

## *Committee Update*

# Update on Continuous Distribution of Kidneys and Pancreata

*OPTN Kidney & Pancreas Transplantation Committees*

*Prepared by: Lindsay Larkin and Joann White, MPH  
UNOS Policy and Community Relations Department*

## Contents

Executive Summary	2
Background	3
Progress So Far	5
NOTA and Final Rule Analysis	37
Conclusion	39
Considerations for the Community	39
Appendix: Glossary of Terms	40



# Update on Continuous Distribution of Kidneys and Pancreata

*Sponsoring Committees:*                      *Kidney & Pancreas Transplantation*  
*Public Comment Period:*                      *August 3, 2022 – September 28, 2022*

## Executive Summary

This paper provides an update to the community about the continuous distribution of kidneys and pancreata projects being developed by the OPTN Kidney and Pancreas Transplantation Committees (the Committees). Continuous distribution will replace the current classification approach, which draws hard boundaries between types of patients, with a composite score that simultaneously takes into account donor and candidate attributes used in allocation. This score will be constructed with multiple attributes that align with the National Organ Transplant Act (NOTA) and the OPTN Final Rule.<sup>1,2</sup>

This paper builds upon the 2021 *Continuous Distribution of Kidneys and Pancreata Concept Paper* and 2022 *Continuous Distribution of Kidneys and Pancreata Request for Feedback* and contains most recent discussions and decisions regarding attributes and their associated rating scales. Input into the first round of modeling is also outlined.<sup>3,4</sup> Finally, this paper provides an overview of next steps for the continuous distribution of kidneys and pancreata projects.

The end of this document has a glossary of terms to help readers.

---

<sup>1</sup> NOTA, 42 U.S.C. § 273 et. seq.

<sup>2</sup> 42 C.F.R. § 121.8

<sup>3</sup> *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

<sup>4</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

## Background

Continuous distribution is a points-based framework that assigns a composite allocation score (CAS) that takes into account all of a candidate's characteristics. The goal of this project is to replace the current **classification-based framework**, which draws hard boundaries between types of patients with a **points-based framework**, creating a CAS.<sup>5</sup> This score would be constructed with multiple attributes that align with NOTA and the OPTN Final Rule.<sup>6</sup>

As detailed in the 2021 Concept Paper, **Figure 1** shows how these five sub-scores combine into a composite allocation score.<sup>7</sup> Combining multiple sub-scores together into one CAS allows holistic consideration of all of the factors that must be considered to satisfy the regulatory requirements for organ allocation policies. Finally, by constructing the CAS around the performance goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule.<sup>8</sup>

**Figure 1: Components of Composite Allocation Score**



**Figures 2** and **3** show how potential kidney, pancreas, or kidney-pancreas (KP) composite allocation scores could function. Candidates would receive points for each of the different attributes used to prioritize candidates. The amount of points given to each candidate would depend upon the candidate's specific situation, the rating scale for that attribute, and the amount of weight given to that attribute.

The maximum amount of points given for any attribute is determined by the weight given to that attribute. In **Figure 3**, the amount of points given to a candidate varies depending upon the candidate's specific circumstances. The classification-based system currently prevents all patients in a lower classification from being prioritized ahead of any patients in a higher classification, regardless of considerations regarding medical need, inequities in access, or benefit of transplantation (**Figure 2**). A continuous distribution framework will eliminate hard boundaries resulting from the current system, in which candidates are grouped into classifications. Candidates will receive points for various attributes and all of these attributes can be considered as part of a composite allocation score (**Figure 3**). A candidate's CAS will determine the order in which the candidate will receive an organ offer.

<sup>5</sup> Continuous distribution aims to create a more fair and patient-focused system for organ allocation. 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/>

<sup>6</sup> 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.

<sup>7</sup> *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

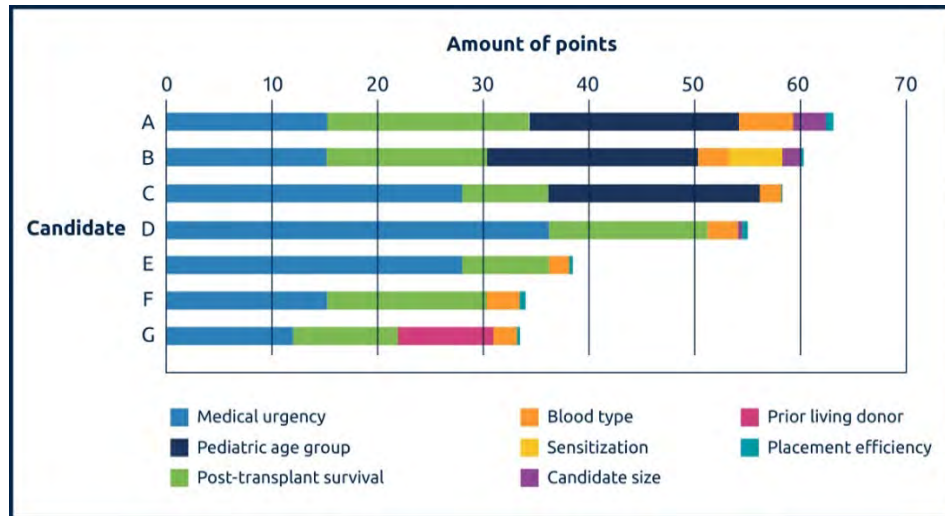
<sup>8</sup> 42 CFR § 121.8

**Figure 2: Sample Allocation Policy (Current)<sup>9</sup>**

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

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

10



<sup>9</sup> Note that candidates are placed into specific classifications and cannot move between them.

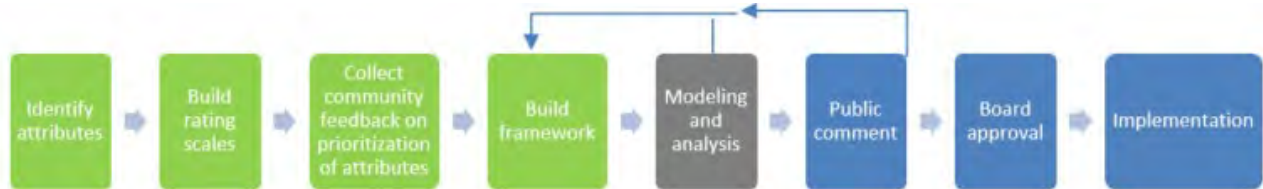
<sup>10</sup> Note each color represents a different attribute and the length of the bar shows the points credited to that attribute. Note that candidates receive points for multiple considerations and can move up or down depending on each attribute.

work with OPTN, SRTR, and outside researchers to develop evidence-based rating scales for each attribute.<sup>11,12</sup>

## Progress So Far

The Committees are tasked with developing a comprehensive proposal for the continuous distribution of kidneys and pancreata. The project is progressing through several phases, as seen in **Figure 4**. For more details on the project plan and each step in the process, please refer to the Committee’s earlier Concept Paper and Request for Feedback papers.<sup>13,14</sup>

**Figure 4: Project Overview<sup>15</sup>**



In 2020, the Kidney and Pancreas Committees formed a joint workgroup (hereinafter, the Workgroup) to conduct their continuous distribution projects simultaneously. The goal of working jointly is to align efforts and to identify where allocation practices should overlap and where they should differ between organ types. The Workgroup includes members of the OPTN Kidney, Pancreas, Pediatric, Minority Affairs, Ethics, and Histocompatibility Committees as well as additional experts in transplantation. Additionally, a cross-organ group of OPTN leaders are often consulted to build consensus around common approaches. The Committees will continue to include additional cross-committee and subject matter expertise as the projects develop.

In January 2022, the Kidney and Pancreas Committees publicly released two online value prioritization exercises specific to kidney and pancreas. The exercises used an Analytic Hierarchy Process (AHP) methodology.<sup>16,17</sup> The results from the AHP exercises (summarized below) provided insight on trends seen across and within demographic groups related to the identified attributes and recommendations on how these attributes should be weighted.<sup>18</sup> The Committees reviewed the results of the AHP exercises along with public comment feedback from the previous papers to help inform their discussions

<sup>11</sup> The SRTR is the Scientific Registry of Transplant Recipients. They provide statistical and other analytic support to the OPTN for purposes including the formulation and evaluation of organ allocation and other OPTN policies.

<sup>12</sup> An attribute’s rating scale is the assignment of all possible values of the attribute to a number ranging between 0 and 1. Attribute values assigned higher ratings are valued more highly for prioritizing patients, and vice versa, consistent with allocation policy goals. Converting attribute values to ratings using a consistent (0-100) scale allows attributes of various types (for example, blood types and waiting times) to be combined into a single, composite allocation score.

<sup>13</sup> *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

<sup>14</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

<sup>15</sup> The first four, green boxes indicate steps that have already occurred. The grey box is the current stage of the project. The three, blue boxes indicate the forthcoming stages of the project.

<sup>16</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

<sup>17</sup> Learn more about the AHP prioritization exercises on the OPTN website here: [https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD\\_BuildTheFramework](https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework)

<sup>18</sup> The full reports for both the kidney and pancreas AHP exercises can be found on the OPTN website here: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>

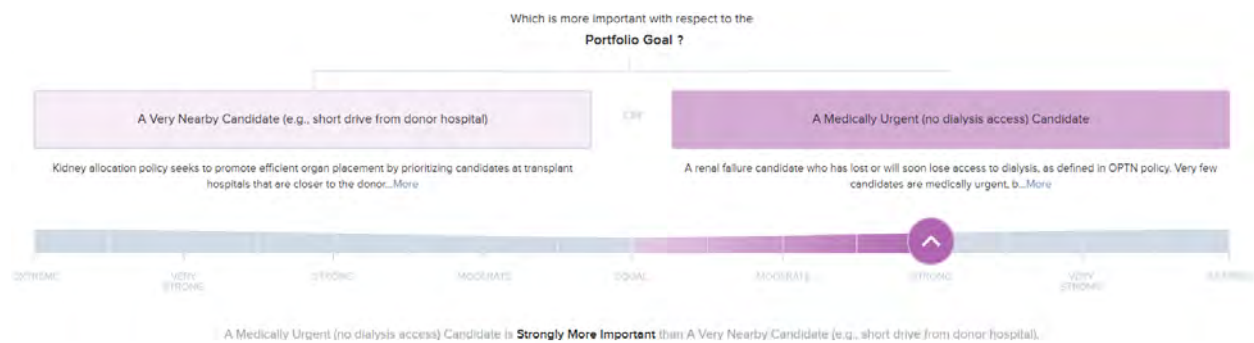
and development of a modeling request for an SRTR simulation to analyze the impact of these attributes weighted in the continuous distribution framework. Additional information on those discussions and decisions is explained in further detail below.

## Analytic Hierarchy Process (AHP) Exercise

AHP is a multi-criteria decision making methodology that asks participants a series of questions to compare the relative importance of a set of criteria through multiple pairwise comparisons.<sup>19</sup> Similar to the approach used by the OPTN Lung Committee, the Kidney and Pancreas Committees utilized this approach for its strengths in collecting value judgments from a broad and diverse community.<sup>20,21</sup>

In this exercise, participants provided their value judgments for each pairwise comparison of attributes, or patient profiles, in the project hierarchy (see **Figure 5**). Attribute comparisons were rated from 1 (equal importance) to 9 (extremely important).

**Figure 5: Sample Pairwise Comparison**



## Kidney and Pancreas AHP Exercise Results

Participants were asked to indicate their preferences between pairs of attributes, described as patient profiles, in terms of how important each attribute should be in prioritizing candidates for kidney or pancreas transplantation.<sup>22</sup> For example, to compare the relative importance of the medical urgency and candidate biology attributes, participants were asked to compare “a medically urgent candidate” with “a biologically difficult to match candidate”. Participants were instructed to assume two otherwise identical patients differed only in the attributes being compared, reflecting the extremes of two different attributes. These pairwise comparisons were then aggregated into overall preferences, or relative importance “weights,” for the different attributes. Within each pairwise comparison, there is some variance across the demographic groups but general consistency overall. The full AHP reports for both the kidney and pancreas AHP exercises are available on the OPTN website.<sup>23</sup>

<sup>19</sup> Meeting summary for August 20, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>20</sup> See generally Mark, T. L., & Swait, J., 2004. *Using stated preference and revealed preference modeling to evaluate prescribing decisions*. Health economics.

<sup>21</sup> See generally, Lin, Carol and Harris, Shannon 2013. *A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study*. Journal of Multi-Criteria Decision Analysis.

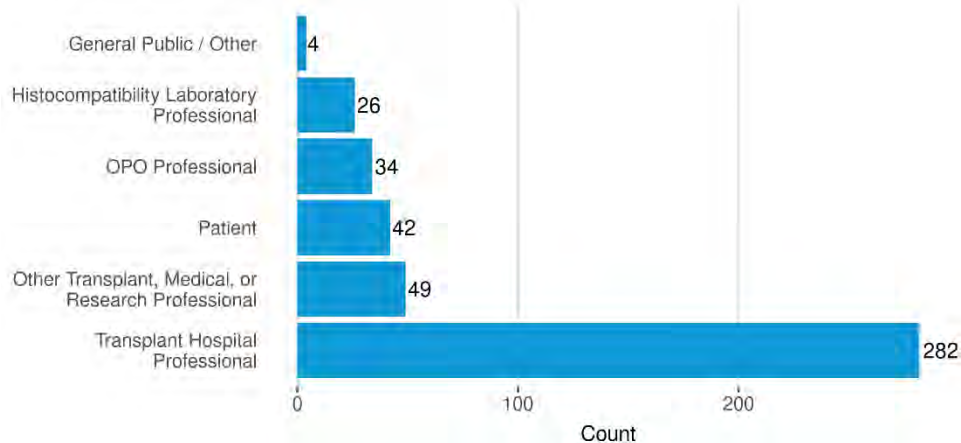
<sup>22</sup> For example, “Candidate Biology” was described as “An extremely (biologically) difficult to match candidate”.

<sup>23</sup> The full reports for both the kidney and pancreas AHP exercises can be found on the OPTN website here: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>

## Participation

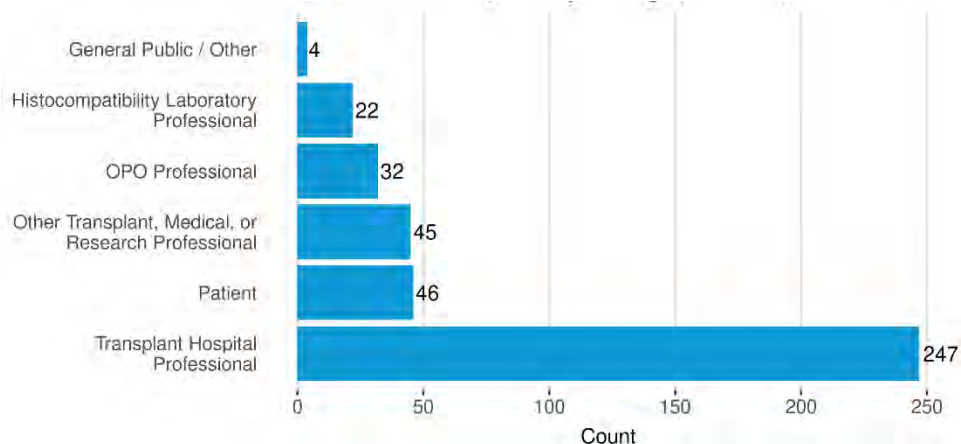
The AHP exercises opened on January 27 and closed on March 23, 2022, and were presented at 11 regional meetings and 10 OPTN committee meetings.<sup>24</sup> **Figures 6 and 7** show the participation by demographic group. 431 individuals submitted responses to the kidney exercise and 390 to the pancreas exercise. When registering for the exercises, participants were asked for their relationship to transplant. The most frequent participant group was transplant hospital professionals, followed by other transplant, medical, or research professionals, patients, organ procurement organization (OPO) professionals, histocompatibility laboratory professionals, and general public/other. It's also important to note participants may belong to more than one demographic group (ex. a transplant hospital professional who is also a transplant recipient).

**Figure 6: Kidney AHP Exercise Participation by Demographic Group**



431 individuals participated in the exercise. Participants may belong to more than one demographic group; as such, the sum of all demographic groups is greater than the total number of participants.

**Figure 7: Pancreas AHP Exercise Participation by Demographic Group**



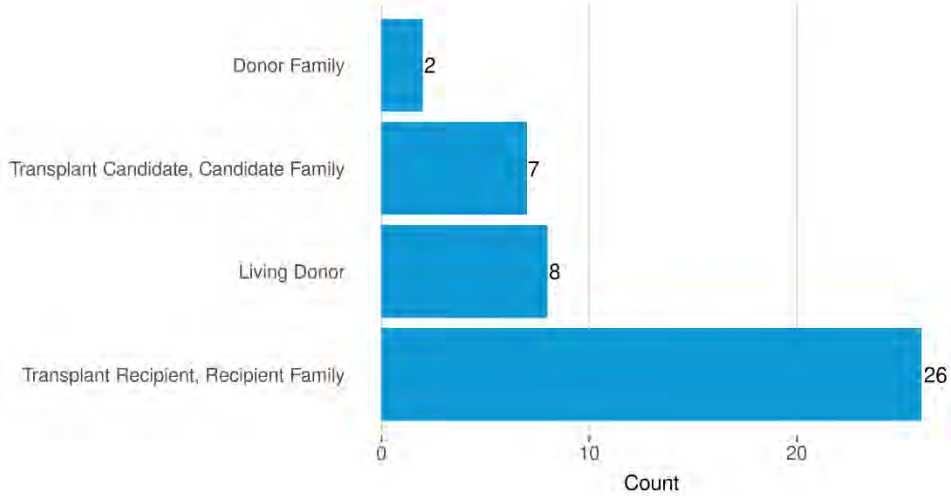
390 individuals participated in the exercise. Participants may belong to more than one demographic group; as such, the sum of all demographic groups is greater than the total number of participants.

<sup>24</sup> OPTN Ethics, Multi-Organ Transplant, Transplant Coordinators, Transplant Administrators, Minority Affairs, Pediatrics, Patient Affairs, Organ Procurement Organization, Living Donor, and Histocompatibility Committees.

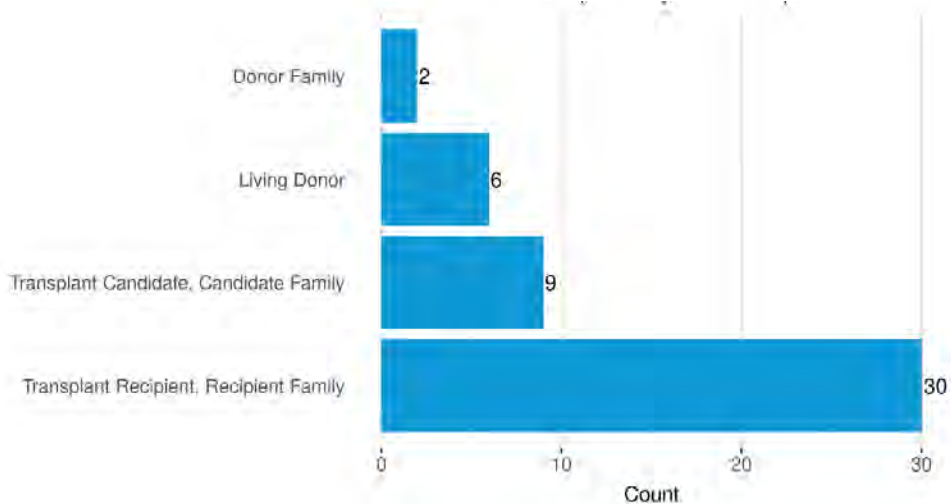


Figures 8 and 9 show the participation of the different patient populations included under the Patient demographic category. Within the patient populations, the majority of the participants were either transplant recipients or recipient family members.

**Figure 8: Kidney AHP Exercise Patient Participation by Patient Population**



**Figure 9: Pancreas AHP Exercise Patient Participation by Patient Population**



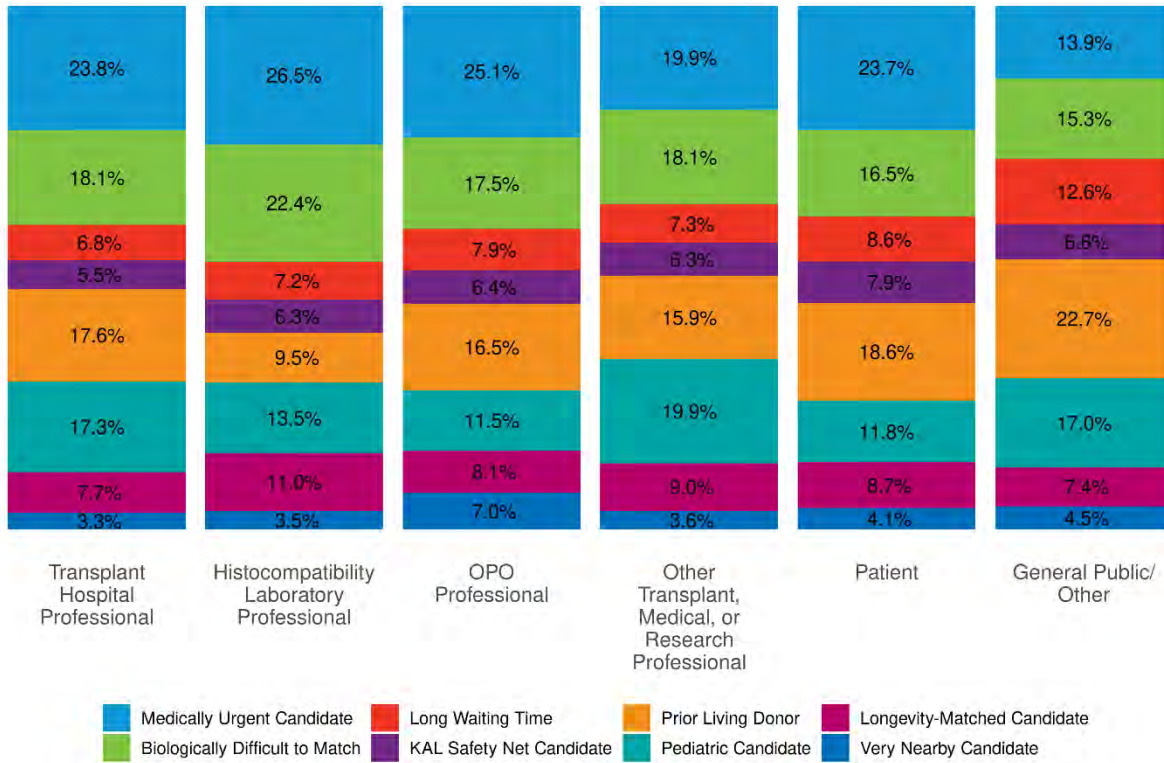
### Overall Ratings

The analysis revealed general consistency in the weights across the different demographic groups, as shown in **Figures 10 and 11**. When viewed as rankings, the most important attribute for kidney was “a medically urgent (no dialysis access) candidate” (medical urgency), while the most important attribute for pancreas was “an extremely (biologically) difficult to match candidate” (candidate biology). The least important attribute for both kidney and pancreas was “a very nearby candidate, e.g. short drive from donor hospital” (placement efficiency). Additionally, participants were asked when comparing these attributes not to consider the frequency of the event, but rather how much priority the candidate should receive in the event that this actually occurs (ex. prior living donor). In viewing these overall ratings, bear in mind that this is not a public opinion survey; the results should consider the participant’s



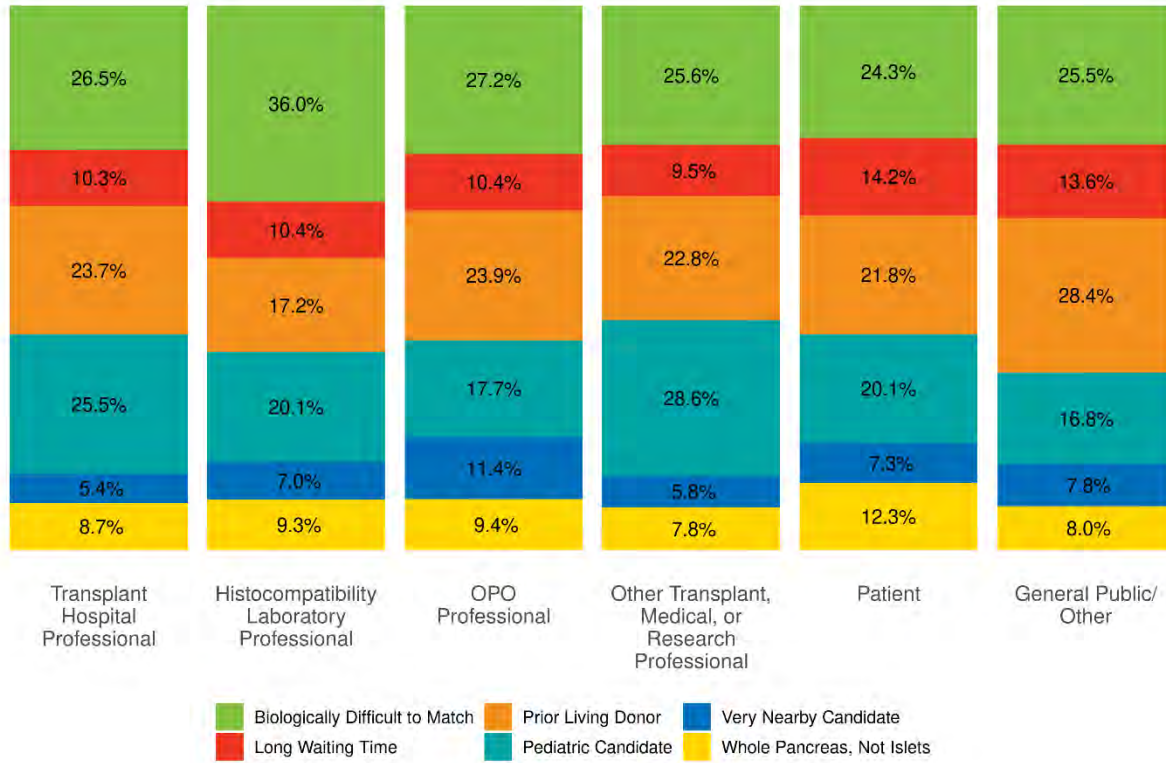
comments alongside the ratings, and this is only one piece of evidence that the committee will use to develop their policy proposals. These comments can be found in the full AHP reports available on the OPTN website.<sup>25</sup>

**Figure 10: Kidney AHP Exercise Overall Ratings by Demographic Group**



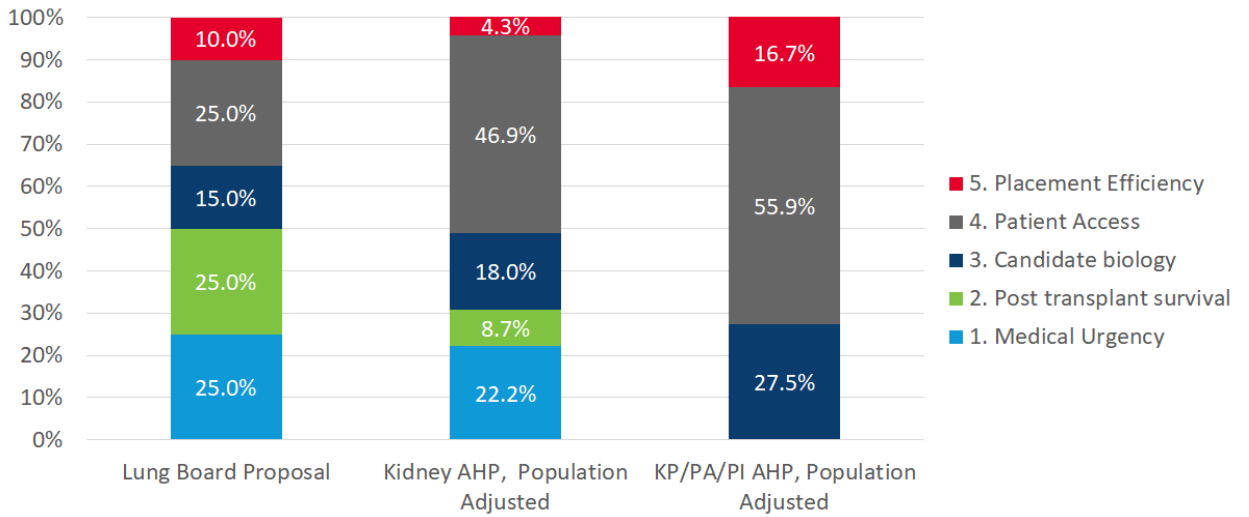
<sup>25</sup> The full reports for both the kidney and pancreas AHP exercises can be found on the OPTN website here: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>

**Figure 11: Pancreas AHP Exercise Overall Ratings by Demographic Group**



The OPTN has now conducted AHP exercises for three organ systems, as compared in **Figure 12**. While the OPTN seeks a consistent framework for allocation in continuous distribution, there is also the need to tailor the allocation systems to the clinical needs of each organ system. Similarly, all three exercises placed the least emphasis on placement efficiency. It is important to note that each exercise had more organ-specific attributes, so the number of pairwise comparisons under each goal may differ (ex. the kidney exercise included a medical urgency attribute where the pancreas exercise did not).

**Figure 12: Cross-Organ AHP Results**



Finally, **Figures 13** and **14** show a view of the Kidney and Pancreas Committees' specific results.

**Figure 13: Kidney Committee Ratings**

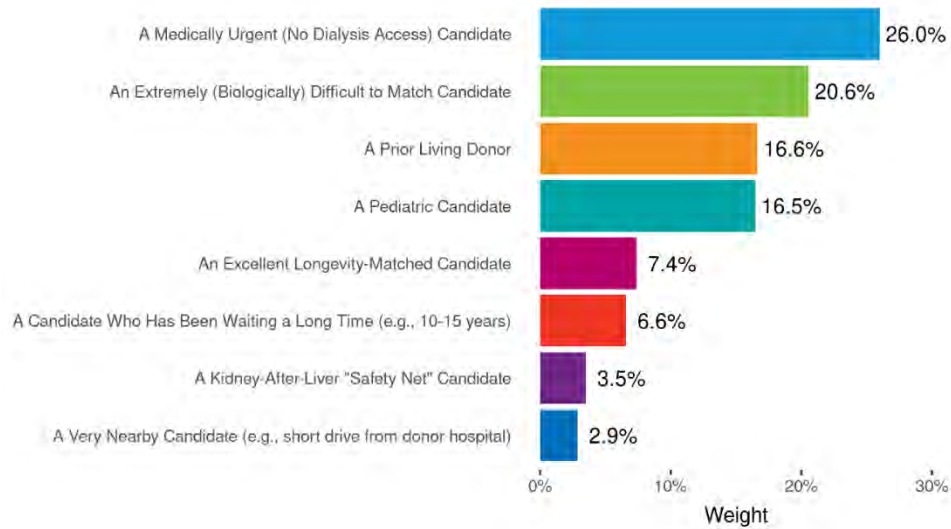
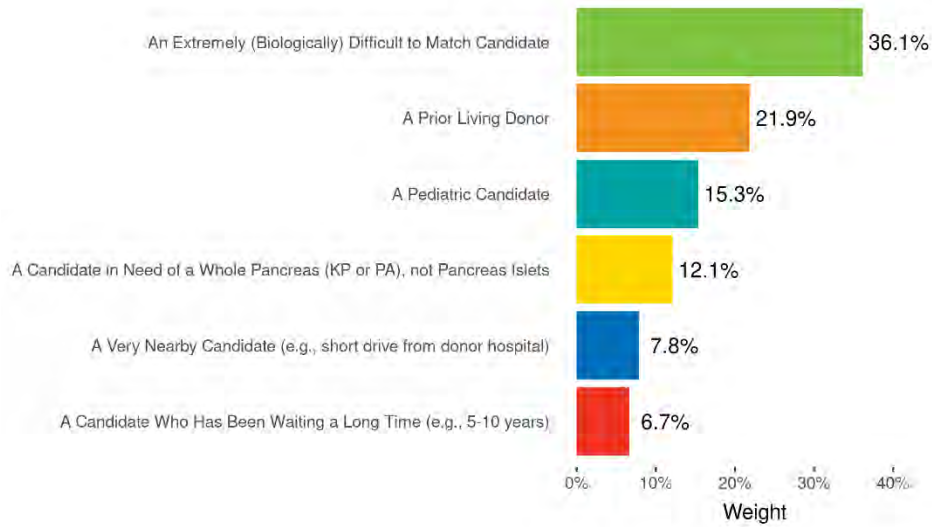


Figure 14: Pancreas Committee Ratings



The Committees and the Workgroup reviewed this analysis, along with their own priorities and the requirements in NOTA and the OPTN Final Rule. Importantly, the AHP exercise is not being rigidly used to prescribe weights for the composite allocation score. Rather, weights derived from AHP are used to guide the Committees in selecting attribute weights for SRTR simulation modeling and later optimization in a way that is informed by the transplant community. Using these weights as a baseline, the Workgroup then selected a set of scenarios, or a set of attribute weights and rating scales, to model and eventually build into the composite allocation score.

### Determining Rating Scales for Attributes

The Committees chose a rating scale for each attribute that is summarized in **Table 1** for kidney and **Table 2** for pancreas. These rating scales are included in this first Kidney-Pancreas Simulated Allocation Model (KPSAM) request. The 2022 Request for Feedback details the Committee and Workgroup discussions for most of the attribute rating scales except for a few that were awaiting further input.<sup>26</sup> Those particular rating scale discussions are explained further in the subsections below.

<sup>26</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

**Table 1: Kidney Attributes and Rating Scales**

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) <sup>27</sup>	Post-Transplant Survival	Continuous longevity matching <sup>28</sup>
Blood Type	Candidate Biology	Current screening + blood type points (with same curve as CPRA)
CPRA	Candidate Biology	Steep, non-linear curve
Prior Living Donors	Patient Access	Binary (yes/no)
Pediatrics	Patient Access	Binary (yes/no)
Kidney after Liver (KAL) 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 nautical miles (NM) inner plateau, 85% at 250NM, 25% at 500NM, 0% at 5181 NM

**Table 2: Pancreas, Kidney-Pancreas (KP), Islets Attributes and Rating Scales**

Attributes	Goal	Rating Scale
Blood Type	Candidate Biology	Relax KP screening + identical before compatible
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-utilization/Avoid organ wastage	Binary (yes/no)

**Medical Urgency Definition (Kidney):** Recently updated OPTN kidney policy contains a specific definition for medical urgency, which includes a candidate’s imminent loss of dialysis.<sup>29</sup> Therefore, the kidney-specific objective for this category is to “prioritize those with high mortality due to imminent loss of dialysis” and the specific medical urgency definition was identified as an attribute. In reviewing the

<sup>27</sup> EPTS assumed to be 1 percent for pediatric candidates.

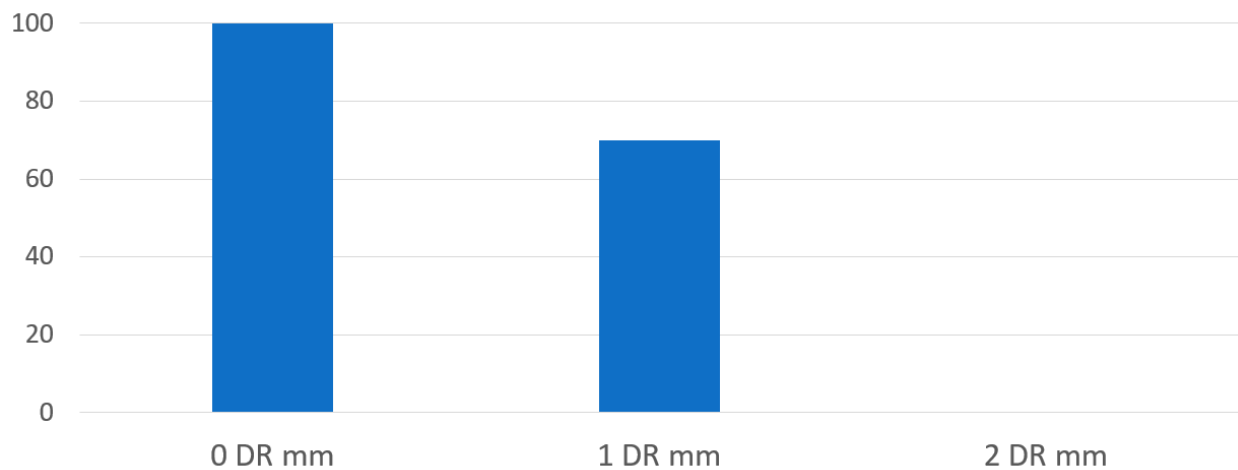
<sup>28</sup>  $R_{LM} = (0.5 + 2*(EPTS/100 - 0.5) * (KDPI/100 - 0.5))$

<sup>29</sup> Meeting summary for October 8, 2021 meeting, OPTN Kidney Transplantation Committee.

results of the kidney AHP exercise, this attribute was consistently given high value across the demographic groups (see **Figure 10**). As described in the previous paper, the Kidney Committee approved a binary (yes or no) rating scale for this attribute depending on whether the candidate meets the medical urgency criteria outlined in the current policy.<sup>30</sup> For the CAS, medically urgent candidates will receive 100 percent of the medical urgency attribute weight while non-medically urgent candidates will receive zero points for this attribute.

**HLA Matching (Kidney):** Per the previous paper, the Workgroup agreed to a rating scale where DR antigen matching would be prioritized with points being assigned based on the level of HLA mismatch for kidney allocation only. **Figure 15** shows the recommended DR rating scale, with zero points for 2DR mismatch (mm), one point for 0DR mm, and 0.7 points for 1DR mm. Due to lack of available data, the Workgroup agreed not to include HLA matching as an attribute for pancreata but may consider adding the attribute back in a future iteration of the framework as more data becomes available.<sup>31</sup> Some recent public comment feedback suggests that the weighting of HLA matching should be small in comparison to other equal or similar attributes due to additional factors within post-transplant survival that are hard to predict or classify.

**Figure 15: HLA DR Matching Rating Scale**



**EPTS (Kidney):** The previous paper outlined potential options the Workgroup was considering for mapping EPTS and KDPI scores in the new system.<sup>32</sup> These options included converting the current top 20 percent EPTS to top 20 percent KDPI model, using EPTS independent of KDPI, and expanding longevity matching across the full spectrum of KDPI and EPTS (ex. low EPTS candidates receiving longevity matching points for low KDPI kidneys, and vice versa).

The Workgroup sought feedback from the community on the possibility of expanding longevity matching in the new system. Recent public comment showed mixed feedback with some in support of maintaining current practice and others in support of considering a continuous scale for EPTS and KDPI. Multiple commenters suggested consideration for weight differing depending on KDPI (low weight after 20 percent and increased weight after 85 percent) due to EPTS and KDPI being independent variables.

<sup>30</sup> Meeting summary for August 20, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>31</sup> Meeting summary for August 20, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>32</sup> To learn more about EPTS and KDPI calculations, visit the OPTN website here: <https://optn.transplant.hrsa.gov/data/allocation-calculators>

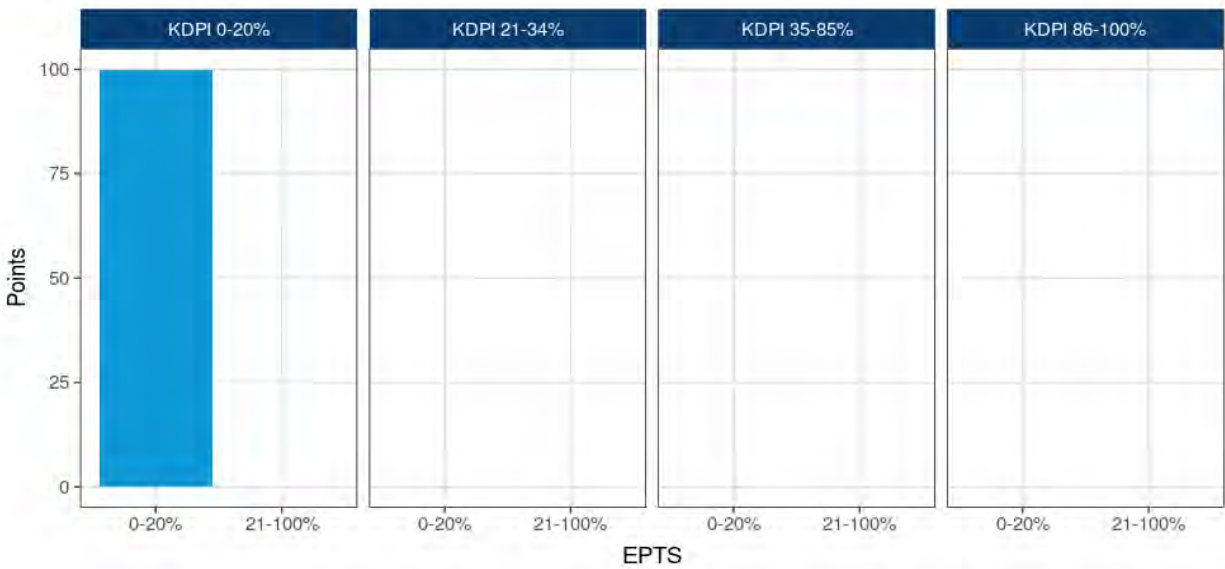


There was also a suggestion to add more granularity to EPTS and that combining with KDPI could create a stronger predictive calculation for continuous distribution.

The Kidney Committee reviewed public comment feedback along with three potential rating scale options as described below:

- Categorical longevity matching scale (Maintain top 20 to top 20 cutoff):** The categorical rating scale option would replicate current policy in a points based framework. **Figure 16** shows an example of the categorical scale maintaining the top 20 to top 20 cutoff.<sup>33</sup>

**Figure 16: Categorical Longevity Matching Rating Scale (Maintain top 20 to top 20 cutoff)**



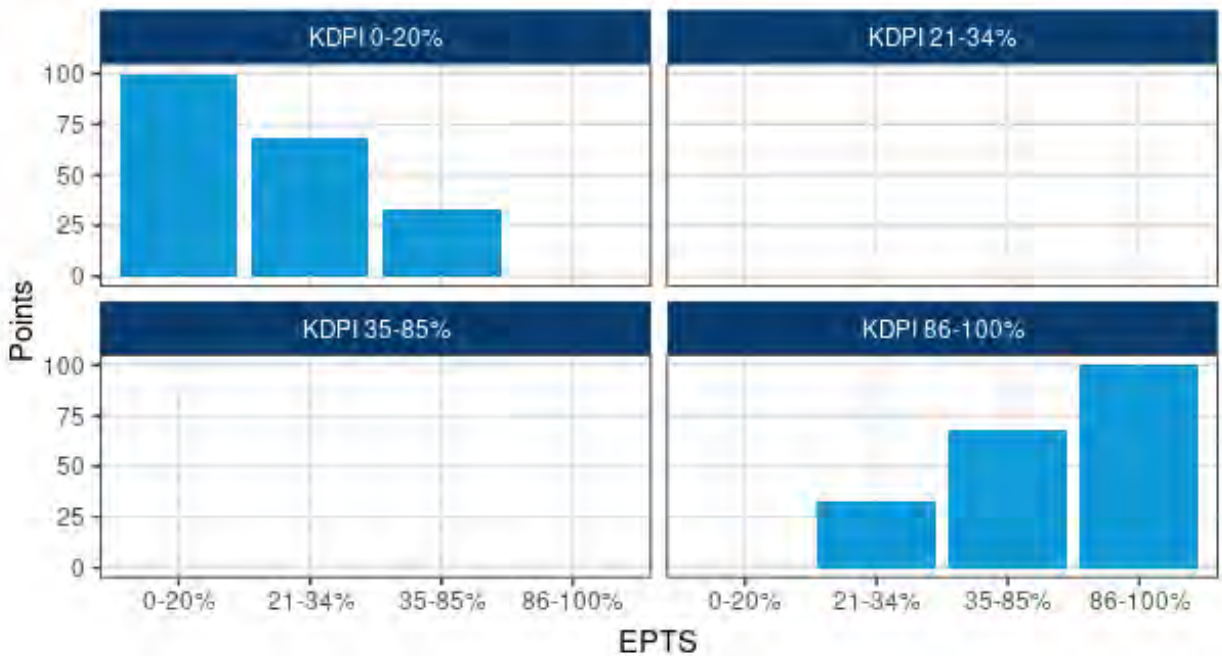
- Categorical longevity matching scale:** This option builds upon the previous option. Rating scales for attributes can be placed into categories dependent upon different donor characteristics.<sup>34</sup> **Figure 17** shows a hypothetical example that awards points for EPTS based upon different KDPI ranges.

<sup>33</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

<sup>34</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

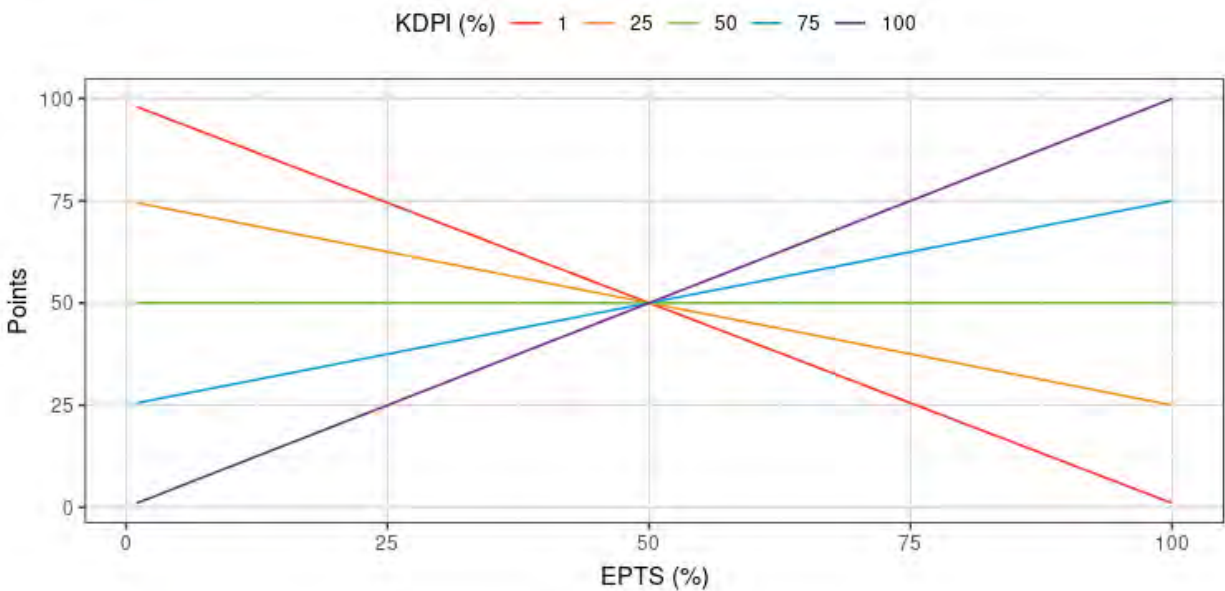


**Figure 17: Categorical Longevity Matching Rating Scale**



- Continuous longevity matching rating scale:** Figure 18 illustrates an example of the curved rating scale option. This approach would continue the practice of prioritizing low KDPI kidneys for candidates expected to have the best outcomes, and would have an extended curve for candidates in-between those low and high extremes.<sup>35</sup>

**Figure 18: Continuous Longevity Matching Rating Scale**



<sup>35</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

In discussing these rating scale options, the Kidney Committee supported the continuous rating scale option as they felt it more accurately reflects outcomes. Further, the Committee agreed that the system has a responsibility to make the best use of donor kidneys, meaning kidneys with the highest expected longevity should be allocated to candidates with the longest expected survival.<sup>36</sup>

Additionally, current kidney allocation does not assign an EPTS score to pediatric candidates. For modeling, pediatric candidates will be assigned the lowest possible EPTS score versus calculating an EPTS score for them individually. Subsequently, the Pediatric Committee is developing a data request to evaluate the predictive ability of EPTS in pediatric candidates.<sup>37</sup> The request is to calculate an EPTS score for pediatric candidates and assess whether it validates with post-transplant outcomes. If EPTS is predictive for pediatric candidates, then the Pediatric Committee will submit a second data request to ensure the predictive ability in pediatric sub-populations.

**CPRA (Kidney, Pancreas, and Kidney-Pancreas):** Per the previous paper, the Workgroup agreed on a steep, non-linear scale should be used for CPRA for both kidney and pancreas allocation to preserve priority for 99 and 100 percent CPRA candidates.<sup>38</sup> 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 19** (base of 100 was used in the lung continuous distribution project).<sup>39</sup> The Workgroup decided to include this steeper curve in each modeling scenario in an effort to better distinguish between the very high CPRA candidates. The Workgroup will evaluate the modeling results to determine if the steeper curve has the desired effect and its impact on low to medium CPRA candidates.

---

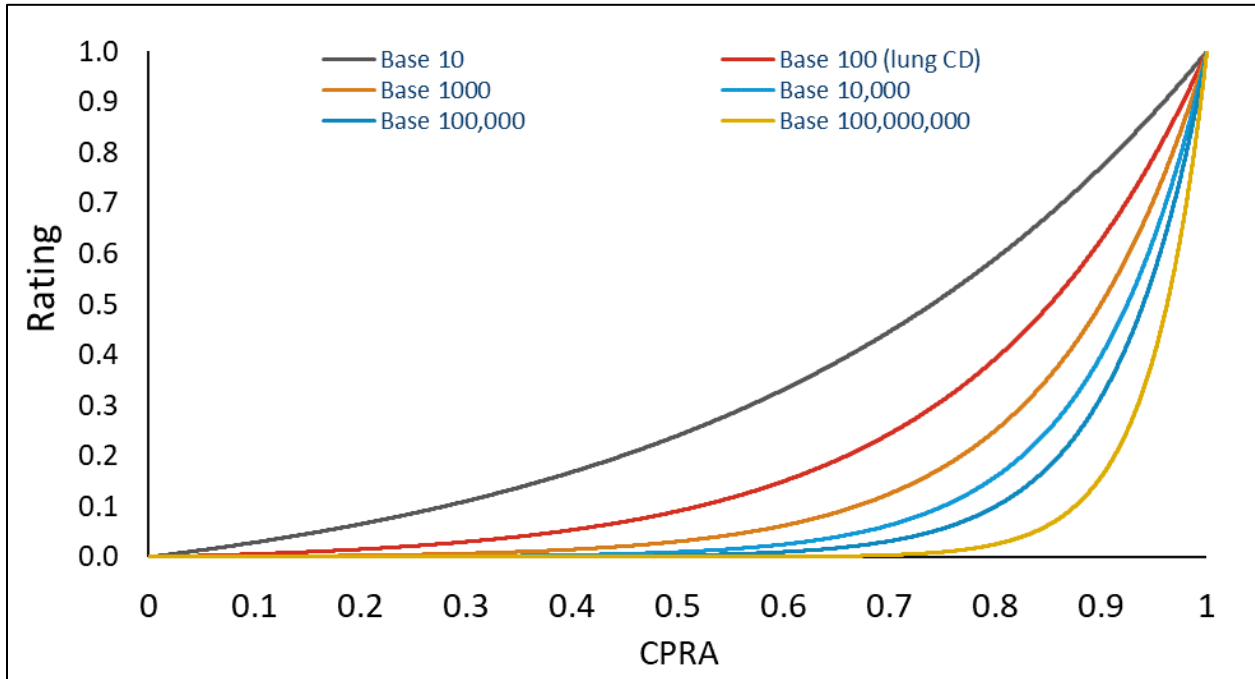
<sup>36</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

<sup>37</sup> Meeting summary for May 18, 2022 meeting, OPTN Pediatric Committee.

<sup>38</sup> Meeting summary for May 21, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>39</sup> Meeting summary for April 29, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

**Figure 19: Options for CPRA Curve**



**Blood type (Kidney, Pancreas, and Kidney-Pancreas):** As described in the Request for Feedback, kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with screening for blood types O and B to provide equity in the system.<sup>40</sup> In current kidney allocation, blood type O kidneys are reserved for blood type O recipients because of biological disadvantages in finding compatible donors.<sup>41</sup> 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.<sup>42</sup> The Workgroup recognizes the framework would need to allow for compatibility while accounting for the disadvantaged blood types.<sup>43</sup>

The Workgroup sought further community input on the best approach for a blood type rating scale. Public comment results showed support for prioritizing blood types O and B and for prioritizing non-A1/non-A1B kidneys to O and B candidates. Some commenters supported maintaining current screening policy for blood type O and B candidates and others supported a rating scale that would incorporate blood type and CPRA together in a combined score.

The Kidney and Pancreas Committees revisited this attribute after the close of public comment. The Kidney Committee discussed two rating scale options as described below:

- **Screening Option:** This option replicates current policy in a points-based framework and will screen off certain blood types (ex. non-O for O, except for O-ABDR mm). A points-based scale would still be

<sup>40</sup> OPTN Policy 8.5.D: Allocation of Kidneys by Blood Type as of June 15, 2022.

<sup>41</sup> Based on OPTN Data as of June 23, 2022.

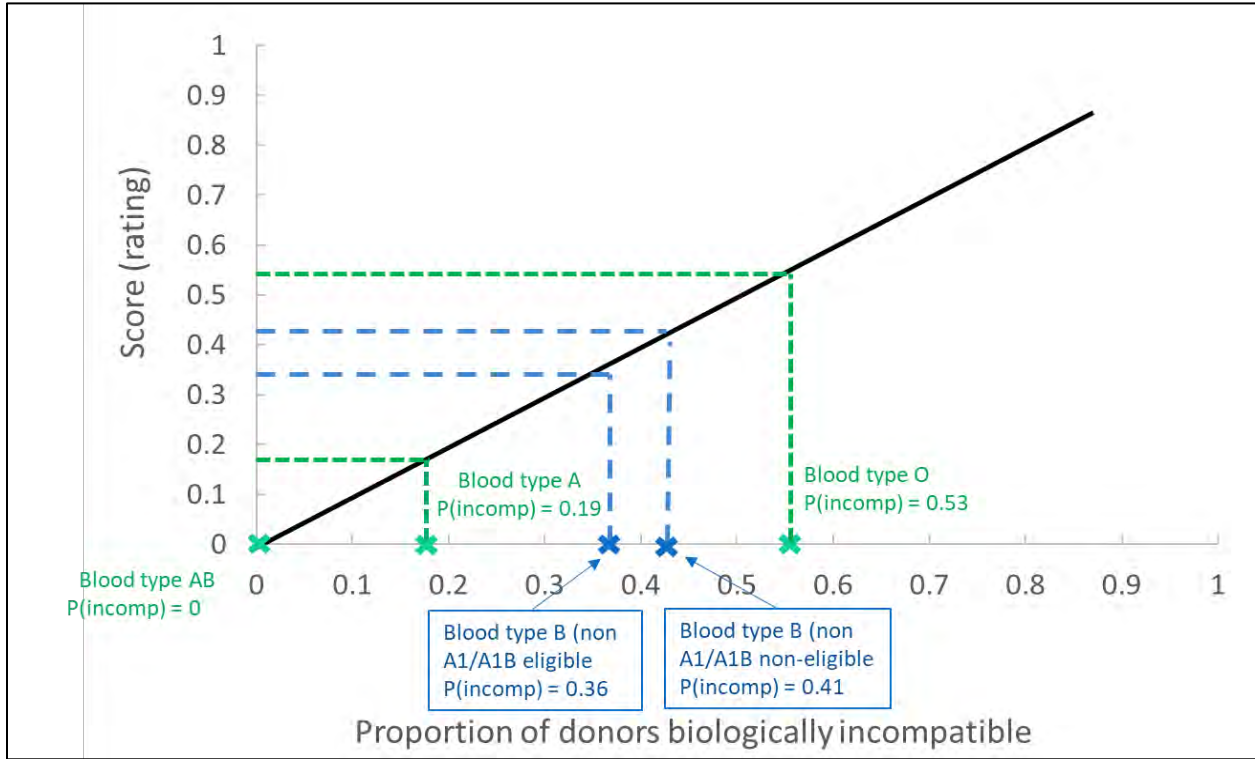
<sup>42</sup> OPTN Policy 11.5.D: Blood Type for Kidney-Pancreas Allocation as of June 15, 2022.

<sup>43</sup> Meeting summary for October 9, 2020 meeting, OPTN Pancreas Transplantation Committee.

considered to distinguish between compatible blood types.

- **Points Option:** This option would award points to candidates based upon their blood type and biological disadvantage.<sup>44</sup> This approach would be similar to CPRA and the technique used in lung continuous distribution. **Figure 20** provides an example.

**Figure 20: Example Rating Scale for Blood Type Points Option**



The Kidney Committee discussed these options and ultimately supported maintaining screening for blood type O and B for kidney allocation as those candidates have such limited access. Additionally, the Kidney Committee supported a rating scale that incorporates blood type and CPRA together, similar to **Figure 20**.<sup>45,46</sup>

The Pancreas Committee and the Workgroup discussed whether current blood type screening for KP allocation should be maintained in continuous distribution. Workgroup members stated that removing KP blood type screening would likely improve pancreas utilization with minimal impact on kidney alone candidates, as KP transplants comprise the majority of pancreata that are transplanted, but a relatively small proportion of all kidneys that are transplanted. After much discussion, the Workgroup supported removing KP blood type screening for this reason. The Workgroup also supported a binary rating scale that would prioritize identical over compatible blood types (see **Figure 21**).<sup>47</sup>

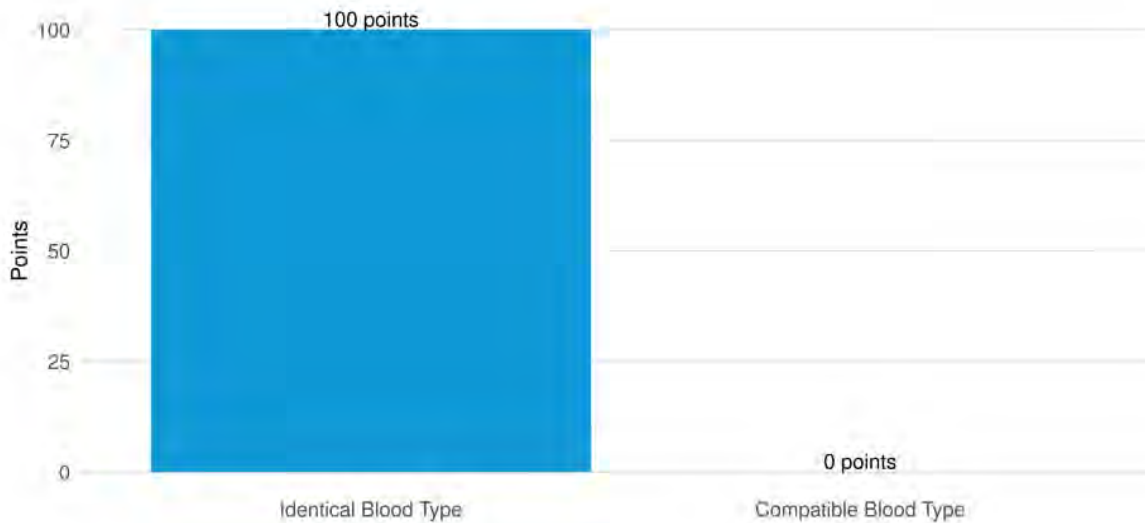
<sup>44</sup> Gragert L, Kadatz M, Alcorn J, Stewart D, Chang D, Gill J, Liwski R, Gebel H, Kransdorf E, Gill J, Lan J. "ABO-Adjusted CPRA": A Unified Metric for Immunologic Compatibility in Kidney Transplantation [abstract]. Am J Transplant. 2022; 22 (suppl 3).

<sup>45</sup> Meeting summary for April 23, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>46</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

<sup>47</sup> Meeting summary for April 22, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

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



**Prior living donor (Kidney, Pancreas, and Kidney-Pancreas):** As described in the previous paper, the Workgroup recommends utilizing a binary (yes or no) scale for all prior living donors.<sup>48</sup> The AHP results showed high weight placed on access for prior living donors across all demographic groups for both kidney and pancreas.<sup>49</sup> Additionally, the Patient Affairs Committee hosted a focus group of patient and living donor members to discuss the AHP results specific to this attribute.<sup>50</sup> The group agreed that prior living donors of any organ deserve significant priority on the basis of reciprocity and as a safety net in recognition of their significant gift.

**Pediatrics (Kidney, Pancreas, and Kidney- Pancreas):** The Workgroup previously agreed to a binary (yes or no) rating scale for pediatrics.<sup>51</sup> For pancreas, candidates who are under the age of 18 at the time they are registered on the waiting list will receive the full benefit of pediatric points. For kidney, the rating scale would be conditional on donor characteristics; candidates under the age of 18 would receive the full benefit of the pediatric points if specific donor criteria are met to match current pediatric prioritization within specific KDPI sequences. The AHP results showed high weight placed on access for pediatric candidates across all demographic groups for both kidney and pancreas.<sup>52</sup>

<sup>48</sup> Meeting summary for September 17, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>49</sup> The full reports for both the kidney and pancreas AHP exercises can be found on the OPTN website here: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>

<sup>50</sup> Meeting summary for March 30, 2022 meeting, OPTN Patient Affairs Committee.

<sup>51</sup> Meeting summary for January 29, 2021 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>52</sup> The full reports for both the kidney and pancreas AHP exercises can be found on the OPTN website here: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>

In 2020, the Kidney and Pediatric Committees formed a Workgroup to explore prioritization for pediatric candidates for pediatric donor kidneys with a KDPI score between 35 and 85 percent.<sup>53,54,55,56</sup> The Kidney-Pediatric Workgroup's recommendation to expand this prioritization was planned to be included as part of the continuous distribution project.<sup>57,58</sup> Community feedback in recent public comment cycles has also shown support for expanding pediatric priority for these types of kidneys. As part of the first modeling request, the Workgroup decided to incorporate this increased prioritization into each scenario.

**Waiting time (Kidney, Pancreas, and Kidney-Pancreas):** In the current system, waiting time is used to distinguish between candidates within the same classification. According to kidney, pancreas, and KP policy, one day of waiting time equals 1/365 of a point; therefore, one point is equivalent to approximately one year of waiting time.<sup>59, 60</sup>

As described in the previous paper, the Workgroup discussed several options for incorporating waiting time into a rating scale and sought further public comment.<sup>61</sup> When the Workgroup previously discussed the attribute, there was concern with establishing a ceiling for waiting time as it was felt to penalize the rare candidates who have very long waiting times. Workgroup members emphasized that many candidates with substantial amounts of waiting time are due to issues with access to transplant. The ability to backdate waiting time to the start of dialysis attempts to address those disadvantaged patients. Other Workgroup members questioned if having a ceiling would promote placement efficiency as candidates with long waiting times are also often highly sensitized and would receive a large amount of national offers. The Workgroup also discussed whether there should be an additional consideration for those candidates who qualify for waiting time based on dialysis, meaning those candidates who have been on dialysis longer receive greater points compared to those not on dialysis.

The Workgroup sought further feedback from public comment, the OPTN Ethics Committee, and the OPTN Patient Affairs Committee's patient focus group mentioned above.<sup>62,63</sup> On the subject of pre-dialysis waiting time, there was some support for considering GFR-qualified and dialysis waiting time differently, with support for weighting dialysis waiting time higher. There was also a recommendation to give points for pre-emptive listing to encourage pre-emptive transplant. Some members of the patient focus group felt long waiting times and extended use of dialysis can increase a patient's medical complexity and impact their outcomes as a recipient. Others expressed concerns for organ utility, questioning whether medically complex patients with long dialysis times would be the best longevity match.

There was general support for significant weighting of waiting time and no limit to waiting time. The Ethics Committee noted that capping waiting time does not address unfair disadvantages with access to

<sup>53</sup> Meeting summary for July 14, 2020 meeting, OPTN Kidney Transplantation Committee Kidney-Pediatric Workgroup.

<sup>54</sup> Meeting summary for August 10, 2020 meeting, OPTN Kidney Transplantation Committee Kidney-Pediatric Workgroup.

<sup>55</sup> Meeting summary for September 14, 2020 meeting, OPTN Kidney Transplantation Committee Kidney-Pediatric Workgroup.

<sup>56</sup> Meeting summary for September 21, 2020 meeting, OPTN Kidney Transplantation Committee.

<sup>57</sup> Meeting summary for October 14, 2020 meeting, OPTN Policy Oversight Committee.

<sup>58</sup> Meeting summary for October 16, 2020 meeting, OPTN Kidney Transplantation Committee.

<sup>59</sup> OPTN Policy 8.3: Kidney Allocation Score as of June 23, 2022.

<sup>60</sup> OPTN Policy 11.2: Pancreas Allocation Score as of June 23, 2022.

<sup>61</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

<sup>62</sup> Meeting summary for October 21, 2021 meeting, OPTN Ethics Committee.

<sup>63</sup> Meeting summary for March 30, 2022 meeting, OPTN Patient Affairs Committee.

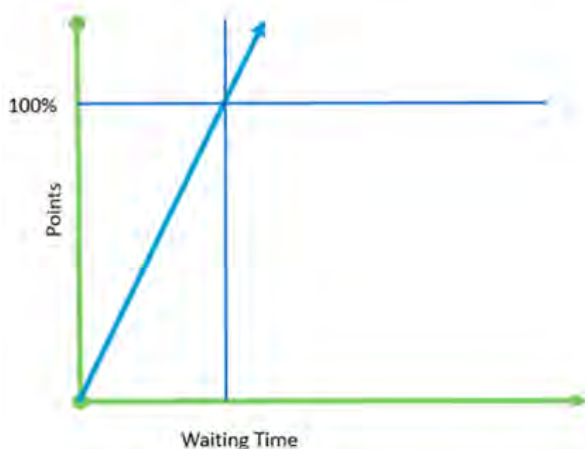


transplant.<sup>64</sup> There was some support for a linear rating scale that would then curve with decreasing point values after a specified threshold of waiting time, and for that threshold to be based to a degree on transplant survival benefit related to waiting time. Additionally, there was a suggestion to use a more staggered rating scale, where different weights were applied the more waiting time a candidate receives (ex. years 0-4 were equal, 4-8 years were slightly higher, etc.).

The Kidney and Pancreas Committees reviewed the results of public comment, AHP exercises, and the Ethics Committee and Patient Focus Group discussions in considering a rating scale recommendation for waiting time. The Committees considered two rating scale options for waiting time. The first option was a linear rating scale with a threshold. This approach would continue the linear function (i.e., each day of waiting time is worth the same amount) and allow candidates to receive an unlimited amount of waiting time points. The Committees would still choose a threshold that captures most candidates in this approach. Candidates with a waiting time higher than this threshold would receive points greater than the weight assigned to this attribute. Candidates with less waiting time would naturally receive less point value than the weight assigned to the attribute. This approach would allow the system to distinguish between candidates with any amount of waiting time. It would, however, create a small number of candidates who will receive more than 100 percent of the maximum weight for this attribute. An example of this rating scale can be seen in **Figure 22**.

The second option was the two-part linear to curve rating scale as seen in **Figure 23**. This approach allows the system to distinguish between candidates with extreme amounts of waiting time yet also retains the 0-100 rating scale. In this model, the Committee again chooses a threshold that will capture most candidates. Below that threshold, candidates receive waiting time points in a linear fashion. Above that threshold, candidates will continue to accrue waiting time points, but will accrue points more slowly.

**Figure 22: Linear Rating Scale with Threshold**



**Figure 23: Two-Part Linear Rating Scale with a Threshold and Curve**



After discussion, the Kidney Committee supported the no ceiling approach and felt it would be the most equitable option. The Committee emphasized long waiting times could be due to a multitude of reasons other than medical complexity, such as disparities in access to transplant.<sup>65</sup> Similarly, the Kidney

<sup>64</sup> Meeting summary for October 21, 2021 meeting, OPTN Ethics Committee.

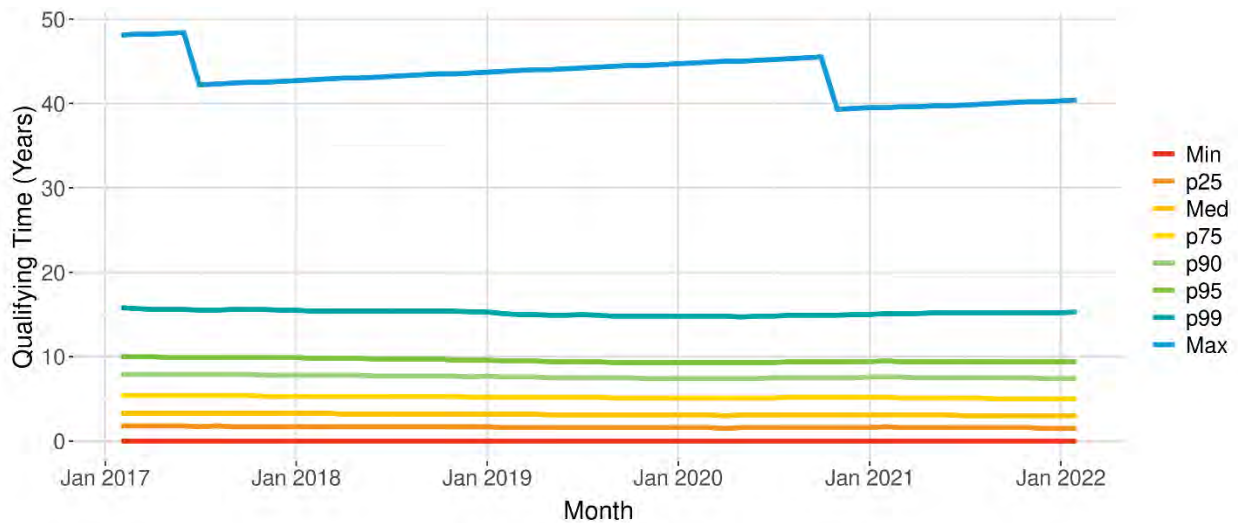
<sup>65</sup> Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.



Committee decided not to introduce a difference in waiting time scales for pre-dialysis vs. dialysis candidates as to not penalize those pre-dialysis candidates with access to transplant. After reviewing data on average waiting times for kidney candidates as shown in **Figure 24**, the Workgroup recommends setting the threshold that captures most candidates at 10 years.<sup>66</sup>

The Pancreas Committee supported the linear to curve approach and felt this would be the most equitable option for pancreas and KP. The Committee acknowledged there are factors that could contribute to the impact of waiting time, such as variabilities in program logistics (ex. high turndown rates or poor organ availability) and sensitization.<sup>67</sup> After reviewing data on average waiting times for pancreas and KP candidates as shown in **Figure 25**, the Pancreas Committee recommended an inflection point of 90 percent at five years and a shallower line beyond five years to max.

**Figure 24: Qualifying Time for Kidney Registrations by Month<sup>68</sup>**

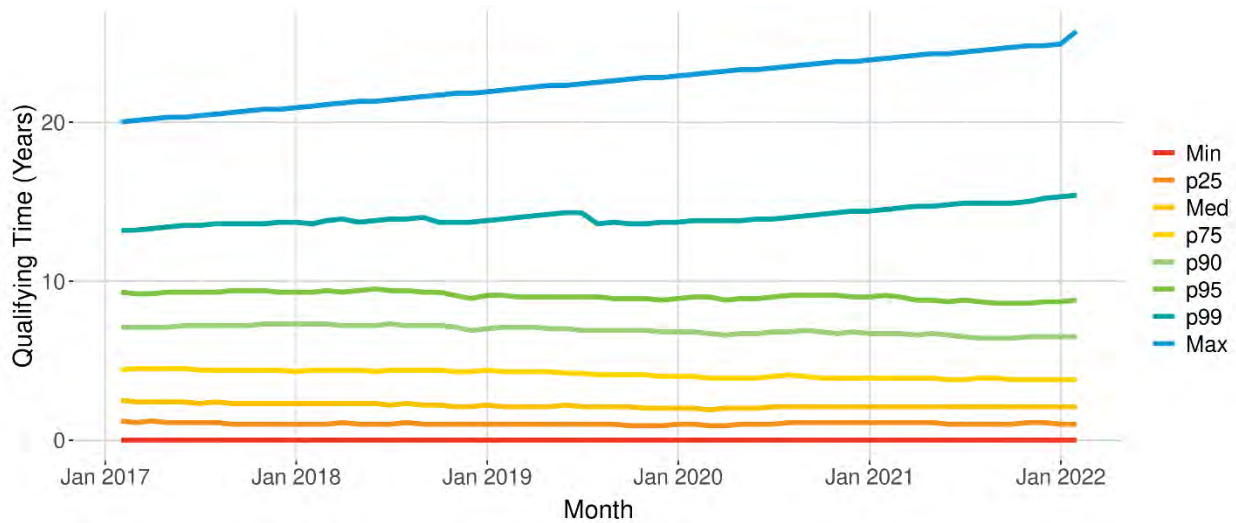


<sup>66</sup> Meeting summary for April 22, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>67</sup> Meeting summary for April 11, 2022 meeting, OPTN Kidney Pancreas Transplantation Committee.

<sup>68</sup> OPTN Data as of June 30, 2021.

**Figure 25: Qualifying Time for Kidney-Pancreas and Pancreas Registrations by Month<sup>69</sup>**



**Kidney-after-Liver (KAL) Safety Net (Kidney):** As described in the previous Request for Feedback, the Workgroup recommended a binary (yes or no) scale for KAL Safety Net and maintaining the existing KDPI threshold of 20 percent and greater.<sup>70</sup> The Workgroup requested additional community input on the KDPI threshold for KAL safety net as well as the criteria to qualify for priority. There was support for the recommended binary rating scale in public comment. Additionally, there was a suggestion of considering a tiered approach for safety net rating scales and taking medical urgency into account. Another comment suggested safety net patients having access to Sequence A, KPDI 0-20 percent donor organs only if the candidate’s EPTS score is in the top 20 percent. The Committees will consider these suggestions as part of their ongoing discussions in the development of this project.

**Proximity Efficiency (Kidney, Pancreas, and Kidney-Pancreas):** 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.<sup>71,72</sup> 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.<sup>73</sup> Beyond distance and cost, efficient placement emphasizes swift and effective donor organ and recipient matching.

As described in the previous paper, the Workgroup favors a simple, piece-wise linear approach to proximity efficiency as shown in **Figure 26**.<sup>74</sup> In this example, an “inner plateau” can be added to

<sup>69</sup> OPTN Data as of June 30, 2021.

<sup>70</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

<sup>71</sup> OPTN Policy 8.3: Kidney Allocation Score, Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital as of June 23, 2022.

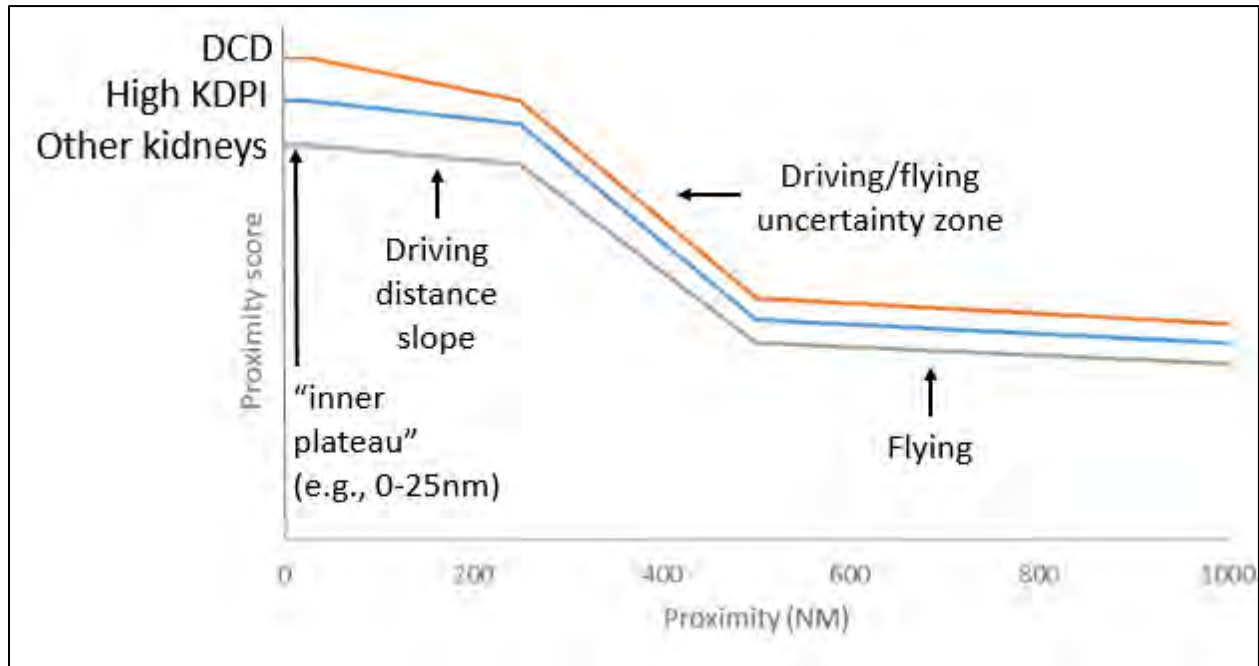
<sup>72</sup> OPTN Policy 11.2: Pancreas Allocation Score, Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital as of June 23, 2022.

<sup>73</sup> 42 C.F.R. §121.8(a)(8)

<sup>74</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

prioritize candidates listed at a hospital very close to a donor hospital (ex. within 25 NM). Building off of the 250 NM circle previously established by the Kidney and Pancreas Committees, additional data can be used to help establish a cut off between driving vs. flying and incorporate a driving vs. flying “uncertainty zone” for intermediate distances where either travel mode may be used.<sup>75,76</sup> Additionally, the piece-wise linear approach could assign more points to efficiency depending on organ quality or donor type (ex. DCD, high KDPI, etc.) as certain organs are less tolerant of longer travel time. The piece-wise linear scale preserves the distance inflection points of 250 NM previously established by the Committees and considers other measures of efficiency all on the same scale.

**Figure 26: Simple, Piece-Wise Linear Approach<sup>77</sup>**



The results of the AHP exercise assigned very low importance to the proximity efficiency attribute relative to other attributes. However, placement efficiency continues to be a subject of significant community interest, especially due to the recent implementation of the circles-based kidney and pancreas policies.<sup>78,79</sup> Comments were submitted regarding increased workloads for OPOs, transplant centers, and HLA labs to send and evaluate kidney and pancreas offers due to the new allocation policy. Commenters also expected this to increase more with broader allocation and felt the large volume of offers could increase cold ischemic time and decreases the likelihood of placement with each offer decline. Commenters supported innovations to help promote efficiency such as offer filters and predictive analytics to match organs available with transplant programs who have a high likelihood of accepting an organ based on past acceptance practices. Some commenters recommended reducing variability in transplant program and OPO practices. Commenters encouraged the Workgroup to consider administrative burden, cost, impact on travel patterns, and ease of delivery of organs to

<sup>75</sup> *Eliminate the Use of DSA and Region from Kidney Allocation Policy*, OPTN Kidney Transplantation Committee, August 2019.

<sup>76</sup> *Eliminate the Use of DSA and Region from Pancreas Allocation Policy*, OPTN Pancreas Transplantation Committee, August 2019.

<sup>77</sup> All values depicted in this figure are for demonstration purposes only.

<sup>78</sup> *Eliminate the Use of DSA and Region from Kidney Allocation Policy*, OPTN Kidney Transplantation Committee, August 2019.

<sup>79</sup> *Eliminate the Use of DSA and Region from Pancreas Allocation Policy*, OPTN Pancreas Transplantation Committee, August 2019.

transplant programs when discussing efficiency. Other commenters suggested donor assessment would be more fluid in a continuous distribution system.

Commenters also emphasized proximity being an important aspect to pancreas allocation and utilization as programs rarely import or accept pancreata from distant donor hospitals. A comment suggested allocating pancreata closer to the donor hospital in an attempt to decrease late declines for kidney-pancreas (KP).

Overall, commenters supported the piece-wise linear approach, and emphasized that the assignment of points should differ depending on organ quality and donor type (ex. high KDPI). Additionally, the OPO Committee hosted a focus group to review AHP results.<sup>80</sup> The focus group discussed the practicality of placing and transporting a kidney, commenting that organs from a nearby candidate are easier to transport in comparison to an organ from a candidate further from the donor hospital. The group further noted efficiency of allocating and placing an organ is often complicated by additional logistical factors.

On the topic of proximity efficiency, the Committees and the Workgroup considered public comment received from the 2021 Concept Paper and the 2022 Request for Feedback as well as the AHP results and comments.<sup>81</sup> The Pancreas Committee supported the piece-wise linear rating scale with a 50 NM inner plateau. The Committee discussed considerations for logistical factors related to pancreas allocation. These factors include time of the recovery and availability of a surgeon with specialized pancreas recovery expertise in determining the slope of the rating scale.<sup>82</sup> The “uncertainty zone” beyond 250 NM when programs may drive or fly is not consistent for pancreas, since some programs will go further distances to recover the organ.<sup>83</sup> The Pancreas Committee agreed on a 25 percent inflection point at 250 NM with a gentle slope down to zero percent at 5181 NM to address some of the potential disparities due to the factors discussed, as seen in **Figure 27**.<sup>84</sup> The Pancreas Committee also emphasized having higher priority for this attribute for pancreas as opposed to kidney.<sup>85</sup>

For kidneys, the Workgroup supported an inner plateau of 50 NM with a driving slope to 85 percent at 250 NM. Additionally, the Workgroup recommended an uncertainty zone slope to 25 percent at 500 NM, after which the slope would gradually decline to zero percent at 5181 NM, as seen in **Figure 28**.<sup>86,87</sup> The Workgroup acknowledged there are other considerations for proximity efficiency including the kidney’s KDPI and discussed testing the effects of changing the weights for proximity efficiency and for higher KDPI kidneys in modeling, as described in subsections below.<sup>88</sup>

<sup>80</sup> Meeting summary for March 28, 2022 meeting, OPTN Organ Procurement Organization (OPO) Committee.

<sup>81</sup> *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

<sup>82</sup> Meeting summary for April 11, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>83</sup> Meeting summary for April 18, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>84</sup> Meeting summary for April 18, 2022 meeting, OPTN Pancreas Transplantation Committee.

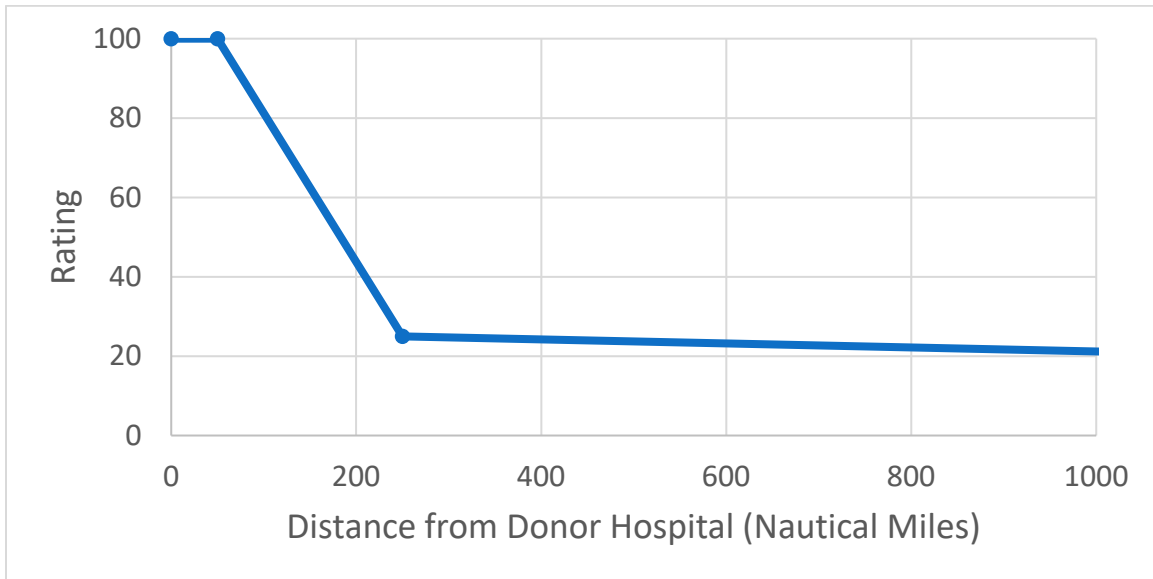
<sup>85</sup> Meeting summary for April 11, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>86</sup> Meeting summary for April 8, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

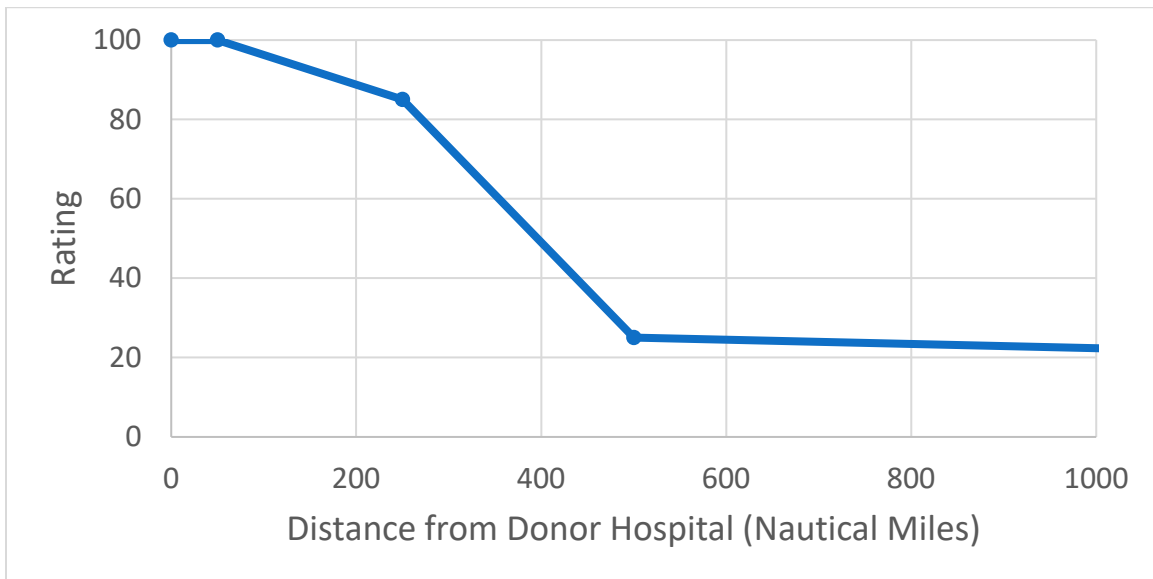
<sup>87</sup> Meeting summary for April 22, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>88</sup> Meeting summary for April 29, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

**Figure 27: Proximity Efficiency Rating Scale for Pancreas/KP/Islets**



**Figure 28: Proximity Efficiency Rating Scale for Kidneys**



## Kidney-Pancreas Simulated Allocation Model (KPSAM) Request

Upon the close of public comment, the Committees and the Workgroup reviewed the AHP exercise results and community feedback to decide on preliminary weights for modeling. In discussing this first modeling request, the Workgroup considered that the decisions informing the modeling request are not final. Rather, the first round of modeling would be used to test the effects of what would happen in more extreme scenarios, which can then be fine-tuned with mathematical optimization and the next

round of modeling. The first KPSAM request was submitted in April and results are expected by late summer or early fall.<sup>89</sup>

The Workgroup and Committee’s previous discussions and recommendations regarding attributes and rating scales for the new framework were incorporated into the modeling request as shown in **Figures 29 and 30**.<sup>90,91</sup>

Attribute	Rating Scale
Medical Urgency	Binary
HLA Matching	0, 1, or 2 DR mm
EPTS/KDPI	Continuous longevity matching
Blood Type	Current screening + blood type points
CPRA	Steep non-linear curve
Prior Living Donor	Binary
Pediatrics	Binary
KAL Safety Net	Binary
Qualifying Time	Linear, exceeds 100% beyond 10 years, no cap
Proximity Efficiency	Piecewise linear, 50 NM inner plateau, 85% at 250 NM, 25% at 500 NM, 0% at 5181 NM

**Figure 30: Pancreas Rating Scales**

Attribute	Rating Scale
Blood Type Identical	Relax KP screening + Identical before compatible
CPRA	Steep non-linear curve
Prior Living Donor	Binary
Pediatrics	Binary
Qualifying Time	Linear to curve. Inflection point: 90% at 5 years, shallower line beyond 5 years to max
Proximity Efficiency	Piecewise linear, 50 NM inner plateau, 25% at 250 NM, 0% at 5181 NM
Whole Pancreas (KP/PA), Not Pancreas Islets	Binary

Additionally, the Workgroup agreed to incorporate weight modifiers into the new system to replicate priority in existing policy dependent on donor characteristics.<sup>92</sup> Those donor modifiers are shown in **Figures 32 and 33**. These weight modifiers would depend on the characteristics of the donor (e.g. KDPI for kidney allocation, and donor age and BMI for pancreas allocation). For example, current kidney

<sup>89</sup> Meeting summary for April 29, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>90</sup> *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

<sup>91</sup> *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.

<sup>92</sup> Meeting summary for April 15, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.



allocation includes kidney-after-liver safety net priority for kidneys with a KDPI of 21-100 percent, while KAL safety net candidates do not receive priority for kidneys with KDPI 0-20 percent. If the donor has a KDPI of 0-20 percent, the donor modifier would be zero for this particular attribute. If the donor has a KDPI of 21 – 100 percent, the donor modifier would be one, and so on (see **Figure 31**). The weight, rating scale score, and donor modifier would be multiplied for each attribute, then summed across all the attributes to get a candidate’s composite allocation score.

**Figure 31: Example of Kidney-After-Liver Equation with Donor Modifier**

$$CAS_{KAL} = \text{Weight}_{KAL} * \text{Rating Scale}_{KAL} * \text{Donor Modifier}_{KAL}$$

Donor	Donor Modifier	Kidney After Liver Candidate	Not Kidney After Liver Candidate
KDPI 0-20	0	$5.9 * 1 * 0 = 0$	$5.9 * 0 * 0 = 0$
KDPI 21-100	1	$5.9 * 1 * 1 = 5.9$	$5.9 * 0 * 1 = 0$

For kidney allocation, the Workgroup replicated donor modifiers to reflect current priority by KDPI sequences. One exception is the expansion of pediatric candidate priority for pediatric donor kidneys with KDPI of 35-85 percent as described in the pediatric section above.

**Figure 32: Kidney Weight Modifiers**

Attribute	KDPI 0-20%	KDPI 21-34%	KDPI 35-85%	KDPI 86-100%
Medical Urgency	1	1	1	1
HLA Matching	1	1	1	1
EPTS/KDPI	1	1	1	1
Blood Type	1	1	1	1
CPRA	1	1	1	1
Prior Living Donor	1	1	1	0
Pediatrics	1	1	1	0
KAL Safety Net	0	1	1	1
Qualifying Time	1	1	1	1
Proximity Efficiency	1	1	1	1

Current pancreas allocation includes two sequences based on donor age and BMI.<sup>93,94</sup> 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

<sup>93</sup> OPTN Policy 11.5.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2 as of June 23, 2022.

<sup>94</sup> OPTN Policy 11.5.G: Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m2 as of June 23, 2022.



reviewed data showing that the utilization of the whole organ pancreas declines as donor age increases, particularly for donors age 40 and older, and very few pancreata are transplanted from donors over age 50.<sup>95</sup> 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.<sup>96</sup> 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.

**Figure 33: Pancreas Weight Modifiers**

Attribute	Donor Age ≤ 40 & Donor BMI ≤ 30	Donor Age > 40 or Donor BMI > 30
Blood Type Identical	1	1
CPRA	1	1
Prior Living Donor	1	1
Pediatrics	1	1
Waiting Time	1	1
Proximity Efficiency	1	1
Whole Pancreas (KP/PA), Not Pancreas Islets*	1	-1

For this first modeling request, the Workgroup chose to include the following five scenarios (see **Figures 34-38**):

1. **Current Policy:** This scenario uses current policy and classifications to produce a baseline. This scenario will provide a representation of the attributes as they are currently outlined in policy. The baseline will allow the Committees to evaluate the impact of the recommended attributes and rating scales in the new framework.
2. **Combined Community Feedback Results:** This run is the continuous distribution option closest to the community and committee AHP results. Scenarios 2-5 also include some items the Committees and Workgroup have discussed incorporating into continuous distribution such as expanded longevity matching, pediatric priority for sequence C kidneys from pediatric donors, and a steeper CPRA curve as described in the relevant sections above.
3. **Increased Longevity:** This scenario increases the weight/importance of transplant outcomes from 10 percent to 40 percent divided between DR matching and longevity. The weights for all other attributes are decreased proportionally.
4. **Increased Placement Efficiency:** This scenario increases the importance of proximity efficiency from 10 percent to 30 percent. The weights for all other attributes are decreased proportionally.
5. **Harder to Place Kidneys:** This scenario increases placement efficiency for hard to place kidneys (high KDPI) with increased donor weight modifiers for KDPI 86-100 percent.

<sup>95</sup> Meeting summary for April 11, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>96</sup> Meeting summary for April 11, 2022 meeting, OPTN Pancreas Transplantation Committee.

**Figure 34: First Modeling Scenario, Current Policy**

Goal	Kidney alone	KP/PA/PI
Medical Urgency	n/a	n/a
Transplant Outcomes	n/a	n/a
Candidate Biology	n/a	n/a
Patient Access	n/a	n/a
Placement Efficiency	n/a	n/a

**Figure 35: Second Modeling Scenario, Combined Community Feedback Results**

Goal	Kidney alone	KP/PA/PI
Medical Urgency	Medical Urgency 15%	0%
Transplant Outcomes	DR Matching 5% Longevity 5%	0%
Candidate Biology	Blood Type 5% CPRA 15%	Blood Type Identical 15% CPRA 15%
Patient Access	Pediatrics 15% Prior Living Donors 15% Waiting Time 10% KAL Safety Net 5%	Pediatrics 20% Prior Living Donors 20% Waiting Time 10%
Placement Efficiency	Proximity Efficiency 10%	Organ Registration 10% Proximity Efficiency 10%

**Figure 36: Third Modeling Scenario, Increased Longevity**

Goal	Kidney alone	KP/PA/PI
Medical Urgency	Medical Urgency 10%	0%
Transplant Outcomes	DR Matching 20% Longevity 20%	0%
Candidate Biology	Blood Type 3.3% CPRA 10%	Blood Type Identical 15% CPRA 15%
Patient Access	Pediatrics 10% Prior Living Donors 10% Waiting Time 6.7% KAL Safety Net 3.3%	Pediatrics 20% Prior Living Donors 20% Waiting Time 10%
Placement Efficiency	Proximity Efficiency 6.7%	Organ Registration 10% Proximity Efficiency 10%

**Figure 37: Fourth Modeling Scenario, Increased Placement Efficiency**

Goal	Kidney alone	KP/PA/PI
Medical Urgency	Medical Urgency 11.67%	0%
Transplant Outcomes	DR Matching 3.89% Longevity 3.89%	0%
Candidate Biology	Blood Type 3.89% CPRA 11.67%	Blood Type Identical 11.67% CPRA 11.67%
Patient Access	Pediatrics 11.67% Prior Living Donors 11.67% Waiting Time 7.78% KAL Safety Net 3.89%	Pediatrics 15.56% Prior Living Donors 15.56% Waiting Time 7.78%
Placement Efficiency	Proximity Efficiency 30%	Organ Registration 7.78% Proximity Efficiency 30%

**Figure 38: Fifth Modeling Scenario, Harder to Place Kidneys**

Attribute	KDPI 0-20%	KDPI 21-34%	KDPI 35-85%	KDPI 86-100%
Medical Urgency	1	1	1	1
HLA Matching	1	1	1	1
EPTS/KDPI	1	1	1	1
Blood Type	1	1	1	1
CPRA	1	1	1	1
Prior Living Donor	1	1	1	0
Pediatrics	1	1	0	0
KAL Safety Net	0	1	1	1
Qualifying Time	1	1	1	1
Proximity Efficiency	1	1	1	3

## Other Considerations

Due to the structural changes inherent in converting from a classification-based system to a points-based system, the Committees are exploring necessary changes to other areas of policy. These include considerations that are more operational in nature, as described below:

- Dual Kidney
- En bloc
- Facilitated Pancreas Allocation
- Mandatory KP Offers
- National Offers
- Screening and Filters
- Released Organs
- Review Boards

### Dual Kidney

Kidney policy was updated in 2019 to increase utilization of high KDPI kidneys by providing the option to allocate them as dual kidneys to provide a patient survival advantage over single high KDPI kidney transplantation.<sup>97</sup> This policy update also designated an allocation pathway for dual kidneys by allowing

<sup>97</sup> *Improving Dual Kidney Allocation*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.

transplant programs to opt in to dual kidney offers for their patients. The original intent of this policy change was to increase organ utilization for kidneys that are considered more marginal.

The policy added dual kidney classifications to the sequence tables within policy for donor kidneys with KDPI scores of 35 percent and above. Functionally, this means dual kidney offers appear on the same match run as single kidney offers, causing those candidates who are opted in for dual offers to appear on the match run twice. This policy's two two-year monitoring report shows that 44.44 percent of dual kidney transplants were actually allocated from the single kidney classifications.<sup>98</sup> Feedback from the OPO community indicates this is done to avoid organ wastage due to increased ischemic time, late turndowns, etc.<sup>99</sup>

With the removal of the classification-based system, the Kidney Committee is exploring options for transitioning dual kidney allocation to a continuous distribution framework.

### *En Bloc*

Similar to dual kidney allocation, kidneys from small pediatric donors less than 18kg are allocated together (en bloc) to be transplanted into a single recipient. Currently, all en bloc kidneys are allocated according to Sequence A, or KDPI 0-20 percent.<sup>100</sup> The actual KDPI of en bloc kidney donors is masked, as the KDPI score does not accurately reflect the potential function and risk of receiving two kidneys together.<sup>101</sup> The Kidney Donor Risk Index (KDRI) includes a coefficient to account for en bloc receipt that is currently not utilized.<sup>102</sup> The Kidney Committee discussed incorporating this KDRI value into en bloc allocation, and ultimately recognized that rating scales for KDPI and the interaction of KDPI and EPTS will necessarily impact rating scales and allocation for en bloc kidneys.<sup>103</sup> Therefore, the Workgroup is recommending assigning a unique KDPI score to en bloc kidneys by utilizing the en bloc coefficient included in the KDRI.<sup>104</sup>

### *Facilitated Pancreas Allocation*

Current OPTN policy permits OPOs and the OPTN to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery.<sup>105</sup> Additionally, OPOs only have access to facilitated allocation after all pancreas and KP offers to candidates registered at programs within 250 NM of the donor hospital have been declined. After much discussion, the Pancreas Committee agreed that facilitated pancreas should be incorporated into the continuous distribution framework.

The Pancreas Committee is working to determine how the facilitated pancreas policy should be operationalized in the continuous distribution framework. The Pancreas Committee is considering including candidates registered at programs within 100 NM (as opposed to the current 250 NM distance in policy) of the donor hospital on facilitated pancreas match runs in addition to candidates registered at

<sup>98</sup> OPTN Descriptive Data Request. "Allocation of Dual and En Bloc Kidneys Two Year Post-Implementation Monitoring Report." Prepared for OPTN Kidney Transplantation Committee, March 18, 2022.

<sup>99</sup> Meeting summary for June 9, 2022 meeting, OPTN OPO Committee.

<sup>100</sup> OPTN Policy 8.6.B: Allocation of En Bloc Kidneys as of June 23, 2022.

<sup>101</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.

<sup>102</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.

<sup>103</sup> Meeting summary for October 8, 2021 meeting, OPTN Kidney Transplantation Committee.

<sup>104</sup> Meeting summary for May 20, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>105</sup> OPTN Policy 11.7.B: Facilitated Pancreas Offers as of June 23, 2022.

programs qualified to receive facilitated pancreas offers. The decrease in distance from 250 NM to 100 NM would be based on the proposed proximity efficiency rating scale inner plateau referenced above.<sup>106</sup> The Pancreas Committee reasons that closer proximity will allow for an increase in the utilization of the pancreas.<sup>107</sup> The Pancreas Committee is also considering whether or not candidates based on sensitization or 0-ABDR mismatch should be bypassed.

The Pancreas Committee has also discussed the three-hour timeframe prior to scheduled organ recovery time requirement. There was some consideration in determining if the three-hour timeframe is feasible to coordinate a recovery team that is experienced in recovering pancreata. The Pancreas Committee sought input from the OPO Committee on the use of the facilitated pancreas tool in a continuous distribution framework. The OPO Committee recommended that the new policy extend the facilitated pancreas timeframe, such that the tool may be applied four or five hours before scheduled organ recovery time, as opposed to the current three hours.<sup>108</sup> The OPO Committee also noted logistical challenges to recovering pancreata, and emphasized that a long facilitated pancreas timeframe could encourage transplant programs to send their own recovery team. The Pancreas Committee initially recommended keeping the time requirement of three hours as currently outlined in policy, but will continue to discuss other options. The Pancreas Committee will also continue discussions on appropriate criteria to qualify programs as facilitated pancreas programs.

### *Mandatory KP Offers*

If a host OPO has both a kidney and a pancreas to offer for allocation, current OPTN Policy requires the OPO to offer the kidney and pancreas according to the first four classifications as outlined below in **Table 3**. The OPO may then continue to offer the kidney and pancreas together according to the remaining classifications, or offer the kidney to candidates on the kidney match run and offer the pancreas according to the remaining classifications.<sup>109</sup> The first four classifications consist of all KP and PA candidates within 250 NMs of the donor hospital and candidates who are both highly sensitized (CPRA greater than or equal to 80 percent) and a 0-ABDR mismatch with the donor.

---

<sup>106</sup> Meeting summary for June 22, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>107</sup> Meeting summary for June May 16, 2022 meeting, OPTN Pancreas Transplantation Committee.

<sup>108</sup> Meeting summary for May 18, 2022 meeting, OPTN OPO Committee.

<sup>109</sup> OPTN Policy 11.5.A: Kidney-Pancreas Allocation Order as of June 23, 2022.



**Table 3: Allocation of Pancreas and Kidney-Pancreas by Classifications**

Classification	Donors Age <50 with BMI <30	Donors Age >50 or BMI > 30
1	250 NM, 0-ABDR MM, 80%-100% CPRA, PA/KP	250 NM, 0-ABDR MM, 80%-100% CPRA, PA/KP
2	250 NM, 80%-100% CPRA, PA/KP	250 NM, 80%-100% CPRA, PA/KP
3	Nation, 0-ABDR MM, 80%-100% CPRA, PA/KP	Nation, 0-ABDR MM, 80%-100% CPRA, PA/KP
4	250 NM, PA/KP	250 NM, PA/KP
5	Nation, 80%-100% CPRA, PA/KP	250 NM, Islets
6	Nation, PA/KP	Nation, Islets
7	250 NM, Islets	Nation, 80%-100% CPRA, PA/KP
8	Nation, Islets	Nation, PA/KP

The Workgroup has discussed the use of a CAS threshold as a transitional solution to mirror current policy.<sup>110</sup> With the use of the CAS threshold, OPOs would be required to offer the KP to all KP candidates at or above that CAS before offering to kidney candidates on the kidney match run, or continuing to offer the KP on the KP match run.

The Workgroup recognized the importance of balancing mandatory KP offers appropriately, weighing utilization, waitlist mortality, equity in access, and efficiency considerations. The Workgroup wants to maintain a level of prioritization for KP patients similar to current policy’s prioritization, in order to reduce waitlist mortality for kidney-pancreas candidates and to encourage utilization of pancreata.<sup>111</sup> The Workgroup determined that the CAS threshold should consider placement efficiency, ensuring OPOs have the opportunity to place the kidneys on the kidney match run.<sup>112</sup>

The Workgroup is currently seeking further input on mandatory KP offer policy from the OPTN Ad Hoc Multi-Organ Transplantation Committee and the community at large.

### National Offers

OPTN Policy 8.7.B: *National Kidney Offers* requires OPOs to turn allocation of deceased donor kidneys over to the OPTN Contractor for offers to candidates with CPRA less than 100 percent and non-0-ABDR mismatch candidates more than 250 NM away from the donor hospital (also known as “national offers”). The use of the minimum acceptance criteria (MAC) screening tool allows the OPTN Contractor to more efficiently allocate the organ according to OPTN policy. The transition to a continuous distribution framework would remove “national” classifications. Additionally, the OPO community has expressed interest in gaining the ability to offer these types of kidneys themselves with assistance from the OPTN contractor as needed. Therefore, the Workgroup decided this requirement was no longer necessary, and determined the role of the OPTN contractor as the required entity in offering organs nationally would instead provide optional assistance.<sup>113</sup>

<sup>110</sup> Meeting summary for January 7, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>111</sup> Meeting summary for January 7, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>112</sup> Meeting summary for February 4, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

<sup>113</sup> Meeting summary for May 20, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

## *Screening and Filters*

Broader distribution in circles-based allocation has increased match run complexity, impacting allocation efficiency. Screening tools will be critical to securing allocation efficiency and practicality, in order to ensure organ utilization. Several efforts are underway to improve system efficiency, including an ongoing effort to redefine provisional yes, and proposals to optimize the usage of offer filters.

Offer filters serve as a tool that allows transplant hospitals to enter multi-factorial criteria in order to screen offers more precisely. This tool aims to reduce the number of unwanted organ offers that organ procurement organizations (OPOs) need to make, and that transplant programs need to respond to, as well as decrease cold time and increase organ acceptance, particularly for the hard to place organs. The OPTN Operations and Safety Committee is currently working on an offer filters project with a goal to increase the number of transplants by getting to organ offer acceptance faster. More information on this project is currently available for public comment, titled “Optimizing Usage of Kidney Offer Filters”.

The Kidney Minimum Acceptance Criteria (MAC) tool utilizes candidate-specific minimum acceptance criteria, to screen kidney candidates from the match. This minimum acceptance criteria is reported annually by transplant programs to indicate the types of organ offers a program would *not* accept for a candidate from a donor more than 250 nautical miles away. The MAC tool is currently utilized by the OPTN Contractor to accelerate national organ placement. With national offers becoming available to OPOs, the MAC tool will need to be revised and updated for broader use in continuous distribution.

## *Released Organs*

Current policy regarding released kidneys allows the OPO to continue allocation according to the original match run or a released kidney match run, using the previously accepting transplant hospital as the location of the kidney.<sup>114</sup> Current policy regarding released kidney-pancreas (KP), pancreas, and pancreas islets allows the OPO to continue allocation according to the original match run or allocate the KP, pancreas, or islets to a potential transplant recipient at the program originally accepting the organ. If the released KP is allocated to a pancreas-alone candidate, the OPO must allocate the kidney according to the original kidney match run or a released kidney match run using the previously accepting transplant hospital as the location of the kidney.

The Workgroup is considering two potential approaches to incorporating released organs that include increasing the weight of proximity efficiency (with the goal of increasing utilization by reducing travel and prioritizing nearby candidates), or determining what locations are appropriate to base a released organ match run around (i.e., the original donor hospital or the current location of the organ).

The Committees will continue discussions and seek input on how best to incorporate the released organs policy into the continuous distribution framework as it relates to kidneys and pancreata.

## *Review Boards*

Review boards comprise of representatives from active transplant programs who evaluate exception requests from transplant programs whose candidates may not meet policy requirements. Currently, there are review boards for OPTN heart, liver, and lung transplant waiting lists. Operational guidelines and policy outline process and timelines for review boards. Review board members quickly review

---

<sup>114</sup> OPTN Policy 5.9: Released Organs as of June 23, 2022.



specific score or status requests for candidates on the waiting list and collectively determine (by vote) whether the candidate has an urgency and potential for benefit comparable to that of other candidates at the requested score or status based on clinical information that complies with OPTN policies.

With continuous distribution prioritizing candidates based on composite allocation score (CAS), the development of organ-specific review boards would address clinical exceptions that may need further evaluation and consideration. The role of review boards is to allow clinical peers to intervene when unique clinical situations arise which are not fully addressed or contemplated by specific clinical criteria in policy.

Consideration and discussions of having a review board for both kidney and pancreas is currently underway. The Workgroup will work to determine how this may be incorporated and structured within the continuous distribution framework.

## Next Steps

The Committees and the Workgroup will continue work on building the continuous distribution framework for kidneys and pancreata allocation and will continue to discuss allocation components outside of the CAS. Upon analyzing KPSAM modeling, the Committees and the Workgroup will work to develop a second, mathematically optimized KPSAM modeling request and associated attribute weight adjustments (as applicable).<sup>115,116</sup> Additionally, the Committees will continue to educate and update the community as this project develops.<sup>117</sup>

## NOTA and Final Rule Analysis

The Committees submit this request for feedback under the authority of NOTA, which requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,”<sup>118</sup> and the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>119</sup> The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”<sup>120</sup> While this paper does not propose policy changes at this time, the concepts presented in this paper:

<sup>115</sup> Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021.

<sup>116</sup> Mankowski M, Wood N, Segev D, Gentry S. Designing Continuous Distribution for Liver Allocation [abstract]. Am J Transplant. 2022; 22 (suppl 3).

<sup>117</sup> For updates on these projects, visit the Continuous Distribution page of the OPTN website: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>.

<sup>118</sup> 42 U.S.C. §274(b)(2)(B)

<sup>119</sup> 42 CFR §121.4(a)

<sup>120</sup> 42 C.F.R. §121.8(a)

**Are based on sound medical judgment:** The construction of the individual ratings scales and weights will be based on simulation modeling, OPTN data, and research presented by multiple parties, as well as operational evidence and experience. The Committees will also rely upon peer-reviewed literature as well their own clinical experience and judgment in making determinations regarding assigning weights and ratings to each attribute.

**Seek to achieve the best use of donated organs:** One of the best uses of a donated organ is that it is transplanted into the most medically urgent candidate. The Workgroup will consider the weight of the Medical Urgency Definition attribute. Finally, before the policy proposal is released for public comment, it will be modeled by the SRTR to assess its impact on waitlist mortality and post-transplant outcomes.

**Are specific for each organ:** The proposed continuous distribution framework is consistent across all organs, but the weights and rating scales will be organ specific. In this case, kidneys and pancreata.

**Are designed to avoid wasting organs:** As described above, the Workgroup identified multiple attributes specifically designed to avoid wasting organs, described as decreasing the number of organs that are recovered but not ultimately transplanted (ex. dual vs. single, en bloc). The OPTN has previously discussed attributes, such as the likelihood of organ offer acceptance, which would also have a positive effect on this Final Rule requirement.<sup>121</sup> Additionally, before the policy proposal is released for public comment, it will be modeled by the SRTR to assess the impact on not utilized organs, as well as the impact on total number of transplants.

**Are designed to...promote patient access to transplantation:** The Workgroup included several attributes to ensure that similarly situated candidates have equitable opportunities to receive an organ offer. This includes the two attributes under the goal of Candidate Biology (CPRA and candidate blood type) and the four attributes under Patient Access (prior living donors, pediatrics, waiting time, and Kidney-after-Liver Safety Net). The inclusion of these attributes is likely to increase access to transplantation for these patients, who otherwise have inequitable access to transplant.

**Are designed to...promote the efficient management of organ placement:** The Workgroup will consider indicators of efficiency associated with procuring and transplanting kidneys and pancreata, including, but not limited to, travel costs and the proximity between the donor and transplant hospitals. The Workgroup is continuing to discuss other attributes related to placement efficiency and requests feedback on other potential attributes related to the efficient management of organ placement.

**Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** The Workgroup is considering the candidate's place of listing to the extent that doing so is required for the purpose of achieving efficient placement of the organs, specifically for Proximity Efficiency (travel efficiency and placement efficiency).

**Consider whether to adopt transition procedures:** The OPTN may be able to compare the ultimate policy proposal analyses and modeling to determine whether any candidates will be treated less favorably under the future policy, and if there is a need for transition procedures for those candidates or others. This would allow members and patients time to prepare for these changes. The Committees will

---

<sup>121</sup> Briefing to the OPTN Board of Directors on Establish Continuous Distribution of Lungs, OPTN Lung Transplantation Committee, December 2021.

continue discussions on transition procedures as the project progresses.

## **Conclusion**

This project serves as an opportunity to rethink how the OPTN and the transplant community develop kidney and pancreas allocation policies. This update details the work that the Kidney and Pancreas Committees have performed to date and how they will move forward toward eventual policy proposals.

## **Considerations for the Community**

The Committees encourage all interested individuals to comment on this paper in its entirety.

## Appendix: Glossary of Terms

The following terms are used throughout the concept paper.

**Analytical Hierarchy Process (AHP):** An AHP is an example of a stated preference analysis. This analysis asks participants to state their preferences in a pairwise comparison.

**Attribute:** Attributes are criteria used to classify then sort and prioritize candidates. For example, in lung allocation, our criteria include medical urgency, travel mode, ischemic time, blood type compatibility, and others.

**Classification-based framework:** A classification-based framework groups similar candidates into classifications or groupings. We then sort candidates within those classifications. A candidate will only appear in the classification that is most beneficial to them. This is the framework currently used to allocate organs.

**Composite Allocation Score:** A composite allocation score combines points from multiple attributes together. This concept paper proposes the use of composite allocation scores in a points-based framework.

**Concentric Circles:** This distribution framework utilizes the distance between the donor hospital and the candidate's transplant hospital to prioritize organ offers to candidates. These distances are grouped into zones at specific nautical mile distances. This introduces a hard boundary in how candidates are prioritized.

**Calculated Panel Reactive Antibody (CPRA):** The percentage of deceased donors expected to have one or more of the unacceptable antigens indicated on the waiting list for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different ethnic groups in proportion to their representation in the national deceased donor population.

**Distance:** The distance between the donor hospital and transplant hospital is either the straight line or travel distance. Straight line distance is the current method for calculating distance and represents the shortest two points. Travel distance is the most likely distance that the organ would travel between two points. For example, a straight line distance would be the shortest distance between hospitals on either side of a body of water; whereas, the travel distance would be the distance that somebody might drive on the roads and bridges around the body of water.

**Framework:** A collection of policies and procedures used to distribute organs. Examples include concentric circles and continuous distribution.

**Ischemic Time:** Ischemic time is broken into three subparts: procurement, transit, and transplant time. Procurement time begins at cross-clamp and ends at transit departure time. OPO and procurement practices, among other things, influence procurement related ischemic time. Transit time is the time in between departure from the procurement location and delivery at the transplant hospital. Transplant time is then the time between delivery at the transplant hospital and the start of anastomosis.

**Points-based framework:** A points-based framework gives each candidate a score or points. Organs are then offered in descending order based upon the candidate's score. This concept paper proposes a points-based framework for organ allocation.

**Rating Scale:** A rating scale describes how much preference is provided to candidates within each attribute. Applying the rating scale to each candidate's information and combining it with the weight of the attribute results in an overall composite score for prioritizing candidates.

**Revealed Preference:** A revealed preference analysis looks at actual decisions to determine the implicit preferences of the decision maker. This is compared with a stated preference analysis (for example, AHP) that asks the decision maker to state their preferences in an experiment.

**Stated Preference:** A stated preference analysis asks participants to state their preferences in a pairwise comparison. AHP is an example of stated preference analysis.

**Weight:** Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. For example, should waitlist mortality be more or less important than post-transplant outcomes? Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.