OPTN

Briefing Paper

Kidney / Pancreas Workgroup Board Report

OPTN Kidney Transplantation Committee, OPTN Pancreas Transplantation Committee

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Kidney / Pancreas Workgroup Board Report

Executive Summary

The Final Rule (hereafter "Final Rule") sets requirements for allocation polices 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 centers to decide whether to accept an organ offer, avoiding wasting organs, avoiding futile transplants, promoting patient access to transplantation and promoting efficiency.[1] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of registration, except to the extent required" by the other requirements of the Final Rule.[2]

At its December 2018 meeting, the OPTN Board of Directors directed the organ-specific committees to pursue removal of DSA and regions from their allocation systems. This directive was made on the grounds that DSAs and regions, as allocation units, are not rationally determined or consistently applied, and thus may create inequalities in candidates' access to organ transplantation. The Board directed the committees to replace their use with a rationally determined substitute that could be consistently applied and aligns with the Final Rule.

With this charge in mind, the Committees sought to develop a policy which distributes organs as broadly as possible, with any geographic limitations to allocation based specifically on requirements of the Final Rule. Members of the OPTN Kidney Transplantation Committee, Pancreas Transplantation Committee and Pediatric Transplantation Committee participated in the Kidney/Pancreas Workgroup (hereafter "the Workgroup") in order to remove DSA and region from kidney and pancreas allocation policies. The Workgroup reviewed OPTN data on current distribution practices, engaged Workgroup members on their collective clinical experience, and utilized the OPTN's "Geographic Organ Distribution Principles and Models"[3] to develop a modeling request with five potential distribution options that would eliminate DSA and region from kidney and pancreas allocation policies.

The Workgroup presented these initial proposed framework variations and the findings of the SRTR modeling in a concept paper titled, "Eliminate the Use of DSAs and Region in Kidney and Pancreas Distribution" and released the document for community feedback during the Spring 2019 OPTN Public Comment period. The intent of the concept paper was to update the community on the Workgroup deliberations and obtain member feedback on allocation framework variations, concentric circle sizes, appropriate levels of proximity points, and whether the kidney and pancreas committees should pursue separate distribution solutions.

Feedback received during the public comment period informed the Workgroup's deliberations during meetings in February and March 2019. The Workgroup added members of the Minority Affairs Committee and OPO Committee members to diversify perspectives in Workgroup discussions. During this time, members composed a second SRTR data request to consider additional variations for kidney and pancreas distribution that more closely align with community feedback. The second modeling request was submitted to the SRTR on April 1, 2019.

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[1] 42 C.F.R. § 121.8(a).
[2] 42 C.F.R. § 121.8(a)(8).
[3] Geographic Organ Distribution Principles and Models Recommendations Report, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

The Kidney Committee and Pancreas Committee expect to receive the results of the second round of modeling in June. The Workgroup and individual Kidney and Pancreas Committees will meet to consider and analyze the second round of modeling and prepare public comment proposals for the Fall 2019 OPTN Public Comment period. The OPTN Board of Directors will consider these policy proposals at their December 2019 meeting. The purpose of this report is to keep the OPTN Board of Directors informed and up to date regarding the progress of removing DSA and region from both kidney and pancreas allocation, and describe next steps for Fall 2019 public comment.

Concept Paper

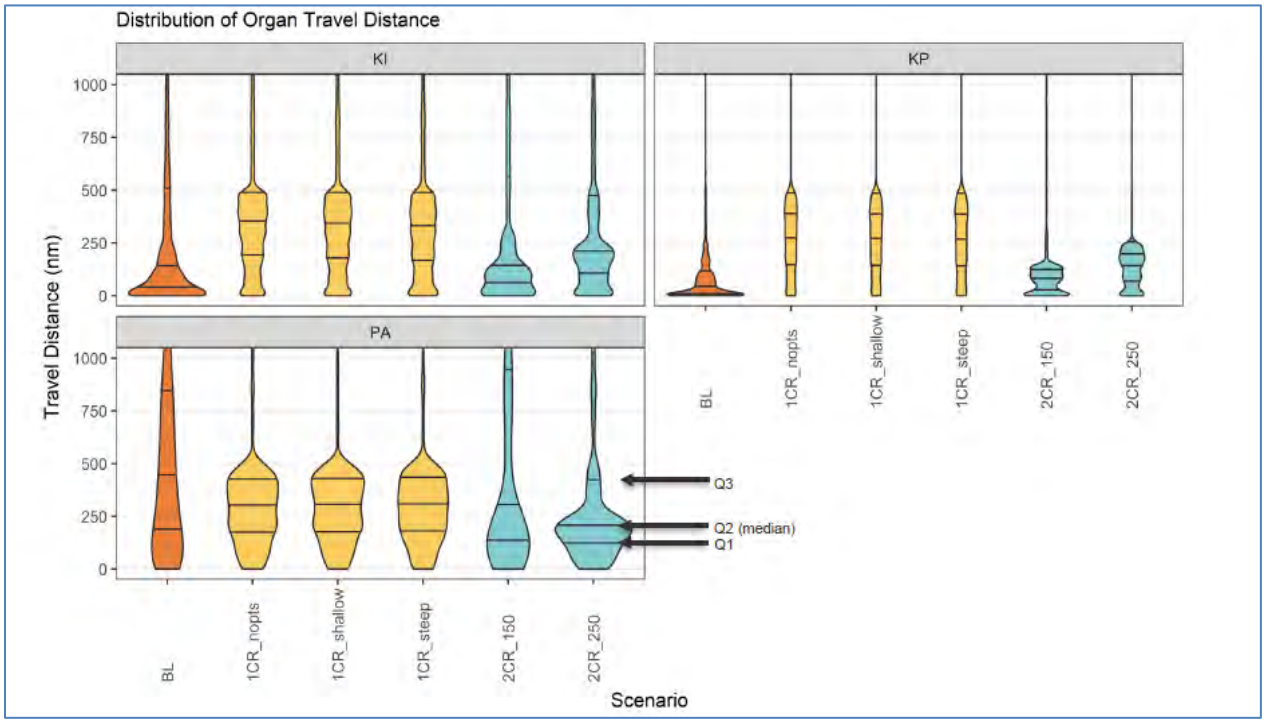
In December 2018, immediately following the receipt of the KPSAM modeling analysis report from the SRTR, the Workgroup met several times to discuss the primary conclusions and discuss a path forward. All the proposed simulations showed broader distribution compared to the baseline, which approximates current state. During the results presentation by SRTR, it was heavily emphasized that the KPSAM modeling is based on current allocation patterns and practices when measuring concrete metrics such as total transplant count, transplant rates, and waitlist mortality, unlike metrics for changes in characteristics of recipients. According to the SRTR analysis report, "the KPSAM was fit on acceptance occurring within a local (DSA), regional, and national framework, wherein there's a strong preference for local offers. Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given policy scenario were adopted, although they typically predict the direction of subgroup changes."[4,5] However, the KPSAM can estimate relative direction of the possible effects of policy change.

The major themes of the modeling report's findings are outlined below.

Broader Distribution

Each of the five initially proposed framework variations resulted in distribution broader than the current baseline system that utilizes DSAs and regions. An illustration of the distribution distances is displayed below in Figure 3.

Figure 3: Distribution of Organ Travel Distance (SRTR)



[4] 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.

[5] 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.

In Figure 3, the top left square represents kidney distribution, the top-right square represents kidney-pancreas distribution, and the bottom-left square represents pancreas distribution. Each of the five proposed variations would broaden kidney and kidney-pancreas distribution compared to the baseline, which represents distribution under the current policy. By contrast, pancreas-alone distribution is projected to be less broad overall. The distribution shapes of the fixed concentric circles variations more closely mimic the current shape of the current system when compared to the shapes of the hybrid variations. Also, SRTR modeling revealed that the proximity point values chosen for this round of modeling ultimately did not significantly alter the shape of organ distribution when compared to the single circle 500 NM no points variation for kidney or kidney-pancreas. This is a finding that would lead to further consideration of proximity points following the Spring 2019 OPTN Public Comment period.

Transplant Rate, Transplant Count, and Outcomes

Modeling conducted by the SRTR based on a data request submitted by the Workgroup produced the results in Figures 4, 5 and 6.

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

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

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

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

Figure 6: Outcomes Metrics for Five Proposed Framework Variations, Kidney - Pancreas (SRTR)

Scenario	Transplant Rate in Patient Years Mean (Min, Max)	Transplant Count (N) Mean (Min, Max)	Waitlist Mortality Rate in Patient Years Mean (Min, Max)	Waitlist Mortality Count (N) Mean (Min, Max)	Graft Failure Rate in Patient Years Mean (Min, Max)
BL	0.295 (0.278, 0.308)	210 (200, 218)	0.019 (0.017, 0.021)	13 (12, 15)	0.306 (0.241, 0.398)
1CR_nopts	0.195 (0.185, 0.2)	146 (138, 150)	0.018 (0.017, 0.02)	14 (13, 15)	0.355 (0.225, 0.579)
1CR_shallow	0.195 (0.185, 0.209)	145 (138, 154)	0.019 (0.019, 0.02)	14 (14, 15)	0.345 (0.224, 0.521)
1CR_steep	0.194 (0.186, 0.208)	144 (139, 155)	0.019 (0.017, 0.021)	14 (13, 16)	0.358 (0.258, 0.53)
2CR_150	0.226 (0.212, 0.239)	166 (157, 175)	0.02 (0.018, 0.023)	15 (13, 17)	0.297 (0.21, 0.357)
2CR_250	0.203 (0.194, 0.222)	151 (145, 164)	0.02 (0.017, 0.022)	14 (13, 16)	0.316 (0.224, 0.415)

For kidney, each of the proposed variations shows a decrease in transplant rate and in transplant count, with minimal to no changes in waitlist mortality rate in patient years, waitlist mortality count in patient years, and graft failure rate in patient years. Modeling also projected a decrease in transplant count and rate for pancreas alone (Figure 6). For kidney-pancreas, an increase in transplant rates and counts was

projected, but similar to kidney, waitlist mortality rate held steady across modeling options (Figure 5). Part of the decrease in kidney and pancreas could in part be attributed to an increase in kidney-pancreas. This certainly does not explain the overall decrease, but may play at least a small role. As noted previously, the SRTR accept-decline module included preference for organ offers based on program DSA, and was therefore severely limited in predicting changes in behavior if DSA and region were removed from allocation. Waitlist mortality was virtually identical across the runs.[6]

Impact on Subgroups

SRTR modeling of transplant rates by insurance type showed an increase for Medicaid and Medicare compared to private insurance for KP transplants, a similar rate of Medicare and private transplant rate for kidney, and a transplant rate for pancreas that was similar across insurance type. SRTR modeling showed overlapping transplant rates for kidney and pancreas by urbanicity, with a slight increase across urbanicity subgroups for KP. The modeling showed a relatively higher transplant rate for candidates with a higher Calculated Panel Reactive Antibody (cPRA) across kidney, pancreas and KP compared to lower cPRA candidates. The KPSAM demonstrated an increase in transplant rate across all pediatric subgroups compared to adult populations. Additionally, the modeling showed relatively more kidney and pancreas transplants occurring in African-American recipients compared to white recipients. For KP, there was a similar increase across ethnicity categories. For kidney, there was a slight projected increase in transplant rate for candidates with more than 10 years of dialysis time. This evidence indicates that the options considered are not likely to have a negative impact on patient access to transplant once listed by increasing disparity, and could improve access for some subpopulations.[7]

Discussion of Different Distribution for Kidney and Pancreas

In light of the SRTR results, the OPTN Pancreas Transplantation Committee members felt that the data demonstrated a greater benefit to separating pancreas transplantation distribution because of the differing results seen in particular for kidney and KP metrics (kidney and pancreas metrics, overall, were more closely aligned). The Workgroup agreed the kidney and pancreas transplant communities should weigh in on whether pancreas and kidney should have different distribution solutions.

Based on the discussion and the Workgroup's desire to collect more evidence and community feedback before deciding on a new allocation framework for kidney and pancreas allocation, the Workgroup decided to publish a concept paper for the OPTN Fall Public Comment period. By providing the community with an opportunity to provide feedback before pursuing a policy solution, the Workgroup hoped to employ the most reasonable framework variation with a rationale grounded in the Final Rule. Additionally, pursuing a concept paper would allow the Workgroup to gather more evidence and a second round of SRTR modeling with new variations before pursuing a formal policy proposal for the consideration of the OPTN Board of Directors in Fall 2019.

The Concept Paper in Public Comment

The KP Workgroup's concept paper was available for public comment from January 22 through March 22. The concept paper, sponsored by the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, requested feedback from commenters and voting members at OPTN regional meetings on the following questions:

- Which framework do you prefer?
- Within the framework you selected, which circle size(s) do you prefer?
- Which points variation do you prefer for the hybrid framework?
- Should there be different distribution systems for kidney and pancreas organs?

[6] Ibid.
[7] Ibid.

The concept paper also requested feedback on the following qualitative questions:

- How do you think replacing DSA and Region with either fixed concentric circles or the hybrid framework outlined in this presentation would affect organ acceptance behavior?
- Do you have suggestions of what to include in a subsequent SRTR modeling request by the KP Workgroup?

The Workgroup sought to utilize the preferences and the clinical expertise and experience of the OPTN community to help inform their decisions for a second round of modeling. Furthermore, they sought to help offset the limitations of the KPSAM in modeling changes in behavior by asking the community directly how operation would change for them in practice should any of the proposed variations be recommended to the OPTN Board of Directors.

In presentations at each of the OPTN regional meetings, representatives of the OPTN Kidney and Pancreas Transplantation Committees clearly identified that the five allocation framework variations would not be the only variations considered by the Workgroup and that no definitive policy decisions had been made.

Feedback from OPTN regional meetings provided rationale for the Workgroup to move forward with a hybrid framework and for the Kidney and Pancreas Committees to propose separate framework proposals in Fall 2019, as illustrated in Figures 7 and 8, below. It is important to note that the figures reflect feedback only from voting members at the regional meetings, and non-voting members may have had opinions not reflected in their overall meeting vote. Nevertheless, regional feedback is an important tool to consider and general consensus was indicated in the feedback on these questions.

Figure 7: OPTN Region Feedback on Framework Preference

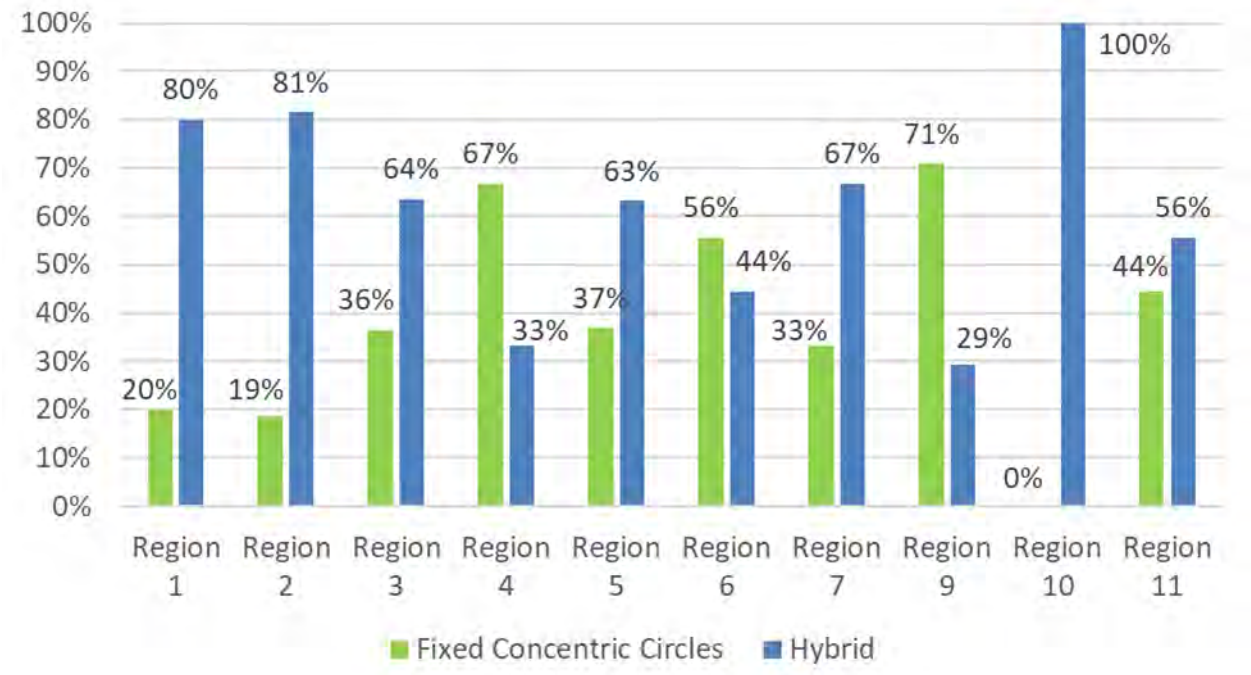
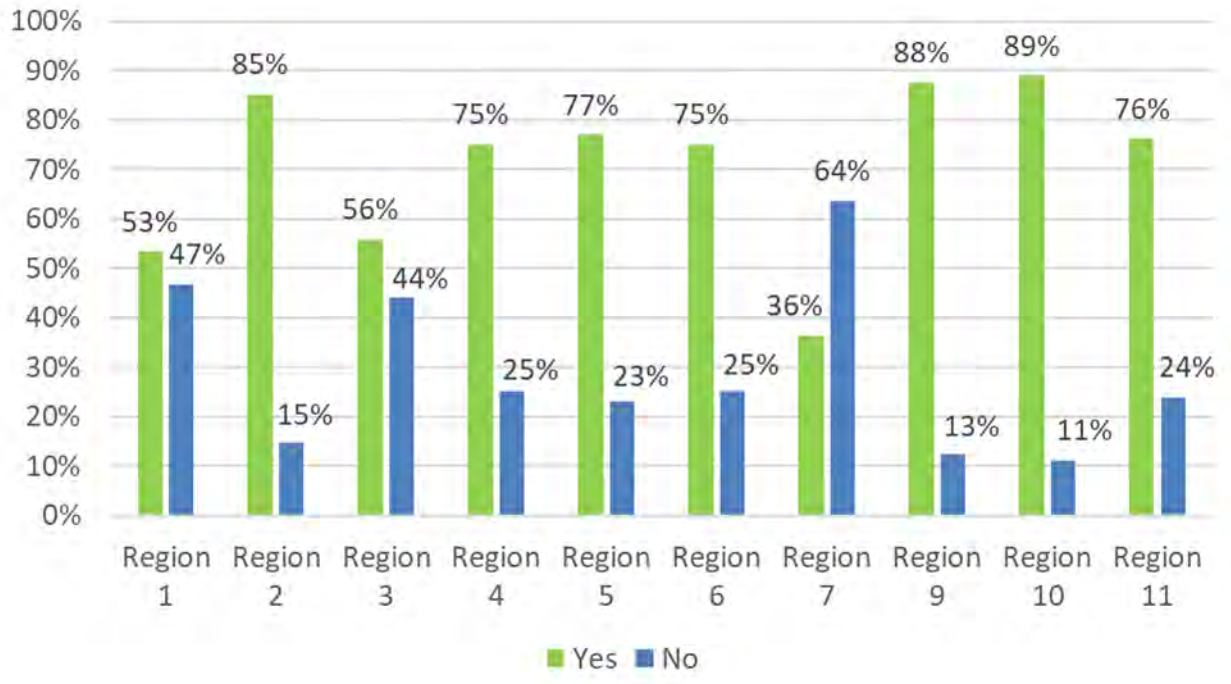


Figure 8: OPTN Region Feedback on Separate Proposals for Kidney and Pancreas Committees



The concept paper received an additional 61 comments through the OPTN Public Comment website. The Workgroup and individual Kidney and Pancreas Committees reviewed public comment feedback as it came through the site and as it was received throughout public comment.

Based on the feedback received, the Workgroup moved forward into their Spring 2019 meetings with the following conclusions:

- A majority of OPTN regions supported the hybrid framework, including a majority of OPO and transplant hospital respondents. The only non-member (general public) who responded supported fixed distance, as did the only transplant association that responded to this question.
- A majority of OPTN public comments supported kidney and pancreas identifying separate solutions to change geographic units of distribution
- Commenters indicated more support for 500 NM and 150 NM circles than 250 NM and 300 NM but there was no clear consensus
- Public comments indicated more support for steep slopes but there was no clear consensus

In addition to these quantitative observations, a number of qualitative trends emerged:

- Concern about the projected decreases in transplant rate and transplant counts associated with the initial proposed variations
- Concern about potential increased travel costs associated with broader distribution of kidneys and pancreata
- Some support for moving straight to a model of continuous distribution without the current intervening policy solution
- Emphasis on considering the effects of proposed policy on socioeconomically disadvantaged candidates
- Some support for future modeling that accounts for population density or donor kidney donor risk index (KDPI)

The Second Modeling Request

The KP Workgroup convened in February and March 2019 to review public comment feedback, collaborate with the SRTR on future modeling, and consider any relevant research that might help guide policy decision moving forward. The Workgroup added members from the OPTN Minority Affairs Committee and the OPTN Organ Procurement Organizations Committee in order to engage relevant stakeholders and help address concerns raised in public comment. The Workgroup also utilized the Kidney and Pancreas Committee in-person meetings (on March 25, 2019 and March 27, 2019, respectively) to further discussion and help the Workgroup arrive at a second SRTR modeling request.

At each of the Workgroup meetings, UNOS staff incrementally presented public comment and OPTN regional meeting feedback received up until the start of each meeting. As the quantitative and qualitative trends listed in the "Public Comment" section of this paper began to take shape, the Workgroup began to discuss how community feedback could be taken into account in a second SRTR modeling request.

Hybrid Framework and Separate Proposals

Based on the feedback from the OPTN regional meetings and the input received on the OPTN Public Comment website, as well as the shared desire of the Workgroup to distribute organs as broadly as feasible, the Workgroup unanimously supported moving forward with modeling hybrid framework variations exclusively in the next round of SRTR modeling.

Furthermore, the Workgroup voted unanimously that the kidney and pancreas members of the Workgroup would utilize the same data request for SRTR modeling to maximize the available bandwidth. However, the OPTN Kidney and Pancreas Transplantation Committees will pursue separate policy proposals for the OPTN Fall public comment period unless one variation proves the most advantageous to both organ types.

Changes to the KPSAM Accept / Decline Module

The projected decline in transplant rate and count for the different variations modeled was a major concern during public comment. Changes in transplant rate and count are affected by several factors, including the accept/decline model used. The accept/decline module for the first SRTR request included a local indicator where local was defined as the organ recovery in the same DSA as the transplant hospital, thus the very element of allocation that the project sought to eliminate (DSA) was used in predicting whether an offer was accepted or not. Because the purpose of the modeling request is to identify alternatives to DSA and region in kidney and pancreas distribution, including DSA in predicting acceptance behavior is problematic. Offer acceptance patterns are likely to change and expand beyond DSA boundaries as DSAs are removed as units of distribution. Additionally, the accept/decline model with local indicator likely contributed to lower transplant counts in the first KPSAM report because fewer offers at the beginning of the match run were made "locally" under variations that removed DSA and region with broader distribution systems. The Workgroup agreed that alternative accept/decline models should be considered for future SRTR requests.

Because of the limitations of the accept/decline model used in the 2018 modeling request, SRTR began working on updating the accept/decline model to better reflect what would actually result from policy changes. The SRTR introduced the Workgroup to two model options it developed:

- Accept/decline model 1: Uses candidate and donor factors to predict acceptance. This includes the distance the organ would have to travel (geography) and offer number.
- Accept/decline model 2: Uses only donor factors to predict acceptance. This does not include distance the organ would have to travel because distance is dependent on the candidate characteristics, but still includes offer number.

The Workgroup conducted an informal poll that indicated their support for the SRTR utilizing an accept/decline model based on only donor factors and offer number to predict acceptance. While the Workgroup acknowledges that there are limitations and advantages to each of the accept/decline models presented, the Workgroup agreed that including candidate characteristics was problematic because it is less reliant on geography and therefore may better predict changes in behavior under a new allocation framework less reliant on local offers.[8] The Workgroup agreed that most helpful accept/decline model would be donor characteristics only. The KPSAM in the second modeling request will therefore use only donor characteristics in its accept/decline module.

Variation Circle Sizes

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

The Workgroup discussed how they could justify, with their professional clinical experience and opinion, a 150 NM circle if the modeling came back with the most favorable results (larger increases in transplant counts and better outcomes) considering that other organs more limited in their ability to sustain long cold times have created distribution changes with larger circles (thoracic distribution). A pancreas Workgroup member noted that 150 NM was a popular option among the regions and felt that after asking for feedback the Workgroup was obligated to listen to the regional feedback. The OPTN Kidney Transplantation Committee Chair agreed and felt that concern was one additional reason to include 150 NM as a modeling option. The 150NM/300 NM variation also saw the smallest decreases to transplant rate and transplant count in the first round of modeling.

Proximity Points Variations

The higher the proximity points, the more geography weighs against other factors (such as CPRA, waiting time, and histocompatibility mismatches – KAS currently gives points for these characteristics). Regardless of proximity points, a patient cannot move from one classification to another on the match run. Proximity points simply “reshuffle” candidates against each other, in terms of identified characteristics as well as geography *within* their classification.

Some Workgroup members expressed interest in having no points within the circle to avoid prioritizing programs slightly closer to a donor hospital within a driving distance. Other Workgroup members considered that 500 NM is too far for most driving distances, and an option in which a “driving zone” treated centers within 150 NM or 250 NM of the donor hospital equally and these centers received the same number of points. The Workgroup considered that the points inside and outside the circle should be increased compared to the previous SRTR request, since little variation was seen between 500 NM hybrid options with no points, one point inside the circle and two points outside, and two points inside the circle and four points outside in the 2018 SRTR request.

The Workgroup agreed to include modeling variations with no points inside the circle, four points inside the circle, and 10 points inside the circle. Workgroup also indicated support for modeling variations with eight points outside of the circle and 20 points outside of the circle. Furthermore, the Workgroup chose to explore two variations with a “point plateau” inside of the circle. These variations will be further outlined in the section below titled, “Variations included in the Second SRTR Modeling Request.”

Pediatric and Prior Living Donor Prioritization

Throughout the spring Workgroup meetings, the OPTN Kidney Transplantation Committee members of the Workgroup continued to express interest in including further prioritization for pediatric and Prior Living Donor (PLD) candidates with kidney classification tables as part of the greater geography project.

[8] Meeting Summary for March 23, 2019 meeting, OPTN/UNOS Kidney Pancreas Workgroup.

The Workgroup discussed the three identified options for the Kidney Committee to model in regards to pediatric priority.

- Do nothing since pediatrics see more access under new geography boundaries
- Move PLD and local pediatrics below highly sensitized (local only)
- Move PLD and all pediatrics below highly sensitized (local only)

The OPTN Pancreas Transplantation Committee Chair inquired whether SRTR has modeled a baseline model with only the proposed pediatric change. An SRTR staff member explained that pediatric patients currently have priority above all local adults and that a baseline model with this pediatric priority change hasn't been conducted yet. Another SRTR staff member also explained that it is a consistent effect across models to see an increase in pediatric transplants as distribution becomes broader.

The Workgroup polled unanimously in favor of including a baseline model with pediatric prioritization, a baseline model without the pediatric prioritization, and 9 other variations with further prioritization of local pediatric and PLD in the second modeling request. Including the baseline with the prioritization of pediatrics will be used as a basis of comparison with the 9 other variations.

Figure 9 illustrates where local pediatric and PLD candidates will be placed in the allocation tables for the purposes of modeling.

Figure 9: 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

Discussion of Other Public Comment Feedback

Travel Costs

A theme of public comment that the Workgroup could not incorporate in its SRTR request reflected concerns about the impact of changes to the distribution system on travel costs incurred by the transplant program or OPO. The OPTN does not collect data on transportation cost or mode that would allow the Workgroup to estimate the impact of changing distribution. A Workgroup member asked for the median travel distances for different models and whether there's a way to estimate cost differences. UNOS staff informed the Workgroup that available data is limited and impact on travel cost would be difficult to determine. Another difficulty compounding the lack of data is the variation in cost type and amount depending on geography and urbanicity. The Workgroup did consider impact on travel costs in their discussions and used their own experiences as well as community feedback to inform which distances were modeled, but systemic analysis is difficult to perform at the current time without additional data collection.

Socioeconomic Status (SES) Impact

The community also indicated in public comment that impact by socio-economic status (SES) should be strongly considered in the alternative distribution options being discussed by the Workgroup. In its 2018 SRTR modeling request, the Workgroup included impact on low SES candidates by insurance type, median income at listing, and urbanicity. According to the modeling results, no significant impact was projected to occur across SES subgroups that were examined. The Workgroup takes the concerns of the community seriously and will continue to consider the impact of modeling variations on these metrics approximating socio-economic status.

Transition to Continuous Distribution

While some members of the community expressed support for moving towards continuous distribution immediately, the Workgroup recognizes that doing so would not be feasible in the timeline to send a policy proposal (or proposals) to the Board in December 2019 removing DSA and region from kidney and pancreas distribution. The Workgroup would have to determine the appropriate importance that should be given, not just to geography, but to other aspects of allocation (e.g. sensitization, pediatric priority, blood type compatibility) – not only as individual aspects of allocation but also in relation to each other. Addressing all of these issues in the timeline outlined to comply with the Final Rule would not be feasible. Incorporating elements of continuous distribution in the hybrid option may ease the transition to continuous distribution in the future, as it is the ultimate goal of the OPTN to transition to this framework for all organ allocation systems.

Donor KDPI

Members of the community expressed interest in tying geographic distribution to the KDPI of the donor organ. KDPI indicates the risk of posttransplant kidney graft failure, with a higher KDPI indicating a higher risk of posttransplant graft failure.[9] Organs with lower KDPIs can withstand more ischemic time than organs with higher KDPIs, and community members questioned whether higher KDPI organs could be reserved for distribution to a smaller circle than higher KDPI organs. The Workgroup considered this feedback in teleconferences scheduled during public comment. While this is an important consideration, the complexity of stratifying by KDPI would be prohibitive given the timeline and the goals of the Workgroup to replace DSA and region with a distribution alternative more compliant with the Final Rule. KDPI and geography will be considered in tandem when the distribution systems eventually move to a continuous distribution framework.

Population Density

Some feedback in public comment questioned why population density wasn't considered as an alternative to distance, since it impacts travel costs and distribution. One reason is because consideration of population density would result geographic units uniform by population. Such boundaries, based on population, would not represent a rationale reason to restrict the distribution of organs based on the Final Rule, whereas boundaries uniform in distance can act as proxies for means of transportation and can account for differences in CIT by organ type. It is also important to note that population density does not necessarily equal donor potential.

Support for Kidney and Pancreas having Separate Distribution Solutions

The Workgroup reviewed community feedback that kidney and pancreas should have separately-pursued distribution proposals, and voted to pursue such a solution. When modeling comes back, it will likely be a combination of Workgroup meetings and individual Pancreas Committee and Kidney Committee meetings to review the modeling results and devise separate solutions for each respective distribution system. In all likelihood, the Pancreas Committee and Kidney Committee will sponsor separate proposals, but continue

[9] A Guide to Calculating and Interpreting the Kidney Donor Profile Index (KDPI), available at: https://optn.transplant.hrsa.gov/resources/allocation-calculators/kdpi-calculator/.

to collaborate throughout public comment on these interconnected and related distribution systems (see "The Path Forward" for more details)

Variations included in the Second SRTR Modeling Request

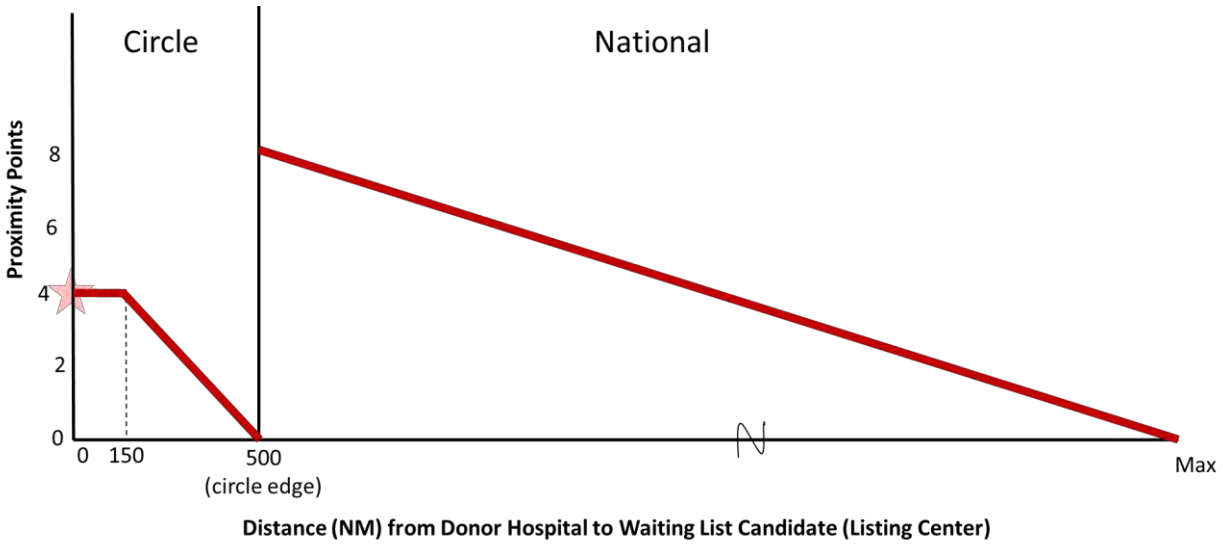
Figure 10 illustrates the hybrid framework variations that will be modeled based on the deliberations and decisions of the KP Workgroup.

Figure 10: Second Round Modeling Variations

			Linearly Assigned Proximity Points			
	Circle Sizes (NM)		Inside the Circle		Outside the Circle	
Model #	Kidney	KP/Pancreas	Kidney	KP/Pancreas	Kidney	KP/Pancreas
1(PLD/Ped Baseline)	N/A	N/A	N/A	N/A	N/A	N/A
2	500	500	0	0	8	8
3	500	500	4	4	8	8
4	500	150	0	0	8	8
5	250	250	2	2	4	4
6	250	250	0	0	8	8
7	250	150	0	0	8	8
8	150	150	0	0	8	8
9	150	150	0	0	20	20

In addition, two models will be simulated that introduce a proximity point plateau within the circle. For all candidates falling within a certain distance of the donor hospital, the maximum amount of proximity points will be assigned to them to create a "zone of equivalence." This is to approximate equal treatment of programs within a reasonable driving distance of the donor hospital. From there, proximity points will be assigned linearly to the edge of the circle. Those variations are illustrated in Figures 11 and 12 below:

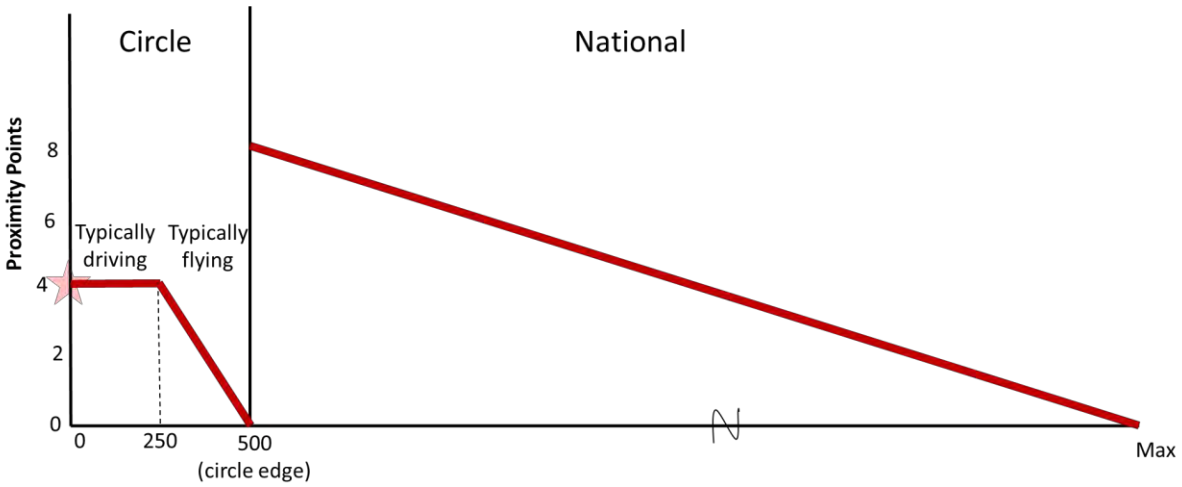
Figure 11: Model Variation 10: 500NM Circle With Proximity Point Plateau Inside Circle



Model variation 10 illustrated in Figure 11 above includes a proximity points plateau that ends at 150 NM inside of the 500 NM circle. Modeling variation 11 pictured in Figure 12 below includes a proximity points plateau at 250 NM inside of the 500 NM circle. In review of UNOS Organ Center data and liver data on

driving distance, and also utilizing Committee and Workgroup discussions of how far it is typical to drive for a procurement, the Workgroup chose to include both 150 NM and 250 NM as potential "zones of equivalence" to reflect potential limits of driving distances before procurement switches to flying. This rationale ties back to the Final Rule by promoting for the efficient management of the OPTN.[10]

Figure 12: Model Variation 11: 500NM Circle With Proximity Point Plateau Inside Circle (2)



The Workgroup voted unanimously to include these hybrid variations with proximity point plateaus within the circle in order to gauge the effects on distribution to address the community feedback that points inside the circle do not make sense in terms of efficiency until a certain distance is reached. These variations measure the effects of two of those distances within the hybrid framework: 150 NM and 250 NM.

The Path Forward

Moving forward, the Kidney and Pancreas Committees intend to develop and implement strategies to most effectively foster community collaboration and support for the forthcoming proposal. The following are a list of initiatives identified as necessary to effectively present a proposal with broad community support.

Frequent Summer Meetings

Based on the input from SRTR staff, the second round of modeling is expected to be received by mid-June. This will require an expeditious turnaround on behalf of the Workgroup and UNOS support staff to publish a public comment proposal for the public comment period beginning on August 2, 2019.

Workgroup members and Kidney and Pancreas committee members will meet frequently in the months of June and July 2019 in order to most effectively analyze the modeling results, choose an allocation framework to propose, and develop a public comment proposal for community review.

Proactive Community Engagement

In addition to stakeholder outreach, UNOS staff and workgroup leadership are currently developing a plan to host an outward-facing event(s) in order to reach out to stakeholder groups and collect community feedback and sentiment after receiving the modeling but prior to submitting a policy proposal for Fall 2019 public comment. This will allow the community to actively engage in the policy development process

[10] 42 C.F.R. § 121.8(a).

before a proposal is constructed while also allowing members and non-members alike to see the results of the second round of modeling.

Regional Meeting Focus

UNOS staff working alongside the KP workgroup intend to apply a focused effort at the Fall 2019 regional meetings to ensure that the proposal is accurately and effectively presented, questions and comments are thoughtfully addressed, and ideas for post-public comment changes can be heard and reported directly to Workgroup members.

Post-Public Comment Changes

The OPTN Fall Public Comment period ends on October 2, 2019. UNOS staff and committee leadership began crafting a meeting schedule in April 2019 to allow the Workgroup to meet throughout the public comment period and incrementally observe trends in feedback and variation preference (should multiple variations be proposed).