OPTN

Request for Feedback

Update on Continuous Distribution of Kidneys and Pancreata

OPTN Kidney & Pancreas Transplantation Committees

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

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OPTN

Update on Continuous Distribution of Kidneys and Pancreata

Sponsoring Committees: *Kidney & Pancreas Transplantation*
Public Comment Period: *January 27, 2022 – March 27, 2022*

Executive Summary

This request for feedback provides an update to the community about the continuous distribution of organs, specifically kidneys and pancreata. Continuous distribution would replace the current classification approach, which draws hard boundaries between types of patients (for example, blood type compatible vs. identical; sensitized vs. not; inside vs. outside a circle), 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.[1,2]

This paper builds upon the 2021 concept paper and contains updated information about the attributes that have been discussed by the Kidney-Pancreas Continuous Distribution Workgroup (the Workgroup), how these attributes align with NOTA and the Final Rule, and how this work to date may influence the anticipated conversion to continuous distribution.[3] Finally, this paper provides an overview of the policy development approach for continuous distribution of kidneys and pancreata, along with a request for community members to provide feedback.

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

[1] NOTA, 42 U.S.C. § 273 et. seq.
[2] 42 C.F.R. § 121.8
[3] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."

Background

Continuous distribution (CD) is a points-based framework that assigns a composite score 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 (compatible vs. identical; sensitized vs not; inside a circle vs. outside), with a **points-based framework**. This score would be constructed with multiple attributes that align with NOTA and the OPTN Final Rule. To construct the score, the OPTN Kidney and Pancreas Committees (the Committees) must make two general decisions: 1) how much weight or importance to place on each attribute and 2) how to rate candidates within each attribute. Regarding the ratings, the Committees have been and will continue to work with OPTN and SRTR researchers to develop evidence based rating scales for each attribute.[4,5]

Classification-based framework: A classification-based framework that places similar candidates into ordered classifications or groupings. Candidates are then sorted within those classifications. This is the framework currently used to allocate organs.

Points-based framework: A points-based framework that assigns a composite score or points to each candidate. Organs are then offered in descending order based upon the candidate's score. This concept paper describes a points-based framework for organ allocation.

As explained in the 2021 concept paper, continuous distribution prioritizes waiting list candidates based on a combination of points awarded for factors related to medical urgency, expected post-transplant outcome, candidate biology, patient access, and the efficient management of organ placement.[6] Continuous distribution will eliminate hard boundaries, which currently preclude a patient from being prioritized ahead of patients on the other side of the boundary.[7,8] By using this kind of calculation, there would not be hard boundaries, and candidates would be ranked on a match run based on a combination of donor and candidate clinical characteristics as well as placement efficiency.

Composite Allocation Score

The National Organ Transplant Act (NOTA) of 1984, as amended, and the OPTN Final Rule contain multiple requirements for organ allocation policies, all of which must be addressed and balanced consistent with existing evidence and the expertise of the members of the OPTN Board of Directors and relevant committees.[9] A continuous distribution policy would rank organ candidates by a composite score that aligns with the different requirements found in NOTA and the OPTN Final Rule. As detailed in the 2021 concept paper, **Figure 1** shows how these five sub-scores combine into a composite score.[10]

[4] 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.
[5] 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.
[6] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."
[7] J. J. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," Am J Transplant 18, no. 11 (Nov 2018).
[8] Jon Snyder, "Systems without Geographic Boundaries". Presented to the OPTN Ad Hoc Geography Committee meeting, March 26, 2018.
[9] 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.
[10] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."

Figure 1: Components of Composite Allocation Score

[11] **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 the below example (**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.

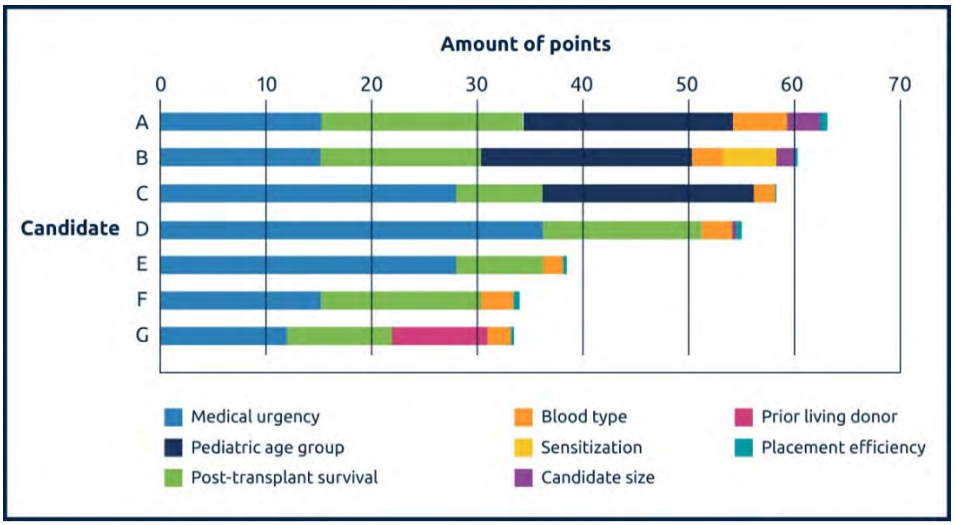
[11] 42 CFR § 121.8.

Figure 2: Sample Allocation Policy (Current)[12]

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	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type 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	0-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

[13]



Project Plan

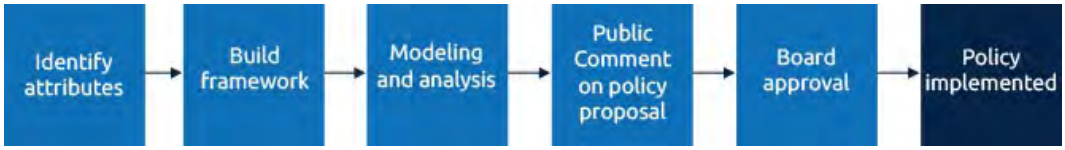
[12] Note that candidates are placed into specific classifications and cannot move between them.
[13] Each color represents a different attribute and the length of the bar shows the points credited to that attribute. Note that candidates receive points for multiple considerations and can move up or down depending on each attribute.

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.

Progress So Far

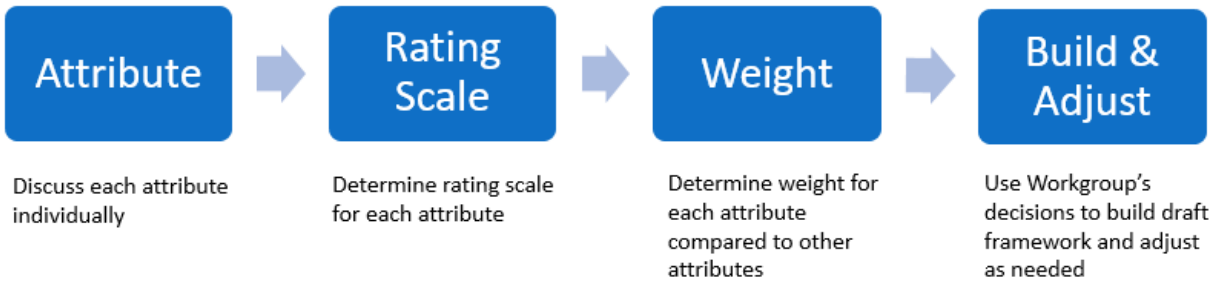
The proposal for the continuous distribution of kidneys and pancreata will be developed through several phases, as seen in **Figure 4**. Since the 2021 concept paper, the Workgroup has begun evaluating each attribute by reviewing how it is currently used for allocation and how best to convert that model into a points-based rating scale.[14] Once a rating scale is developed for each attribute, the Workgroup will then assign weights that determine the relative importance of each attribute in the CAS. Weights will be determined based on value judgements obtained from the transplant community, the results of allocation simulation modeling, subject matter expertise, legal requirements, and committee deliberations. In keeping with the requirements for evidence based allocation policies, clinical and operational data will be used as much as possible to determine the specific point assignments (ex. blood type and CPRA).

Figure 2: Project Overview[15]



The Workgroup has been evaluating each attribute by reviewing how it is currently used for allocation and how best to convert that model into a points-based rating scale. Once a rating scale is developed for each attribute (ex. linear, non-linear, binary, etc.), the Workgroup will then assign weights to specifics within each attribute to determine priority within the scales, as outlined in **Figure 5**. In keeping with the requirements for evidence based allocation policies, clinical and operational data will be used as much as possible to determine the specific point assignments (ex. blood type and CPRA). For attributes that do not lend themselves to clinical or operational analysis, consensus building methods are used to build their evidence for their points. More details on the Workgroup's discussions and those consensus building methods can be found in the subsections below.

Figure 5: Process for Assigning Values to Attributes



[14] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."
[15] The Workgroup is currently in the "Build Framework" phase.

Determining Rating Scales for Attributes

The Workgroup reviewed current policy, current data, developed relevant data requests, and then reviewed potential rating scales for the corresponding attribute. The Workgroup also sought input from cross-committee subject matter experts where applicable, in addition to considering public comment feedback. The Workgroup identified some attributes that would benefit from further community feedback before determining a rating scale and those specific feedback questions are outlined in the subsections below.

Table 1 shows a list of those attributes and their categorizations as developed by the Workgroup.[16] There are similarities of attributes across organs as well as attributes that are more specific to each respective organ. Detail of the Workgroup's deliberations on attributes, rating scales, and opportunities for further input can be found below. The weights for each attribute, and how they interact with each other are pending further public comment input, community preference exercises, and modeling.

Table 1: Kidney-Pancreas Continuous Distribution Workgroup Identified Attributes

	Medical Urgency	Post-Transplant Survival	Candidate Biology	Patient Access	Placement Efficiency
Kidney	• Medical Urgency Definition	• HLA Matching • EPTS	• Blood Type* • CPRA*	• Prior Living Donors* • Pediatrics* • Kidney-after-Liver Safety Net • Waiting Time*	• Travel Efficiency* • Proximity Efficiency* • Dual vs. Single • En Bloc
Pancreas			• Blood Type* • CPRA*	• Prior Living Donors* • Pediatrics* • Waiting Time*	• Travel Efficiency* • Proximity Efficiency*

*Also identified as a kidney-pancreas attribute
Note: Islets also identified as an attribute of non-utilization, described below

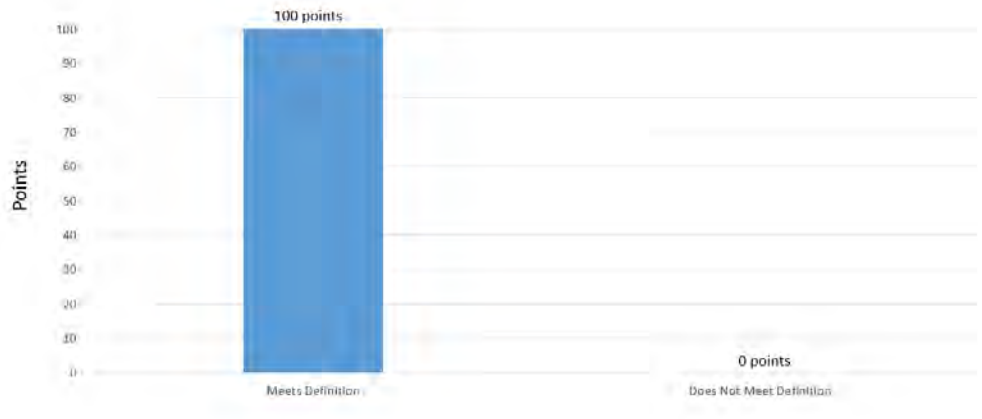
Medical Urgency

The OPTN Final Rule requires allocation policies to "seek to achieve the best use of donated organs."[17] One way to achieve the best use of a donated organ is to transplant the organ into a candidate who has the greatest medical urgency. Also, the Final Rule requires the OPTN to "[set] priority rankings … for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent…"[18] With this focus, the Workgroup looked to current policy for how to rank candidates according to medical urgency as outlined below:

[16] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."
[17] 42 CFR § 121.8(a)(2).
[18] 42 CFR § 121.8(b)(2).

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.[19] Therefore, the kidney goal for this category was specified as "prioritize those with high mortality due to imminent loss of dialysis" and the specific medical urgency definition was identified as an attribute. The Kidney Committee approved a binary (yes or no) rating scale (**Figure 6**) for this attribute depending on if the candidate meets the medical urgency criteria outlined in current policy.[20] For the CAS, medically urgent candidates will receive 100 percent of the medical urgency attribute weight (to be determined) while non-medically urgent candidates will receive zero points for this attribute.

Figure 6: Example of a Binary Rating Scale



The Workgroup is seeking community input on the following questions:

- Do you agree with the medical urgency definition rating scale recommendation for kidney?
- How should the medical urgency definition attribute be weighted in the composite allocation score?

Post-Transplant Survival

The OPTN Final Rule requires allocation policies be designed "to avoid futile transplants."[21] A futile transplant occurs if the recipient of the organ is unlikely to survive very long after the transplant, or if the transplanted organ is not likely to survive very long in the recipient post-transplant. The Workgroup identified the following attributes for post-transplant survival:

HLA Matching (Kidney): HLA matching has been associated with longer graft survival.[22,23,24,25] In today's kidney policy, HLA matching between the donor and candidate is used to give additional priority (for 0-ABDR mismatches as well as 0 or 1 DR mismatches) to candidates on an individual basis.[26] The current

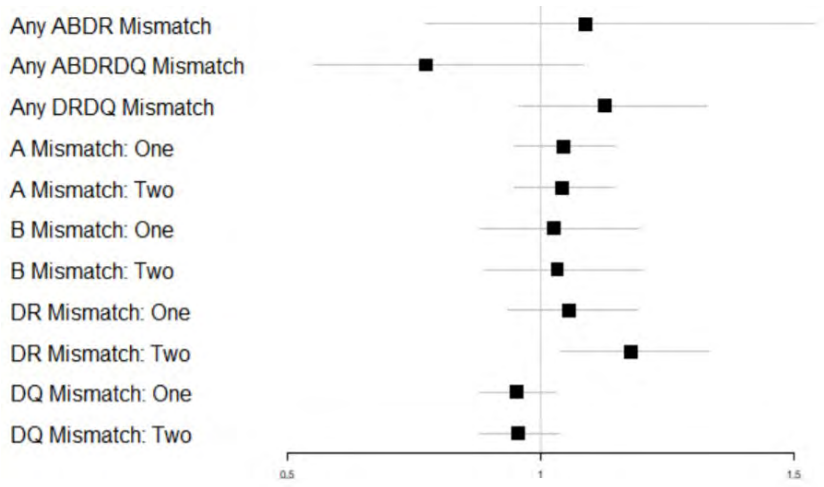
[19] OPTN Policy 8.5.A.i: Medically Urgent Status for Adult and Pediatric Candidates as of October 7, 2021.
[20] OPTN Kidney Transplantation Committee. 2021, October 8. Kidney Transplantation Committee Meeting Summary.
[21] 42 CFR § 121.8(a)(5).
[22] Williams, Robert C. PhD; Opelz, Gerhard MD; McGarvey, Chelsea J. MD; Weil, E. Jennifer MD; Chakkera, Harini A. MD The Risk of Transplant Failure With HLA Mismatch in First Adult Kidney Allografts From Deceased Donors, Transplantation: May 2016 - Volume 100 - Issue 5 - p 1094-1102 doi: 10.1097/TP.0000000000001115
[23] Paramesh, A.S., Zhang, R., Baber, J., Yau, C.L., Slakey, D.P., Killackey, M.T., Ren, Q., Sullivan, K., Heneghan, J. and Florman, S.S. (2010), The effect of HLA mismatch on highly sensitized renal allograft recipients. Clinical Transplantation, 24: E247-E252.
[24] Foster, B.J., Dahhou, M., Zhang, X., Platt, R.W., Smith, J.M. and Hanley, J.A. (2014), Impact of HLA Mismatch at First Kidney Transplant on Lifetime With Graft Function in Young Recipients. American Journal of Transplantation, 14: 876-885
[25] Napat Leeaphorn, Jeremy Ryan A. Pena, Natanong Thamcharoen, Eliyahu V. Khankin, Martha Pavlakis and Francesca Cardarelli. HLA-DQ Mismatching and Kidney Transplant Outcomes. CJASN May 2018, 13 (5) 763-771.
[26] OPTN Policy 8.3: Kidney Allocation Score as of October 7, 2021.

pancreas allocation system is based on candidate registration and proximity; however, HLA matching is incorporated in sorting for each classification.[27,28,29]

In evaluating this attribute, the Workgroup aimed to consider (1) the impact of HLA matching on graft survival and (2) any correlation between likelihood of getting a well matched transplant and other factors (race/ethnicity) to evaluate the potential unintended consequences of prioritizing better HLA matches. The Workgroup sought the input of the OPTN Histocompatibility Committee and after much discussion, submitted a data request to the SRTR to evaluate binary 0-ABDR mismatch and 0-ABDRDQ mismatch variables, as well as level of matching for A, B, DR and DQ loci. [30,31,32] Due to limited HLA matching data for pancreata, the data report included outcomes data for kidney-alone recipients only.

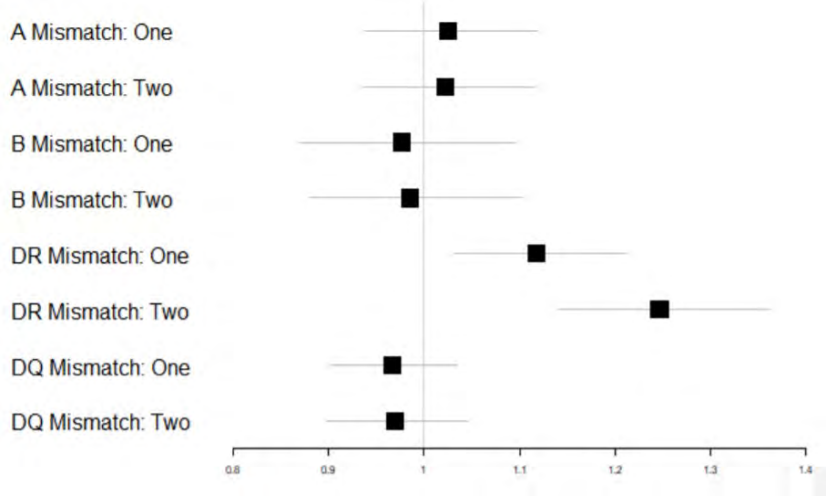
The report concluded that mismatches at the DR locus are most strongly associated with the hazard of graft failure (**Figures 7** and **8**). [33] Upon review of the report and further input from the Histocompatibility Committee, the Workgroup determined the data does not support including A, B, or DQ antigen level matching and that 0-ABDR did not seem to have much of an advantage. Therefore, there is no justification for prioritizing 0-ABDR mismatches, but there is justification to prioritize DR antigen matching. [34,35]

Figure 7: Graft Failure, All-Effects Model[36]



[27] OPTN Policy 11.5.E: Sorting within Each Classification as of October 7, 2021.
[28] OPTN Kidney Transplantation Committee. 2020, September 25. Kidney Continuous Distribution Workgroup Meeting Summary.
[29] OPTN Kidney and Pancreas Transplantation Committees. 2020, December 18. Continuous Distribution Workgroup Meeting Summary.
[30] OPTN Histocompatibility Committee. 2021, March 9. Histocompatibility Committee Meeting Summary.
[31] OPTN Kidney and Pancreas Transplantation Committees. 2021, March 12. Continuous Distribution Workgroup Meeting Summary.
[32] OPTN Kidney and Pancreas Transplantation Committees. 2021, March 26. Continuous Distribution Workgroup Meeting Summary.
[33] Scientific Registry of Transplant Recipients, 2021, August 20. Impact of HLA Matching on Graft Survival in Kidney Transplant Recipients Presentation to the Kidney Pancreas Continuous Distribution Workgroup.
[34] OPTN Histocompatibility Committee. 2021, March 9. Histocompatibility Committee Meeting Summary.
[35] OPTN Kidney and Pancreas Transplantation Committees. 2021, August 20. Continuous Distribution Workgroup Meeting Summary.
[36] Scientific Registry of Transplant Recipients, 2021, August 20. Impact of HLA Matching on Graft Survival in Kidney Transplant Recipients Presentation to the Kidney Pancreas Continuous Distribution Workgroup.

Figure 8: Graft Failure, All-Loci Model[37]



The Workgroup also discussed that the potential effects of any recommended rating scale for HLA matching on minority populations are unknown and stressed the importance of modeling any HLA matching prioritization for unintended disparities. For kidney allocation, the Workgroup agreed to a rating scale where DR antigen matching would be prioritized with points being assigned based on the level of HLA mismatching. The Workgroup added a caveat that this rating scale would be dependent on additional information regarding other populations that may be disadvantaged through modeling. Due to lack of available data, the Workgroup also agreed to not 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.[38]

The Workgroup is seeking community input on the following questions:

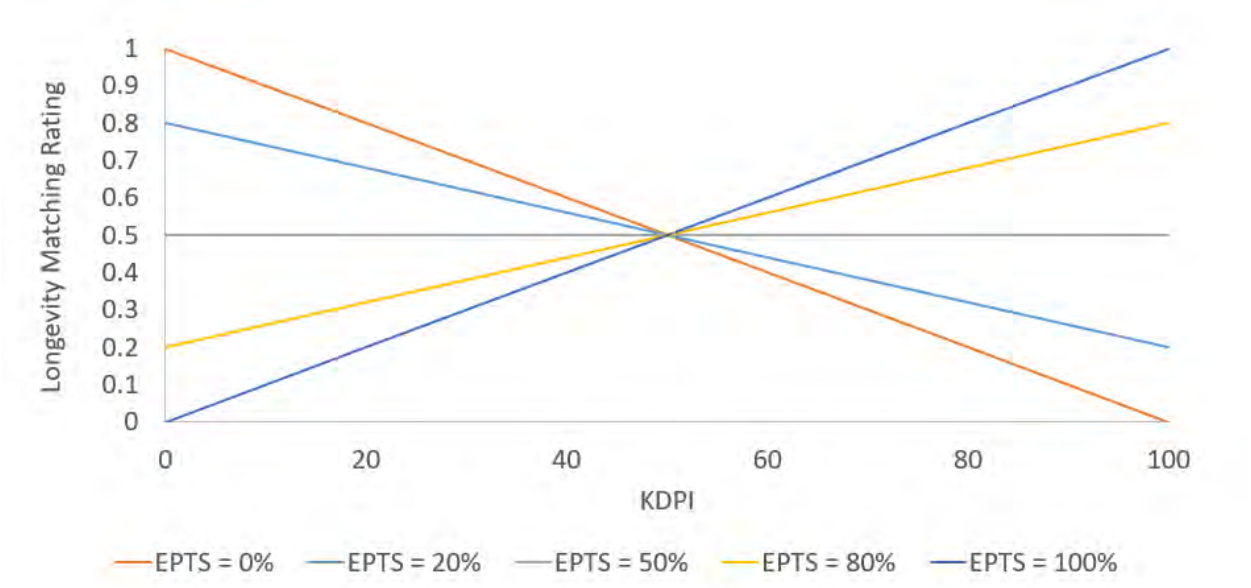
- Do you agree with the HLA matching rating scale recommendation for kidney?
- How should the HLA matching attribute be weighted in the composite allocation score?
- How would prioritizing DR antigen matching affect different populations?
- How should HLA matching be considered for pancreata?

EPTS (Kidney): Estimated Post Transplant Survival (EPTS) scores are currently used in kidney allocation to predict a candidate's projected longevity with a functioning graft post-transplant.[39] The EPTS score works together with the Kidney Donor Profile Index (KDPI) score of the donor's kidney to match the organ to the appropriate candidate.[40,41] The Workgroup recognizes the importance of KDPI/EPTS longevity matching and discussed how to incorporate that relationship into the framework.[42]

The Workgroup reviewed and discussed several options to incorporate longevity matching including 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 as seen in **Figure 9** (ex. low EPTS candidates receiving longevity matching points for low KDPI kidneys, and vice versa).

[37] Scientific Registry of Transplant Recipients, 2021, August 20. Impact of HLA Matching on Graft Survival in Kidney Transplant Recipients Presentation to the Kidney Pancreas Continuous Distribution Workgroup.
[38] OPTN Kidney and Pancreas Transplantation Committees. 2021, August 20. Continuous Distribution Workgroup Meeting Summary.
[39] OPTN Policy 8.5.A: Candidate Classifications as of October 7, 2021.
[40] OPTN Policy 8.5.A: Candidate Classifications as of October 7, 2021.
[41] OPTN Kidney Transplantation Committee. 2020, September 25. Kidney Continuous Distribution Workgroup Meeting Summary.
[42] OPTN Kidney and Pancreas Transplantation Committees. 2021, July 30 Continuous Distribution Workgroup Meeting Summary.

Figure 9: Longevity Matching Rating Scale Example



The Workgroup discussed how the four factors included in the EPTS calculation – age, time on dialysis, prior transplant recipient, and diabetic state – were originally chosen by the Kidney Committee with the motivation of keeping EPTS understandable to patients and keeping data burdens for transplant centers low.[43,44] The Workgroup acknowledged there is debate on the limitations of the current EPTS and KDPI calculations and agreed it would be difficult to rely on these tools too heavily in the new framework.[45,46,47] The Workgroup also recognized that in the new continuous distribution system, KDPI and EPTS can be continually re-evaluated and adjusted as the new system is expected to be much more flexible.

The Committee is considering whether 1) to keep the four match runs, with different candidate rankings depending upon the donor KDPI, or 2) smooth out hard edges between these four match runs. (See **Figure 9** as one potential option).

The Workgroup is seeking community input on the following questions:

- Should the initial implementation of kidney continuous distribution mirror current approach to longevity matching, by awarding points to EPTS Top 20 percent candidates for KDPI Top 20 percent kidneys? Or should a more sophisticated approach be considered?
- How should EPTS be used in the new allocation framework?
- What are some measures of post-transplant survival for pancreata that should be considered?

[43] OPTN Kidney and Pancreas Transplantation Committees. 2021, July 30 Continuous Distribution Workgroup Meeting Summary.
[44] OPTN. *A Guide to Calculating and Interpreting the Estimated Post-Transplant Survival (EPTS) Score Used in the Kidney Allocation System (KAS)*. 2020, April 21.
[45] Clayton PA, McDonald SP, Snyder JJ, Salkowski N, Chadban SJ. External validation of the estimated posttransplant survival score for allocation of deceased donor kidneys in the United States. American Journal of Transplantation. 2014 Aug;14(8):1922-6.
[46] Cannon RM, Locke JE, Orandi BJ, Anderson DJ, Davis EG, Mackelaite L, Dave H, Eng M, Jones CM. Impact of donor hepatitis C virus on kidney transplant outcomes for hepatitis C positive recipients in the direct acting antiviral era: time to revise the kidney donor risk index?. Transplantation. 2020 Jun;104(6):1215.
[47] OPTN Kidney and Pancreas Transplantation Committees. 2021, July 30. Continuous Distribution Workgroup Meeting Summary.

Candidate Biology

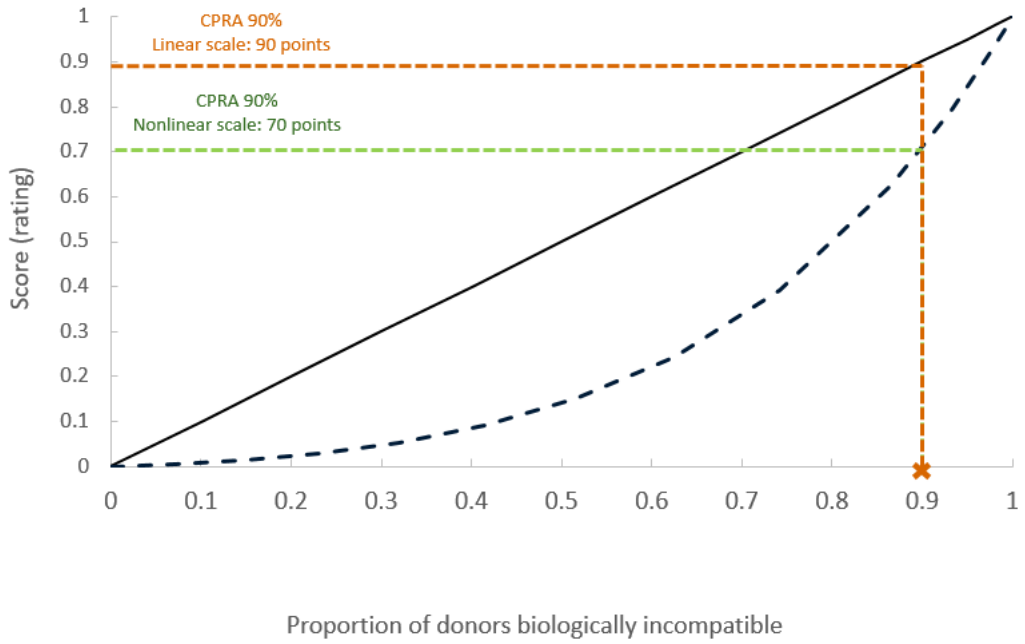
NOTA requires the OPTN to match organs to consider candidates "whose immune system makes it difficult for them to receive organs,"[48] and the OPTN Final Rule requires allocation policies to "promote patient access to transplantation."[49] Some candidates have difficulty finding a suitable donor due to biological incompatibilities. The OPTN has long used different mechanisms, for example the CPRA sliding scale in kidney allocation policy, to reduce these biological differences in transplant access.[50]

CPRA (Kidney, Pancreas, and Kidney-Pancreas): Currently, OPTN kidney policy permits highly sensitized kidney patients to be prioritized for allocation in the form of additional points.[51] The reason for this policy is to grant greater access for these candidates who might otherwise struggle to receive organ offers due to being biologically unable to accept organs from many donors. OPTN pancreas policy also prioritizes highly sensitized pancreas candidates who have a CPRA greater than or equal to 80 and 0-ABDR mismatch.[52, 53]

The Workgroup emphasized priority for highly sensitized candidates should be maintained in the new system.[54] For example, 100 percent CPRA candidates will still need significant priority, as they have much lower transplant rates than less sensitized patients. During Workgroup discussions, Pancreas Committee members agreed to mirroring kidney policy's CPRA points scale for pancreas and kidney-pancreas so there would be similar prioritization.[55] The Workgroup agreed 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.[56] **Figure 10** is an example of what a steep, non-linear scale could look like for CPRA compared to a linear scale.

[48] 42 U.S.C. §274(b)(2)(A)(ii)
[49] 42 CFR § 121.8(a)(5).
[50] OPTN Policy 8.3, Table 8-2 Points for CPRA as of October 7, 2021.
[51] OPTN Policy 8.3: Kidney Allocation Score as of October 7, 2021.
[52] OPTN Policy 11.1: Calculated Panel Reactive Antibody (CPRA) as of October 7, 2021.
[53] OPTN Pancreas Transplantation Committee. 2020, October 9. Pancreas Continuous Distribution Workgroup Meeting
[54] OPTN Kidney and Pancreas Transplantation Committees. 2021, May 21. Continuous Distribution Workgroup Meeting Summary.
[55] OPTN Pancreas Transplantation Committee. 2020, October 9. Pancreas Continuous Distribution Workgroup Meeting Summary.
[56] OPTN Kidney and Pancreas Transplantation Committees. 2021, May 21. Continuous Distribution Workgroup Meeting Summary.

Figure 10: Example of a Steep, Non-Linear Rating Scale for CPRA



The Workgroup is seeking community input on the following questions:

- Do you agree with the rating scale recommendations for CPRA?
- How should the CPRA attribute be weighted in the composite allocation score?

Blood type (Kidney, Pancreas, and Kidney-Pancreas): Kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with prioritization for blood types O and B to provide equity in the system.[57] In current kidney allocation, blood type O kidneys are reserved for blood type O recipients because of biological disadvantages in finding compatible donors.[58] Pancreas allocation classifies candidates according to compatible blood type matches as outlined in policy.[59] The Workgroup recognizes the framework would need to allow for compatibility while accounting for the disadvantaged blood types.[60]

In considering how to incorporate blood type compatibility and sensitization into a continuous distribution framework, the Workgroup reviewed the use of a common scale developed for the Continuous Distribution of Lungs and requested similar data on blood type and CPRA for kidney and pancreas canddiates.[61] **Table 2** shows the number of compatible deceased donors and probability of compatibility by blood type, based on a total of 11,925 deceased kidney donors recovered in 2020.[62]

[57] OPTN Policy 8.5.D: Allocation of Kidneys by Blood Type as of October 7, 2021.
[58] Based on OPTN Data as of April 23, 2021.
[59] OPTN Policy 11.5.D: Blood Type for Kidney-Pancreas Allocation as of October 7, 2021.
[60] OPTN Pancreas Transplantation Committee. 2020, October 9. Pancreas Continuous Distribution Workgroup Meeting Summary.
[61] OPTN Kidney and Pancreas Transplantation Committees. 2021, January 15. Continuous Distribution Workgroup Meeting Summary.
[62] OPTN Kidney and Pancreas Transplantation Committees. 2021, April 23 Continuous Distribution Workgroup Meeting Summary.

Table 2: Number of Compatible Deceased Kidney Donors and Probability of Compatibility by Blood Type[63]

Candidate ABO	Compatible blood type	N. Compatible Donors	Prob. Of Compatibility	Prob. Of Incompatibility
O	O (5661)	5,661	0.47	0.53
A	O (5661) + A (4435)	10,096	0.85	0.15
B	O (5661) + B (1390)	7,051	0.59	0.41
AB	O (5661) + A (4435) + B (1390) + AB (439)	11,925	1.00	0.00

Table 3 shows the same information for pancreas recipients based on 1,265 deceased pancreas donors recovered in 2020. [64]

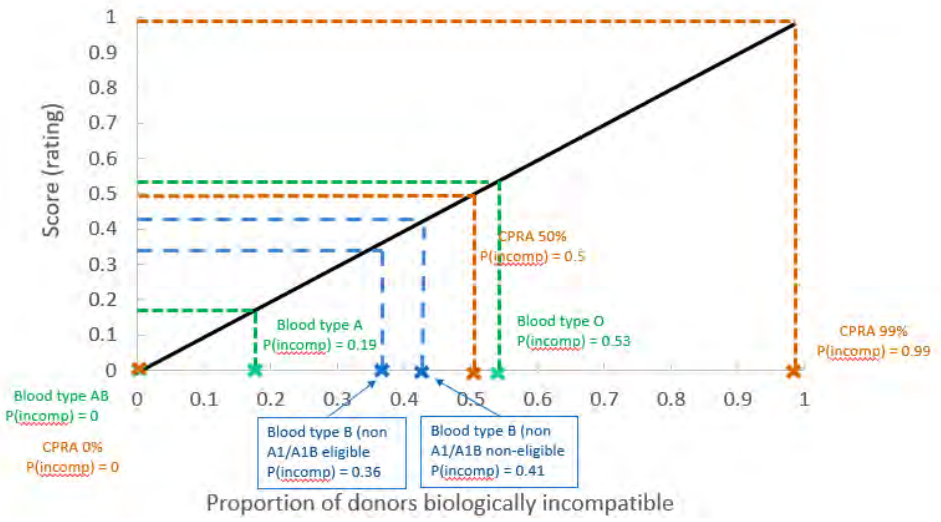
Table 3: Number of Compatible Deceased Pancreas Donors and Probability of Compatibility by Blood Type[65]

Candidate ABO	Compatible blood type	N. Compatible Donors	Prob. Of Compatibility	Prob. Of Incompatibility
O	O (659)	659	0.52	0.48
A	O (659) + A (441)	1,100	0.87	0.13
B	O (659) + B (150)	809	0.64	0.36
AB	O (659) + A (441) + B (150) + AB (15)	1,265	1.00	0.00

The Workgroup considered whether these donor kidneys should also be accessible by other blood types, such as highly sensitized with blood type B.[66] The Workgroup considered using a linear approach for the blood type rating scale, with candidates of each blood group receiving points equal to the blood groups' probability of incompatibility. The Workgroup also considered having a linear scale for blood type and aligning it with CPRA to allow for blood type O donor kidneys to go to non-O candidates in those rare situations of high sensitization (**Figure 11**). For example, a blood type O candidate with a CPRA of zero would receive 53 points for having blood type O and 0 points for their sensitization. However, a blood type AB candidate with a CPRA of 100 would receive 100 points due to their high sensitization and 0 points for blood type. In this situation, assuming all else is equal, the highly sensitized candidate would receive more priority than the blood type O candidate.

[63] Based on OPTN Data as of April 23, 2021.
[64] OPTN Kidney and Pancreas Transplantation Committees. 2021, April 23 Continuous Distribution Workgroup Meeting Summary.
[65] Based on OPTN Data as of April 23, 2021.
[66] OPTN Kidney and Pancreas Transplantation Committees. 2021, April 23 Continuous Distribution Workgroup Meeting Summary.

Figure 11: Example Rating Scale Incorporating Blood Type and CPRA Together



Through discussion, the Workgroup determined there would be very few circumstances where a blood type O kidney should be offered to any candidate other than blood type O and emphasized these blood group relationships should be protected.[67] However, the Workgroup is interested in exploring if non-A1 donor kidneys could be prioritized for other blood groups. Additionally, Pancreas Committee representatives emphasized blood type may need to be considered differently for pancreas alone allocation to encourage organ utilization. Therefore, the Workgroup is seeking further community input on the best approach for a blood type rating scale.

The Workgroup is seeking community input on the following questions:

- How should different blood types be prioritized against each other in the new system?
- Should non-A1/non-A1B donor kidneys be prioritized for other blood groups? If so, which blood groups?

Patient Access

The OPTN Final Rule requires allocation policies to "promote patient access to transplantation,"[68] and NOTA requires the OPTN to "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children."[69] The Patient Access category addresses transplant access for candidates under the age of 18, prior living donors, etc. The Workgroup agreed with the overall goal of providing appropriate transplant access in addition to maintaining prioritization for certain populations. With this goal in mind, the Workgroup is interested in increasing transplant access for pediatric candidates as well as adding prior living donor priority to pancreas and kidney-pancreas allocation.

[67] OPTN Kidney and Pancreas Transplantation Committees. 2021, April 23. Continuous Distribution Workgroup Meeting Summary.
[68] 42 CFR Sec. 121.8(a)(5).
[69] 42 U.S.C. §274(b)(2)(M)

Prior living donor (Kidney, Pancreas, and Kidney-Pancreas): Starting in 1996, all prior living donors received priority for kidney transplants.[70,71] Additionally, the Board and multiple committees have discussed the prioritization of prior living donors over the years and have consistently determined that prior living donors should receive some priority in organ allocation.[72,73,74,75,76,77,78,79,80,81,82] To be consistent with current kidney allocation policy and past discussions, the Workgroup favors including priority for prior living donors in pancreas and kidney-pancreas continuous distribution as well.[83]

To assist with discussion, the Workgroup sought the advice of the OPTN Ethics and Living Donor Committees. These groups determined there are both ethical and legal justifications for providing this priority to prior living donors and offered these principles to the organ-specific committees with the expectation that they be applied globally across organ types.[84,85] Additionally, the Workgroup reviewed data related to prior living donors on the transplant waiting list. There were 7,395 living donors in 2019 alone, while prior living donor need for transplant has historically been very low as shown in **Table 4**.[86,87] Since 2010, between 0.10-0.18 percent of kidney candidates added to the Waitlist per year have received priority as prior living donors.[88]

Table 4: Number of prior living donors added to the transplant waiting list by waitlisted organ and donated organ (April 1, 1994 – July 26, 2019) [89]

Donated Organ	Waitlisted Organ				
	Kidney	Liver	Heart	Lung	Intestine
Kidney	189	16	13	13	2
Liver	2	8	0	0	0
Lung	1	0	0	1	0

Upon review of data and the Ethics and Living Donor Committee's recommendations, the Workgroup recommends utilizing a binary (yes or no) scale for prior living donors.[90] The Workgroup further agreed

[70] Report of the Kidney and Pancreas Transplantation Committee to the Board of Directors, June 26-27, 1996. (Pages 83-84)
[71] OPTN Policy 8.3: Kidney Allocation Score
[72] OPTN Kidney Committee Meeting Summary, April 7, 2006.
[73] OPTN Kidney Committee Meeting Summary, May 13, 2011.
[74] OPTN Kidney Committee Meeting Summary, August 27, 2012.
[75] "Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant", Public Comment March 16, 2012 – June 25, 2012. Approved by the OPTN Board of Directors at November 2012 meeting.
[76] "Revising Kidney Paired Donation Pilot Program Priority Points", OPTN Kidney Transplantation Committee, Public Comment August 14 - October 14, 2015. Approved by the OPTN Board of Directors at December 2015 meeting.
[77] OPTN Liver Committee Meeting Summary, September 17, 2014.
[78] OPTN Kidney Committee Meeting Summary, March 25, 2019.
[79] OPTN Kidney Committee Meeting Summary, August 19, 2019.
[80] OPTN Ethics Committee Meeting Summary March 11, 2021.
[81] OPTN Living Donor Committee Meeting Summary May 12, 2021.
[82] OPTN Lung Transplantation Committee. 2021, December 6. "Briefing to the OPTN Board of Directors on Establish Continuous Distribution of Lungs."
[83] OPTN Pancreas Transplantation Committee. 2020, September 25 Pancreas Continuous Distribution Workgroup Meeting Summary.
[84] OPTN Ethics Committee. 2021, March 11. Ethics Committee Meeting Summary.
[85] OPTN Living Donor Committee. 2021, 12 May. Living Donor Committee Meeting Summary.
[86] Based on OPTN Data as of November 12, 2021.
[87] J. Wainright, D. Klassen, A. Kucheryavaya, and D. Stewart, Delays in Prior Living Kidney Donors Receiving Priority on the Transplant Waiting List. Clinical journal of the American Society of Nephrology: CJASN, 11(11), 2047–2052 (2016). https://doi.org/10.2215/CJN.01360216.
[88] Based on OPTN data as of August 10, 2021.
[89] Data for prior living donors who donated between April 1, 1994 and July 26, 2019. Based on OPTN data as of July 26, 2019.
[90] OPTN Kidney and Pancreas Transplantation Committees. 2021, September 17 Continuous Distribution Workgroup Meeting Summary.

with the Living Donor Committee's recommendation to provide this priority to candidates who have previously donated any organ.

The Workgroup is seeking community input on the following questions:

- Do you agree with the rating scale recommendations for Prior Living Donor Candidates?
- How should the prior living donor attribute be weighted in the composite allocation score?
- What other factors should be considered in the prioritization of these candidates?

Pediatrics (Kidney, Pancreas, and Kidney- Pancreas): Currently, OPTN policy prioritizes pediatric kidney candidates for kidneys with a KDPI of 34 percent or less and pediatric candidates do not receive an EPTS score. Pediatric candidates are not currently prioritized for pancreas allocation. As described in the August 2021 concept paper, the Workgroup favors adding priority for pediatric candidates under pancreas and kidney-pancreas as well.[91]

The Workgroup first developed a data request for kidney, KP, and pancreas to assess the following: [92]

- Pediatric candidate characteristics by age, race/ethnicity, diagnosis, multi-organ transplant, CPRA, HLA matching
- Pediatric waiting list outcomes including waiting time, transplant rate, and waiting list mortality
- Pediatric transplant recipient characteristics by age, race/ethnicity, diagnosis, multi-organ, HLA matching, CPRA, HLA mismatch
- Characteristics of donor used in pediatric transplant by age, race/ethnicity, KDPI
- Deceased and living donor transplant trends in pediatric and adult recipients

The data showed that there were very few pediatric KP and pancreas listings and transplants and the majority of the listings and transplants were multi-organ. [93] For kidney, the waiting times were longest for children under 6 years old (**Table 5)**. Most of those children had a 0 percent CPRA, and a small percentage were highly sensitized with a 98-100 percent CPRA (**Figure 12**). Pediatric kidney transplant recipients most frequently received an adult donor while pediatric KP and pancreas recipients most frequently received a pediatric donor.[94]

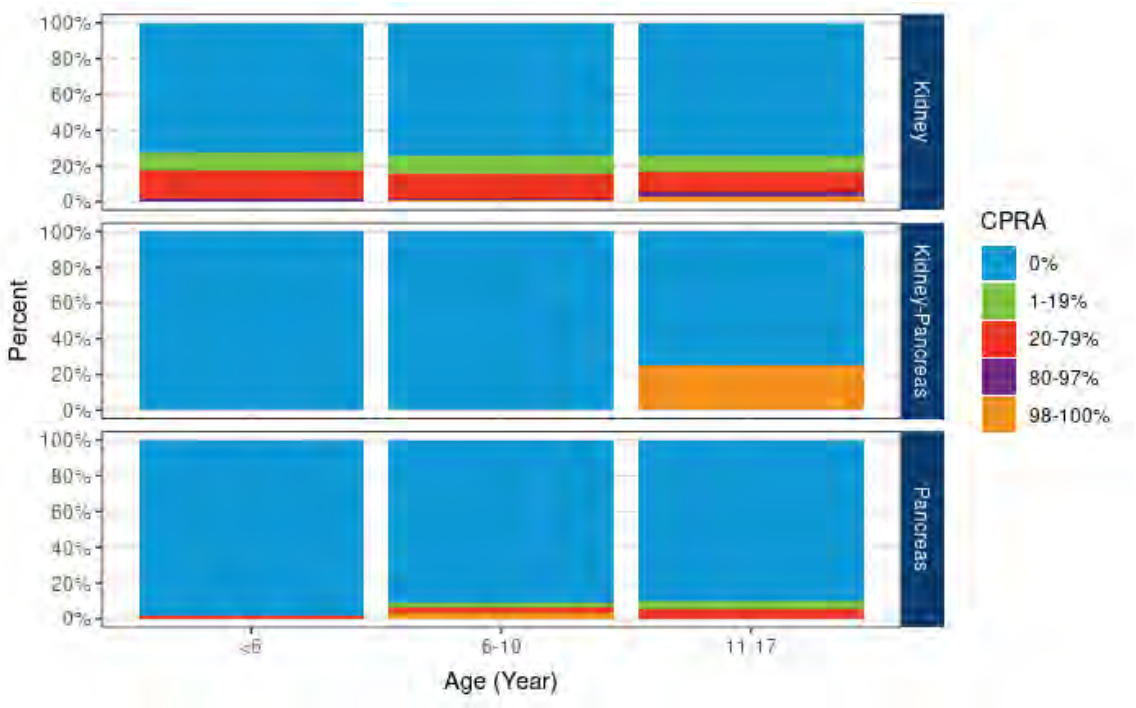
Table 5: Median Time to Transplant for Kidney Candidates by Age at Listing[95]

Age at Listing	Registrations	Median time to transplant (Years)
<6	459	4.22
6-10	323	2.45
11-17	1195	2.03

Notes: Candidates added during 2016-2017

[91] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."
[92] OPTN Kidney and Pancreas Transplantation Committees. 2021, January 29 Continuous Distribution Workgroup Meeting Summary.
[93] OPTN Kidney and Pancreas Transplantation Committees. 2021, January 29 Continuous Distribution Workgroup Meeting Summary.
[94] OPTN Kidney and Pancreas Transplantation Committees. 2021, January 29 Continuous Distribution Workgroup Meeting Summary.
[95] Based on OPTN data as of July 2021.

Figure 12: Deceased Donor Transplant by Age at Transplant and CPRA[96]



There was discussion regarding KDPI and using it to stratify donors. In consultation with the Pediatrics Committee and a review of literature, there was some concern raised regarding KDPI not being a good measure for pediatric donors and creating a longevity mismatch as KDPI often underestimates kidney function and quality in pediatric donors.[97] Pediatric kidneys with high KDPIs are not typically allocated to those recipients with the highest longevity. Additionally, literature points to KDPI as a poor predictor of transplant outcomes for pediatric patients compared to adults.[98]

There was a public comment that suggested creating age-based categories for pediatric candidates, distinguishing between younger and older children (ex. 1-6, 7-12, and 13-18 years old) with younger age groups receiving more priority. The basis for this differential in points would be related to the adverse effects of end stage renal disease (ESRD) on growth and development being more substantial in the younger patients. The Workgroup discussed considerations for prioritization of the KDPI of 35-85 percent and the donor age group of 6-10 years old.[99] The Workgroup discussed current pediatric priority in KDPI sequences and that opening up Sequence C (KDPI 35-85 percent) to all pediatric candidates would be too burdensome for transplant programs given the increased volume of offers. There is a subset of those donors, primarily the younger donors, who may have had acute kidney injury that caused their KDPI to increase, and could be teased out in order to prioritize those donors for pediatric candidates. The Workgroup suggested that it may be possible to create an extra Sequence for the younger donors; younger donors would be pulled out of Sequence C, allowing a way to give the

[96] Based on OPTN data as of July 2021.
[97] Parker, W. F., Thistlethwaite, J. R., Jr, & Ross, L. F. (2016). Kidney Donor Profile Index Does Not Accurately Predict the Graft Survival of Pediatric Deceased Donor Kidneys. *Transplantation, 100*(11), 2471–2478.
[98] OPTN Kidney and Pancreas Transplantation Committees. 2021, January 29 Continuous Distribution Workgroup Meeting Summary.
[99] OPTN Kidney and Pancreas Transplantation Committees. 2021, July 16. Continuous Distribution Workgroup Meeting Summary.

pediatric programs and recipients priority, without opening them up to all of the higher KDPI kidneys from the adult population. This could be a possible addition as part of a future iteration of the continuous distribution project.

The Workgroup agreed to a binary (yes or no) rating scale for pediatrics. 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 kidneys, the rating scale would be conditional on donor factors; candidates under the age of 18 would receive the full benefit of the pediatric points if specific donor criteria are met (ex. KDPI less than 34 percent).

The Workgroup is seeking community input on the following questions:

- Do you agree with the rating scale recommendations for pediatric candidates?
- How should the pediatric attribute be weighted in the composite allocation score?
- What other factors should be considered in the prioritization of these candidates?

Waiting time (Kidney, Pancreas, and Kidney-Pancreas): In the current system, waiting time accounts for a prominent part of a kidney candidate's allocation score. According to kidney, pancreas, and KP policy, one day of waiting time equals approximately 1/365 of a point, therefore one point is equivalent to approximately one year of waiting time.[100,101]

The Workgroup discussed several options for incorporating waiting time into a rating scale.[102] One option would be to have a linear waiting scale as shown in **Figure 13**. In this version of a rating scale, as waiting time increases, points increase in a linear, direct fashion similar to current policy where every additional day of waiting time is equal. A potential limitation for this rating scale is weight dilution, meaning most candidates would fall in the bottom quarter of the scale. Therefore, very few would receive the maximum points resulting in a scale that does not clearly differentiate between candidates.

Another option the Workgroup reviewed was a rating scale that would still use a linear line but would add a threshold (ex. 10 years of waiting time) where those outside of the threshold would have additional weight. This example can be seen in **Figure 14**. This scale option would keep waiting time on a linear scale, but would make weights variable for candidates with more extreme waiting times.

A third option the Workgroup reviewed as seen in **Figure 15** was to add a cap, or "ceiling" to waiting time where points would not be awarded above a specified threshold (ex. all candidates would receive the full rating beyond 10 years of waiting time). This rating scale would be mathematically simple and keeps a consistent weight on the rating scale, but doesn't distinguish between candidates that have waiting times greater than the ceiling threshold.

The final option the Workgroup discussed was a linear option with a curve as seen in **Figure 16**. This scale would incorporate a linear scale up to a specified amount of waiting time, after which the scale would slowly curve with each additional day worth less than the one before. This model would maintain a 0-100 rating scale and a given weight and would distinguish between candidates with a significant waiting time.

[100] OPTN Policy 8.3: Kidney Allocation Score as of October 7, 2021.
[101] OPTN Policy 11.2: Pancreas Allocation Score as of October 7, 2021.
[102] OPTN Kidney and Pancreas Transplantation Committees. 2021, October 15. Continuous Distribution Workgroup Meeting Summary.

Figure 13: General Linear Rating Scale

Figure 14: Linear Rating Scale with Threshold

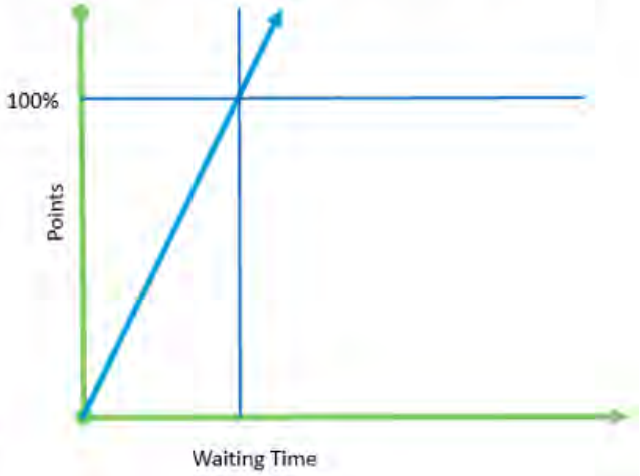


Figure 15: Linear Rating Scale with Ceiling

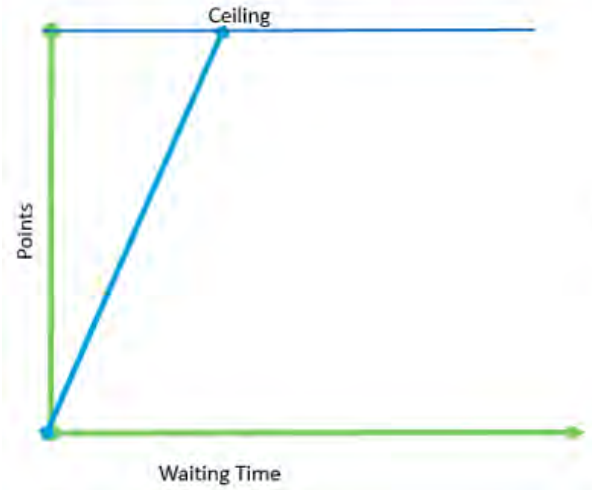


Figure 16: Linear Rating Scale with a Curve

After reviewing the options the Workgroup expressed concern with establishing a ceiling for waiting time as it appears to penalize the rare candidates who have high waiting time.[103] Kidney Committee members emphasized many candidates with large amounts of waiting time are due to access issues and the ability to backdate waiting time to start of dialysis attempts to address those disadvantaged patients. Other Workgroup members questioned if having a ceiling would promote placement efficiency as candidates with large amount of waiting time are also often highly sensitized and would receive a large amount of offers on a national level. The Workgroup also discussed whether there should be 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 is seeking community input on the following questions:

[103] OPTN Kidney Transplantation Committee. 2021, October 15. Kidney Continuous Distribution Workgroup Meeting Summary.

- What are your thoughts on the options for waiting time outlined above? Are there other options that should be considered?
- Should there be a difference in points for those candidates on or off dialysis?

Kidney-after-Liver (KAL) Safety Net (Kidney): The Kidney-after-Liver (KAL) Safety Net describes a section of OPTN policy that provides increased priority on the kidney waiting list for liver recipients with continued kidney disease or dysfunction shortly after transplant.[104] The Workgroup agreed to include this as an attribute in the new framework.[105]

In current kidney policy, to qualify for KAL Safety Net priority, a prior liver recipient must be registered on the kidney waiting list prior to the one-year anniversary of their most recent liver transplant date. Additionally the candidate must have a qualifying creatinine clearance (CrCl) or glomerular filtration rate (GFR) level or be on dialysis within 60-365 days of the liver transplant. Candidates meeting the safety net criteria qualify for prioritization for kidneys with KDPI scores of 20 percent or above as seen in **Table 6**.

Table 6: Kidney Classifications by Sequence

Sequence A* KDPI 0-20%	Sequence B KDPI 20-34%	Sequence C KDPI 35-85%	Sequence D KDPI 86-100%
100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% – 99% Highly Sensitized 0-ABDR mismatch Inside Circle Top 20% EPTS 0-ABDRmm (All) Inside Circle (All) National Pediatrics National (Top 20%) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% – 99% Highly Sensitized 0-ABDR mismatch **Inside Circle KAL Safety Net** Inside Circle (All) National Pediatrics National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98% – 99% Highly Sensitized 0-ABDR mismatch **Inside Circle KAL Safety Net** Inside Circle (All) National (All) Inside Circle (Dual) National (Dual)	100% Highly Sensitized Inside Circle Medically Urgent 98% – 99% Highly Sensitized 0-ABDR mismatch **Inside Circle KAL Safety Net** Inside Circle (All) Inside Circle (Dual) National (All) National (Dual)
*En Bloc (Sequence E) is a replication of Sequence A for candidates that have opted in to receive en bloc offers Note: “Inside Circle” refers to allocation within a 250 NM circle from the donor hospital			

The Workgroup considered whether the KDPI threshold should be changed to 35 percent or greater to allow for those kidneys with a KDPI of 35 or less potentially being allocated to more pediatric candidates.[106] Based off of original kidney sequence discussions when the policy was developed, there had been mixed public comment feedback on whether to include the safety net in the KDPI 20-34 percent sequence. However, after looking at data, the Kidney Committee observed that the majority of kidneys allocated were allocated through the 20-34 percent and 25-85 percent sequences and thought

[104] OPTN Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List as of October 7, 2021.
[105] OPTN Kidney Transplantation Committee. 2020, October 9. Kidney Continuous Distribution Workgroup Meeting Summary.
[106] OPTN Kidney and Pancreas Transplantation Committees. 2021, October 1. Continuous Distribution Workgroup Meeting Summary.

removing the existing priority would reduce access.[107] Additionally, pediatric candidates are currently prioritized above KAL Safety Net candidates.

The Workgroup recommends a binary (yes or no) scale for KAL Safety Net and maintaining the existing KDPI threshold.[108] The Workgroup requests additional community input on the KDPI threshold for KAL safety net as well as the criteria to qualify for priority.

The Workgroup is seeking community input on the following questions:

- Do you agree with the rating scale recommendation for kidney-after-liver safety net candidates?
- How should the kidney-after-liver safety net attribute be weighted in the composite allocation score?
- Do you agree with maintaining the existing KDPI threshold?
- Do you have additional input on the criteria to qualify for kidney-after-liver safety net priority?

Placement Efficiency

The OPTN Final Rule does not define the "efficient management of organ placement." [109] However, a Federal Register notice related to the development of the OPTN Final Rule can provide some guidance for interpreting this clause. It stated:

> Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient.[110]

The Placement Efficiency category encompasses the amount of resources required to identify a suitable candidate willing to accept the organ and deliver the organ for transplant.

Travel and Proximity Efficiency (Kidney and Pancreas): Current kidney and pancreas allocation policy uses proximity between the donor hospital and transplant hospital to assign points to candidates.[111,112] Transportation costs generally increase as the distance between the donor and transplant hospitals increase. Geographic proximity (e.g., distance between donor and transplant candidate's hospital) may be considered to the extent necessary to satisfy requirements in the Final Rule: e.g., efficient management of organ placement and the avoidance of futile transplants due to increased ischemic time.[113] Outside of distance and cost, efficient placement emphasizes swift and effective donor organ and recipient matching. This is particularly important for kidneys, as kidney match runs can include many thousands of potential recipients and kidneys are often allocated and placed post-recovery. Current allocation provides for more efficient placement for both kidneys and pancreata, such as facilitated pancreas allocation and minimum acceptance criteria for kidneys.

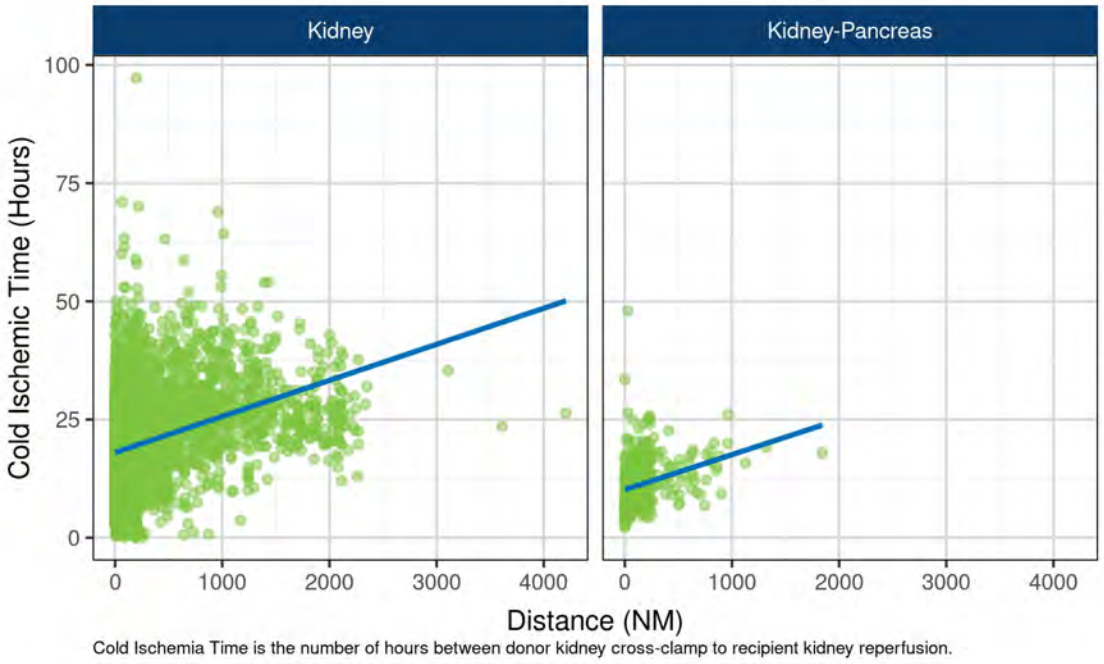
[107] OPTN Kidney Transplantation Committee, "Simultaneous Liver Kidney (SLK) Allocation." 2016.
[108] OPTN Kidney and Pancreas Transplantation Committees. 2021, October 1. Continuous Distribution Workgroup Meeting Summary.
[109] 42 CFR Sec. 121.8(a)(2).
[110] 63 FR 16315 (1998).
[111] OPTN Policy 8.3: Kidney Allocation Score, Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital
[112] 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
[113] 42 C.F.R. §121.8(a)(8)

In approaching discussions on placement efficiency, the Workgroup considered public comment received from the 2021 concept paper.[114] This is an area of significant community interest, especially due to the recent implementation of the circles-based kidney and pancreas policies.[115,116] Comments were submitted regarding increased workloads for OPOs, transplant centers, and HLA labs to evaluate kidney and pancreas offers due to the new allocation policy. Commenters also expected this to increase more with broader allocation and feel the large volume of offers increases 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 transplant programs when discussing efficiency. Other commenters suggested donor assessment would be more fluid in a continuous distribution system.

The Workgroup discussed the relationship between candidate proximity and placement efficiency and recognized the cost of transportation is just one factor of placement efficiency.[117] There are several measures of inefficiencies that could have an association with proximity, such as ischemia time and discard rates due to higher cold time. Using cold time as an example, **Figure 17** looks at the relationship between cold ischemic time and distance for kidney and KP. While cold time tends to increase with distance, that's not always the case. There are instances where organs accrue more cold time without traveling very far (ex. logistical challenges). However, cold ischemic time is difficult to predict and not known at the time a match is run. What is known at time of match is the distance between the donor and recipient, therefore distance is used as a crude proxy for ischemic time.[118]

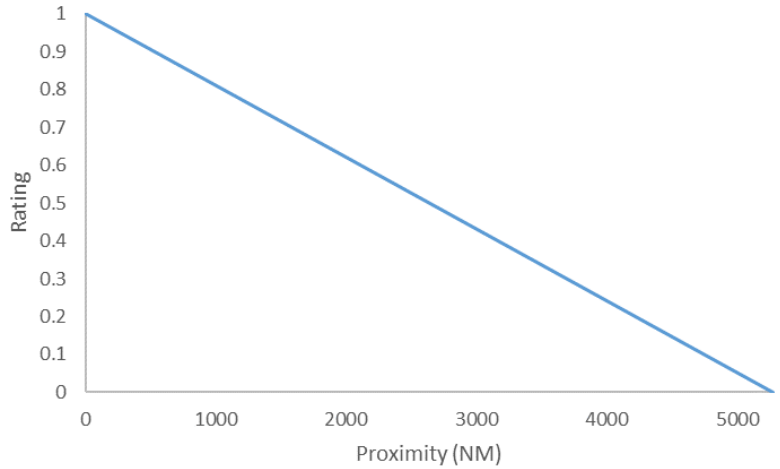
[114] OPTN Kidney and Pancreas Transplantation Committees, 2021 "Continuous Distribution of Kidneys and Pancreata Concept Paper."
[115] OPTN Kidney Transplantation Committee. "Eliminate the Use of DSA and Region from Kidney Allocation Policy." Implemented March 15, 2021.
[116] OPTN Pancreas Transplantation Committee. "Eliminate the Use of DSA and Region from Pancreas Allocation Policy." Implemented March 15, 2021.
[117] OPTN Kidney and Pancreas Transplantation Committees. 2021, November 5 Continuous Distribution Workgroup Meeting Summary.
[118] OPTN Kidney and Pancreas Transplantation Committees. 2021, November 5. Continuous Distribution Workgroup Meeting Summary.

Figure 17: Distance vs. Cold Ischemic Time for Deceased Donor Kidney and KP Transplants, March 15 - August 31, 2021[119]



Understanding that travel and proximity efficiency often go hand in hand, the Workgroup reviewed options for rating scales that merge the two attributes together. The Workgroup first considered a simple, linear approach as shown in **Figure 18**, which would rely on a single scale to approximately account for all types of inefficiencies linked to proximity (ex. ischemic time, offer refusals, transport and coordination costs, etc.). The Workgroup agreed this approach would be easily understood but is too simplified.[120]

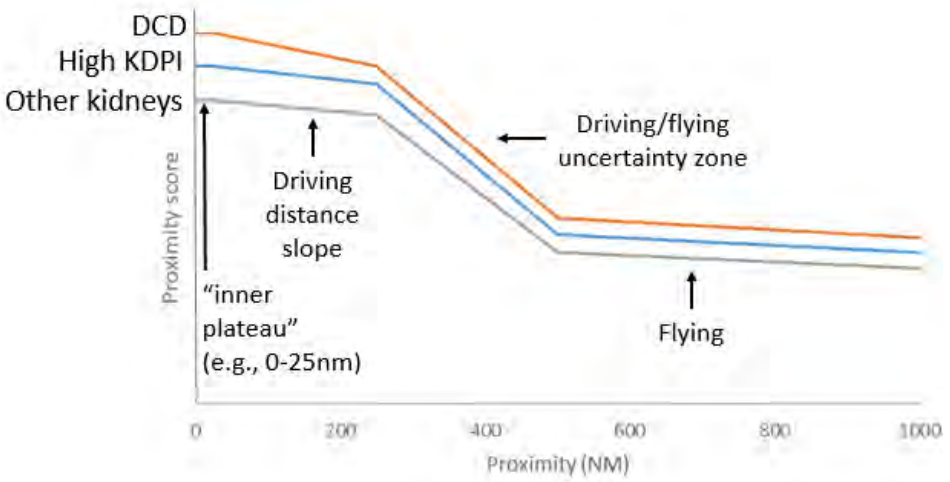
Figure 18: Simple, Linear Approach



[119] Based on OPTN data as of November 2021.
[120] OPTN Kidney and Pancreas Transplantation Committees. 2021, November 5. Continuous Distribution Workgroup Meeting Summary.

Expanding on the simple, linear approach above, the Workgroup then considered a more piece-wise linear approach that would include more consideration for logistical concerns (i.e. driving vs. flying) and donor factors. As shown in **Figure 19**, an "inner plateau" can be added to prioritize candidates listed at a hospital very close to a donor hospital (ex. within 25 nautical miles [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. [121,122] Additionally, the piece-wise linear approach could assign more point to efficiency depending on organ quality or donor type (ex. DCD, high KDPI, etc.) as certain donor factors are less able to tolerate broader distribution.

Figure 19: Simple, Piece-Wise Linear Approach*



*All values depicted in Figure 21 are for demonstration purposes only

The Workgroup also reviewed the rating scales used by the OPTN Lung Committee for their continuous distribution framework. The Lung framework has two rating scales for placement efficiency, both tied to the straight-line distance between the donor and transplant hospital. The Travel Efficiency, or "travel cost" rating scale (**Figure 20**), includes costs associated with travel mode and distance (ex. cost of driving vs. cost of air travel). The Proximity Efficiency, or "S-curve" rating scale, (**Figure 21**) includes other inefficiencies associated with attempting to place organs to further-away candidates such as travel logistics, coordination costs, offer refusals, ischemic time, etc. The travel efficiency scale was informed by data and while the proximity efficiency scale was developed from subject matter expertise.

[121] OPTN Kidney Transplantation Committee. "Eliminate the Use of DSA and Region from Kidney Allocation Policy." Implemented March 15, 2021.
[122] OPTN Pancreas Transplantation Committee. "Eliminate the Use of DSA and Region from Pancreas Allocation Policy." Implemented March 15, 2021.

Figure 20: Travel Efficiency rating scale

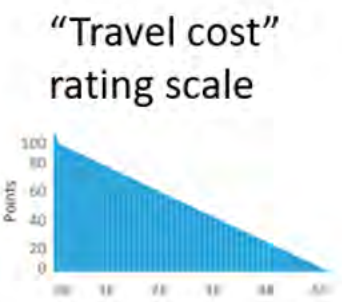


Figure 21: Proximity Efficiency rating scale

One consideration is that travel cost data is not available for kidneys or pancreata. The Lung Committee based their metrics on liver-related data as lungs and livers travel similarly to lungs.[123,124] However, kidneys can travel further and have considerable variability. The Workgroup felt the two scale approach used by the Lung Committee would not be suitable for kidneys and pancreata. The Workgroup considered the options presented and were more favorable of the simple, piece-wise linear approach as described above (**Figure 19**).[125,126]

The Workgroup emphasized that donor quality is important in kidney allocation and determines the importance of travel distance and efficiency. The Workgroup discussed other considerations for distance including the preference for driving vs. flying, travel costs, and also the time of day or night the organs are offered as flights become more or less available. Kidney Committee representatives also expressed higher KDPI kidneys should be kept closer to the donor hospital as travel time could affect marginal kidneys more. The Workgroup favored the simple, piece-wise linear scale as it preserves the distance inflection points of 250 NM previously established by the Committees and considers other measures of efficiency all on the same scale. The Workgroup also emphasized the weight of this attribute should differ for the KP and pancreas alone frameworks.

Additionally, there are other ways in which to consider placement efficiency outside of the continuous distribution framework such as the use of screening tools, offer filters, provisional yes, offer acceptance, and travel tools to name a few. Some of these innovations are actively being worked on in other OPTN Committees and Workgroups.

Using **Figure 19** as a visual example of the simple, piece-wise linear scale, the Workgroup would appreciate community feedback on the following questions:

- Do you agree with the Workgroup's approach to placement efficiency?
- When considering placement efficiency, what donor factors should be weighted differently?
- What should the distance for the "inner plateau" be?
- How steep or shallow should the driving/flying uncertainty zone be?
- How should placement efficiency for kidneys and pancreata be weighted differently in the total composite allocation score?
- What are some other measures of the efficient management of organ placement that should be

[123] OPTN Lung Transplantation Committee. 2021, December 6. "Briefing to the OPTN Board of Directors on Establish Continuous Distribution of Lungs."
[124] Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL, Axelrod DA. The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients. *Am J Transplant*. 2016 Feb;16(2):583-93. doi: 10.1111/ajt.13569. Epub 2016 Jan 18. PMID: 26779694.
[125] OPTN Kidney and Pancreas Transplantation Committees. 2021, November 5. Continuous Distribution Workgroup Meeting Summary.
[126] OPTN Kidney and Pancreas Transplantation Committees. 2021, November 15. Continuous Distribution Workgroup Meeting Summary.

taken into account in a points-based framework?
- How could the Workgroup account for administrative burden of organ placement?
- What other methodologies should be considered for predicting ischemic time?

Dual vs. Single (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.[127] This policy update also designates an allocation pathway for dual kidneys by allowing transplant programs to opt in to dual kidney offers for their patients. The original intent of this policy is to increase organ utilization for kidneys that are considered more marginal. Originally this was identified as an attribute for consideration under the Placement Efficiency category. The Workgroup seeks community feedback on how best to operationalize dual kidney allocation in the continuous distribution framework.

The Workgroup is seeking community input on the following questions:
- How should dual kidneys be operationalized in the new continuous distribution framework?

En Bloc (Kidney): 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.[128] 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.[129] The Kidney Donor Risk Index (KDRI) includes a coefficient to account for en bloc receipt.[130] 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.[131]

The Kidney Committee had extensive discussion on the interaction of donor and recipient factors when it comes to en bloc allocation. For example, size mismatch and vascular disease are among the candidate characteristics considered for candidates deciding to opt in to receiving or evaluating en bloc kidney offers. The Workgroup also considered the effects of donor weight on en bloc kidney function and utilization, as larger donor en bloc kidneys will function differently and have better projected outcomes than smaller donor en bloc kidneys. The Kidney Committee contemplated a sliding scale based on donor weight, such that en bloc kidneys from a 10kg donor were allocated differently than those from a 17kg donor.[132]

The Kidney Committee agreed to utilize a binary (yes or no) rating scale for the en bloc attribute, dependent on candidate opt in and donor factors outlined in policy, contingent on further discussions regarding KDPI and EPTS. [133] The Workgroup requests community input on how to best incorporate en bloc kidneys into the new continuous distribution framework.

The Workgroup is seeking community input on the following questions:
- Do you agree with the en bloc rating scale recommendation for kidney?

[127] OPTN Kidney Transplantation Committee, "Policy Notice: Improving Dual Kidney Allocation."
[128] OPTN Policy 8.6.B: Allocation of En Bloc Kidneys as of October 7, 2021.
[129] OPTN Kidney Transplantation Committee, "Policy Notice: Improving Allocation of En Bloc Kidneys."
[130] OPTN Kidney Transplantation Committee. "Briefing Paper to the OPTN Board of Directors on Improving Allocation of En Bloc Kidneys." June 2017.
[131] OPTN Kidney Transplantation Committee. 2021, October 8. Committee Meeting Summary.
[132] OPTN Kidney Transplantation Committee. 2021, October 8. Committee Meeting Summary.
[133] OPTN Kidney Transplantation Committee. 2021, October 8. Committee Meeting Summary.

- How should en bloc kidneys be operationalized in the new continuous distribution framework?

Non-Utilization

In addition to the goals and attributes listed above, the Pancreas Committee representatives identified islets as an attribute related to non-utilization, or increasing the number of transplants by optimizing the utilization of organs. The Final Rule requires allocation policies to "be designed to avoid wasting organs."[134]

Islets (Pancreas): Islet transplantation is the injection of pancreatic islet cells into a patient's liver so that the patient can begin to produce insulin on their own.[135] Currently in policy, islet candidates are registered if they are either insulin dependent or have a hemoglobin A1c (HbA1c) value greater than 6.5 percent.[136] The islet field is one way to progress pancreas transplantation and is included in each allocation sequence for KP and pancreas in current policy.[137,138] The Workgroup agreed this attribute should be included and discussed distinguishing prioritization among pancreas whole organ candidates and islet candidates by mirroring current policy for now, where older and higher body mass index (BMI) donor organs are prioritized to islet candidates. [139]

After much discussion, the Committee agreed that islets should be included as an attribute with a binary (yes or no) rating scale. Additionally, whole organs would be prioritized first; priority points would be allocated to islet candidates based on certain criteria. Current policy outlines allocation classifications for KP, pancreas, and islets based on the following donor criteria: 1) 50 years old and less with a BMI less than or equal to 30kg/m^2 or 2) more than 50 years old with a BMI greater than 30kg/m^2. The Pancreas Committee discussed how utilization of pancreas starts to decline at donor age 35. It was explained that data showed very few pancreas transplants were performed from donor age 35 or BMI 30, which decreased to 0 transplants from donor age 40, or BMI 30. [140] The Pancreas Committee suggested decreasing the donor age to 40 or BMI greater than 30 with consideration on increasing islet priority for donors who meet both of these criteria.

The Committee discussed this attribute being re-categorized and that islets could also potentially fall under the placement efficiency category.[141] The Committee will continue to discuss placement of this attribute to align with the rationale mentioned.

The Workgroup is seeking community input on the following questions:

- How should islets be operationalized in the new continuous distribution framework?

Other Attributes Considered

Facilitated Pancreas (Pancreas): 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

[134] 42 CFR Sec. 121.8(a)(2).
[135] OPTN Patient Education, "Questions and Answers for Transplant Candidates about Pancreas, Pancreas-Kidney, and Islet Allocation."
[136] OPTN Policy 11.3.C: Islet Registration Status
[137] OPTN Pancreas Transplantation Committee. 2020, November 20 Pancreas Continuous Distribution Workgroup Meeting Summary.
[138] OPTN Policy 11.5.E: Sorting Within Each Classification
[139] OPTN Pancreas Transplantation Committee. 2020, November 20 Pancreas Continuous Distribution Workgroup Meeting Summary.
[140] OPTN Pancreas Transplantation Committee. 2021, November 15 Pancreas Continuous Distribution Workgroup Meeting Summary.
[141] OPTN Pancreas Transplantation Committee. 2020, November 20 Pancreas Transplantation Committee Meeting Summary.

recovery.[142] The Workgroup initially agreed to include facilitated pancreas as an attribute categorized as avoid organ wastage/non-utilization. [143]

The Pancreas Committee discussed various ways facilitated pancreas could be included in the continuous distribution framework.[144] After further discussion, the Pancreas Committee agreed that facilitated pancreas would be better to categorize under the Placement Efficiency category. The Pancreas Committee then discussed how points may be awarded: implementing facilitated pancreas as it is currently in policy or awarding boost points to facilitated programs. If facilitated pancreas were to remain how it is currently in policy, where non-facilitated programs are bypassed, boost points may not be the best tool to achieve this. By awarding boost points to facilitated programs, this would include identifying those aggressive programs and awarding them points or doing this in addition to applying a screening criteria.[145]

The Pancreas Committee also discussed potential priority being given within facilitated pancreas based on proximity, especially since pancreata are more likely to be utilized the closer the donor and transplant hospitals are to each other. The Pancreas Committee agreed that the distance component should be included in facilitated pancreas, but will await further data to determine any changes to the distance component within facilitated pancreas.[146]

After further discussion, the Pancreas Committee determined that due to various components that could create changes in the current facilitated pancreas structure, facilitated pancreas would not be included as an attribute in this iteration of the project.[147]

Ischemic Time (Kidney and Pancreas): As described in the 2021 concept paper, ischemic time is not directly used in current allocation. Instead, distance is used as a proxy for multiple attributes (proximity efficiency and ischemic time). Understanding that ischemic time is determined based on various factors besides proximity and is not known at the time of match, the Workgroup requests additional community feedback on potential methodologies for predicting ischemic time.

Medical Urgency for KP vs. Pancreas vs. Islets (Pancreas): As described in the 2021 concept paper, medical urgency is not addressed in pancreas policy currently.[148] The Pancreas Committee voiced that in pancreas transplantation, medical urgency and determining the sickest candidate is challenging and has not been done. During the fall 2021 public comment period, commenters inquired about discussions on medical urgency as it pertained to pancreata. There were some comments that expressed the possibility to quantify hypoglycemic unawareness as an aspect of medical urgency for pancreas recipients. Other comments expressed concern that there is the lack of literature available to establish a defined way to compare waitlist mortality and medical urgency for a solitary pancreas recipient to that of a kidney-pancreas (KP) recipient. Due to its complexities, the Pancreas Committee plan to discuss potential

[142] OPTN Policy 11.7.B*:* Facilitated Pancreas Offers
[143] OPTN Pancreas Transplantation Committee. 2020, October 23 Pancreas Continuous Distribution Workgroup Meeting Summary.
[144] OPTN Pancreas Transplantation Committee. 2021, October 4 Pancreas Continuous Distribution Workgroup Meeting Summary.
[145] OPTN Pancreas Transplantation Committee. 2021, October 4 Pancreas Continuous Distribution Workgroup Meeting Summary.
[146] OPTN Pancreas Transplantation Committee. 2021, November 15 Pancreas Continuous Distribution Workgroup Meeting Summary.
[147] OPTN Pancreas Transplantation Committee. 2021, November 15 Pancreas Continuous Distribution Workgroup Meeting Summary.
[148] OPTN Kidney and Pancreas Transplantation Committees, 2021 “Continuous Distribution of Kidneys and Pancreata Concept Paper.”

medical urgency criteria for KP/pancreas and how it may be incorporated in a future iteration of the project.[149]

Pancreas after Kidney (PAK) (Pancreas): The Workgroup initially agreed to include this attribute with consideration on differentiating between candidates receiving a pancreas after receiving a living donor kidney and candidates receiving a pancreas after receiving a deceased donor kidney. [150] The Workgroup explained further that a KP candidate who receives a living donor kidney is bringing a living donor kidney into the system when they could have been listed for a KP, which would have taken a kidney out of the system. The initial thought was that if a patient on the kidney list receives a living donor kidney transplant and then needs a pancreas, that patient should receive additional points for a pancreas to come with or shortly after the kidney. There was some concern raised on the need to consider the demographics that historically do not have a high volume of living donors, to ensure candidates are not being disadvantaged.[151]

Although there was much discussion in regards to prioritizing PAK transplants after a living donor kidney transplant, it was noted that there was a need for more discussion on addressing PAK transplants after deceased donor kidney transplant. Additionally, there may also be other criteria besides being a recipient of a living donor kidney that may need further discussion and consideration. After much consideration, the Pancreas Committee decided not to include this attribute.[152] The Pancreas Committee will discuss this attribute in further detail and determine if this attribute may be incorporated in a later iteration of the continuous distribution framework.

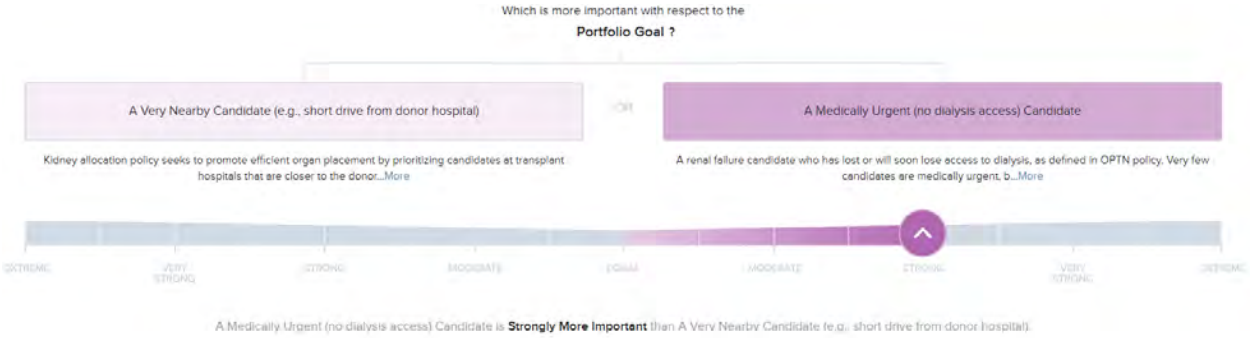
Next Steps

The Workgroup, with input from the community, will need to determine the importance of each attribute against each other. Organ allocation requires the balancing of multiple goals. The field of operations research provides many tools for evaluating what are known as multi-criteria decisions. While the preceding analysis used traditional analytical methods to determine how to smooth and prioritize categories of candidates, the next analysis will require a different method. The task of weighing attributes against each other is values laden rather than a clinical or operational question. For example, the proper balance between equity and utility is a frequent discussion amongst the committees when they develop organ allocation policies. The OPTN Final Rule contains requirements that apply to permissible considerations for setting organ allocation policies[153] and the OPTN has adopted principles that support the values held by the organization.[154,155,156] Similar to the approach used by the Lung Committee, the Kidney and Pancreas Committees will utilize an Analytical Hierarchy Process (AHP) for its strengths in collecting feedback from a broad and diverse community.[157,158]

[149] Pancreas Transplantation Committee. 2020, October 9. Pancreas Transplantation Committee Meeting Summary.
[150] Pancreas Transplantation Committee. 2020, November 2020. Pancreas Continuous Distribution Workgroup Meeting Summary.
[151] Kidney-Pancreas Continuous Distribution Workgroup. 2021, October 2021. Kidney-Pancreas Continuous Distribution Workgroup Meeting Summary.
[152] OPTN Pancreas Transplantation Committee. 2021, October 4 Pancreas Continuous Distribution Workgroup Meeting Summary.
[153] 42 C.F.R. §121.8(a).
[154] OPTN Ethics Committee, 2015 "Briefing Paper on Ethical Principles in the Allocation of Human Organs."
[155] OPTN Ad Hoc Geography Committee, 2018 "Briefing Paper on Frameworks for Organ Distribution."
[156] OPTN Pediatric Transplantation Committee, 2014 "Briefing Paper on Ethical Principles of Pediatric Organ Allocation."
[157] *See generally* Mark, T. L., & Swait, J., 2004. *Using stated preference and revealed preference modeling to evaluate prescribing decisions*. Health economics.
[158] *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.

The prioritization exercise will show each participant a pair of attributes that will be used to prioritize candidates. (For example **Figure 22** shows profile-based descriptions related to medical urgency and travel efficiency). Participants will then be asked 1) which attribute is more important and 2) *how much* more important is that attribute. Participants are also encouraged to leave comments to explain their rationale as this information is very helpful to the Workgroup's deliberations.

Figure 22: Pairwise Comparison Example



At the conclusion of the exercise, participants will be able to see their personal priorities for these attributes. The Committees will then review the overall priorities by specific attributes or demographics in order to better understand the community's preferences.

The Committees will review and discuss the differences between the baseline of current policies and the community's expressed priorities, along with a comparison against the OPTN's obligations in NOTA and the OPTN Final Rule, to develop a modeling request for the SRTR. The Committees will look for agreement across all of those resources and explore the reasoning for minority or different opinion. After reviewing those results and refining the relative weights of the attributes in the composite allocation score, the Committees will submit a modeling request to the SRTR. The Committees will *not* be bound to the majority perspective of the prioritization exercise, for the Committees *must* put forward a proposal that meets OPTN statutory and regulatory requirements. The Committees will review the results of that modeling prior to releasing a policy proposal for public comment.

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,"[159] 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."[160] 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

[159] 42 U.S.C. §274(b)(2)(B).
[160] 42 CFR §121.4(a).

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."[161] While this paper does not propose policy changes at this time, the concepts presented in this paper:

Are based on sound medical judgment: The construction of the individual ratings scales and weights will be based on objective clinical and operations evidence, including simulation modeling and research presented by multiple parties. 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.[162] Additionally, before the policy proposal is released for public comment, it will be modeled by the SRTR to assess the impact on discarded 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 travel efficiency and placement efficiency.

[161] 42 C.F.R. §121.8(a)
[162] OPTN Lung Transplantation Committee. 2021, December 6. "Briefing to the OPTN Board of Directors on Establish Continuous Distribution of Lungs."

Consider whether to adopt transition procedures: The OPTN may be able to compare the ultimate policy proposal with the results of a revealed preference analysis 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 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 paper explains the work that the Kidney and Pancreas Committees have performed to date and how it will move forward toward a policy proposal.

Community Feedback

If you wish to participate in the AHP exercise to prioritize the attributes, please click here. This will bring you to a registration form. After you register your email address, you will receive an email from REDCap@unos.org with instructions regarding the prioritization exercise.

In reviewing this request for feedback, we encourage readers to consider the following questions:

- What other factors should be incorporated into the allocation of kidneys and pancreata within a continuous distribution framework?
- The Workgroup asks for community feedback on the shapes of rating scales for each attributes (ex. linear, non-linear, binary, etc.). Additionally, the Workgroup welcomes feedback on how each attribute should be weighted in the composite allocation score.

Medical Urgency

- Do you agree with the medical urgency definition rating scale recommendation for kidney?
- How should the medical urgency definition attribute be weighted in the composite allocation score?

Post-Transplant Survival

- Do you agree with the HLA matching rating scale recommendation for kidney?
- How should the HLA matching attribute be weighted in the composite allocation score?
- How would prioritizing DR antigen matching affect different populations?
- How should HLA matching be considered for pancreata?
- Should the initial implementation of kidney continuous distribution mirror current approach to longevity matching, by awarding points to EPTS Top 20 percent candidates for KDPI Top 20 percent kidneys? Or should a more sophisticated approach be considered?
- How should EPTS be used in the new allocation framework?
- What are some measures of post-transplant survival for pancreata that should be considered?

Candidate Biology

- Do you agree with the rating scale recommendations for CPRA?

- How should the CPRA attribute be weighted in the composite allocation score?
- How should different blood types be prioritized against each other in the new system? Should non-A1/non-A1B donor kidneys be prioritized for other blood groups? If so, which blood groups?

Patient Access

- Do you agree with the rating scale recommendations for Prior Living Donor Candidates?
- How should the prior living donor attribute be weighted in the composite allocation score?
- What other factors should be considered in the prioritization of these candidates?
- Do you agree with the rating scale recommendations for pediatric candidates?
- How should the pediatric attribute be weighted in the composite allocation score? What other factors should be considered in the prioritization of these candidates?
- What are your thoughts on the options for waiting time outlined above? Are there other options that should be considered?
- Should there be a difference in points for those candidates on or off dialysis?
- Do you agree with the rating scale recommendation for kidney-after-liver safety net candidates?
- How should the kidney-after-liver safety net attribute be weighted in the composite allocation score?
- Do you agree with maintaining the existing KDPI threshold?
- Do you have additional input on the criteria to qualify for kidney-after-liver safety net priority?

Placement Efficiency

- Do you agree with the Workgroup's approach to placement efficiency?
- When considering placement efficiency, what donor factors should be weighted differently?
- What should the distance for the "inner plateau" be?
- How steep or shallow should the driving/flying uncertainty zone be?
- How should placement efficiency for kidneys and pancreata be weighted differently in the total composite allocation score?
- What are some other measures of the efficient management of organ placement that should be taken into account in a points-based framework?
- How could the Workgroup account for administrative burden of organ placement?
- What other methodologies should be considered for predicting ischemic time?
- Do you agree with the en bloc rating scale recommendation for kidney?
- How should dual kidneys, en bloc kidneys, and islets be operationalized in the new continuous distribution framework?

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 we use 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.