ("Up to 2") shows how each candidate's total KAS points would change if proximity points were awarded in a linear fashion with a maximum of 2 points going to candidates listed at a program zero miles away from the donor hospital (i.e., at the same hospital). For example, points for the candidate at sequence #1 – listed at a center 100.09 miles away from the donor hospital -- would rise from 9.12 to 10.73. However, the candidate at sequence #2 – just 11.55 miles away – would rise from 9.07 to 11.01, and thus candidate #2 would now be ranked #1 due to proximity points.

Candidate sequence numbers that would change due to proximity points are highlighted in yellow. As the maximum proximity points rise to 4, 10, and 20, the number of highlighted candidates increases, indicating the greater effect that proximity would have as the proximity point function becomes steeper.

Based on this simulation and the results of the first KPSAM modeling, the Workgroup decided that the maximum points awarded inside and outside of the fixed-distance circle should be increased in the second KPSAM modeling request.

Some Workgroup members expressed interest in utilizing no proximity points within the fixed-distance circle to avoid prioritizing programs within a reasonable driving distance to the donor hospital.[38] Other Workgroup members suggested a "points plateau" or "zone of equivalence" that utilized proximity points inside the fixed distance circle but awarded the same amount of points to candidates within 150 NM or 250 NM of the donor hospital so as to negate the effect of distance within that range.[39] **Figure 8** illustrates how proximity points are awarded inside the circle in variations where a "points plateau" is utilized. The Workgroup agreed to model two variations with a "points plateau" and several variations with no points inside the fixed distance circle to identify how these variations impacted key metrics.

Figure 8: Variations Containing a Points Plateau Inside the Fixed Distance Circle

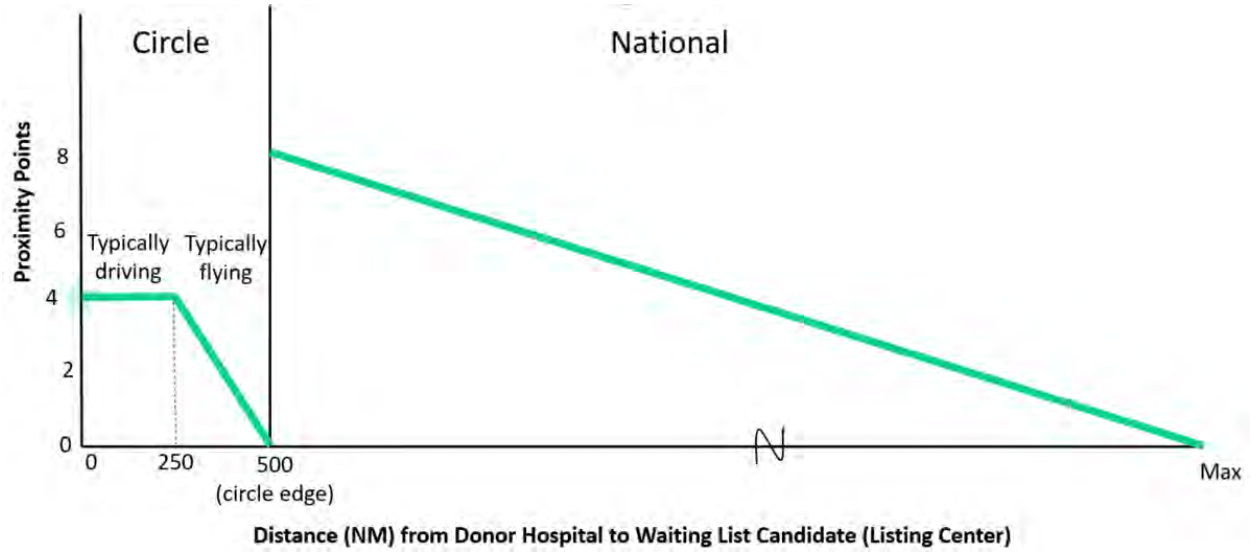


Figure 9, below, outlines the variations modeled in the second KPSAM request. This reflects the consensus of the Workgroup and various stakeholder committees, as well as the important feedback received during public comment.

Figure 9: Second KPSAM Modeling Request: Variations Requested

Model Number	Scenario	Circle Size: KI	Circle Size: KP/PA	Inner Circle Maximum Points	Outside of Circle Maximum Points
BL-ped	BL-ped (Baseline)	L/R/N	L/R/N	NA	NA
2	500.500.0.8	500	500	0	8
3	500.500.4.8	500	500	4	8

[38] Meeting Summary for March 28, 2019 meeting, OPTN Kidney Pancreas Workgroup.
[39] Meeting Summary for March 28, 2019 meeting, OPTN Kidney Pancreas Workgroup.

Model Number	Scenario	Circle Size: KI	Circle Size: KP/PA	Inner Circle Maximum Points	Outside of Circle Maximum Points
4	500.150.0.8	500	150	0	8
5	250.250.2.4	250	250	2	4
6	250.250.0.8	250	250	0	8
7	250.150.0.8	250	150	0	8
8	150.150.0.8	150	150	0	8
9	150.150.0.20	150	150	0	20
10	500.500.step150	500	500	4* (flat from 0-150NM)	8
11	500.500.step250	500	500	4* (flat from 0-250NM)	8

Changes to the KPSAM Accept / Decline Models

Several factors impact changes in transplant rate and count within the simulations, including the accept/decline models used. Importantly, the accept/decline models used in the SAMs are built using historic match run data; for this request, the match run data was from 2017. The accept/decline models for the first KPSAM modeling request included a "local indicator" as a component in predicting offer acceptance such that offers that came from a candidate's local DSA was more likely to be accepted. Because the purpose of these particular simulations is to predict changes that result from the *removal* of DSA and region in kidney and pancreas distribution, including DSA as a key predictor of acceptance behavior may result in inaccurate predictions for a future system that does not rely on DSAs for organ distribution. The accept/decline model with a local indicator likely contributed to lower projected transplant rates and counts in the first KPSAM modeling because fewer offers at the beginning of the match run were made "locally" under variations that replaced DSA and region with broader distribution systems. Because the first KPSAM accept/decline model included DSA as an acceptance predictor for a future state in which DSA would not be used, the Workgroup agreed that alternative accept/decline models should be considered in subsequent KPSAM requests.

Understanding the limitations of the accept/decline models used in the 2018 modeling request, the SRTR began work on updating the accept/decline models to better reflect the realities of the policy changes under current consideration. The SRTR presented the Workgroup with two options:[40]

- Accept/decline models 1: Use candidate and donor factors to predict acceptance. This includes the distance the organ would have to travel (geography) and offer number, but not whether the offer was "local" (same DSA) or "non-local" (received from another DSA).
- Accept/decline models 2: Use only donor factors to predict acceptance. This does not include distance the organ would have to travel because distance is dependent on the candidate characteristics, but still includes offer number.

Because the accept/decline models were created using match run data that was generated under current policy, it assumes that acceptance behavior will 'remain the same' under new allocation rules. This assumption is more credible for donor factors and less credible for candidate factors, particularly when new allocation rules may affect the priority given to certain types of candidates relative to current policy. Donor factors that lead to acceptance or decline are much more independent of the allocation system. In contrast, the reprioritization of candidates based on factors such as dialysis time is likelier to

[40] Meeting Summary for March 5, 2019 meeting, OPTN Kidney Pancreas Workgroup.

result in acceptance behavior changes on behalf of those candidates. By removing candidate factors from the models, the model no longer makes assumptions about how these factors influence acceptance.

The Workgroup decided and the Committee agreed that the SRTR should utilize accept/decline models based only on donor factors and offer number to predict acceptance. While the Workgroup acknowledges that there are limitations and advantages to each of the accept/decline models presented, members agreed that including candidate characteristics was problematic in light of the fact that acceptance behavior for candidates is more dependent on the allocation system in place, and the acceptance behavior currently in place is likely to change under a new allocation framework that, among other things, is less reliant on local offers.[41] Therefore, in the second modeling request, KPSAM uses only donor characteristics in its accept/decline models.[42]

KPSAM Modeling Results

Alongside committee clinical and professional experience, the SRTR KPSAM is an important tool that OPTN committees use when developing changes to organ allocation policy. The second SRTR analysis report for this project, released in June 2019, models the effects of replacing current DSA and region boundaries in kidney and pancreas allocation policies with hybrid framework variations illustrated in **Figure 9**. This report reflects the changes made to the KPSAM accept/decline model and focused on hybrid options that preserved proximity points, which align with community preferences for these potential solutions as well as Final Rule requirements to avoid unnecessary organ loss and to promote the efficient management of organ placement by avoiding unnecessary ischemic or travel time.

African American candidates, Asian American candidates, candidates with Medicare, and cPRA ≥ 80% candidates received projected greater access to transplants within almost all of the variations. The impact on candidates with Medicare is especially significant given that the Final Rule identifies policies that reduce inequities resulting from socioeconomic status as a priority.[43] The variations showed only miniscule differences between key metrics, including overall transplant rate and count. These projected impacts on key subgroups will be outlined in greater detail in the next section, titled, “Committee Analysis.”

KPSAM results projected that proximity points would be successful in reducing travel distance of organs within the fixed-distance circle but were less impactful in national allocation. The KPSAM analysis report stated,

> “Proximity points within the circle tend to reduce the distance traveled. For example, the median distance in run 500.500.0.8 for a kidney transplant was 303 NM, but in run 500.500.4.8 (which employed a maximum of 4 proximity points [inside the fixed-distance circle]) the median distance for a kidney transplant was 199 NM. The effect of proximity points outside the circle was less strong, likely because relatively few transplant were predicted there (10%-20%).”[44]

[41] Meeting Summary for March 23, 2019 meeting, OPTNS Kidney Pancreas Workgroup.
[42] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)
[43] 42 C.F.R. § 121.4(a)(3).
[44] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)

KPSAM limitations include the inability to account for changes in organ acceptance behavior or to predict beyond one year of waiting list outcomes, and that many transplants occur that are accepted far down the match (beyond the 200th sequence) that wouldn't be reflected in the output. For these reasons, KPSAM output should not be considered a perfect reflection of reality but rather an approximation. KPSAM results should be relied upon for assessing anticipated directional changes and for some insights into the magnitude of those changes, but not for precise estimates (particularly for small patient subpopulations).

Committee Analysis

Removing DSA and region in favor of a circle with proximity points complies with the Final Rule by providing rationally determined and consistent boundaries while permissibly taking into account system efficiency. Specifically, the Final Rule requirement that organ distribution not be based on a candidate's place of listing or residence indicates that the distribution of the circle should be as broad as possible except to the extent required by the other factors listed in the Final Rule. Even with a large initial distribution circle, use of proximity points achieves compliance with the Final Rule efficiency factors by limiting unnecessary travel and preservation time added to the pancreas or kidney-pancreas and providing some priority for candidates closer to the donor hospital. Distributing broadly also positively corresponds to another Final Rule requirement that organ allocation be designed to promote patient access to transplantation.

Committee members utilized their collective sound medical judgment, clinical and operation experience, as well as the results of the KPSAM modeling in order to inform their analysis and decisions. The below sections illustrate that key metrics indicate similar outcomes across the variations modeled. With similar impact across key metrics and variations, the Committee considered that broader distribution is more in compliance with the Final Rule than a more restricted distribution size. This indicated to the Committee that a 500 NM option would be most appropriate. Within the 500 NM variation options, the Committee considered that importance be placed on preserving efficiency by including steep proximity points both inside and outside the circle. The committee believes that the metrics they considered, outlined in the analysis to follow, illustrate the balance struck between broader distribution and system efficiency without negatively impacting patient outcomes by choosing a proposed solution that utilizes a large initial circle of 500 NM and steep proximity points both inside and outside the circle.

Waitlist Mortality Count, Waitlist Mortality Rate, and Graft Failure Rate

In 2014, the Pancreas Committee identified variation in waitlist mortality as an important metric to consider in increasing equity in access to pancreas transplantation.[45] **Figure 10** shows variance in waitlist mortality according to 2017 OPTN data.[46] Kidney-pancreas waitlist mortality rate by DSA (censored at removal from the waitlist) did not show an increase in the variance of waitlist mortality under the proposed solution or any of the other variations modeled, which abides with the Committee's objectives (**Figure 11**). Pancreas-alone waitlist mortality rate by DSA (censored at removal from the waitlist) also did not increase in variance (**Figure 12**). The Committee does not believe the proposed solution would have an increased impact on waitlist mortality for kidney-pancreas or pancreas-alone populations. Given that the proposed solution implies broader distribution than variations with a smaller distribution circle, the KPSAM waitlist mortality data provides support for the Committee's proposed solution of a 500 NM circle with steep points.

[45] Policy Oversight Committee Update, Board of Directors Meeting, OPTN/UNOS Policy Oversight Committee, June 25, 2013.
[46] Urban, Read. UNOS Research, 2017 OPTN data.

Waitlist mortality count, waitlist mortality rate per patient year (censored at removal from the waitlist), and graft failure rate per patient year were also requested by the Committee and included in an appendix report. The waiting list mortality rates from KPSAM are censored at removal from the waiting list, so they only reflect the risk of death while waiting. They are not a measure of pre-transplant mortality, or survival post-listing, since they do not include deaths that may occur after removal from the waiting list for non-transplant reasons. **Figures 11 and 12** below shows simulated projections on these three metrics for each of the modeled variations:

Figure 10: Average Waitlist Mortality Rate per Patient Year by DSA. 2017, as modeled by KPSAM (Average is taken from 10 iterations)

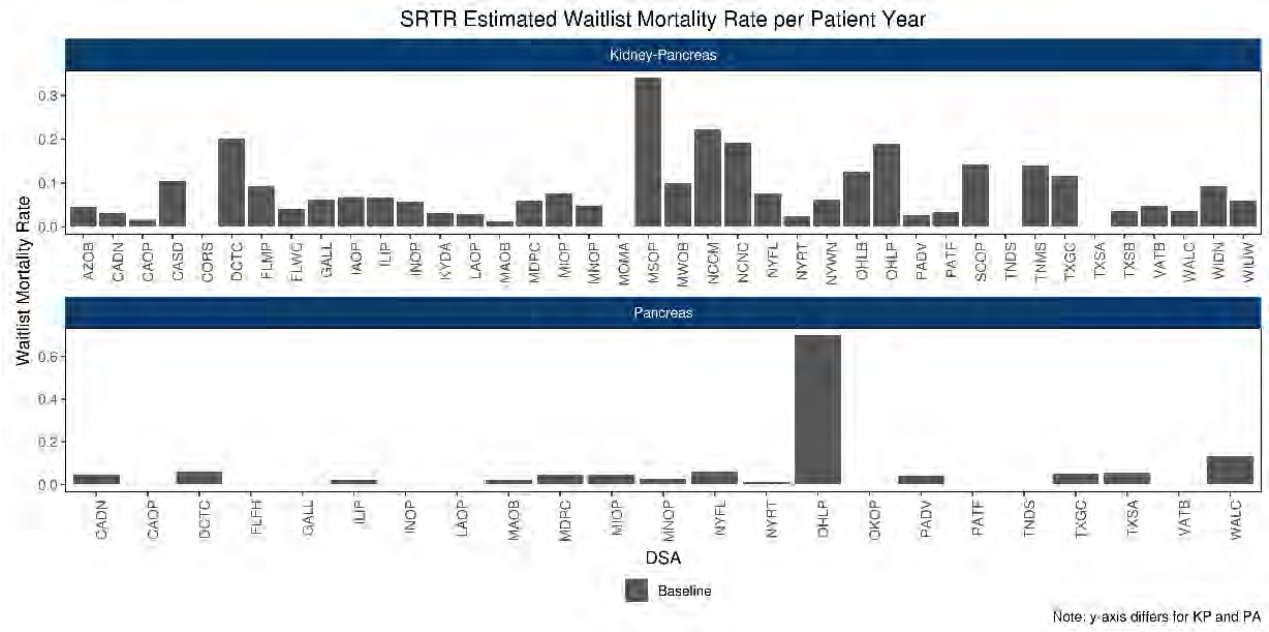


Figure 11: Average Baseline (BL) and Proposed Solution Waitlist Mortality by DSA for Kidney-Pancreas (Average is taken from 10 iterations)

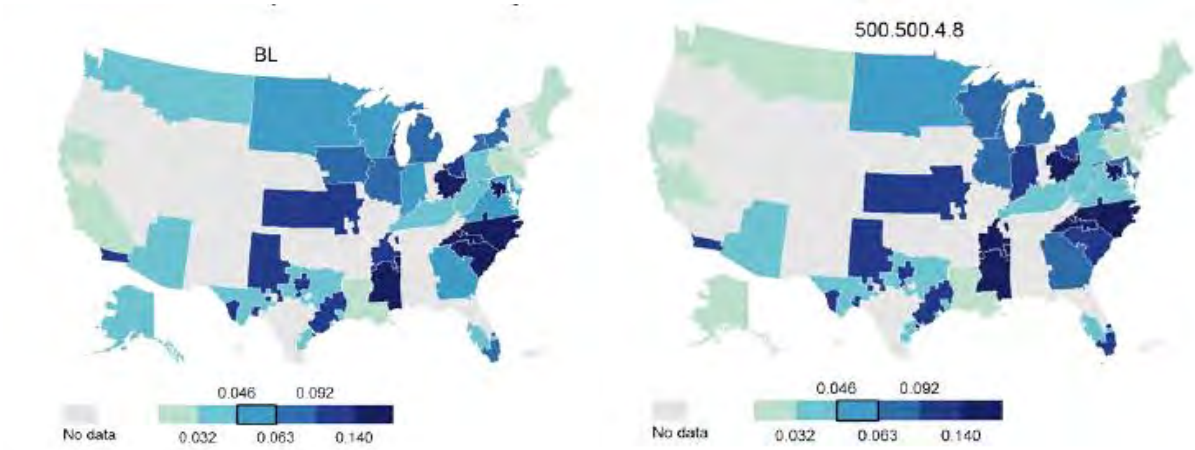
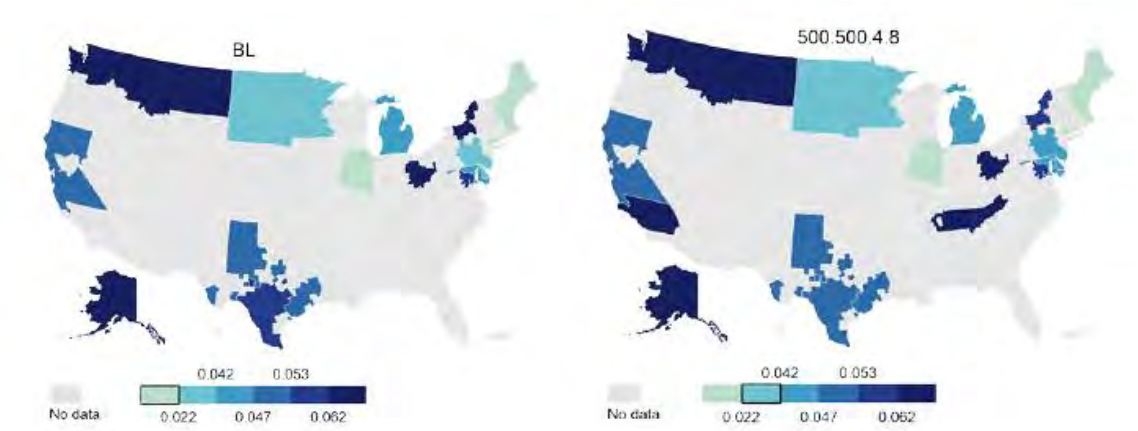


Figure 12: Average Baseline (BL) and Proposed Solution Waitlist Mortality by DSA for Pancreas (Average is taken from 10 iterations)



With the understanding that that the Final Rule requires justification for not distributing organs as broadly as possible, the Committee recognized that none of the projected variations seen in the waitlist mortality count, waitlist mortality rate by patient year, or graft failure rate by patient year sufficiently justified a fixed circle with any radius less than 500NM.

Travel Distance and Preservation Time

Broader distribution is a tenet supported by the OPTN Board of Directors, as evidenced by the Board-approved principle of distribution that "organs should be distributed as broadly as is feasible."[47] The Final Rule also specifies that organ allocation shall not be based on a candidate's place of listing or residence.[48] With those principles in mind, the Committee sought to find a variation that effectively balanced broader distribution with operation and systemic efficiency. It was this consideration that led the Workgroup to reject consideration of a purely 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 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 efficient management and potential increases in organ loss due to increased ischemic time, which can impact graft outcomes.[49]

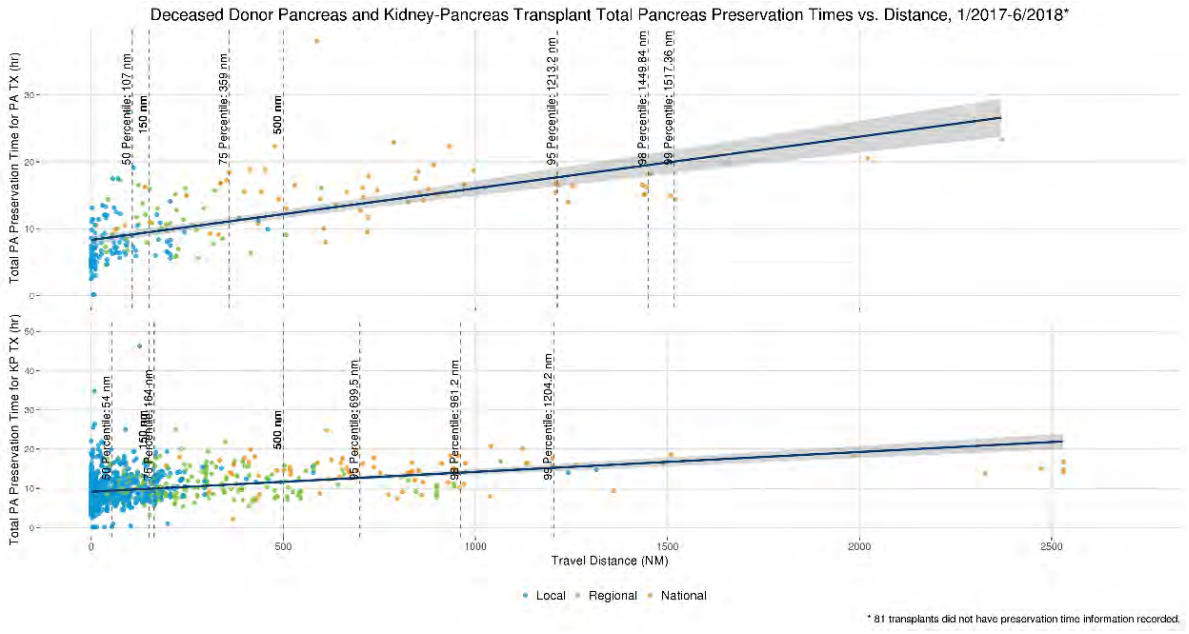
For their analysis, the Committee examined the current preservation time and travel distances, and the projected changes in travel distance and the percentage of organs traveling further than 250 NM, and the percentage of organs traveling more than 500 NM. The Committee also sought to examine the shape of distribution, the distribution of travel distance, the percentage of organs traveling further than

[47] 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 July 6, 2019).
[48] 42 C.F.R. § 121.8(a)(8).
[49] *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution,* OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).

500 NM as well as further than 250 NM, which the Workgroup had previously noted as a reasonable distance to denote a transition between organs driven and organs flown based on UNOS Organ Center travel data.[50]

Figure 13 shows the relationship between acceptance practices, distance and preservation time for both pancreas-alone (top) and kidney-pancreas (bottom). The trend line displays illustrate the association between travel distance and preservation time, indicating a typical local preservation time between 8 and 10 hours for both kidney-pancreas and pancreas. As travel distance increases in pancreas-alone transplants, preservation time tends to increases more when compared to KP transplants. However, preservation time for both KP and pancreas time can vary according to the graph, confirming Committee member discussion that transplant programs vary in their comfort level accepting and transplanting pancreata that may have more preservation time and come from a greater distance.[51]

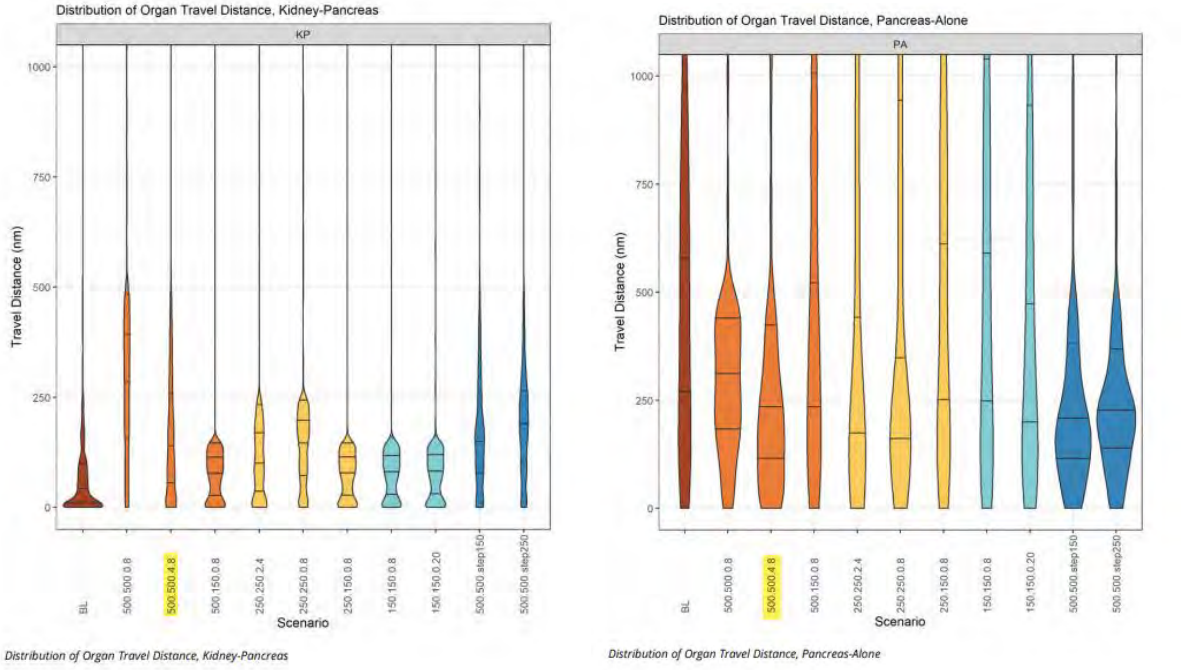
Figure 13: Pancreas Preservation Time vs. Distance



The Committee also considered potential changes in the distribution of organ travel distance for kidney-pancreas and pancreas, to identify how organ travel may change under the proposed alternatives to DSA and region. **Figure 14** uses violin plots to project the shape of distribution across the KPSAM variations for kidney-pancreas and pancreas (the Committee's proposed solution of 500.500.4.8 is highlighted).

[50] *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution,* OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).
[51] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.

Figure 14: Distribution of Organ Travel Distance, Kidney-Pancreas and Pancreas-alone (Average is taken from 10 iterations)



These plots indicate that KPs would travel farther under the proposed 500 NM solution compared to other solutions that utilized 150 or 250 NM. While pancreas-alone travel distance declined compared to the baseline for a 500 NM circle, this is to be expected. Most DSAs are much smaller than 500 NM, and broader distribution suggests more pancreas programs could get an offer before going to the national level. The Committee also observed in the percentage of organs traveling more than 250 NM an increase in KP and a decrease in pancreas-alone.

At an in-person meeting in Baltimore on June 25, 2019, the Committee discussed whether preservation time should limit the distance traveled and the circle size chosen.[52] Committee members indicated the answer was "not necessarily." Most pancreata are transplanted locally – but certain more aggressive programs do accept pancreata from further away and successfully transplant the organs. Committee members noted that pancreas-alone transplants occur at programs that tend to be more aggressive, and such behavior characteristics are difficult to model in the KPSAM. The Committee considered that a 500 NM circle with proximity points inside the circle would concentrate acceptance to programs closer to the donor hospital while still allowing more aggressive programs the opportunity to transplant pancreata from farther away. This could increase competition with less aggressive programs, which could help with utilization by encouraging less aggressive programs to consider viable pancreata they may not have otherwise. Utilization rates of pancreata varies greatly depending on DSA and is a problem in the pancreas transplant community.[53] Committee members also considered that a larger circle could allow programs to work with different organ procurement organizations (OPOs) if they are facing issues with their local OPO. Finally, the Committee considered that the Final Rule specifies that a candidate's

[52] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.
[53] Urban, Read. UNOS Research, 2017 OPTN data.

place of listing or residence should not impact allocation, and broader distribution would indicate that geography would play less of a role than it would if initial distribution were confined to a smaller circle.

Access to Transplant for Vulnerable Populations

The KPSAM results indicated that specific vulnerable subpopulations of candidates are projected to benefit from removing DSA and region and may have enhanced access to transplant relative to the status quo. Specifically, high cPRA candidates (**Figure 15**), Asians and African Americans (**Figure 16**), and candidates with Medicare (**Figure 17**) all stand to have increased equity in access to transplant with broader, more consistent distribution. Highlighted in each graph is the modeling variation supported by the Committee in this public comment proposal (500.500.4.8, or 500 NM circle with up to 4 points inside the circle and up to 8 points outside the circle). This is consistent with Final Rule requirements that organ allocation promote patient access to transplantation and not be based on candidate's place of residence or listing.

It is important to note Committee member feedback on the projected decreases in pancreas-alone metrics.[54] According to member medical expertise and experience, members noted that most pancreas-alone transplants are performed by more aggressive programs that will continue to accept and transplant pancreas-alone despite changes to the distribution units. Aggressive pancreas programs, defined as transplanting on average more than 4 pancreata a year, are responsible for over 87% of pancreas-alone transplants since 2014.[55] Therefore, the Committee considered that the decrease in pancreas-alone across key metrics may not occur or may not occur to the extent seen in the modeling.

The projected increase in key metrics for KP may not be as great because of the same reason: program behavior. Less aggressive programs may change their behavior over time, but the projected increase may not occur to the extent modeled by the KPSAM. The Committee also considered that there are only about 150 non-multivisceral pancreas-alone transplants in 2017 and the trends seen are reflecting a very small number of transplants.[56] Changes seen in the modeling may indicate the direction if not the level of change to expect with the proposed modifications to pancreas distribution.

[54] Meeting Summary for June 25, 2019 meeting, OPTN Pancreas Committee, https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/.
[55] Urban, Read. UNOS Research, 2019 OPTN data.
[56] 2019 OPTN data (accessed July 10, 2019).

Figure 15: Transplant Rate by cPRA: Kidney-Pancreas and Pancreas

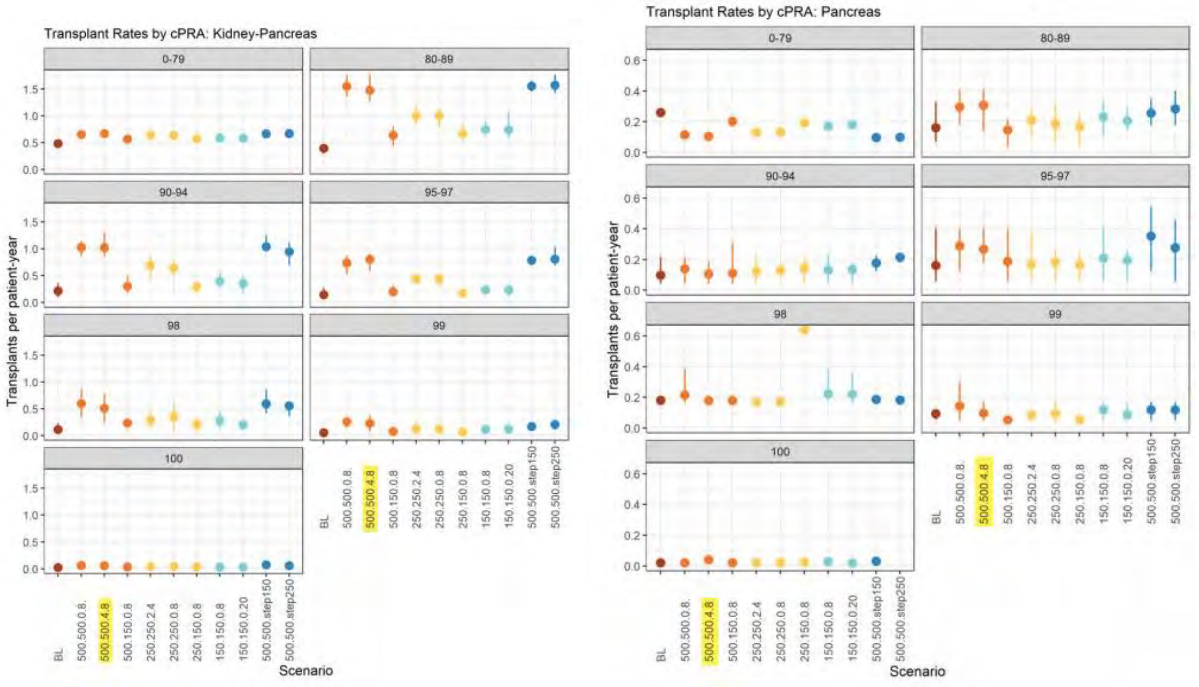


Figure 15 highlights the impact on high cPRA candidates in their access to transplant by measuring transplant rate by cPRA for both kidney-pancreas and pancreas. The graphs demonstrate increased access for both high cPRA kidney-pancreas and pancreas candidates. While a 500.500.0.8 variation may show increased transplant rate relative to the 500.500.4.8 variation, the Committee considered it important that proximity points inside the circle preserve local access and address concerns about inefficiencies, travel costs and travel logistics. This is also in compliance with Final Rule requirements that organ allocation shall be designed to avoid unnecessary organ loss and promote the efficient management of organ placement. Both 500 NM options represent an increase in access for high cPRA candidates compared to the current system (BL, or baseline) as well as compared to the other options modeled.

Figure 16: Transplant Rates by Race: Kidney-Pancreas and Pancreas

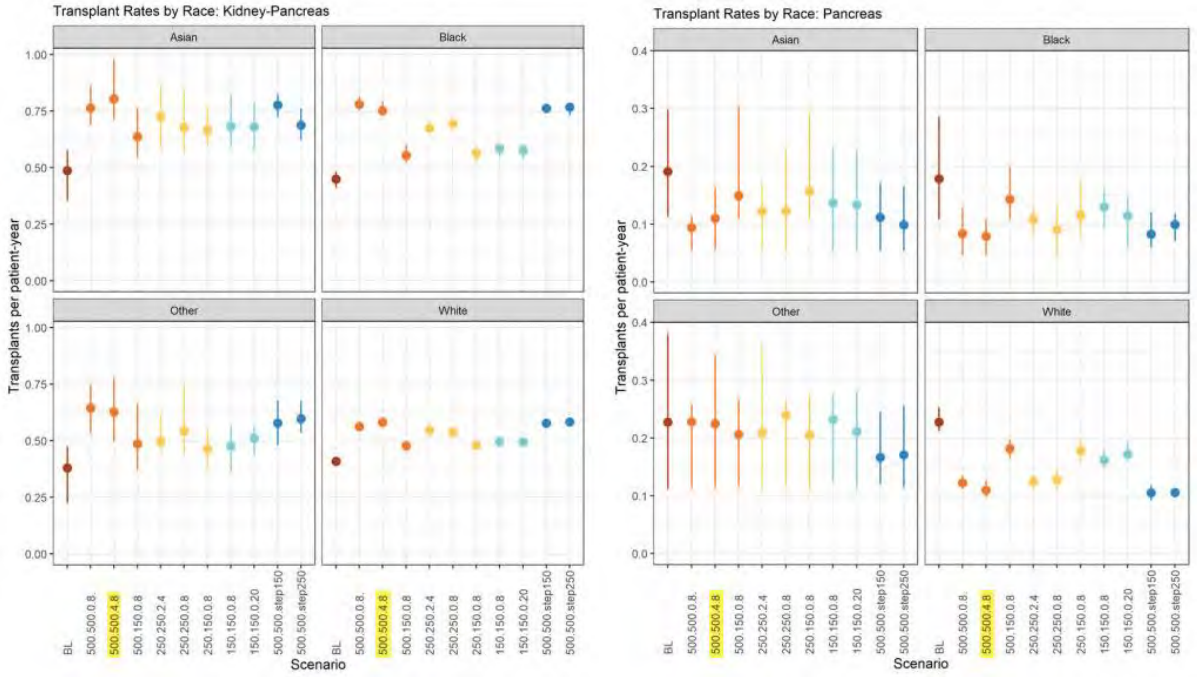
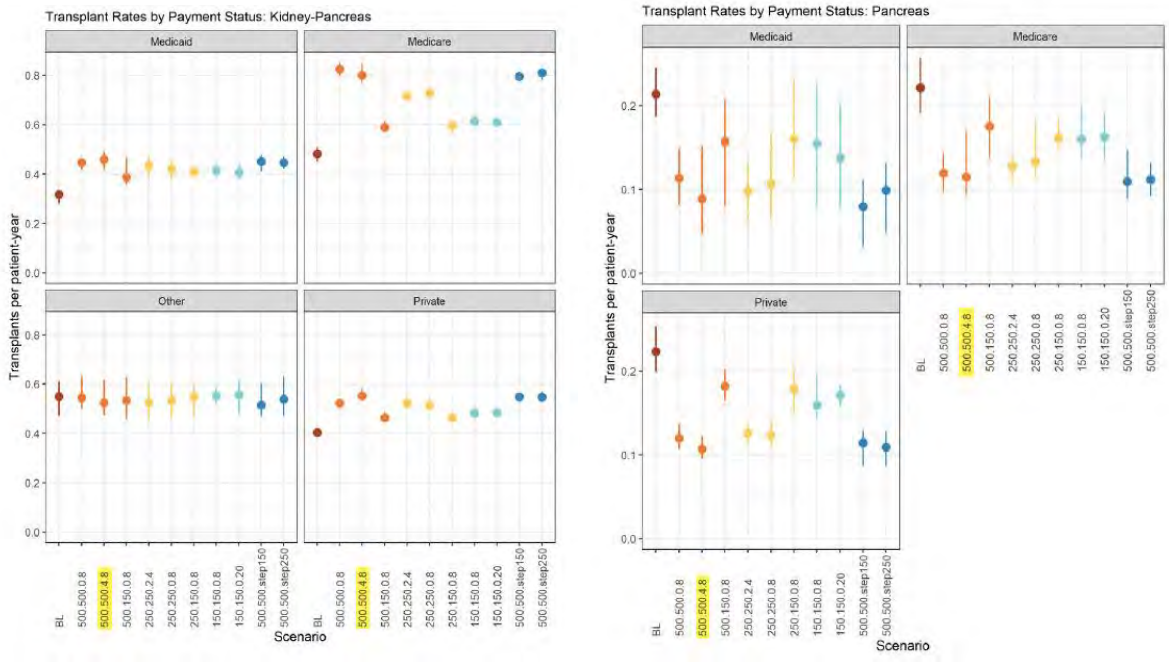


Figure 16 shows a relative increase for African American and Asian American KP candidate transplant rates compared to white KP candidate transplant rates, with the 500 NM options showing more of a relative increase in access compared to the other options modeled. Pancreas-alone shows a decrease in transplant rate across race which the Committee does not think will be reflected in reality once these changes are enacted, for reasons stated previously. The pancreas-alone percent of transplants performed by race in the KPSAM results support this conclusion. While the overall pancreas-alone transplant rate goes down, it appears that the rates go down proportionally for each race group, meaning there isn't one race that is more impacted by the decline than others. That is supported when considering the distribution of transplants by race- the percentages of transplant recipients by race is fairly constant.

Figure 17: Transplant Rates by Payment Status: Kidney-Pancreas and Pancreas



Figures 15 through **17** show the range of transplant rates across the 10 iterations per scenario as a vertical line extending from the minimum value to the maximum value for that scenario. A point along the line marks the mean value of that metric across the 10 iterations. **Figure 17** shows a projected relative increase in KP candidates with Medicare getting transplanted compared to those with private insurance, with a greater difference in transplant rate for the 500 NM scenarios. Insurance type is an important indicator of socioeconomic status (SES), which is a metric the community expressed concern and interest in during the public comment period of the KP Concept Paper.[57] The Final Rule also indicates the importance of developing policies that reduce inequities in socioeconomic status.[58] A relative increase for low SES candidates was also seen in the KP median household income by zip code, which showed a relatively higher transplant rate for candidates in zip codes with a median income less than $70,000. Transplant percentages by urbanicity were relatively unchanged for kidney-pancreas and pancreas.

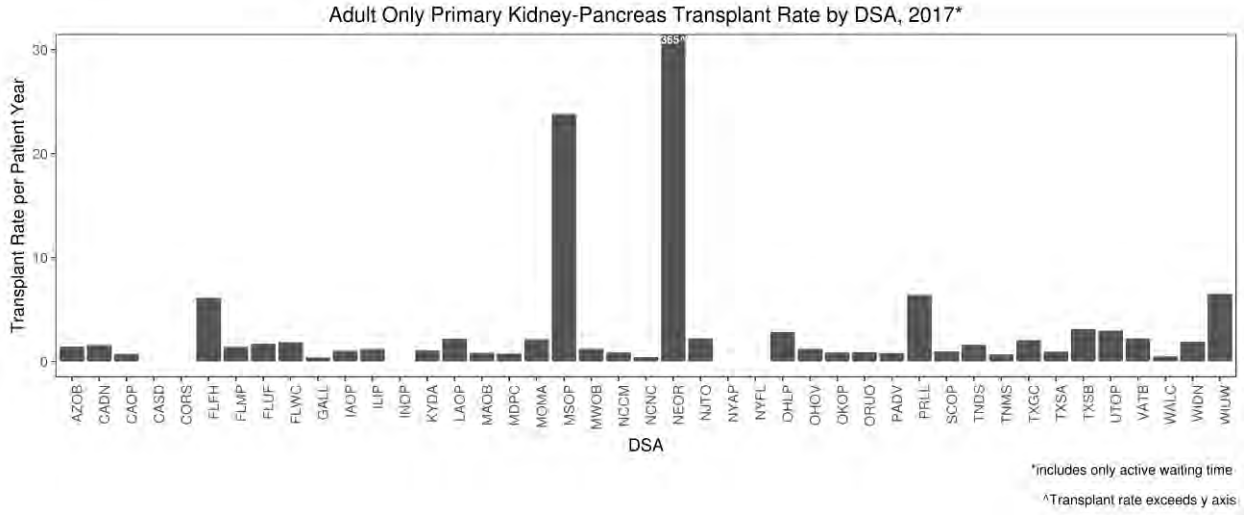
Access for patients that need a pancreas transplant is dependent on the size and shape of their DSA, which varies and is inconsistent. The modeling demonstrated how certain vulnerable populations would benefit by an increase in access to transplantation and how that impact may vary according to circle size and proximity points. This is consistent with the Final Rule requirement to promote patient access to transplant, and to create policies that address inequities in SES. The Committee determined that a 500 NM circle from the donor hospital would enhance access for candidates of certain vulnerable populations, including candidates that may come from a lower SES background, by broadening distribution while making that access more consistent across the country.

Overall Transplant Count and Transplant Rate

[57] *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution,* OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).
[58] 42 C.F.R. § 121.4(a)(3

Figures 18 and **19** show the variation in transplant rate across DSA for kidney-pancreas and pancreas, respectively. **Figures 19** and **20** shows the projected increase in kidney-pancreas and pancreas transplant rate variance with the proposed solution when compared to the simulated baseline. The increased variance reflects more aggressive programs competing with less aggressive programs for pancreata. While the variance may increase, so could the competition between programs that vary in offer acceptance and pancreas utilization. More aggressive programs may take advantage of organ offers in the larger circle to a greater extent than less aggressive programs. At the same time, proximity points will ensure that less aggressive programs closer to the donor hospital would still have an opportunity to transplant their candidates. Instead of reflecting a potential inequity, the Committee considers that increased competition between pancreas programs could improve equity by allowing more candidates access to transplant at programs that do not decline viable pancreata and transplant their candidates quickly.[59] The increased competition could spur increased utilization of pancreata, decreased discard rate, and encourage programs that have been less aggressive to accept viable pancreata they previously would have declined. This could impact the Final Rule requirement that organ allocation should promote patient access to transplant, and also the Final Rule requirement that organ allocation should promote the efficient management of organ placement and avoid unnecessary organ loss.

Figure 18: Adult Only Primary Kidney-Pancreas Transplant Rate by DSA, 2017



[59] OPTN/UNOS Descriptive Data Request. "Pancreas Functional Inactivity." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, September 27, 2018.

Figure 19: Adult Only Primary Pancreas-Alone Transplant Rate by DSA, 2017

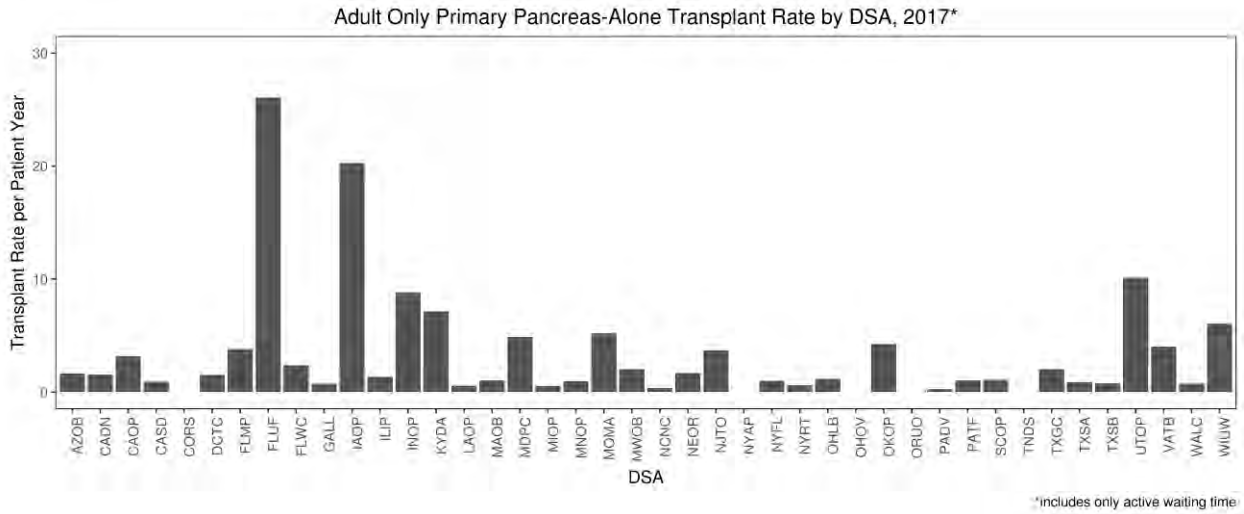


Figure 20: SRTR Simulated Average Kidney-Pancreas Transplant Rate by DSA

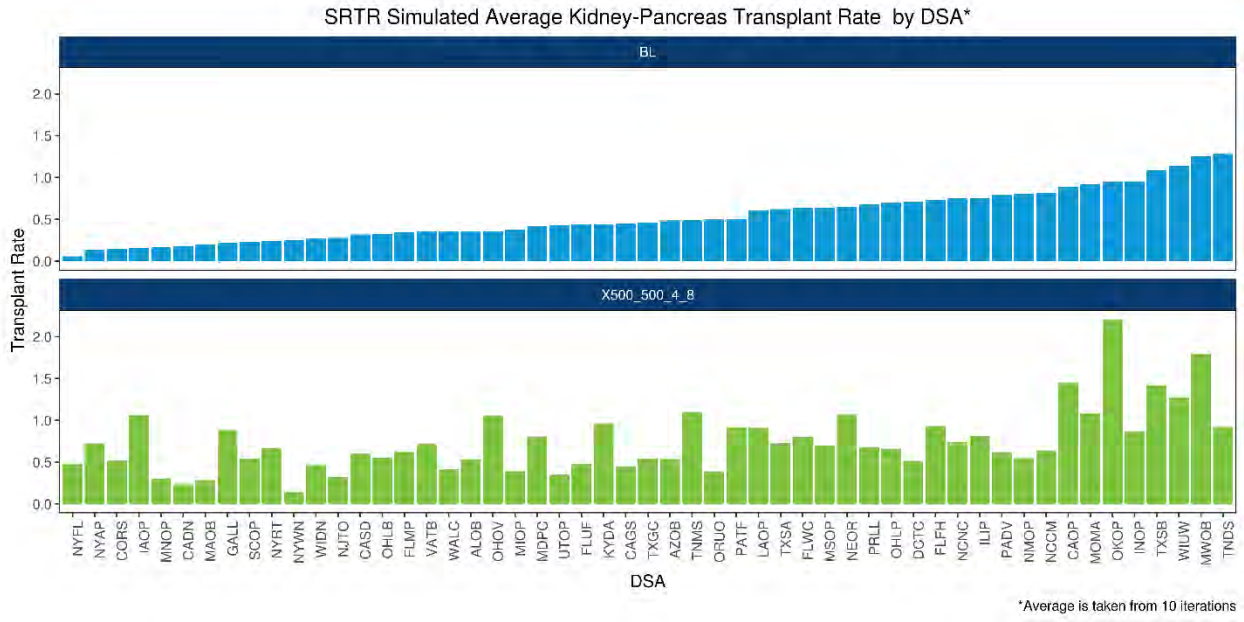


Figure 21: SRTR Simulated Average Pancreas Transplant Rate by DSA

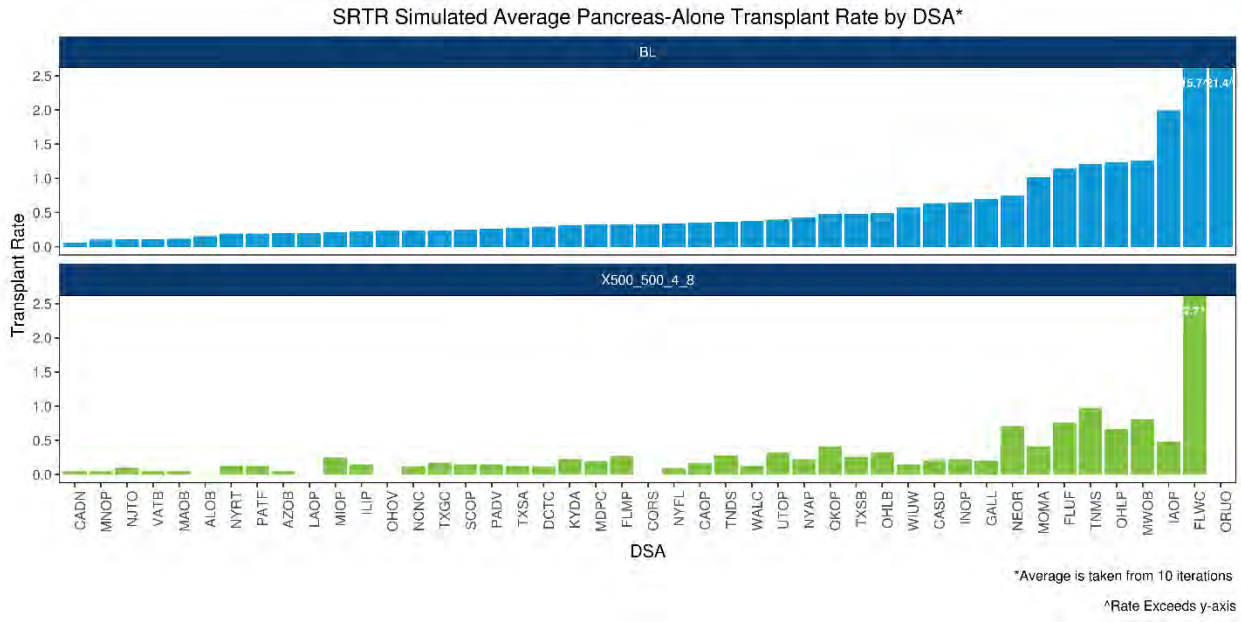


Figure 22 below show simulated projections on kidney-pancreas and pancreas-alone transplant rate for each of the modeled variations:

Figure 22: Transplant Rate for Kidney-Pancreas and Pancreas Transplants from KPSAM Modeling

Scenario	KP Transplant Rate per Patient-Year	PA Transplant Rate per Patient-Year
BL – Peds Priority	0.422	0.221
500.500.0.8	0.623	0.118
500.500.4.8	0.631	0.107
X500.150.0.8	0.501	0.177
X250.250.2.4	0.583	0.124
X250.250.0.8	0.581	0.124
X250.150.0.8	0.507	0.171
X150.150.0.8	0.523	0.158
X150.150.0.20	0.521	0.165
X500.500.step150	0.626	0.109
X500.500.step250	0.63	0.108

The second and third columns illustrate the differences in transplant rate per patient year of each of the modeled variations from the modeled baseline for KP and PA, respectively. For KP, the transplant rate shows a projected increase while pancreas-alone shows a projected decrease. However, as discussed previously, the Committee considers that the modeling does not reflect program behavior and the projected decrease/increase may not occur to the degree indicated by the modeling. The Committee focused mostly on the KP results, expressing agreement that the projected pancreas-alone decrease is less likely to occur than the modeling indicates, and also considering that the majority of pancreas transplants are KP.

The total number of kidney transplants (kidney alone combined with KP), varied little across model variations, and almost no change was seen from baseline. As expected, the decrease in kidney alone, and simultaneous increase in kidney-pancreas, saw the largest change in the biggest circles (e.g. 500 NM) and change was minimized in the smaller circles (e.g. 150 NM). KPSAM results showed that proximity points were successful in reducing travel of the organ inside the circle, but were less impactful in national allocation in terms of efficiency. However, the proximity points outside the 500 NM circle still impact how candidates appear on the match run.[60]

Figure 23 shows the projected impact on pancreas transplant counts for KP, pancreas-alone, and the combined changes compared to baseline. It demonstrates the total change in pancreas transplant counts from baseline increased, with an increase in KP offsetting a decrease in pancreas-alone. The Committee considers the increase in KP and decrease in pancreas-alone demonstrated in the modeling may be exaggerated and not reflective of reality.

Figure 23: KPSAM Modeling Pancreas Transplant Counts

Model	KP Transplant Count	PA Transplant Count	Total PA Transplants (KP & PA)	KP Change from BL	PA Change from BL	Total PA Change from BL
BL – Dec Rerun	822	160	982			
BL – Peds Priority	815	163	978			
500.500.0.8	1111	92	1203	36.3%	-43.6%	23.0%
500.500.4.8	1122	84	1206	37.7%	-48.5%	23.3%
X500.150.0.8	937	133	1070	15.0%	-18.4%	9.4%
250.250.2.4	1056	96	1152	29.6%	-41.1%	17.8%
250.250.0.8	1052	96	1148	29.1%	-41.1%	17.4%
250.150.0.8	945	129	1074	16.0%	-20.9%	9.8%
150.150.0.8	970	120	1090	19.0%	-26.4%	11.5%
150.150.0.20	966	125	1091	18.5%	-23.3%	11.6%
500.500.step150	1118	81	1199	37.2%	-50.3%	22.6%
500.500.step250	1124	83	1207	37.9%	-49.1%	23.4%

Figure 24 shows the impact on kidney transplant count for KP, kidney-alone and the combined changes.

[60] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)

Figure 24: KPSAM Modeling Kidney Transplant Counts

Model	KI Transplant Counts	KP Transplant Counts	Total KI Transplants (KI & KP)	KI Change from BL	KP Change from BL	Total KI Change from BL
BL- Current KAS	13062	822	13884			
BL- Peds Priority	13080	815	13895			
500.500.0.8	12748	1111	13859	-2.5%	36.3%	-0.3%
500.500.4.8	12766	1122	13888	-2.4%	37.3%	-0.1%
500.150.0.8	12965	937	13902	-0.9%	15.0%	0.1%
250.250.2.4	12830	1056	13886	-1.9%	29.6%	-0.1%
250.250.0.8	12832	1052	13884	-1.9%	29.1%	-0.1%
250.150.0.8	12945	945	13890	-1.0%	16.0%	0.0%
150.150.0.8	12915	970	13885	-1.3%	19.0%	-0.1%
150.150.0.20	12946	966	13912	-1.0%	18.5%	0.1%
500.500.step150	12720	1118	13838	-2.8%	37.2%	-0.4%
500.500.step250	12727	1124	13851	-2.7%	37.9%	-0.3%

Figure 24 demonstrates minimal change in total transplant counts for all variations when compared to baseline. The results show that while increases in the number of KP transplants vary greatly across each of the modeled variations, the changes and variation in total kidney alone transplants vary much less and represent minimal changes. Furthermore, the changes in overall total kidney transplant counts when compared to baseline are even less varied and overall minuscule.

The KPSAM showed that the larger the circle utilized, the greater the increase in median travel distance of organs increased.[61] Kidney-pancreas transplant rates increased across all broader distribution scenarios modeled, with the largest KP transplant rate increases correlating to larger fixed-distance circles. As the pancreas circle size increases, KP transplant counts increased, leading to subsequent decreases in kidney and pancreas-alone transplants. This is due to the priority KP candidates are given over kidney and pancreas-alone candidates at the current local level.[62] As noted previously, Committee members think the projected increase in KP that impacts kidney and pancreas-alone may be exaggerated because modeling cannot accurately approximate program behavior. Some programs may act more conservatively with the changed KP distribution, reflecting a smaller increase in KPs and smaller decrease in kidney and pancreas-alone. Alternatively, the behavior of more aggressive pancreas-alone programs may indicate that the decrease in pancreas-alone is less than projected.

Nearly all variations yielded similar results in terms of projected effects on key subpopulations. This is significant in terms of compliance with the Final Rule. Given similar results across key subpopulations, the Committee considered a larger circle of 500 NM to be more compliant with the Final Rule because it decreases the importance of geographic location of the candidate's place of listing or residence.

[61] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)
[62] OPTN Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_11 (accessed July 9, 2019).

Consensus Achieved

The Committee analysis and deliberation reflected consensus on certain key elements of the solution:

A fixed-distance circle size of 500 NM should be utilized in the proposed hybrid framework

The Committee concluded that the lack of noteworthy variation in overall transplant counts, transplant rates, waitlist mortality rate by patients year, and graft failure rates by patient year among the modeled variation could not justify a circle size limited to a distance less than 500 NM given the requirements of the Final Rule for not basing organ allocation on a candidate's place of residence or listing. Furthermore, transplant rates for certain vulnerable populations, including highly-sensitized candidates, Asian and African American candidates, and socioeconomically-disadvantaged candidates increased most under 500 NM variations, which also indicates compliance with the Final Rule requirement to develop policies that reduce inequities resulting from socioeconomic status.

The fixed distance circle, in general, provides a consistently applied and reasonably determined mechanism as a replacement for DSA. The framework is consistently applied because every circle around every transplant program is the same size for the first phase of allocation (exactly 500 NM), regardless of where a candidate is listed. Furthermore, the hybrid framework is reasonably determined based on sound medical judgment, which included the collective clinical and operational experience of the OPTN Pancreas Transplantation Committee, historical data, stakeholder input, and simulation modeling to determine a framework that removes DSA and region from pancreas allocation policies.

Proximity points should be implemented inside and outside of the fixed-distance circle

The Committee considered that a 500 NM circle with proximity points inside the circle would concentrate acceptance to programs closer to the donor hospital while still allowing more aggressive programs the opportunity to transplant pancreata from farther away. This could increase competition with less aggressive programs, which could help with utilization by encouraging less aggressive programs to consider viable pancreata they may not have otherwise. This is significant for the Final Rule requirements that organ allocation shall be designed to avoid unnecessary organ loss and shall promote the efficient management of organ placement. Some members expressed concern about travel logistics and efficiency with a larger circle, and the Committee overall felt that having proximity points may mitigate some of the concerns about efficiency by having priority for closer candidates while still preserving the opportunity for more aggressive programs to accept farther away organs. Including steep proximity points is also in accordance with the Final Rule requirements related to efficient management of organ placement and avoiding unnecessary organ loss.

The Committee also that national classifications should reflect similar prioritization based on proximity to avoid inefficiencies and unnecessary travel when possible. By having steep (8) points outside the circle, candidates closer to the 500 NM boundary would receive priority over candidates farther away, and travel could be minimized.

A proximity points plateau should not be utilized in the proposed framework, may add value for released organs

Though certain Committee initially thought negating the effect of distance within 150 NM or 250 NM of the donor hospital inside of a 500 NM fixed-circle would add some projected or operational efficiencies

or perhaps material improvements in clinical outcomes, neither of these suppositions were borne out in the KPSAM modeling results. Additionally, from an implementation and community education standpoint, introducing such a mechanism to the proposed system may not be advisable unless the value it added seemed significant. The committee concluded that a proximity points plateau would not be included in the proposed allocation framework.

The Committee believes that a proximity points plateau may have some operational value in the case of released organs when the host OPO elects to utilize import backup. This is because there is no additional allocation circle beyond the 150 NM fixed-distance circle proposed in the import backup solution outlined in the section below titled, “Impact on OPTN Policy 5.9: Released Organs (Import Back up).”

Recommended Solution

Based on these decisions, the Committee determined that the 500 NM fixed circle with a maximum of 4 points inside the circle and a maximum of 8 points outside the circle would provide a rational foundation for pancreas distribution while improving equity in access to transplant for certain vulnerable populations and potentially furthering competition between pancreas programs that could decrease variance in offer acceptance and increase utilization, in accordance with the Final Rule requirement to avoid unnecessary organ loss (wasting organs). The proposed solution would also be in accordance with the Final Rule requirement that organ allocation to be based on a candidate’s place of residence or listing except to the extent necessary by utilizing a broader circle than other options considered by the Committee. The inclusion of steep proximity points reflect consideration of the Final Rule requirements to avoid unnecessary organ loss and to promote efficient management of organ placement. Finally, the KPSAM modeling indicates that certain vulnerable socioeconomic populations may benefit from the proposed solution, which accords with the Final Rule requirement to develop policies that reduce inequities resulting from SES. The Committee unanimously supported removing DSA and region in pancreas allocation and using instead a 500 NM circle around the donor hospital, with up to 4 proximity points inside the circle and up to 8 proximity points outside the circle.

Compliance with National Organ Transplantation Act (NOTA) and Final Rule

The proposed solution removes DSA and region from pancreas/KP/islet allocation policy and allocates using a NM distance that strikes an appropriate balance with the Final Rule requirements. This distance has a neutral effect on waitlist mortality and distributes pancreata as broadly as feasible while increasing the potential for pancreas utilization and reducing the potential impact of long preservation times on post-transplant mortality with the use of proximity points. This impacts the Final Rule requirements that organ allocation shall not be based on the candidate’s place of residence or listing except to the extent required. It also reflects compliance with the Final Rule requirement to avoid unnecessary organ loss and to promote the efficient management of organ placement by limiting travel distance with proximity points. In addition, the solution improves access for certain vulnerable populations including Asian and African American populations, candidates with Medicare insurance, and high-cPRA candidates. The Final Rule specifically indicates that the OPTN should develop policies that reduce inequities resulting from socioeconomic status. Overall the proposed policy represents an improvement in pancreas allocation by making it more consistent with the Final Rule and removing an inconsistently applied unit of geographic distribution.

Facilitated Pancreas Allocation

Facilitated placement in pancreas allocation allows OPOs and the OPTN Organ Center to offer organs to a list of pancreas programs that import a certain number of pancreata (5 pancreata in a 2 year period) when the OPO is within 3 hours of procurement and has already offered the organ to local candidates.[63] This aspect of pancreas allocation provides the opportunity for increased efficiency and potentially more utilization of pancreata by offering imported pancreata to those programs most likely to use them. The facilitated placement policy needs to be updated because the facilitated pancreas programs are defined using pancreata imported from outside of a program's DSA, which is no longer applicable with a circle based distribution systems around donor hospitals. Instead of defining a program as eligible for facilitated placement by the number of pancreata imported from outside the DSA, under the proposed changes the program would be defined as eligible for facilitated placement based on a certain number of pancreata imported from outside a nautical mile distance from the transplant program.

The Committee reviewed data regarding the current use of facilitated placement, including the number of programs that qualify for facilitated placement, the number of transplants performed via facilitated offers, and the distribution of facilitated transplant volume. Currently 39 programs qualify to receive facilitated offers.[64] There were 29 transplants performed via facilitated offers, which were accepted and transplanted by 15 of the 39 qualifying programs. If facilitated pancreas program eligibility changed from importing 5 pancreata from outside the program DSA in the 2 previous years to importing 5 pancreata from outside a 500 NM circle around the transplant program in the 2 previous years, the number of eligible programs would shrink from 39 to 16. The analysis indicated that 75% of facilitated pancreas transplants would still have occurred if programs were qualified according to importing outside a 500 NM circle instead of outside the program's DSA, and 79% would have occurred under the threshold of 2 transplants within the previous two years.

The Committee considered that, given the other changes to allocation removing DSA and region, a more inclusive definition for pancreas programs to qualify as facilitated would be beneficial. Instead of only 16 programs that would qualify by importing 5 pancreata within the previous 2 years, 26 programs would qualify if the definition was changed to 2 imported transplants in 2 years. This would provide the opportunity for smaller programs that may receive fewer facilitated or import offers to participate and grow their programs. The Committee also considered that most transplants occur outside of facilitated placement and the projected change should not be significant. As part of this change, the Committee will closely monitor the impact on facilitated placement offers, frequency and transplant volume of facilitated placement, and number of programs that continue to qualify.

Some Committee members considered that allowing more pancreas programs to qualify could increase the potential loss in efficiency and was concerning. A simple majority of Committee members supported a threshold of 2 transplants in 2 years. Based on the varying concerns of Committee members, the Committee agreed to ask the community in public comment whether 2 or 5 transplants within 2 years should qualify a pancreas program for facilitated allocation.

[63] OPTN *Policy 11.6: Facilitated Pancreas Allocation* (Accessed July 9, 2019).
[64] Urban, Read. UNOS Research, 2019 OPTN data.

OPTN Policy 5.9: Released Organs (Import Back Up)

OPTN Policy 5.9: Released Organs specifies that transplant programs must let the host OPO know when an organ is not transplanted in the intended recipient. The host OPO that originally procured the organ has the opportunity to continue allocating according to the original match run or delegate that responsibility to the receiving OPO (the OPO in the DSA of the transplant program that received the organ). The latter practice is known as "local back up" and is utilized to limit preservation time and prevent inefficiencies in organ allocation by providing OPOs for options regarding what to do with organs that are not transplanted into the original, intended recipient.

Removing DSA and region in allocation and instead using a 500 NM circle means that more organs may travel farther and accrue more preservation time. If not addressed in the policy changes by creating special allocation tables for released organs, organs would travel according to the allocation tables that specify a 500 NM circle around the donor hospital. If an organ is sent 499 NM away to a program that for some reason cannot accept it for its candidate, the organ would need to be shipped to the next person on the list who could be almost 1000 NM away. Given that the organs have already accrued a certain preservation time, shipping them that far could impact the tenet of the Final Rule to avoid unnecessary organ loss.

There are different situations in which the host OPO may wish to continue allocating according to the original match run, however. To optimize the flexibility of the system while ensuring utilization and efficiency, the Committee is considering a solution by which the host OPO may:

- Allocate according to the original match run OR
- Delegate allocation to the receiving OPO. The receiving OPO runs a new match run based on new allocation tables in policy that use a smaller NM distance from the transplant program

The benefit of this solution is that it is equitable in still using the match run to determine who should receive the organ. At the same time, it avoids inefficiencies by allowing a new match run based on a smaller NM distance around the transplant program. Finally, the Committee considers that this solution provides flexibility for the host OPO in choosing the appropriate option depending on the particular situation that arises.

The Committee discussed what initial import back up distance around the receiving transplant program should be used for kidney-pancreas and pancreata that are reallocated. As **Figure 13** indicates, pancreas preservation times in current practices are typically around 10-12 hours. The Committee also considered that it is less common in their clinical experiences to have a kidney-pancreas reallocated together than to have kidney-alone reallocated from a kidney-pancreas that could not be transplanted in the original intended recipient. Given that the kidney-pancreas or pancreas has already been allocated once, the likelihood of another program accepting the reallocated organs indicated to the Committee that the initial import back up distance should be very small. The Committee agreed the kidney-pancreas should be prioritized above kidney-alone in the reallocation in the rare event the host OPO decides to reallocate both the kidney and pancreas together. This preserves the prioritization already present in pancreas allocation.

The Committee considered 150 NM an appropriate distance. The preservation time on the pancreas or kidney-pancreas may preclude sending the organs very far, but the Committee did not consider it appropriate that a center keep the kidney-pancreas ("center back up") if there were other programs within an initial distance of 150 NM. Some Pancreas Committee members considered that a smaller

circle should be used for kidney-pancreas and pancreas-alone because of concerns about preservation time and utilization. Other members considered that the Committee should have the same import back up option as kidney allocation, because of consistency in allocation and clarity for members and patients. The Kidney Committee is utilizing a 150 NM circle around the receiving transplant program and steep (8) proximity points for candidates more than 150 NM away, depending on the candidate transplant program proximity. The Committee approved a 150 NM circle over a 100 NM circle by a simple majority. Because of the differences in perspective among Committee members, the Committee is asking the community whether 150 NM or 100 NM should be utilized. The Committee is also asking that outside the initial circle, whether the proposed solution of steep points or a second circle of 500 NM should be utilized. The Committee will make a final recommendation to the Board based on community feedback.

Alternative Solutions Considered

The Committee considered solutions that would use a smaller circle size, as well as those utilizing fewer or no proximity points. However, the Committee takes seriously the directive of the OPTN Board of Directors to distribute as broadly as possible.[65] KPSAM modeling indicated the smaller circle solutions were substantively similar across the relevant metrics requested by the Committee. Given the similarities between the modeling results, and the Final Rule directive that geography not be considered except to the extent necessary, the Committee considered that alternative solutions utilizing smaller circles than 500 NM would not be optimal for maximizing compliance or equity. However, the Committee understands the importance of efficiency and avoiding a negative impact on transplant rate or organ utilization. The Committee rejected solutions that utilized less or no proximity points because the Committee considers that having steep proximity points may mitigate the effect of large circle sizes around donor hospitals on operational efficiency and preservation times. The Committee also concluded a national pancreas allocation system would be too inefficient and problematic from an organ quality and patient outcomes perspective without addressing all the other components of the pancreas allocation system as will be done under a continuous distribution framework transition. The Committee considers a 500 NM circle with up to 4 points inside and up to 8 points outside strikes an appropriate balance between the different alternative solutions considered.

Which populations are impacted by this proposal?

This proposal directly impacts pancreas and kidney-pancreas candidates by providing access to candidates in a broader geographic area. Based on OPTN data as of June 27, 2019, there were 813 pancreas and 1,638 kidney-pancreas candidates on the respective waiting lists. This proposal will indirectly affect kidney-alone candidates due to the impact of broader distribution and prioritization of SPK candidates.

Certain populations may get relatively increased access based on the proposed changes, including Asian Americans, African Americans, candidates with high cPRA, and candidates with Medicare insurance. Latino KP transplant access increases but not relative to non-Latino populations.[66]

[65] 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 July 6, 2019).

[66] Scientific Registry of Transplant Recipients, *KI2019_01_AnalysisReport_Update*, June 21, 2019, https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed July 3, 2019)

Implementation

How will the OPTN implement this proposal?

Programming changes will be required for this proposal. This will be a “Large” size effort in terms of IT implementation.

Changes will be made to the combined kidney-pancreas & pancreas match allocation to remove DSA and Region and allocate using a nautical mile circle. In addition to that, classification titles in the combined KP/PA allocations will also be changed to remove references to “local” and “regional”.

UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices.

How will members implement this proposal?

Transplant Hospitals

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

The changes to pancreas distribution may also impact overall transplantation program costs, as broader distribution may increase the number, distance, and time of additional pancreas fly outs. Some programs may need to hire more transplant surgeons to travel further to recover pancreata from donors. Transplants hospitals may want to establish a process for sharing organ acquisition cost information as part of their outreach to new OPOs.

OPOs

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

OPO practices may be impacted by the modifications of the broader SPK prioritization that will be implemented. Such changes may impact OPO costs, as well. Finally, OPO practices may be impacted by the modifications to import back up policy. Should a host OPO delegate import back up, import OPOs will run new match runs based on the original intended recipients transplant hospital.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

This proposal will not change the current routine monitoring of members. All policy requirements, as well as any data entered in UNet℠, may be subject to OPTN review, and members are required to

provide documentation as requested. OPTN contractor staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will continue to investigate potential policy violations.

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

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet (e.g., TIEDI forms may take 60+ days to be submitted)) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy:

Waitlist

1. Total kidney-pancreas and pancreas registrations on the waitlist (snapshot by month)
2. Kidney-pancreas and pancreas registrations added to the list, overall and by age, gender, ethnicity, cPRA, blood type, and insurance status at time of listing
3. % of candidates in active status
4. Waitlist mortality per 100 patient years, overall and by candidate age, gender, ethnicity, cPRA, blood type

Transplants

1. Donor, recipient and transplant characteristics: # and % of transplants by recipient age, ethnicity, waiting time (days on the waiting list), ABO, cPRA, HLA-ABDR mismatch level, diagnosis, DCD, inside/outside fixed circle, preservation time and cold ischemic time (CIT).
    a. Distribution of kidney-pancreas and pancreas travel distance (NM), overall and by inside/outside fixed circle
2. Change in access by location: N and % of transplants by
    a. Distribution type (local/regional/national)
    b. OPTN region
    c. Donor service area (DSA)
    d. (deidentified) transplant center
    e. State
3. Deceased donor transplants per 100 patient years by recipient age, ethnicity, ABO, cPRA, HLA-ABDR mismatch level, and DSA
4. Variance in deceased donor transplant rate across DSA
5. Rates of receiving kidney-pancreas and pancreas offers per 100 patient years by recipient age, ethnicity, ABO, cPRA, and HLA-ABDR mismatch level

Utilization and Efficiency of Allocation

1. # pancreas donors recovered for transplantation
2. # and % of pancreata recovered but not utilized (discarded), overall
3. # and % of pancreata discarded by discard reason
4. # and % pancreata with a final acceptance

5. Offer acceptance per 100 patient years by recipient age, ethnicity, waiting time (days on the waiting list), ABO, cPRA, and inside/outside fixed circle among organs with a final acceptance.
6. Distribution of sequence number of final acceptor
7. Distribution of time between electronic offer and cross-clamp
8. # and % by cPRA, of kidney-pancreas and pancreas offers refused due to a positive cross-match

Outcomes

The following analyses are reserved for future (1-year, 2-year) reports as enough data become available:

1. Post-transplant graft and patient survival rates, overall and stratified by recipient age, gender, ethnicity, cPRA, blood type, HLA-ABDR mismatch, CIT and preservation time.

Facilitated Pancreas Allocation

1. # and % of programs that qualify for facilitated pancreas allocation
2. Frequency of facilitated allocation use by OPOs
3. Transplant volumes that laced with facilitated pancreas allocation
4. Criteria for qualification, specifically whether distance from donor hospital or volume of transplants within two years is an acceptable threshold to qualify

Summary

DSA and region need to be removed as units of distribution from pancreas allocation because they are inconsistently drawn and not rationally determined. The Committee has considered all available evidence and expertise in proposing the current solution: to remove DSA and region and allocate using a 500 NM circle around the donor hospital with up to 4 points inside the circle and up to 8 points outside the circle. This will improve equity in access to transplant by increasing access for certain vulnerable populations and furthering competition between pancreas programs that could decrease geographic variance in utilization rates. The Committee will consider all public comment feedback in October before voting to send the proposed changes to the Board with any modifications from public comment feedback. The Board will review and vote on the proposal at its December 2019 in-person meeting.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding:

What considerations should be taken into account to select a circle size that distributes pancreata broadly and efficiently?

Proximity points are intended to contribute to efficiency in the broader distribution of pancreata. Should they be used inside the 500NM circle? Should they be used outside the 500NM circle?

What operational concerns should the committee consider as this policy is being prepared for OPTN board action and implementation?

For import back up, should the initial distance from the transplant program be 150 NM or another distance, when considering the efficient reallocation of pancreas and kidney-pancreas? Should proximity points be included outside the initial import match run circle to limit travel costs and preservation time, or should there be a secondary circle of 500 NM to address those concerns?

Should programs qualify for facilitated placement if the program performs 2 or 5 transplants in 2 years from pancreata imported beyond 500 NM from the transplant program?

Policy Language

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

[Subsequent heading numbers, and any table captions and cross-references, affected by the re-numbering of these policies will also be changed as necessary.]

1.2 Definitions

~~Zero antigen~~ 0-ABDR mismatch

A candidate is considered a ~~zero antigen~~ 0-ABDR mismatch with a deceased or living donor if *all* of the following conditions are met:

1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A ~~zero-antigen~~ 0-ABDR mismatch may also be referred to as a zero mismatch or ~~0-ABDR~~ zero antigen mismatch.

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

11.2 Pancreas Allocation Score

Candidates receive an allocation score according to *Table 11-1*.

Table 11-1: Allocation Points

If the candidate is:	Then the candidate receives this many points:
Registered for pancreas or islet transplant	1/365 points for each day since candidate's registration date
Registered for kidney-pancreas transplant and meets the qualifying criteria described in *Policy 11.3: Waiting Time*	1/365 points for each day since meeting the qualifying criteria in *Policy 11.3: Waiting Time*
Meets the qualifying criteria described in *Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*	*See Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*

If the candidate is:	Then the candidate receives this many points:
Meets the qualifying criteria described in *Table 11-3: Points for Allocation of Released Pancreas and Kidney-Pancreas based on Proximity to Receiving Transplant Program*	*See Table 11-3: Points for Allocation of Released Pancreas and Kidney-Pancreas based on Proximity to Receiving Transplant Program*

Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is within 500 nautical miles of the donor hospital	4-(4/500 x distance in nautical miles between the candidate's hospital of registration and the donor hospital)
Registered at a transplant program that is 500 nautical miles or more away from but within 2,500 nautical miles of the donor hospital	8-[8/(2500-500) x distance in NM between the candidate's hospital of registration and the donor hospital - (8*500/(2500-500))]
Registered at a transplant program that is 2,500 nautical miles or more away from the donor hospital	0

Points based on proximity to donor hospital will be rounded to the hundredth decimal place.

Table 11-3: Points for Allocation of Released Pancreas and Kidney-Pancreas based on Proximity to Receiving Transplant Program

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program within 150 nautical miles of the receiving transplant program of the original intended recipient	0
Registered at a transplant program that is 150 nautical miles or more away from but within 2500 nautical miles of the receiving transplant program of the original intended recipient	8 - [(8 /(2500-150)) x distance in nautical miles between the candidate's hospital of registration and the receiving transplant program of the original intended recipient – 8 - [(8 /(2500-150))]
Registered at a transplant program 2,500 nautical miles or more away from the receiving transplant program of the original intended recipient	0

Points based on proximity to transplant program will be rounded to the hundredth decimal place.

11.4.A Kidney-Pancreas Allocation Order

For allocation of a kidney-pancreas released by the receiving transplant program of the original intended recipient, see *Policy 11.7: Allocation of Released Kidney-Pancreas*.

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO ~~must offer the kidney and pancreas in the following order~~:

1. ~~The host OPO m~~Must offer the kidney and pancreas according to classifications 1~~–5~~3 in *Table~~s~~ 11-45: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-~~5~~6: Allocation of Kidney~~s~~ and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m^2*.

2. Then, the host OPO may do *either*:
   a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-45* and *Table 11-~~5~~6*.
   b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-~~4~~5* and *Table 11-~~5~~6* and offer the kidney to kidney candidates according to *Policy 8: Allocation of Kidneys*.

The host OPO may switch between options 2.a and 2.b above at any time after completing step 1 above.

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO must offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Table~~s~~ 11-45: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-~~5~~6: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m^2*.

OPOs may not allocate a kidney to a potential pancreas recipient who is receiving the pancreas offer due to the match run prioritization of the potential recipient's isolated pancreas registration.

11.4.C Organ Offer Limits

Any pancreas that will be ~~shared~~ allocated as ~~zero antigen~~ 0-ABDR mismatches, either alone or in combination with kidneys, must be offered within eight hours after procurement.

If there are at least 10 ~~zero antigen~~ 0-ABDR mismatched potential recipients on the match run, the pancreas must be offered to the first 10 ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients. If there are less than 10 ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients, the pancreas must be offered to all ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients.

If these offers are not accepted then the host OPO must:

- Allocate the ~~organ~~ kidney according to the match run under *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to *Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*-.
- Allocate the organ for the remaining ~~zero antigen~~ 0-ABDR mismatched potential recipients.

11.4.D Blood Type for Kidney-Pancreas Allocation

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in *Table 11-~~3~~4* below:

11-~~3~~4: Allocation of Kidney-Pancreas by Blood Type

Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O or blood type A, B, or AB if the candidate has a ~~zero antigen~~ 0-ABDR mismatch with the deceased donor and a CPRA greater than or equal to 80 percent
Blood Type A	Blood type A or AB
Blood Type B	Blood type B
Blood Type AB	Blood type AB

11.4.E Sorting Within Each Classification

Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted in the following order: ~~based on waiting time (longest to shortest).~~

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2

Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m^2 will be allocated to candidates according to *Table 11-45* ~~based on waiting time~~.

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²

Classification	Candidates that are	And registered at a transplant program that is within this distance from the donor hospital:
1	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	500NM
2	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	500NM
3	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	Nation
4	Pancreas or kidney-pancreas candidates	500NM
5	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	Nation
6	Pancreas or kidney-pancreas candidates	Nation
7	Islet candidates	500NM
8	Islet candidates	Nation

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m2

Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m² are allocated to candidates according to *Table 11-~~5~~6* ~~based on waiting time~~ below.

Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m²

Classification	Candidates that are:	And registered at a transplant program that is within this distance from the donor hospital:
1	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	500NM
2	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	500NM

Classification	Candidates that are:	And registered at a transplant program that is within this distance from the donor hospital:
3	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	Nation
4	Pancreas or kidney-pancreas candidates	500NM
5	Islet candidates	500NM
6	Islet candidates	Nation
7	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	Nation
8	Pancreas or kidney-pancreas candidates	Nation

11.5 Reallocation of Unsuitable Islets

Islets must be allocated to the most medically suitable candidate based on the transplant ~~hospital~~ program's Investigational New Drug (IND) application, as approved by the United States Food and Drug Administration (FDA). After islet processing is completed, the transplant ~~hospital~~ program must determine and document *both*:

1. Whether the islet preparation meets the transplant ~~hospital~~ program's islet product release criteria contained in the IND.
2. Whether the islets are medically suitable or medically unsuitable for the candidate that accepted the islets.

If the islets are found medically unsuitable for the candidate, the transplant ~~hospital~~ program must document the reason the islets were determined to be medically unsuitable for the candidate.

If the transplant ~~hospital~~ program determines that the islets are medically unsuitable for the candidate, the transplant ~~hospital~~ program will reallocate the islets according to *all* of the following criteria:

1. To a candidate that is medically suitable
2. To a candidate that is registered at a transplant ~~hospital~~ program covered by the same IND
3. The candidate's ~~waiting time (ranked longest to shortest)~~ allocation score according to Table 11-1: Allocation Points

The transplant ~~hospital~~ program that reallocates the islets must document that it followed this ~~P~~policy.

11.6 Facilitated Pancreas Allocation

11.6.A Transplant Program Qualifications

A transplant program qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of ~~five~~ two pancreas recovered from deceased donors located at hospitals more than 500 NM away from the transplant program. ~~recovered from deceased donors outside its DSA.~~ This includes pancreas transplanted as part of a multi-organ transplant.

11.6.B Facilitated Pancreas Offers

OPOs and the ~~Organ Center~~ OPTN Contractor are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or ~~Organ Center~~ OPTN Contractor must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all ~~local~~ pancreas and kidney-pancreas offers made to candidates registered at transplant programs within 500 nautical miles of the donor hospital have been declined.

11.7 Allocation of Released Pancreas and Released Kidney-Pancreas

For pancreas or kidney-pancreas allocated according to *Policy 5.9: Released Organs*, the host OPO may

1. Continue allocation according to the original match run, or
2. Delegate allocation of the kidney, pancreas, or kidney-pancreas to the OPTN Contractor or the OPO serving the receiving transplant program's DSA.

If the host OPO delegates allocation of the kidney, the OPTN Contractor or receiving OPO must offer the kidney to kidney candidates according to *Policy 8.7: Allocation of Released Kidneys*.

If the host OPO delegates the pancreas or kidney-pancreas, the OPTN Contractor or receiving OPO must execute a released kidney-pancreas match run and allocate the kidney-pancreas or pancreas using this updated match run.

For released pancreas, the receiving OPO must allocate the organ according to *Table 11-7: Allocation of Released Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2* and *Table 11-8: Allocation of Released Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m^2*.

For released kidney-pancreas, the receiving OPO

1. Must offer the kidney and pancreas according to classifications 1–3 in *Table 11-7: Allocation of Released Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2* and *Table 11-8: Allocation of Released Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m^2*.

2. Then, the receiving OPO may do *either*:
   a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-7* and *Table 11-8*.
   b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-7* and *Table 11-8* and offer the kidney to kidney candidates according to *Policy 8.7: Allocation of Released Kidneys*.

The receiving OPO may switch between options 2.a and 2.b above at any time after completing step 1 above.

Table 11-7: Allocation of Released Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2

Classification	Candidates that are	And registered at a transplant program that is within this distance from the receiving transplant program of the original intended recipient
1	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	150NM
2	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	150NM
3	Pancreas or kidney-pancreas candidates	150NM
4	Islet candidates	150NM
5	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	Nation
6	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	Nation
7	Pancreas or kidney-pancreas candidates	Nation

8	Islet candidates	Nation

Table 11-8: Allocation of Released Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m²

Classification	Candidates that are:	And registered at a transplant program that is within this distance from the receiving transplant program of the original intended recipient
1	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	150NM
2	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	150NM
3	Pancreas or kidney-pancreas candidates	150NM
4	Islet candidates	150NM
5	0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates	Nation
6	Islet candidates	Nation
7	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates	Nation
8	Pancreas or kidney-pancreas candidates	Nation

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