OPTN

Committee Update

Continuous Distribution of Kidneys and Pancreata

OPTN Kidney and Pancreas Transplantation Committees

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Development of Second Modeling Request

As detailed in the January 2023 update, the Committee received the results of their first Organ Allocation Simulator (OASIM) modeling request, which included draft rating scales for each attribute and a series of scenarios to model different weights. The full report contains additional details on the methods used and is available on the OPTN website.[23] It is important to note that the OASIM results are estimates of what might have happened in the historic cohort under the different allocation policy scenarios. All of the simulation results assume the allocation policy is the only thing that is different between the scenarios; all other components of the modeling are the same between scenarios, including candidate and donor populations, offer acceptance behaviors, etc. Additionally, simulations rely on aggregate historical data and cannot predict changes in organ acceptance behavior, screening criteria, or identify trends over time.

The first round of modeling utilized more extreme scenarios in order to provide the Committees with a better understanding of how these attributes will interact together in a continuous distribution framework. This was different than previous OPTN/SRTR modeling requests where committees would typically request modeling on potential policies for implementation; instead, the first modeling request was meant to test extreme examples and not to test potential policies for implementation. As an example, the Committees learned that increasing the proximity efficiency weight reduces travel distance; however, it is also lowers the transplant rate for highly sensitized candidates due to reduced travel for kidneys allocated to high CPRA patients. By modeling more extreme weight scenarios, the Committees were able to identify some of the potential trade-offs and interactions between attributes. From November 2022 – March 2023, the Committees worked with researchers from the Massachusetts Institute of Technology (MIT) and the Scientific Registry of Transplant Recipients (SRTR) to help narrow the acceptable policy options. Details of the Committee's discussions and work are in the subsections below.

Mathematical Optimization

MIT's analysis used mathematical optimization and artificial intelligence to inform the Committee's policy development. Through mathematical optimization, the Committees were able to focus in on a range of acceptable policy options to submit to SRTR for their second OASIM modeling request. MIT augmented the Kidney-Pancreas Simulated Allocation Model (SAM) with machine learning to predict outcomes quickly and accurately by identifying policies (sets of attribute weights and rating scales) that achieved the Committee's prespecified outcomes, outlined below, in near real-time. This mathematical optimization helped narrow the window of options to those with acceptable outcomes metrics. MIT did similar work for the lung continuous distribution project and helped inform the OPTN Lung Transplantation Committee's selection of weight for various attributes.[1] MIT analysis supplemented the Committees with a robust understanding of attribute interactions and effects, and so allowed the Committees to visualize the balance of equity and utility in potential organ allocation policies.

To achieve this goal, MIT developed an interactive tool for the Kidney and Pancreas Committees to use that showed the impact of different weight selections in real time. Additionally, the tool allowed for the

[1] Stewart, Darren. "Moving Toward Continuous Organ Distribution." Current Transplantation Reports 8, no. 4 (November 22, 2021): 301–13. https://doi.org/10.1007/s40472-021-00352-z.)

Committees to optimize on specific outcomes and metrics. The Committees were able to select desired outcomes, from which the tool provided various weight scenarios that could meet those objectives. The policy analyzer tool developed by MIT would find the policy scenario, amongst tens of thousands of options, that best met the goals of the community. In other words, instead of specifying certain weights to predict outcomes, this tool allowed the Committees to shift focus by utilizing the desired outcomes to determine the most effective weights to achieve those outcomes amongst thousands of policy options.

To help inform MIT's analysis and develop the second OASIM request, the Committees held extensive discussions regarding the objective of each attribute, and what objectives can be achieved by the inclusion of the attribute. These discussions detailed the Committee's expectations of how the CAS framework should perform once allocation transitions to continuous distribution. To develop and affirm these objectives, the Committees considered current policy standards, available data, mathematical optimization, and collective community feedback from previous public comment cycles.

Kidney Committee Discussions

In finalizing these objectives, the Committees considered all attributes collectively, as they will interact together to form a total composite allocation score (CAS). Giving more weight, or proportion of potential points, to one attribute means other attributes would receive less weight as they all interact together. The relationship between the attributes creates tradeoffs in terms of outcomes, in some cases. For example, the results of the first OASIM report showed when the weight decreases on qualifying time, transplant rates decrease for Black candidates and those on dialysis for more than five years. Alternatively, when the weight increases for qualifying time, this influences transplant rates for low EPTS groups.

The Kidney Committees discussed these potential tradeoffs and interactions between the attributes to develop a series of objectives for what each attribute should accomplish, as seen in **Table 1**.[2,3,4] In addition to the specific attribute objectives, the Committee also set constraints, for example, racial, gender, and geographic disparity could be no worse than current policy.

[2] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[3] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.
[4] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.

Table 1: Kidney Allocation Objectives

Attributes	Goal	Modeling Objective
Medical Urgency Definition	Medical Urgency	Maintain high priority similar to current policy
DR Matching	Post-Transplant Survival	Maintain similar priority to current policy Minimize graft failure
EPTS/KDPI	Post-Transplant Survival	Match low KDPI kidneys to low EPTS candidates Maintain transplant rates for EPTS 0-20 Equalize access for EPTS 21+
Blood Type	Candidate Biology	No decrease in access, especially for O and B blood type candidates
CPRA	Candidate Biology	Equalize access across CPRAs Maximize access for CPRA 99.9+
Prior Living Donors	Patient Access	Maintain high priority, similar to pediatric access
Pediatrics	Patient Access	Maintain high priority, similar to PLD access
Safety Net	Patient Access	Maintain similar priority to current policy
Qualifying Time	Patient Access	Maximize median qualifying time at transplant
Proximity Efficiency	Placement Efficiency	Minimize distance traveled, especially for high KDPI kidneys Relax constraint for pediatric and highly sensitized candidates

Medical Urgency

Medical Urgency Definition: Kidney policy currently contains a specific definition for medical urgency which includes a candidate's total or imminent loss of dialysis.[5] Additionally, candidates meeting this definition receive priority for KDPI 0-85 percent kidneys as seen in **Table 2**. The Committee agreed that medically urgent candidates should maintain a high level of priority, similar to the level of priority currently granted to medically urgent candidates. [6,7]

[5] OPTN Policy 8.4.A.i: Medically Urgent Status for Adult and Pediatric Candidates as of March 16, 2023.
[6] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.
[7] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.

Table 2: Current Kidney Classification Priority Levels Based on KDPI Sequences

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 Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle (Top 20% EPTS) 0-ABDRmm (All) Inside Circle (All) National Pediatrics National (Top 20% EPTS) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National Pediatrics National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National (All) Inside Circle (dual) National (dual)	100% Highly Sensitized Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ADBRmm Inside Circle Safety Net Inside Circle Inside Circle (dual) National National (dual)

Post-Transplant Survival

DR Matching: In current kidney allocation policy, additional priority is given to candidates based on the level of HLA matching between the donor and the candidate. Candidates receive additional priority for being a 0-ABDR mismatch with the donor, and points for having 0 or 1 DR-locus mismatch.[8] As described in previous papers, the Kidney-Pancreas Continuous Distribution Workgroup and Histocompatibility Committee's review of data concluded there is not justification for continuing to prioritize 0-ABDR mismatches, but there is justification to prioritize DR antigen matching.[9,10,11] The Committee agreed that the objectives of the DR matching attribute are to 1) maintain similar priority to current policy and 2) minimize graft failure.[12,13]

Longevity Matching: Current policy prioritizes 0-20 percent KDPI kidneys for 0-20 percent EPTS candidates. For the first round of OASIM modeling, the Kidney Committee elected to model a continuous longevity matching rating scale for estimated post-transplant survival (EPTS) and KDPI.[14] The continuous longevity matching rating scale aimed to continue the practice of prioritizing low-KDPI kidneys for candidates expected to have the best outcomes and gives higher EPTS scores greater priority for higher KDPI kidneys. Modeling results showed that a consequence of the continuous longevity

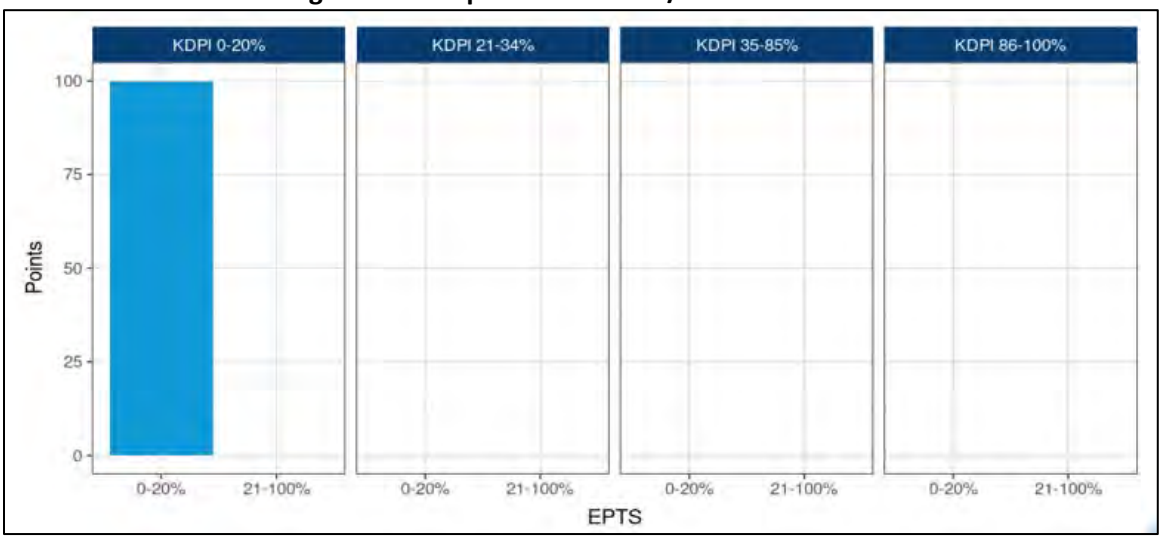
[8] OPTN Policy 8.2: Kidney Allocation Score as of March 16, 2023.
[9] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[10] OPTN Histocompatibility Committee Meeting Summary, March 9, 2021.
[11] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, August 20, 2021.
[12] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.
[13] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.
[14] OPTN Kidney Transplantation Committee Meeting Summary, April 1, 2022.

matching scale appears to be lower transplant rates in 35-50 year old candidates and increased graft failure rates in older kidney recipients. However, simulated post-transplant graft failure rates were expected to be lower in 18-34 and 35-49 year olds at one and 10 years post-transplant, particularly when more weight was placed on this attribute.[15] Additionally, public comment feedback was mixed on the subject of expanding longevity matching beyond top 20 EPTS to top 20 KDPI matching. Some members were supportive of having a more direct relationship between EPTS and KDPI while others supported maintaining current policy.[16]

After reviewing the results of the OASIM report, the Committee continued to explore multiple expanded longevity matching rating scales. The Committee considered both categorical and expanded rating scale options (**Figures 1-3**) to include:

- Most similar to current policy, EPTS 0-20 candidates receive priority for KDPI 0-20 kidneys, all candidates with EPTS 21-100 have equal access
- EPTS 0-20 candidates receive priority for KDPI 0-20 kidneys and EPTS 86-100 candidates receive priority for KDPI 86-100 kidneys, with EPTS 21-85 candidates having equal access
- The expanded scale included in the first OASIM modeling, which matches EPTS and KDPI scores in a linear fashion
- An expanded scale with peaks that prioritizes EPTS scores for their corresponding KDPI scores, with gradually decreasing priority for other KDPI kidneys
- An expanded scale similar to the peaks option, but adds a correction factor to equalize access across EPTS categories

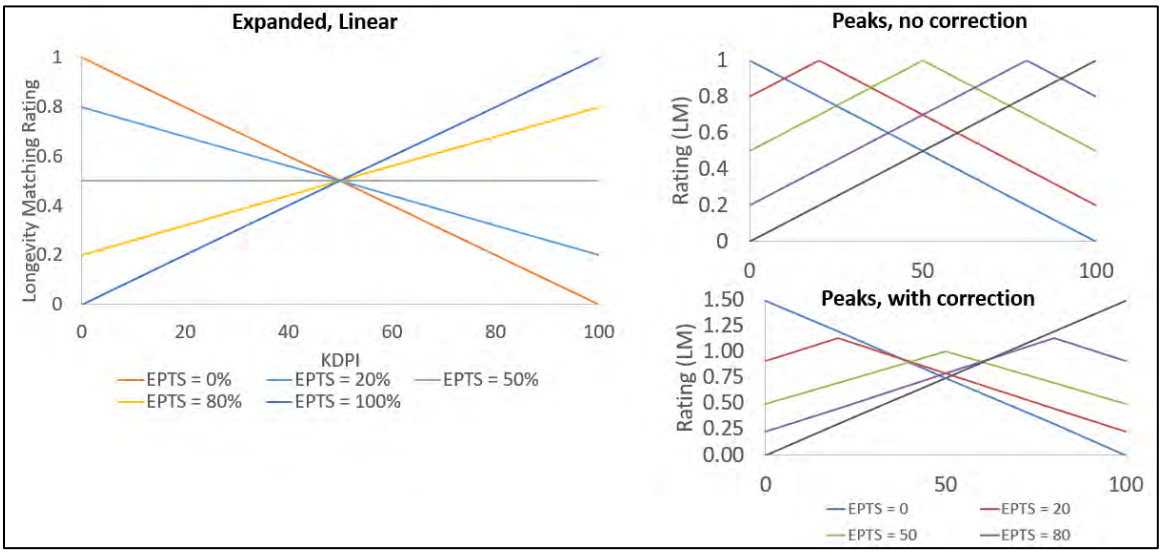
Figure 1: Example of EPTS 0-20 / KDPI 0-20 Scale



[15] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[16] OPTN Kidney Transplantation Committee Meeting Summary, November 21, 2022.

Figure 2: Example of EPTS 0-20 / KDPI 0-20 Scale and EPTS 86-100 / KDPI 86-100 Scale

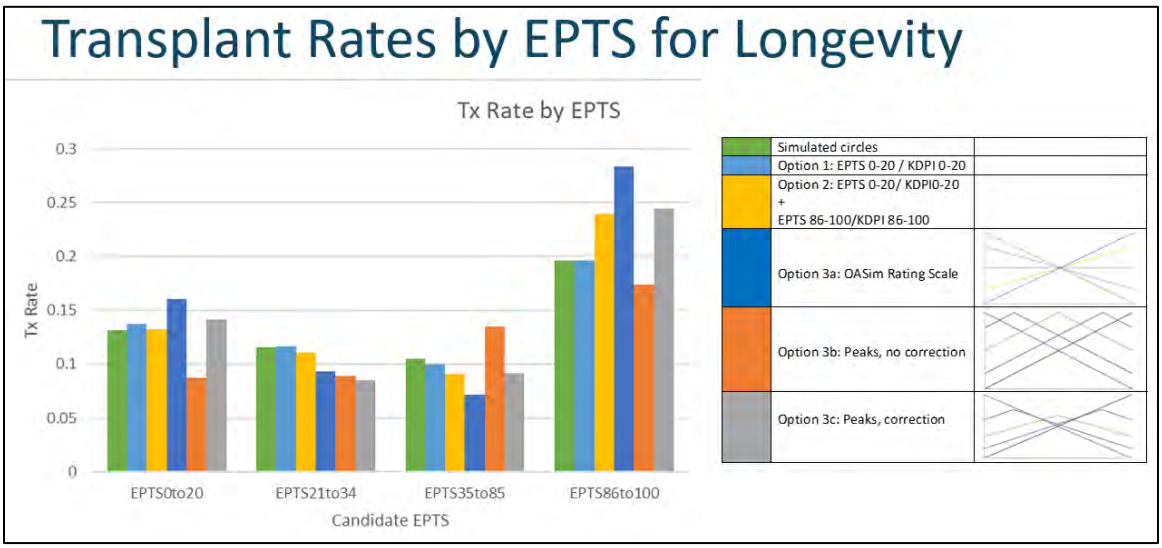
Figure 3: Examples of Expanded Longevity Matching Scales



To help inform discussion, the Committee reviewed projected metrics for each rating scale option with the help of MIT. For example, the Committee compared the projected transplant rate for each rating scale option across EPTS groups as shown in **Figure 4**.[17,18]

[17] OPTN Kidney Transplantation Committee Meeting Summary, November 28, 2022.
[18] OPTN Kidney Transplantation Committee Meeting Summary, December 19, 2022.

Figure 4: Example of Kidney Committee's Analysis of Longevity Matching Rating Scale Options[19]



The Committee also sought input from the OPTN Ethics Committee on how to consider the longevity matching attribute, especially in relation to other attributes. Ethics Committee members validated that the concept of longevity matching has difficult ethical considerations, and how to eliminate KDPI sequence cutoffs is difficult to determine. Both the Kidney and Ethics Committees also raised concerns for candidate preference versus physician decision as it pertains to longevity matching, especially with high KDPI matching scenarios. The Ethics Committee expressed support for the goal of eliminating categorical allocation, but also agreed KDPI sequences may not be able to be eliminated for the first iteration of continuous distribution. [20,21,22]

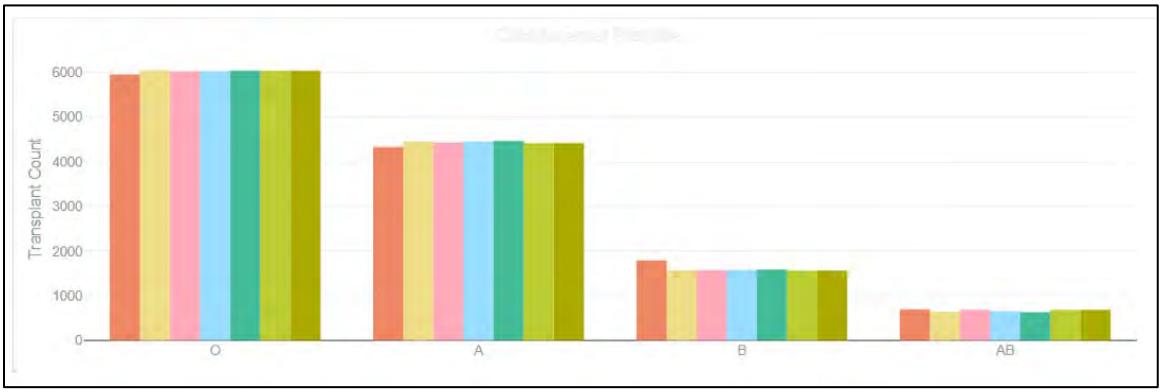
After careful consideration and discussion, the Kidney Committee concluded there is a lack of clear community consensus on what the objective should be for EPTS 21-100 candidates. The Committee also agreed the calculations for EPTS and KDPI should be revisited as a future project prior to expanding the direct relationship between EPTS and KDPI further.[23,24,25,26,27] The Committee decided to move forward a continuous distribution framework that mirrors the existing EPTS/KDPI matching (i.e. 0-20 EPTS candidates prioritized for 0-20 KDPI kidneys), and will continue to explore this option in a future iteration of continuous distribution.[28] With the 0-20 EPTS/0-20 KDPI attribute in mind, the Committee agreed on objectives of 1) match low KDPI kidneys to low EPTS candidates, 2) maintain transplant rates for EPTS 0-20 candidates, and 3) equalize access for EPTS 21-100 candidates.[29]

[19] As simulated by MIT for the OPTN Kidney Transplantation Committee.
[20] OPTN Kidney Transplantation Committee Meeting Summary, December 12, 2022.
[21] OPTN Ethics Committee Meeting Summary, December 15, 2022.
[22] OPTN Kidney Transplantation Committee Meeting Summary, December 19, 2022.
[23] OPTN Kidney Transplantation Committee Meeting Summary, November 21, 2022.
[24] OPTN Kidney Transplantation Committee Meeting Summary, November 28, 2022.
[25] OPTN Kidney Transplantation Committee Meeting Summary, December 12, 2022.
[26] OPTN Kidney Transplantation Committee Meeting Summary, December 19, 2022.
[27] OPTN Kidney Transplantation Committee Meeting Summary, February 6, 2023.
[28] OPTN Kidney Transplantation Committee Meeting Summary, February 6, 2023.
[29] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.

Candidate Biology

Blood Type: Blood type is an attribute which includes both candidate and donor information. Kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with prioritization for blood types O and B as these candidates have more limited compatibility.[30] In the spirit of current policy, the Committee agreed with the objective for blood type to be no decrease in access for O and B blood type candidates.[31] Through review of the OASIM results and MIT's dashboard metrics, the Committee identified the points used in the original blood type rating scale could potentially decrease access for blood type B candidates as shown in **Figure 5**. Essentially, the points used in the original rating scale would need a very high weight to promote access for blood type B candidates. In response, the Committee decided to adjust the rating scale for blood type. [32] To do this, UNOS staff reviewed the number of candidates added to the waitlist compared to the number of kidneys recovered in 2022 by blood type, and calculated the amount of candidates per compatible donor by screening rules in policy (ex. a larger number of candidates per donor indicates more competition for a compatible organ). The candidate per donor value for all blood types informed the new blood type rating scale. MIT's analysis indicated that this new approach would increase access for blood type B candidates. The Committee included the new rating scale in their OASIM request to evaluate further. [33]

Figure 5: Example of Policy Scenarios with Transplant Counts by Blood Type[34]

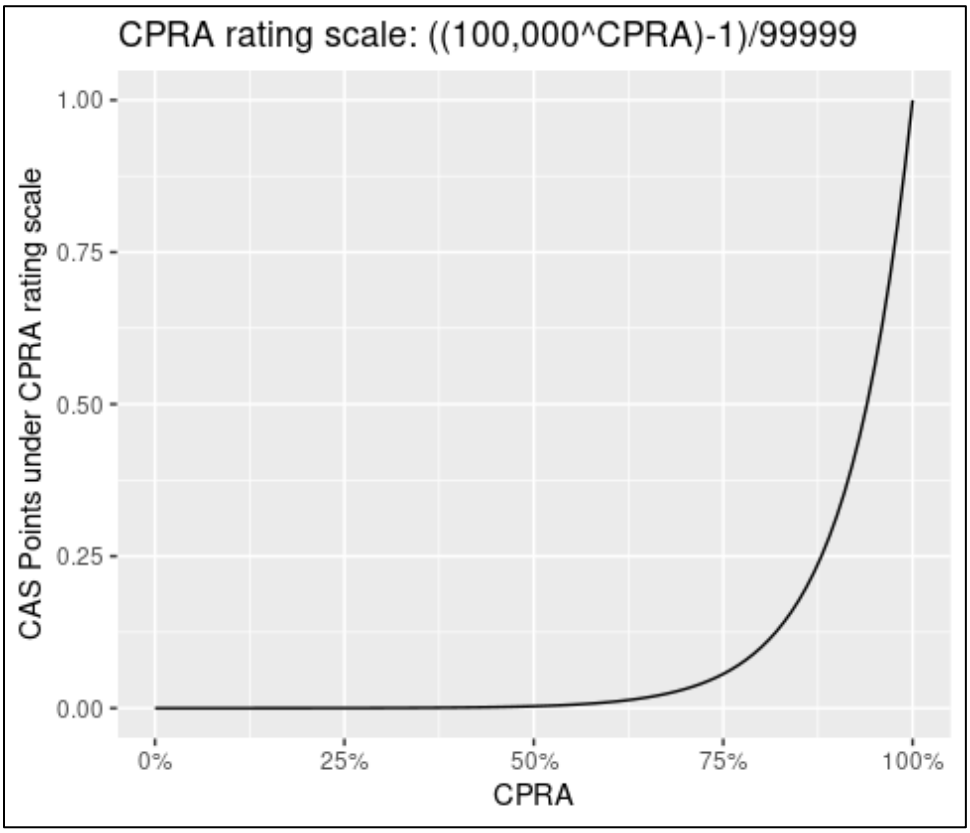


CPRA: Current kidney allocation policy prioritizes high CPRA patients via both classifications and in the form of additional points. 100 percent CPRA candidates currently receive a significant amount of priority, as do nearby 99 and 98 percent CPRA patients. Candidates also receive additional points based on their CPRA, with the most points granted to the highest CPRA patients.[35] The original intent of this policy was to grant greater access for these candidates who might otherwise struggle to receive organ offers due to being biologically unable to accept organs from most donors. In continuous distribution, CPRA points would no longer be awarded based on categories (ex. 20-29, 30-39, … 98, 99, 100 percent). Instead, granular CPRA will be used to award priority along an exponential continuum as shown in **Figure 6**. This type of scale is intended to take into account the fact that CPRA differences at the high

[30] OPTN Policy 8.4.D: Allocation of Kidneys by Blood Type as of March 16, 2023.
[31] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.
[32] OPTN Kidney Transplantation Committee Meeting Summary, February 13, 2023.
[33] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.
[34] This is an example of policy scenarios simulated by MIT and do not reflect the final policy scenarios selected by the OPTN Kidney Transplantation Committee for OASIM modeling.
[35] OPTN Policy 8.2: Kidney Allocation Score, Table 8-2: Points for CPRA as of March 16, 2023.

end of the scale (close to 100 percent) reflect much larger differences in access to transplant compared to differences at lower CPRA values.

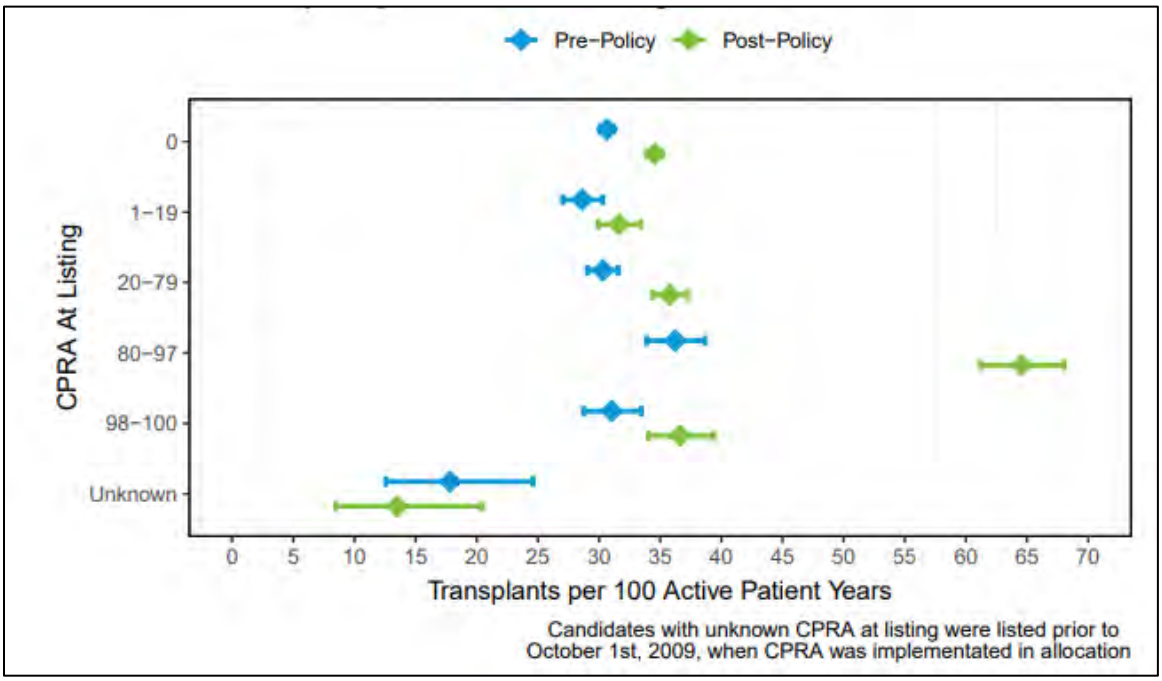
Figure 6: Kidney CPRA Points on a Steep, Non-Linear Rating Scale



In the first round of OASIM modeling, the weight on the CPRA attribute ranged from 10 to 15 percent. The results showed there was no substantial difference in the transplant rates for any of the scenarios compared to current policy for candidates with CPRA less than 80 percent. For CPRA 80-98 percent candidates, the transplant rates were lower when relatively less weight was placed on CPRA. For candidates with the highest CPRAs (98-100 percent), all scenarios showed varying degrees of decreases in transplant rates compared to current policy.[36] For context, the Committee also reviewed data on CPRA categories as shown in **Figure 7** which suggests potential over-prioritization for certain CPRA groups.[37] This data was also considered in light of the recently implemented changes to the CPRA calculation.[38]

[36] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[37] Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report. June 22, 2022.
[38] *Change Calculated Panel Reactive Antibody (CPRA) Calculation*, OPTN Histocompatibility Committee, implemented January 26, 2023.

Figure 7: Transplants per 100 Active Patient Years for Kidney Registrations Ever Waiting[39]
March 14, 2020 – March 14, 2022



Public comment indicates a strong community sentiment for prioritizing highly sensitized candidates (ex. 99 percent CPRA and above) since their compatible donor pool is so small. Other comments suggest other CPRA groups are currently overprioritized and that CPRA points should allow for equal access, not increased access.

With all of these considerations in mind, the Committee held extensive discussions on what the objective for the CPRA attribute should be.[40,41,42] For CPRA, the Committee agreed with the objectives of 1) equal access across CPRAs and 2) maximize access for CPRA 99.9+ percent candidates. Additionally, given the limited donor pool for the highest sensitized, the Committee decided to relax the constraint on distance for high CPRA candidates in the MIT modeling to allow for more access to compatible donor kidneys.[43,44]

Patient Access

Pediatric: Current kidney policy prioritizes pediatric candidates for kidneys with a KDPI of 34 percent or less as shown in **Table 2** above. In continuous distribution, this attribute would be conditional on donor factors; candidates registered before the age of 18 would receive the full benefit of the pediatric points if specific donor criteria are met (ex. KDPI 0-34 percent kidneys, and KDPI 35-85 percent kidneys from pediatric donors). Public comments and the values prioritization exercise from 2022 have shown large

[39] Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report. June 22, 2022.
[40] OPTN Kidney Transplantation Committee Meeting Summary, December 12, 2022.
[41] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[42] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.
[43] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[44] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.

support for high pediatric priority to be maintained in the new system.[45] In reviewing the first OASIM results, there were numerous comments submitted expressing concern for potential increases in distance for pediatric candidates.[46]

Through the Committee's discussions and review of all policy scenarios, the Committee agreed the pediatric priority attribute should maintain the same high level of priority in continuous distribution as it does in the current system, similar to prior living donor access.[47,48] The Committee also discussed the potential travel distance increases for pediatric candidates and recognized the results of the first OASIM request were extreme and lacked any constraints on distance. Additionally, OASIM modeling cannot currently predict acceptance behavior. As described in sections below, the Committee determined a tolerable threshold should be established for median travel distance for all kidneys. However, the Committee also determined this distance constraint may need to be relaxed for pediatric candidates so as not to limit access to offers for those prioritized candidates.[49]

Prior Living Donor: Starting in 1996, prior living donors received priority for kidney transplants. This prioritization is given to kidney candidates in the form of extra points as well as classification priority for KDPI 0-85 kidneys as seen in above **Table 2.**[50] The Kidney Committee is committed to maintaining this high level of priority within continuous distribution for both prior and future living donors. [51,52] Therefore, the Committee set an objective for the prior living donor attribute to maintain the same high level of priority, similar to pediatric priority, to reflect priority found in current policy.[53]

Safety Net: The "Safety Net" is a term to describe a section of OPTN policy that provides increased priority on the kidney waiting list for recipients of other organ types (ex. heart, liver, and lung) with continued kidney disease or dysfunction shortly after transplant.[54,55] These candidates currently receive some classification priority for KDPI 20-100 percent kidneys as shown in **Table 2**. The Committee agreed for the safety net attribute, these candidates should maintain similar priority to current policy.[56]

Qualifying Time: Qualifying time, or overall waiting time, currently accounts for a large part of a kidney candidate's allocation score.[57] Current policy considers one day of waiting time as equivalent to approximately 1/365 of a point; therefore one point is equivalent to one year of waiting time.[58,59] Waiting time for adult kidney candidates is calculated based on either the earliest date of regularly administered dialysis as an end stage renal disease patient, or the earliest date with a qualifying eGFR or creatinine clearance measurement once registered on the waiting list. [60] Pediatric kidney candidates qualify to begin accruing waiting time once they are added to the waiting list, but may also calculate

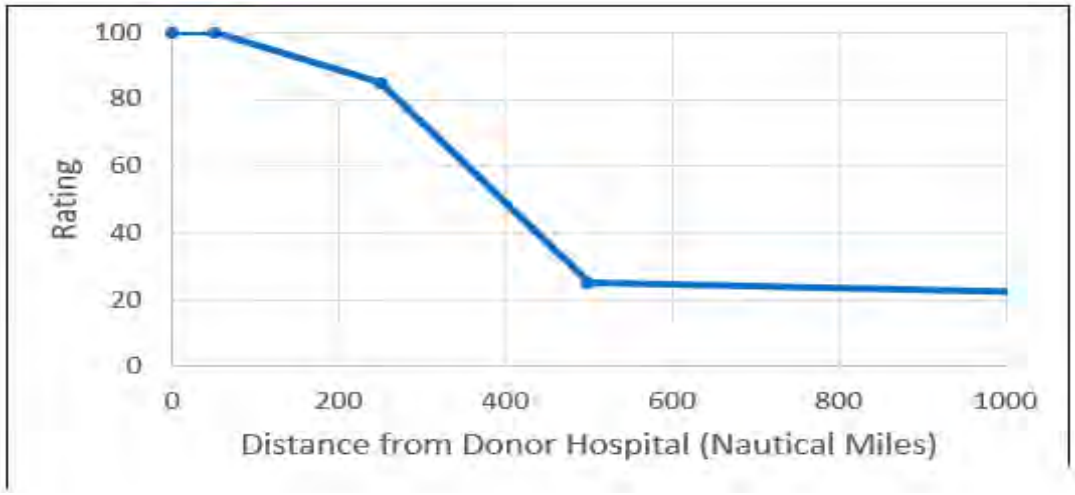
[45] Continuous Distribution of Kidneys, Winter 2022 Prioritization Exercise Community Results. April 6, 2022.
[46] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[47] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[48] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.
[49] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[50] OPTN Policy 8.2: Kidney Allocation Score as of March 16, 2023.
[51] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[52] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, September 17, 2021.
[53] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.
[54] OPTN Policy 8.4.G: Prioritization for Liver Recipients on the Kidney Waiting List as of March 16, 2023.
[55] Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation Policy Notice.
[56] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.
[57] Note: Qualifying time is inclusive of total time on dialysis.
[58] OPTN Policy 8.2: Kidney Allocation Score as of March 16, 2023.
[59] OPTN Policy 8.3.A: Waiting Time for Candidates Registered at Age Years or Older as of March 16, 2023.
[60] OPTN Policy 8.3.A: Waiting Time for Candidates Registered at Age Years or Older as of March 16, 2023.

their waiting time from the earliest date of regularly administered dialysis, if this dialysis date predates their registration on the waiting list.[61] Understanding the importance overall waiting time has on a candidate's place on the kidney wait list, the Committee sought to maximize the median qualifying time at transplant (higher median qualifying time at transplant indicates the policy is transplanting candidates who have been waiting the longest sooner).[62]

Placement Efficiency

Proximity Efficiency: Current kidney allocation policy uses proximity between the donor hospital and transplant hospital to classify and assign points to candidates.[63] The results of the previous values prioritization exercise placed very low importance on distance relative to other attributes.[64] However, public comment feedback has continuously shown that efficiency and travel distance are of significant community interest and concern. In addition to efficiency efforts outlined in the *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback*, the first iteration of the composite allocation score will contain an attribute for proximity efficiency which accounts for distance from a donor hospital and potential candidate, as seen in **Figure 8**.[65] The Committee and the Kidney-Pancreas Continuous Distribution Workgroup also acknowledged that donor factors such as KDPI should be considered for proximity efficiency as well; this is reflected in the increased donor modifier for high KDPI kidneys that was included in the first OASIM request. [66] The increased donor modifier for KDPI 86-100 percent kidneys is intended to prevent these kidneys from traveling as far as other kidneys.

Figure 8: Proximity Efficiency Rating Scale for Kidneys



In reviewing results of the first OASIM request, the median travel distance was higher for all scenarios compared to current policy, with the exception of the "all donor efficiency" scenario that placed high

[61] OPTN Policy 8.3.B: Waiting Time for Candidates Registered prior to Age 18 as of March 16, 2023.
[62] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.
[63] OPTN Policy 8.2: Kidney Allocation Score, Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital as of March 16, 2023.
[64] Continuous Distribution of Kidneys, Winter 2022 Prioritization Exercise Community Results. April 6, 2022.
[65] *Continuous Distribution of Kidneys and Pancreata Committee Update*, OPTN Kidney and Pancreas Transplantation Committees, August 2022.
[66] *Continuous Distribution of Kidneys and Pancreata Committee Update*, OPTN Kidney and Pancreas Transplantation Committees, August 2022.

weight on the proximity efficiency attribute.[67] The OASIM addendum report also showed the increased donor modifier for high KDPI kidneys had the intended effect of keeping those kidneys closer to the donor hospital.[68]

As mentioned above, the Committee agreed a threshold should be established for median travel distance of all kidneys to minimize distance traveled, especially for high KDPI kidneys.[69,70,71] Additionally, the Committee agreed this distance constraint may need to be relaxed for pediatric and high CPRA candidates to maintain their priority access.

Disparities

Upon review of the first OASIM results, there was some concern for potential decreases in transplant rate for Black candidates. Additionally, comments encouraged the Committee to avoid scenarios that exacerbate socioeconomic disparities. In addition to these disparities, there were also concerns raised for geographic disparities, especially for areas of the country that have low population density and unique travel considerations (ex. Pacific northwest). In addition to the attribute-based objectives outlined above, the Committee also agreed on an overall constraint to ensure racial, gender, and geographic disparities are no worse than in current policy.[72]

MIT Optimization

Once the Committee's objectives were established, MIT was able to augment the Kidney-Pancreas Simulated Allocation Model (KPSAM) with machine learning to explore outcomes by identifying attribute weights that align with the Committee's objectives. The optimization tool simulated over 50,000 policy options to determine how different attribute weights affect a variety of outcomes. In addition to the constraints set by the objectives, the simulated policies were designed so that, as compared to current policy, key metrics were optimized while other metrics were maintained. The MIT team then took these established constraints and tested the effects of allowing distance traveled to increase by 10, 25, and 50 percent, and allowing 0-20 EPTS transplant rate to decrease by three and five percent as shown in **Figure 9**. By allowing some constraints to relax incrementally, the Committees were able to see some benefits in other areas. For example, the optimization showed a benefit of longer travel distances is some decrease in disparities. Additionally, a benefit of slightly lower transplant rates for EPTS 0-20 percent candidates is transplanting longer waiting time candidates sooner. These constraints were relaxed in some scenarios to determine the effect on other metrics such as donation service areas (DSA) and transplant rate disparities.

[67] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[68] Scientific Registry of Transplant Recipients, *KI2022_01_Addendum*, January 4, 2023.
[69] OPTN Kidney Transplantation Committee Meeting Summary, November 14, 2022.
[70] OPTN Kidney Transplantation Committee Meeting Summary, January 27, 2023.
[71] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.
[72] OPTN Kidney Transplantation Committee Meeting Summary, February 14, 2023.

Figure 9: Optimized Policy Scenarios with Relaxed Constraints

	Travel Distance		
EPTS 0-20 Transplant Rate	**Maximum 0% Increase**	**Maximum 10% Increase**	**Maximum 25% Increase**
Maximum 0% Decrease	Policy A	Policy B	Policy C
Maximum 3% Decrease		Policy D	Policy E
Maximum 5% Decease			Policy F

The Committee reviewed four optimized policy scenario options as shown in **Figure 10**. The rating scales for all attributes are consistent across all scenarios and include an increased donor modifier for KDPI 86-100 percent kidneys for the Proximity Efficiency attribute. In reviewing the scenarios, the Committee considered the relative relationship between the attribute weights rather than the individual weights as all of the attributes will interact together.

Figure 10: Kidney OASIM Scenarios

	Optimized Policy Scenarios				
Attribute	**A**	**B**	**D**	**E**	**Range of Weights (min - max)**
Medical Urgency	15%	15%	15%	15%	15
DR Mismatch	5.6%	8.1%	4.5%	8.2%	4.5 - 8.2
Longevity Matching (Top 20 to Top 20)	6.6%	5.1%	9.6%	7.7%	5.1 - 9.6
Blood Type	14.6%	15.2%	9.8%	14.3%	9.8 – 15.2
CPRA	6.4%	5.8%	6.2%	5.4%	5.4 – 6.4
Prior Living Donor	15.1%	15%	15.1%	15%	15
Pediatric	15.1%	15.9%	16.7%	14.1%	14.1 – 16.7
Safety Net	5%	5%	5%	5%	5
Qualifying Time	5.6%	5.3%	7.7%	6.7%	5.3 – 7.7
Proximity Efficiency	11%	9.6%	10.4%	8.6%	8.6 - 11

The Committee then reviewed some key metrics for the policy scenarios including median distance, number of graft failures, transplant rate by EPTS, CPRA, and blood type groups, pediatric transplant rate, average waiting time, median qualifying time at transplant, and transplant rate disparities (ABO, CPRA, DSA, racial, sex, and Latino transplant rate disparities) as shown in **Figures 11-20**.

Figure 11: Median Distance (NM) for Each Policy[73]

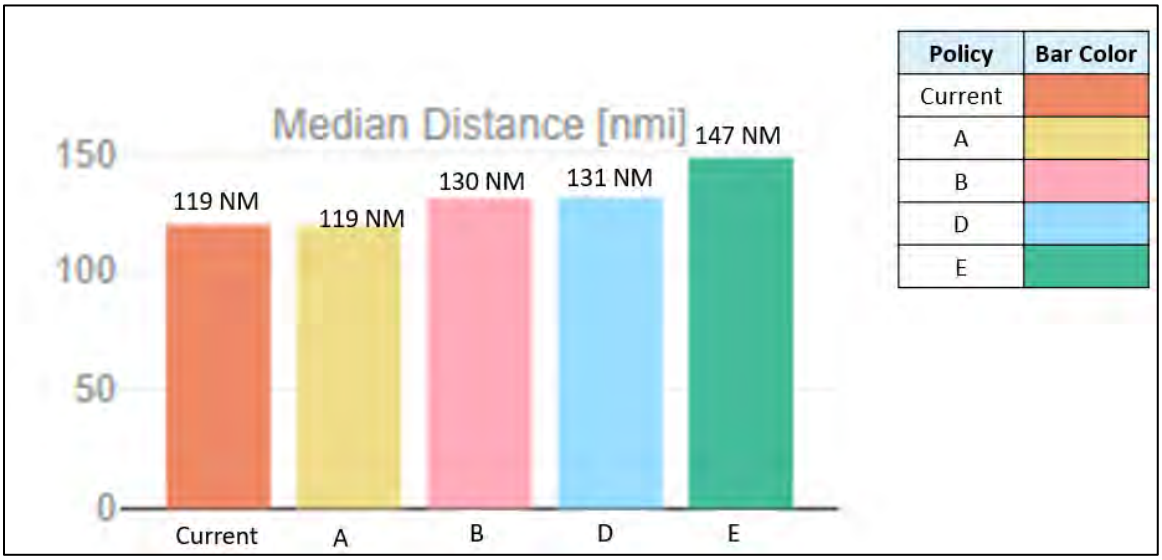
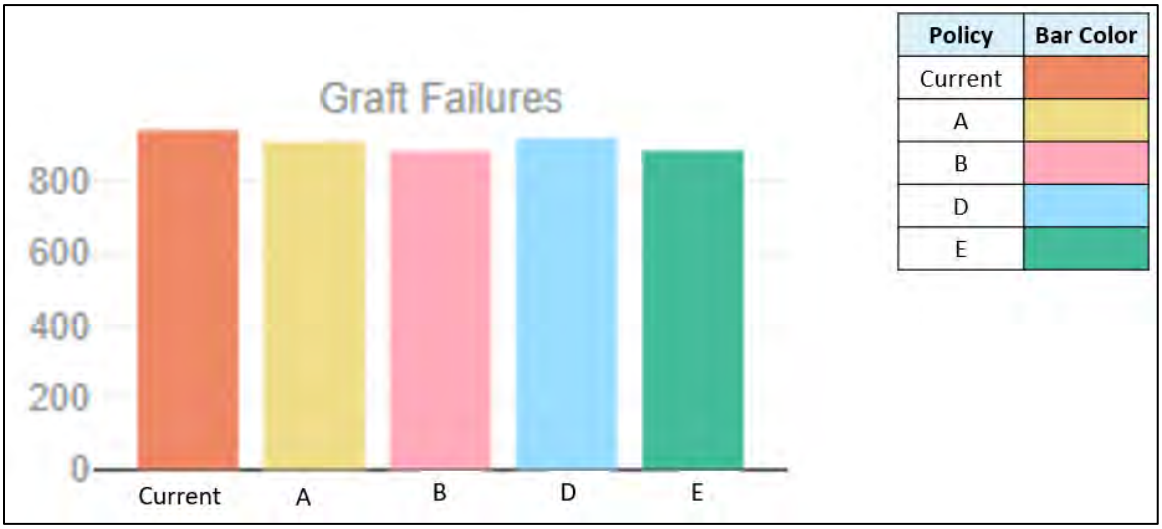
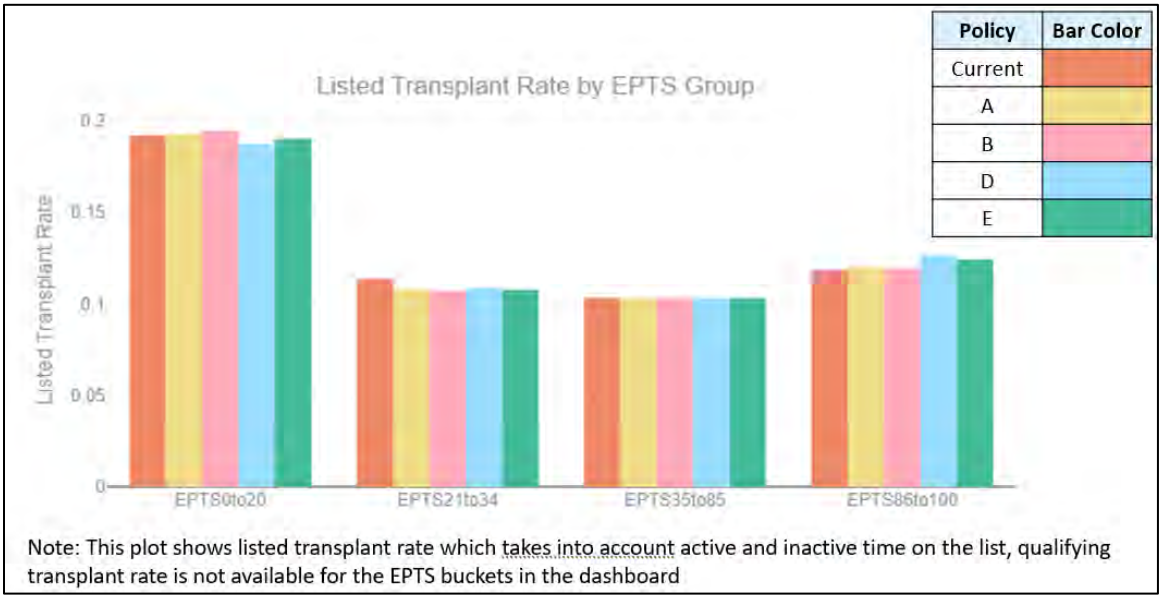


Figure 12: Number of Graft Failures for Each Policy[74]



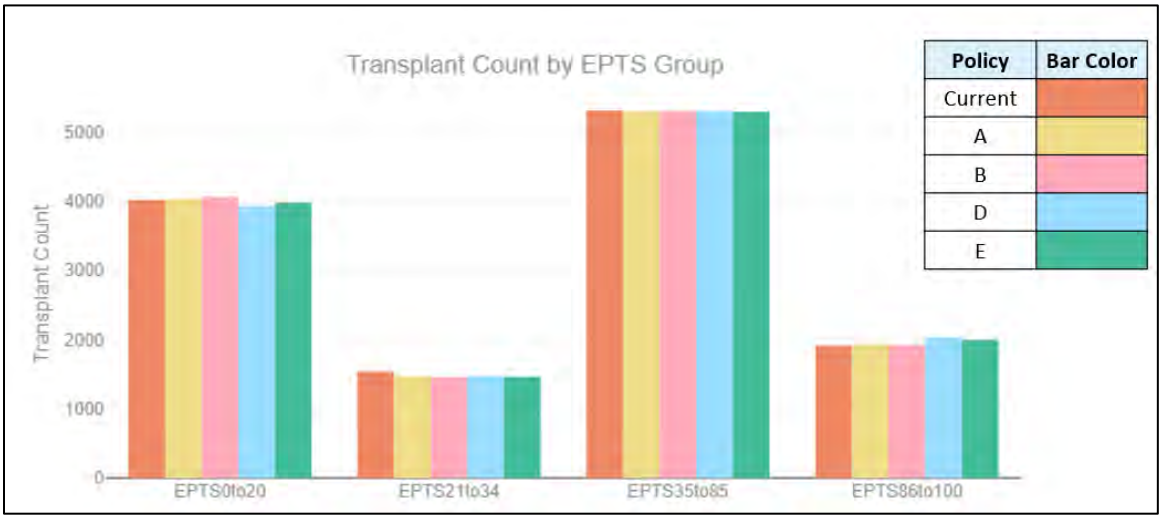
[73] As simulated by MIT for the OPTN Kidney Transplantation Committee. The median distance (in nautical miles) from the transplant hospital to donor hospital for all recipients transplanted within the simulation period.
[74] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of graft failures within a year after transplant.

Figure 13: Transplant Rate by EPTS Groups[75]



Note: This plot shows listed transplant rate which takes into account active and inactive time on the list, qualifying transplant rate is not available for the EPTS buckets in the dashboard

Figure 14: Transplant Counts by EPTS Group[76]



[75] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of transplants divided by the total amount of time on the waiting list (active plus inactive) within the simulation period.
[76] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of transplants within the simulation period.

Figure 15: Transplant Rate by CPRA Group[77]

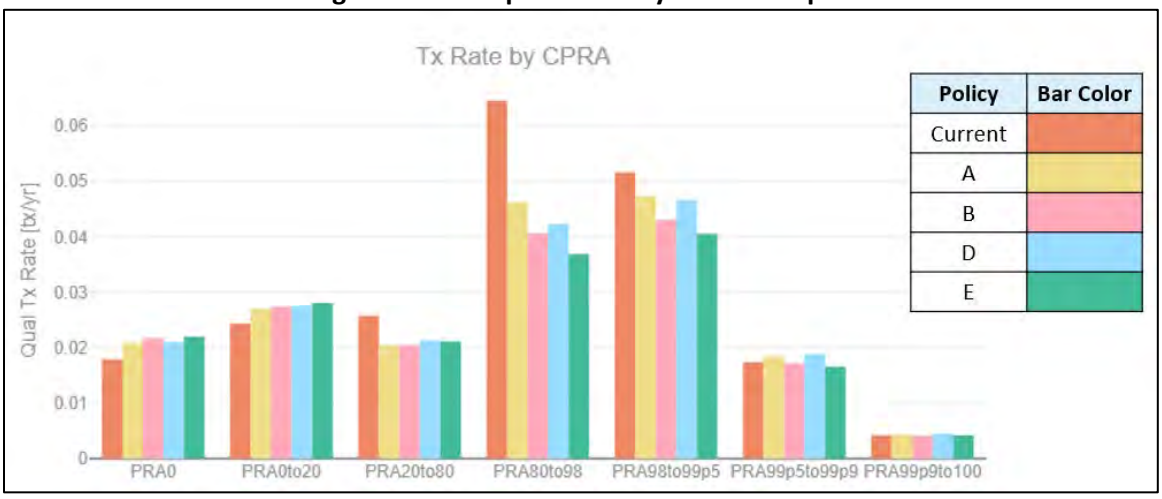
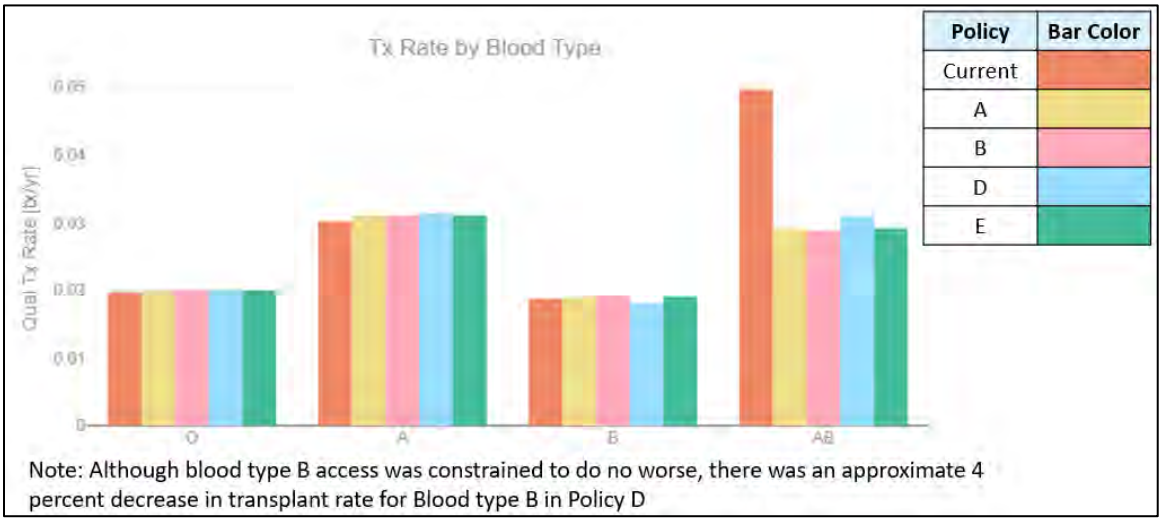


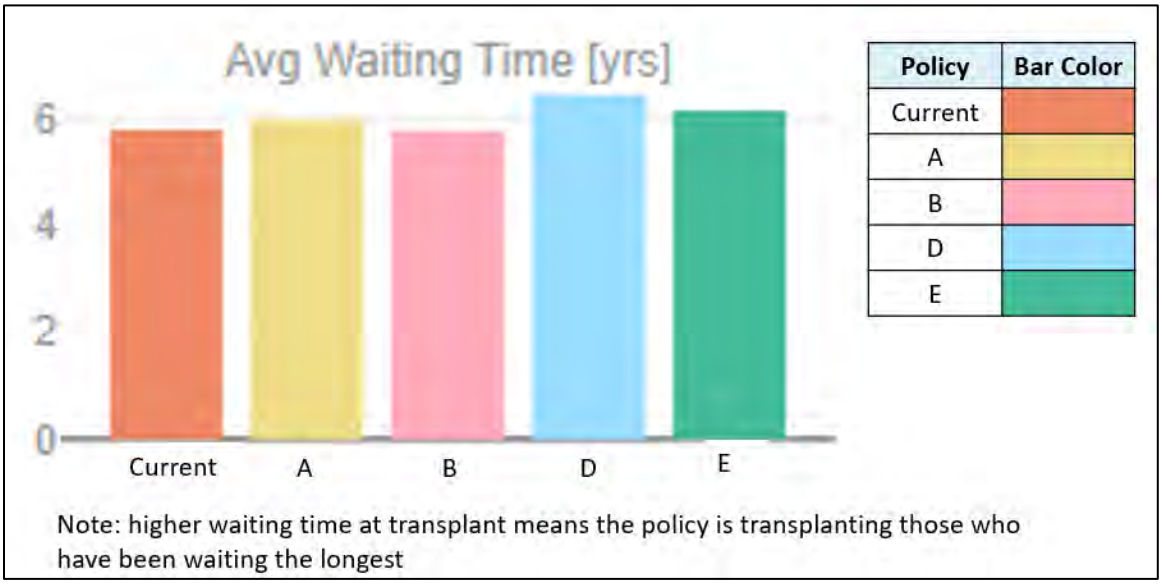
Figure 16: Transplant Rate by Blood Type[78]



[77] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of transplants divided by the total amount of qualifying time (including dialysis time) of patients who were ever waiting during the simulation period.
[78] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of transplants divided by the total amount of qualifying time (including dialysis time) of patients who were ever waiting during the simulation period.

Figure 17: Pediatric Transplant Rate[79]

Figure 18: Average Waiting Time at Transplant[80]



[79] As simulated by MIT for the OPTN Kidney Transplantation Committee. Calculated as the number of transplants divided by the total amount of qualifying time (including dialysis time) of patients who were ever waiting during the simulation period.

[80] As simulated by MIT for the OPTN Kidney Transplantation Committee. The average qualifying time for all candidates who received a transplant. Note a higher waiting time at transplant means the policy is transplanting those who have been waiting the longest.

Figure 19: Median Qualifying Time at Transplant by EPTS Group[81]

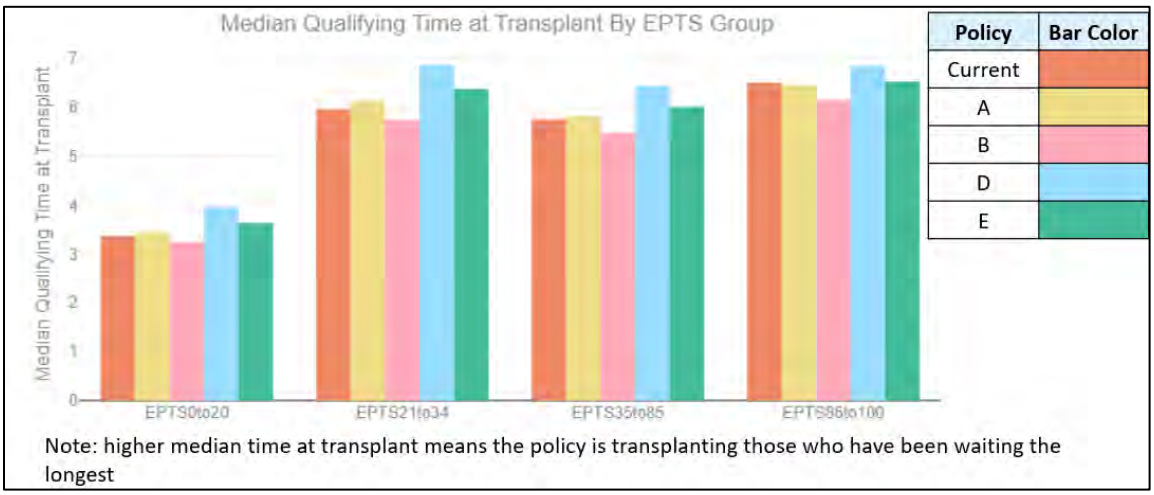
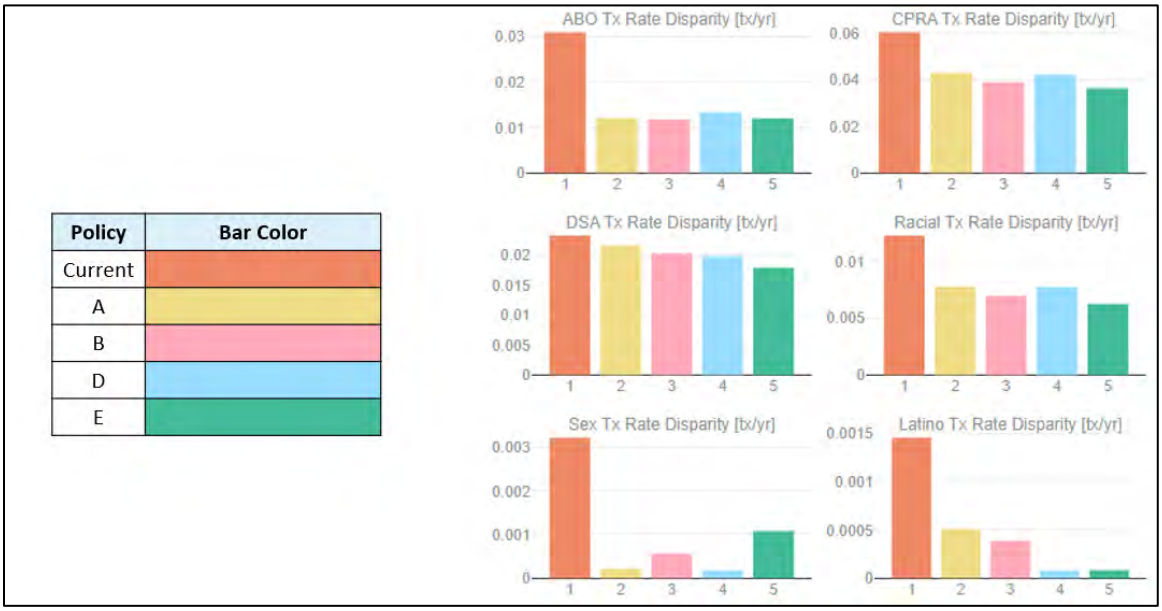


Figure 20: Transplant Rate Disparities[82]



The four policies reviewed by the Committee met several of the Committee's stated objectives for development of continuous distribution:

- Maintaining high priority for pediatric, prior living donor, and medically urgent candidates
- Maintain/slightly increase access for CPRA 99.9+ percent candidates while balancing the access between other CPRA groups
- On average, increase access for candidates with longer waiting times
- Decrease disparities in transplant rates by blood type, CPRA group, DSA, racial group, sex, and

[81] As simulated by MIT for the OPTN Kidney Transplantation Committee. The median qualifying time (includes dialysis time) for all candidates who received a transplant. Note higher median time at transplant means the policy is transplanting those who have been waiting the longest.
[82] As simulated by MIT for the OPTN Kidney Transplantation Committee. The highest transplant rate minus the lowest transplant rate over several groups of candidates. For example, the ABO transplant rate disparity is the highest minus lowest transplant rate between blood type A, B, O, and AB candidates. For geographic disparity, the average difference in transplant rate between geographic regions is used rather than the highest minus lowest.

ethnicity
- Emphasis on access for Blood Type B and O candidates

Allowing for slight decreases or variation in EPTS 0-20 access and increases in travel distance allow for some gains in other areas:
- Increasing distance as shown in Policy B, D, and E allows for decreased disparity (including geographic disparity)
- Decreasing EPTS 0-20 access will increase access for candidates with long waiting times, as shown in Policy D and E

OASIM Request

The four policy options outlined above in **Figure 10** were approved by the Kidney Committee on March 14, 2023 and submitted as scenarios to be included in the second OASIM request.[83] This second round of modeling narrows the focus to test those attributes and associated rating scales and weights that would most likely be considered for the final proposal. Results of the second OASIM modeling request are expected in the summer of 2023.

Pancreas Committee Discussions

The Pancreas Committee discussed the potential tradeoffs and interactions between the attributes to develop a series of objectives for what each attribute should accomplish, as seen in **Table 3**.

Table 3: Pancreas Allocation Objectives

Attributes	Goal	Modeling Objectives
Blood Type	Candidate Biology	Maintain KP screening and rules outlined in current policy
CPRA	Candidate Biology	Equitable access across CPRAs
Prior Living Donors	Patient Access	High priority in rare event candidate is a prior living donor
Pediatrics	Patient Access	High priority in rare event there is a pediatric candidate
Qualifying Time	Patient Access	Priority for candidates who have higher wait time
Proximity Efficiency	Placement Efficiency	Increase utilization of pancreata; minimize distance traveled for pancreas alone
Organ Registration	Placement Efficiency	Whole organs prioritized over islets Increase utilization of pancreata; Prioritize whole pancreas candidates for donor age ≤ 45 & BMI ≤ 30, and prioritize islet candidates for donors > 45 or BMI >30

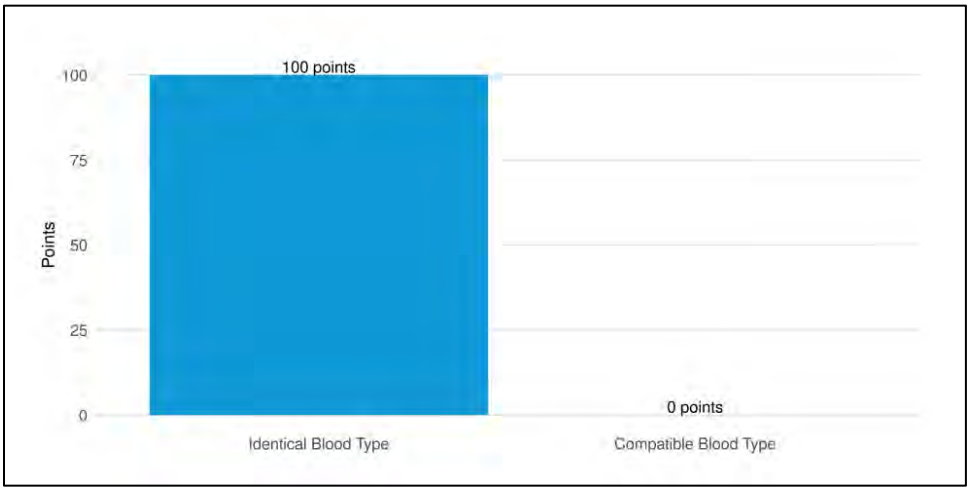
Candidate Biology

Blood Type: In current policy, pancreas allocation classifies candidates according to compatible blood type matches while kidney-pancreas allocation classifies candidates, similar to kidney allocation, according to compatible, incompatible, and permissible blood type matches.[84] There is currently no

[83] OPTN Kidney Transplantation Committee Meeting Summary, March 14, 2023.
[84] OPTN Policy 11.4.D: Blood Type for Kidney-Pancreas Allocation as of March 16, 2023.

prioritization for identical over compatible blood types for pancreas and kidney-pancreas allocation.[85] For the first OASIM request, the Pancreas Committee supported a binary rating scale that would prioritize identical over compatible blood types (see **Figure 21**), which would be a change from current policy as previously outlined. [86] There was also discussion whether current blood type screening for KP allocation should be maintained in continuous distribution.

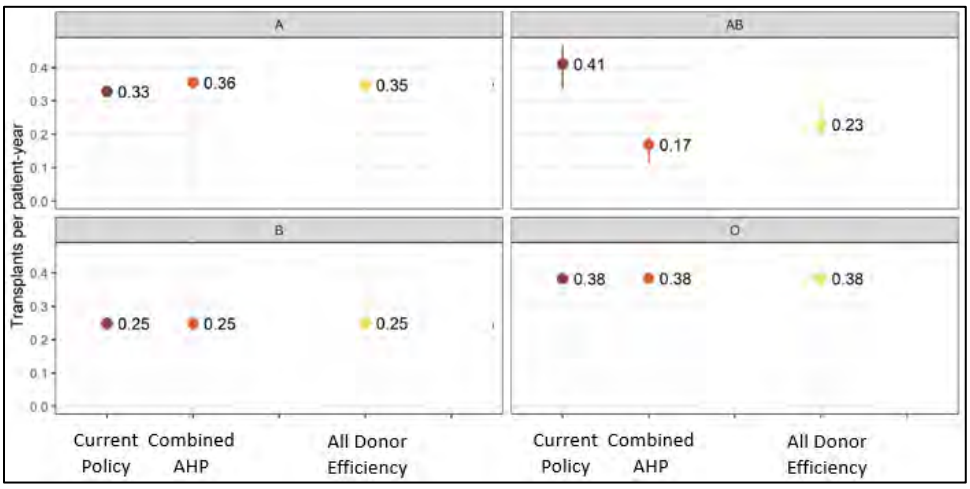
Figure 21: Binary Rating Scale for Blood Type (Pancreas)



The Pancreas Committee reviewed the OASIM results (**Figure 22**), which showed the transplant rates for A, B, and O candidates under both the Combined Analytical Hierarchy Process (AHP) and All Donor Efficiency scenarios were very similar to those under the simulation of current policy. The Pancreas Committee focused their review on these two scenarios specifically as the Increased Longevity and High KDPI Efficiency scenarios were kidney specific and not relevant to the pancreas discussions. This is likely because the blood type screening rules for KP already limit KP offers to blood type identical candidates in most cases, and the KP transplant numbers are a lot higher than pancreas-alone transplants.[87] However, in the upper right facet of the figure, there is a notable drop in transplant rates for blood type AB candidates in the scenarios modeled as compared with current policy. This is likely because KP candidates with blood type AB appear on match runs for donors with blood types A and AB, and in current policy receive the same amount of priority as candidates with blood type A for blood type A donors. With the binary rating scale for blood type modeled for the continuous distribution scenarios in the first OASIM request, blood type A candidates would receive 100% of the points for the ”blood type identical” attribute on a match run for a blood type A donor, while blood type AB candidates would receive 0 points for this attribute, resulting in decreased priority for the majority of donors that they would be eligible to match with based on blood type.

[85] OPTN Policy 11.4.D: Blood Type for Kidney-Pancreas Allocation as of March 16, 2023.
[86] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, April 22, 2022.
[87] OPTN Pancreas Transplantation Committee Meeting Summary, January 27, 2023.

Figure 22: Transplant Rates by Blood Type: Pancreas and Kidney-Pancreas[88]



After much discussion, the Pancreas Committee re-evaluated and established that the objective for allocation by blood type was to maintain screening for KP as outlined in current policy, noting that one blood type should not have more access over another blood type, consistent with current policy. The Pancreas Committee reviewed and discussed the rating scale recommendation of prioritizing identical ABO over compatible ABO and determined that this was not in alignment with the objective established. The Pancreas Committee also discussed the idea of removing current screening for KP candidates, which was previously considered during the July 2017 public comment cycle in the Pancreas Committee's *Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types* proposal.[89] The proposal was not supported by the Kidney Committee at the time due to concern on the potential impact on blood type O kidney-alone candidates. The OPTN Board of Directors referred the proposal back to the committee for further work on the project.[90]

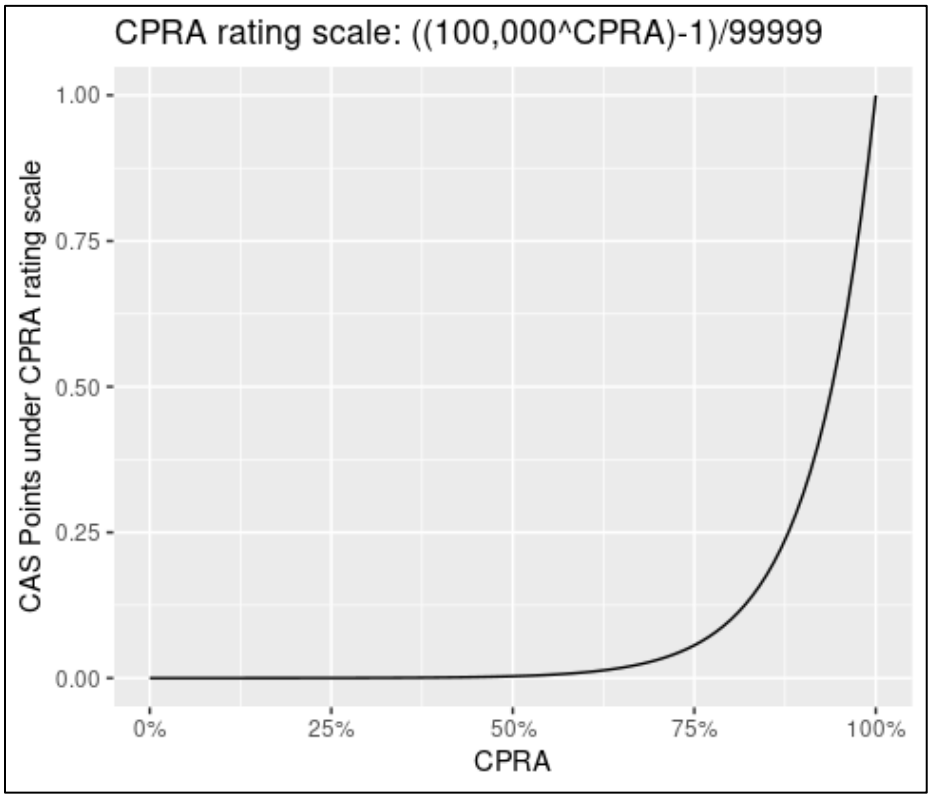
Upon further review of the objectives established and the points mentioned above, the Pancreas Committee decided to maintain current screening for KP candidates and remove the Blood Type attribute for this first iteration of the project. The Committee discussed concern related to a disproportionate amount of wait time between each of the blood types (specifically, blood type B candidates) and determined to further monitor and discuss in a future iteration of CD.[91]

CPRA: Current policy prioritizes highly sensitized (CPRA greater than or equal to 80 percent) pancreas and KP patients, but there is currently no increased prioritization for the highest CPRA patients as seen in current kidney policy. [92] The Pancreas Committee agreed on a steep, non-linear rating scale for CPRA for pancreas allocation to preserve priority for 99 and 100 percent CPRA candidates (**Figure 23**).[93] This attribute received a high value weight within both the kidney and pancreas AHP exercises. Public comment feedback also showed support for a steep, non-linear scale and for high CPRA candidates to be given a heavy weight. In considering the first modeling request, the Workgroup decided to incorporate a steeper CPRA curve (based on an exponential function with a base of 100,000) as shown in **Figure 23**

[88] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[89] *Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types*, OPTN Pancreas Transplantation Committee, July 2017.
[90] OPTN Pancreas Transplantation Meeting Summary, January 16, 2018.
[91] OPTN Pancreas Transplantation Committee Meeting Summary, January 27, 2023.
[92] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, October 9, 2020.
[93] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, May 21, 2021.

(base of 100 was used in the lung continuous distribution project).[94] The Committee decided to include this steeper curve in each modeling scenario in an effort to better distinguish between the very high CPRA candidates. In the first modeling request, CPRA received a 15 percent weight for the Combined AHP scenario and an 11.67 percent weight for the "All Donor Efficiency" scenario.[95]

Figure 23: Rating Scale for CPRA; Steep, Nonlinear Curve (base 100,000) (Pancreas)

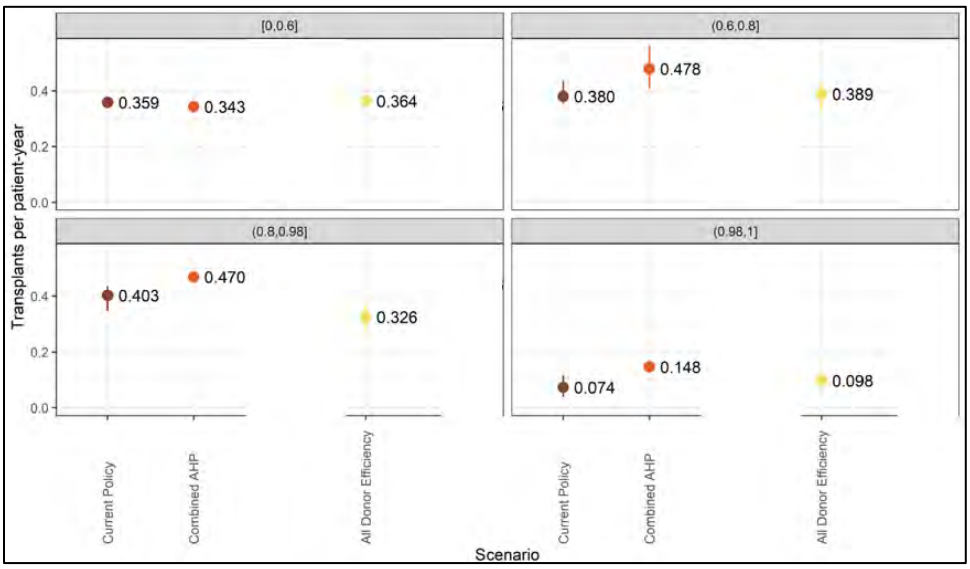


The Pancreas Committee reviewed the OASIM results (**Figure 24**), which showed the following:

- Similar transplant rates for CPRA 0-60 percent candidates across scenarios, and as compared to current policy.
- For the most highly sensitized candidates (CPRA 99-100 percent), the transplant rate is lower across all scenarios and current policy relative to other CPRA groups. However, the Combined AHP scenario showed a moderate increase in transplant rate for this category as compared to current policy, and the All Donor Efficiency scenario showed a slight increase in transplant rate as compared to current policy.
- For CPRA 60-80 percent and 80-98 percent categories, transplant rates increased under the Combined AHP scenario as compared to current policy. Under the All Donor Efficiency scenario, transplant rates were similar or slightly decreased for these middle CPRA groups as compared to current policy.

[94] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, April 29, 2022.
[95] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.

Figure 24: Transplant Rates by CPRA Groups[96]



The Pancreas Committee discussed their objectives and initially discussed prioritizing highly sensitized candidates as their compatible donor pool is very small. The Pancreas Committee initially came to a consensus that 80-98 and 98-100 percent CPRA candidates should have a higher transplant rate than projected by the modeling results as these cases are rare and should be prioritized when presented.[97] After further discussion, the Pancreas Committee established an objective of equitable access across CPRA groups.

Patient Access

Prior Living Donors: Prior living donors are not currently prioritized for pancreas allocation. For continuous distribution, the Pancreas Committee supports including priority points for prior living donors in pancreas and kidney-pancreas continuous distribution.[98] Public comment feedback showed general support for prioritizing prior living donors; however, some concern was shown for the high weight given to the attribute in modeling due to prior living donor cases being rare to never events in pancreas transplantation. The Pancreas Committee acknowledged during their review and discussions that the attribute weights are not intended to be reflective of frequency of events. For the first modeling request, the Pancreas Committee assigned the pediatric attribute a 20 percent weight for the Combined AHP scenario and a 15.56 percent weight for the "All Donor Efficiency" scenario. Due to small event counts, no OASIM results are available for this attribute.[99] The Pancreas Committee decided that in the rare event a candidate is a prior living donor for pancreas/KP allocation, there should be a high priority for these candidates.[100]

Pediatrics: Currently, pediatric priority is not included in pancreas allocation policy. The Pancreas Committee decided that pediatric priority should be incorporated into continuous distribution, and

[96] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[97] OPTN Pancreas Transplantation Committee Meeting Summary, December 12, 2022.
[98] OPTN Pancreas Continuous Distribution Workgroup Meeting Summary, September 25, 2020.
[99] OPTN Pancreas Transplantation Committee Meeting Summary, December 12, 2022.
[100] OPTN Pancreas Transplantation Committee Meeting Summary, December 12, 2022.

acknowledged that pediatric pancreas transplant is a rare event.[101] Similar to prior living donor, public comment feedback generally showed support for pediatric priority; however, some commenters noted concern for the high weight given to the pediatric attribute in the modeling because it is a rare event. Similar to the above attribute, the Committee clarified that weights are more representative of the importance of an attribute rather than the prevalence that it will be used. For the first modeling request, the Pancreas Committee assigned the pediatric attribute a 20 percent weight for the Combined AHP scenario and a 15.56 percent weight for the "All Donor Efficiency" scenario.

In review of the OASIM results, the Pancreas Committee reviewed the following:

- Higher transplant rates for pediatric candidates compared to current policy for both modeled scenarios (**Figure 25**)

Figure 25: Transplant Rates by Age: Pancreas and Kidney-Pancreas[102]

The Pancreas Committee decided on an objective, similar to that of prior living donor, that in the rare event there is a pediatric candidate for pancreas/KP, there should be a high priority for these candidates. [103]

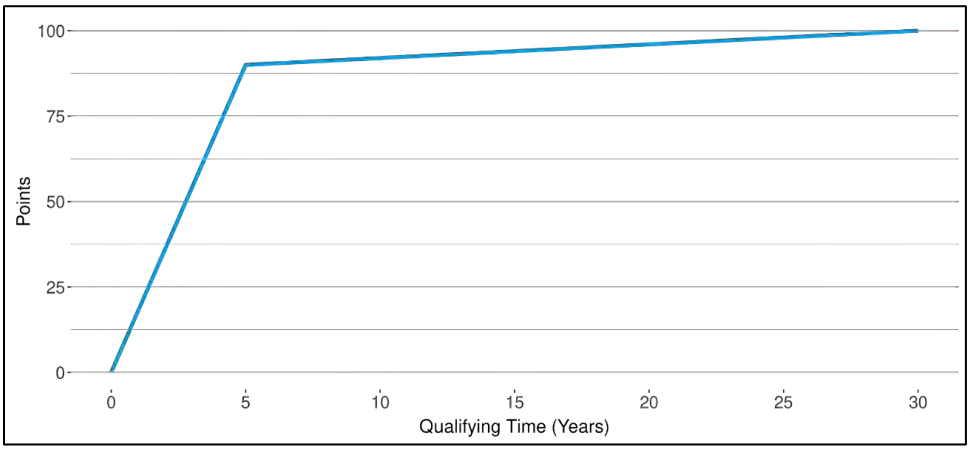
Qualifying Time: In the current system, waiting time is used to distinguish between candidates within the same classification. According to current kidney, pancreas, and KP allocation policy, one day of waiting time equals 1/365 of a point; therefore, one point is equivalent to approximately one year of waiting time.[104, 105]

The Pancreas Committee supported a two-piece linear approach (**Figure 27**) as the most equitable option for pancreas and KP for assigning points based on waiting time. The Committee acknowledged

[101] OPTN Pancreas Continuous Distribution Workgroup Meeting Summary, November 6, 2020.
[102] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[103] OPTN Pancreas Transplantation Committee Meeting Summary, December 12, 2022.
[104] OPTN Policy 8.2: Kidney Allocation Score as of March 16, 2023.
[105] OPTN Policy 11.1: Pancreas Allocation Score as of March 16, 2023.

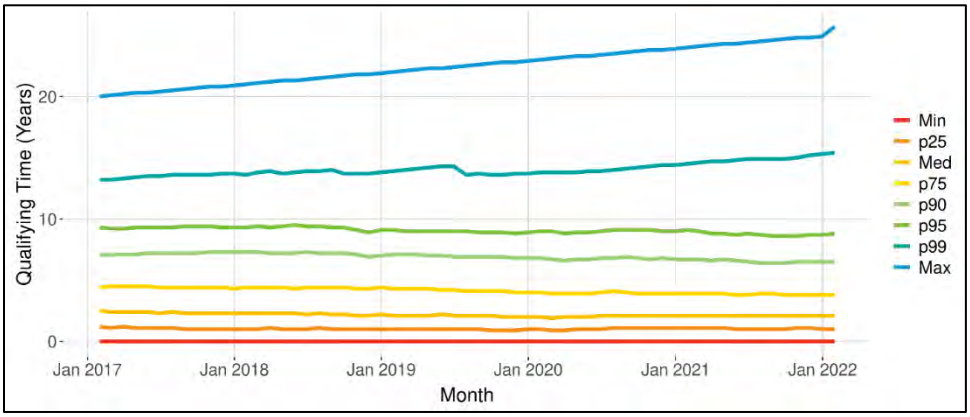
there are other factors that could result in increased waiting time for individual candidates, including variabilities in program logistics and sensitization.[106]

Figure 27: Two-Piece Linear Rating Scale for Qualifying Time (Pancreas)



The Pancreas Committee reviewed data on average waiting times for pancreas and KP candidates (**Figure 28**) to inform the decision about where to put the inflection point on the two-piece linear rating scale. The Pancreas Committee recommended an inflection point of 90 percent at five years and a shallower line beyond five years to max. Starting at the far left of the two-piece linear rating scale, (**Figure 27**), when a candidate is listed they will accrue points for waiting time in a linear fashion where each day is worth the same as the next day, up until 5 years. A candidate with five years of qualifying time will receive 90 percent of the total possible points for the qualifying time attribute.[107]

Figure 28: Qualifying Time for Kidney-Pancreas and Pancreas Registrations by Month[108]

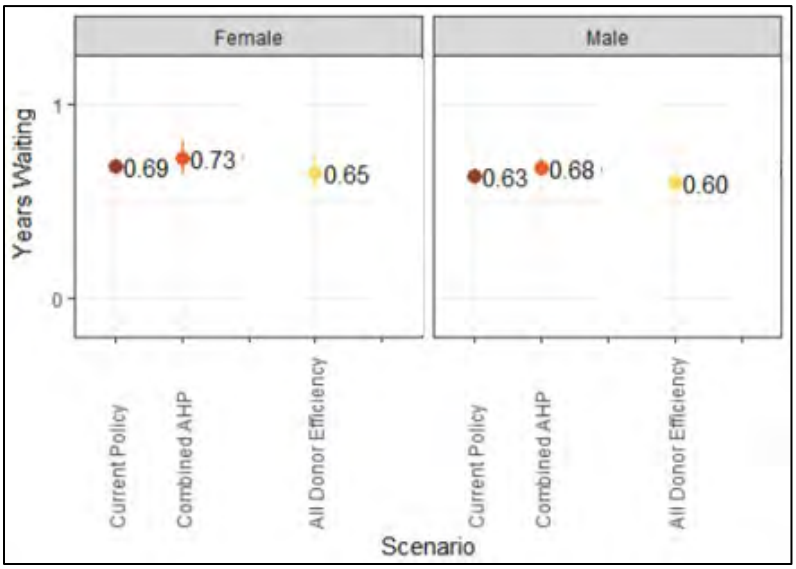


The January 2023 OASIM addendum report included some results for median time from listing to transplant as well as some additional breakdowns of median distance by different candidate characteristics.[109] **Figure 29** shows the simulation results (stratified by recipient sex) for median days from listing to transplant for pancreas/KP recipients for the simulation of current policy and the

[106] OPTN Pancreas Transplantation Committee Meeting Summary, April 11, 2022.
[107] OPTN Pancreas Transplantation Committee Meeting Summary, January 9, 2023.
[108] OPTN Data as of June 30, 2021.
[109] Scientific Registry of Transplant Recipients, *KI2022_01_Addendum*, January 4, 2023.

Combined Analytical Hierarchy Process (AHP) and All Donor Efficiency scenarios. The figure shows that median time from listing to transplant was similar under both CD scenarios relative to current policy. The median waiting time was found to be slightly higher under Combined Analytical Hierarchy Process (AHP) scenario and slightly lower under All Donor Efficiency scenario compared with the simulation of current policy. The slight difference between the Combined AHP and All Donor Efficiency scenarios may be attributable to the slightly higher weight on qualifying time in the Combined AHP relative to the weight on proximity efficiency, resulting in an increased priority for candidates who have been waiting longer.[110]

Figure 29: Median Time from listing to Transplant for Pancreas/Kidney-Pancreas Recipients[111]



The Pancreas Committee agreed that priority for candidates who have higher wait time should be the established objective for the qualifying time attribute.[112]

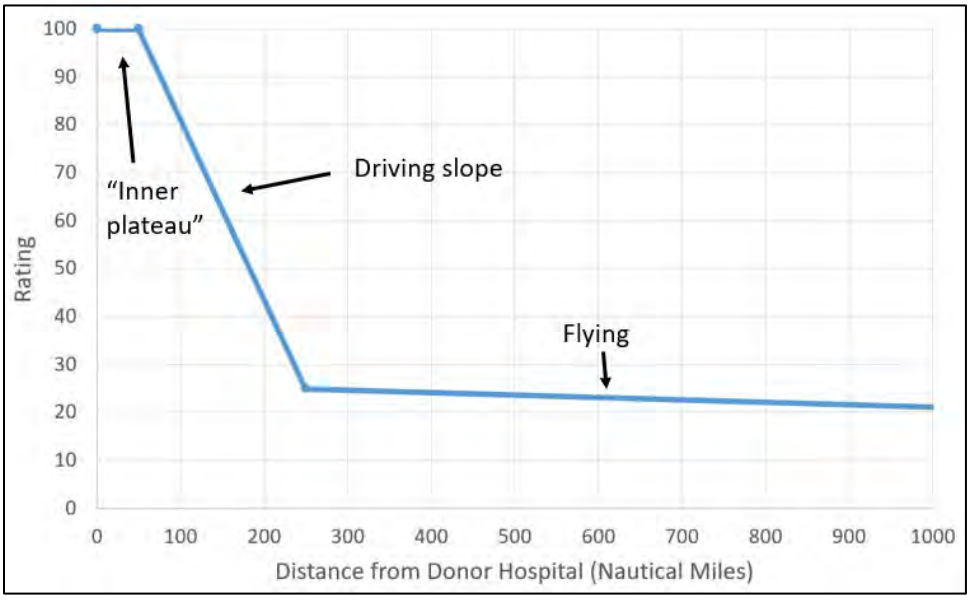
Placement Efficiency

Proximity Efficiency: Current kidney and pancreas allocation policy uses distance in nautical miles between the donor hospital and transplant hospital to place candidates into classifications and to assign proximity points within classifications.[113,114] Transportation costs generally increase as the distance between the donor and transplant hospitals increases. Geographic proximity (e.g., distance between donor and transplant candidate's hospital) may only be considered to the extent necessary to satisfy requirements in the Final Rule: e.g., efficient management of organ placement and the avoidance of organs not being utilized due to increased ischemic time.[115] Beyond distance and cost, efficient placement emphasizes swift and effective donor organ and recipient matching.

[110] OPTN Pancreas Transplantation Committee Meeting Summary, January 9, 2023.
[111] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[112] OPTN Pancreas Transplantation Committee Meeting Summary, January 9, 2023.
[113] OPTN Policy 8.2: Kidney Allocation Score, Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital as of March 16, 2023.
[114] OPTN Policy 11.1: Pancreas Allocation Score, Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital as of March 16, 2023.
[115] 42 C.F.R. §121.8(a)(8)

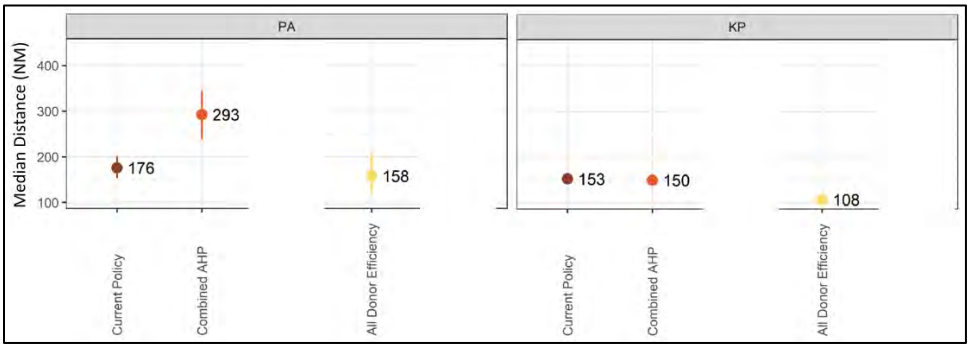
The Committee decided on a piece-wise linear rating scale for the proximity efficiency attribute, as demonstrated in **Figure 30**. The scale has an inner plateau to 50 NM to account for candidates very close to the donor hospital; not to disadvantage candidates slightly further away, but still within close-range driving distance. The scale then slopes down to 250 NM as the "driving slope," as most organs within this distance are driven and not flown. After 250 NM, the scale has a gradual downward slope to 5,000 NM to account for organs that would need to be flown. [116]

Figure 30: Piece-wise Linear Rating Scale for Proximity Efficiency (Pancreas)[117]



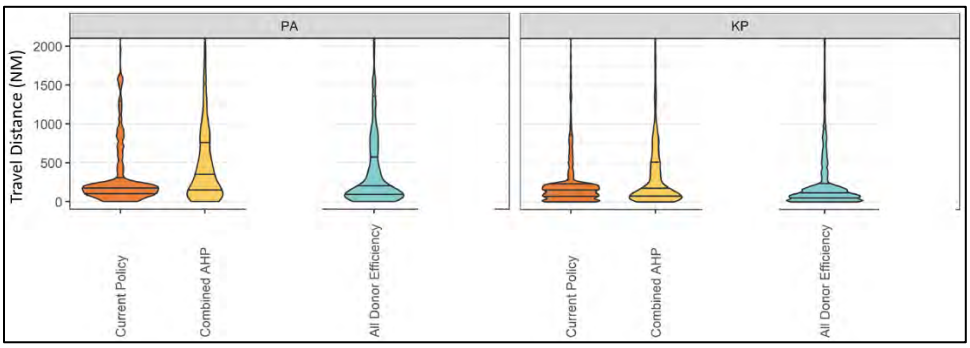
The Pancreas Committee reviewed the OASIM results that modeled the distribution of travel distance (**Figure 32**) and median travel distance (**Figure 31**).

Figure 31: Median Distance[118]



[116] OPTN Pancreas Transplantation Committee Meeting Summary, January 9, 2023.
[117] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[118] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.

Figure 32: Distribution of Distance (Pancreas and KP)[119]



The results showed the following:

- Kidney-Pancreas:
  - *Combined AHP*: Median distance similar to simulated current policy
  - *All Donor Efficiency*: Median distance lower than simulated current policy
- Pancreas:
  - *Combined AHP:* Median distance higher than simulated current policy
  - *All Donor Efficiency:* Median distance lower than simulated current policy

The Pancreas Committee discussed the overall goal of increasing the utilization of pancreata and agreed that the objective for the proximity efficiency attribute should be to minimize distance traveled for KP and pancreas alone.[120, 121]

Organ Registration: Current pancreas allocation includes two sequences based on donor age and body mass index (BMI).[122,123] Whole pancreas (pancreas and kidney-pancreas) candidates receive priority over islet candidates for donors less than 50 years old who have a BMI less than 30, while islet candidates receive priority over some whole pancreas candidates for donors over age 50 or who have a BMI greater than 30. The Pancreas Committee reviewed data showing that the utilization of the whole organ pancreas declines as donor age increases, particularly for donors ages 40 and older, and very few pancreata are transplanted from donors over age 50.[124] These pancreata, however, can be ideal islet donors. There was support on prioritizing pancreas candidates from donors less than 40 years old and prioritizing islet candidates from donors 50 years old or older with a transition between 40 and 50 years old.[125] The Pancreas Committee agreed on weight modifiers that would prioritize whole pancreas candidates for donor age less than or equal to 45 and BMI less than or equal to 30, and prioritize islet candidates for donors age greater than 45 or BMI greater than 30.

The Pancreas Committee reviewed the previous recommendations for the organ registration attribute and the corresponding donor modifiers used for modeling. The Pancreas Committee discussed how much priority islet candidates should receive for each classification:[126]

- Donors Age <50 with BMI <30

[119] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[120] OPTN Pancreas Transplantation Committee Meeting Summary, November 7, 2022.
[121] OPTN Pancreas Transplantation Committee Meeting Summary, January 27, 2023.
[122] OPTN Policy 11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2 as of March 16, 2023.
[123] OPTN Policy 11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m2 as of March 16, 2023.
[124] OPTN Pancreas Transplantation Committee Meeting Summary, April 11, 2022.
[125] OPTN Pancreas Transplantation Committee Meeting Summary, April 11, 2022.
[126] OPTN Pancreas Transplantation Committee Meeting Summary, January 20, 2023.

- Donors Age >50 or BMI >30

The Pancreas Committee established the following objectives for organ registration:[127]

- Whole organs prioritized over islets
- Increase utilization of pancreata; Prioritize whole pancreas candidates for donor age ≤ 45 & BMI ≤ 30, and prioritize islet candidates for donors > 45 or BMI >30

The organ registration attribute was unable to be modeled, however, the Pancreas Committee intend to review the modeling results of the other attributes once available to determine the appropriate weight for the organ registration attribute.

MIT Optimization and Tableau Sensitivity Analysis

The Pancreas Committee discussed appropriate weighting for the CPRA, pediatric, and prior living donor attributes. The Pancreas Committee reviewed how these scenarios would be expected to perform using the MIT dashboard for metrics that can be simulated. For those attributes that could not be modeled, a sensitivity analysis tool was used. For instance, the OPTN does not currently collect data on prior living donor status for pancreas and there are very few pediatric pancreas candidates. A sensitivity analysis is used to change a single variable slightly to measure the impact on an outcome. For continuous distribution of kidneys and pancreata, a sensitivity tool is used to evaluate these variables. For example, if a change is made to the weight of any attribute, the new match run will be shown as the outcome.

There are various functionalities within the Tableau sensitivity tool. In the context of the Pancreas Committee discussions, the two candidate comparisons are used, which entails clinical criteria being entered for two candidates and observing how their CAS would be ranked against each other. Further information on how the two candidate comparison was used is detailed later in this appendix.

The Pancreas Committee initially reviewed six scenarios (**Figure 33**) that looked at a range of different ratios of proximity efficiency to qualifying time while maintaining appropriately high access for high CPRA/pediatrics/prior living donors. The Pancreas Committee discussed the relative importance of proximity efficiency and qualifying time, as these attributes would be driving the scores for the majority of kidney-pancreas (KP) and pancreas candidates.

The Pancreas Committee identified the proximity efficiency and qualifying time attributes as being the key drivers among the attributes for pancreas allocation, however, the Pancreas Committee discussed the need in still maintaining high access for the other attributes (CPRA, pediatrics, and prior living donor).[128] The Pancreas Committee then reviewed six scenarios and weights that looked at different ratios of weights for proximity efficiency and qualifying time (QT).[129] As demonstrated in **Figure 33**, it is noted that in moving across the scenarios from left to right, there is an increase of the relative importance assigned to proximity efficiency relative to the weight of qualifying time.

[127] OPTN Pancreas Transplantation Committee Meeting Summary, January 20, 2023.
[128] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.
[129] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.

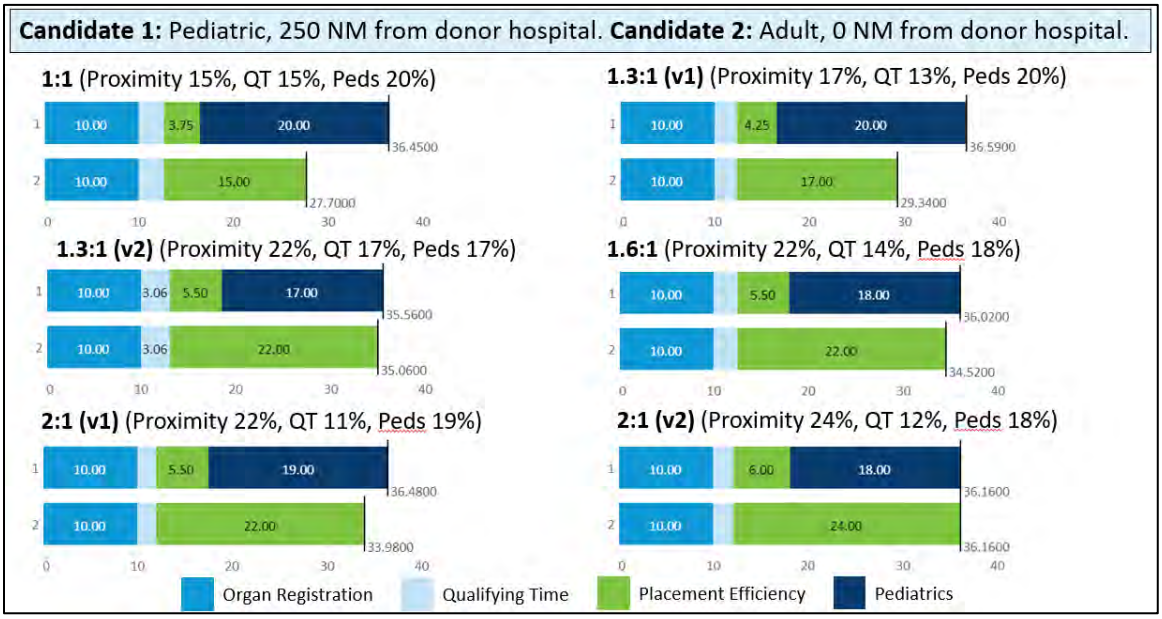
Figure 33: Potential Scenarios Reviewed for OASIM Modeling Request

Increasing weight on proximity relative to QT →

	Proximity Efficiency : Qualifying Time Ratio					
Attribute	**1:1**	**1.3:1 (v1)**	**1.3:1 (v2)**	**1.6:1**	**2:1 (v1)**	**2:1 (v2)**
Proximity Efficiency	15%	17%	22%	22%	22%	24%
Qualifying Time	15%	13%	17%	14%	11%	12%
CPRA	20%	20%	17%	18%	19%	18%
Pediatrics	20%	20%	17%	18%	19%	18%
Prior Living Donor	20%	20%	17%	18%	19%	18%
Organ Registration	10%	10%	10%	10%	10%	10%

As previously mentioned, to evaluate whether these scenarios would provide appropriately high access for pediatric candidates and prior living donors, the Tableau sensitivity tool was used to compare CAS for different candidate profiles (**Figure 34**).

Figure 34: Tableau Sensitivity Tool Two Candidate Comparisons



In all of the comparisons as demonstrated above in **Figure 34**:

- Candidate one (represented by the top bar) is a pediatric candidate registered at a transplant program 250NM from the donor hospital
- Candidate two (bottom bar) is an adult registered 0NM from the donor hospital
- Both candidates are otherwise identical aside from their distance and pediatric status:
- Both candidates are registered for a PA/KP, meaning they receive the same amount of points for organ registration
- And both candidates have been waiting for exactly one year, meaning they receive the same amount of points for qualifying time

The length of the bars shows what these candidate's CAS scores would be under each of the six scenarios. The 1:1 scenario (upper left) shows a high weight for pediatrics and a much higher score than the nearby adult candidate. In contrast, the 2:1 (v2) scenario (bottom right) shows the highest weight on proximity, resulting in a tie between these two candidates' scores. The Pancreas Committee wanted the pediatric candidate to have a higher score than the nearby adult candidate and therefore voted to not send the 2:1 (v2) scenario for final modeling.[130]

The Pancreas Committee strongly supported the 1:1 scenario to model proximity efficiency and qualifying time at an equal weight, as the other scenarios places higher weight on proximity efficiency than qualifying time. The Pancreas Committee discussed having variation among the modeling of the remaining scenarios and decided the 1.3:1 (v2) would provide some contrast to the 1:1 scenario to review in comparison to the 1.3:1 (v1) scenario.[131] Therefore, the Pancreas Committee voted to not send the 1.3:1 (v1) scenario for final modeling.[132]

OASIM Request

The Pancreas Committee discussed the MIT dashboard results and the Tableau candidate comparisons as previously outlined and ultimately selected the four policy options outlined below (**Figure 35**), which includes a range from a 1:1 ratio to 2:1 ratio.

Figure 35: Pancreas OASIM Scenarios Submitted for second OASIM Request

	Proximity Efficiency : Qualifying Time Ratio			
Attribute	**1:1**	**1.3:1 (v2)**	**1.6:1**	**2:1 (v1)**
Proximity Efficiency	15%	22%	22%	22%
Qualifying Time	15%	17%	14%	11%
CPRA	20%	17%	18%	19%
Pediatrics	20%	17%	18%	19%
Prior Living Donor	20%	17%	18%	19%
Organ Registration	10%	10%	10%	10%

These four scenarios were approved by the Pancreas Committee on March 6, 2023 and submitted as scenarios to be included in the second OASIM request. [133] This second round of modeling narrows the focus to test those attributes and associated rating scales and weights that would most likely be considered for the final proposal. Results of the second OASIM modeling request are expected in the summer of 2023.

[130] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.
[131] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.
[132] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.
[133] OPTN Pancreas Transplantation Committee Meeting Summary, March 6, 2023.

Appendix A: Attributes and Rating scales

Kidney Attributes and Rating Scales*

**as included in the second OASIM request*

Attributes	Goal	Rating Scale
Medical Urgency	Medical Urgency	Binary (yes/no)
HLA Matching	Post-Transplant Survival	0, 1, or 2 DR mismatch
Estimated Post Transplant Survival (EPTS)/Kidney Donor Profile Index (KDPI)[134]	Post-Transplant Survival	0-20% EPTS Priority for 0-20% KDPI Kidneys
Blood Type	Candidate Biology	Current screening + blood type points
CPRA	Candidate Biology	Steep, non-linear curve
Prior Living Donors	Patient Access	Binary (Yes/No)
Pediatrics	Patient Access	Binary (Yes/No)
Safety Net	Patient Access	Binary (Yes/No)
Waiting Time	Patient Access	Linear, exceeds 100% beyond 10 years (no ceiling)
Proximity Efficiency	Placement Efficiency	Piecewise linear, 50 NM inner plateau, 85% at 250NM, 25% at 500NM, 0% at 5181 NM

Pancreas, Kidney-Pancreas (KP), Islets Attributes and Rating Scales*

**as included in the second OASIM request*

Attributes	Goal	Rating Scale
CPRA	Candidate Biology	Steep, non-linear curve
Prior Living Donors	Patient Access	Binary (yes/no)
Pediatrics	Patient Access	Binary (yes/no)
Waiting Time	Patient Access	Two-piece linear, inflection point: 90% at 5 years; shallower line beyond 5 years to max
Proximity Efficiency	Placement Efficiency	Piecewise linear, 50 NM inner plateau, 25% at 250 NM, 0% at 5181 NM
Whole Pancreas (KP/PA), Not Pancreas Islets	Non-use/Avoid organ wastage	Binary (yes/no)

[134] Pediatric candidates will be assigned the lowest possible EPTS score.

Appendix B: Continuous Distribution Resources

For additional information on the continuous distribution framework and the work of the OPTN, visit: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/

The Kidney and Pancreas Committees have released four previous updates for public comment including:

- Summer 2021 *Continuous Distribution of Kidneys and Pancreata Concept Paper*
- Winter 2022 *Continuous Distribution of Kidneys and Pancreata Request for Feedback*
- Summer 2022 *Continuous Distribution of Kidneys and Pancreata Committee Update*
- Winter 2023 *Continuous Distribution of Kidneys and Pancreata Committee Update*

Supplemental reports:

- *Continuous Distribution of Kidneys Winter 2022 Prioritization Exercise Community Results*
- *Continuous Distribution of Pancreata Winter 2022 Prioritization Exercise Community Results*
- *SRTR Organ Allocation Simulator (OASIM) Modeling Results*, October 2022 and January 2023

Other continuous distribution resources:

- *Continuous Distribution Overview*
- *Ethical Considerations of Continuous Distribution in Organ Allocation White Paper*
- *Continuous Distribution of Lungs*
- *Continuous Distribution of Livers and Intestines*