OPTN

Committee Update

Continuous Distribution of Kidneys and Pancreata

OPTN Kidney and Pancreas Transplantation Committees

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Continuous Distribution of Kidneys and Pancreata

Sponsoring Committee: *Kidney and Pancreas Transplantation*
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Executive Summary

This paper provides an update to the community about the continuous distribution of kidneys and pancreata projects being developed by the OPTN Kidney and Pancreas Transplantation Committees (the Committees). Continuous distribution will replace the current classification approach, which draws hard boundaries between classifications that exist in the current kidney and pancreas allocation system, ultimately resulting in more equity for candidates on the waitlist and increased transparency in the allocation of kidneys and pancreata. The continuous distribution framework includes 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 following earlier papers: [3,4,5]

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

This paper contains recent discussions and decisions regarding attributes, their associated rating scales, results of the Committee's first modeling request, and considerations for utilization and the development of kidney and pancreas specific review boards. Finally, this paper provides an overview of the next steps for the continuous distribution of kidneys and pancreata projects.

The end of this document has a series of appendixes to help readers, including:

- Appendix A: Glossary of Key Terms
- Appendix B: Attributes, Rating Scales, and Workgroups
- Appendix C: Continuous Distribution Resources

[1] NOTA, 42 U.S.C. § 273 et. seq.
[2] 42 C.F.R. § 121.8
[3] *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.
[4] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[5] *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, August 2022.

Background

Continuous distribution is a points-based framework that assigns a composite allocation score (CAS) that takes into account all of a candidate's characteristics. The goal of this project is to replace the current **classification-based framework**, which draws hard boundaries between classifications that exist in the current kidney and pancreas allocation system, with a **points-based framework**, creating a CAS.[6] This score would be constructed with multiple attributes that align with NOTA and the OPTN Final Rule.[7]

As detailed in the 2021 Concept Paper, **Figure 1** shows how these five goals combine into a composite allocation score.[8] Within each goal, the Committees have identified different attributes. Candidates will be assigned a certain number of points for each attribute, which will then be combined to create sub-scores that align with the different goals, which are then weighted against each other to create the overall CAS.

Figure 1: Components of Composite Allocation Score

Combining multiple sub-scores into one CAS allows holistic consideration of all factors that must be considered to satisfy the regulatory requirements for organ allocation policies. Finally, by constructing the CAS around the performance goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule.[9]

Figures 2 and 3 how the transition from the existing allocation policy classification to 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.

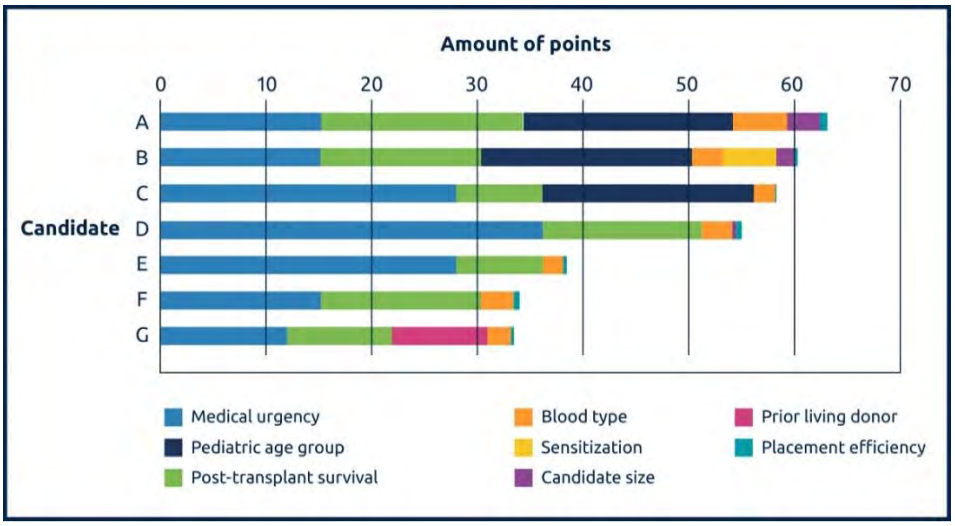
[6] Continuous distribution aims to create a more fair and patient-focused system for organ allocation. See Appendix C for more resources on continuous distribution.
[7] 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.
[8] *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.
[9] 42 CFR § 121.8.

Figure 2: Sample Allocation Policy (Current)[10]

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 of a Composite Allocation Score Match Run (Proposed)[11]



The maximum amount of points given for any attribute is determined by the weight given to that attribute. In **Figure 3**, the amount of points given to a candidate varies depending upon the candidate's specific circumstances. In the classification-based system, all patients in a higher classification are prioritized ahead of candidates in a lower classification, regardless of considerations regarding medical need, inequities in access, or benefit of transplantation (**Figure 2**). A continuous distribution framework will eliminate hard boundaries between classifications existing in the current system, in which

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

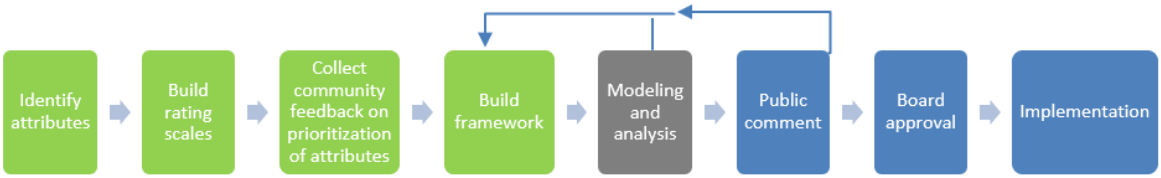
candidates are grouped into classifications. Candidates will receive points for various attributes and all of these attributes can be considered as part of a composite allocation score (**Figure 3**). A candidate's CAS will determine the order in which the candidate will receive an organ offer.

To construct the score, 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 the OPTN, SRTR, and external contracted researchers from the Massachusetts Institute of Technology (MIT) to develop evidence-based rating scales for each attribute.[12,13]

Project Plan

The Committees are tasked with developing a comprehensive proposal for the continuous distribution of kidneys and pancreata. The project is progressing through several phases, as seen in **Figure 4**. For more details on the project plan and each step in the process, please refer to the Committee's earlier papers.[14,15,16]

Figure 4: Project Overview[17]



Progress So Far

As detailed in the August 2022 update, the Committees submitted the first modeling request to SRTR which included draft rating scales for each attribute and a series of scenarios to model different weights as detailed below:[18]

1. **Current Policy**: This scenario used current policy and classifications to produce a baseline. This scenario will provide a representation of the attributes as they are currently outlined in policy. The baseline will allow the Committees to evaluate the impact of the recommended attributes and rating scales in the new framework.
2. **Combined Community Feedback Results/Combined AHP**: This run is the continuous distribution

[12] 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.
[13] An attribute's rating scale is the assignment of all possible values of the attribute to a number ranging between 0 and 100. 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.
[14] *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.
[15] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[16] *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, August 2022.
[17] The first four, green boxes indicate steps that have already occurred. The grey box is the current stage of the project. The three, blue boxes indicate the forthcoming stages of the project.
[18] *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, August 2022.

option closest to the community and committee analytical hierarchy process (AHP) values exercise results. Scenarios 2-5 also include some items the Committees and Workgroup have discussed incorporating into continuous distribution such as expanded longevity matching, pediatric priority for sequence C kidneys from pediatric donors, and a steeper CPRA curve as described in the relevant sections below.

3. **Increased Longevity**: This scenario increased the weight/importance of transplant outcomes from 10 percent to 40 percent divided between human leukocyte antigen DR (HLA-DR) and longevity matching. The weights for all other attributes were decreased proportionally.
4. **Increased Placement Efficiency/All Donor Efficiency**: This scenario increased the weight/importance of proximity efficiency from 10 percent to 30 percent. The weights for all other attributes were decreased proportionally.
5. **Harder to Place Kidneys/High KDPI Efficiency**: This scenario increased placement efficiency for harder to place kidneys (high KDPI) with an increased donor weight modifier for KDPI 86-100 percent.

As described in the last update, this first round of modeling is being used to better understand the effects of what would happen in more extreme scenarios, which can then be fine-tuned with mathematical optimization and the next round of modeling. The results of the first modeling request were submitted to the OPTN and released to the Committees on October 20, 2022.[19] The Pancreas and Kidney Committees conducted their initial review of the modeling results on November 1 and November 7, 2022, respectively, and those discussions are ongoing.[20,21] Key takeaways from the results of the first modeling request are outlined below.

Modeling Key Takeaways

Longevity matching for kidney

- The Kidney Committee elected to model a continuous longevity matching rating scale for estimated post-transplant survival (EPTS) and KDPI, instead of converting the top 20 percent EPTS to top 20 percent KDPI model used in current allocation.[22] The continuous longevity matching rating scale continues the practice of prioritizing low-KDPI kidneys for candidates expected to have the best outcomes. This rating scale also gives higher EPTS scores greater priority for higher KDPI kidneys; this mechanism does not exist in current policy.
- Longevity matching of kidneys, with higher KDPI kidneys going to high EPTS candidates, was most pronounced in the "increased longevity" scenario, as expected.
- A consequence of the modeled continuous longevity matching scale appears to be lower transplant rates in 35-50 year old candidates. However, post-transplant graft failure rates were lower in 18-34 and 35-49 year olds at 1 and 10 years, particularly under the "increased longevity" scenario.
- An expected consequence of expanded longevity matching, present to some degree in all continuous distribution scenarios, appears to be increased graft failure rates in older kidney recipients.

[19] Scientific Registry of Transplant Recipients, *SRTR KI2022_01*, October 20, 2022.
[20] Meeting summary for November 1, 2022 meeting, OPTN Pancreas Transplantation Committee.
[21] Meeting Summary for November 7, 2022 meeting, OPTN Kidney Transplantation Committee.
[22] Meeting Summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee.

Proximity efficiency for kidney

- Median travel distance increased in all continuous distribution scenarios relative to the simulation of current policy. Median travel distance was lower under the "all donor efficiency" or "increased weight for proximity efficiency for high KDPI kidneys" scenario, where the weight on the proximity efficiency attribute was the highest, demonstrating that median travel distance can be reduced by increasing the proximity efficiency attribute weight.
- Pediatric candidates saw the largest increase in median distance for all scenarios, likely due to the amount of priority awarded to pediatric candidates through the pediatric attribute. While pediatric candidates will have access to offers from further away, these offers may not be accepted in practice; which could inflate the distance seen in the simulations.

Other takeaways for kidney

- Transplant rates for Black candidates and for candidates on dialysis longer than five years were lower under the "all donor efficiency" and "increased longevity" scenarios, where less weight was placed on qualifying time.
- Changes in transplant rates varied by OPTN region. Regions with lower transplant rates under the continuous distribution scenarios tended to be those with already high transplant rates.
- Transplant rates decreased for highly sensitized (harder to match) candidates with high CPRA (greater than 80 percent) under the "all donor efficiency" and "increased longevity" scenarios, where less weight was placed on CPRA (despite the steep CPRA rating scale used).

Key takeaways for pancreas and kidney-pancreas

- For pancreas, median distance was higher than the simulation of current policy under the "combined AHP" scenario, and lower than the simulated current policy under the "all donor efficiency" scenario, which increased the weight on the proximity efficiency attribute.
- For kidney-pancreas, median travel distance under the "combined AHP" scenario was similar to that of the simulation of current policy, while median distance under the "all donor efficiency" scenario was lower than the simulated current policy.
- Transplant rates for A, B, and O blood type candidates under all continuous distribution scenarios were similar to the simulation of current policy, while transplant rates for AB candidates were notably lower under all continuous distribution scenarios relative to the simulation of current policy. This is likely due to the "blood type identical" attribute, which awards priority to candidates with blood types identical to a given donor over candidates with compatible blood types.
- Transplant rates for pediatric candidates were higher under all continuous distribution scenarios relative to the simulation of current policy, likely due to the inclusion of the pediatric attribute.

The full report contains additional details on the methods used and can be found on the OPTN website.[23] It is important to note that the simulation results are estimates of what would have happened in the historic cohort under the different proposed allocation polices. All of the simulation results assume the allocation policy is the only thing that is different between the scenarios; all other components of the modeling are the same between scenarios. Additionally, simulations rely on aggregate historical data and cannot predict changes in organ acceptance behavior, screening criteria, or identify trends over time. The full report contains additional details on all sub-models used in the simulations.

[23] Scientific Registry of Transplant Recipients, *SRTR KI2022_01*, October 20, 2022.

Other Considerations

While awaiting the results of the first modeling request, two new workgroups were formed to focus on considerations outside the composite score and to develop new kidney and pancreas-specific review boards as detailed below.

Kidney and Pancreas Utilization Considerations of Continuous Distribution Workgroup

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

- Dual Kidney
- En bloc
- Facilitated Pancreas Allocation
- Mandatory Kidney-Pancreas Offers
- National Offers
- Minimum Acceptance Criteria (MAC)
- Screening and Filters
- Released Organs

The Kidney and Pancreas Utilization Considerations of Continuous Distribution Workgroup's (Utilization Considerations Workgroup) main scope will be to transition the operational aspects of Kidney and Pancreas allocation to a continuous distribution framework, with minimal changes to current operational requirements. The Utilization Considerations Workgroup recognizes the challenges accepted by more complex match runs and will also focus on tools and policies to make the organ placement system more efficient. The Utilization Considerations Workgroup will discuss each topic and develop recommendations, which will then be sent to the Kidney and Pancreas Committees for approval. Approved recommendations will be incorporated into the future Kidney and Pancreas Continuous Distribution proposals. The Utilization Considerations Workgroup will review and provide input and potential solutions for certain operational factors.

Dual Kidney

Kidney allocation policy was last changed to standardize the allocation of dual kidneys to provide a patient survival advantage over single high KDPI kidney transplantation.[24] This policy update also designated an allocation pathway for dual kidneys by allowing transplant programs to opt-in to receive dual kidney offers for their candidates. The intent of this policy change was to increase organ utilization for kidneys that are considered harder to place.

The policy added dual kidney classifications to the allocation sequences within policy for donor kidneys with KDPI scores of 35 percent and above. Functionally, this means dual kidney offers appear on the same match run as single kidney offers, causing those candidates who are opted-in for dual offers to appear on the match run twice. The policy's two-year monitoring report shows that 44.44 percent of dual kidney transplants were allocated from the single kidney classifications.[25] Feedback from the OPO

[24] *Improving Dual Kidney Allocation*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[25] OPTN Descriptive Data Request. "Allocation of Dual and En Bloc Kidneys Two Year Post-Implementation Monitoring Report." Prepared for OPTN Kidney Transplantation Committee, March 18, 2022.

community indicates this is done to avoid organ wastage due to increased ischemic time and late turndowns.[26]

With the removal of the classification-based system, the Utilization Considerations Workgroup is exploring more efficient options to transition dual kidney allocation to a continuous distribution framework and improve related system efficiencies.

En Bloc

Similar to dual kidney allocation, kidneys from small pediatric donors less than 18kg are allocated together (en bloc) to be transplanted into a single recipient. All en bloc kidneys are allocated according to Sequence A, or KDPI 0-20 percent.[27] The Kidney Donor Risk Index (KDRI) includes a coefficient to account for en bloc that is currently not utilized.[28] 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 necessitate having a specific KDPI score for en bloc kidneys.[29] Therefore, the Workgroup is recommending assigning a unique KDPI score to en bloc kidneys by utilizing the en bloc coefficient included in the KDRI. [30]

Facilitated Pancreas Allocation

Current OPTN policy permits OPOs and the OPTN to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery.[31] Additionally, OPOs only have access to facilitated allocation after all pancreas and KP offers to candidates registered at programs within 250 nautical miles (NM) of the donor hospital have been declined. Since continuous distribution will remove hard boundaries, including the current distance-based classifications, it would be impractical to maintain the requirement for OPOs to offer to all candidates within 250 NM before making facilitated pancreas offers in the continuous distribution framework.

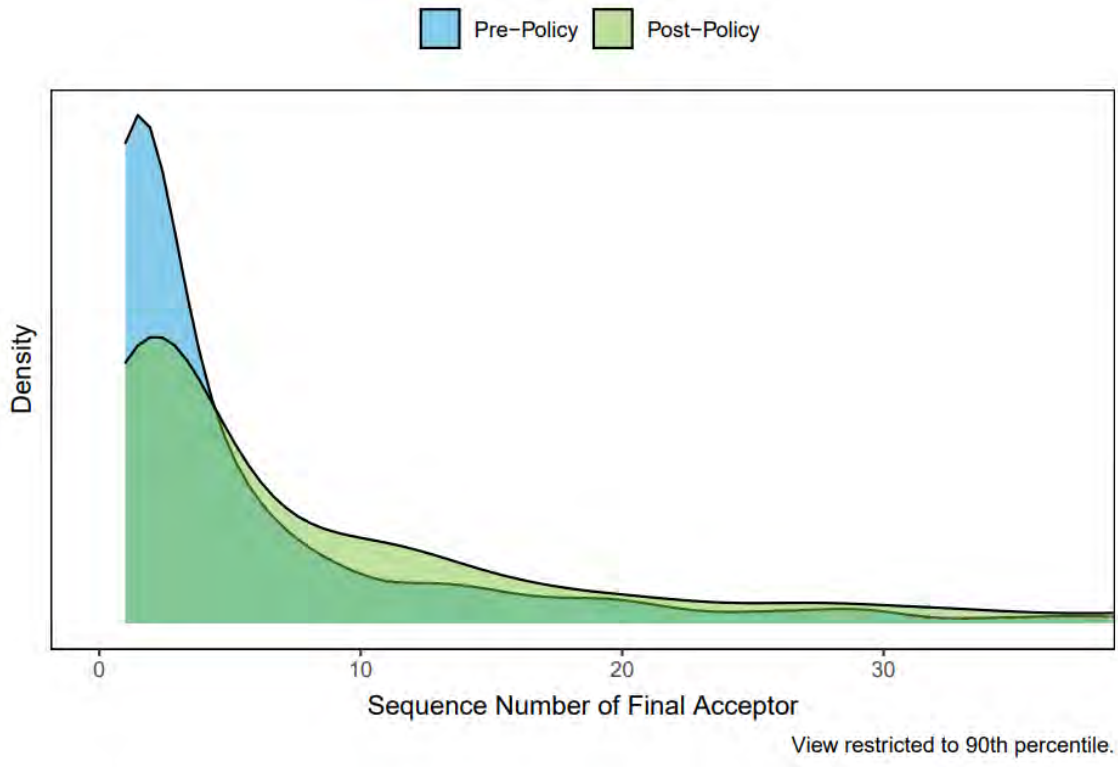
With the removal of the distance-based classifications, the Pancreas Committee discussed permitting OPOs to apply facilitated pancreas bypasses from any point on the match run as long as no pancreas offer has been accepted within the timeframe specified in policy. Additionally, while facilitated pancreas bypasses only apply to pancreas candidates in the current system (meaning KP candidates are not bypassed when facilitated pancreas allocation is used), there was discussion in applying bypasses to both pancreas and KP candidates in the new framework to improve efficiency.[32]

The Pancreas Committee also recommended that when facilitated pancreas bypasses are applied, candidates registered at programs within 100 NM of the donor hospital will remain on the match run in addition to candidates registered at programs qualified to receive facilitated pancreas offers. Using this 100 NM distance, as opposed to the 250 NM distance in current policy, should improve efficiency while ensuring that candidates at nearby programs still receive offers.[33]

[26] Meeting summary for June 9, 2022 meeting, OPTN OPO Committee.
[27] OPTN Policy 8.6.B: Allocation of En Bloc Kidneys as of October 27, 2022.
[28] *Improving Allocation of En Bloc Kidneys*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[29] Meeting summary for October 8, 2021 meeting, OPTN Kidney Transplantation Committee.
[30] Meeting summary for May 20, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.
[31] OPTN Policy 11.7.B: Facilitated Pancreas Offers as of October 27, 2022.
[32] Meeting Summary for Augist 1, 2022 meeting, OPTN Pancreas Transplantation Committee.
[33] Meeting summary for June 22, 2022 meeting, OPTN Pancreas Transplantation Committee.

There was discussion on whether to maintain the three-hour timeframe prior to scheduled organ recovery time requirement. There was some debate about whether the three-hour timeframe is enough time to feasibly coordinate a recovery team that is experienced in recovering pancreata. The OPO Committee was consulted for additional input on the use of the facilitated pancreas tool in a continuous distribution framework. The OPO Committee recommended that the new policy extend the facilitated pancreas timeframe, such that facilitated pancreas bypasses may be applied four or five hours before scheduled organ recovery time, as opposed to the current three hours.[34] The OPO Committee also noted logistical challenges to recovering pancreata, and emphasized that a longer facilitated pancreas timeframe could encourage transplant programs to send their recovery team. In the *Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report,* data (**Figure 5**) showed that when looking at the distribution of sequence number of final acceptor for pancreas and KP math runs, the median sequence number of the final acceptor is 5 and 75th percentile is 15.[35] This suggests that pancreata placement tend to be early on the match run. Although the data does not indicate timing relative to cross clamp, it also suggests that extending the timeframe would not be detrimental to non-facilitated pancreas offers. The Pancreas Committee discussed extending the timeframe from three to five hours prior to the scheduled donor organ recovery.[36] The Pancreas Committee will also continue discussions on appropriate criteria to qualify programs as facilitated pancreas programs.

Figure 5: Distribution of Sequence Number of Final Acceptor for Pancreas/Kidney-Pancreas Match Runs March 15, 2020 - March 14, 2022 by Policy Era



[34] Meeting summary for May 18, 2022 meeting, OPTN OPO Committee.
[35] Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report. June 22, 2022.
[36] Meeting summary for June 22, 2022 meeting, OPTN Pancreas Transplantation Committee.

Mandatory KP Offers

If a host OPO has both a kidney and a pancreas to offer for allocation, OPTN Policy requires the OPO to offer the kidney and pancreas according to the first four classifications as outlined below in **Table 1**. The first four classifications consist of all KP and PA candidates within 250 NMs of the donor hospital and candidates who are both highly sensitized (CPRA greater than or equal to 80 percent) and a 0-ABDR mismatch with the donor regardless of distance from the donor hospital. The OPO may then continue to offer the kidney and pancreas together on the KP/pancreas match, or offer isolated kidney and pancreas on their respective matches.[37] In transitioning to a points-based allocation system, there is discussion and consideration in a new threshold for required KP shares.

Table 1: Allocation of Pancreas and Kidney-Pancreas by Classifications

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

The Kidney Pancreas Continuous Distribution Workgroup has discussed the use of a CAS threshold as a solution to mirror current policy.[38] With the use of the CAS threshold, OPOs would be required to offer the KP to all KP candidates at or above that CAS before having the option to offer to kidney candidates on the kidney match run, or continuing to offer the KP on the KP match run . The Ad Hoc Multi-Organ Transplantation Committee (MOT Committee) supported estimating a minimum CAS threshold for required KP shares.[39] However, for the first round of modeling, the Workgroup opted for the model to offer to all KP candidates before making offers to kidney-alone candidates. This decision was based on feedback from the OPO Committee that many OPOs continue making offers on the kidney-pancreas match run after completing required shares.

The Kidney Pancreas Continuous Distribution Workgroup recognized the importance of balancing mandatory KP offers appropriately, weighing utilization, waitlist mortality, equity in access, and efficiency considerations. The goal is to maintain priority for KP patients similar to current policy's prioritization, in order to reduce waitlist mortality for kidney-pancreas candidates and to encourage utilization of pancreata.[40] The Workgroup agreed that the CAS threshold should consider placement efficiency, ensuring OPOs have the opportunity to place the kidneys on the kidney match run.[41] The Multi-Organ Transplantation (MOT) Committee was consulted; they emphasized the importance of

[37] OPTN Policy 11.5.A: Kidney-Pancreas Allocation Order as of October 27, 2022.
[38] Meeting summary for January 7, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.
[39] Meeting summary for February 14, 2022 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee.
[40] Meeting summary for January 7, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.
[41] Meeting summary for February 4, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.

keeping pancreata local when possible in order to promote their utilization.[42] OPO representatives on the MOT Committee have reported challenges with kidney-pancreas combinations traveling extended distances, only for the pancreas to be declined.[43]

The Utilization Considerations Workgroup is currently seeking further input on mandatory KP offer policy from the MOT Committee and the community at large that would be considered for a future iteration of this project. Additional considerations for required KP shares are discussed in further detail in the MOT Committee's *Identify Priority Shares in Kidney Multi-Organ Allocation* concept paper that is also out for public comment.[44]

National Offers and Minimum Acceptance Criteria

Current OPTN Policy *8.7.B: National Kidney Offers* requires OPOs to turn allocation of deceased donor kidneys over to the OPTN Contractor for offers to candidates with CPRA less than 100 percent and non-0-ABDR mismatch more than 250 NM away from the donor hospital (also known as "national offers"). When this occurs, the OPTN Contractor may use minimum acceptance criteria (MAC) screening. The Kidney Minimum Acceptance Criteria (MAC) utilizes candidate-specific minimum acceptance criteria, to screen kidney candidates from the match. Transplant programs report minimum acceptance criteria annually to indicate the types of organ offers a program would *not* accept for a candidate from a donor more than 250 NMs away. The MAC is currently utilized by the OPTN Contractor to accelerate national organ placement. Historically, national offers have been used as a surrogate for harder to place kidneys and hence, the MAC are useful to help quickly and efficiently place these kidneys.

The transition to a continuous distribution framework would remove "national" classifications. The OPO community has expressed interest in gaining the ability to offer these types of kidneys themselves with assistance from the OPTN contractor as needed. Therefore, the Kidney Pancreas Continuous Distribution Workgroup decided the requirement to utlilze the OPTN Contractor was no longer necessary and determined that the role of the OPTN contractor as the required entity in offering organs nationally would instead be to provide optional assistance.[45] With the eventual elimination of geographic circles and dissolution of national offers, the Utilization Considerations Workgroup will discuss and recommend criteria for OPOs to use MAC screening.

Screening and Filters

Broader distribution in circles-based allocation has increased match run complexity, impacting allocation efficiency.[46,47,48] Screening tools will be critical to enable allocation efficiency and practicality, in order to ensure organ utilization. Several efforts are underway to improve system efficiency, including an ongoing effort to redefine provisional yes, and proposals to optimize the usage of offer filters.[49,50,51]

[42] Meeting summary for May 9, 2022 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee.
[43] Meeting summary for June 13, 2022 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee.
[44] *Identify Priority Shares in Kidney Multi-Organ Allocation Concept Paper*, OPTN Ad Hoc Multi-Organ Transplantation Committee, January 2023.
[45] Meeting summary for May 20, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.
[46] Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report, July 1, 2022.
[47] Perspective on the Complex Kidney Underutilization Problem. Darren Stewart, Bekir Tanriover, Gaurav Gupta. Kidney360 Oct 2022.
[48] Meeting summary for September 8, 2021 meeting, OPTN Organ Procurement Organization Committee.
[49] *Redefining Provisional Yes and the Approach to Organ Offers Concept Paper*, OPTN Operations and Safety Committee, August 2022.
[50] *Optimizing Usage of Kidney Offer Filters Concept Paper*, OPTN Operations and Safety Committee, August 2022.
[51] *Optimizing Usage of Kidney Offer Filters Proposal,* OPTN Operations and Safety Committee, January 2023.

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

Released Organs

OPTN *Policy 5.9: Released Organs* details what must occur if an accepted organ is subsequently released by a transplant program. [52] Current policy regarding released kidneys allows the OPO to continue allocation according to the original match run or a released kidney match run, using the previously accepting transplant hospital as the location of the kidney. Current policy regarding released kidney-pancreas (KP), pancreas, and pancreas islets allows the OPO to continue allocation according to the original match run or allocate the KP, pancreas, or islets to a potential transplant recipient at the program originally accepting the organ. If the released KP is allocated to a pancreas-alone candidate, the OPO must allocate the kidney according to the original kidney match run or a released kidney match run using the previously accepting transplant hospital as the location of the kidney.

The Kidney-Pancreas Continuous Distribution Workgroup (the CD Workgroup) has discussed how to convert the released organs policy for kidney and pancreas into the continuous distribution framework. For kidney, the CD Workgroup decided to maintain the current options to either continue allocation according to the original match run, or run a released organ match run using the previously accepting transplant hospital as the location of the kidney when it is released.[53] The CD Workgroup also favored increasing the weight on placement efficiency (via a weight modifier) for released organ match runs. For pancreas and KP, the CD Workgroup decided to maintain the existing policy in the continuous distribution framework, meaning OPOs may continue allocation according the original match run or reallocate to a potential transplant recipient at the program originally accepting the organ. The Utilization Considerations Workgroup also reviewed the CD Workgroup's recommendations and were supportive, citing the recommendation could potentially reduce cold ischemic time for these organs.[54] The appropriate weight modifier for a released organ match run will be determined once the Kidney Committee has decided on the placement efficiency attribute weight.

Kidney and Pancreas Review Boards Workgroup

With the transition to continuous distribution, each organ system will establish a review board in the spirit of the Board's original charge to create a uniform allocation system across organs.[55] OPTN policies cover a multitude of situations, including infrequent events. However, medicine is incredibly complex and constantly evolving. Understanding and predicting every possible clinical situation is not feasible; therefore, review boards are being developed to consider those more unique clinical events. Currently, review boards review specific, urgent-status patient registrations on the OPTN heart, liver, and lung transplant waitlist. Review board members, based on the information provided compared to policy and

[52] OPTN Policy 5.9: Released Organs as of October 27, 2022.
[53] Meeting summary for August 5, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup.
[54] Meeting summary for October 12, 2022 meeting, OPTN Kidney and Pancreas Transplantation Committees Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup.
[55] Executive Summary for December 3-4, 2018 meeting, OPTN Board of Directors.

guidelines, determine whether a candidate is as medically urgent as similar candidates. The guidelines specify requirements for review board members, initial review and appeal process steps, process timeframe, and possible outcomes. Organ-specific committees also develop clinical guidance to supplement the exception process; these resources are not meant to be clinically prescriptive or define a standard of care, rather, to provide objective criteria or more detailed supplementary information to guide transplant programs and review boards in decision-making. As an example, the OPTN Heart Transplantation Committee issued guidance for pediatric heart exception requests.[56]

A new Workgroup, the Kidney and Pancreas Review Boards Workgroup, was created to focus on the development of kidney and pancreas-specific review boards. This group is comprised of representatives from the Kidney, Pancreas, Pediatric, and Data Advisory Committees. The Kidney and Pancreas Review Boards Workgroup will identify candidate-based attributes that could qualify for exception requests within the continuous distribution framework. This Workgroup will also develop operational and clinical guidance for the new review boards. All recommendations from this Workgroup will then be reviewed and endorsed by the Kidney and Pancreas Committees for inclusion in the eventual continuous distribution proposal.

Next Steps

The Committees, along with the previously mentioned workgroups, will continue work on building the continuous distribution framework for kidney and pancreas allocation. The Committees are reviewing the results of the first modeling request, along with feedback received in previous public comment cycles, to submit a second, more refined modeling request in early 2023. In addition to these tools, the OPTN will also be consulting Massachusetts Institute of Technology (MIT) optimizations to hone in on a range of potential acceptable policy options. MIT will augment the SRTR's modeling, now known as the Organ Allocation Simulator (OASIM), with machine learning to quickly and accurately predict outcomes by identifying attribute weights that achieve any set of pre-specified outcomes in near real-time. This mathematical optimization helps narrow the options to those with an acceptable equity vs. utility balance. MIT did similar work for the lung continuous distribution project and helped inform the OPTN Lung Transplantation Committee's selection of weight for various attributes.[57] The specific metrics MIT will evaluate will be determined by Committee discussions.

In addition to determining what to include in a second modeling request, the supplementary workgroups will continue discussing considerations outlined above to provide recommendations to the Committees. The Kidney-Pancreas Continuous Distribution Workgroup, which is comprised of representatives from the Kidney, Pancreas, Pediatrics, Histocompatibility, Ethics, Minority Affairs, and OPO Committees, will also continue to meet regularly to check in on project progress and offer feedback. The Committees will ultimately form policy proposals for the continuous distribution of kidneys and pancreata to be released for public comment and then submitted to the OPTN Board of Directors for consideration. Additionally, the Committees will continue to educate and update the community as this project develops.[58]

[56] *Guidance Addressing the Use of Pediatric Heart Exceptions*, OPTN Heart Transplantation Committee.
[57] *Establish Continuous Distribution of Lungs*, OPTN Lung Transplantation Committee, August 2021.
[58] See Appendix C for more resources on continuous distribution.

NOTA and Final Rule Analysis

The Committees submit this update 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,"[59] 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."[60] 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."[61] 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 simulation modeling, OPTN data, and research presented by multiple parties, as well as operational and experiential evidence. 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. Before the final 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 Committees identified areas 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.[62]

Are designed to…promote patient access to transplantation: The Committees 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

[59] 42 U.S.C. §274(b)(2)(B)
[60] 42 CFR §121.4(a)
[61] 42 C.F.R. §121.8(a)
[62] *Briefing to the OPTN Board of Directors on Establish Continuous Distribution of Lungs*, OPTN Lung Transplantation Committee, December 2021.

transplantation for these patients, who otherwise have limited equitable access to transplant.

Are designed to…promote the efficient management of organ placement: The Committees 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 Committees are 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 Committees are considering the candidate's place of listing to the extent that doing so is required for the purpose of achieving efficient placement of the organs, specifically for Proximity Efficiency (travel efficiency and placement efficiency).

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

Conclusion

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

Considerations for the Community

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

Appendix A: Glossary of Key Terms

The following terms are used throughout the concept paper.

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

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

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

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

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

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

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

Dual Kidney Transplant: Dual transplantation is the use of both adult donor kidneys into a single adult recipient.

En Bloc Kidney Transplant: When two kidneys from the same small pediatric donor, along with the vena cava and aorta, are transplanted into a single recipient.

Estimated Post Transplant Survival (EPTS): The EPTS score is a numerical measure used to allocate kidneys in the kidney allocation system. Every adult patient on the kidney waitlist receives an EPTS score. EPTS scores range from zero to 100 percent. Candidates with a lower EPTS score are expected to experience more years of graft function compared to candidates with higher EPTS scores.

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

Human Leukocyte Antigen (HLA): The 'code' for someone's HLA can be found on a specific place on a chromosome, called a locus. Everyone has a chromosome from both parents, so you can have up to two different antigens at each locus. In general, loci are named with letters (e.g., A, B, DR) and the different types of antigens coded at those loci, called alleles, are assigned numbers. A candidate's level of HLA mismatch with a donor is determined by how many unique antigens the donor has but the candidate does not.

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.

Kidney Donor Risk Index (KDRI) and Kidney Donor Profile Index (KDPI): The KDRI combines a variety of donor factors to summarize the risk of graft failure after kidney transplant into a single number. The KDPI is a remapping of the KDRI onto a cumulative percentage scale, such that a donor with a KDPI of 80 percent has higher expected risk of graft failure than 80 percent of all kidney donors recovered the previous year.

Longevity Matching: 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.

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.

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.

Appendix B: Attributes, rating scales, and workgroups

Kidney Attributes and Rating Scales*

**as included in the first round of OASIM modeling*

Attributes	Goal	Rating Scale
Medical Urgency	Medical Urgency	Binary (yes/no)
HLA Matching	Post-Transplant Survival	0, 1, or 2 DR mismatch
Estimated Post Transplant Survival (EPTS)/Kidney Donor Profile Index (KDPI)[63]	Post-Transplant Survival	Continuous longevity matching[64]
Blood Type	Candidate Biology	Current screening + blood type points (with same curve as CPRA)
CPRA	Candidate Biology	Steep, non-linear curve
Prior Living Donors	Patient Access	Binary (yes/no)
Pediatrics	Patient Access	Binary (yes/no)
Kidney after Liver (KAL) Safety Net	Patient Access	Binary (Yes/No)
Waiting Time	Patient Access	Linear, exceeds 100% beyond 10 years (no ceiling)
Proximity Efficiency	Placement Efficiency	Piecewise linear, 50 NM inner plateau, 85% at 250NM, 25% at 500NM, 0% at 5181 NM

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

**as included in the first round of OASIM modeling*

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

[63] EPTS assumed to be 1 percent for pediatric candidates.

[64] R_{LM} = (0.5 + 2*(EPTS/100 -0.5) * (KDPI/100 – 0.5))

OPTN Kidney and Pancreas Continuous Distribution Working Groups

Group Title	Description
Kidney and Pancreas Transplantation Committees	The Committees will be the primary sponsors of the continuous distribution projects and focus on the overall construction of the continuous distribution frameworks. Over the next few months the Committees will be dedicating their time to reviewing and adjusting these frameworks with the help of modeling and public comment feedback. The Committees will also be reviewing recommendations from other Workgroups for endorsement for inclusion in the eventual public comment proposals. The Committees consist of regional and at large representatives from transplant programs, OPOs, histocompability labs, and the patient community.
Kidney-Pancreas Continuous Distribution Workgroup	This existing Workgroup will continue to meet on a monthly basis and serve as a check-in meeting between the Kidney and Pancreas Committees and other stakeholder committee representatives to report out on project work and collect feedback. This group includes representation from the Kidney, Pancreas, Pediatrics, Histocompatibility, Ethics, Minority Affairs, and OPO Committees.
Utilization Considerations of Kidney and Pancreas Continuous Distribution	This Workgroup focuses on the operational aspects of kidney and pancreas allocation that encourage optimization of kidney and pancreas utilization while transitioning to a continuous distribution framework. This Workgroup has a practical focus on utility and efficiency, and is composed of representatives from the OPO, Operations and Safety, Transplant Coordinator, Data Advisory, Kidney, and Pancreas Committees, who comprise a set of clinical and practical allocation experienced perspectives. This Workgroup is charged with developing recommendations for transitioning utilization and efficiency optimization tools, and ensuring that these tools function effectively in a Continuous Distribution framework.
Kidney and Pancreas Review Boards Workgroup	This Workgroup will focus on the development of review boards for both kidney and pancreas. This group includes representation from the Kidney, Pancreas, Pediatric, and Data Advisory Committees.

Appendix C: Continuous Distribution Resources

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

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

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

Supplemental reports:

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

Other continuous distribution resources:

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