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Briefing to the OPTN Board of Directors on

Elimination of DSA and Region from Kidney Allocation Policy

OPTN Kidney Transplantation Committee

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Eliminate the Use of DSA and Region in Kidney Allocation Policy

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Sponsoring Committee:	*OPTN Kidney Transplantation Committee*
Public Comment Period:	*August 2, 2019 – October 2, 2019*
Board of Director's Date:	*December 3, 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, 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 8: Allocation of Kidneys currently uses DSA and region as geographic units of distribution. DSA and region are poor units of distribution between donors and transplant candidates due to variation in size and shapes, resulting in an inconsistent application for all candidates. As a result, the use of DSA and region in kidney distribution presents a potential conflict with the Final Rule. The proposed solution removes DSA and region as units of distribution in kidney allocation policy, and would allocate using consistently applied units of distribution that are intended to ensure that the most urgent candidates are prioritized, thereby promoting more equitable access to transplantation.

The OPTN Kidney Transplantation Committee (hereafter, "Committee") proposes removing DSA and Regions within kidney allocation policy in favor of a single fixed distance circle with a radius of 250

[1] 42 C.F.R. § 121.8(a)(1)-(5).
[2] 42 C.F.R. § 121.8(a)(8).

nautical miles (NM) with the donor hospital at its center. The 250 NM circle would include proximity points that award candidates inside the fixed circle a maximum of two points and award candidates outside of the fixed circle a maximum of four points based on their distance from the donor hospital. The 250 NM circle represents a hard boundary, so candidates located outside of the circle will not be placed above candidates inside the circle on the match run as a result of additional proximity points. The goal of these changes is to make kidney 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 time and costs, logistical complications, and inefficiencies through the use of proximity points.

Also included in this policy proposal are changes that further prioritize pediatric and prior living donor candidates by moving them up the KAS KDPI sequences in which they currently receive priority.

The Committee remains committed to the advancement of allocation policies towards the OPTN Board of Directors' vision of continuous distribution. Members see the following proposal as forward progress and innovation towards that goal while achieving the overall purpose of removing DSA and region from allocation policies in alignment with the Final Rule.

Purpose of Proposal

The OPTN is required to develop policies for the equitable distribution of cadaveric organs in potential transplant recipients. This proposal address the problem that "the use of DSAs and Regions in…organ allocation policies has not and cannot be justified under the OPTN Final Rule."[3] The use of DSA and region as units of distribution for deceased donor kidney allocation results in disparities in access to transplant for waitlisted candidates. Specifically, access to transplant for kidney candidates is impacted by DSA, which conflicts with the principle of the Final Rule stating that allocation policies, "shall not be based on a candidate's place of residence or place of listing" except to the extent required by other regulatory requirements.[4]

This proposal seeks to remove DSA and region from kidney allocation policy and allocate using geographic units that are consistently applied, in accordance with Final Rule requirements that organ allocation not be based on a candidate's residence or place of listing except to the extent required by other regulatory requirements and to result in a more equitable allocation system for kidney candidates.[5]

The proposal serves as a transitional step from current policy towards the direction of continuous distribution.

Background

DSAs and Regions 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.[6] DSA borders were drawn to define the boundaries in which an OPO is obligated to recover organs, not for equitable organ distribution purposes.

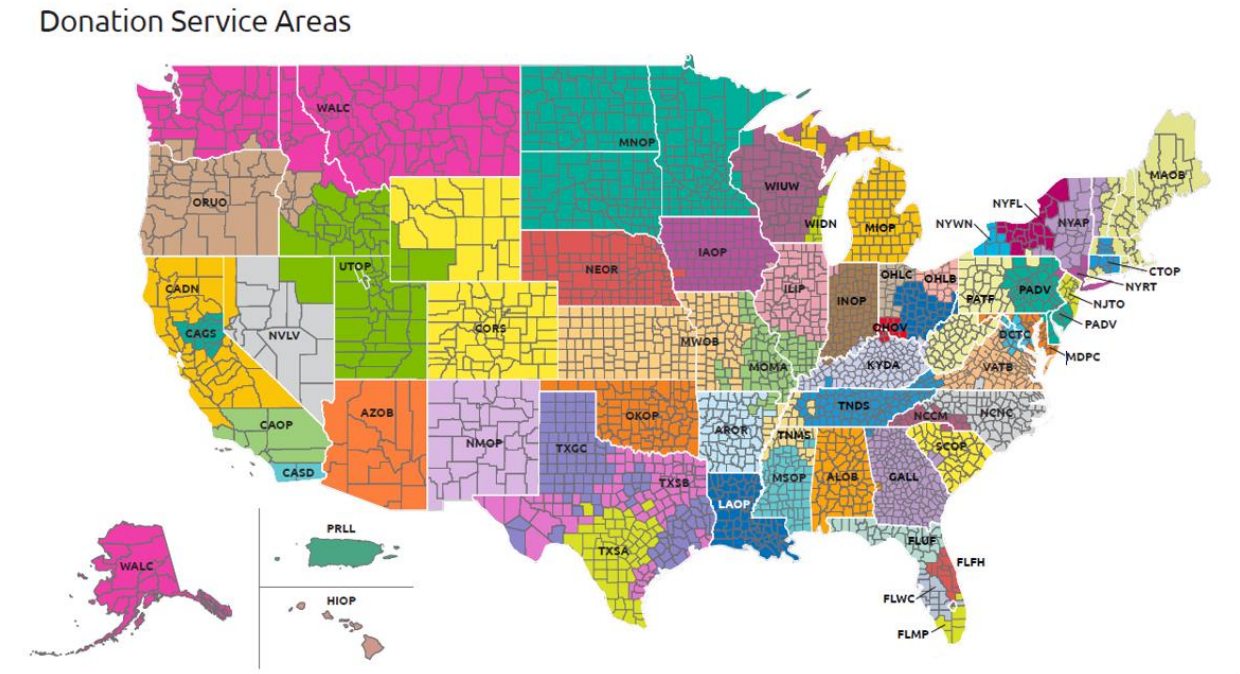
Allocation circles were developed based on the sound medical judgement of the Committee, and validated in modeling for intended and unintended consequences.[7] Furthermore, circles were deemed compliant with the Final Rule by the Ad Hoc Geography Committee.[8]

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 geographic size. These regions are used for multiple purposes (collecting public comment, Board and committee representation, etc.) but were not designed to optimize organ

[3] Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.
[4] 42 C.F.R. §121.8(a).
[5] 42 C.F.R. § 121.8
[6] Definition of Donation Service Area (DSA), OPTN Glossary. https://optn.transplant.hrsa.gov/resources/glossary/#D (accessed October 31, 2019).
[7] Meeting Summary for October 21, 2019 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/3344/20191021_kidney-in-person-meeting-summary.pdf (accessed November 19, 2019).
[8] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed October 31, 2019).

distribution.[9] **Figure 1** and **Figure 2** below illustrate the current geographic layout of DSAs and OPTN regions across the country.[10]

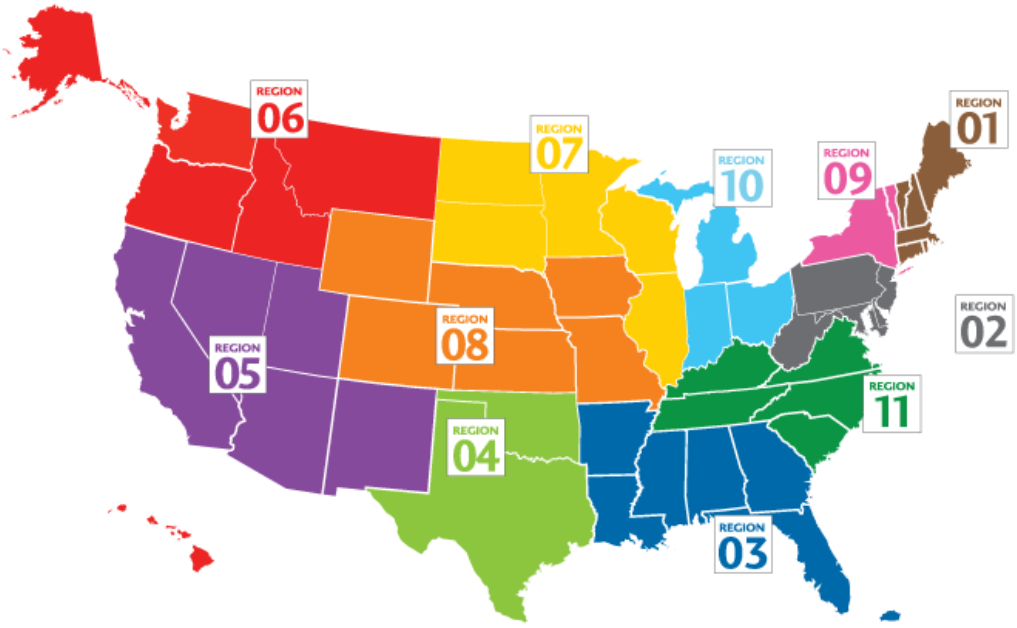
Figure 1: Geographic Layout of DSAs across the United States



[9] OPTN Bylaws Article IX: Regions. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Article_09 (accessed October 31, 2019).

[10] "Regions." Organ Procurement and Transplantation Network. https://optn.transplant.hrsa.gov/members/regions/ (accessed October 31, 2019).

Figure 2: Map of OPTN Regions across the United States



The Final Rule sets requirements for allocation polices developed by the OPTN, including: sound medical judgement, best use of organs, preserving the ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency.[11] The Final Rule also stipulates that allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of Section 121.8 of the Final Rule.[12] Finally, the Final Rule includes a performance goal for allocation policies of "distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency."[13]

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. 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."[14] 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

[11] 42 C.F.R. §121.8(a).
[12] 42 C.F.R. §121.8(a)(8).
[13] 42 C.F.R. §121.8(b)(3).
[14] 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

> 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."[15]

The Institute of Medicine made this same conclusion in 1999.[16] 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."[17] 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."[18] 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."[19]

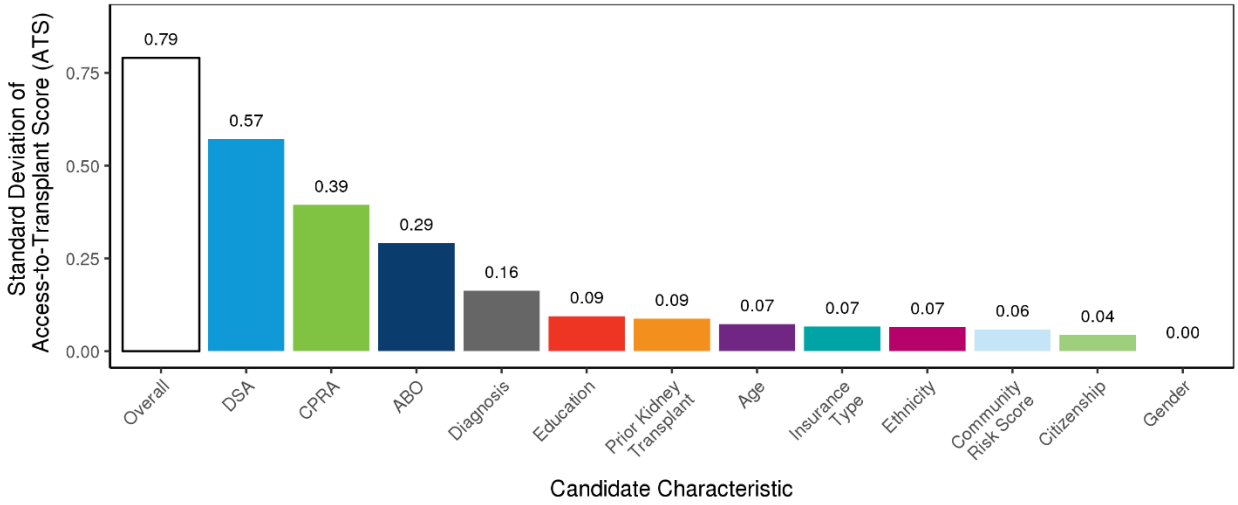
The OPTN Board of Directors has also concluded that organs are to be distributed as broadly as possible and in compliance with the OPTN Final Rule, as evidenced by the Principles of Geography composed and affirmed by a Board vote in December 2018.[20]

Equity in Access in Kidney Allocation

One way that equity in access can be measured by examining the degree to which candidates' rates of transplant vary depending on patient characteristics.[21] 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, and ethnicity, and produces a score to measure how each factor affects variability in transplant access.[22] 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 3**).[23]

[15] 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.
[16] National Academies Press, "Organ Procurement and Transplantation." (1999).
[17] 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 October 31, 2019).
[18] 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.
[19] Advisory Committee on Organ Transplantation Recommendation 51, August 2010. https://www.organdonor.gov/about-dot/acot/acotrecs51.html (accessed October 31, 2019).
[20] Meeting Summary for December 3-4, 2018 meeting, OPTN Board of Directors. https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf (accessed October 31, 2019).
[21] 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.
[22] OPTN Descriptive Data Request. "Report on Equity in Access." Presented to the OPTN Board of Directors Meeting, December 2016.
[23] OPTN Descriptive Data Request. "Report on Equity in Access." Presented to the OPTN Board of Directors Meeting, December 2016.

Figure 3: Standard Deviation of Transplant Score and DSA for Kidney Transplants

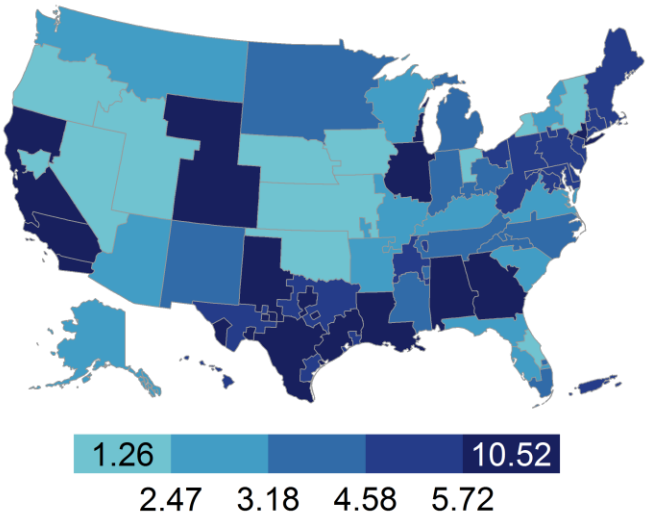


Additionally, adjusted estimated median waiting time to deceased donor kidney transplant vary greatly across the nation, as shown in **Figure 4**. For example, estimated median waiting times in areas of California are as high as 10.52 years. In contrast, in some areas of the country, estimated median wait times are as low as 1.28 years. This evidence indicates that the use of DSA in organ allocation 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 except to the extent required by other regulatory requirements.[24] This demonstrated level of observable variation in access to kidney transplant and in estimated median waiting times across the country directly contradicts the principles of the OPTN Final Rule, which states that allocation policies, “Shall not be based on the candidate's place of residence or place of listing” except to the extent required by other regulatory requirements.[25]

[24] 42 C.F.R. § 121.8
[25] 42 C.F.R. § 121.8(a).

Figure 4: Adjusted Median Waiting Time to Deceased Donor Kidney Transplant across the United States, 3/1/2015 – 3/1/2016

Post-KAS

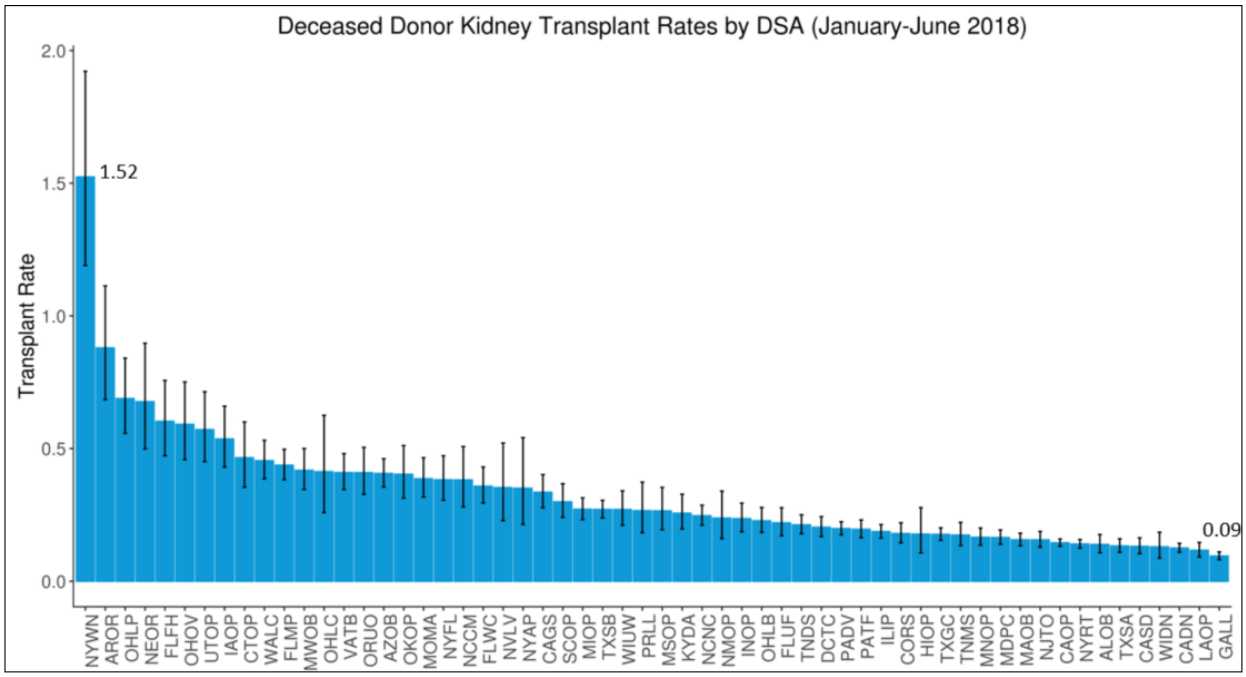


*Adjusted for candidate's age, sex, race, ABO blood type, and cPRA; and program-specific covariates

One further illustration of disparities in access across DSAs is illustrated in **Figure 5**, which depicts variations in transplant rate across DSA. Note that data illustrated are unadjusted transplant rates based on OPTN data.[26]

[26] Stewart DE, Wilk AR, Klassen DK. KAS Turns Four: The State of Deceased Donor Kidney Allocation in the U.S. *OBM Transplantation* 2019;3(1):17; doi:10.21926/obm.transplant.1901041.

Figure 5: Kidney Alone Transplant Rate across DSAs (January to June 2018)



Proposal for Board Consideration

The purpose of this proposal is to remove DSA and region from kidney allocation, and replace them with units of distribution that will be applied consistently nationwide.

The proposal represents a removal of DSA and region from kidney allocation policy in alignment with the Final Rule as well as a transitional step from current policy towards the goal of implementing a framework of continuous distribution.

The proposal the Committee is recommending for approval by the OPTN Board of Directors includes the following:

1. A single fixed-distance circle of 250 NM around the donor hospital.
2. Proximity points added to a candidate's allocation score based on the distance between their center of listing and the donor hospital. Candidates listed inside of the circle can receive a maximum of two (2) proximity points. Candidates listed outside of the circle can receive a maximum of four (4) proximity points.
3. Increased prioritization in kidney allocation for pediatric candidates and prior living donors who are registered at hospitals that are within 250 NM of the donor hospital.

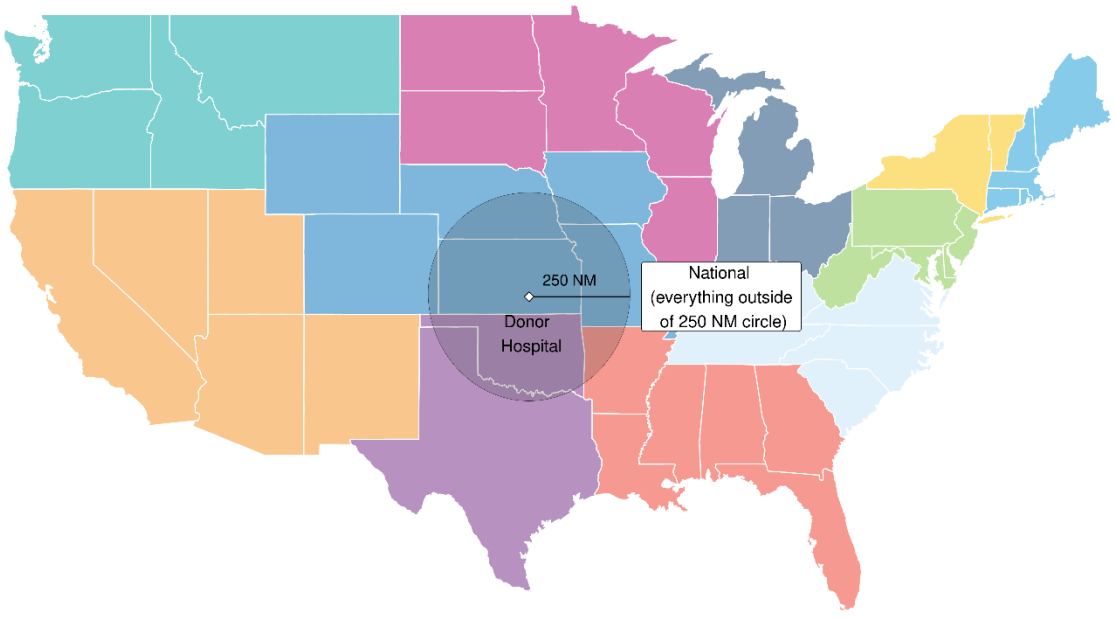
The Committee proposed the 500 NM solution for public comment because it accomplished the objective of replacing DSA and region in kidney allocation with a consistently applied distribution unit while broadening distribution and providing an increase in equity in access to transplant based on metrics available from KPSAM modeling. However, public comment feedback reflected significant concerns with the 500 NM solution implications for Final Rule considerations of unnecessary organ loss, efficient management of organ placement, and best use of organs.

The Committee recognized that the proposal distributed for public comment may weigh the factor of distributing organs as far as feasible too heavily, perhaps at the expense of other required considerations such as achieving the best use of organs, avoiding unnecessary organ loss, and promoting efficient management of organ placement. The Committee agreed that increased travel and logistical complexity may have the effect of increasing ischemic time or organ discards, and potentially impact patient graft outcomes. Furthermore, the Committee decided following public comment that reducing the circle size from the larger size initially proposed would mitigate the potential impact on patient outcomes, ischemic time, and organ loss.[27] Therefore the Committee modified the proposal from a 500 NM fixed-distance circle to a 250 NM fixed-distance circle to mitigate the logistical concerns raised in public comment.

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 and is consistently applied across the country.[28] The hybrid framework removes regional distribution, so any organs that move beyond the single fixed-distance circle would be considered "national" organ offers. This method is illustrated in **Figure 6** below, utilizing a 250 NM circle:[29]

Figure 6: Visualization of Single Fixed-Distance 250NM Circle for DSA



[27] Meeting Summary for October 21, 2019 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/3344/20191021_kidney-in-person-meeting-summary.pdf (accessed November 19, 2019).
[28] *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (accessed October 31, 2019)
[29] *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 October 31, 2019).

Proximity Points

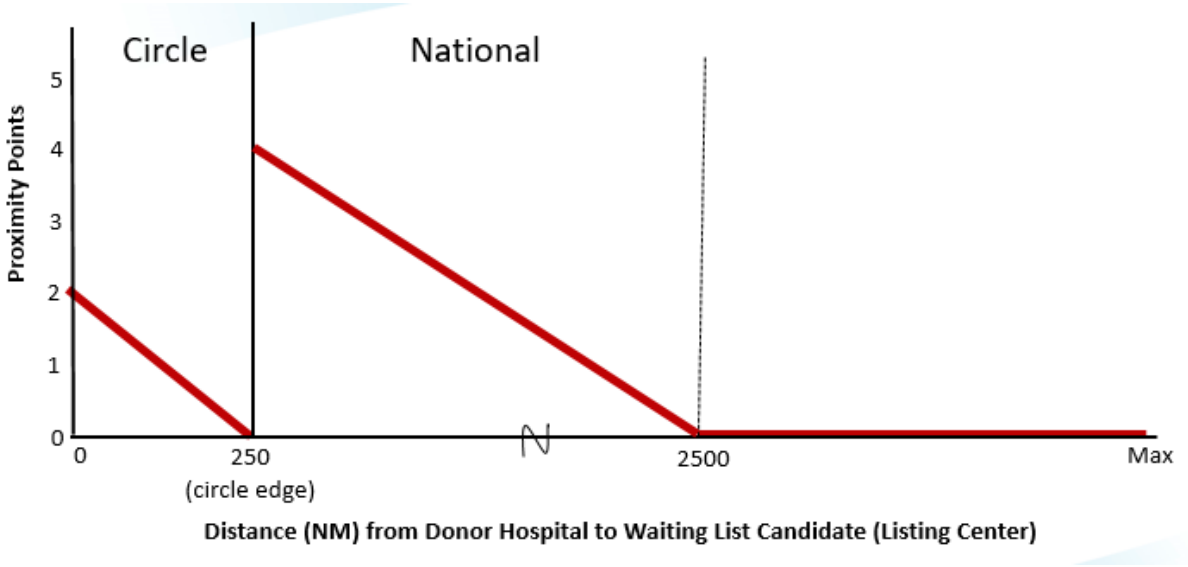
The hybrid framework awards proximity points to candidates based on the distance between the program where a candidate is registered and the donor hospital.[30] The intent of proximity points is to promote the efficient management of organ placement and avoid unnecessary organ loss by reducing unnecessary transportation time, cold ischemic time, cost, and the potential for higher offer refusal rates. Proximity points are also intended to have the effect of preventing sending a kidney further away for a candidate with only slightly higher waiting time compared to a nearby candidate."[31]

Candidates listed at centers closer to the donor hospital will receive more proximity points than those listed at centers further away. This mechanism serves to limit travel time and cost and thus foster the efficient placement of organs, as outlined in the OPTN Final Rule.[32] The current kidney allocation system is still utilized to determine the order of candidate classifications to receive organ offers on the match run. Proximity points would represent an additional value to the kidney allocation score, currently based on factors such as dialysis/waiting time and HLA mismatch with the donor, for example, that orders candidates within classifications that could change the order of the candidates with such classifications. For example, within each classification, the kidney allocation system currently prioritizes candidates based on values assigned for various candidate characteristics, such as cPRA and time waiting. Proximity points would be another value assigned to each candidate within the classification. Based on the current kidney allocation tables, one proximity point can be thought of as equivalent to one year of waiting time or an HLA mismatch of 1.[33] Importantly, no matter how many proximity points are awarded, 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. For example, under proposed policy, a CPRA 98% adult candidate could never be prioritized above an inside the circle pediatric candidate, as their classification falls below that of pediatrics.

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 two points. The solution utilizes a 250 NM fixed distance circle, so a candidate listed at a transplant program located 125 NM from the donor hospital would be awarded one proximity point. It is possible that no candidate inside the 250 NM circle accepts the organ offer; at which point, candidates outside of the circle that are not prioritized on the match run for other characteristics such as high sensitization, will receive the organ offer. At this stage of allocation, a candidate can receive a maximum of four proximity points. A candidate listed at a center 250.1 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 2,500 NM. Beyond 2,500 NM, no proximity points are awarded. Therefore, a candidate listed at a transplant program located 1,375 NM miles away from the donor hospital would be awarded two proximity points. **Figure 7** illustrates the linear nature in which proximity points are awarded inside of the fixed-distance circle and outside the fixed-distance circle.

[30] *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (accessed October 31, 2019).
[31] *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 October 31, 2019).
[32] 42 C.F.R. § 121.8.
[33] 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 October 31, 2019).

Figure 7: Illustration of Proximity Points Allocation (250.2.4 Variation)



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 candidate's position on a match run compared to waiting time (and other factors) for kidney candidates. Therefore, if the maximum number of proximity points awarded is high, then points awarded for other candidate characteristics may have relatively less effect on candidate match run placement, especially when considering the large amount of points awarded for high-CPRA candidates.[34]

Regardless of the maximum number of proximity points utilized, a candidate cannot move from one classification to another on the match run. Therefore, candidates cannot cross the line representing the circle edge in **Figure 7**, with the exception of mandatory national shares outlined in policy. Proximity points simply reorder candidates against each other, in terms of identified characteristics as well as geography *within* their classification.

Pediatric and Prior Living Donor Prioritization

The OPTN Kidney Transplantation Committee members of the Workgroup continued to express interest in including further current local, future inside circle, prioritization for pediatric and Prior Living Donor (PLD) candidates within kidney classification tables as part of the greater geography project. This prioritization would only occur within the circle. This effort represents a continuation of work that was in progress and subsequently paused in order to address geography within the Kidney Transplantation Committee, though prior living donor prioritization was not originally a piece of those paused projects.[35]

Figure 8 illustrates where inside circle pediatric and PLD candidates were placed in the allocation tables for the purposes of modeling.

[34] OPTN Policy 8.5 Kidney Allocation Classifications and Rankings. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_8 (accessed October 31, 2019).
[35] Meeting Summary for January 8, 2018 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/2419/kidney_meetingsummary_20180108.pdf (accessed October 31, 2019).

Figure 8: Candidate Priority by Sequence in Kidney Allocation

Sequence A KDPI 0-20%	Sequence B KDPI 20-34%	Sequence C KDPI 35-85%	Sequence D KDPI 86-100%
100% Highly Sensitized Inside circle prior living donor Inside circle pediatrics 98-99% Highly Sensitized 0-ABDRmm Inside circle top 20% EPTS 0-ABDRmm (all) Inside circle (all) National pediatrics National (top 20%) National (all)	100% Highly Sensitized Inside circle prior living donor Inside circle pediatrics 98-99% Highly Sensitized 0-ABDRmm Inside circle safety net Inside circle adults National pediatrics National adults	100% Highly Sensitized Inside circle prior living donor 98-99% Highly Sensitized 0-ABDRmm Inside circle safety net Inside circle National	All Highly Sensitized 0-ABDRmm Inside circle safety net Inside circle National

Proposal Submitted for Public Comment

This original proposal submitted by the OPTN Kidney Transplantation Committee for OPTN Public Comment contained five key components:[36]

1. A single fixed-distance circle of 500 NM around the donor hospital.
2. Proximity points added to a candidate's allocation score based on the distance of their center of listing from the donor hospital. Candidates listed inside of the circle can receive a maximum of four (4) proximity points. Candidates listed outside of the circle can receive a maximum of eight (8) proximity points.
3. Increased prioritization in kidney allocation for pediatric candidates and prior living donors who are registered at hospitals that are within 500 NM of the donor hospital.
4. A revised medical urgency policy that proposed creating a medical urgency classification and implementing a prospective review process to receive the classification
5. A new import backup policy to address instances when a kidney cannot be transplanted into its original intended recipient

The allocation framework containing the single fixed distance circle at 500 NM and the addition of proximity points was referred to in the proposal as a "hybrid" framework, as it contained elements of two of the frameworks proposed to the OPTN Board of Directors by the Ad Hoc Geography Committee: a fixed-distance circle framework and the framework of continuous distribution.[37,38] The single 500 NM fixed-distance circle was adapted from the fixed-distance circle framework and the inclusion of geographic proximity points, one of many variables that could be assigned point values in a framework of continuous distribution, was adapted from that framework. The Ad Hoc Geography Committee

[36] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed October 31, 2019).
[37] *Eliminate the Use of DSA and Region in Kidney Allocation Policy*, OPTN Kidney Transplantation Committee, August 2019. https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf (accessed October 31, 2019).
[38] *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, July 2018. https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (accessed October 31, 2019).

ultimately did not arrive at a consensus for a uniform policy for allocation to and from geographically isolated hospitals.

Community Feedback and Committee Response

The Committee seriously considered a 250.2.4 solution prior to public comment, with some Committee members initially supporting 250 NM over a 500 NM solution before the Committee ultimately supported a 500 NM for public comment. Given the strong support for 250 as an alternative to the 500 NM solution, the Committee included discussion of the 250 NM alternative in the public comment proposal to inform the public comment and solicit feedback. The 250.2.4 alternative was clearly listed as an option the public could consider, and public comment feedback indicated that a majority of commenters supported an alternative to the 500 NM solution because of concerns about the impact on ischemic time, organ loss and efficient placement. Of the alternatives listed in public comment feedback, the 250.2.4 solution received the most support.

The OPTN Fall 2019 Public Comment period opened on August 2, 2019 and closed on October 2, 2019. During the span of those two months, Committee representatives presented the proposal at 11 OPTN Regional meetings and reported regional sentiment as well as comprehensive feedback to the Committee, which continued to meet in order to receive and consider feedback incrementally as the comment period progressed.

In addition, Committee leadership presented the proposal and sought feedback from thirteen OPTN Committees. Sentiment from each of these key stakeholder committees as well as their area-specific feedback and expertise were reported back to the greater Committee for consideration as policy development progressed.

Furthermore, the Committee publicized, organized, and conducted 6 informational webinars during the OPTN Fall Public Comment Period. Some of these webinars were customized for the purposes of educating and receiving feedback from a diverse group of stakeholders, including webinars focused specifically on the patient community, program directors, and the media. Other webinars were open to the public, recorded for those who could not attend, and posted to the OPTN website. Each of these webinars provided the committee with insightful feedback for the committee's consideration.

Each of these mechanisms for educating the community and soliciting constructive feedback was essential to the committee's policy development process and informed their deliberation as they developed a final proposal for OPTN Board consideration. The community sentiment, key themes presented within the collective feedback, and the resulting proposal modification are highlighted in the sections to follow.

Community Sentiment

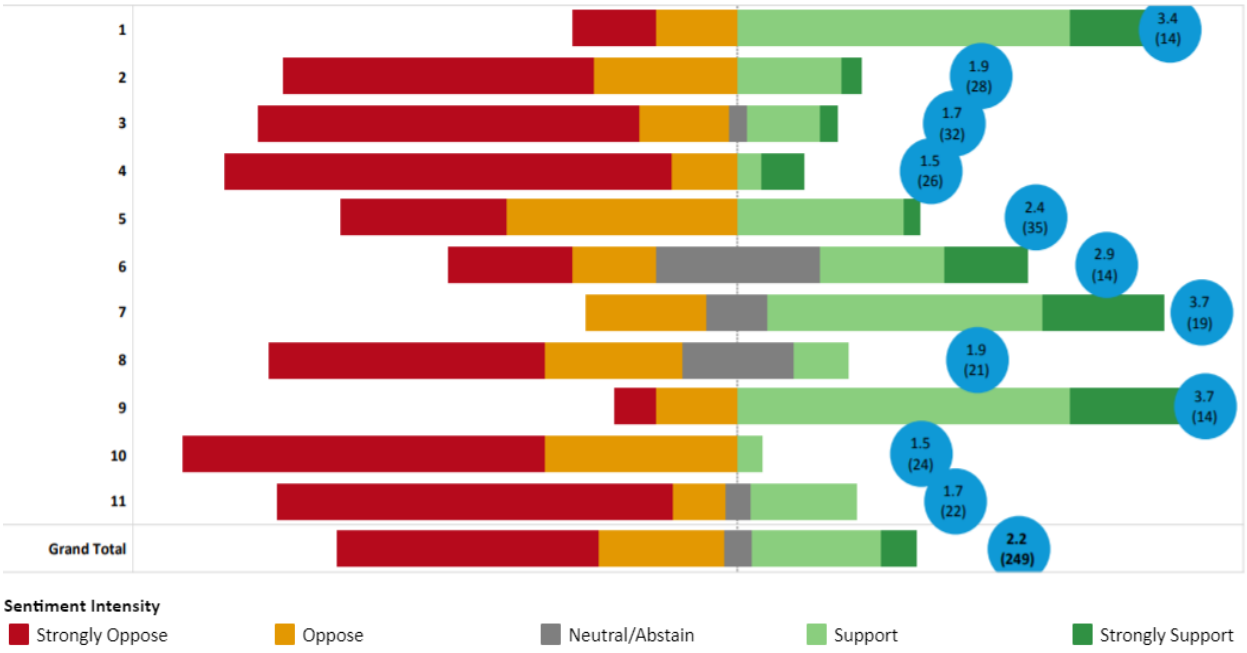
The proposal received mixed sentiment throughout the community, and feedback varied depending on region, member type, and stakeholder focus.

Sentiment Among OPTN Regions

At several OPTN Regional meetings, community members and stakeholders recognized the need to remove DSA and region from allocation policy, but disagreed with the Committee's proposed approach.

Figure 9 illustrates the sentiment for the Committee's proposal received at the OPTN Fall 2019 Regional Meetings.

Figure 9: Regional Sentiment at OPTN Fall 2019 Regional Meetings



Eight of the 11 regions expressed negative sentiment towards the proposed 500.500.4.8 (also referred to as a 500.4.8) hybrid framework solution. However, two of those eight regions expressed a majority positive sentiment for an alternative variation, specifically one the utilizes a 250 NM fixed-distance circle for kidney allocation, a maximum of two proximity points awarded to candidates inside of the circle, and a maximum of four proximity points outside of the circle, otherwise known as the 250.250.2.4 (also referred to as a 250.2.4) variation.

Region 5 expressed negative sentiment for the proposal on the basis of proximity points alone, accepting that a 500 NM circle as the first unit of allocation would be appropriate, but disagreeing with the principle of awarding candidates priority for proximity to the donor hospital.

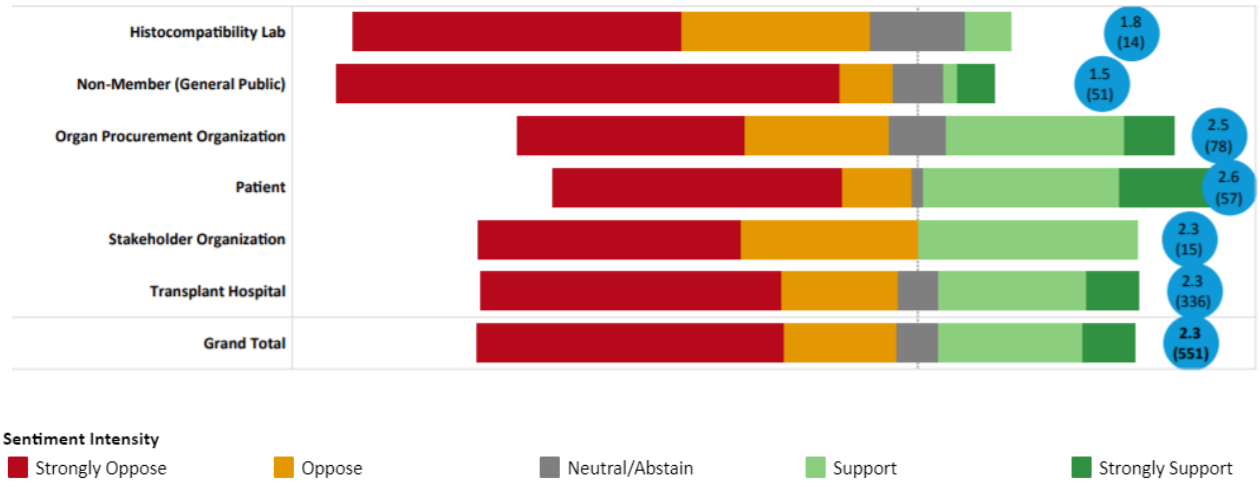
Three OPTN regions expressed a majority positive sentiment for the proposal as written, though these meetings did elicit insightful conversation around similar feedback themes expressed in other regions, highlighted in the section above.

Sentiment Among Different Member Types

Sentiment for the proposal was similarly mixed among different member types during the OPTN Fall 2019 Public Comment period, though the community was able to draw some important conclusions from the results.

Figure 10 illustrates sentiment for the Committee's proposal by member type. Red indicates strong opposition, yellow indicates general opposition, gray represents neutral sentiment or abstentions, light green represents general support, and dark green represents strong support.

Figure 10: Proposal Sentiment by Member Type



The Committee noted the positive sentiment (compared to other member types) that the proposal received among respondents that identified themselves as "Patients." The Committee believes that the proactive outreach to educate the patient community during the public comment period with a patient-focused national webinar could have positively affected the sentiment of these individuals. Though the proposal is somewhat complicated in the mechanisms it employs, the Committee believes that effectively communicating the projected gains in equity in access among candidates contributed to a positive patient reception.

Several stakeholder organizations provided feedback on the proposal, largely supporting the Committee's initiative to remove DSA and region from allocation policy though critical of the use of a 500 NM circle as the first unit of allocation. The American Society of Transplant Surgeons (ASTS) did not support the proposal as written, instead recommending that the Committee pursue the 250.250.2.4 alternative, citing the gains in geographic equity in access that could still be achieved while alleviating logistical pressures that could arise as a result of transitioning from the current allocation system to a system with a 500 NM circle as the first unit of allocation. The American Society of Transplantation (AST) did not support the proposal, expressing concern that such broad distribution could send organs from high-performing OPOs to low-performing OPOs and that increased logistical costs and resource needs could result in longer cold-ischemic times, delayed graft function, and increased discards. NATCO, the Organization for Transplant Professionals (NATCO), likewise did not support the proposal and instead favored a more incremental approach to broader distribution with a smaller allocation circle and periodic post-implementation evaluation. The Association of Organ Procurement Organizations (AOPO) did not indicate a formal sentiment; however, their narrative comments indicated that the organization would prefer that the Committee propose a framework utilizing an initial distribution circle of 250 NM to reduce the logistical stress of the projected increases in air travel associated with the proposed solution. The American Society for Histocompatibility and Immunogenetics (ASHI) supported the proposal though expressed concern about potential difficulties with histocompatibility testing. Finally, the National Kidney Foundation (NKF) indicated support for the proposal but recommended that the Committee consider a more step-wise approach to implementation, beginning with a 250 NM circle to

reduce concerns about increased cold-ischemic times. The NKF also recommended post-implementation evaluation before expanding distribution to a broader unit of allocation.

Sentiment among transplant hospitals and organ procurement organization was more balanced, though these organizations did make it clear that there are significant logistical considerations that the Committee needs to take into account concerning organ travel and procurement. Similar themes concerning the effects of OPO performance in equity in allocation as well as the projected impacts for access among individual transplant programs were observed within comments from these member types.

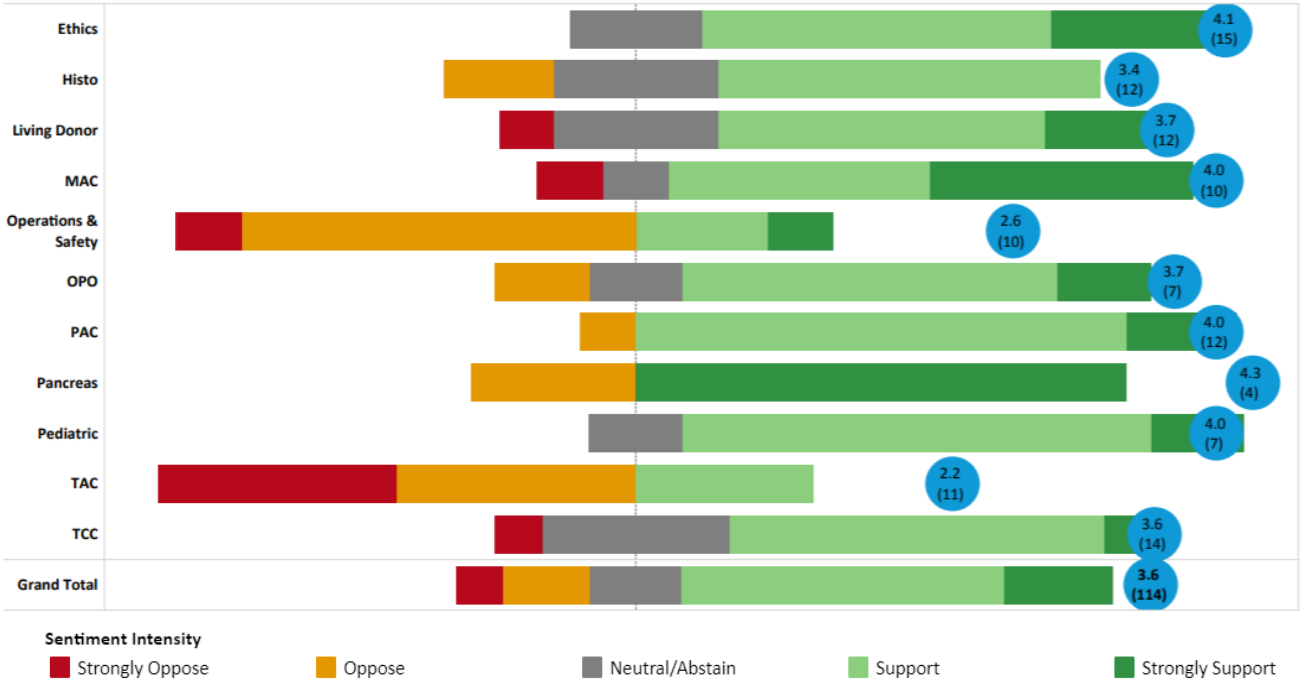
Sentiment among histocompatibility laboratories leaned more negative, though ASHI, the major stakeholder representing these organizations, expressed support for the proposal. Committee outreach to these organizations yielded some constructive feedback. Specifically, members at the annual ASHI conference, held from September 23rd to September 27th in Pittsburgh, PA, stated apprehension about the volume of tissue-typing material necessary to physically crossmatch candidates within 500 NM of the donor hospital in the initial allocation. Additionally, the expected increase in import offers from outside what is currently considered their local area correlates with an increase in this administrative burden.

Sentiment Among OPTN Committees

During the OPTN Fall 2019 Public Comment period, leadership of the committee presented the proposal to thirteen OPTN Committees to receive sentiment and feedback for consideration.

Figure 11 represents the sentiment registered by OPTN Committees for the proposal.

Figure 11: OPTN Committee Sentiment for Proposal



The majority of OPTN Committees responded positively to the proposal as written, though their collective insight still added to committee deliberation as their comments aligned with some of the same concerns echoed in the community. For example, the OPO Committee expressed concerns about the projected increased in percentage of kidneys that may fly, based on a surrogate measure of kidneys traveling further than 250 NM, and whether the commercial air travel infrastructure had the capacity to accommodate this change efficiently. The OPTN Histocompatibility Committee reinforced the need for the Committee to consider possible complications that could result in increased demand for crossmatching material and the associated administrative burden at histocompatibility labs. The OPTN Pediatric Committee supported the increased priority for pediatric patients in kidney allocation tables but expressed concerns that projected increases in simultaneous kidney-pancreas transplants might disadvantage some pediatric candidates.

Two OPTN committees, the Operations and Safety Committee and the Transplant Administrators Committee (TAC), express a majority sentiment in opposition of the proposal. The Operations and Safety Committee's feedback mostly surrounded the proposed solution for import backup, though members did express that they would prefer that a framework utilizing a 250 NM should ultimately be pursued. TAC expressed their belief that proposed 500 NM radius may be too large because the distance may increase travel time for blood samples, organs and recovery teams while adding costs and more complex logistics. TAC similarly proposed a framework utilizing a 250 NM circle as a more feasible option for the Committee to consider.

Public Comment Feedback Themes

During the OPTN Fall 2019 Public comment period, it became clear to the Committee that a number of key themes surrounding the proposal required further committee attention and consideration. Comments surrounding these themes were abundant and often repeated similar concerns and constructive criticisms. Some of these themes were considered by the Committee in conversations since the project's inception; however, the breadth of perspective offered by members, patients, OPTN Committees, and stakeholder organizations presented new opportunities for discussion and further examination during and immediately following the public comment period.

The Committee seriously considered the feedback from the community. The purpose of OPTN public comment is to engage the community and listen to their feedback, concerns and suggestions.

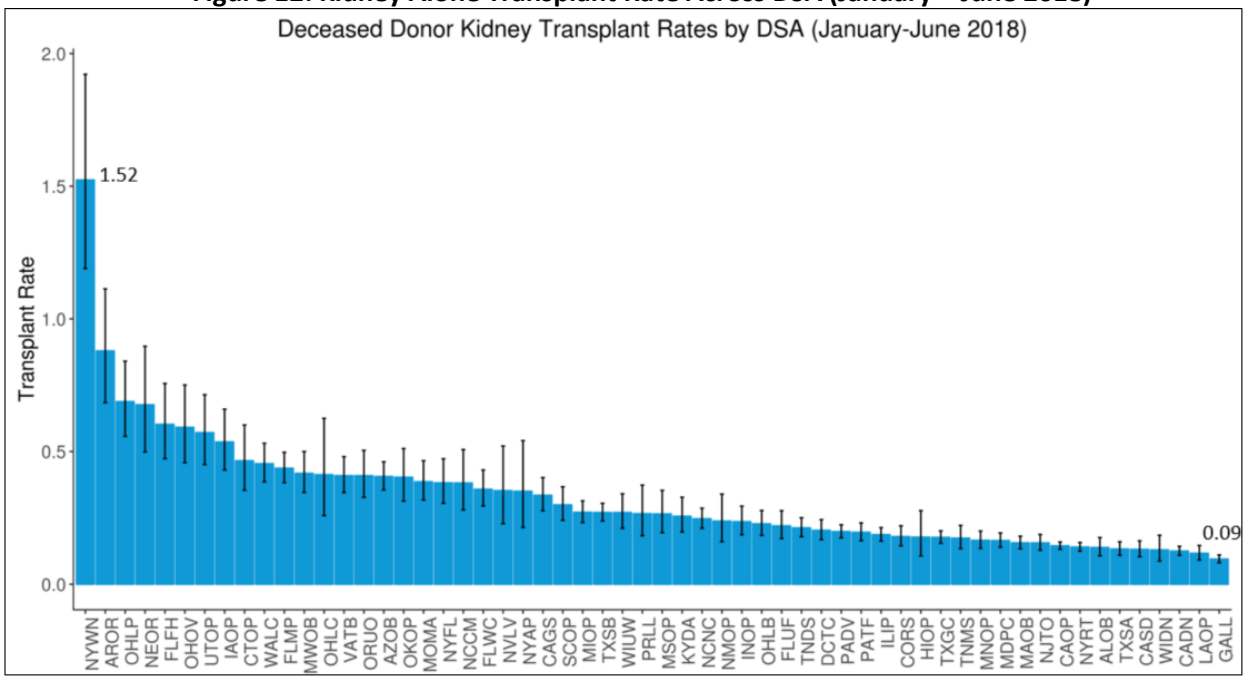
OPO Performance

One of the primary criticisms expressed about the Committee's proposal is the sentiment that the presence of DSAs and regions in allocation policy is not the largest determining factor in determining a candidate's access to transplant, but rather the performance and the practices of the OPO facilitating their allocation.

Figure 12 depicts variations in transplant rate across each of the DSAs. Note that data illustrated are unadjusted transplant rates based on OPTN data.[39]

[39] Stewart DE, Wilk AR, Klassen DK. KAS Turns Four: The State of Deceased Donor Kidney Allocation in the U.S. OBM Transplantation 2019;3(1):17; doi:10.21926/obm.transplant.1901041. http://ver01.lidsen.com/journals/transplantation/transplantation-03-01-041#figure06 (accessed September 18, 2019)

Figure 12: Kidney Alone Transplant Rate Across DSA (January – June 2018)



Many comments expressed the belief that by removing DSA and region from allocation policy as a means to promote greater equity in access to transplant (see **Figure 19**), the Committee is in effect taking organs that would be allocated by high-performing OPOs and sending them to lower-performing DSAs, or DSAs with transplant hospitals that have more stringent acceptance practices. Some community members familiar with OPO operations argue that many DSAs with lower transplant rates contain transplant hospitals with much more stringent acceptance standards and thus only accept low-KDPI kidneys. Such commenters posit that making offers of organs that are harder to place to these transplant hospitals that are already less likely to accept them due to their stringent acceptance standards could result in allocation inefficiencies, longer cold times, delayed graft outcomes, and higher rates of discard.

Several comments also pointed to the need for improving performance monitoring of OPOs either as a required component of or alternative in its entirety to this project. Indeed, community desire for improved performance monitoring metrics for OPOs and transplant systems alike is well-documented. Most recently, the OPTN's Ad Hoc Systems Performance Committee (SPC) delivered a report to the Board of Directors in June 2019 making several specific recommendations for improving both OPO and transplant program performance monitoring metrics.[40] In September 2019, the OPTN Board President utilized the SPC's report in part to issue a response to an August 2019 request for public comment on OPO performance monitoring metrics from the Centers for Medicare & Medicaid (CMS). The OPTN's submission offered specific recommendations for data collection and analytical methodologies in support of enhanced OPO performance monitoring.[41] As the SPC recognized in its work, OPO

[40] Neil, Heather, Overacre, B., Rabold M., Haynes C.R. PDF file. 10 June 2019. "Table 9: OPO Metrics Beyond Organ Yield." *OPTN Ad Hoc Systems Performance Committee Report to the OPTN Board,* p. 9. https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

[41] Johnson, Maryl R. to Alpha-Banu Wilson and Diane Corning, Centers for Medicare & Medicaid (CMS), U.S. Department of Health & Human Services. *Copy of the OPTN Response to Proposed Revisions of Organ Procurement Organizations Conditions of Coverage (Section XVIII) as submitted via the Federal Register.* 17 Sept. 2019.

performance is but one of several variables impacting system operations and equity in access. The OPTN is committed to continuing the work of improving transplantation systems performance as a whole. Further, the Kidney Committee also recognized the impact of system performance from the onset of this project. However, the purpose of this project is to remove DSA and region from kidney allocation policies, and following the directive of the OPTN Board of Directors to remove DSA and regions from kidney allocation policy, that the performance of OPOs is a variable in organ allocation. However, the purpose of this project is to remove DSA and region from kidney allocation policies, and the Committee has been working diligently to achieve that end. The KPSAM modeling that was conducted did project greater equity in access to transplant across the country and for key candidate subgroups as a result of removing DSA and region and replacing it with a hybrid framework; however, the Committee understands that hat there are many factors, including member performance, that impact equity in the system.[42] Because DSAs and regions cannot be justified under the Final Rule, the Committee must address how kidneys will be allocated in their absence. Based on their sound medical judgement and collective experience, while using the KPSAM modeling as a tool, the Committee believes that a hybrid framework with a single allocation circle and proximity points is best approach to immediately eliminate DSA and region in compliance with the Final Rule.[43]

Members of the committee understand that greater gains in equity can be achieved as the allocation system evolves and moves towards the OPTN Board-endorsed continuous distribution framework, including more comprehensive OPO performance monitoring, but the stated goal of this project remains unchanged.

Limitations of and Modifications to the KPSAM Modeling

While limitations exist within the KPSAM acceptance model, it is important to keep in mind that the KPSAM can be very useful in estimating the relative direction of possible effect for policy changes. Previous experience with the SAMs suggests that they typically predict the direction of subgroup changes, but under-predict the number of transplants that would occur in reality if a given policy scenario were adopted.[44]

Both the SRTR and the Committee have been transparent about the limitations of the KPSAM modeling in evaluating the move from DSA/Region to circles, both in the concept paper published in December 2018 concept paper as well as the proposal published for the OPTN Fall 2019 Public Comment period. Specifically, the Committee has been oriented to the fact that the KPSAM modeling is a tool to be used in combination with their collective experience and that that KPSAM cannot model changes in program behaviors under new allocation policies. Furthermore, concerning offer acceptance, one aspect of the simulation results strongly affected by acceptance probability is the number of projected transplants. KPSAM uses a simple model of organ discard: if an organ is offered 200 times without an acceptance, it is marked as discarded.[45]

[42] Meeting Summary for September 16, 2019. OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/3299/20190916_kidney-committee_meeting_summary.pdf (accessed November 19, 2019).
[43] George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.
[44] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774; Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.
[45] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774; Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol.* 2014;25(8)1842-8.

Comments at OPTN Regional meetings as well as on the OPTN Public Comment website took issue with some of the metrics, limitations, and structure of the KPSAM modeling and analysis. These included criticisms about the use of transplant rate by DSA as a measure of equity in access and the Committee's decision to adopt SRTR-proposed changes to the KPSAM accept/decline model to more accurately predict the effects of changes in allocation by removing DSA as a determinant factor in modeled acceptance behavior.

The acceptance models are the components of KPSAM least aligned with the underlying data, and are therefore the most difficult to implement. Specifically, the acceptance models use offer data only for eventually accepted kidneys, but KPSAM uses the acceptance models to determine not only who accepts the kidney but whether a kidney is discarded. However, the acceptance models, by definition, contain no information on when a kidney is discarded. Additionally, the acceptance models in KPSAM are based on offer data from 2017, and therefore assume that acceptance behavior under alternative allocation systems will be similar to acceptance behavior under the previous allocation system in 2017. Together, these issues represent significant limitations to KPSAM in evaluating transplants in a totally new allocation schema.

KPSAM discards kidneys offered 200 times without acceptance. Historically, this mechanism of kidney discard is used for convenience, but it has important consequences. When the distribution of factors that predict acceptance changes across different allocation systems, the acceptance models will predict that kidneys will require more or fewer offers before being accepted. However, the acceptance models cannot determine whether kidneys requiring more offers will be discarded, because they include no information on the mechanism causing discard. Instead, they indicate only that such kidneys will require more offers before being accepted. Thus, for the second KPSAM request, factors were excluded from the acceptance models if their distribution within a match run was likely to change across different allocation systems. The SRTR believes excluding such factors allows KSPAM to more accurately predict the potential distribution of transplants.

The acceptance models in the first round of KPSAM modeling included donor factors (e.g., age or offer number), candidate factors (e.g., dialysis time at offer), and donor/candidate interactions (e.g., a "local indicator" for whether a candidate was listed in the same DSA as the donor). The distributions of candidate factors and donor/candidate interactions within match runs are likely to change across different allocation systems, because they largely determine candidates' relative allocation priority (i.e., how candidates are ordered within the same tier of allocation). This is particularly true for the current KPSAM modeling requests because broader sharing ensures that candidates with high relative allocation priority (e.g., longer times on dialysis) will be closer to the beginning of the match run than they would be under current allocation policy. Additionally, broader sharing will obviously reduce the proportion of local offers at the beginning of the match run. Thus, the acceptance model for the second KPSAM request included only donor factors because their distributions within a match run are unlikely to change across different allocation systems.

The KPSAM acceptance models also assume that acceptance behavior under the alternative allocation system will be the same as under the current allocation system. However, acceptance behavior related to factors correlated with the current allocation system may change under alternative allocation systems in which the role and/or importance of the factor changes. The "local indicator" is an obvious example. This factor is highly important in the current allocation system but is less meaningful in allocation systems without DSAs. Thus, local offers are currently associated with more ideal offers (i.e., closer to the beginning of the match run), while non-local offers are currently associated with less than

ideal offers (i.e., later in the match run). It is not clear that this preference for local offers will remain in an alternative allocation scheme that does not include DSAs.

SRTR began a detailed investigation of the acceptance model component of KPSAM in December 2018, almost immediately after submitting the first request to the OPTN Kidney and Pancreas Committees. The SRTR determined that the local indicator was significantly reducing the number of transplants in the first request, but that candidate characteristics, e.g., dialysis duration at offer, were also reducing the number of transplants, although at a lower magnitude than the local indicator. However, as detailed above, the investigation also revealed the limitations of using the acceptance models to determine discard, i.e., their lack of data on the actual discard process. For these reasons, estimating the number of transplants from KPSAM is difficult and fraught. Instead, a lower number of transplants in KPSAM indicates that the alternative allocation systems would require more offers to place such kidneys. Because KPSAM cannot determine whether alternative allocation systems that require more offers before a kidney is accepted would cause fewer transplants, the acceptance model for the second KPSAM modeling request included only donor factors.

It is important to reiterate the usefulness of the KPSAM in indicating the potential direction of effect for policy changes. Specific limitations do not invalidate the benefit the KPSAM can provide to Committees in considering possible paths forward in modifying policy, in conjunction with stakeholder input, public feedback, and Committee member experience and expertise.

Transplant Rate

Regardless of the precise degree to which different factors contribute to variation in transplant rates, waitlisted patients are currently experiencing marked differences in the rate at which they are transplanted. The current policy proposal to distribute kidneys using a large fixed circle instead of DSA and regional boundaries is predicted to dramatically reduce – (by approximately 70%) – the variation experienced by waitlisted candidates around the country in their experienced rates of transplantation. Given the magnitude of the predicted variance reduction, and the well-documented disparities in supply to demand for organs across DSAs, it is likely that proposals to distribute kidneys broadly and irrespective of DSA boundaries will meaningfully reduce disparities in waiting times currently experienced by waitlisted patients.

The Committee exercised sound medical judgment in making its policy recommendation to the Board by utilizing the available data to help inform their policy development, and relying on the clinical and operational experience of their members, as well as feedback received from the transplant community to inform their deliberations and policy development.

Transplant rates, defined as the number of deceased donor kidney transplants divided by the number of patient years on the kidney waiting list during a specified period of time, reflect differences in patient experience among candidates on the waiting list. Transplant rates have been shown to vary 10-20 fold in different areas of the country, which corresponds with drastically different average waiting times for patients after listing. In donor service areas (DSAs) with very high transplant rates, on average, waitlisted patients are transplanted much faster than in areas with low transplant rates.

It is very important to recognize that in the context of assessing projected system-level performance under proposed policy changes, transplant rates are not being used to either (a) measure transplant center “performance,” or (b) develop new, geographic boundaries in attempt to balance transplant

rates (e.g., "optimized districts"). Rather, transplant rates are just one of many metrics, including the number of transplants, waiting list mortality rates, and early post-transplant graft and patient survival rates, being used to assess the impact of a proposed change on the national kidney allocation system.

Transplant rate differences are not solely the result of any single factor but rather result from a complex, multifactorial mix of underlying causes, including differences in the inherent supply to demand for kidneys in a local area. It has been shown that the geographic distribution of kidney donation rates (a measure of organ supply) does not align with the geographic distribution of ESRD incidence (a measure of demand).[46] Given that donor service area boundaries were not constructed with the intent of balancing supply to demand, this misalignment is not surprising. For example, it has been shown that some areas of the country with high kidney donor rates (>25.7 donors per million population) have relatively low ESRD incidence rate (<300 ESRD cases per million population), and vice versa.[47,48]

It has also been shown that the 10-20 fold difference in transplant rates across DSAs cannot be explained by differences in candidate characteristics ("case mix").[49,50] However, other factors in addition to inherent supply-to-demand differences that may contribute to geographic variation in transplant rates include differences in center-level offer acceptance rates; geographic differences in ESRD patient referral behaviors and listing rates; as well as variation in OPO performance.[51,52,53,54,55]

In light of differences in referral and listing practices, it has been argued that ESRD disease burden in a geographic area is a more appropriate denominator for calculating transplant rates. However, it has been shown that transplant rates calculated with ESRD disease burden as the denominator still reveal substantial variation (5-fold disparity) in access to transplant across the country under a DSA-based allocation system.[56] Variation in "transplants per ESRD population" in a given geographic area thus reflect the likelihood of being added to the waiting list, as well as the effects of allocation policy, organ availability, and center acceptance practice variation. The use of transplants per waitlisted patient-year is a more appropriate metric for assessing allocation policy changes because it removes variation in likelihood of being added to the list and focuses on patients with the potential to receive an offer.

[46] Mathur AK, Ashby VB, Sands RL, Wolfe RA. Geographic variation in end-stage renal disease incidence and access to deceased donor kidney transplantation. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons. 2010;10(4 Pt 2):1069-80.
[47] Ibid.
[48] Sheehy E, O'Connor KJ, Luskin RS, Howard RJ, Cornell D, Finn J, et al. Investigating geographic variation in mortality in the context of organ donation. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons. 2012;12(6):1598-602.
[49] Stewart DE, Wilk AR, Toll AE, Harper AM, Lehman RR, Robinson AM, et al. Measuring and monitoring equity in access to deceased donor kidney transplantation. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons. 2018.
[50] Zhou S, Massie AB, Luo X, Ruck JM, Chow EKH, Bowring MG, et al. Geographic disparity in kidney transplantation under KAS. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons. 2017.
[51] Husain SA, King KL, Pastan S, Pazter RE, Cohen DJ, Radhakrishnan J, et al. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. JAMA Netw Open. 2019;2(8):e1910312.
[52] Mohan S, Chiles MC. Achieving Equity through Reducing Variability in Accepting Deceased Donor Kidney Offers. Clinical journal of the American Society of Nephrology : CJASN. 2017.
[53] Patzer RE, Plantinga LC, Paul S, Gander J, Krisher J, Sauls L, et al. Variation in Dialysis Facility Referral for Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. Jama. 2015;314(6):582-94.
[54] Ibid.
[55] Goldberg DS, French B, Abt PL, Gilroy RK. Increasing the Number of Organ Transplants in the United States by Optimizing Donor Authorization Rates. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons. 2015;15(8):2117-25.
[56] Ibid.

It has also been shown that differences in center acceptance practices help to explain some geographic disparities in access to liver transplants. Nevertheless, the supply to demand explains a much greater proportion of this geographic disparity, suggesting that geographic disparities cannot solely or even primarily be explained by differences in organ offer acceptance rates.[57]

Regarding the contribution of OPO performance to geographic variation in transplant rates, it has been shown that policies designed to reduce geographic disparities in liver transplantation through optimized districts were not predicted to systematically increase transplant volumes in DSAs with low-performing OPOs, and vice versa. Rather, the observed and predicted net transplant volume changes were uncorrected with OPO performance suggesting that differences in OPO performance were not a central cause of geographic disparities in access to liver transplantation.[58,59]

Efficiency in Placement

A large volume of feedback was received by the Committee concerning the efficient placement of organs in an allocation framework that utilizes a 500 NM fixed-distance circle as the first unit of distribution. The community expressed concern about the projected increase in the percentage of kidneys that would be flying, logistical complications affecting the current system that may be temporarily affected by a transition to a significantly broader distribution framework, and the effects that both of these concerns might have on cold ischemic times, delayed graft function, and organ discards. While the Committee initially believed that increases in travel would be outweighed by gains in equity and a reduction in transplant rate on a national level, it was this feedback received from the community that initially informed the Committee's decision to reconsider the 250 NM variation. The 250 variation retains much of the same equity gains and reduction of variance in access to transplant as was projected for the 500 NM variation while reducing the associated risks of longer travel times, including increased cold ischemic times, greater risk for organ loss, and greater possibility of graft failure.

A noticeable trend in feedback concerning logistics and efficient placement is the unreliability of commercial airline industry, which would may have to be utilized more frequently in the proposed system with a 500 NM fixed-distance circle. The logistical hurdles associated with commercial air travel, including delays, connecting flights, indirect flight paths, cancellations, and the potential for lost cargo, introduce potential risk into the post-procurement process. The Committee considered myriad feedback from transplant programs and OPOs about the realities of kidney procurement and how reliance on commercial air travel introduces increased risk for longer cold ischemic times and organ loss. These concerns largely informed the Committee's decision to reduce the allocation circle size from 500 NM to 250 NM, as they believed that increasing these risks and potentially decreasing the efficiency of organ placement justified a distribution shape less broad than initially proposed.

A metric often cited as concerning to the community is the percent of organs that the KPSAM modeling projected would travel beyond 250 NM in the proposed framework, a distance the Committee stated is an adequate representation at which point transportation method likely relies on flying more so than driving (given that the KPSAM is currently unable to predict whether a kidney would fly or drive). The KPSAM modeling showed that under current allocation practices, approximately 18 percent of organs

[57] Wey A, Pyke J, Schladt DP, Gentry SE, Weaver T, Salkowski N, et al. Offer acceptance practices and geographic variability in allocation model for end-stage liver disease at transplant. Liver Transpl. 2018;24(4):478-87.
[58] Gentry SE, Chow EK, Massie A, Luo X, Shteyn E, Pyke J, et al. Liver sharing and organ procurement organization performance under redistricted allocation. Liver Transpl. 2015;21(8):1031-9.
[59] Gentry SE, Chow EK, Massie A, Luo X, Zaun D, Snyder JJ, et al. Liver sharing and organ procurement organization performance. Liver Transpl. 2015;21(3):293-9.

are allocated beyond 250 NM. Under the 500 NM framework, with its associated proximity points both inside and outside of the 500 NM fixed-distance circle, that percentage was projected to increase to approximately 41 percent. The 500 NM variation without proximity points, for context, projected approximately 61 percent of kidneys would travel beyond the distance of 250 NM. This reduction of 20 percentage points was a consideration when selecting the 500.500.4.8 framework for the proposal, as that 20 percentage point reduction in the percentage of organs moving beyond 250 NM demonstrated the value of proximity points and the Committee believes would help mitigate logistical concerns.

It is noteworthy that many comments, often in tandem with comments expressing concern about the percentage of organs flying, noted that many of these logistical complications could be assuaged if the Committee considered a framework utilizing a 250 NM circle. Some comments even cited the fact that KPSAM modeling projections showed that the 250.250.2.4 variation showed less kidneys traveling beyond 250 NM than the baseline. The 250.250.2.4 variation projected that approximately 10 percent of kidneys would travel beyond 250 NM, though the median travel distance would still increase from approximately 57 NM at baseline to approximately 126 NM.

Many commenters expressed concern that a 500 NM circle, because it was projected to increase the percentage of organ that would have to fly and because longer distances could equate to more cold ischemic time, could lead to adverse outcomes such as delayed graft function or organ discards. Many commenters highlighted that such concerns are elevated in rural areas of the country that do not have a major airport in close proximity. It was noted that longer ischemic times could increase the need for post-transplant recipient testing, which could lead to longer lengths of stay after transplant, increased use of pharmacy and labs, and increased utilization of dialysis.

Community sentiment that increased cold ischemic times that could occur from distributing as broadly as 500 NM from the transplant hospital could lead to increased discards was of particular concern to the Committee. Many comments stressed that relying so heavily on commercial air travel could cause more organ discards.

Medical Urgency

One of the critical pieces of feedback sought by the Committee during the OPTN Fall 2019 Public Comment period was clinical characteristics that current transplant centers and DSAs use to define a candidate as medically urgent under current OPTN Policy 8.2.A, which states,

> "Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency. If there is more than one kidney transplant program in the DSA, then the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record."[60]

The Committee proposed adding a classifications to the allocation tables for medically urgent candidates that would vary in priority depending on the KDPI of the donor kidney. The Committee agreed that in order to add such a classification, a consistent national definition that defines a medically urgent

[60] OPTN Policy 8.2.A Exceptions Due to Medical Urgency, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (accessed October 31, 2019).

candidate would have to be developed.[61] By defining what constitutes medical urgency, the Committee could more effectively develop a process by which candidates that meet that definition receive the classification and are thus elevated in priority on subsequent match runs.

The Committee reached out to a number of transplant programs within DSA that have operationalized a consistent system for seeking DSA approval for granting medical urgency to a candidate under current policy. The feedback received from these programs was largely consistent with feedback received during the community in public comment concerning a medical urgency definition: that such a definition include a candidate's loss of vascular access or an inability to receive dialysis.

Some feedback suggested a requirement that one or more physicians independent of the transplant program conduct an independent review prior to a classification being received.

The Committee considered these definitions and requirements and speculated on a few types of review that could potentially be proposed, including requiring supporting documentation and a retrospective review, or possibly a review board similar to the National Liver Review Board.

It became clear as this development progressed that it would be necessary for the Committee to go back out for another Public Comment in order to more strictly define medically urgent candidates to capture cases that fall outside those meeting the requirements of loss of vascular access or inability to receive dialysis. Furthermore, the Committee would need to conduct more evidence-gathering regarding OPTN resources necessary for a number of potentials proposals in order to put forth a responsibly-considered proposal for OPTN Board approval.

Import Backup

The committee's proposal for the operationalization of import backup, colloquially known as local backup, in an allocation system without DSAs or regions as units of allocation received underwhelming attention during the OPTN Fall 2019 Public Comment period.

In the context of the proposed hybrid framework with an initial allocation unit of a 500 NM circle, proposed allowing host OPOs to delegate import backup to receiving or "import" OPOs who would then run their own match runs with the original intended recipient's transplant program at the center of a 150 NM fixed-distance circle, to reduce additional travel.

Some commenters noted that in a system with a 500 NM fixed-distance circle as the first unit of allocation, a 150 NM may still be too big for the purposes of import backup if the Committee wishes to limit cold ischemia times.

Some feedback praised the flexibility this would give to the host OPO to either retain or release an organ to the import OPO; however, some commenters expressed that the host OPO should still run the new match even if import backup is delegated to reduce the administrative burden of the importing OPO. Conversely, other commenters expressed that allowing a host OPO to delegate import backup introduces too much variability into the system.

[61] Meeting Summary for July 8, 2019. OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/3149/20190708_kidney-committee_meeting-summary.pdf (accessed October 31, 2019).

Similar to the proposal for medical urgency, It became clear as the OPTN Fall 2019 Public Comment period progressed that it would be necessary for the Committee to go back out for another Public Comment in order to conduct more evidence-gathering in order to put forth a responsibly-considered proposal for OPTN Board approval.

Evaluation of Key Factors

Transplant Rate

As stated in the "Community Feedback" section, a significant concern among members of the transplant community was that the transition from current practice immediately to a 500 NM hybrid framework would lead to increased organ discards, as could be inferred by the very slight decline in the transplant rate seen when comparing baseline practices to the 500.500.4.8 variation. The committee took this concern into consideration, and believe that a proposal for a less-broad framework, the 250.250.2.4 variation, could assuage these community concerns and furthermore be defensible as broader distribution than the baseline while additionally achieving the best use of organs, as outlined in the Final Rule.[62]

Figure 13 below shows simulated projections on transplant rate and transplant count for each of the modeled variations.

Figure 13: Average Transplant Rate for Kidney Transplants from KPSAM Modeling Average from 10 Iterations per Scenario

Scenario	Transplant Rate per Patient-Year	Transplant Rate Per Patient Year (Minimum, Maximum)
BL	0.118	(0.117,0.119)
500.500.0.8	0.115	(0.114,0.116)
500.500.4.8	0.115	(0.114,0.116)
500.150.0.8	0.117	(0.115,0.118)
250.250.2.4	0.116	(0.115,0.117)
250.250.0.8	0.116	(0.115,0.117)
250.150.0.8	0.117	(0.116,0.118)
150.150.0.8	0.117	(0.116,0.118)
150.150.0.20	0.117	(0.116,0.118)
500.500.step150	0.115	(0.114,0.116)
500.500.step250	0.115	(0.114,0.115)

The second column illustrates the differences in transplant rate per patient year of each of the modeled variations from the modeled baseline. The difference between the highest and lowest scenario only differs at the thousandth decimal place. These results emphasize that greater equity in access based on geography could be achieved among modeled variations with 500 NM and 250 NM fixed-distance circles without considerable decreases in the overall transplant rate. The Committee believes that gains in overall equity justify the negligible projected decrease in the overall transplant rate. Furthermore, projected decreases are smaller for the 250.250.2.4 variation when compared to the originally proposed 500.500.4.8 variation.

[62] 42 C.F.R. §121.8(a)(8).

Transplant Rate by Socioeconomic and Geographic Factors

One of the major themes that emerged from community feedback received during the OPTN Spring 2019 Public Comment period concerning the KP Concept Paper was that the committee should continue to apply focus on effects in access for socio-economically disadvantaged populations.[63] Furthermore, some community members expressed concern that rural populations would be disadvantaged by broader distribution. The committee chose to examine changes in transplant rate by candidate payment status and urbanicity.

Figure 14 illustrates the modeled variation's projected effects on the percent of transplants by payment status for the two baseline scenarios and the committee's two preferred variations.

Figure 14: Percent of Transplants by Payment Status (Kidney-Alone)

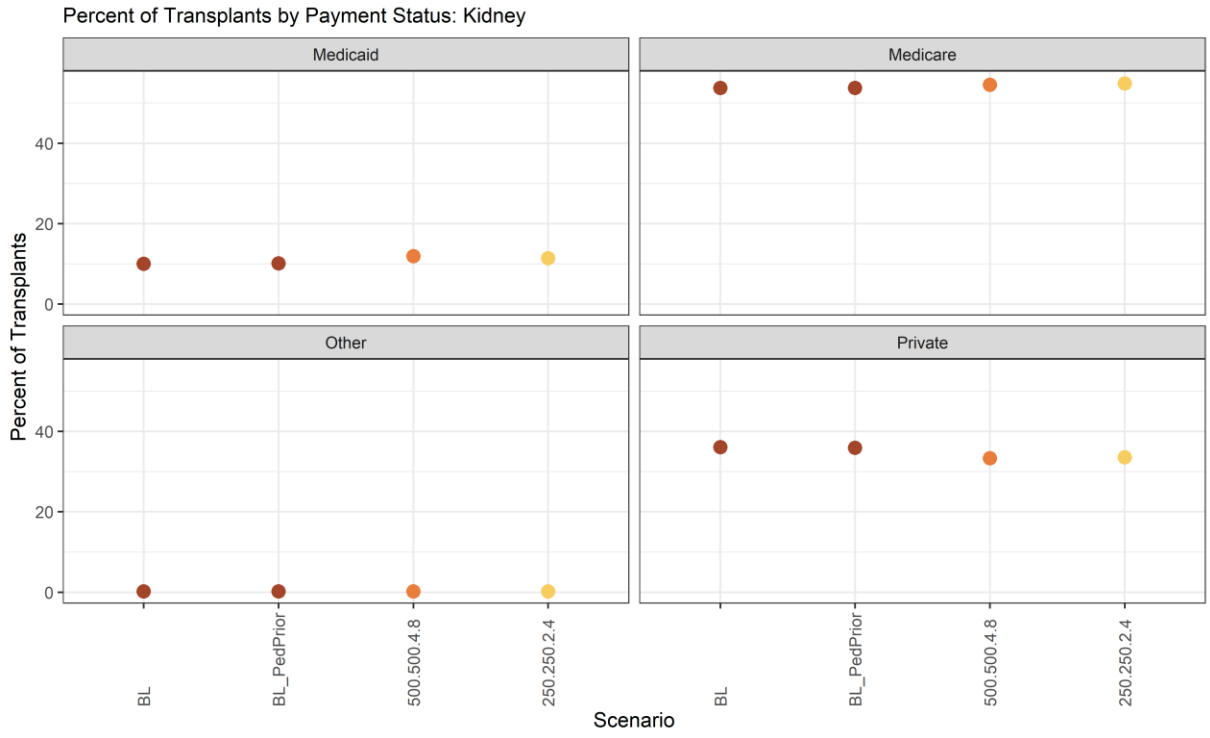
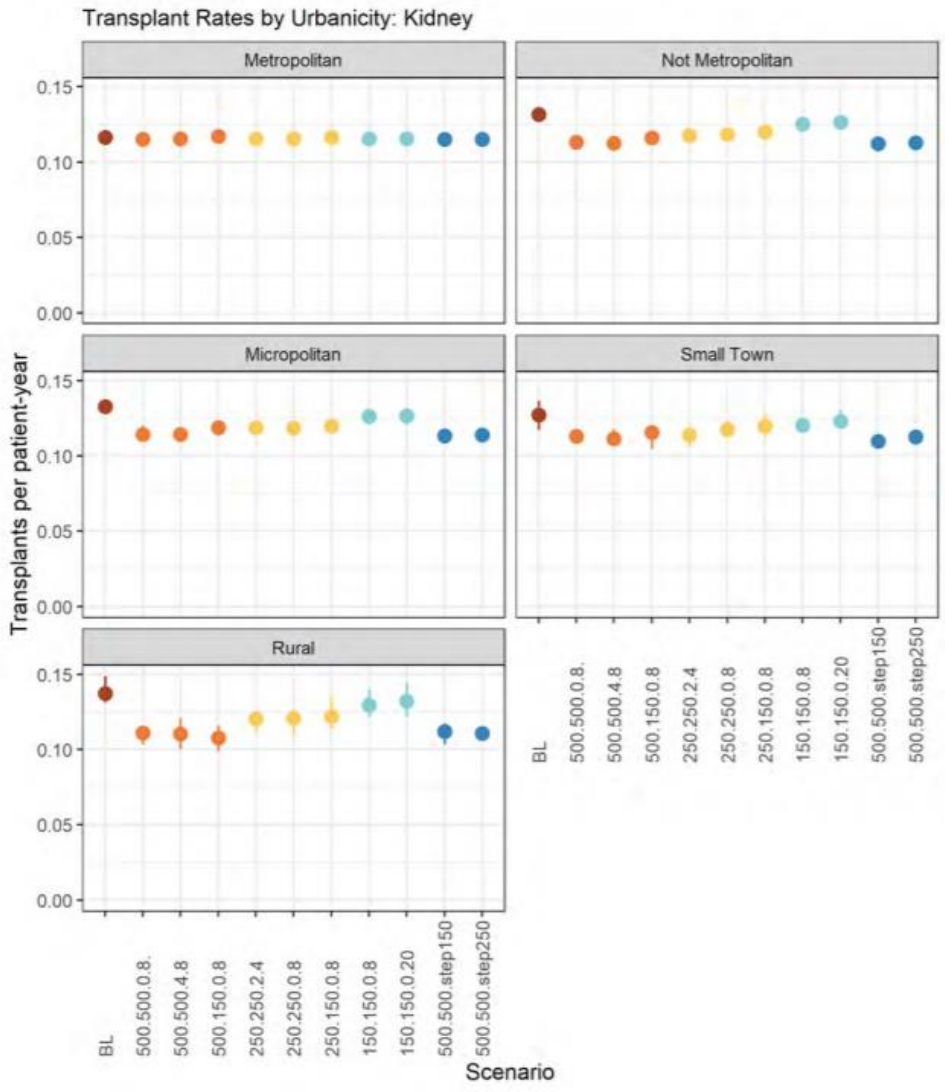


Figure 14 demonstrates a projected increase in the percentage of transplants for candidates enrolled in Medicaid for both the 250.250.2.4 and the 500.500.4.8 variations. Candidates enrolled in "Other" forms of insurance coverage saw similar projected outcomes. Movement was marginal among both variations for candidates enrolled in Medicare, and both variations showed slight decreases in for candidates enrolled in private insurance, though that decrease was smaller in the 250.250.2.4 variation. 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.[64]

Figure 15 outlines the projected changes in transplant rate by urbanicity.

[63] Meeting Summary for March 25, 2019 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf (accessed November 19, 2019).
[64] 42 C.F.R. § 121.4(a)(3).

Figure 15: Transplant Rates by Urbanicity (Kidney-Alone)



The committee observed that while projected transplant counts remained relatively consistent across all variations for candidates in metropolitan areas (big cities), there were offsetting decreases in transplant rates for candidates in all of the other urbanicity subgroups, though the differences are negligible. However, these projected decreases are smaller amongst the 250.250.2.4 variation than the initially proposed 500.500.4.8 variations. Although transplant rates in non-metropolitan areas declined under broader distribution compared to what they were at baseline, they are now more similar to transplant rates for metropolitan candidates. It can be concluded that broader distribution is not disadvantaging non-metropolitan candidates compared to metropolitan candidates; it is lessens the variance in their access.

As can be expected, these changes are smallest in variations that use the smallest fixed-distance circle size of 150 NM. This is likely because under KAS, approximately 50 percent of kidneys are distributed

within 72 miles.[65] Though kidneys are characterized by the longest tolerable cold ischemic times among transplantable organs,[66] they tend to be distributed very locally. As the first unit of allocation expands to 150 NM, 250 NM, or 500 NM, the median travel distance for kidneys will likely increase and more candidates beyond the range of what might be considered "local" under current practice will have greater access. 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 except to the extent required by other regulatory requirements.[67]

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

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. **Figure 16** below shows simulated projections on these three metrics for each of the modeled variations:

Figure 16: Average Waitlist Mortality Count, Average Waitlist Mortality Rate, and Average 1-Year Post-transplant Graft Failure Rate from KPSAM Modeling
Average from 10 Iterations per Scenario

Scenario	Waitlist Mortality Rate per Patient-Year	Waitlist Mortality Count (N)	1-Year Post-transplant Graft Failure Rate
BL	0.047	5,237	0.075
500.500.0.8	0.048	5,266	0.079
500.500.4.8	0.048	5,276	0.079
500.150.0.8	0.048	5,265	0.078
250.250.2.4	0.047	5,261	0.077
250.250.0.8	0.047	5,263	0.077
250.150.0.8	0.047	5,251	0.077
150.150.0.8	0.047	5,249	0.076
150.150.0.20	0.047	5,255	0.075
500.500.step150	0.048	5,270	0.077
500.500.step250	0.048	5,273	0.075

[65] *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 October 31, 2019).
[66] *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).
[67] 42 C.F.R. § 121.8

Scenario	Waitlist Mortality Rate per Patient-Year (Minimum, Maximum)	Waitlist Mortality Count (N) (Minimum, Maximum)	1-Year Post-transplant Graft Failure Rate (Minimum, Maximum)
BL	(0.047,0.048)	(5207,5268)	(0.072,0.081)
500.500.0.8	(0.047,0.048)	(5238,5282)	(0.077,0.083)
500.500.4.8	(0.047,0.048)	(5255,5291)	(0.076,0.082)
500.150.0.8	(0.047,0.048)	(5244,5284)	(0.075,0.082)
250.250.2.4	(0.047,0.048)	(5247,5271)	(0.074,0.08)
250.250.0.8	(0.047,0.048)	(5252,5277)	(0.075,0.083)
250.150.0.8	(0.047,0.048)	(5228,5274)	(0.074,0.08)
150.150.0.8	(0.047,0.048)	(5233,5270)	(0.073,0.08)
150.150.0.20	(0.047,0.048)	(5228,5294)	(0.071,0.078)
500.500.step150	(0.047,0.048)	(5252,5280)	(0.074,0.081)
500.500.step250	(0.047,0.048)	(5264,5279)	(0.073,0.076)

The committee observed that the graft failure rate per patient year only varied at the thousandth decimal place. Furthermore, the graft failure count varied by less than one percent between the highest and lowest value across all modeled variation. Finally, graft failure rate per patient year only varied at the thousandth decimal place. The minimums and maximums of the modeled variations often overlap with the minimums and maximums at baseline over ten simulated runs, indicating minimal differences from baseline in the projected changes across key metrics for both the 500.4.8 and 250.2.4 variations.

The Committee originally believed 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 500 NM. However, when considering additional logistical implications associated with an initial transition from DSAs and regions to a 500 NM hybrid variation, as well as the volume of kidneys donated when compared to other organs, the Committee re-evaluated their initial conclusion. Based on their sound medical judgement and feedback received during the OPTN Fall Public Comment period, the committee believes that the 250.250.2.4 variation, which sees no projected change in waitlist mortality rate, no projected change in waitlist mortality count, and no projected increase in graft failure rate.

Review of Travel Distance Data

The Committee considered that a solution that represents a more incremental change and avoids an exponential increase in flying kidneys would be a better solution to align with the Final Rule and reflect community concerns. The Committee therefore re-considered KPSAM modeling on distribution of travel distance to ascertain if the alternative proposal of 250 NM would result in most kidneys traveling a distance that can be covered by ground transportation. **Figure 17** shows violin plots to project the shape of distribution across the modeled KPSAM variations.

Figure 17: Distribution of Organ Travel Distance, Kidney-Alone
Averaged Results from 10 Iterations per Scenario

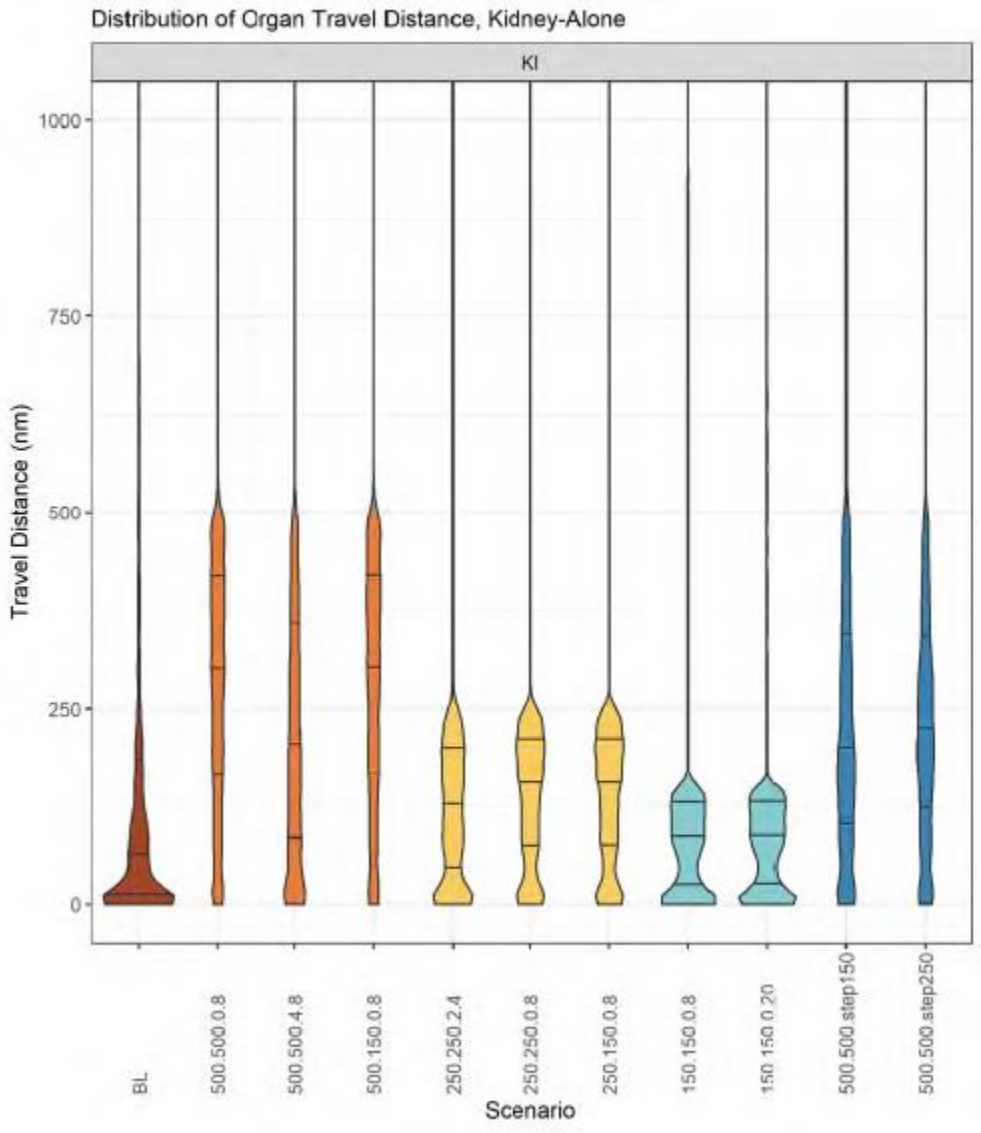


Figure 17 illustrates the projected differences in the shape of distribution that results from differently sized fixed distance circles among the modeled variations as well as the projected effects of proximity points. Overall, this figure shows how the circle size limits the projected travel distance – in general, travel tapers off sharply outside the size of the circle. The figure also demonstrates the impact of proximity points, which lowers the first quartile distance for the 250.250.2.4 solution compared to the 250.250.0.8 variation. The 250 NM solution limits geographic distribution more than the 500 NM, reflecting public comment concerns regarding the logistical challenges of a 500 NM circle with proximity points. Specifically, **Figure 17** demonstrates how travel is projected to be limited to largely drivable distances (250 NM) with a 250 NM circle, thereby addressing the concerns of the community regarding

travel logistics and the increase in flying that would result from a 500 NM circle. The Committee recognizes that in some areas of the country, kidneys mare drive for longer distances than 250 NM.[68]

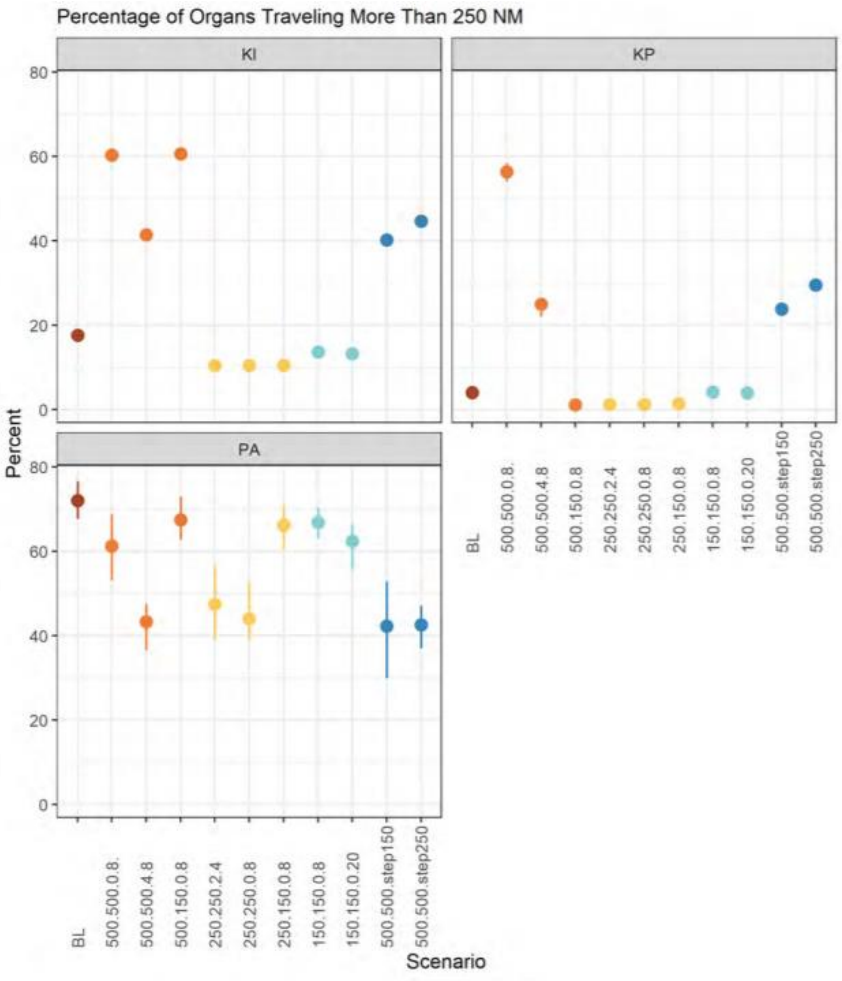
The Committee continues to believe that proximity points within the first allocation circle offer value in a 250 NM framework because it recognizes that the time it takes to drive 250NM miles differs significantly throughout the country. Those differences may result in hours of cold ischemic time and varying patient outcomes, and thus it's the sound medical judgement of the Committee to continue to utilize proximity points in a framework utilizing 250 NM. Furthermore, the median travel distance of a kidney is reduced from approximately 156 NM in the 250.250.0.8 framework to approximately 126 NM in the 250.250.2.4 variation. This was considered by the Committee, as members see value in proximity points not only for affecting the efficient placement of organs and not undertaking associated risks of longer travel, such as increased cold ischemic times and a greater chance for organ loss, if there is a candidate with similar medical characteristics and wait time closer to the donor hospital. Understanding that the median travel distance of the Committee's initial proposal of the 500.500.4.8 variation was approximately 199 NM, the committee sought to address the logistical concerns of the community and the efficiency of organ placement as much as possible while still eliminating DSA and region with the broadest feasible distribution.

Review of Percentage of Kidneys Traveling Beyond 250 NM Data

In considering a modified proposal, the Committee also re-reviewed the projected percentage of organs traveling beyond 250 NM, which the Committee had previously established as an acceptable approximation for a change in travel method from driving to flying. **Figure 18** illustrates that the previously proposed 500 NM solution would imply more than 40% of kidneys would travel beyond 250 NM, and probably be flown to reach their intended recipient. Comparatively, a 250 NM circle would indicate that only about 10% of kidneys may fly.

[68] Meeting Summary for October 21, 2019 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/3344/20191021_kidney-in-person-meeting-summary.pdf (accessed November 19, 2019).

Figure 18: Percentage of Organs Traveling Beyond 250 NM
Averaged Results from 10 iterations per Scenario



The Committee found the potential difference in organs flown to be important given the concerns raised during public comment. The Committee considered that the potential decrease in organs flown with the 250 NM solution would mitigate many of the logistical challenges related to flying kidneys commercially by preserving the option that the organs be driven. By limiting the logistical impact, the Committee considers the 250 NM solution would better align with the Final Rule requirements to achieve the best use of organs, avoid organ loss and promote efficient placement of organs by minimizing organ loss, longer ischemic times, and a potential decrease in utilization.

Preserved Increase in Equitable Access

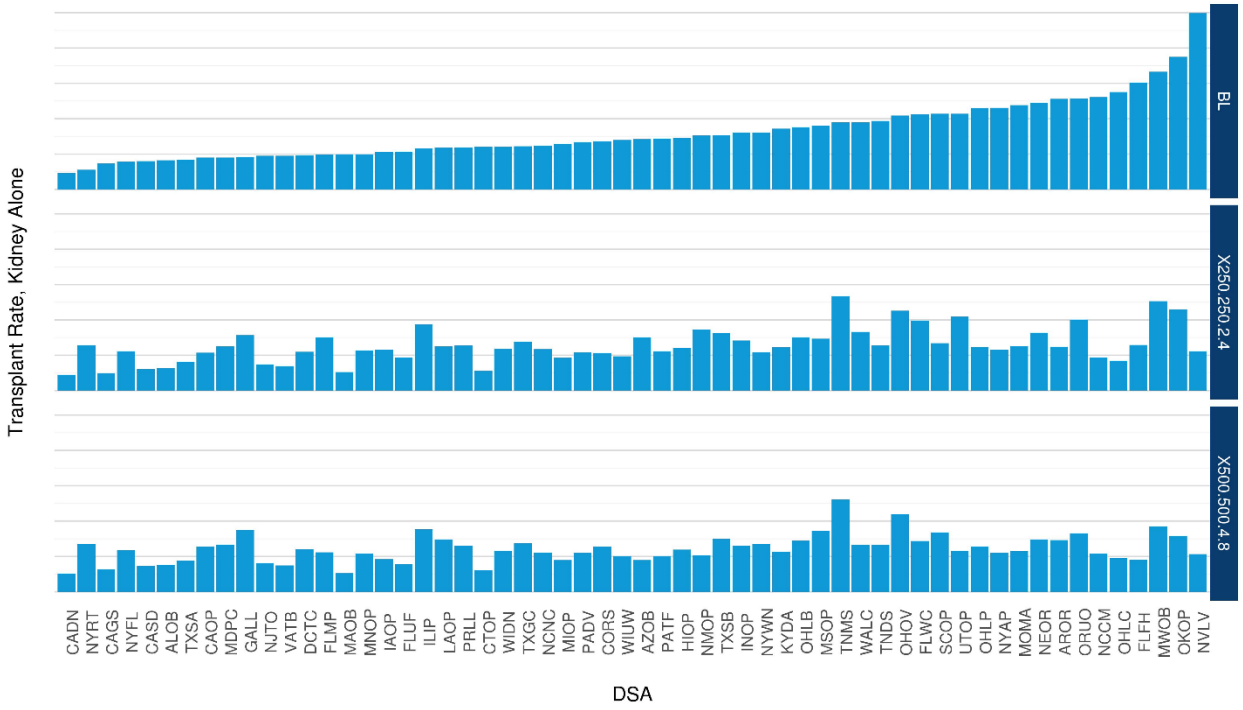
A major objective of this proposal is to improve equity in access to kidney transplantation. In general, the projected gains in equity seen with the 500 NM solution are preserved with the 250 NM solution. This is true for geographic equity measured by variance in transplant rate by DSA, as well as projected increases in equity in access for vulnerable populations (highly sensitized, pediatric, and candidates on Medicaid or Medicare). The Committee considers that the 250 NM option keeps the significant gain in equity for these vulnerable populations without the logistical hurdles and associated outcomes such as organ loss and less efficient placement that the 500 NM solution faces. The Committee considers that

the projected decrease in logistical challenges of flying kidneys, along with the preserved increase in equity, indicate that 250 NM is a better incremental change that aligns with the Final Rule requirement to distribute as broadly as feasible while achieving the best use of organs, avoiding organ loss and promoting efficient placement of organs.

The Final Rule stipulates that allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of Section 121.8 of the Final Rule.[69] Additionally, the Final Rule includes a performance goal for allocation policies of "Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency."[70]

Figure 19 illustrates how the proposed allocation framework reduces disparities in access among the DSAs compared to current practice under KAS.

Figure 19: Kidney Transplant Rate by DSA



By examining DSA-level data provided in the KPSAM analysis report, the committee was able to observe the projected effects on transplant rate by DSA of their two preferred variations compared to baseline. **Figure 19** demonstrates that greater equity in access to transplant based on a candidate's place of listing across the country is achieved under both the 500.500.4.8 variation (represented by the plot on the bottom) as well as the 250.250.2.4 variation (represented by the plot in the middle). The committee recognizes that the biggest observable differences in the reduction of variance by DSA can be seen when comparing the baseline to the 500.500.4.8 variation; however, when comparing the 500.500.4.8 variation to the 250.250.2.4 variation, the differences are more marginal. The committee, guided by the understanding that distribution should be as broad as possible, limited only by other components of the

[69] 42 C.F.R. §121.8(a)(8).
[70] 42 C.F.R. §121.8(b)(3).

Final Rule[71] believes that the 250.250.2.4 variation can still achieve greater equity than current allocation system that utilizes DSA and regions as units of allocation.

Time on Dialysis

Committee members wanted to ensure that patients with the longest times on dialysis would receive greater access to transplants. By enhancing access to transplant for candidates with the highest dialysis times, some of the most medically urgent candidates will receive organs. **Figure 20** below illustrates the projected time on dialysis at time of transplant among the committees two preferred variations compared to baseline. Within the graphic, "BL" represents a baseline scenario without further prioritization for pediatric patients and "BL_PedsPrior" represents a baseline scenario when pediatric patients receive increased priority in allocation tables, as illustrated in **Figure 8.** The 500.500.4.8 and 250.250.2.4 modeled variations also include the increased pediatric candidate priority.

Figure 20: Projected Time on Dialysis at Time of Transplant from KPSAM Modeling Results (Averaged Results from 10 Iterations per Scenario)

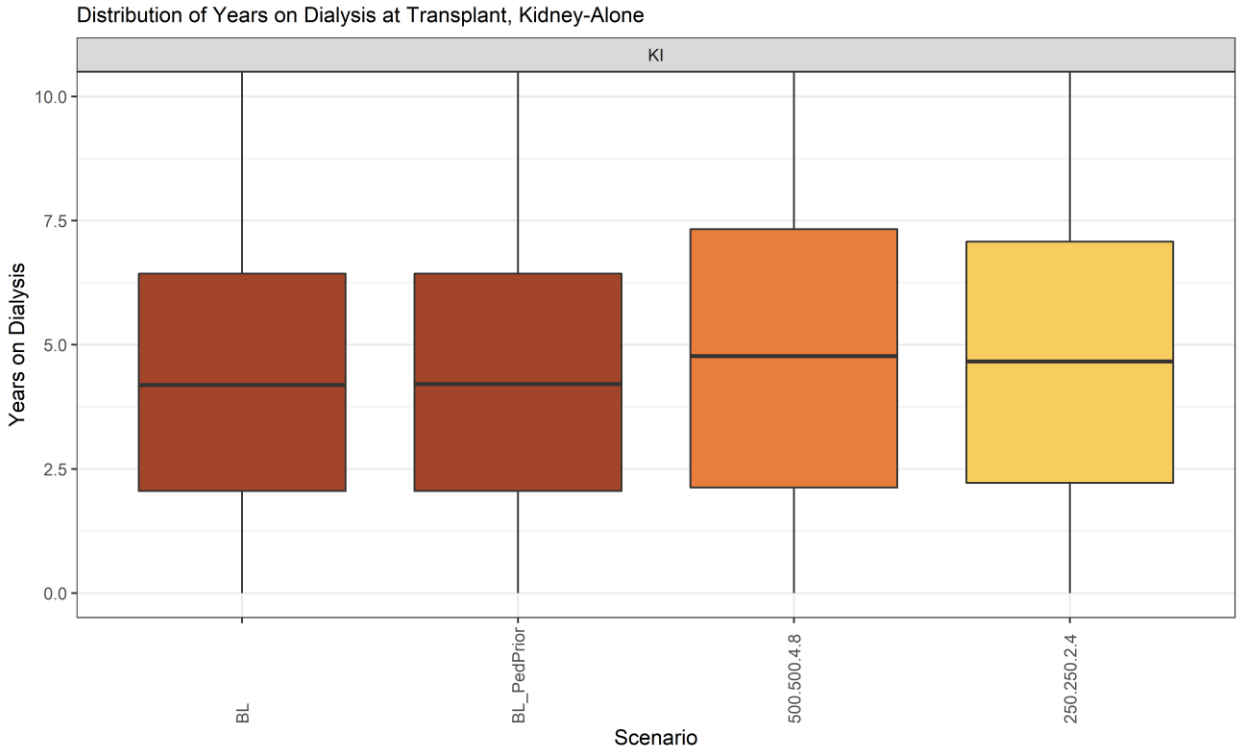


Figure 20 illustrates that both the 250 and 500 NM variations expand access for candidates with more accrued dialysis time. The broader the box, the greater the distribution of years of dialysis among candidates that were projected to receive transplants. The yellow bar, representing the 250.2.4 variation, reaches higher on the y-axis than either of the red bars representing the baseline runs, which means that the distribution of candidates receiving transplants in the 250.2.4 variation included more candidates with more years on dialysis.

[71] 42 C.F.R. §121.8(a)(8).

Based on their sound medical judgement and feedback received during the OPTN Fall Public Comment period, the committee believes that the 250.250.2.4 variation achieves greater access for candidates with more than 5 years of dialysis time compared to baseline.

High Calculated Panel Reactive Antibody (CPRA) Candidates

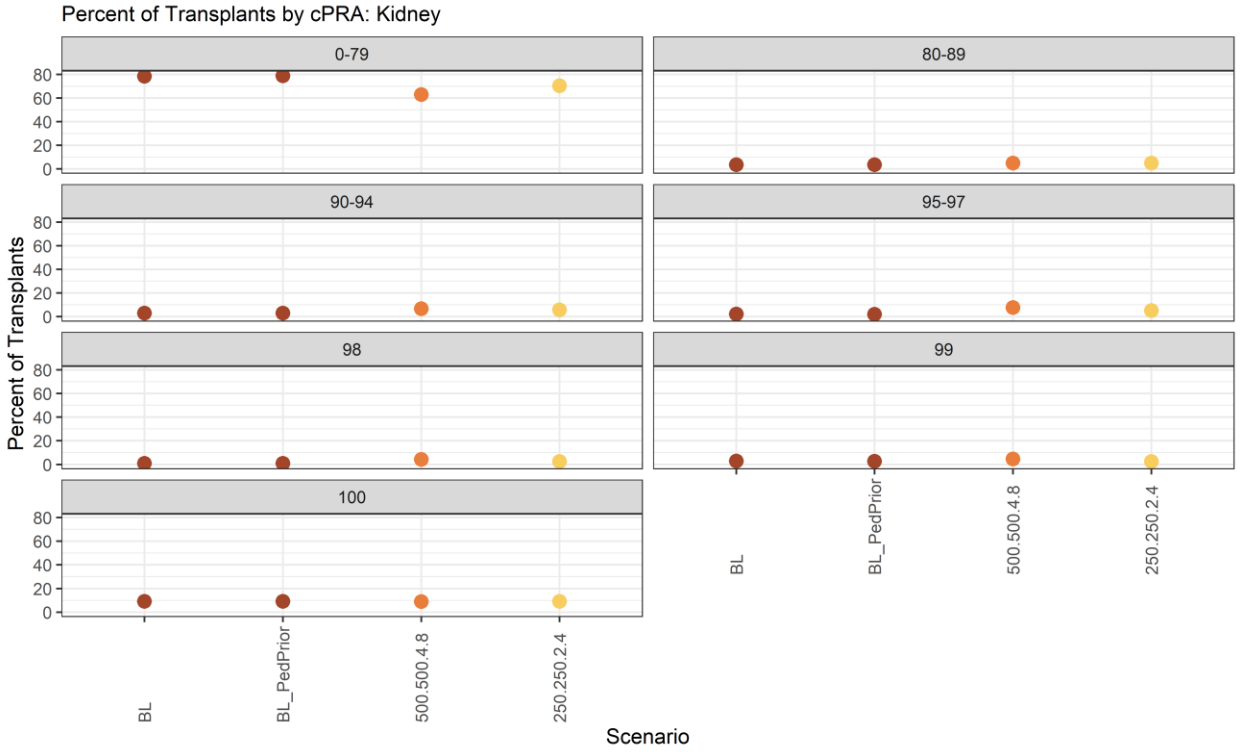
Candidates with high cPRA scores represent another subgroup of interest to the Committee in terms of equity in access to transplant. Given the difficulty of finding organ matches for these candidates due to the possession of antibodies that make graft rejection more likely, the committee wants to maintain their access in order to promote greater equity system-wide.

Because the hybrid framework removes regional classification from allocation policy, the committee had to decide how to prioritize 99% cPRA candidates. Currently in KAS, these candidates receive mandatory regional shares, while 100% cPRA candidates receive mandatory national shares. The committee decided to place 99% cPRA in classifications just above 98% cPRA candidates in inside circle shares.[72] This decision was made following committee review of post-KAS implementation data which the Committee concluded may indicate the possibility that some CPRA 99% candidates received a greater percent of transplants than intended.[73]

Figure 21 below shows the range of results across the 10 simulations as a vertical line extending from the minimum value to the maximum value for that metric and scenario. A point along that line marks the mean value of the metric across the 10 iterations.

[72] Meeting Summary for March 28, 2019 meeting, OPTN Kidney Pancreas Workgroup. https://optn.transplant.hrsa.gov/media/3031/20190328_kp_workgroup_min.pdf (accessed November 19, 2019).
[73] Meeting Summary for October 15, 2018 meeting, OPTN Kidney Transplantation Committee. https://optn.transplant.hrsa.gov/media/2743/20181015_kidney_committee_minutes.pdf (accessed November 19, 2019).

Figure 21: Projected Effects on Transplant Rate by cPRA



The committee noted that very marginal projected decreases can be seen in candidates with a cPRA from 0 to 79; however, these projected decreases are stymied by transitioning to the 250.250.2.4 variation when compared to the originally proposed 500.500.4.8 variation. The 250.250.2.4 variation still achieves greater projected access for candidates with cPRA values between 80 and 97 when compared to baseline, though projected increases for candidates with cPRA values of 98 and 99 are smaller than those that may be achieved under the initial proposal. Transplant rates for candidates with cPRA 100 remained relatively unchanged given they remain at the top of the list.

Based on their sound medical judgement and feedback received during the OPTN Fall 2019 Public Comment period, the committee believes that the 250.250.2.4 variation, which still achieves greater access for candidates with cPRA values between 80 and 99 when compared to baseline.[74]

Pediatric Candidate Transplant Access

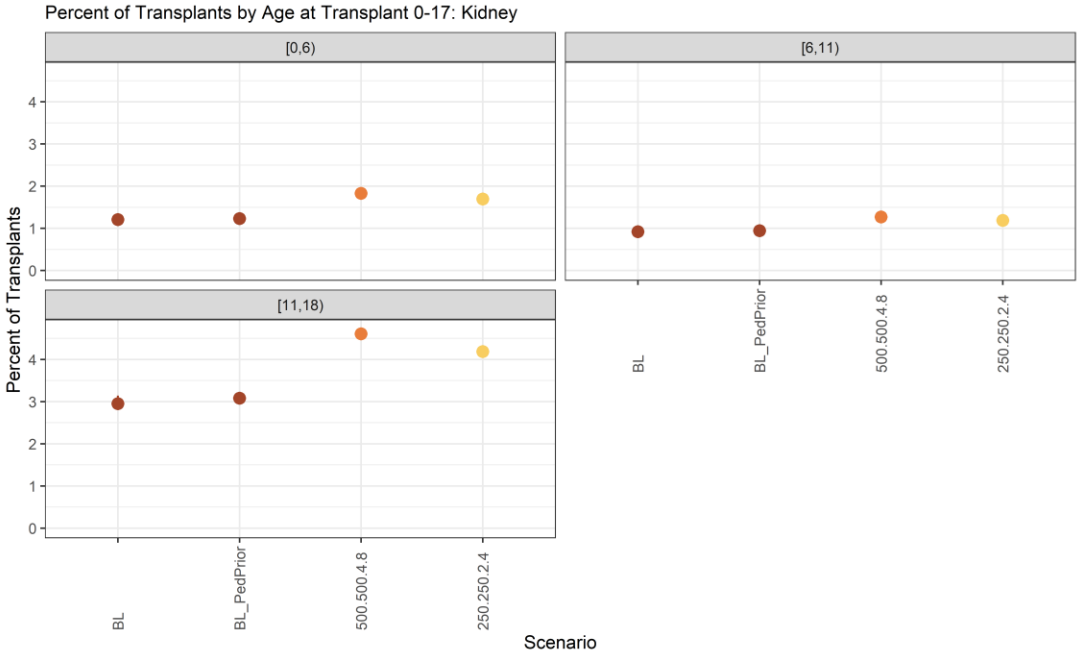
As previously stated, the Committee was interested including further pediatric prioritization as a component of this project. This interest galvanized when the first round of KPSAM modeling, which did not include any additional pediatric prioritization, projected that pediatric candidates received greater access to transplant as distribution broadened.[75] Members of the committee expressed the aspiration to include increased pediatric prioritization in kidney allocation tables in the second round of modeling in order to observe any noticeable effects on the new round of framework variations.[76] Workgroup

[74] 42 C.F.R. §121.8(a)(8).
[75] Scientific Registry of Transplant Recipients, *SRTR KI2018_01*, December 7, 2018, https://optn.transplant.hrsa.gov/media/2768/kp_analysisreport_20181207.pdf (accessed November 19, 2019).
[76] Meeting Summary for March 28, 2019 meeting, OPTNS Kidney Pancreas Workgroup.

members expressed the need to do so with two baselines: one baseline that included the increased pediatric priority in allocation tables, and one that did not. By performing two baselines scenarios, the committee could effectively compare increased access for pediatric candidates that resulted from broader distribution to those that occurred as a direct result of the allocation table changes.[77]

Figure 22 shows the projected effects on pediatric candidate access that resulted in the Committee's two preferred variations in the second round of KPSAM modeling.

Figure 22: Percent of Transplants by Age (Pediatric)



The projected results illustrate that observable increases in transplant rate and count occur amongst all of the pediatric-age subgroups in each of the two preferred variations. The Committee recognizes that of the total net gain in projected percent of patients receiving transplants within each age subgroup, the majority of that projected increase is observed when transitioning from baseline practices to the 250.250.2.4 variation, and that subsequent gains from the 250.250.2.4 to the 500.500.4.8 variation are much less significant in comparison.

Additionally, the committee observed that the increases that resulted in only further prioritizing them in allocation tables were relatively marginal. It appears that increases in transplant rate among pediatric candidates can be correlated much more closely with broader distribution than baseline practices than with additional allocation table priority.

https://optn.transplant.hrsa.gov/media/3031/20190328_kp_workgroup_min.pdf (accessed November 19, 2019).
[77] Ibid.

Alignment of Modified Proposal with OPTN Strategic Plan

- *Increase the number of transplants*: This proposal is not expected to affect the number of total transplants.
- *Improve equity in access to transplants*: This proposal would increase equity in access to transplants. It reduces variance in access to transplants national wide and improves access to transplant for vulnerable populations.
- *Improve waitlisted patient, living donor, and transplant recipient outcomes*: There is no impact on this goal.
- *Promote living donor and transplant recipient safety*: There is no impact on this goal.
- *Promote the efficient management of the OPTN*: The proposal could impact the percentage of kidney transplants that require air transportation and thereby impact costs and affect recovery team safety. It is important to note, however, that the OPTN currently does not collect transportation mode nor can the KPSAM simulate it.

Final Rule / NOTA Compliance of the Modified Proposal

The OPTN Final Rule says that organ allocation "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by other elements of the Final Rule.[78] The elements that may constrain organ distribution include sound medical judgment, the best use of donated organs, avoiding unnecessary organ loss, avoiding futile transplants, promoting patient access to transplantation, and promoting the efficient management of organ placement. The best use of organs, avoiding unnecessary organ loss, and promoting the efficient management of organ placement[79] may provide justification for constraining geographic distribution of organs due to the impact on ischemic time, travel logistics, utilization and outcomes.

The Committee considered these constraints when evaluating how to remove DSA and region from kidney allocation. In particular, these constraints led to the Committee rejecting the option of a national kidney allocation framework and supporting a 500 NM circle with proximity points for public comment. Members considered that a 500 NM circle size would improve equity in access to transplant, while proximity points would mitigate the impact of the size of the circle on ischemic time, outcomes, utilization and travel logistics. This was based on the Committee's sound medical judgement, as well as projections when considering various circle sizes in two rounds of KPSAM modeling. Since one proximity point has been aligned to one year of waiting time as one example, candidates closer to the donor hospital would receive what would equate to four years of waiting time for their proximity. This, the Committee considered, would limit the median travel distance, which could reduce logistical hurdles and the likelihood that long ischemic time could negatively impact patient outcomes, result in futile transplants, or negatively impact utilization of the donated organs. The Committee also considered a 250 nautical mile circle with proximity points as an alternative solution throughout both rounds of modeling and the various committee and KP Work Group meetings, because some members had concerns about logistical impact and utilization of the 500 NM solution even with the proximity points.

While the Committee previously considered that the inclusion of proximity points with a 500 NM circle mitigated the potential impact on travel logistics, the detailed concerns from public comment made the Committee reconsider whether the 500 NM would be an appropriate distribution unit. Specifically, the

[78] 42 C.F.R. § 121.8
[79] 42 C.F.R. § 121.8

Committee considered that the significant logistical challenge of flying more kidneys commercially may negatively impact outcomes and utilization and how those challenges could affect efficiency of placement and increased risk for organ loss or graft failure. This in turn raises potential concerns about the Final Rule requirements to achieve the best use of organs, avoid unnecessary organ loss, and promote efficient management of organ placement. Ultimately, the Committee believes that the 250 NM proposal still makes significant steps towards achieving more equity in access to transplant, while the proposed proximity points help to minimize the risk of poor utilization of donated organs, futile transplants by way of poor post-transplant outcomes, and logistical challenges associated with transporting organs further distances.

Implementation and Operational Considerations

Potential Fiscal Impact of Proposal

Allocation change detailed in this proposal will affect the costs incurred by most transplant centers, but is directly the result of volume, geography, and current contractual agreements.

Some centers may experience loss in volume, while others may see an increase. Loss in volume may cause a decrease in program revenue or even closure of the kidney program. Increase in volume may result in greater revenue, but also greater cost per transplant. Increase in flight cost (travel time) and recovery team procurement costs are possible. It is not clear if procurement would be performed locally or by the transplant hospital. If flying to procure or needing flights to transport kidneys increases, more rural areas may bear a disproportionate coast burden to transport kidneys and/or conduct perfusion.

Patient population mix is a consideration in costs, as well. Centers with a substantial population of older patients may incur additional costs associated with longer wait times and maintaining candidates on the Waitlist, particularly in metropolitan areas. Costs associated with delayed graft function, due to extended cold ischemia time, may increase with this population. Use of dialysis in the post-transplant phase may cause increase in cost.

While additional costs associated with an increase in travel time and procurement efforts may be covered by Medicare via the Cost Report, it is possible that additional costs may *not* be covered by non-Medicare payers unless existing contractual agreements are renegotiated.

Both Transplant Center and OPO staff would require training and communication about new policies. Transplants Centers would likely implement the new allocation in 3-6 months, while OPOs would be able to train and adjust more quickly. Additional staff or staff hours may be necessary, dependent on change on volume.

Members

Allocation change detailed in this proposal will affect the costs incurred by most transplant centers, but is directly the result of volume, geography, and current contractual agreements.

Some centers may experience loss in volume, while others may see an increase. Loss in volume may cause a decrease in program revenue or even closure of the kidney program. Increase in volume may result in greater revenue, but also greater cost per transplant. Increase in flight cost (travel time) and recovery team procurement costs are possible. It is not clear if procurement would be performed locally

or by the transplant hospital. If flying to procure or needing flights to transport kidneys increases, more rural areas may bear a disproportionate coast burden to transport kidneys and/or conduct perfusion.

Patient population mix is a consideration in costs, as well. Centers with a substantial population of older patients may incur additional costs associated with longer wait times and maintaining candidates on the Waitlist, particularly in metropolitan areas. Costs associated with delayed graft function, due to extended cold ischemia time, may increase with this population. Use of dialysis in the post-transplant phase may cause increase in cost.

While Medicare will cover (via the Cost Report) increase in travel time and procurement efforts, it is possible, if not likely, that additional costs may *not* be covered by non-Medicare payers unless existing contractual agreements are renegotiated.

Both Transplant Center and OPO staff would require training and communication about new policies. Transplants Centers would likely implement the new allocation in 3-6 months, while OPOs would be able to train and adjust more quickly. Additional staff or staff hours may be necessary, dependent on change on volume.

OPTN

The kidney team in the Policy and Community Relations (PCR) department accounts for an estimated 2,500 hours in development of the proposal, including meetings, analysis, policy development, writing, outreach, and travel. Additionally, Research worked closely with the PCR team to develop, review, and monitor data reports and consult in internal and committee meetings.

An enterprise-level effort, estimated at 5,500 hours, will be required to program the proposed allocation changes to remove Designated Service Areas (DSA) and change organ offer notification limits. This is about 2,000 additional hours compared to programming efforts for the change in pancreas allocation proposal. Communications will create a robust campaign, including directed outreach to media, patients, and members, to disseminate changes associated with any allocation changes (kidney and/or pancreas) through multiple platforms and points in time. Communications estimates up to 500 hours to execute this effort.

Significant ongoing monitoring (IT and Research) annually is estimated to create reports and status updates to evaluate outcomes. Both departments estimate several hours per week will be required.

OPTN Actions

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

Changes will be made to the kidney allocation and 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 kidney and 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. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal.

Member actions

Transplant Hospitals

As a result of the increased distance, transplant hospitals will receive offers from OPOs they may not have worked with previously. Transplant hospitals will need to develop these relationships for future organ acceptances. 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 kidney distribution may also impact overall transplantation program costs, as broader distribution may increase the number, distance, and time of additional kidney fly outs. Some programs may need to hire more procurement surgeons to travel further to recover kidneys 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.

Post-Implementation Monitoring

Member Compliance

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.

Policy Evaluation

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 and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy. To assess the policy's impact on pediatric populations as well as the geographic variation in pediatric populations, when feasible, metrics will be stratified by pediatric age groupings, DSA and OPTN Region:

Waitlist

1. Total kidney registrations on the waitlist (snapshot by month)
2. Kidney registrations added to the list, overall and by age, gender, ethnicity, cPRA, blood type, diagnosis, time on dialysis, and insurance status at time of listing
3. % of candidates in active status
4. % of candidates multi-listed

5. Waitlist mortality per 100 patient years, overall and by candidate age, gender, ethnicity, cPRA, blood type, diagnosis, EPTS score, and time on dialysis.

Transplant

1. Donor, recipient and transplant characteristics: number and percent of transplants by recipient age, ethnicity, waiting time (days on the waiting list), time on dialysis, ABO, cPRA, HLA-ABDR mismatch level, diagnosis, EPTS score, KDPI, DCD, inside/outside fixed circle, and cold ischemic time (CIT).
    a. Distribution of kidney travel distance (NM), overall and by inside/outside fixed circle
    b. Distribution of KDPI by inside/outside fixed circle and pediatric age group (pediatric recipients only)
    c. Distribution of KDPI by inside/outside fixed circle and cPRA
    d. Distribution of KDPI by inside/outside fixed circle and prior living donor status
    e. Distribution of KDPI by inside/outside fixed circle and CIT
2. Change in access by location: N and % of transplants by
    a. Share type (local/regional/national)
    b. OPTN region
    c. Donation Service Area (DSA)
    d. (de-identified) transplant center
    e. State
3. Deceased donor transplants per 100 patient years by recipient age, ethnicity, time on dialysis, ABO, cPRA, HLA-ABDR mismatch level, diagnosis, EPTS score, and DSA.
4. Variance in deceased donor transplant rate across DSA
5. Rates of receiving kidney offers per 100 patient years by recipient age, time on dialysis, ethnicity, ABO, cPRA, HLA-ABDR mismatch level, diagnosis, and EPTS score.
6. Rates of delayed graft function (DGF)
7. Number and percent of multi-organ kidney transplants by type (KP, SLK, HR-KI, other), overall and by KDPI

Utilization and Efficiency of Allocation

1. Number kidney donors recovered for transplantation, overall and by KDPI
2. Number and percent of kidneys recovered but not utilized (discarded), overall and by KDPI
3. Number and percent of kidneys discarded by discard reason
4. Number and percent kidneys with a final acceptance
5. Offer acceptance per 100 patient years by recipient age, ethnicity, waiting time (days on the waiting list), time on dialysis, ABO, cPRA, diagnosis, EPTS score, DCD, 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. Number and percent by cPRA, of kidney offers refused due to a positive cross-match
9. Number of candidates transplanted with medically urgent classification, overall and sorted by KDPI

Outcomes

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

- Post-transplant graft and patient survival rates, overall and stratified by recipient age, gender, ethnicity, cPRA, blood type, diagnosis, time on dialysis, HLA-ABDR mismatch, EPTS score, KDPI, and CIT.

Conclusion

The Committee determined that the 250 NM fixed circle with a maximum of two points inside the circle and a maximum of four points outside the circle would provide greater equity in kidney distribution while improving equity in access to transplant for certain vulnerable populations. The Committee considered myriad feedback about the realities of kidney procurement and how reliance on commercial air travel introduces increased risk for longer cold ischemic times and organ loss. These concerns largely informed the Committee's decision to reduce the allocation circle size from 500 NM to 250 NM, as they believed that increasing these risks and potentially decreasing the efficiency of organ placement justified a distribution shape less broad than initially proposed. The inclusion of proximity points is expected to help avoid unnecessary organ loss and to promote efficient management of organ placement. The Committee supported removing DSA and region in pancreas allocation and using instead a 250 NM circle around the donor hospital, with up to two proximity points inside the circle and up to four proximity points outside the circle and agreed that the proposed solution is compliant with the Final Rule. The Committee agreed import back up and medical urgency modifications needed further consideration.

The Committee remains committed to the advancement of allocation policies towards the OPTN Board of Directors' vision of continuous distribution. Members see the following proposal as forward progress and innovation towards that goal while achieving the overall purpose of removing DSA and region from allocation policies in alignment with the Final Rule.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

5.1 Minimum Acceptance Criteria

~~Minimum acceptance criteria define which import deceased donor organs will be offered by the Organ Center to transplant hospitals from OPOs outside the receiving transplant hospital's Donation Service Area (DSA).~~

5.1.A Kidney Minimum Acceptance Criteria

Kidney transplant programs must report to the OPTN Contractor annually minimum kidney acceptance criteria for offers for deceased donor kidneys more than 250 nautical miles away from the transplant program. The kidney minimum acceptance criteria will not apply to imported ~~zero antigen~~ 0-ABDR mismatch ~~(0-ABDR)~~ offers or offers to highly sensitized candidates according to *Policy 8.5.F: Highly Sensitized Candidates*.

Policy 8: Allocation of Kidneys

8.2 Exceptions

8.2.A Exceptions Due to Medical Urgency

~~Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency.~~

~~If there is more than one kidney transplant program in the DSA, then the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record.~~

Reserved.

8.3 Kidney Allocation ~~Points~~ Score

Candidates receive ~~points according to~~ an allocation score according to the total of all points assigned in *Table 8-1* ~~and *8-2 below*~~.

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*

Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points
Meets the qualifying criteria described in *Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	*See Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*

*****Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.

Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital

For purposes of this section, distance is calculated in nautical miles between candidate's hospital of registration and the donor hospital.

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the donor hospital	$2 - \left[\left(\frac{2}{250-0}\right) \times distance\right]$
Registered at a transplant program that is more than 250 nautical miles away from but 2500 nautical miles or less away from the donor hospital	$4 - \left[\left(\left(\frac{4}{2500-250}\right) \times distance\right) - \left(4 \times \frac{250}{2500-250}\right)\right]$
Registered at a transplant program that is more than 2500 nautical miles away from the donor hospital	0

8.5.F Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in ~~allocation~~ classifications 1 through ~~10~~ 8 according to *Tables 8-6 and 8-7;* classifications 1 through 7 according to *Table 8-8;* and classifications 1 through 6 in *Table 8-9*, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and sign a

written approval of the unacceptable antigens listed for the candidate. The transplant program must document this approval in the candidate's medical record.

8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-~~5~~ 6* below.

~~Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~When the donor is this blood type:~~
~~1~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible~~	~~Any~~
~~2~~	~~OPO's DSA~~	~~CPRA equal to 100%, blood type identical or permissible~~	~~Any~~
~~3~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible~~	~~Any~~
~~4~~	~~OPO's region~~	~~CPRA equal to 100%, blood type identical or permissible~~	~~Any~~
~~5~~	~~Nation~~	~~0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible~~	~~Any~~
~~6~~	~~Nation~~	~~CPRA equal to 100%, blood type identical or permissible~~	~~Any~~
~~7~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible~~	~~Any~~
~~8~~	~~OPO's DSA~~	~~CPRA equal to 99%, blood type identical or permissible~~	~~Any~~
~~9~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible~~	~~Any~~
~~10~~	~~OPO's region~~	~~CPRA equal to 99%, blood type identical or permissible~~	~~Any~~
~~11~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible~~	~~Any~~
~~12~~	~~OPO's DSA~~	~~CPRA equal to 98%, blood type identical or permissible~~	~~Any~~
~~13~~	~~OPO's DSA~~	~~0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type identical~~	~~Any~~
~~14~~	~~OPO's region~~	~~0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run,~~	~~Any~~

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		CPRA greater than or equal to 80%, and blood type identical	
15	Nation	0 ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0 ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0 ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's region	0 ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any
19	Nation	0 ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Any
20	OPO's region	0 ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0 ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0 ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type B	O
23	OPO's region	0 ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0 ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
25	OPO's region	0 ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
26	Nation	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
27	OPO's region	0 ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
28	Nation	0 ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	O
29	OPO's region	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0 ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type permissible	Any
32	OPO's region	0 ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0 ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
35	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
36	OPO's region	0 ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
37	Nation	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0 ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Top 20% EPTS, blood type B	A2 or A2B
43	OPO's DSA	Top 20% EPTS, blood type permissible or identical	Any
44	OPO's DSA	0 ABDR mismatch, EPTS greater than 20%, blood type identical	Any
45	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any
46	Nation	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any
47	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
48	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
49	OPO's DSA	0 ABDR mismatch, EPTS greater than 20%, and blood type B	O
50	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
51	Nation	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
52	OPO's region	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
53	Nation	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
54	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	Any
55	OPO's region	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
57	OPO's region	0 ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
58	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
59	OPO's DSA	EPTS greater than 20%, blood type B	A2 or A2B
60	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
61	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
62	OPO's region	Top 20% EPTS, blood type B	A2 or A2B
63	OPO's region	Top 20% EPTS, blood type permissible or identical	Any

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~When the donor is this blood type:~~
~~64~~	~~OPO's region~~	~~EPTS greater than 20%, blood type B~~	~~A2 or A2B~~
~~65~~	~~OPO's region~~	~~All remaining candidates, blood type permissible or identical~~	~~Any~~
~~66~~	~~Nation~~	~~Registered prior to 18 years old, blood type permissible or identical~~	~~Any~~
~~67~~	~~Nation~~	~~Top 20% EPTS, blood type B~~	~~A2 or A2B~~
~~68~~	~~Nation~~	~~Top 20% EPTS, blood type permissible or identical~~	~~Any~~
~~69~~	~~Nation~~	~~All remaining candidates, blood type permissible or identical~~	~~Any~~

Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any

7	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
8	CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
10	CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
12	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
14	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
15	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	O
17	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O

19	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	O
20	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
22	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
24	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any
25	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Top 20% EPTS, blood type B	250NM	A2 or A2B
27	Top 20% EPTS, blood type permissible or identical	250NM	Any
28	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
29	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any

30	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
31	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	O
32	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O
33	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
34	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
35	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
36	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
37	EPTS greater than 20%, blood type B	250NM	A2 or A2B
38	All remaining candidates, blood type permissible or identical	250NM	Any
39	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
40	Top 20% EPTS, blood type B	Nation	A2 or A2B
41	Top 20% EPTS, blood type permissible or identical	Nation	Any

42	All remaining candidates, blood type permissible or identical	Nation	Any

8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-~~6~~ 7* below.

~~Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~When the donor is this blood type:~~
~~1~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~2~~	~~OPO's DSA~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~3~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~4~~	~~OPO's region~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~5~~	~~Nation~~	~~0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~6~~	~~Nation~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~7~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~8~~	~~OPO's DSA~~	~~CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~9~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~10~~	~~OPO's region~~	~~CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~11~~	~~OPO's DSA~~	~~0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical~~	~~Any~~
~~12~~	~~OPO's DSA~~	~~CPRA equal to 98%, blood type permissible or identical~~	~~Any~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~When the donor is this blood type:~~
~~13~~	~~OPO's DSA~~	~~0-ABDR mismatch, blood type identical~~	~~Any~~
~~14~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical~~	~~Any~~
~~15~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical~~	~~Any~~
~~16~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical~~	~~Any~~
~~17~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical~~	~~Any~~
~~18~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical~~	~~Any~~
~~19~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical~~	~~Any~~
~~20~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~21~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~22~~	~~OPO's DSA~~	~~0-ABDR mismatch, blood type B~~	~~O~~
~~23~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B~~	~~O~~
~~24~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B~~	~~O~~

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than	Any

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~When the donor is this blood type:~~
		~~or equal to 20%, less than 18 at time of match, and blood type permissible~~	
~~37~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible~~	~~Any~~
~~38~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible~~	~~Any~~
~~39~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible~~	~~Any~~
~~40~~	~~OPO's DSA~~	~~Prior living donor, blood type permissible or identical~~	~~Any~~
~~41~~	~~OPO's DSA~~	~~Registered prior to 18 years old, blood type permissible or identical~~	~~Any~~
~~42~~	~~OPO's DSA~~	~~Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical~~	~~Any~~
~~43~~	~~OPO's DSA~~	~~Blood type B~~	~~A2 or A2B~~
~~44~~	~~OPO's DSA~~	~~All remaining candidates, blood type permissible or identical~~	~~Any~~
~~45~~	~~OPO's region~~	~~Registered prior to 18 years old, blood type permissible or identical~~	~~Any~~
~~46~~	~~OPO's region~~	~~Blood type B~~	~~A2 or A2B~~
~~47~~	~~OPO's region~~	~~All remaining candidates, blood type permissible or identical~~	~~Any~~
~~48~~	~~Nation~~	~~Registered prior to 18 years old, blood type permissible or identical~~	~~Any~~
~~49~~	~~Nation~~	~~Blood type B~~	~~A2 or A2B~~
~~50~~	~~Nation~~	~~All remaining candidates, blood type permissible or identical~~	~~Any~~

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	CPRA equal to 98%, blood type permissible or identical	250NM	Any

11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, blood type B	250NM	O
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, blood type permissible	250NM	Any
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any

23	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type permissible or identical	250NM	Any
29	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
30	Blood type B	Nation	A2 or A2B
31	All remaining candidates, blood type permissible or identical	Nation	Any

8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-~~7~~ 8* below and the following:

- Classifications 1 through ~~47~~ 29 for one deceased donor kidney
- Classification~~s~~ ~~48 through 50~~ 30 and 31 for both kidneys from a single deceased donor

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~And the donor is this blood type:~~
~~19~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical~~	~~Any~~
~~20~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~21~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~22~~	~~OPO's DSA~~	~~0-ABDR mismatch, and blood type B~~	~~O~~
~~23~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B~~	~~O~~
~~24~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B~~	~~O~~
~~25~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B~~	~~O~~
~~26~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B~~	~~O~~
~~27~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B~~	~~O~~
~~28~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B~~	~~O~~
~~29~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B~~	~~O~~
~~30~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B~~	~~O~~
~~31~~	~~OPO's DSA~~	~~0-ABDR mismatch, blood type permissible~~	~~Any~~
~~32~~	~~OPO's region~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible~~	~~Any~~
~~33~~	~~Nation~~	~~0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible~~	~~Any~~

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Blood type B	A2 or A2B
45	OPO's region	All remaining candidates, blood type permissible or identical	Any
46	Nation	Blood type B	A2 or A2B
47	Nation	All remaining candidates, blood type permissible or identical	Any

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, blood type identical	250NM	Any

11	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
15	0-ABDR mismatch, and blood type B	250NM	O
16	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
17	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
20	0-ABDR mismatch, blood type permissible	250NM	Any
21	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
22	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any

23	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
25	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G*: *Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
26	Blood type B	250NM	A2 or A2B
27	All remaining candidates, blood type permissible or identical	250NM	Any
28	Blood type B	Nation	A2 or A2B
29	All remaining candidates, blood type permissible or identical	Nation	Any
30	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-~~8~~ 9* below and the following:

- Classifications 1 through ~~30, 32, 34~~ 20, 22 and ~~35~~ 23 for one deceased donor kidney

- Classifications ~~31, 33, and 36~~ 21 and 24 for both kidneys from a single deceased donor

~~Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~	~~And the donor is this blood type:~~
~~1~~	~~OPO's DSA~~	~~0 ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~2~~	~~OPO's DSA~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~3~~	~~OPO's region~~	~~0 ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~4~~	~~OPO's region~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~5~~	~~Nation~~	~~0 ABDR mismatch, CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~6~~	~~Nation~~	~~CPRA equal to 100%, blood type permissible or identical~~	~~Any~~
~~7~~	~~OPO's DSA~~	~~0 ABDR mismatch, CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~8~~	~~OPO's DSA~~	~~CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~9~~	~~OPO's region~~	~~0 ABDR mismatch, CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~10~~	~~OPO's region~~	~~CPRA equal to 99%, blood type permissible or identical~~	~~Any~~
~~11~~	~~OPO's DSA~~	~~0 ABDR mismatch, CPRA equal to 98%, blood type permissible or identical~~	~~Any~~
~~12~~	~~OPO's DSA~~	~~CPRA equal to 98%, blood type permissible or identical~~	~~Any~~
~~13~~	~~OPO's DSA~~	~~0 ABDR mismatch, blood type permissible or identical~~	~~Any~~
~~14~~	~~OPO's region~~	~~0 ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical~~	~~Any~~
~~15~~	~~Nation~~	~~0 ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical~~	~~Any~~
~~16~~	~~OPO's region~~	~~0 ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~17~~	~~Nation~~	~~0 ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical~~	~~Any~~
~~18~~	~~OPO's DSA~~	~~0 ABDR mismatch, blood type B~~	~~O~~
~~19~~	~~OPO's region~~	~~0 ABDR mismatch, CPRA greater than or equal to 80%, and blood type B~~	~~O~~

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
23	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	Any
29	OPO's region	Blood type B	A2 or A2B
30	OPO's region	All remaining candidates, blood type permissible or identical	Any
31	Nation	Blood type B	A2 or A2B
32	Nation	All remaining candidates, blood type permissible or identical	Any

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91 **Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%**

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
6	CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
8	CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any

11	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
12	0-ABDR mismatch, blood type B	250NM	O
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
15	0-ABDR mismatch, blood type permissible	250NM	Any
16	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
17	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
18	Prior liver recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
19	Blood type B	250NM	A2 or A2B
20	All remaining candidates, blood type permissible or identical	250NM	Any
21	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any

22	Blood type B	Nation	A2 or A2B
23	All remaining candidates, blood type permissible or identical	Nation	Any
24	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

8.7 Administrative Rules

8.7.A Choice of Right versus Left Donor Kidney

If both kidneys from a deceased donor are able to be transplanted, the transplant program that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% ~~in classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8* above~~ (classifications 1 through 8 in *Tables 8-6 and 8-7;* classifications 1 through 7 in *Table 8-8;* and classifications 1 through 6 in *Table 8-9*), or to a combined kidney and non-renal organ candidate, the host OPO determines whether to offer the left or the right kidney.

8.7.B National Kidney Offers

The host OPO must allocate deceased donor kidneys according to *Table 8-~~9~~ 10* below. For purposes of this section, national candidates are those candidates registered at transplant programs more than 250 nautical miles from the donor hospital.

Table 8-~~9~~ 10: National Kidney Offers

If the organ offer is for:	Then the host OPO must:
A national 0-ABDR mismatch candidate	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
A national 100% CPRA candidate in match classifications 1 through ~~10~~ 4 in allocation sequences according to *Tables 8-5* through *8-8.*	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
Any other national candidates	Contact the Organ Center for assistance allocating the kidney

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