OPTN

Concept Paper

Continuous Distribution of Kidneys and Pancreata Concept Paper

OPTN Kidney & Pancreas Transplantation Committees

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

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Continuous Distribution of Kidneys and Pancreata Concept Paper

Sponsoring Committees: *Kidney & Pancreas Transplantation*
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Executive Summary

This concept paper provides an update to the community about the continuous distribution of organs, specifically kidneys and pancreata. Continuous distribution means replacing the current classification approach, which draws hard boundaries between types of patients (for example, blood type compatible vs. identical; sensitized vs. not; inside a circle vs. outside), 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 NOTA and the OPTN Final Rule. This paper contains information about the attributes that have been discussed by the Kidney and Pancreas Continuous Distribution Workgroup. Finally, this paper provides an overview of the policy development approach and next steps 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.

Background

In 2018, the Board of Directors chose to replace the current classification-based allocation system with a points-based continuous distribution framework.[1] The current system contains several hard boundaries. Continuous distribution aims to eliminate hard boundaries built into the current classification based system, ultimately resulting in more equity for patients in addition to more transparency in the system. The continuous distribution framework has significant flexibility to be adapted, producing efficiencies not only in allocation but also in policy development and implementation.

The Kidney and Pancreas Committees have embarked on the initial steps of developing a proposal to implement the continuous distribution framework. This framework will eventually replace the current classification-based allocation system with a points-based allocation system.

What is Continuous Distribution?

A continuous distribution system prioritizes waiting list candidates based on a combination of points awarded for factors related to medical urgency, expected post-transplant outcome, patient access (equity), and the efficient management of organ placement. Continuous distribution will eliminate hard boundaries, which currently preclude a patient from being prioritized ahead of patients on the other side of the boundary.[2][3] 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.

Classification-based framework: A classification-based framework 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 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.

There are many complex decisions that must be made to fully realize the potential of continuous distribution. Some organs already use scaled points within the classification-based system. For example, there is a scale for sensitization points used in kidney allocation, as well as proximity points that are applied both within and outside of the 250 nautical mile distribution circle.[4] This concept of using points instead of hard boundaries could benefit other aspects of organ allocation; for example, removing the hard boundaries used with kidney profile index (KDPI) score and estimated post-transplant survival (EPTS). It also provides a framework to account for other variables to calculate a score for each candidate, besides proximity. In this way, the move toward continuous distribution might best be described as a move from a classification-based framework to a points-based framework.

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[1] OPTN Board of Directors. 2018, December 3-4. Executive Summary. https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf

[2] J. J. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," Am J Transplant 18, no. 11 (Nov 2018), https://doi.org/10.1111/ajt.15115

[3] Jon Snyder, "Systems without Geographic Boundaries". Presented to the OPTN Ad Hoc Geography Committee meeting, March 26, 2018.

[4] OPTN Policy 8.3: Kidney Allocation Points.

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 and relevant committees.[5] A continuous distribution policy would rank organ patients by a composite score that aligns with the different requirements found in NOTA and the OPTN Final Rule. **Figure 1** shows how these five sub-scores combine into a composite score. Each sub-score is explained below.

Figure 1: Components of Composite Allocation Score

Medical urgency score The Final Rule requires that allocation policies "seek to achieve the best use of donated organs" and requires priority of organs based upon "objective medical criteria." OPTN policies use several different approaches to prioritize candidates based upon their medical urgency: model for end-stage liver disease (MELD), heart statuses, etc. Medically urgent kidney candidates are those who have exhausted or are at risk of imminent loss of the ability to receive dialysis.

Post-transplant survival score: The Final Rule requires the consideration of allocation policies that would avoid futile transplants. Another way to think about this is to consider post-transplant outcomes. OPTN policies use several approaches to consider post-transplant outcomes: EPTS, HLA mismatching, etc. Ischemic time can also impact the post-transplant outcomes for a transplant.

Candidate biology score: The Final Rule calls for allocation policies to "promote patient access to transplantation."[6] Some candidates have difficulty finding a suitable donor due to biological incompatibilities. The OPTN has long used different mechanisms, for example the calculated panel reactive antibodies (CPRA) sliding scale found in kidney and pancreas allocation policy, to reduce these biological differences in transplant access.[7]

Patient access score: The Final Rule requires allocation polices be designed to "promote patient access to transplantation." OPTN policies use several approaches for this purpose; this proposal focuses on pediatric or age classifications, and priority for prior living donors. Additionally, NOTA requires that allocation policies "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[8]

Placement efficiency score: The Final Rule requires that organ allocation policies be designed to promote the "efficient management efficiency of organ placement." The efficient management of

[5] 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.
[6] 42 CFR Sec. 121.8(a)(5).
[7] OPTN Policy 8.3: Table 8-2 Points for CPRA.
[8] 42 U.S.C. Sec. 274(b)(2)(M).

the organ placement system can be impacted by many things. Some people have suggested that allocation systems that allocate organs quicker would lead to a more efficient system and could also decrease organ discards. There may be other factors that drive more efficient placement of organs. This model can accommodate those other factors and the committee is interested in feedback and suggestions on factors concerning the efficient management of organ placement.

Combining multiple scores together allows us to consider all of the factors that must be considered to satisfy the regulatory requirements for organ allocation policies. It will also allow us to understand the role of each score across the organs. For example, some organ systems may place more importance on post-transplant outcomes than other organs. Finally, by constructing the composite score around the performance goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule.[9] Error! Reference source not found. 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 (see **Figure 3**), the amount of points given to a candidate varies depending upon the candidate's specific circumstances. The classification-based system currently precludes all patients in a lower classification from being prioritized ahead of any patients in a higher classification, irrespective of considerations regarding medical need, inequities in access, or benefit of transplantation (See **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 (See **Figure 3**). A candidate's composite allocation score will determine the order in which the candidate will receive an organ offer.

[9] 42 CFR Sec. 121.8(b).

Figure 2: Sample Allocation Policy (Current)

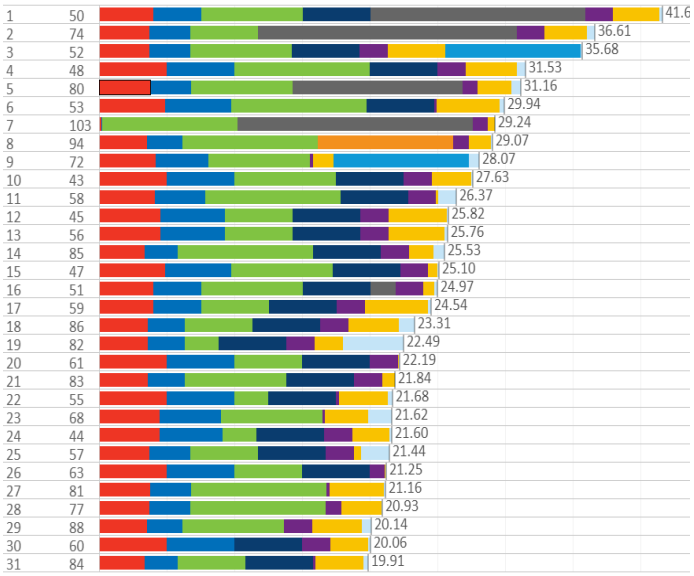
Note that candidates are placed into specific classifications and cannot move between them.

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

Figure 3: Example Match Run (Proposed)

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.

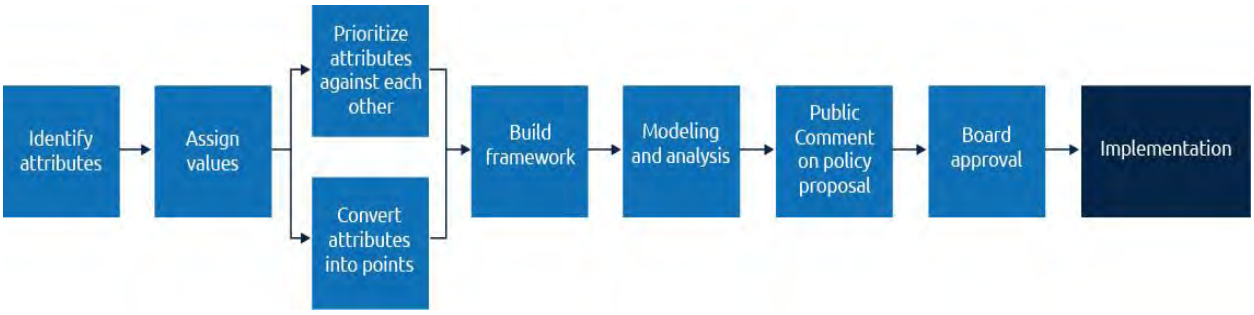


Project Plan

Kidney and pancreas allocation practices are closely related and often interdependent. Much like the Kidney and Pancreas Committee's projects to eliminate the use of DSA and region in kidney and pancreas allocation policy, the Kidney and Pancreas Transplantation Committees formed a joint workgroup (hereinafter, the Workgroup) to conduct their continuous distribution projects simultaneously. The goal of working jointly is to align efforts and to identify where allocation practices should overlap and where they should differ between organ types. The Workgroup is comprised of members of the Kidney, Pancreas, Pediatric, Minority Affairs, and Histocompatibility Committees as well as additional experts in transplantation. Additionally, a cross-organ group of OPTN leaders are often consulted to build consensus around common approaches. The Committees will continue to include additional cross-committee and subject matter expertise as the projects develop.

The proposal for the continuous distribution of kidneys and pancreata will develop through several phases, as seen in **Figure 4**. Each step is explained below.

Figure 4: Project Overview



Identify attributes: The Workgroup identified all of the ways that OPTN policy currently classifies and sorts kidney and pancreas candidates. This includes waiting time, blood type matching, sensitization, etc. Other attributes may be considered for inclusion as well. Once individual attributes have been identified, the Workgroup will then need to categorize these attributes according to their purpose in organ allocation. The Workgroup will use the required considerations set by the OPTN Final Rule to categorize the attributes.[10]

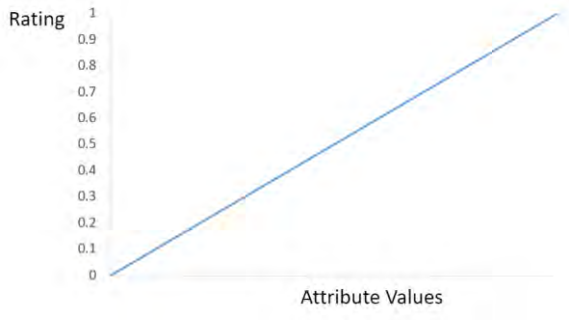
Assign values: The Workgroup will assign values to each of the identified attributes to its applicable NOTA/Final Rule requirement. This will help the Workgroup evaluate iterations of the proposal for regulatory compliance. It also allows the Workgroup to devise common scales for attributes that have a shared goal. Additionally, the attributes outlined below align with the ethical principles of equity and utility. These principles have been expressed consistently by the 1986 Taskforce on Transplantation and in the OPTN Ethical Principles in the Allocation of Human Organs.[11]

Convert attributes into points: [12] Each attribute must be converted into points via a rating scale that allows us to compare attributes and prioritize candidates within the attribute. To convert each attribute to a scale, the Workgroup will first look at how the attribute is used, evaluating whether it is a score, and if the relative differences in points are linear or distributed according to some other function. If the attribute utilizes categories, the Workgroup will consider how to smooth the hard boundaries between those categories. These rating scales (as seen in **Figure 5**) will be built from objective clinical or operational data evidence as much as possible.

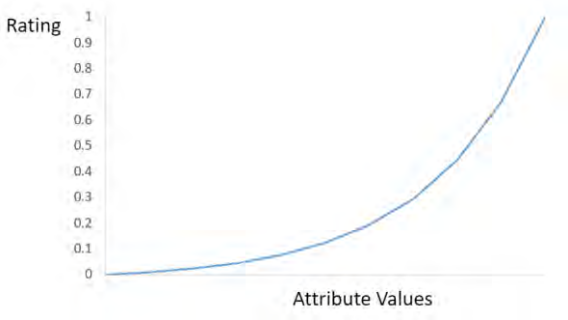
[10] 42 CFR 121.8(a).
[11] *Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Donation*. OPTN. 2015. *Ethical Principles in the Allocation of Human Organs*. Note: Equity is sometimes referred to as justice in these sources.
[12] The Workgroup is currently in this phase.

Figure 5: Examples of Rating Scales

Linear Rating Scale



Non-Linear Rating Scale



Prioritize attributes against each other: The Workgroup must weigh the relative importance of each attribute against each other to determine each attribute's influence in the overall score. This is a values and compliance decision as opposed to clinical or operational decision.

Build framework: Using the points and attribute weighting from the previous steps, the Workgroup will then construct a composite score for kidney, pancreas, and kidney-pancreas allocation.

Modeling and Analysis: The Scientific Registry of Transplant Recipients (SRTR) will then use simulation modeling to predict outcomes under the new framework.[13] The Workgroup will review these results and make final determinations to develop a proposal.

Public comment on policy proposal and Board consideration: Once SRTR modeling is complete, the proposal will follow the standard OPTN processes. This will include additional Workgroup and Committee discussions, community education and feedback, public comment for a policy proposal, and eventually a Board decision.

Attributes: Attributes are criteria that are used to classify then sort and prioritize candidates.

Rating Scale: A rating scale describes how much preference is provided to candidates within each attribute. Rating scales are derived from clinical and operational data or value judgements.

Weights: Weights reflect the relative importance or priority of each attribute toward our overall goal of organ allocation. Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates. Weights are derived from values-based decisions.

At multiple steps throughout the project, the OPTN will provide education to and solicit feedback from the transplant community. These outreach efforts include the release of this concept paper and will continue through the lifecycle of this project.

[13] 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.

Progress So Far

From September 2020 – January 2021, the Workgroup worked through the first phase of identifying attributes related to kidney, pancreas, and kidney-pancreas. In January 2021, the Workgroup began focusing on the second phase of assigning values to the identified attributes. More details on the Workgroup's discussions can be found in the subsections below.

Identifying Attributes

As part of the first phase of the project, the Workgroup met separately to establish goals to be used across the continuous distribution framework and identified those attributes specific to their respective organ. The Workgroup agreed with most of the previously established goal definitions used by the Lung Committee, but recognized the need to develop some goals that were specific to kidney or pancreas (ex. post-transplant survival).[14] **Table 1** outlines the kidney and pancreas-specific goals for each category.

Table 1: Kidney-Pancreas Workgroup Identified Goals

	Medical Urgency	Post-Transplant Survival	Candidate Biology	Patient Access	Placement Efficiency
Kidney Goals	Prioritize those with high mortality due to imminent loss of dialysis	Increasing graft/longevity matching	Increase transplant opportunities for patients who are medically harder to match	Appropriate transplant access	Consider resource requirements required to match, transport, and transplant an organ
Pancreas Goals	Prioritize sickest candidates first to reduce waiting list mortality	Prioritize candidates who are expected to survive for at least one year after receiving a transplant	Increase transplant opportunities for patients who are medically harder to match	Increase transplant access for patients under the age of 18 and patients who previously donated an organ or part of an organ	Consider resource requirements required to match, transport, & transplant an organ

The Workgroup then identified and categorized attributes that were specific to kidney and pancreas (respectively). After which the two groups came together to compare their specific goals and attributes, and also to discuss attributes related to kidney-pancreas transplantation. **Table 2** shows a list of the attributes and their categorizations as developed by the Workgroup. There are similarities of attributes across organs as well as attributes that are more specific to each respective organ.

[14] OPTN Lung Transplantation Committee, 2019 "Continuous Distribution of Lungs" https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf

Table 2: Kidney-Pancreas Workgroup Identified Attributes

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

*Also identified as a kidney-pancreas attribute

**Islets and Facilitated Pancreas were also identified as attributes of non-utilization, described below.

Medical Urgency

The OPTN Final Rule calls for allocation policies to "seek to achieve the best use of donated organs."[15] 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 calls for 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…"[16] The broad definition for medical urgency is the "amount of risk to a candidate's life or long term health without receiving an organ transplant". The Workgroup recognized a need to define kidney and pancreas specific goals as medical urgency would be defined differently depending on the organ type. With this focus, the Workgroup identified the following attributes:

Medical Urgency Definition (Kidney): Recently updated kidney policy contains a specific definition for medical urgency which includes a candidate's imminent loss of dialysis.[17] Therefore, the kidney goal was amended as "prioritize those with high mortality due to imminent loss of dialysis" and the specific medical urgency definition was identified as an attribute.

KP vs. Pancreas vs. Islets (Pancreas): Currently, medical urgency is not addressed in pancreas policy. The Pancreas Committee voiced that in pancreas transplantation, medical urgency and determining the sickest candidate is challenging and has not been done. Hypoglycemia unawareness and severe diabetes are present indications that are used in listing pancreas alone candidates. Candidates who need a kidney-pancreas transplant may have somewhat more urgency than a pancreas alone transplant as these patients are already on dialysis and waiting for two organs. However, it would be difficult to prioritize one type of transplantation over another as there are other factors that could

[15] 42 CFR Sec. 121.8(a)(2).
[16] 42 CFR Sec. 121.8(b)(2).
[17] OPTN Kidney Transplantation Committee, 2020 "Addressing Medically Urgent Candidates in New Kidney Allocation Policy" https://optn.transplant.hrsa.gov/media/3840/2020-06_kid_med_urgency_policy_notice.pdf

be considered. Due to its complexities, this attribute will be discussed in further detail in a future update to discuss multi-organ transplantation (MOT) and how this can potentially be included in the continuous distribution framework.

Post-Transplant Survival

The OPTN Final Rule calls for allocation policies "to avoid futile transplants."[18] Post-Transplant Survival, defined as "a candidate's expected longevity with a functioning graft" is another category where the Workgroup recognized a need to define kidney and pancreas specific goals.[19, 20] Kidney allocation currently uses an EPTS score to predict outcomes after kidney transplant, therefore Kidney Committee members felt a post-transplant survival goal should be long-term graft and patient survival. Pancreas allocation policy does not currently have a way to quantify post-transplant survival for pancreas, therefore Pancreas Committee members drafted a goal to prioritize candidates who are expected to survive for at least one year after receiving a transplant. The Workgroup identified the following attributes for post-transplant survival:

HLA Matching (Kidney and Pancreas): HLA matching has been associated with longer graft survival.[21,22,23,24] In today's kidney policy, HLA matching between the donor and candidate is used to give additional priority to candidates on an individual basis.[25] The pancreas allocation score is based on candidate registration and proximity; however, HLA matching is incorporated in sorting for each classification.[26,27,28]

Ischemic Time (Kidney and Pancreas): Ischemic time is not directly used in current allocation. Instead, distance is used as a proxy for multiple attributes (proximity efficiency and ischemic time). For this reason, each attribute is discussed separately. Understanding that ischemic time is determined based on various factors besides proximity and is not known at the time of match, the Workgroup will explore potential methodologies for predicting ischemic time.

EPTS (Kidney): As mentioned above, EPTS is currently used in kidney allocation to predict a candidate's

[18] 42 CFR Sec. 121.8(a)(5).
[19] OPTN Kidney and Pancreas Transplantation Committees. 2020, September 11 Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4088/20200911_kidney_pancreas_continuous-distribution-wg_meeting-summary.pdf
[20] OPTN Pancreas Transplantation Committee. 2020, September 25 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4126/20200925_pancreas_continuousdistribution_wg_summary.pdf
[21] 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
[22] 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.
[23] 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
[24] 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.
[25] OPTN Policy 8.3: Kidney Allocation Score
[26] OPTN Policy 11.5.E: Sorting within Each Classification
[27] OPTN Kidney Transplantation Committee. 2020, September 25. Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4128/20200925_kidney_continuousdistribution_wg_summary.pdf
[28] OPTN Kidney and Pancreas Transplantation Committees. 2020, December 18 Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4349/20201218_kidney-pancreas_cd_-wg_summary.pdf

projected longevity with a functioning graft. The EPTS score works together with the KDPI score of the donor's kidney to match the organ to the appropriate candidate.[29,30] The Workgroup recognizes the importance of KDPI/EPTS longevity matching and will determine how to incorporate that relationship into the framework as part of the next phase of the project.

Candidate Biology

NOTA requires the OPTN to match organs to consider candidates "whose immune system makes it difficult for them to receive organs,"[31] and the OPTN Final Rule calls for allocation policies to "promote patient access to transplantation."[32] 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.[33]

Similar to the Lung Committee's approach, the Workgroup looked to current policy for 1) which biological characteristics to include and 2) how to prioritize candidates according to their candidate biology. After much discussion, the Workgroup identified blood type and CPRA as key attributes for both organ types and for combined kidney-pancreas. Since both attributes consider the same clinical issue (disadvantages in transplant access due to biological incompatibility with donors), clinical data can be used to inform the degree to which these attributes and their levels should be prioritized in the composite allocation score.

Blood type (Kidney, Pancreas, and Kidney-Pancreas): In current policy, blood type is an attribute which includes both candidate and donor information. Kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with prioritization for blood types O and B to provide equity in the system.[34] Pancreas allocation classifies candidates according to compatible blood type matches as outlined in policy.[35] The Workgroup recognizes the framework would need to allow for compatibility while accounting for the disadvantaged blood types.[36]

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.[37] 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 policy also prioritizes highly sensitized pancreas patients, but there is currently no increased prioritization as seen in current kidney policy.[38]

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[29] OPTN Policy 8.5.A: Candidate Classifications
[30] OPTN Kidney Transplantation Committee. 2020, September 25. Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4128/20200925_kidney_continuousdistribution_wg_summary.pdf
[31] 42 U.S.C. §274(b)(2)(A)(ii)
[32] 42 CFR Sec. 121.8(a)(5).
[33] OPTN Policy 8.3, Table 8-2 Points for CPRA.
[34] OPTN Policy 8.5.D: Allocation of Kidneys by Blood Type
[35] OPTN Policy 11.5.D: Blood Type for Kidney-Pancreas Allocation
[36] OPTN Pancreas Transplantation Committee. 2020, October 9 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4146/20201009_panc_continuousdistribution-wg_summary.pdf
[37] OPTN Policy 8.3: Kidney Allocation Score
[38] OPTN Pancreas Transplantation Committee. 2020, October 9 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4146/20201009_panc_continuousdistribution-wg_summary.pdf

The new continuous distribution framework has potential for improving access for the most highly sensitized candidates that are currently disadvantaged.[39,40] If the Workgroup follows the lead of the Lung Committee, CPRA points would no longer be awarded based on categories (e.g., 20-29, 30-39,… 98, 99, 100 percent). Instead, granular CPRA with at least 6 decimal values will be used to award priority along a continuum. Using a smooth rating scale instead of additional CPRA classifications will help address access for the most highly sensitized candidates. A nonlinear rating scale is anticipated to take into account the fact that CPRA differences at the high end of the scale (close to 100 percent) reflect much larger differences in access to transplant compared to differences at lower CPRA values. During Workgroup discussions, Pancreas Committee members suggested mirroring kidney policy's CPRA points scale for pancreas and kidney-pancreas so there would be similar prioritization.[41]

Patient Access

The OPTN Final Rule requires allocation policies to "promote patient access to transplantation,"[42] 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."[43] The Patient Access category "addresses transplant access for candidates under the age of 18, prior living donors, etc." In December 2014, the OPTN implemented the Kidney Allocation System (KAS). The KAS was developed in response to higher-than-necessary discard rates of kidneys, variability in access to transplants for candidates who are harder to match due to biologic reasons, inequities resulting from the way waiting time was calculated, and a matching system that results in unrealized life years and high re-transplant rates.[44] Under KAS, pediatric candidates do not have priority for KDPI >35 kidneys and, therefore, pediatric candidates do not have consistent access to kidneys from young pediatric donors.[45] Additionally, some research suggests the changes in pediatric priority under KAS have also led to a lower overall offer rate for pediatric candidates.[46] The Workgroup agreed with the overall goal to provide appropriate transplant access in addition to creating equity 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.

Prior living donor (Kidney, Pancreas, and Kidney-Pancreas): Living donation is generally considered to

[39] Jackson KR, Covarrubias K, Holscher CM, Luo X, Chen J, Massie AB, Desai N, Brennan DC, Segev DL, Garonzik-Wang J. The national landscape of deceased donor kidney transplantation for the highly sensitized: Transplant rates, waitlist mortality, and posttransplant survival under KAS. Am J Transplant. 2019 Apr;19(4):1129-1138. doi: 10.1111/ajt.15149. Epub 2018 Nov 26. PMID: 30372592; PMCID: PMC6433516.

[40] Jackson KR, Motter JD, Kernodle A, Desai N, Thomas AG, Massie AB, Garonzik-Wang JM, Segev DL. How do highly sensitized patients get kidney transplants in the United States? Trends over the last decade. Am J Transplant. 2020 Aug;20(8):2101-2112. doi: 10.1111/ajt.15825. Epub 2020 Mar 12. PMID: 32065704. This one wasn't published when the kidney committee looked at this issue in 2017 but it seems to have a similar conclusion.

[41] OPTN Pancreas Transplantation Committee. 2020, October 9 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4146/20201009_panc_continuousdistribution-wg_summary.pdf

[42] 42 CFR Sec. 121.8(a)(5).

[43] 42 U.S.C. §274(b)(2)(M)

[44] OPTN Kidney Allocation System. https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/

[45] Parker WF, Ross LF, Richard Thistlethwaite J Jr, Gallo AE. Impact of the kidney allocation system on young pediatric recipients. Clin Transplant. 2018;32:e13223. https://doi.org/10.1111/ctr.13223

[46] Formica RN. A critical assessment on kidney allocation systems. Transplant Rev. 2017;31:61-67.

be safe and end stage organ failure is relatively rare among living donors.[47] Starting in 1996, all prior living donors received priority for kidney transplants.[48] This prioritization is given to kidney candidates in the form of extra points.[49] To be consistent with kidney allocation policy, the Workgroup favors including priority points for prior living donors in pancreas and kidney-pancreas continuous distribution as well.[50]

Pediatrics (Kidney, Pancreas, and Kidney- Pancreas): Currently, OPTN policy prioritizes pediatric candidates for kidneys with a KDPI of 34 percent or less as shown in **Table 3**.[51] Pediatric candidates are not currently prioritized for pancreas allocation. Similar to the prior living donor attribute, the Workgroup favors adding priority for pediatric candidates under pancreas and kidney-pancreas as well.[52] Further input is requested to determine if further expansion of KDPI should be considered for pediatric candidates. The Workgroup also requests community feedback on alternatives to KDPI for directing organs to pediatric candidates.

Table 3: 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-ABDRmm Inside Circle Top 20% EPTS 0-ABDRmm (All) Inside Circle (All) National Pediatrics National (Top 20%) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor **Inside Circle Pediatrics** Inside Circle Medically Urgent 98% – 99% Highly Sensitized 0-ABDRmm 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-ABDRmm 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-ABDRmm 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			

Waiting time (Kidney, Pancreas, and Kidney-Pancreas): In the current system, waiting time accounts for

[47] Wainright et al. 2017. *The Impact of the New Kidney Allocation System on Prior Living Kidney Donors' Access to Deceased Donor Kidney Transplants: An Early Look. Transplantation.* 17: 1103-111. https://doi: 10.1111/ajt.14102 *citing* Muzaale AD, Massie AB, Wang MC, et al. 2014. *Risk of end-stage renal disease following live kidney donation*. JAMA 311: 579– 586. and Mjoen G, Hallan S, Hartmann A, et al. 2014. *Long-term risks for kidney donors*. Kidney Int. 86: 162– 167.

[48] Smith JM, Biggins SW, Haselby DG, et al. 2012. *Kidney, pancreas and liver allocation and distribution in the United States*. Am J Transplant. 12(12):3191-212. https://doi.org/10.1111/j.1600-6143.2012.04259.x

[49] OPTN Policy 8.3: Kidney Allocation Score

[50] OPTN Pancreas Transplantation Committee. 2020, September 25 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4126/20200925_pancreas_continuousdistribution_wg_summary.pdf

[51] OPTN Policy 8.3: Kidney Allocation Score

[52] OPTN Pancreas Transplantation Committee. 2020, November 6 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4233/20201106_panc_continuousdistribution-wg_summary.pdf

a large part of a kidney candidate's allocation score. According to kidney policy, one day of waiting time equals approximately 1/365 of a point, therefore one point is equivalent to one year of waiting time.[53] Waiting time for adult candidates is defined as the start of regularly administered dialysis or being registered on the waiting list with a qualifying eGFR or creatinine clearance measurement. According to pancreas policy, wait time for pancreas candidates begins on the date the candidate is first registered as a pancreas candidate on the wait list.[54] In the same manner as kidney, one day of waiting time equals approximately 1/365 of a point for pancreas and kidney-pancreas candidates, therefore one point is equivalent to one year of waiting time. The Workgroup agreed to include waiting time as an attribute and plans to discuss how much weight waiting time should have in the new framework and the shape of the waiting time rating scale in the next phase discussions. The Workgroup would appreciate community feedback on this topic.

Simultaneous Liver-Kidney (SLK) Safety Net (Kidney): The SLK Safety Net is a term to describe 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.[55] The Workgroup agreed to include this as an attribute in the new framework.[56]

Pancreas after Kidney (PAK) (Pancreas): The Workgroup agreed to include this attribute so that living donor kidney transplants are not disincentivized if the PAK wait times were longer than the simultaneous pancreas kidney (SPK) wait times.[57] The Workgroup agreed to include this attribute and will consider whether to differentiate PAK patients between pancreas after living donor kidney and pancreas after deceased donor kidney. [58]

Placement Efficiency

The OPTN Final Rule does not define the "efficient management of organ placement." [59] 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.[60]

[53] OPTN Policy 8.3: Kidney Allocation Score
[54] OPTN Policy 11.4: Waiting Time
[55] OPTN Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List
[56] OPTN Kidney Transplantation Committee. 2020, October 9 Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4147/20201009_kidneycontinuousdistributionwg_summary.pdf
[57] OPTN Pancreas Transplantation Committee. 2020, October 23. Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4176/20201023_panc_continuousdistribution_wg_summary.pdf
[58] Pancreas Transplantation Committee. 2020, November 2020. Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4254/20201120_pancreas_continuous_distribution_summary.pdf
[59] 42 CFR Sec. 121.8(a)(2).
[60] 63 FR 16315 (1998).

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. The Workgroup agreed with the overall goal to consider other factors to match, transport, and transplant an organ.

Travel efficiency (Kidney and Pancreas): Current kidney and pancreas allocation policy uses proximity between the donor hospital and transplant hospital to assign points to candidates.[61,62] Transportation costs generally increase as the distance between the donor and transplant hospitals increase. The Workgroup determined this was an important attribute to include, especially when considering pancreata have a shorter cold ischemic time. [63, 64] The Workgroup is interested in feedback on the best ways to incorporate proximity and the efficient management of organ placement in a points based system.

Proximity efficiency (Kidney and Pancreas): 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.[65] 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.

Dual vs. Single (Kidney): Kidney policy was updated in 2019 to increase utilization of high KDPI kidneys by allocating them as dual kidneys to provide a patient survival advantage over single high KDPI kidney transplantation.[66] 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. Originally this attribute was placed under the Candidate Biology category, but the Workgroup decided the attribute was more appropriate under Placement Efficiency because it is intended to increase organ utilization and better related to the ability to place organs more efficiently.[67]

En Bloc (Kidney): Similar to dual kidney allocation, kidneys from small pediatric donors less than 18 kg are allocated together (en bloc) to be transplanted into a single recipient.[68] This attribute is placed under Placement Efficiency because if a candidate is willing to accept en bloc kidneys, it utilizes kidneys that may otherwise be left unrecovered or unutilized.

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[61] OPTN Policy 8.3: Kidney Allocation Score, Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital
[62] 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
[63] OPTN Pancreas Transplantation Committee. 2020, September 25 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4126/20200925_pancreas_continuousdistribution_wg_summary.pdf
[64] OPTN Kidney Transplantation Committee. 2020, October 9 Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4147/20201009_kidneycontinuousdistributionwg_summary.pdf
[65] 42 C.F.R. §121.8(a)(8)
[66] OPTN Kidney Transplantation Committee, Policy Notice "Improving Dual Kidney Allocation." https://optn.transplant.hrsa.gov/media/2370/kidney_policynotice_20171221.pdf
[67] OPTN Kidney Transplantation Committee. 2020, October 23 Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4173/20201023_kidneycontinuousdistributionwg_summary.pdf
[68] OPTN Policy 8.6.B: Allocation of En Bloc Kidneys

Non-Utilization

In addition to the goals and attributes listed above, Pancreas Committee representatives identified two additional attributes 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."[69] The Workgroup added two pancreas-specific attributes: the use of islets as well as extending the process of the facilitated pancreas structure that would promote the utilization of pancreata.

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.[70] 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.[71] The islet field is one way to progress pancreas transplantation and it is important to recognize that one can transplant beta cell function in different ways.[72] The Workgroup agreed this attribute should be included. The Workgroup discussed distinguishing prioritization among pancreas whole organ candidates and islet candidates by mirroring current policy for now, where higher body mass index (BMI) donor organs are prioritized to islet candidates. [73] The Workgroup will later discuss this in more detail.

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 recovery.[74] The Workgroup agreed that facilitated pancreas has a structure that could be expanded to avoid non-utilization and should be included as an attribute.

Next Steps

The Workgroup has recently begun Phase II of the project, assigning values by converting attributes into points and prioritizing attributes against each other. The Workgroup will evaluate 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, the Workgroup will then assign weights to specifics within each attribute to determine priority within the scales, as outlined in **Figure 6**. 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 points.

[69] 42 CFR Sec. 121.8(a)(2).
[70] OPTN Patient Education, "Questions and Answers for Transplant Candidates about Pancreas, Pancreas-Kidney, and Islet Allocation." https://optn.transplant.hrsa.gov/learn/patient-education/questions-and-answers-for-transplant-candidates-about-pancreas-pancreas-kidney-islet-allocation/
[71] OPTN Policy 11.3.C: Islet Registration Status
[72] OPTN Pancreas Transplantation Committee. 2020, November 20 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4254/20201120_pancreas_continuous_distribution_summary.pdf
[73] OPTN Pancreas Transplantation Committee. 2020, November 20 Pancreas Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4254/20201120_pancreas_continuous_distribution_summary.pdf
[74] OPTN Policy 11.7.B*:* Facilitated Pancreas Offers

Figure 6: Process for Assigning Values to Attributes

The Workgroup, with input from the community, will need to determine the importance of each attribute against each other. After public comment, the workgroup will review feedback on the concept paper. They will use this to continue their work building the points, weighing the attributes, and refining their overall approach to this project. Following that work, the Workgroup will weigh the attributes against each other. Once those two steps are combined, the Workgroup will develop the framework for a composite score to distribute kidneys and pancreata. The project will then follow traditional OPTN processes for developing organ allocation policies. The SRTR will model one or more frameworks under consideration by the workgroup. The Workgroup will continue to educate and solicit feedback from the community on these concepts as this project develops.

Longevity Matching

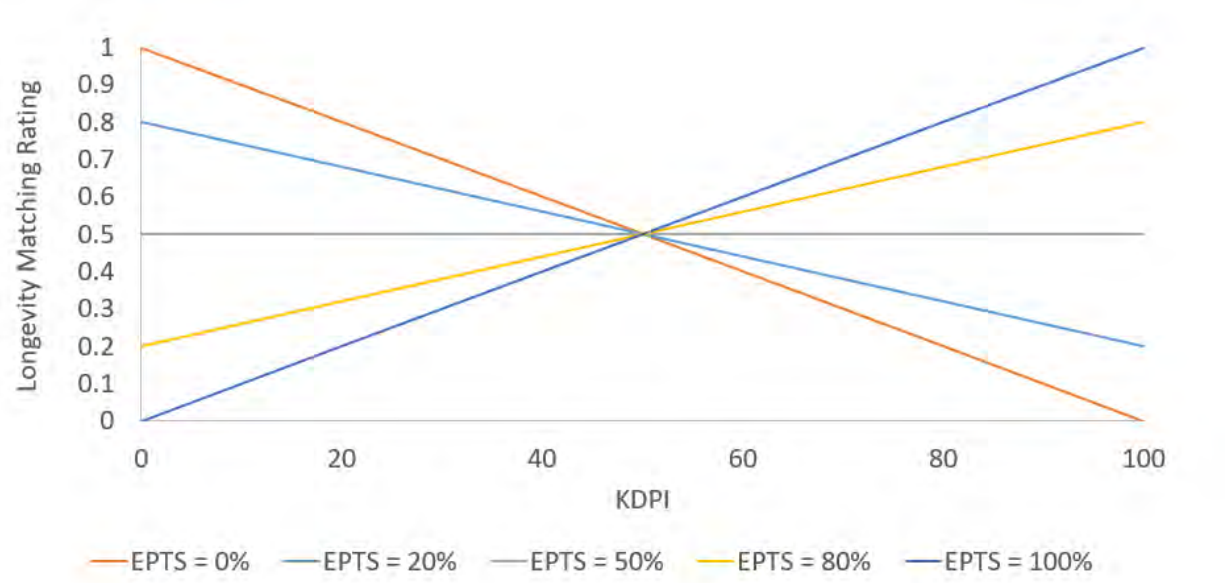
In the current system, donor kidneys are allocated depending on their KDPI and are thus divided into four sequences as shown in **Table 3**. The four sequences result in four separate match runs which adds a layer of complexity when attempting to convert the current system into a continuous distribution framework. Maintaining four KDPI sequences would need to have different rating scales and weights for each of the sequences. Additionally, having four separate sequences perpetuates hard boundaries that inhibit optimal distribution. Ideally, the new framework would function with one comprehensive match run and would still account for the nuances of the donor kidney's KDPI as it relates to the prioritization of other attributes. The Workgroup is interested in exploring options to accomplish this goal and requests community feedback and ideas on potential solutions.

One such solution for moving the current system into one match run and to eliminate the hard boundaries of four separate sequences is to award points for longevity matching, or linking KDPI and EPTS together to provide the best expected outcome for the organ and the candidate, consistent with the Final Rule requirement to "achieve the best use of donated organs."[75] A form of longevity matching already exists in the kidney allocation system by prioritizing the top 20 percent KDPI kidneys to the top 20 percent EPTS candidates. However, it is not a factor for approximately 80 percent of kidney allocations. For example, EPTS 21 percent candidates are not prioritized despite little practical difference in projected survival rates from EPTS 19 percent candidates. Continuous Distribution provides an opportunity to overcome these limitations by awarding points for longevity matching for all candidates.

[75] 42 C.F.R. §121.8(a)(2)

As an example, a longevity matching rating scale as seen in **Figure 7** would incorporate KDPI and EPTS together to prioritize very low EPTS candidates for very low KDPI kidneys and very high EPTS candidates for very high KDPI kidneys.

Figure 7: Longevity Matching Rating Scale Example



The Workgroup is seeking community feedback and ideas on potential solutions for converting the four KDPI sequences into the continuous distribution framework. Additionally, the Workgroup would like input on the potential options for longevity matching as outlined above.

Community Input

Before the new framework can be developed, the Committee, with input from the community, will need to determine the importance of each attribute against each other. At multiple steps throughout the project, the OPTN will provide education to and solicit feedback from the transplant community. These outreach efforts include the release of this concept paper and will continue through the lifecycle of this project.

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 a 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[76] and the OPTN has adopted principles that support the values held by the organization.[77,78, 79] The Lung Committee used a hybrid approach of different multi-criteria decision

[76] 42 C.F.R. §121.8(a)
[77] OPTN Ethics Committee, 2015 "Ethical Principles in the Allocation of Human Organs briefing paper,"
[78] OPTN Ad Hoc Geography Committee, 2018 "Frameworks for Organ Distribution briefing paper."
[79] OPTN Pediatric Transplantation Committee, 2014 "Ethical Principles of Pediatric Organ Allocation briefing paper,"

making (MCDM) methodologies to develop their project and utilized an Analytical Hierarchy Process (AHP) for its strengths in collecting feedback from a broad and diverse community. This approach is also under consideration for the kidney and pancreas continuous distribution projects.

Future Applications

The increased flexibility in a points-based framework will allow new attributes or more nuance to be added more easily. The current project will focus on converting and smoothing existing policy concepts into a points-based framework for kidney, pancreas, and kidney-pancreas, and new attributes would not be added to the system at this time unless they were needed to smooth existing cliffs. However, below are some potential attributes that could be included in the future.

Disadvantaged populations: Several committees have discussed how to promote access to transplant for different disadvantaged populations on the waiting list. Using a classification-based framework, committees have created new classifications for disadvantaged populations then decided where to place those classifications relative to other classifications. Using a points-based framework, points could potentially be granted to disadvantaged populations in order to provide equity in access to transplant.

Changes in Transportation Practices: The last few years have seen advances in transplant that have the potential to impact the cost, the clinical impact of, or the length of time to transport organs. These advances include the use of donor recovery centers, organ perfusion, and drones.[80] A classification-based framework that uses zones or other hard geographic boundaries cannot easily incorporate these new advances. A points-based framework that separates geographic considerations into clinical outcomes and system efficiency can more easily accommodate these changes.

Multi Organ Considerations: One of the challenges in multi organ allocation is comparing the medical priority of candidates using organ specific definitions of medical priority.[81] Using a common points-based framework will allow easier comparison of candidates across organ types. This will also allow common reviews of system and member performance across organ types.

Donor Specific Factors: Most organs have different allocation algorithms for different classes of donors (for example, donation after circulatory death (DCD) vs. donation after brain death organs).[82] A points-based framework could maintain similar ratings scales for all donors and change only those ratings scales that are relevant for differences in donors.

Likelihood of Acceptance: One perceived advantage of limiting ischemic time is that hospitals are more likely to accept organs with less ischemic time. These acceptance behaviors, which could change, also raise the prospect that points could be used to account for offers that are likely to be declined

[80] Organ Donor Recovery Performed at an Organ Procurement Organization (OPO)-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield. Journal of the American College of Surgeons. (regarding the use of donor recovery centers). Barbas AS, Goldaracena N, Dib MJ, Selzner M. Ex-vivo liver perfusion for organ preservation: Recent advances in the field. Transplant Rev (Orlando). 2016;30(3):154-60 (regarding the use of organ perfusion). Scalea JR, Restaino S, Scassero M, Blankenship G, Bartlett ST, Wereley N. An Initial Investigation of Unmanned Aircraft Systems (UAS) and Real-Time Organ Status Measurement for Transporting Human Organs. IEEE J Transl Eng Health Med. 2018;6:4000107 (regarding the use of drones).

[81] OPTN Ethics Committee 2019, "Ethical implications of multi-organ transplants" https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

[82] See OPTN Policy 8.5.B: *Deceased Donor Classification* for description of classifying kidneys by KDPI

in order to gain efficiencies in the organ placement system. For example, facilitated pancreas offers could operate through the use of points.[83] These would align with the Final Rule's requirements that organ allocation policies be designed to avoid wasting organs and promote the efficient management of organ placement.[84]

Concurrent Offers: Similarly, some members have opined that the number of transplant programs receiving organ offers at the same time increases complexity in the organ placement system and is inefficient. If so, then effort could be made to decrease the number of transplant programs who receive organ offers at the same time. However, it is not clear whether this should be incorporated into an organ allocation policy, as offers are made to candidates and not to transplant programs.

Waiting Time Inversion: Though the initial implementation of kidney continuous distribution is expected to incorporate current waiting time policy, the new framework would allow for waiting time to be "inverted" for higher KDPI kidneys, which are at higher risk of offer refusal and discard, by prioritizing candidates with the shortest waiting times, as opposed to the longest waiting times, for these kidneys. The intent would be to prioritize patients who may be more incentivized to accept higher KDPI kidneys because they are not likely to receive a low KDPI kidney in the near future. The Workgroup requests community feedback on the idea of waiting time inversion as described.

NOTA and Final Rule Analysis

The Committees submit this concept paper under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[85] The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[86] 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 according to medical urgency. This clause of the OPTN Final Rule will be considered as

[83] OPTN Policy 11.6: Facilitated Pancreas Allocation
[84] 42 CFR Sec. 121.8 (a)(5).
[85] 42 CFR §121.4(a).
[86] 42 C.F.R. §121.8(a)

the Workgroup prioritizes the weight of the attributes under Medical Urgency. 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. If necessary, the Workgroup will be able to adjust the weighting of the attributes to balance these outcomes.

Are specific for each organ: 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 decreasing the number of organs that are recovered but not ultimately transplanted (dual vs. single, en bloc, islets, and facilitated pancreas). The Lung Committee has previously discussed attributes, such as the likelihood of organ offer acceptance, that would also have a positive effect on this Final Rule requirement.[87] 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. If necessary, the Workgroup will be able to adjust the weighting of the attributes to balance the number of transplants against other attributes.

Are designed to…promote patient access to transplantation: The Workgroup included several attributes in the proposed composite allocation score specifically 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 five attributes under Patient Access (prior living donors, pediatrics, waiting time, SLK Safety Net, and PAK). The inclusion of these attributes is likely to increase access to transplantation for these patients.

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 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 requirement to distribute over a broad geographic area reflects professional consensus that organs are a national resource meant to be allocated based on patients' medical need.[88] Specifically, the 1986 Task Force stated that: "The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."[89] The Institute of Medicine made this same conclusion in 1999 and so did the American

[87] OPTN Lung Transplantation Committee, 2021 "Update on the Continuous Distribution of Organs Project." https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf
[88] 42 CFR §121.8(b)(3)
[89] U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, 1987. Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation. Rockville, MD., p. 91, 1987, quoting Hunsicker, LG

Medical Association in 2012.[90,91] Two of the attributes related to efficiency (travel efficiency and placement efficiency) are the only attributes the workgroup is considering incorporating into the future policy that are related to the candidate's place of registration. The Committee will weigh these attributes only as much as is necessary to satisfy the requirements set out in the other provisions of the Final Rule.

Consider whether to adopt transition procedures: A points-based framework will facilitate the use of transition procedures for existing candidates. For example, the OPTN may be able to compare the policy proposal with the results of a revealed preference analysis and modeling to determine who is impacted and if there is a need for transition procedures. This would allow members and patients time to prepare for these changes.

Conclusion

The continuous distribution framework has the potential to restructure the concept of a match run and its classification-based framework and therefore will create a significant change in the framework of organ allocation in the United States. Moving forward, candidates will be prioritized in a more flexible manner. This new framework will permit the transplant community to see how much weight is placed on each attribute. By separating the specific attributes and developing attribute specific points, there will be more flexible solutions for how certain patient populations are prioritized, thereby improving equity in access to organ transplantation. This new framework will also require the community to reconsider how it develops organ allocation policies by balancing the need for evidence-driven decisions based in clinical and operational data with the inherently values-based decisions concerning the multiple goals of a national, organ allocation system.

This project serves as an opportunity to rethink how the OPTN and the transplant community develops organ allocation policies. This concept paper explains the work that the Kidney and Pancreas Committees have performed to date and how it will move forward to a policy proposal. It also demonstrates a framework that can be replicated for other organs while continuing to tailor it for the specific clinical needs of that organ.

Community Feedback

In reviewing this concept paper, 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? Do you agree with the Workgroup's recommended attributes? Are there additional attributes of the current system you would recommend? And what additional attributes would you recommend for consideration as part of a future application?
- 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.
- Are there other measures of the efficient management of organ placement that should be taken

[90] National Academies Press. 1999. Organ Procurement and Transplantation.
[91] American Medical Association. 2012. Opinion 2.16 – Organ Transplantation Guidelines. AMA Journal of Ethics 14(3) pp. 204-214, available at https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-organ-transplantation/2012-03.

into account in a points-based framework?

- How much importance should be placed on waiting time in the continuous distribution framework? How does the community feel about the idea of waiting time inversion (see page 20)?
- Which kidneys should pediatric patients receive priority points for? Which kidneys should pediatric patients not receive priority points for? And what are some alternatives to KDPI for directing organs to pediatric candidates?
- 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 (see page 17)?
- How should more “hard-to-place” kidneys be factored into kidney allocation?
- How should dual and en bloc kidney allocation be operationalized in continuous distribution to maximize the utilization of kidneys?

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.

Cliff: Cliffs are an illustrative term to describe hard boundaries in the attributes used to prioritize candidates. For example, the zones used in concentric circles have hard boundaries at specific distances. Continuous distribution and the move to a points-based framework aim to smooth these hard boundaries.

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. Thoracic organs were the first organs to be allocated using concentric circles.

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.

MCDM: Multi-criteria decision making methodology; Structured, analytical approach that utilizes clinical and operational analysis in addition to values and legal analysis.

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. For example, if all else is equal, should a candidate with an LAS 80 receive twice as much priority as a candidate with an LAS 40? 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.