OPTN

Request for Feedback

Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

OPTN Kidney and Pancreas Transplantation Committees

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Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

Sponsoring Committee: *Kidney and Pancreas Transplantation*
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Executive Summary

This request for feedback provides an update to the community about the continuous distribution of kidneys and pancreata projects currently in development by the OPTN Kidney and Pancreas Transplantation Committees (the Committees). Continuous distribution will replace the current classification-based approach with a composite allocation score (CAS) based framework, which aims to holistically consider donor and candidate attributes in Kidney and Pancreas 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]

However, there are other aspects driving the allocation of kidneys and pancreata in addition to the composite allocation score. Operational considerations, such as dual kidney and facilitated pancreas allocation, play an important role in the allocation framework for each organ type. These considerations emphasize and encourage utilization of potentially medically complex organs, and so aim to ensure that the allocation framework provides appropriate pathways for the timely placement of these organs. Other operational components, such as mandatory kidney-pancreas offers, aim to balance equity and utility of these organs for single and multi-organ candidates. This paper outlines recommendations for the transition of several operational considerations into a continuous distribution framework, and requests community feedback on each component, including:

- Released Organs
- National Kidney Offers
- Kidney Minimum Acceptance Criteria Screening Tool
- Dual Kidney
- En Bloc Kidneys
- Facilitated Pancreas Allocation
- Mandatory Kidney-Pancreas Offers

This paper also provides an update on the Committees' efforts to build Kidney and Pancreas Review Boards, including a request for feedback on defining increased medical urgency among pancreas and kidney-pancreas candidates. Finally, this paper builds upon the previous project updates and provides an overview of the next steps for the continuous distribution of kidneys and pancreata projects. [3,4,5,6]

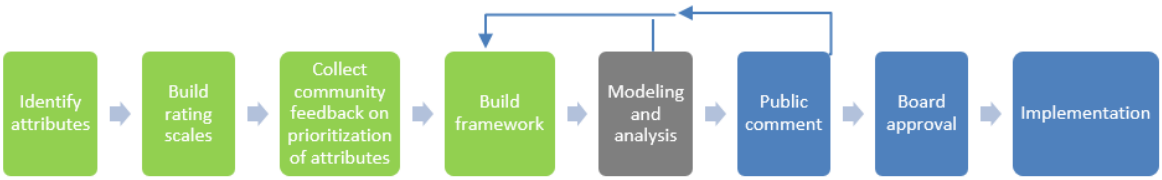
[1] NOTA, 42 U.S.C. § 273 et. seq.
[2] 42 C.F.R. § 121.8
[3] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[4] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[5] *Continuous Distribution of Kidneys and Pancreata Committee Update*, OPTN Kidney and Pancreas Transplantation Committees, August 2022.
[6] *Continuous Distribution of Kidneys and Pancreata Committee Update*, OPTN Kidney and Pancreas Transplantation Committees, January 2023.

Background and Project Progress

Continuous distribution is a points-based framework which assigns a composite allocation score (CAS) that considers all of a candidate's characteristics, in context with several donor 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 holistic CAS that considers both candidate and donor characteristics. This score would be constructed with multiple attributes that align with NOTA and the OPTN Final Rule.[7] A more complete description can be found in **Appendix C.**

The Committees are tasked with developing a comprehensive proposal for the continuous distribution of kidneys and pancreata, and have updated the Community and requested feedback throughout project development.[8,9,10,11] The Committees are currently in the "modeling and analysis" and "building framework" phases of the project, seen in **Figure 1**, which has involved efforts both towards modeling rating scales and weights, as well as the development of solutions for operational considerations such as dual kidney, facilitated pancreas, mandatory kidney-pancreas (KP) offers, and review boards.

Figure 1: Project Overview[12]



Through the "modeling and analysis" phase, the Committees have been and will continue to work with the OPTN, Scientific Registry of Transplant Recipients (SRTR), and contracted researchers from the Massachusetts Institute of Technology (MIT) to develop evidence-based rating scales and weights.[13,14] The full results from the first modeling request can be found on the OPTN website.[15,16] This spring, the Committees submitted their second modeling request to SRTR, with results expected this summer. For more detail on the modeling request and the Committee's discussions, please see the *Committee Update: Development of Second Modeling Request for the Continuous Distribution of Kidneys and Pancreata* resource document on the OPTN website.

[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] *Continuous Distribution of Kidneys and Pancreata Request for Feedback*, OPTN Kidney and Pancreas Transplantation Committees, January 2022.
[10] *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, August 2022.
[11] *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, January 2023.
[12] 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.
[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.
[14] 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.
[15] Scientific Registry of Transplant Recipients, *KI2022_01*, October 20, 2022.
[16] Scientific Registry of Transplant Recipients, *KI2022_01_Addendum*, January 4, 2023.

The Committees have collaborated in their efforts to develop and transition operational considerations outside of the composite allocation score, working with two additional Workgroups – the Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup and the Kidney and Pancreas Review Boards Workgroup. Those discussions are detailed in the sections below.

Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup

Kidney and pancreas allocation includes operational considerations beyond the composite allocation score and candidate prioritization. These considerations are intended to increase kidney and pancreas utilization, particularly from medically complex donors for whom many potential recipients may not be an appropriate match clinically. These considerations include:

- Released Organs
- National Kidney Offers
- Kidney Minimum Acceptance Criteria Screening Tool
- Dual Kidney
- En Bloc Kidneys
- Facilitated Pancreas Allocation
- Mandatory Kidney-Pancreas Offers

The shift from a classification-based system to a points-based system will necessitate changes to the considerations above. The Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup (Utilization Considerations Workgroup) has been charged with developing recommendations for transitioning such considerations to a continuous distribution framework. This Workgroup is composed of representatives from the OPTN Organ Procurement Organization (OPO), Operations and Safety, Transplant Coordinator, Kidney, and Pancreas Committees, who offer a wide spectrum of clinical, operational, and practical allocation experience. As data collection is discussed, the OPTN Data Advisory Committee will also be consulted.

The Utilization Considerations Workgroup's main scope is 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 will focus on tools and policies aimed at increasing efficiency of kidney and pancreas allocation.[17] This Workgroup aimed to leverage existing and future system functionality in support of this goal, and the Utilization Considerations Workgroup's discussions took place in context with efficiency efforts outside of the continuous distribution project. These efforts, many ongoing, include Offer Filters,[18] Predictive Analytics,[19] and imminent improvements to kidney biopsy data collection.[20] Further detail about these efforts can be found in **Appendix B.**

The Utilization Consideration Workgroup's discussions and recommendations were referred to the Kidney and Pancreas Committees for feedback, further discussion, finalization, and approval. The outcome of these discussions is expanded upon below.

[17] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, August 19, 2022.
[18] *Optimizing Usage of Kidney Offer Filters Proposal,* OPTN Operations and Safety Committee, January 2023.
[19] OPTN predictive analytics launched to all kidney transplant programs, UNOS News Bureau; January 26, 2023.
[20] "Standardize Kidney Biopsy Reporting and Data Collection," Policy Notice, OPTN: https://optn.transplant.hrsa.gov/media/tz1ffmdo/data-change_stand-kid-bpsy-rprting-and-data-collec_kid.pdf

Released Organs

OPTN *Policy 5.9: Released Organs* requires that a program who has accepted an organ and subsequently chooses not to transplant the organ must release the organ back to the allocating (host) OPO.[21] However, allocation of released kidneys, KP, pancreata, and pancreas islets are governed by separate policies (*Policy 8.7: Allocation of Released Kidneys* and *Policy 11.7: Allocation of Released Kidney-Pancreas, Pancreas or Islets)*. The Kidney-Pancreas Continuous Distribution Workgroup (the CD Workgroup) discussed how to best transition these released organ policies into the continuous distribution framework. The Utilization Considerations Workgroup also provided additional recommendations to optimize the efficiency of released kidney allocation.

Released Kidney-Pancreas, Pancreas, and Islet Allocation

Current policy regarding released 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.

For pancreas and KP, the CD Workgroup recommends maintaining the existing policy in the continuous distribution framework, meaning OPOs may continue allocation according to the original match run or reallocate to a potential transplant recipient at the program originally accepting the organ.[22] 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.[23] However, the CD Workgroup noted that the clinical considerations of kidneys differ widely from pancreata, particularly as kidneys can tolerate significantly higher cold ischemia times than pancreata.[24,25]

Released Kidney Allocation

Currently, *Policy 8.7: Allocation of Released Kidneys* allows the OPO to either continue allocating according to the original match run or a released kidney match run. The released kidney match run utilizes the accepting transplant hospital as the center of allocation, such that distance is calculated in nautical miles (NM) between the transplant hospital releasing the organ and each candidate's transplant program of registration.[26] The premise behind the released organ match is to improve allocation efficiency when the kidney is a great distance from its original donor hospital, and thus allow the organ to be offered first to candidates nearer to its current location to reduce transportation and cold ischemic time.[27]

[21] OPTN Policy 5.9: Released Organs as of March 16, 2023.
[22] OPTN Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, July 8, 2022.
[23] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, October 12, 2022.
[24] Mei et al, "Pancreas preservation time as a predictor of prolonged hospital stay after pancreas transplantation," J Int Med Res. 2021 Feb
[25] Peters-Sengers et al, "Impact of Cold Ischemia Time on Outcomes of Deceased Donor Kidney Transplantation: An Analysis of a National Registry," Transplant Direct, May 2019.
[26] OPTN Policy 8.7: Allocation of Released Kidneys, as of March 16, 2023.
[27] Modifications to Released Kidney and Pancreas Allocation Policy Notice, implemented March 15, 2021.

While the current form of released kidney allocation policy may easily translate into a continuous distribution system, transitioning this policy provides an opportunity to potentially improve allocation efficiency for released kidneys. Feedback from the OPTN Organ Procurement Organization (OPO) Committee notes that time is of the essence in released kidney allocation, as these organs typically have higher cold ischemic times.[28] This is particularly true of more medically complex donor kidneys, which may not be able to tolerate as much cold ischemic time. The OPO Committee agreed that the released kidney match run should include additional efficiency considerations. [29]

Released Kidney Match Run: Placement Efficiency Weight

The CD Workgroup supported maintaining the current options for OPOs to either continue allocation according to the original match run or run a released organ match run based around the previously accepting transplant program.[30] The CD Workgroup also recommended increasing the weight on the proximity efficiency attribute for released organ match runs.[31] Increased weight for proximity efficiency attribute can be achieved with a separate set of weights for released organ match runs, or through the use of donor weight modifiers. In either case, the released organ match run may also incorporate donor weight modifiers based on the donor's kidney donor profile index score (KDPI), allowing the released match run to better account for differences in donor characteristics and considerations. The Utilization Considerations Workgroup agreed with the recommendation to increase the weight of proximity efficiency on released kidney match runs.[32]

Released Kidney Match Run: Carry Over Refusals

The Utilization Considerations Workgroup also recommends that specific refusals for *qualifying refusal reasons* be "carried over" from the original match run to the released organ match run, such that candidates would not appear on a released match run if refused on the original match run with a qualifying refusal reason.[33] This would improve allocation efficiency of released organs by preventing offers to candidates on the released organ match run who have already refused the organ and will likely refuse the organ again *for the same reason*. For example, if a program declined an organ for a candidate based on positive crossmatch or donor age, it is unlikely that the program would accept the released organ for that same candidate, as neither the crossmatch information nor donor age will have changed. Furthermore, the host OPO allocating the released kidney has the option not to utilize the released kidney match run; in which case, those candidates who have already declined would not receive an additional released organ offer.[34]

As discussed by the Utilization Considerations Workgroup, qualifying refusal reasons to be "carried over" to the released kidney match run would include refusals for things that are *not* expected to change once the organ has been released. This would include refusals for things like positive crossmatch, donor age, or positive infectious disease screening test. Other refusals, for things that *may* change when the kidney is released, would *not* be carried over to the released kidney match run. This would include refusals for logistics reasons, as the logistical considerations of the released kidney may differ significantly from when it was first offered, as the kidney may have traveled. The full list of refusal codes, including those

[28] OPTN OPO Committee Meeting Summary, June 9, 2022.
[29] Ibid.
[30] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, August 5, 2022.
[31] Ibid.
[32] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, September 21, 2022.
[33] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, April 3, 2023.
[34] Ibid.

recommended by the Utilization Considerations Workgroup to be carried over to the released kidney match run and those the Utilization Considerations Workgroup recommended *not* to be carried over, can be found in **Appendix A**.

The Kidney Committee is exploring how to best operationalize this recommended functionality. As discussed, the process of carrying over refusals may work such that candidates for whom the program has refused the initial kidney offer, per a qualifying refusal reason, would not appear on the released kidney match run, and thus would not receive the released organ offer. Having these candidates for whom qualifying refusals have been submitted *not* appear on the match run, as opposed to carrying over the refusals as bypasses, would improve the navigability of the released kidney match run as well as allocation efficiency.[35] **Table 1** provides a visual example below. The Utilization Considerations Workgroup notes that screening candidates for whom the transplant program would not accept the kidney offer from the released kidney match run would help ensure that transplant program offer acceptance ratios are not impacted.[36]

Table 1: Example – Candidates would not appear on released match run if refused on the original match run with a qualifying refusal reason

Original Match Run	Response to Original Match	Released Match Run
Candidate A	Refused for positive crossmatch (qualifying)	Not offered; candidate does not appear on released kidney match
Candidate B	Refused for donor age (qualifying)	Not offered; candidate does not appear on released kidney match
Candidate C	Refused for transportation availability (not qualifying)	Candidate appears on match run, eligible to receive offer again
Candidate D	Refused for positive infectious disease test (qualifying)	Not offered; candidate does not appear on released kidney match
Candidate E	Not yet offered	Candidate appears on match run, eligible to receive offer
Candidate F	Not yet offered	Candidate appears on match run, eligible to receive offer

The Kidney Committee is requesting feedback on released kidney allocation in continuous distribution. Several specific questions are below:

Kidney Committee Recommendations:

[35] Ibid.
[36] Ibid.

- OPOs allocating released kidneys may continue to either allocate kidneys according to the original match run, *or* allocate kidneys using a released kidney match run (utilizing the accepting transplant hospital as location of kidney)
- Increased weight on proximity efficiency for released kidney match runs
- Candidates will not appear on the match run if their program has already refused the organ for a qualifying refusal reason (as found in **Appendix A**)

Feedback Requested:

- Do you support "carrying over" certain refusals to the released kidney match run?
- If so, do you support the refusals recommended to be carried over as found in **Appendix A?**
- Do you support an increased weight for placement efficiency on the released kidney match run?
- If so, how much more important should placement efficiency be on the released kidney match run?
- Are there additional considerations that should be incorporated for released kidney or released pancreas allocation?

National Kidney Offers and Kidney Minimum Acceptance Criteria Screening Tool

Current OPTN *Policy 8.6.B: National Kidney Offers* requires OPOs to contact the OPTN Organ Center for assistance in allocating kidneys to "national" candidates, defined as those candidates outside of 250 NM from the donor hospital, with the exception of 0-ABDR mismatch candidates and 100% CPRA candidates.[37] When this occurs, the OPTN Organ Center takes over kidney allocation, utilizing the Kidney Minimum Acceptance Criteria (KiMAC) screening tool to increase efficiency of allocation by reducing offers to programs that have indicated they would not accept them. Although use of the KiMAC tool is currently not available to OPOs, many in the OPO community have expressed interest in gaining the ability to offer kidneys to "national" candidates themselves, with assistance from the OPTN Organ Center able to be requested at their discretion.[38]

The KiMAC tool allows for additional transplant-program level acceptance criteria to be utilized for "national" kidney offers, defined as those offers from donors greater than 250 NM away, but excluding offers to candidates who may have a 100% CPRA or are being offered 0-ABDR mismatched kidneys. Current policy requires programs to report information about the types of "national" kidney offers they are interested in receiving on an annual basis.[39] If a donor more than 250 nautical miles away from the transplant hospital does not meet a program's minimum criteria standards, the KiMAC tool will apply a bypass to all non-0-ABDR mismatch and non-100 percent CPRA candidates at that program. **Table 2** shows where on the match run the KiMAC currently applies, with the classifications affected in red text.

Because current kidney allocation prioritizes these "national" kidney offers in the final allocation classifications on the match runs, the application of the KiMAC to "offers outside of 250 NM" is

[37] OPTN Policy 8.6.B: National Kidney Offers as of March 16, 2023.
[38] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, January 25, 2023.
[39] OPTN Policy 5.11.A: Kidney Minimum Acceptance Criteria as of March 16, 2023.

essentially acting as a screening tool for the programs for "hard to place" kidneys. By the time the KiMAC is applied, the kidney has been offered to and declined by many candidates and programs.

Table 2: KiMAC Application

Sequence A KDPI 0 – 20%	Sequence B KDPI 20 – 34%	Sequence C KDPI 35 – 85%	Sequence D KDPI 86 – 100%
100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle (Top 20% EPTS) 0-ABDRmm (All) Inside Circle (All) **National Pediatrics** **National (Top 20% EPTS)** **National (All)**	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) **National Pediatrics** **National (All)**	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) **National (All)** Inside Circle (dual) **National (dual)**	100% Highly Sensitized Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ADBRmm Inside Circle Safety Net Inside Circle Inside Circle (dual) **National** **National (dual)**

National Kidney Offers in Continuous Distribution

Under a continuous distribution framework, there will be no clear "national" or "outside of 250 NM" distinction on the match run. Considering this, and OPO community interest in national allocation, the CD Workgroup agreed to remove the requirement posed by *Policy 8.6.B: National Kidney Offers*, such that OPOs will no longer be *required* to contact the OPTN Organ Center for assistance in allocating kidneys outside of 250 NM.[40,41] OPOs seeking assistance with kidney allocation will still be able to do so at their discretion.

Thus, under continuous distribution of kidneys, OPOs will be able to offer through the entirety of the match run, with no requirement to refer the case to the OPTN Organ Center for allocation. As a result, the OPTN Organ Center may not always have an opportunity to apply the KiMAC tool. The KiMAC tool will need to be updated and automated to maintain efficiency and avoid an increase in offers for "hard to place" kidneys that programs have indicated they do not wish to receive. Updates to the KiMAC will be required to ensure that application of the tool is consistent across match runs and donors, regardless of whether the OPO or the OPTN Organ Center is allocating the kidney(s).

[40] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, May 20, 2022.
[41] OPTN Policy 8.6.B: National Kidney Offers as of March 16, 2023.

KiMAC Transition Considerations

Efforts to transition the KiMAC tool into continuous distribution allocation will require several considerations, specifically:

- *How* the tool is applied, or the logistics of OPO application
- *Who* the KiMAC should apply to, or *where* on the match run
- *Which* screening elements should be included in the KiMAC.

The KiMAC currently operates independently, but alongside Offer Filters and the candidate-specific Kidney Donor Acceptance Criteria. Each tool provides a different type and level of screening and filtering, as shown in **Table 3**. You can learn more about the Offer Filters below, in the "Other Efficiency Efforts" section.

Table 3: Screening and Filtering Tools

Efficiency Tool Characteristic	KiMAC	Offer Filters	Kidney Donor Acceptance Criteria
What level of screening does this tool provide?	Screening questions answered based on program-level preferences	Screening questions answered based on program-level preferences, with ability to indicate candidate-based exclusion criteria	Screening questions answered by default with program-level preferences, but customizable candidate by candidate
What is the screening question being asked?	What is the minimum kidney donor characteristics that the program will accept for "national" offers?	What types of kidney donors will the program not accept?	What types of kidney donors will the candidate accept?
Is the tool required for use?	Transplant programs are required to provide responses to the questions and update annually	No requirement for use at this time[42]	Transplant programs are required to provide responses to these fields on each candidate record
When is the tool applied?	Applied *after* match is run, but before national offers are made	Applied and updated as offers are sent out	Applied when the match is run

[42] As of June 26, 2023, the OPTN Board of Directors approved the OPTN Operations and Safety Committee's proposal, *Optimize Usage of Offer Filters*, which will apply default offer filters for each program based on their historic acceptance practices, with the ability for programs to opt out of their default filters. The Board Briefing Paper can be found here: https://optn.transplant.hrsa.gov/media/vyonuirf/optn_osc_offer-filters_bp_june23.pdf

Efficiency Tool Characteristic	KiMAC	Offer Filters	Kidney Donor Acceptance Criteria
How does the tool apply?	Applies as bypass	Applies as a bypass	Screens candidates from the match (candidates who would not accept the donor do not appear on the match run)
To what offers does the tool apply?	Applied for offers to candidates *outside* 250 NM; excludes 0-ABDRmm and 100 percent CPRA candidates	Applies to all offers unless the candidate is excluded from the filter	Applies screening to all matches, prior to offers being sent
Example	The program will not accept offers any donors with cold ischemic time greater than 16 hours for any "national" candidates	The program will not accept any donors with a hypertension history greater than 10 years for any candidates	This candidate will not accept any offer from a donor with a positive hepatitis C test result

While future iterations of filtering and screening will ultimately aim to streamline and combine the efficiency provided by all three tools above, this will require a phased approach.[43] The first step of this approach will involve key updates to the KiMAC tool to determine how the tool can be applied best in a continuous distribution framework.

Why not incorporate KiMAC into Offer Filters? The Utilization Considerations Workgroup considered the potential incorporation of the KiMAC into the Offer Filters tool, and determined several reasons why this may be inappropriate at this time. To begin, the KiMAC is currently required for use by all transplant programs, and programs are required to update their responses to the tool annually. Offer Filters is not currently required for use by transplant programs. Furthermore, the KiMAC tool provides a different, specific level of screening in targeting only non-high CPRA, non-0 ABDR mismatch offers outside of 250 NM, or those classifications towards the end of the match run. Some elements of the KiMAC's application rules, such as application outside of 250 NM and exempting certain candidate populations, can be recreated with the use of multi-factorial filters, as shown below. However, this would require a significant number of complicated filters that could be burdensome to programs, particularly with respect to replicating the donor-age specific screening provided by the KiMAC tool. The Utilization Considerations Workgroup noted that this could reduce efficiency provided by screening, particularly while use of Offer Filters is currently voluntary.[44]

[43] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, January 25, 2023.
[44] Ibid.

Example filter: "Filter kidney offers if hypertension history > 10 years *AND* distance > 250nm *AND* donor age > 60 years *UNLESS* candidate is a 0-ABDR mismatch *or* candidate CPRA > 99%"

Furthermore, the Offer Filters utility cannot duplicate target screening for "hard to place" kidneys provided by KiMAC's application to candidates in the final kidney allocation classifications. In a continuous distribution system, where classifications will not exist, it will be critical to determine how the "hard to place" utility of KiMAC screening can be preserved to maintain efficiency, particularly as the Offer Filters tool remains optional.[45,46]

KiMAC Logistics of Application in Continuous Distribution

The Kidney Committee is exploring automating use of the KiMAC tool in a continuous distribution framework. The tool would pull information directly from the donor record and apply bypasses to appropriate candidates based on the application rules determined by the Kidney Committee, with input from community and cross-Committee feedback. Options for these application rules are discussed below. Like Offer Filters, the KiMAC bypasses will be applied as part of the electronic notification workflow, meaning that the bypasses will be applied and updated on the kidney match run every time the OPO sends out an electronic notification.[47]

KiMAC Screening Criteria in Continuous Distribution

The Utilization Considerations Workgroup is evaluating the full list of KiMAC criteria to determine which elements should continue to be used for screening in continuous distribution. Automating KiMAC allows information to be pulled directly from the donor record. While some elements of current KiMAC screening are collected as data in the OPTN Donor Data and Matching System, others are not. The Utilization Considerations Workgroup has begun evaluating each screening criteria to determine which should endure, including which criteria will require modifications to or additional new data collection in the OPTN Donor Data and Matching System. Each criterion is being discussed with consideration for its screening effectiveness, clinical relevance, and potential impact to OPTN Computer System integration.[48,49,50, 51]

KiMAC Application Rules in Continuous Distribution

The purpose of the KiMAC tool is to accelerate placement of kidneys being offered "nationally." The Kidney Committee hopes to closely replicate the application rules currently utilized by the KiMAC tool, with particular attention to the targeted screening for "hard to place" kidneys provided by the tool, in order to maintain benefits to allocation efficiency provided by the KiMAC.

In reviewing potential solutions, the Utilization Considerations Workgroup and Kidney Committee sought solutions that would preserve allocation order at the top of the match run, utilize a clear definition of "hard to place" kidneys, and preserve offers for 100% CPRA and other highly prioritized

[45] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, February 27, 2023.
[46] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, May 18, 2023.
[47] Ibid.
[48] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, April 18, 2023.
[49] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, April 24, 2023.
[50] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, May 8, 2023.
[51] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, May 18, 2023.

candidates. The Utilization Considerations Workgroup explored several options in determining how best to achieve this, each of which is expanded upon below.

KiMAC Application Rules: Options

The Utilization Considerations Workgroup discussed and considered several options for future state KiMAC application rules:[52]

- **KiMAC applies to the entire match run:** In this option, the KiMAC would apply immediately, and so apply bypasses to any candidate based on program preferences, starting at the first sequence on the match run. This would result in more extreme screening than currently provided by the tool, as more urgent or highly prioritized candidates would be bypassed, which may not be favored by the community. This option would not capture targeted screening for "hard to place" kidneys, and thus would be inconsistent with the KiMAC tool's current application.[53] As a result of the more extreme screening rules, programs may choose broader, less effective screening criteria, in order to ensure highly prioritized candidates receive offers, thereby eliminating the efficiency currently provided by the KiMAC tool. [54] **Table 4** provides an example.

Table 4: KiMAC Applies to Entire Match Run

Candidate	Does the donor meet the program's minimum criteria for acceptance?	KiMAC bypass applies?
Candidate A: 100% CPRA, outside of 250 NM	No	Bypass applies
Candidate B: medically urgent, within 250 NM	No	Bypass applies
Candidate C: outside of 250 NM, 15 years of dialysis time	No	Bypass applies
Candidate D: within 250 NM	No	Bypass applies
Candidate E: outside of 250 NM	Yes	Not bypassed, candidate receives offer
Candidate F: outside of 250 NM	No	Bypass applies

- **KiMAC applies only to relevant candidates more than 250 NM away, excluding certain candidate populations (high CPRA, etc.):** In this option, the KiMAC would apply to candidates more than 250 NM away from the donor, based on program preferences, no matter where on the match run they fell. Certain candidates, such as 100 percent CPRA candidates or 0-ABDR mismatch candidates, would be excluded from any KiMAC bypass, regardless of program preferences or distance from the donor hospital. This option replicates key aspects of current KiMAC screening, but could result in more highly prioritized candidates more than 250 NM away being bypassed. In applying bypasses regardless of candidate position of the match run, this option would not maintain the "hard to place" targeted screening currently provided by the KiMAC tool, which applies only to those "national" candidates towards the end of the match run. This option also maintains several

[52] Ibid.
[53] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, February 8, 2023
[54] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, February 8, 2023

hard boundaries, with little adaptability to the more continuous allocation system.[55] **Table 5** provides an example.

Table 5: KiMAC Applies Only to Candidate >250 NM Away, with Candidate Exclusions

Candidate	Does the donor meet the program's minimum criteria for acceptance?	KiMAC bypass applies?
Candidate A: 100% CPRA, outside of 250 NM	No	Not bypassed, candidate receives offer due to 100% CPRA
Candidate B: medically urgent, within 250 NM	Yes	Not bypassed, candidate receives offer due to being within 250 NM
Candidate C: outside of 250 NM, 15 years of dialysis time	No	Bypass applies, as candidate is outside of 250 NM and program has indicated *no* interest in this type of donor
Candidate D: within 250 NM	No	Not bypassed, candidate receives offer due to being within 250 NM
Candidate E: outside of 250 NM	Yes	Not bypassed, candidate receives offer due to their program indicating interest in this type of donor
Candidate F: outside of 250 NM	No	Bypass applies, as candidate is outside of 250 NM and program has indicated *no* interest in this type of donor

- **KiMAC applies at a specified composite allocation score threshold:** This option would define a specific composite allocation score (CAS) threshold, after which the KiMAC bypasses would apply. This option would provide some consistency in application across match runs. The CAS threshold also ensures that more highly prioritized candidates, or those with higher CAS, would *not* be bypassed by the tool. Furthermore, a CAS threshold defines a specified point on the match run. In specifying a point on the match run, this option might mirror how the KiMAC is currently applied. However, the distribution of candidates might vary, and the use of the CAS threshold will be inflexible to differences in the candidate population appearing on the individual match runs. Finally, any updates to the CAS calculation would require a re-evaluation of the CAS threshold utilized to trigger the KiMAC.[56] **Table 6** provides an example.

[55] Ibid.
[56] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, February 8, 2023

Table 6: KiMAC Applies at Specified CAS Threshold

Candidate	Does the donor meet the program's minimum criteria for acceptance?	KiMAC bypass applies?
Candidate A: 100% CPRA, outside of 250 NM	No	Not bypassed, candidate receives offer
Candidate B: medically urgent, within 250 NM	No	Not bypassed, candidate receives offer
Candidate C: outside of 250 NM, 15 years of dialysis time	No	Not bypassed, candidate receives offer
CAS Threshold, KiMAC Applies		
Candidate D: within 250 NM	No	Bypass applies
Candidate E: outside of 250 NM	Yes	Not bypassed, candidate receives offer as program has indicated they would be interested in this type of donor
Candidate F: outside of 250 NM	No	Bypass applies

- **KiMAC applies at a certain percentage of the match run, excluding certain candidate populations (100 percent CPRA, within 250 NM, etc.):** This option would define a specific point on the match run based on how many candidates appeared on the match run, dividing the match run into two portions. The first portion would not be bypassed by the KiMAC tool, while the second portion would apply KiMAC bypasses, with exclusions for certain candidate populations, such as 100% CPRA candidates or candidates less than 250 NM away from the donor. This option is flexible to differences in candidate populations appearing on individual match runs across the country, while maintaining consistency in application of KiMAC screening across these match runs. Using a threshold ensures that more highly prioritized candidates, those in the first portion of the match run, are not bypassed. By definition, this option targets "hard to place" kidneys by ensuring a portion of the match run has had the opportunity to receive, review, and refuse the organ offer before KiMAC bypasses apply. This mirrors the element of "hard to place" kidney screening in current KiMAC application, by which a portion of the match run has received, reviewed, and refused the organ offer before the tool is applied. Finally, this option avoids screening candidates that should receive the offer due to candidate characteristics or logistical considerations, such as highly sensitized candidates and those candidates within 250 NM. [57] **Table 7** provides an example.

Table 7: KiMAC Applies at Percentage of Match Run, with Candidate Exclusions

Candidate	Does the donor meet the program's minimum criteria for acceptance?	KiMAC bypass applies?
Candidate A: 100% CPRA, outside of 250 NM	No	Not bypassed, candidate receives offer
Candidate B: medically urgent, within 250 NM	No	Not bypassed, candidate receives offer

[57] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, February 8, 2023

Candidate	Does the donor meet the program's minimum criteria for acceptance?	KiMAC bypass applies?
Candidate C: outside of 250 NM, 15 years of dialysis time	No	Not bypassed, candidate receives offer
Percent Threshold – KiMAC Applies		
Candidate X: within 250 NM	No	Not bypassed, candidate receives offer, as candidate is within 250 NM
Candidate Y: outside of 250 NM	Yes	Not bypassed, candidate receives offer
Candidate Z: outside of 250 NM	No	Bypass applies

The Utilization Considerations Workgroup recommend that KiMAC bypasses should be applied at a certain percentage of the match run, with candidate exclusions. The Kidney Committee supports this recommendation, noting that this recommendation creates a definition of "hard to place" kidneys based on attempts at placement. [58]

To determine what percentage of the match run should be used, the Utilization Considerations Workgroup reviewed historic KiMAC application data, as shown in **Figures 2, 3, and 4**. **Figure 2** shows that the KiMAC was historically applied at a median of 7.6 percent of the match run, meaning that 7.6 percent of the match run received offers before the point on the match where KiMAC was applied.[59] The percentage was defined as the sequence number at which the KiMAC was applied divided by the total length of the match run.

Figure 2: KiMAC Application as a Percentage of the Match Run

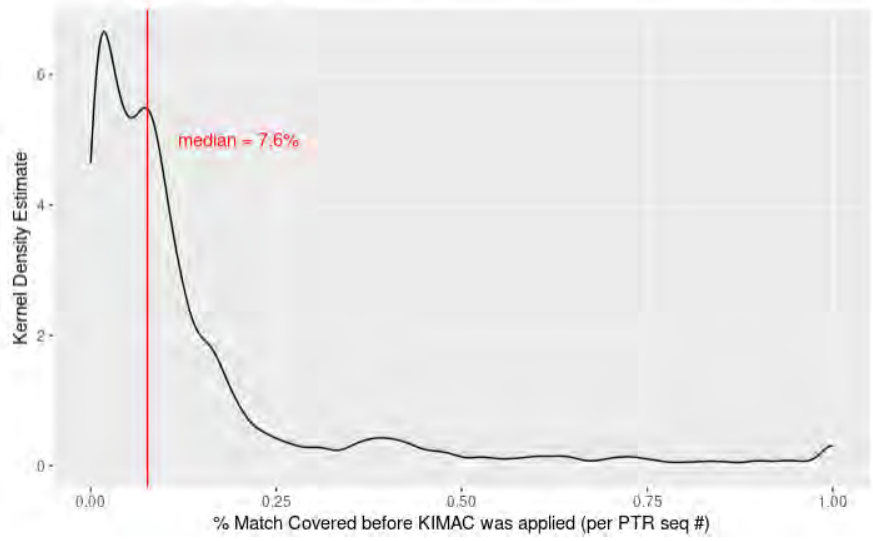
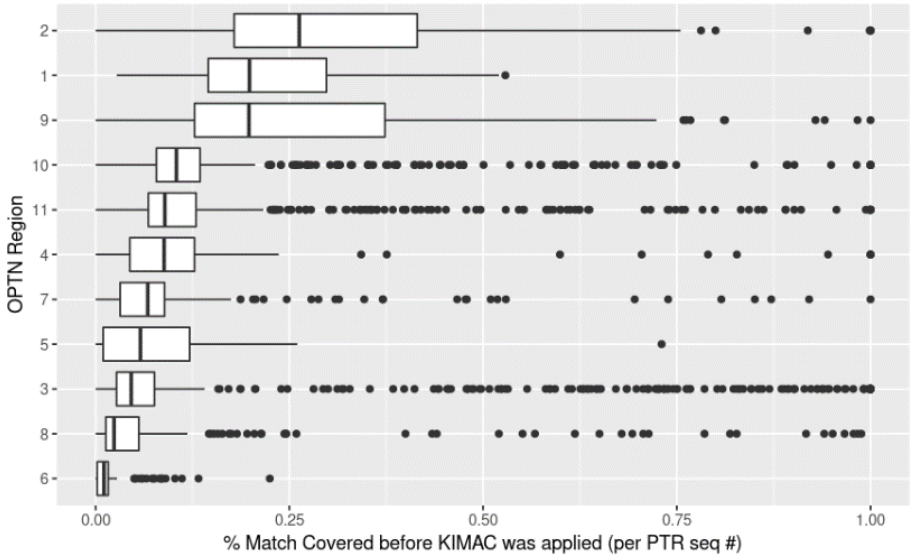


Figure 3 shows the regional differences in median KiMAC application. Of note, Regions 2, 1, and 9 typically see the KiMAC applied later in the match run, at about 20 to 25 percent of the match run.

[58] OPTN Kidney Transplantation Committee Meeting Summary, May 23, 2023.
[59] Ibid.

Regions 2, 1, and 9 are in the northeastern part of the country, which has high populations and program density.[60,61]

Figure 3: KiMAC Application as a Percentage of the Match Run, by Region



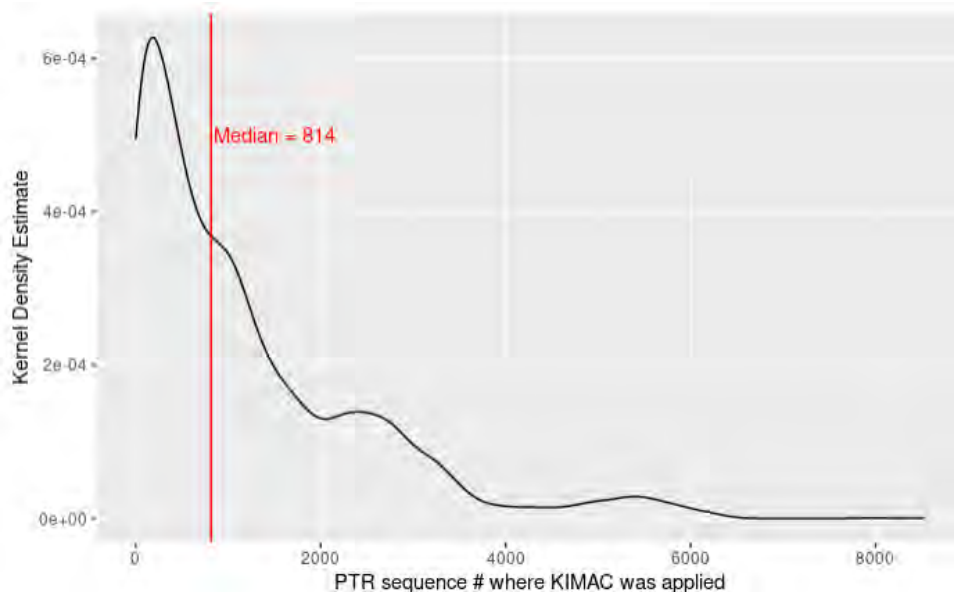
The Utilization Considerations Workgroup noted that the exclusion of candidates at programs within 250 NM of the donor hospital would help to account for regional differences shown in **Figure 3**, as the high population and program density in these regions.

While 7.6 percent of the match run may not seem like much of the match run, **Figure 4** shows that the KiMAC was historically applied at sequence 814. This means that programs received, reviewed, and refused offers for 813 candidates before the KiMAC was applied.

[60] 2020 Population Distribution in the United States and Puerto Rico, US Census. https://www.census.gov/library/visualizations/2021/geo/population-distribution-2020.html

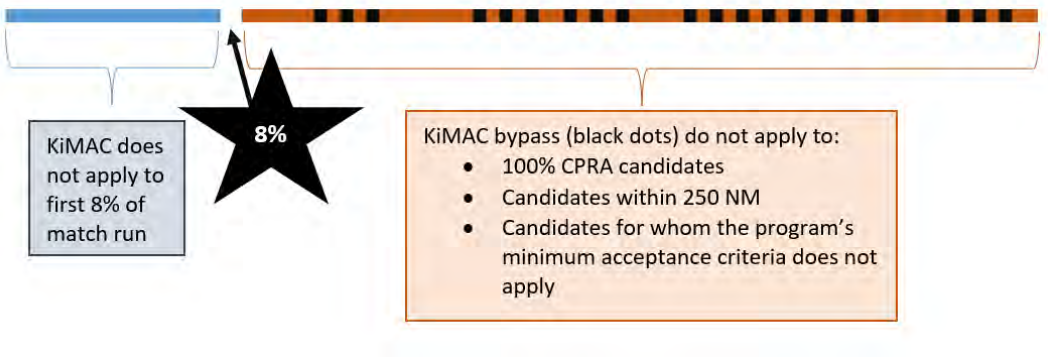
[61] OPTN regional transplant program data accessed June 19, 2023. https://optn.transplant.hrsa.gov/data/view-data-reports/regional-data/

Figure 4: KiMAC Application by Sequence Number



In reviewing this data, the Utilization Considerations Workgroup has recommended that KiMAC bypasses should begin applying to appropriate candidates at eight percent of the match run.[62] This means KiMAC bypasses will not apply to candidates in the first eight percent of the match run and would only apply to candidates (based on their program's selected criteria and candidate characteristics) appearing on the latter 92 percent of the match run. The Kidney Committee agreed that KiMAC bypass application at eight percent of the match run is consistent with current practice as indicated in the data, and aligns with their allocation experience, particularly with harder to place kidneys. The Utilization Considerations Workgroup also noted that this percentage can be adjusted later, if needed, and that programs are able to determine the level of screening they feel is appropriate given the KiMAC's application rules via their responses in the OPTN Waitlist System.[63] **Figure 5** visually explains how this option might work.

Figure 5: Recommended KiMAC Application in Continuous Distribution



The Kidney Committee also recommends that candidates at programs within 250 NM of the donor hospital and 100 percent CPRA candidates are excluded from the KiMAC bypass, meaning that these

[62] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, May 18, 2023
[63] Ibid.

candidates will never be bypassed by the KiMAC tool, regardless of their position on the match run or whether they meet criteria to be bypassed.[64] These candidate exclusions mirror those in existing KiMAC application rules, and the Utilization Considerations Workgroup noted that this will help maintain a similar scope. The Utilization Considerations Workgroup also noted that candidates within 250 NM may be more likely to accept the offer, as the organ may not need to travel a great distance and will have a lower cold ischemic time. The Kidney Committee considered the Utilization Consideration's Workgroup recommendation that 0-ABDR mismatch candidates also be excluded from the KiMAC bypasses, in alignment with current policy.[65] The Kidney Committee ultimately determined that the 0-ABDR mismatch exclusion is not necessary in a continuous distribution framework, particularly as allocation will move to prioritizing level of DR locus mismatch over level of ABDR mismatch.[66] The Committee hopes to evaluate the need for these exclusions by determining how many high CPRA candidates are within the first eight percent of the match run.[67]

Kidney Committee Recommendation:

- The KiMAC would apply to candidates on the last 92% of the match run, based on the program's indicated donor criteria
- The KiMAC would *not* apply to the following candidates:
    - 100% CPRA candidates
    - Candidates within 250 NM
    - Candidates for whom the program's minimum acceptance criteria does not apply

Feedback Requested:

- Do you support applying the KiMAC based on a percentage of the match run, with specific candidate population exceptions?
- If so, does 8% of the match run, with exclusions for candidates within 250 NM of the donor hospital and 100% CPRA candidates seem appropriate?
- Are there other candidate populations that should be excluded from the KiMAC bypass, regardless of whether the donor does not meet their programs' minimum donor criteria?

Dual Kidney Allocation

Dual kidney transplantation is the transplantation of both adult donor kidneys into a single adult recipient. Kidney allocation policy was updated in 2019 to standardize the allocation of dual kidneys with the goal of providing a patient survival advantage over single high KDPI kidney transplantation, as well as encouraging utilization of more medically complex kidneys.[68] This policy requires transplant programs to specify which candidates are willing to accept dual kidney offers in order to receive them.

Policy 8.5.A: Allocation of Dual Kidneys established dual kidney classifications for kidneys with KDPI scores of 35 percent and above.[69] 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 – once for the single kidney offer, and once for the dual kidney offer. As illustrated in

[64] OPTN Kidney Transplantation Committee Meeting Summary, May 23, 2023
[65] Ibid.
[66] Ibid.
[67] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, May 18, 2023
[68] *Improving Dual Kidney Allocation*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[69] OPTN Policy 8.5.A: Allocation of Dual Kidneys, as of March 16, 2023.

Table 8, for kidneys with KDPI 35-85 percent, the dual kidney classifications are the last classifications on the match run. For kidneys with a KDPI 86-100 percent, the dual kidney classifications appear towards the end of the match run, and allocation currently alternates between single and dual kidney offers, depending on whether the candidates are within 250 NM of the donor hospital.

Table 8: Current Dual Kidney Allocation Policy

Sequence C (KDPI 35-85%)	Sequence D (KDPI 86-100%)
• Single Offer – Priority Classifications • Single Offer – Candidates within 250 NM • Single Offer – Candidates outside of 250 NM • **Dual Offer – Candidates within 250 NM** • **Dual Offer – Candidates outside of 250 NM**	• Single Offer – Priority Classifications • Single Offer – Candidates within 250 NM • **Dual Offer – Candidates within 250 NM** • Single Offer – Candidates outside of 250 NM • **Dual Offer – Candidates outside of 250 NM**

On longer match runs, this means that dual kidney offers may not be made until a significant allocation effort has been made, which often translates to longer cold ischemic times. The policy's two-year monitoring report shows that more than 44 percent of dual kidney transplants were allocated from single kidney classifications – confirming that many dual kidney offers occur out of sequence, prior to allocation reaching the dual kidney classifications.[70] Feedback from the OPO community indicates this is done to avoid organ wastage due to increased ischemic time and late turndowns.[71] While previous input from the OPO community supported dual allocation on the same match run as single kidney allocation, , since implementation, the experience and feedback has been that this results in much longer and less efficient match runs.[72,73]

With the removal of the classification-based system, the Utilization Considerations Workgroup has discussed more efficient options to transition dual kidney allocation to a continuous distribution framework. The Utilization Considerations Workgroup recommends a new allocation structure for dual kidneys which aims to address identified inefficiencies by leveraging current and future system functionality.

The Utilization Considerations Workgroup recommended that, to offer the kidneys as dual, the host OPO will need to run a new dual-kidney specific match run, which will include several efficiency considerations, explained below. The Utilization Considerations Workgroup noted that a separate, dual-kidney specific match run will result in candidates appearing once on the single match run, thus improving efficiency from the current model, while still ensuring equity in dual allocation is maintained on the dual kidney match run.[74] The Utilization Considerations Workgroup and the Kidney Committee are currently considering options to determine *when* an OPO may begin allocating kidneys as dual. These options are also expanded upon below.

[70] 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.
[71] OPTN OPO Committee Meeting Summary, June 9, 2022.
[72] *Improving Dual Kidney Allocation*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[73] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, September 21, 2022.
[74] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Meeting Summary, September 21, 2022.

Efficiency Considerations of the Dual Kidney Match Run

A separate, dual kidney specific match run aims to improve allocation efficiency overall. Candidates will only appear once on the single kidney match run, which will shorten the original single kidney match, thus reducing complexity, total number of calls, and increasing efficiency of single allocation.[75] Furthermore, the dual kidney match run in continuous distribution will leverage OPO discretion to a greater degree, and once policy requirements are met regarding dual kidney eligibility, the OPO will have discretion over whether and when to run the dual kidney match run. The dual kidney match run will also include several additional layers of efficiency.

To begin, the dual kidney specific match run will only include candidates opted in to receive dual kidney offers. The Offer Filters tool will also include dual kidney as a filter option, and programs will be able to build dual kidney specific filters.[76] Other screening tools, such as the KiMAC and the candidate-specific kidney donor acceptance criteria, would also apply to the dual kidney match run, as these tools apply to dual kidney offers currently.

The Utilization Considerations Workgroup also noted that there are efficiency benefits to be gained from *not* offering to a candidate who would not accept the dual kidney offer *for the same reason* the single kidney offer was declined. The Utilization Considerations Workgroup recognized that, though a single kidney offer and a dual kidney offer present very different offer types and considerations, it may be appropriate to "carry over" certain refusal reasons when the offer is coming from the same donor, such that candidates would not appear on dual kidney match run if refused on the original match run with a qualifying refusal reason. For example, a program may refuse a single kidney offer for their candidate due to unacceptable antigens or a positive crossmatch, indicating the candidate is not medically compatible with the donor. This would still be true if both kidneys were offered as dual, and so it would be expected that the program would decline the dual kidney offer for that candidate *for the same reason*. To this end, the Utilization Considerations Workgroup also recommends that certain qualifying refusal reason codes be "carried over" to the dual kidney match run, and that programs have the ability to "opt out" of receiving a dual kidney offer from a specific donor.

To achieve this, the Utilization Considerations Workgroup and the Kidney Committee are recommending certain refusal reasons be carried over from the original match run to the dual kidney offer. As discussed, this could work such that candidates whose transplant program refused the offer as a single kidney offer *for a qualifying refusal reason* (i.e. positive physical crossmatch) would *not* appear on the dual kidney match run. The full list of refusal codes, including those recommended to be carried over and those recommended not to be carried over, can be found in **Appendix A.**

Finally, the Utilization Considerations Workgroup recommended programs have the ability to "opt out" of receiving a potential dual kidney offer from a specific donor, particularly if the program does not find that donor a suitable dual kidney donor for any of their candidates. To achieve this, the Utilization Considerations Workgroup has recommended the "donor refusal" functionality should also be updated, to allow programs to submit a donor-related refusal for all candidates for current single kidney and future dual kidney offers from that donor. This functionality would also be renamed for clarity, and the user interface updated for usability.

[75] Ibid.
[76] OPTN Utilization Considerations of Continuous Distribution Workgroup Meeting Summary, October 12, 2022.

Kidney Committee Recommendation:

- In order to allocate kidneys as dual, the host OPO would run a new, dual kidney specific match run:
  - Dual kidney match run includes *only* candidates opted in to receive dual kidney offers
  - Offer filters model takes dual kidney into account, and programs can build dual specific filters
  - Candidates would not appear on dual kidney match run if refused on the original match run with a qualifying refusal reason
  - Programs may decline all future dual kidney offers from a specific donor on the original match run
- Other requirements, such as donor criteria or attempts to allocate the kidneys as single first, would determine *when* an OPO *may* begin allocating the kidneys as dual
- Once the requirement has been met, the OPO would have discretion over whether, and when, the kidneys should be allocated as dual

Feedback Requested:

- Do you support allocating kidneys as dual via a separate, dual kidney specific match run?
- Do you support the proposed efficiency considerations of the dual kidney match run? Are there other considerations that should be incorporated?
- Do you support "carrying over" qualifying refusals from the single kidney match run to the dual kidney match run?
- Should the dual kidney match run incorporate an increased weight on the placement efficiency attribute?
- Should programs be required to obtain patient consent prior to opting candidates into receiving dual kidney offers?

Dual Kidney Allocation Eligibility and Thresholds

The Utilization Considerations Workgroup and the Kidney Committee both considered and discussed multiple options to define *when* an OPO should be able to begin allocating kidneys as dual. There was general agreement across both groups that there should be some level of OPO discretion incorporated into this policy, as those allocating the kidneys will best understand at what point dual allocation may be necessary to ensure utilization of the organs. As a result, the Kidney Committee recommends that the dual kidney allocation threshold is optional, such that once these requirements are met, the OPO will have discretion in whether to begin allocating the kidneys as dual.[77]

Similarly, the Utilization Considerations Workgroup and the Kidney Committee agreed that additional consideration should be given for higher KDPI kidneys, as well as kidneys with extended cold ischemia times, such that these kidneys may be allocated as dual more quickly. Both the Utilization Considerations Workgroup and the Kidney Committee considered that the highest KDPI kidneys might be allocated as dual immediately post-recovery of the organ, as these kidneys have the highest rates of non-use and are often challenging to place.[78] The Kidney Committee agreed that it might be appropriate

[77] OPTN Kidney Transplantation Committee Meeting Summary, May 23, 2023.
[78] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 21, 2022.

to allow higher KDPI kidneys to move to dual allocation earlier.[79] Both the Utilization Considerations Workgroup and the Kidney Committee also agreed that reducing cold ischemic time is critical to dual kidney allocation, particularly as these organs may be medically complex and may not tolerate significant cold ischemic times. The Kidney Committee agreed that dual kidney allocation should attempt to reduce cold ischemic time for these organs, and suggested OPOs may also be able to move to dual kidney allocation more easily at a higher cold ischemic time threshold.[80]

The Kidney Committee is currently considering two different options: creating donor eligibility criteria and requiring allocation as single kidneys first to define when an OPO *may* begin allocating both kidneys as dual.

Option 1: Require Offering as Single Kidneys First

This option would require the OPO to first attempt to allocate single kidneys. This could involve requiring single kidney offer attempts through a percentage of the match run in order to trigger dual kidney allocation. Once a percentage of the match has been offered to and declined, the OPO would have discretion to begin offering the kidneys as dual from the dual kidney match run. This option identifies donor kidneys as "hard to place" by a proportion of eligible candidates who have received and declined the organ offer. While this concept was also presented as a way to capture screening for "hard to place" kidneys in the KiMAC section above, the percentage threshold used for dual kidney could differ from the one used for KiMAC screening. The Kidney Committee seeks feedback and community consideration on what percentage of the match run could be used to allow OPOs to allocate kidneys as dual, and how this percentage threshold may be determined. Specifically, the Kidney Committee seeks feedback from the community whether the percentage threshold should mirror dual kidney classifications in the current system, or if there are specific outcomes that should be balanced.

Option 2: Dual Kidney Eligibility Criteria Under Consideration

This option focuses on donor characteristics and post-recovery organ information, such that donors must meet specific eligibility criteria in order for the kidneys to be offered as dual. In considering potential dual kidney donor eligibility criteria, the Utilization Considerations Workgroup determined donor eligibility requirements should balance a wide enough range of criteria to capture cases where dual kidney allocation may be needed, with a high enough number of criteria to ensure dual kidney allocation is only pursued where appropriate.[81]

The Utilization Considerations Workgroup reviewed data on the characteristics of current dual kidney donors.[82] This data showed that dual kidney donors were more likely to: [83]

- Be a Donation after Circulatory Death (DCD) donor, especially in the KDPI 35-85 percent group
- Have a history of diabetes
- Have a history of hypertension, especially in the KDPI 35-85 percent group
- Have kidneys biopsied, and when biopsied, have a higher degree of glomerulosclerosis

[79] OPTN Kidney Transplantation Committee Meeting Summary, May 23, 2023.
[80] Ibid..
[81] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[82] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, October 12, 2022
[83] Dual Kidney Transplants and Donors by KDPI, OPTN Data, accessed October 10, 2022.

There was no statistically significant difference in serum creatinine across single and dual kidney donors. Generally, this median was between 0.960 mg/dl and 1.245 mg/dl.[84]

The Utilization Considerations Workgroup also reviewed transplant density data, to understand the general trends in rates of dual kidney and single kidney transplant based on KDPI, which can be seen in **Figures 6 and 7**. This data shows a sharp increase in dual kidney transplant density at about KDPI 60 percent.

Figure 6: Kidney Transplants by KDPI and Transplant Type, KDPI 35-85%[85]

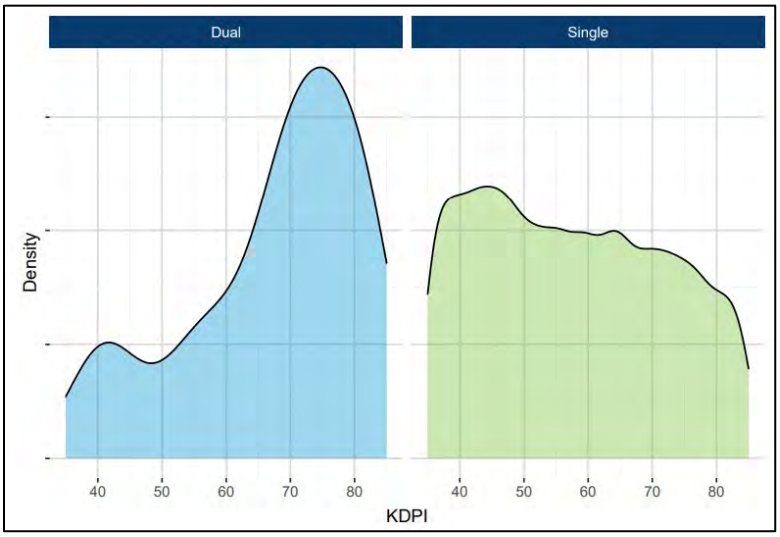
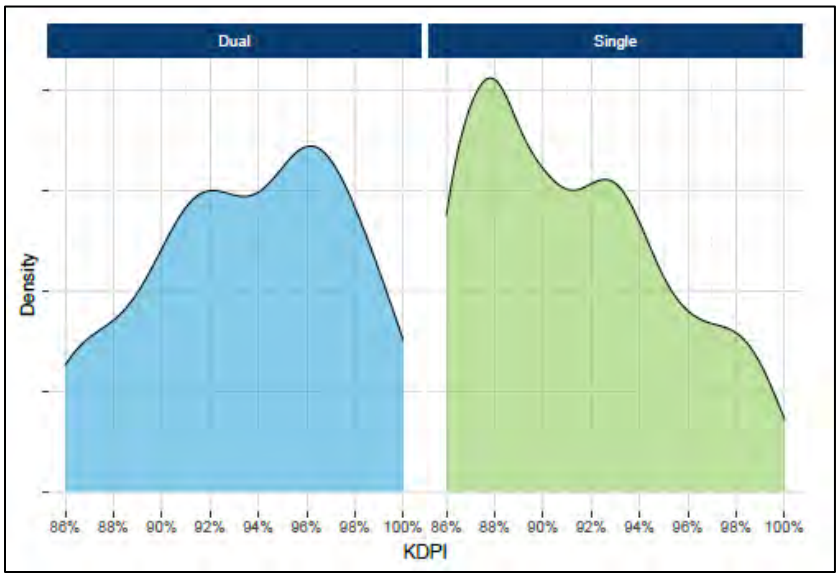


Figure 7: Kidney Transplants by KDPI and Transplant Type, KDPI 86-100%[86]



In discussing which elements should be included in the recommended criteria, the Utilization Considerations Workgroup considered alignment of these criteria with those utilized to require biopsy,

[84] Ibid.
[85] Dual Kidney Transplants and Donors by KDPI, OPTN Data, accessed October 10, 2022.
[86] Kidney Non-Utilization by KDPI and Transplant Type, OPTN Data, accessed January 25, 2023

per *Policy 2.11.A: Required Information for Deceased Kidney Donors*. The Utilization Considerations Workgroup noted that these criteria would likely be similar, and donor characteristics concerning enough to require biopsy may also indicate a potential need for dual kidney allocation.

It is of note that several of these criteria were utilized in a previous version of dual kidney allocation policy. Prior to implementation of the current dual kidney allocation policy, OPTN policy established dual kidney eligibility criteria based on donor age greater than 60 years, estimated creatinine clearance less than 65 mL/min, rising serum creatinine greater than 2.5 mg/dL at time of organ recovery, history of longstanding hypertension or diabetes, and glomerulosclerosis values greater than 15% but less than 50%.[87] For donors that did not meet at least two of the above criteria, OPOs were required to offer both kidneys as single before making any dual kidney offers. The criteria-driven dual kidney allocation policy was replaced due to community consensus that the criteria itself was ambiguous and insufficient to allow OPOs to identify and allocate dual kidneys in a timely manner, particularly for donors who did not meet at least two of the criteria previously listed.[88]

KDPI: In considering KDPI, the Utilization Considerations Workgroup noted that it can be difficult to define when dual kidney allocation may be necessary to ensure utilization of lower KDPI kidneys, as these kidneys may present medical complexities not reflected in the KDPI score. The Utilization Considerations Workgroup agreed that more aggressive criteria specific to donor characteristics outside of the KDPI score will be helpful to appropriately identify lower KDPI kidneys for which dual kidney allocation may be necessary. Current allocation policy incorporates dual kidney classifications for kidneys with a KDPI of 35 and above. In considering kidneys with a KDPI of 35-59 percent, the Utilization Considerations Workgroup recognized that donors with a 35-59 percent KDPI for whom dual kidney allocation is appropriate will likely have very different clinical characteristics than dual kidney donors with a KDPI of 60-100 percent.[89] The Utilization Considerations Workgroup noted that dual allocation may still need to be maintained as a potential option for these donor kidneys, in order to ensure utilization.[90] In considering **Figures 6 and 7**, the Utilization Considerations Workgroup felt that it was appropriate to split the KDPI 35-85 percent threshold, as this represents a very large population of donors, and so recommended creating a KDPI 60-85 percent category and a KDPI 86-100 percent category. The Utilization Considerations Workgroup agreed that KDPI 35-59 percent may need different criteria than KDPI 60-85 percent.[91,92]

The Utilization Considerations Workgroup considered splitting out a category of the highest KDPI kidneys, such as KDPI 98-100 percent, to allow for direct dual allocation, noting that these kidneys are very difficult to place.[93] The Utilization Considerations Workgroup also considered potentially requiring only that these kidneys be recovered, such that OPOs could only allocate the kidneys as single prior to organ recovery, and would not be able to allocate as dual until immediately after the organ was recovered. [94] The Utilization Considerations Workgroup determined that this may not be necessary, and after significant discussion and review of **Figure 7**, ultimately decided to remove the KDPI 98-100

[87] Improving Dual Kidney Allocation, OPTN Kidney Transplantation Committee, approved December 2017: https://optn.transplant.hrsa.gov/media/2220/kidney_pcproposal_dual_201707.pdf
[88] Ibid.
[89] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 14, 2022.
[90] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[91] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 9, 2022.
[92] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[93] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 21, 2022.
[94] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 11, 2023.

percent category, and condense it into KDPI 86-100 percent.[95] The Utilization Considerations Workgroup noted that this would help simplify the policy.[96]

Several criteria discussed by the Utilization Considerations Workgroup are also included in the KDPI calculation and are used to determine each donor's KDPI score. The Utilization Considerations Workgroup agreed that such factors should be accounted for outside of the context of KDPI, as middle or lower range KDPI kidneys may also have a combination of factors that motivate an OPO to move to dual kidney allocation. Furthermore, the calculation for KDPI considers factors like diabetes and hypertension in a binary fashion, while the dual kidney criteria recommended by the Utilization Considerations Workgroup will allow these factors to be considered in context of duration and potentially, management, of these diagnoses. The Utilization Considerations Workgroup concluded that including KDPI calculation factors separately from KDPI will allow dual allocation to be more dynamic and better account for kidneys across a KDPI spectrum for which dual allocation may be appropriate.[97]

DCD Status: DCD status is also included in the KDPI calculation. The Utilization Considerations Workgroup agreed that not all DCD donors for whom dual kidney allocation may be appropriate will have high KDPI kidneys, and thus it is important to consider DCD as a factor outside of the context of KDPI. The Utilization Considerations Workgroup supported including DCD as a criterion for dual kidney eligibility, given data showing dual kidney donors are somewhat more likely to be DCD.[98] Specifically, data revealed that 51 percent of dual kidney donors with KDPI 35-85 percent were DCD, while 42 percent of single kidney donors with KDPI 35-85 percent were DCD. Similarly, 30 percent of dual kidney donors with KDPI 86-100% were DCD, while 27 percent of single kidney donors with KDPI 86-100 percent were DCD donors.[99] The Utilization Considerations Workgroup further considered a warm ischemic time threshold for DCD donors, suggesting DCD donor with 45 minutes of warm ischemic time as a criterion. This is in alignment with the literature, which has shown that prolonged warm ischemia time is associated with increased delayed graft function in kidney recipients of DCD donor kidneys.[100]

Cold Ischemic Time: Time is critical to dual kidney allocation, particularly as these organs may be medically complex and may not tolerate extended cold ischemic time. Furthermore, transportation, time to crossmatch, and distance must also be considered, as they contribute to cold ischemic time after placement.[101]

The Utilization Considerations Workgroup recommended that a cold ischemic time threshold of four hours could apply to all KDPI groupings, on top of other specific criteria requirements, to help ensure attempts at single allocation are made.[102] The Utilization Considerations Workgroup also noted that OPOs will likely know if there is interest in accepting the organs as single kidneys at four hours and may choose to continue single allocation attempts, but that for kidneys where there might be no interest in the single kidney offer, dual kidney allocation may begin.[103] The Utilization Considerations Workgroup shared anecdotally that some OPOs allocate more aggressively once the kidney reaches between 4-6 hours of cold ischemia time.[104] Any cold ischemia time threshold must also consider time to allocate,

[95] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, October 12, 2022.
[96] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 25, 2023.
[97] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 21, 2022
[98] Ibid.
[99] Dual Kidney Transplants and Donors by KDPI, OPTN Data as of October 10, 2022.
[100] Brennan et al, "Impact of warm ischemia time on outcomes for kidneys donated after cardiac death Post-KAS," *Clinical Transplantation*, September 2020: https://pubmed.ncbi.nlm.nih.gov/32654278/
[101] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 9, 2022:
[102] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[103] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 11, 2023
[104] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, February 27, 2023.

time for offer evaluation, transportation, and other aspects of the organ offer acceptance process that must occur prior to transplant. The Utilization Considerations Workgroup agreed that 4 hours of cold time is an appropriate criterion, as dual kidney allocation will need to occur in a timely fashion to minimize cold time for medically complex kidneys.[105]

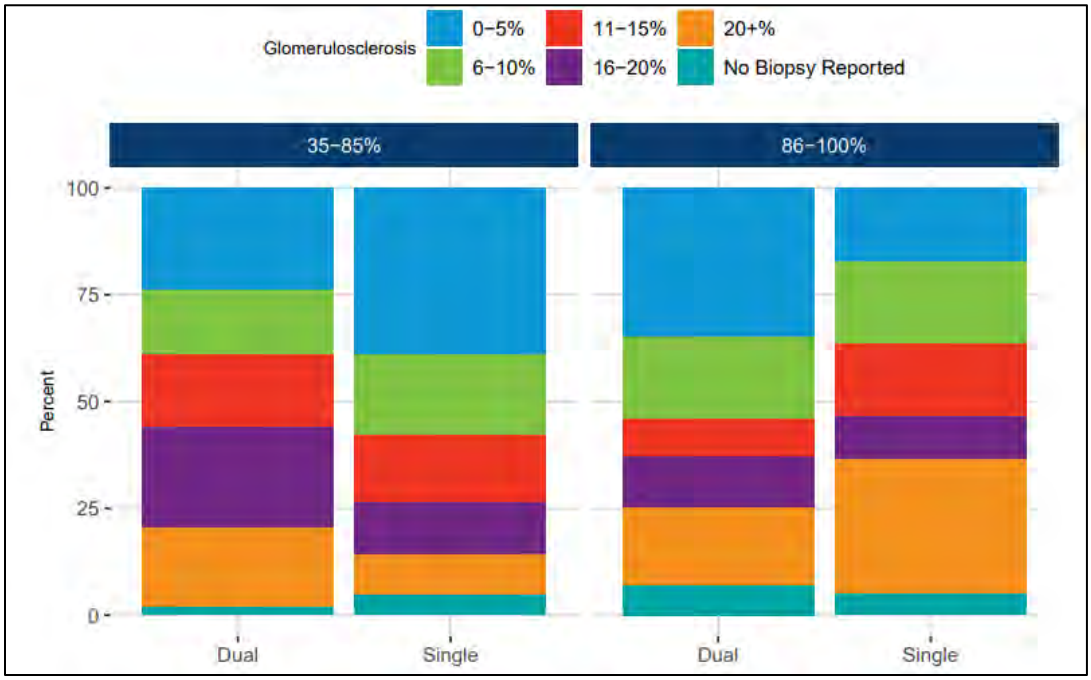
Biopsy Results: The Utilization Considerations Workgroup agreed that criteria and consideration for necessary dual kidney allocation may differ across KDPI, and that post-OR information, such as biopsy results, are also important to consider.[106] This aligns with literature on dual kidney donor selection, which has shown that pre-implantation biopsy results can aide in the selection of donors for dual kidney, regardless of donor age.[107]

Gill *et al*'s 2008 study, "Outcomes of dual adult kidney transplants in the United States: an analysis of the OPTN/UNOS database," utilized glomerulosclerosis between 15 and 50 percent as a donor selection criteria for dual kidney transplantation, and saw successful rates of patient survival at five years post-transplant.[108] Other studies have also utilized biopsy parameters, including glomerulosclerosis, interstitial fibrosis, tubular atrophy, and arterial and arteriolar narrowing.[109,110] The decision to incorporate biopsy results in dual kidney eligibility criteria is also based on the difficulty of placing kidneys with marginal biopsy results. "Biopsy findings" was the most commonly reported reason (38.2%) for kidney non-use.[111] Incorporating biopsy results into the dual kidney eligibility criteria might help encourage dual allocation of kidneys that might not be placed as single kidneys. The Utilization Considerations Workgroup and the Kidney Committee acknowledged that frozen biopsy readings can be subjective, but ultimately decided that biopsies are obtained despite concerns of subjectivity and are considered in the organ offer acceptance and refusal decision.[112]

The Utilization Considerations Workgroup discussed several glomerulosclerosis thresholds between 10 and 20 percent.[113] The Utilization Considerations Workgroup initially considered glomerulosclerosis 20 percent in the context of older donors, who may generally have low nephron mass, and ultimately determined that 10 percent glomerulosclerosis may be a more appropriate threshold. Data reviewed by the Utilization Considerations Workgroup (**Figure 8**) revealed that 86-100 percent KDPI dual kidneys tended to have lower glomerulosclerosis scores, particularly in the 0-5 percent range. The Utilization Considerations Workgroup recommended glomerulosclerosis greater than or equal to 10 percent, particularly in consideration of higher KDPI kidneys. This aligns with the findings of the *Biopsy, Anatomy, and Resistance Effects on Transplant Outcomes (BARETO)* study, which found that significant effects of glomerulosclerosis generally plateaued beyond 10 percent.[114] However, the Utilization Considerations Workgroup recommended the glomerulosclerosis threshold needed to be higher in the criteria utilized for lower KDPI donors.[115]

[105] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 11, 2023
[106] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, October 12, 2022.
[107] Mabood Khalil et al, "Dual Kidney Transplantation: A Review of Past and Prospect for Future." Int Sch Res Notices, 2017.
[108] Gill et al, "Outcomes of dual adult kidney transplants in the United States: an analysis of the OPTN/UNOS database." Transplantation, 2008.
[109] Remuzzi et al, "Early experience with dual kidney transplantation in adults using expanded donor criteria. Double Kidney Transplant Group (DKG)." J Am Soc Nephrol. Dec 1999.
[110] Esker et al, "Technical aspects of unilateral dual kidney transplantation from expanded criteria donors: experience of 100 patients." Am J Transplant, 2010.
[111] Mohan et al, "Factors leading to the discard of deceased donor kidneys in the United States." Kidney Int. 2018.
[112] OPTN Kidney Transplantation Committee Meeting Summary, May 23, 2023.
[113] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, November 9, 2022.
[114] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[115] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 14, 2022.

Figure 8: Dual Kidney Donors by KDPI, Classification, and Glomerulosclerosis



Vascular disease as a biopsy finding was also considered, and it was noted that these findings might be of concern enough to programs to justify dual kidney allocation.[116] Vascular disease is a marker of chronic kidney damage and might provide insight into potential graft function.[117]

The Utilization Considerations Workgroup did note that higher glomerulosclerosis scores or more severe vascular disease without clear potential cause of such damage in the donor's history could point to sampling or quality issues with the biopsy read. The Utilization Considerations Workgroup also recognized that these negative biopsy results may still significantly impact allocation of these kidneys, and that OPOs may need to allocate such kidneys as dual to ensure utilization.[118]

The Utilization Considerations Workgroup noted that post-recovery information, such as biopsy results and anatomy, might be critical to identifying lower KDPI kidneys requiring dual kidney allocation. The Utilization Consideration Workgroup noted that factors used to consider dual kidney eligibility for KDPI 35-59 percent donors should also directly relate to potential kidney graft function, as this may drive more practical allocation. The Utilization Considerations Workgroup recommended moderate or severe vascular disease as a potential criterion, noting this could be cause for concern for programs, and might justify dual kidney allocation.[119] Similarly, cortical necrosis or fibrin thrombi biopsy findings can indicate acute and irreversible kidney damage, and could make allocation more difficult. [120,121] The Utilization Considerations Workgroup specified fibrin thrombi greater than 10 percent could be a significant

[116] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[117] Sethi et al. "Proposal for Standardized Grading" (2017): 787-789.
[118] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 11, 2023
[119] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022.
[120] Fogo et al, "Atlas of Renal Pathology: Cortical Necrosis," American Journal of Kidney Disease. May 2016 https://www.ajkd.org/article/S0272-6386(16)00222-5/fulltext
[121] Hansen et al, "Fibrin thrombi in deceased donor kidneys: Prevalence and influence on graft function and graft survival in transplanted patients," APMIS, 2018: https://pubmed.ncbi.nlm.nih.gov/29154394/

enough finding to indicate the potential need for dual allocation.[122] The Utilization Considerations Workgroup also offered that glomerulosclerosis greater than or equal to 20 percent could be appropriate in considering dual kidney eligibility for KDPI 35-59 percent kidneys, noting the relatively higher proportion of dual kidney donors with findings of glomerulosclerosis greater than 20% compared to single kidney donors, as shown in **Figure 8**.

Terminal Creatinine, Cerebrovascular Accident (CVA) as Cause of Death, and Donor Age: The Utilization Considerations Workgroup recommended that terminal creatinine greater than 1.5 mg/dl, CVA as the cause of death, and donor age 60 or greater be included as potential criteria, noting that the donor would need to meet multiple criteria to qualify for dual allocation.[123] Terminal creatinine can vary as an indicator based on the donor's size or age; in the context of multiple criteria needing to be met, the terminal creatinine threshold remained a recommendation.[124]

Hypertension: The Utilization Considerations Workgroup agreed that a significant history of hypertension could cause concern relating to potential single graft function, as donor hypertension has been found to be an independent risk factor for graft survival.[125] The Utilization Considerations Workgroup also agreed that unmanaged or uncontrolled hypertension should be considered differently from managed hypertension, as the relative resulting organ damage may be more severe in patients with unmanaged disease. The Utilization Considerations Workgroup recommended a history of controlled hypertension of ten years or greater and a history of uncontrolled hypertension of five years or greater as two potential criteria. This is in alignment with relevant literature, which shows hypertension more significantly impacts graft survival when history of hypertension was greater than 10 years.[126] Uncontrolled hypertension (not being treated/managed or resistant to treatment), can be even more detrimental to renal function, and the Utilization Considerations Workgroup felt shorter durations may be appropriate.[127][128]

Diabetes: The Utilization Considerations Workgroup discussed diabetes, and recommended alignment with more standard clinical values and the use of diabetes in other aspects of OPTN policy, such as requirements for deceased donor renal procurement biopsy. As a result, the Utilization Considerations Workgroup recommended any history of diabetes, or unknown history of diabetes with an HbA1c value greater than 6.5 upon final admission or during donor management, as a criterion. Obtaining an HbA1c is relatively common in donor management.[129] Proxies for diabetes, such as proteinuria, were also discussed. Proteinuria may be too complicated as a standalone criterion, and that it is preferable to rely on patient history or an HbA1c value to determine diabetes history.[130] Proteinuria has many causes, and proteinuria alone may not be an appropriate indicator of diabetes.[131] Bendersky *et al.* found that elevated donor HbA1c levels (greater than 6.5) were associated with diminished graft survival five years

[122] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 14, 2022
[123] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022
[124] Ibid.
[125] Ojo et al, "Impact of pre-existing donor hypertension and diabetes mellitus on cadaveric renal transplant outcomes," American Journal of Kidney Disease, 2000: https://pubmed.ncbi.nlm.nih.gov/10873885/
[126] Ojo et al, "Impact of pre-existing donor hypertension and diabetes mellitus on cadaveric renal transplant outcomes," American Journal of Kidney Disease, 2000: https://pubmed.ncbi.nlm.nih.gov/10873885/
[127] "How High Blood Pressure Can Lead to Kidney Damage or Failure," American Heart Association, https://www.heart.org/en/health-topics/high-blood-pressure/health-threats-from-high-blood-pressure/how-high-blood-pressure-can-lead-to-kidney-damage-or-failure
[128] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 7, 2022
[129] Ibid.
[130] Ibid.
[131] "Proteinuria," *Cleveland Clinic*. https://my.clevelandclinic.org/health/diseases/16428-proteinuria#:~:text=Proteinuria%20is%20high%20levels%20of,Urology%20216.444.5600

post-transplant.[132] The Utilization Considerations Workgroup recognized that the diabetes criterion is broad, but noted that if the donor's elevated HbA1c is not concerning in the context of other donor factors, that the OPO may be able to successfully place kidneys individually for single kidney transplant.[133] If programs have indicated they would like to accept the donor kidneys for single kidney transplant, the OPO will have the discretion to place the organs as single kidneys.[134]

Anuria and Dialysis: The Utilization Considerations Workgroup also considered anuria and dialysis as potential indicators of kidney damage or potential opportunity for dual allocation of KDPI 35-59 percent kidneys. Anuria has been clinically defined as a urine output of less than 100ml in a 24 hour period in adult, and can indicate acute damage to the kidneys.[135,136,137] Similarly, dialysis or short-term renal replacement therapy can be utilized to manage renal function and encourage recovery of acute kidney injury in deceased donors.[138] Alignment with the criteria used to require procurement kidney biopsy for deceased donors per *Policy 2.11.A: Required Information for Deceased Kidney Donors* may be appropriate here, as this captures concern for potential damage.[139]

Other Criteria Considered: The Utilization Considerations Workgroup considered other criteria that were not included in the recommended criteria for dual kidney eligibility. One such criterion was estimated glomerular filtration rate (eGFR), which could be used to project nephron mass. Acute injury can, however, cause a donor to have a lower eGFR that may resolve post-transplant with recovery. The Utilization Considerations Workgroup also agreed that if eGFR were to be used, it would need to be via a standard formula calculated by the OPTN Computer System, to ensure standardization. Another considered criterion was "pump numbers," or how well the kidney is able to be perfused using hypothermic machine perfusion. The Utilization Considerations Workgroup noted that pump numbers can be difficult to obtain. Similarly, anatomy-based criteria, such as color, size, and plaque in vessels, were considered and ultimately determined to be too subjective to allow for consistent application. Diffuse petechiae, or the presence of spots visible on the organ, potentially indicative of damage or disease, was discussed for inclusion as a potential indicator of damage, but ultimately removed as it is potentially overly vague.

The Utilization Considerations Workgroup considered surgical damage, and determined that it was not an appropriate consideration in the context of dual kidney allocation, as surgical damage does not necessary speak to potential graft function, and it is difficult to define severity of surgical damage for the purposes of policy requirements. The Utilization Considerations Workgroup also considered disseminated intravascular coagulation (DIC) as a criterion but determined that it would be rare for the OPO to make that determination, as this is usually done by the receiving transplant program.

Kidney Committee Recommendation:

- In order to allocate kidneys as dual, the host OPO would run a new, dual kidney specific match run

[132] Bendersky et al, "Elevated Donor Hemoglobin A1C Impairs Kidney Graft Survival From Deceased Donors with Diabetes Mellitus: A National Analysis," *Experimental and Clinical Transplantation,* January 2019. https://europepmc.org/article/med/30674242
[133] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 25, 2023
[134] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 25, 2023
[135] Min Choi et al. "Etiology and Outcomes of Anuria in Acute Kidney Injury: A Single Center Study" Kidney Research and Clinical Practice, 34 (2015): 13-9.
[136] 7 Peng et al. "Recovery of Renal Function in a Heart Transplantation Recipient with Over 300 Days of Iatrogenic Anuria," Medicine, 97 (2018). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5944477/
[137] Ivan Damjanov MD, PhD in Pathology Secrets (Third Edition) 2009, chapter 15 pg 301-328
[138] 9 Goyal et al. "Acute Kidney Injury," StatPearls, 2021. https://www.ncbi.nlm.nih.gov/books/NBK441896/
[139] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, December 14, 2022

- Other requirements, such as donor criteria or attempts to allocate the kidneys as single first, would determine *when* an OPO *may* begin allocating the kidneys as dual
- Once the requirement has been met, the OPO would have discretion over whether, and when, the kidneys should be allocated as dual

Feedback Requested:

- How should policy define when an OPO may begin allocating kidneys as dual? Should this definition be based on donor criteria, on offering the kidney as single first, or a combination of the two?
- If the dual kidney eligibility requirement is based on offering the kidney as single first, what percentage of the single kidney match run should receive and decline the primary kidney offer before the OPO may move to dual kidney allocation?
- What other considerations should be included in the dual kidney eligibility requirement for when an OPO may begin dual kidney allocation?
- If the dual kidney eligibility threshold is based on criteria, which criteria should be incorporated? Please also provide feedback on specifics in each criteria (i.e. glomerulosclerosis thresholds for different KDPI ranges, or durations of hypertension history)
- If dual kidney eligibility is based on criteria, which criteria *should not* be incorporated?

En Bloc Kidney Allocation

The current en bloc allocation policy was implemented in 2019 and states that the host OPO must offer kidneys from deceased donors less than 18 kilograms (kg) en bloc, if both kidneys are recovered. Transplant hospitals must opt candidates in to receive en bloc offers. Currently, all en bloc kidneys are allocated in the same sequence as donors with a KDPI 0-20 percent via an en bloc-specific match run.[140] Allocating en bloc kidneys under continuous distribution will require tweaks to the policy, as continuous distribution moves away from classifications and each kidney will require a unique KDPI score. The original calculation that KDPI is based upon, known as the Kidney Donor Risk Index (KDRI), was published in 2009 and included en bloc as a factor adjusted for in the original KDRI calculation. [141,142] This factor accounts for expected benefit in post-transplant outcomes for an en bloc transplant (i.e. two kidneys instead of a single kidney). The en bloc factor wasn't initially included in the KDPI calculation because the use of KDPI in allocation policy predates the specification of which donors should be allocated en bloc, and the current KDRI calculation does not currently utilize the en bloc coefficient. [143] The Kidney Committee and the Kidney-Pancreas Continuous Distribution Workgroup 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.[144,145] Therefore, the Committee is recommending utilizing the en bloc coefficient within the KDRI calculation to assign en bloc kidneys a KDPI score in continuous distribution. [146]

[140] OPTN Policy 8.5.B: Allocation of En Bloc Kidneys as of March 16, 2023.
[141] *Improving Allocation of En Bloc Kidneys*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[142] Rao, Panduranga S., Douglas E. Schaubel, Mary K. Guidinger, Kenneth A. Andreoni, Robert A. Wolfe, Robert M. Merion, Friedrich K. Port, and Randall S. Sung. "A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index." Transplantation 88, no. 2 (July 27, 2009): 231-36. doi:10.1097/tp.0b013e3181ac620b.
[143] *Improving Allocation of En Bloc Kidneys*, OPTN Kidney and Pancreas Transplantation Committees, August 2017.
[144] OPTN Kidney Transplantation Committee Meeting Summary, October 8,2021.
[145] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, May 20, 2022.
[146] Ibid.

Feedback Requested:

- Do you support the Committee's recommendations on en bloc kidney allocation?

Facilitated Pancreas

Current OPTN policy permits OPOs and the OPTN Contractor to make facilitated pancreas offers if no pancreas offer has been accepted three hours before the scheduled donor organ recovery.[147] 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.[148] Since continuous distribution will remove hard boundaries, including the current distance-based classifications, candidates within 250 NM could appear anywhere on the match, it will 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 currently only apply to pancreas candidates (meaning KP candidates are not bypassed when facilitated pancreas allocation is used), there was discussion regarding applying bypasses to both pancreas and KP candidates in the new framework to improve efficiency.[149]

After much discussion and consideration of the established goal of increasing utilization of pancreata, the Pancreas Committee recommends applying bypasses to kidney-pancreas (KP) *and* pancreas candidates for facilitated allocation.[150]

The Pancreas Committee also discussed which candidates should not be bypassed based on sensitization and level of mismatch during facilitated allocation. Currently, the facilitated pancreas tool does not bypass any candidates with CPRA 80 percent or greater or candidates who are a 0-ABDR mismatch with the donor, regardless of their program's status as a facilitated pancreas program. The facilitated pancreas tool does bypass all other isolated pancreas candidates at non-facilitated programs more than 250 nautical miles away from the donor hospital. The Committee previously expressed interest in the highly sensitized candidates having some type of priority and not being bypassed.

The Pancreas Committee deliberated on four options as follows:

- Do not bypass candidates who are both highly sensitized (CPRA greater than or equal to 80 percent) and a 0-ABDR mismatch with the donor (current policy)
- Do not bypass candidates who are highly sensitized (CPRA greater than or equal to 80 percent), regardless of 0-ABDR mismatch
- Bypass all candidates at non-facilitated programs, regardless of CPRA or 0-ABDR mismatch
- Do not bypass 0-ABDR mismatch at non-facilitated programs

[147] OPTN Policy 11.6.B*:* Facilitated Pancreas Offers as of March 16, 2023.
[148] Ibid.
[149] OPTN Pancreas Transplantation Committee Meeting Summary, August 1, 2022.
[150] OPTN Pancreas Transplantation Committee Meeting Summary, April 3, 2023.

In review of the options presented, the Committee discussed the data presented in the *Removal of DSA and Region from Pancreas Allocation: 1 Year Report,* that showed the following:[151]

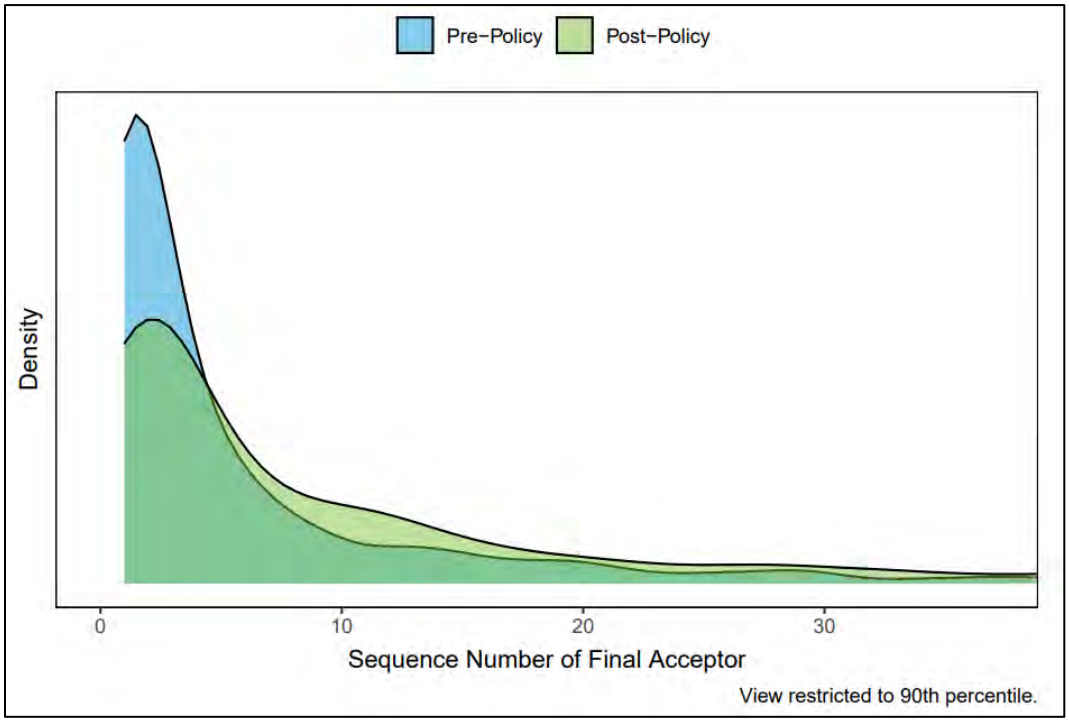
- ~7% of KP and pancreas registrations added in the year post-policy were for highly sensitized candidates (CPRA ≥80%). Most candidates are not sensitized (CPRA 0%).
- Very few KP or PA transplants are 0-ABDR mismatch (<5/year)

In noting that there was not a big impact on highly sensitized and 0-ABDR mismatch candidates, the Pancreas Committee recommend bypassing all candidates at non-facilitated programs more than 250 NM away from the donor, regardless of CPRA or ABDR mismatch level, in support of the established goal of increasing pancreas utilization.[152]

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 coordinate an experienced recovery team feasibly. The OPO Committee was consulted for additional input on the use of the facilitated pancreas tool in a continuous distribution framework.[153] 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.[154] The OPO Committee noted logistical challenges to recovering pancreata and emphasized that a longer facilitated pancreas timeframe may help coordinate remote organ recovery teams. The *Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report,* data (**Figure 9**) showed that when looking at the distribution of sequence number of final acceptor for pancreas and KP match runs, the median sequence number of the final acceptor is five and the 75th percentile is 15. [155] This suggests that pancreata tend to be placed in the first several sequences of 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.

[151] Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report. June 22, 2022.
[152] OPTN Pancreas Transplantation Committee Meeting Summary, April 3, 2023.
[153] OPTN OPO Committee Meeting Summary, May 18, 2022.
[154] Ibid.
[155] Eliminate Use of DSA and Region from Pancreas Allocation 1 Year Post-Implementation Monitoring Report. June 22, 2022.

Figure 9: Distribution of Sequence Number of Final Acceptor for Pancreas/Kidney-Pancreas Match Runs March 15, 2020 - March 14, 2022 by Policy Era



The Pancreas Committee recommended modifications to current policy that would permit OPOs and the OPTN to make facilitated pancreas offers if no pancreas offer has been accepted five hours prior to the scheduled donor organ recovery.[156]

During earlier continuous distribution meetings, the Pancreas Committee discussed and recommended that when facilitated pancreas bypasses are applied, candidates registered at programs within 100 NM of the donor hospital would 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, was considered to improve efficiency while ensuring that candidates at nearby programs still receive offers.[157]

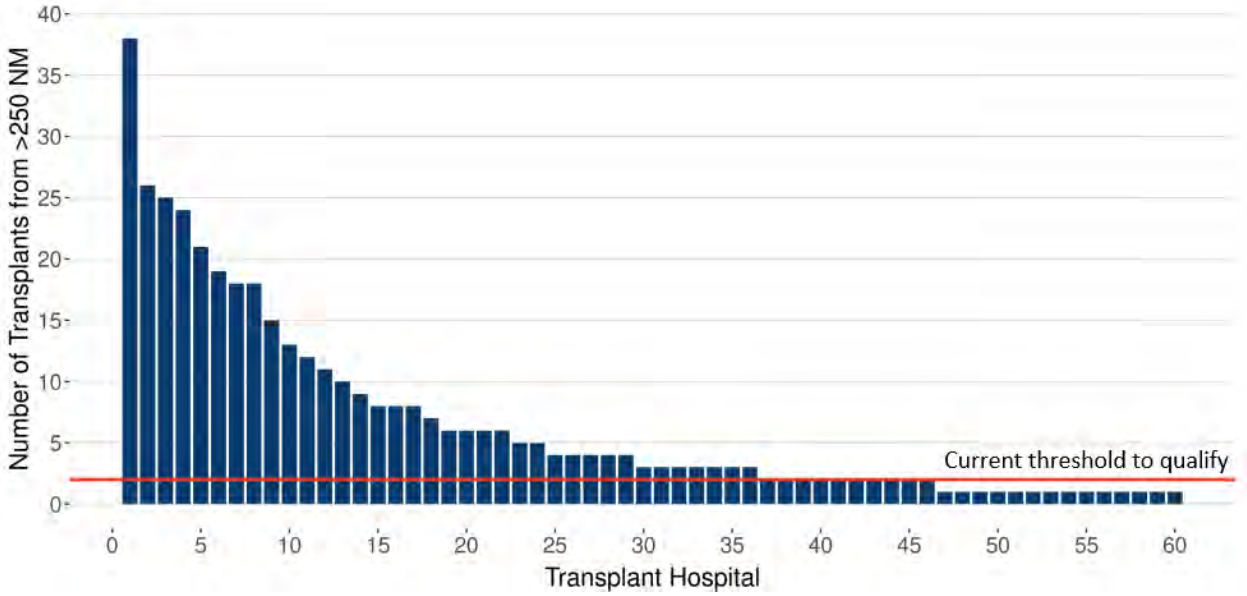
The Utilization Considerations Workgroup reviewed the Pancreas Committee's initial recommendations and provided additional input for consideration. The Utilization Considerations Workgroup recommended the distance utilized in bypassing for facilitated pancreas should be the same distance utilized in the qualifying criteria for facilitated pancreas. The Workgroup recommends that if the 100 NM distance is used, this should also align with distance outlined in qualifying criteria, otherwise, there might be a challenge for transplant programs qualifying for facilitated pancreas.[158] The Utilization Considerations Workgroup cautioned that if the distance for qualifying criteria is greater than distance utilized in bypassing for facilitated pancreas, this could result in increased complexity and thus unintended challenges for a program to qualify for facilitated pancreas.[159]

[156] OPTN Pancreas Transplantation Committee Meeting Summary, April 3, 2023.
[157] OPTN Pancreas Transplantation Committee Meeting Summary, June 22, 2022.
[158] OPTN Kidney and Pancreas Continuous Distribution Utilization Considerations Workgroup Meeting Summary, September 21, 2022.
[159] OPTN Kidney-Pancreas Continuous Distribution Utilization Considerations Workgroup Meeting Summary, September 21, 2022.

The Pancreas Committee agreed with the Utilization Considerations Workgroup's recommendation to use the same distance for bypasses and for the qualifying criteria and after further review and discussion, decided that the current policy in this area is adequate to maintain, which would apply facilitated pancreas bypasses to candidates registered at transplant hospitals greater than 250 NM from the donor hospital.[160]

The Pancreas Committee also discussed the criteria for a transplant program to qualify for facilitated pancreas. **Figure 10** demonstrates the number of pancreata transplanted from donor hospitals over 250 NM away. The red line in the figure indicates the current threshold to qualify for facilitated pancreas (at least 2 transplants from outside 250 NM in previous 2 years). A total of 118 programs transplanted a pancreas during this time period. Within this cohort, 46 programs would qualify for facilitated pancreas under current policy.

Figure 10: Number of Pancreata Transplanted from Donor Hospitals > 250 NM from Transplant Hospital July 1, 2020 – June 30, 2022



The Pancreas Committee discussed modifying the qualifying criteria by requiring programs to have transplanted 4 pancreata instead of 2 within the last two years, reasoning that this requirement change may help determine which programs are more willing to accept a facilitated pancreas offer.[161]

After much discussion, the Pancreas Committee recommended increasing the transplanted criteria from two to four pancreata from donor hospitals greater than 250 NM from the transplant program in the previous two years.[162]

Pancreas Committee Recommendation:

[160] OPTN Pancreas Transplantation Committee Meeting Summary, April 3, 2023.
[161] Ibid.
[162] Ibid.

- OPOs and the OPTN permitted to make facilitated pancreas offers if no pancreas offer has been accepted five hours prior to the scheduled donor organ recovery
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals more than 250NM from the donor hospital
- Apply bypasses to kidney-pancreas (KP) and pancreas candidates
- Bypass all candidates at non-facilitated programs, regardless of CPRA or ABDR mismatch level
- Programs qualify if they have transplanted at least 4 pancreata from donor hospitals more than 250NM from the transplant program in the previous 2 years

Feedback Requested:

- Do you support the recommendation of maintaining the 250NM distance for both the qualifying criteria and when facilitated pancreas bypasses are applied?
- Do you support the proposed qualifying criteria (increasing the number of pancreata transplanted from more than 250 NM from 2 to 4)?

Mandatory Kidney-Pancreas Offers

If a host OPO has both a kidney and a pancreas for allocation, OPTN Policy requires the OPO to offer the kidney and pancreas according to the first four classifications as outlined below in **Table 9**. The first four classifications consist of all KP and pancreas candidates within 250 NM 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.[163] In transitioning to a points-based allocation system, there is discussion and consideration of a new threshold for required KP shares to replace the current classification-based threshold.

Table 9: 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 discussed the use of a CAS threshold as a solution to mirror current policy.[164] With the use of the CAS threshold, OPOs would be required to offer the KP to all KP candidates with a CAS greater than or equal to the CAS threshold before having the

[163] OPTN Policy 11.4.A: Kidney-Pancreas Allocation Order as of March 16, 2023.
[164] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, January 7, 2022.

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 for the first round of SRTR modeling.[165] However, for the first round of modeling, the CD 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.[166]

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 encourage utilization of pancreata.[167]

The Pancreas Committee reviewed these considerations and recommend transitioning the classification-based threshold to a CAS threshold. The Pancreas Committee will continue discussions to determine the specific CAS after weights for the final policy proposal as well as review data on CAS distributions to determine if any other characteristics should be considered within the mandatory KP offer threshold.[168]

Feedback Requested:

- What candidate characteristics should be considered in determining the mandatory KP shares threshold?

Kidney and Pancreas Review Boards Workgroup

The OPTN Board's original charge to create a uniform allocation system will result in each organ system establishing a review board.[169] While OPTN policies consider a multitude of factors and candidate situations, transplantation is complex and constantly evolving. Evidence-based, allocation policy might not be able to account for every possible clinical scenario, particularly unique and urgent cases. Furthermore, as allocation relies on algorithms and scoring systems, review boards will provide a pathway for programs to ensure their patients are prioritized appropriately when their clinical considerations are not well represented by such algorithms. Finally, review boards will allow future Kidney and Pancreas allocation systems to be more nimble and more appropriately consider a greater spectrum of candidates.

Currently, organ-specific review boards consider specific, urgent-status patient registrations on the OPTN heart, liver, and lung transplant waitlist. These reviewers evaluate blinded clinical candidate information and justification narratives to determine whether a candidate should be granted additional priority based on their medical urgency and relative waitlist mortality. Review board members utilize OPTN Policy and Guidance to make these determinations. These guidance documents are typically developed by the relevant organ-specific OPTN Committee, and aim to promote consensus in the community and increased consistency in Review Board clinical decision making. These resources are not meant to be clinically prescriptive or define a standard of care but rather to provide objective criteria or

[165] OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary, February 14, 2022.
[166] OPTN OPO Committee Meeting Summary, March 15, 2023.
[167] OPTN Kidney and Pancreas Transplantation Committees Continuous Distribution Workgroup Meeting Summary, January 7, 2022.
[168] OPTN Pancreas Transplantation Committee Meeting Summary, May 1, 2023.
[169] OPTN Board of Directors Executive Summary, December 3-4, 2018.

more detailed supplementary information to guide transplant programs and review boards in decision-making. For example, the OPTN Heart Transplantation Committee recently issued guidance for pediatric heart exception requests.[170]

In anticipation of the Lung Continuous Distribution implementation, the OPTN Lung Transplantation Committee undertook efforts to update and modify the National Lung Review Board to align with the continuous distribution allocation system.[171] These modifications were based on the OPTN Policy Oversight Committee (POC)-approved cross-organ review board framework, with a few deviations for lung-specific clinical considerations.[172] This cross-organ framework aims to increase consistency and efficiency across review boards, encouraging increased fairness across patients, regardless of the organ system. In transitioning to respective continuous distribution frameworks, each organ-specific committee will consider this cross-organ review board framework and modify existing review board structures to better align with the framework.

The Kidney and Pancreas Review Boards Workgroup (the Review Boards Workgroup) was created to focus on the development of kidney and pancreas-specific review boards in August of 2022. This group is comprised of representatives from the Kidney, Pancreas, Pediatric, and Data Advisory Committees. The Kidney and Pancreas Review Boards Workgroup is working to build and finalize an operational framework for Kidney and Pancreas Review Boards. This operational framework will describe how the Review Boards will function in a continuous distribution framework, including requirements and responsibilities of review board members, initial review and appeal procedures, timing requirements, and case outcome determination. The Review Boards Workgroup will also identify the attributes for which exceptions may be requested. Finally, the Review Boards Workgroup and the Committees will consider potential topics for which additional guidance may be appropriate.

Pancreas Medical Urgency

Currently, medical urgency is not addressed in pancreas policy. The Pancreas Committee has noted challenges to determine and define the relative medical urgency or medical emergency between pancreas candidates. Hypoglycemia unawareness and severe diabetes are considered potential indications for isolated pancreas transplant as a treatment option. The American Diabetes Association defines hypoglycemia unawareness as a condition where a patient is unable to tell when their blood glucose level becomes low, resulting in the patient not knowing when to treat it. Hypoglycemia unawareness puts the patient at increased risk for severe low blood glucose reactions.[173]

Candidates who need a kidney-pancreas transplant may have somewhat more urgency than a pancreas alone transplant as these patients might already be on dialysis and are waiting for two organs. Considerations regarding relative priority between kidney-pancreas candidates and isolated pancreas candidates are complicated. Some of these considerations are outlined above in the *Mandatory KP Shares* section.

During the fall 2021 public comment period, commenters inquired about discussions on medical urgency as they pertained to pancreata. There were comments that expressed the possibility to consider

[170] Guidance Addressing the Use of Pediatric Heart Exceptions, OPTN Heart Transplantation Committee.
[171] Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution, OPTN Lung Transplantation Committee.
[172] OPTN Policy Oversight Committee Meeting Summary, September 30, 2022.
[173] American Diabetes Association. Blood Glucose Testing and Management: Hypoglycemia (Low Blood Glucose). https://diabetes.org/healthy-living/medication-treatments/blood-glucose-testing-and-control/hypoglycemia#:~:text=People%20with%20hypoglycemia%20unawareness%20can,someone%20to%20help%20them%20recover).

hypoglycemia unawareness as an aspect of medical urgency for pancreas recipients. Other comments expressed concern that there is a lack of literature available to establish a defined way to compare waitlist mortality and medical urgency for a solitary pancreas candidate to that of a kidney-pancreas (KP) candidate.

In consideration of these comments, the Pancreas Committee developed the Pancreas Medical Urgency Workgroup to develop recommendations for the Pancreas Committee related to pancreas medical urgency. The Pancreas Medical Urgency Workgroup reviewed data and existing literature regarding hypoglycemia unawareness and pancreas transplant candidate medical urgency.[174] The Pancreas Medical Urgency Workgroup discussed the definition of hypoglycemia unawareness and whether or not patients with it should be able to petition for additional priority.

The Pancreas Medical Urgency Workgroup agreed that hypoglycemia unawareness should be considered in medical urgency criteria and that evidence should provide that diabetes management in those candidates is not effective in preventing it. There was also a recommendation to include criteria showing the candidate has a proven issue with hypoglycemia unawareness (i.e., frequent low blood glucose episodes). However, after consideration of how a definition of medical urgency based in hypoglycemia unawareness could be operationalized, the Pancreas Medical Urgency Workgroup expressed concerns about ensuring access to medical urgency priority for appropriate patients. In determining a medical urgency definition, the Pancreas Medical Urgency Workgroup supported further work in building a consensus-based definition. There were reservations raised by some members that more data should be collected before moving forward with a medical urgency definition. Others noted that, due to the limited size of the pancreas transplantation population, it could take several years to gather sufficient data to build this definition.[175]

The Pancreas Committee considered these recommendations and concerns and discussed the potential inclusion of a review board-based medical urgency attribute. This would allow programs to submit an exception request explaining why the candidate is medically urgent and should receive additional priority. The Pancreas Committee is recommending the addition of a medical urgency attribute to the pancreas continuous distribution framework, with exception requests reviewed by a Pancreas Review Board. The medical urgency attribute would have a binary (yes/no) rating scale, and candidates would only receive medical urgency priority points for approved exception requests. Including medical urgency in this capacity will provide a pathway for medically urgent candidates while also providing information to help further define pancreas medical urgency or criteria based on cases that are presented to the Pancreas Review Board.

The Pancreas Committee is working to develop guidelines regarding Pancreas Medical Urgency exception requests for the Pancreas Review Board and will determine which data should be collected to assess medical urgency further. The Pancreas Committee will need to determine the appropriate relative weight assigned to the Medical Urgency attribute.

Feedback Requested:

- Do you support the inclusion of an exception-based medical urgency attribute for pancreas?
- What clinical considerations should be considered in defining greater medical urgency among pancreas and KP candidates?

[174]OPTN Pancreas Medical Urgency Workgroup Meeting Summary, March 2, 2023.
[175] Ibid.

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,"[176] 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."[177] 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."[178] While this Request for Feedback will not immediately result in an allocation policy change, this request will aid in the development of future allocation policy for all kidneys and pancreata in a continuous distribution framework that meets the criteria above. This effort will also impact equitable allocation through examining the appropriate balance between priority for single and multi-organ candidates as well as exploring medical urgency priority for patients waiting for a pancreas. As continuous distribution seeks to consider candidate and donor characteristics holistically, each item discussed above may impact the candidate's placement on any given match run.

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies” whenever organ allocation policies are revised. Prior to adoption of any allocation policies, the OPTN will 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 request for feedback serves as an opportunity for the community to provide input about how the Kidney and Pancreas Committees can best transition allocation to a continuous distribution framework, striking the critical balance between equity and utility. Specifically, this paper describes and requests feedback on several recommendations under consideration by the Committees on how to best transition the operational components of Kidney and Pancreas allocation into a continuous distribution framework. These recommendations were developed in the context of other efficiency efforts, expanded upon in **Appendix B.** These operational components are critical to allocating kidneys and

[176] 42 U.S.C. §274(b)(2)(B)
[177] 42 CFR §121.4(a)
[179] Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report. July 1, 2022.

pancreata, and aim to emphasize and encourage utilization. Many components specifically provide alternate allocation pathways for potentially medically complex organs to ensure timely placement and use of these gifts of life. These components improve the flexibility and capacity of the allocation system to appropriately consider and accommodate a wide spectrum of unique donor organs. These components include:

- Released Organs
- National Kidney Offers
- Kidney Minimum Acceptance Criteria Screening Tool
- Dual Kidney Offers
- En Bloc Kidney Offers
- Facilitated Pancreas Allocation
- Mandatory Kidney-Pancreas Offers

The Committees welcome community feedback on each component detailed above and request specific feedback on the questions outlined below. All feedback collected in public comment will be reviewed, discussed, and considered by the Committees for finalization of each operational component, which will be incorporated into the continuous distribution policy proposals.

Considerations for the Community

The Committees encourage all interested individuals to comment on this paper in its entirety. The Committees also welcome specific feedback on following questions:

Released Organs

- Do you have any feedback specific to allocation of released kidneys and pancreata in continuous distribution?
- Do you support "carrying over" certain refusals to the released kidney match run? If so, do you support the refusals recommended to be carried over as found in **Appendix A**?
- Do you support an increased weight for placement efficiency on the released kidney match run? If so, how much more important should placement efficiency be on the released kidney match run?
- Are there additional considerations that should be incorporated for released kidney or released pancreas allocation?

Kidney Minimum Acceptance Criteria Screening

- Do you have any feedback specific to the recommended transition of the kidney minimum acceptance criteria screening?
- Do you support the percentage threshold (8% of the match run) selected by the Committee, in combination with candidate exclusions for distance and sensitization, for application of the kidney minimum acceptance criteria screening tool?
- Are there other candidate populations that should be excluded from the KiMAC bypass, regardless of whether the donor does not meet their programs' minimum donor criteria?

Dual Kidney Allocation

- Do you support the recommended approach to dual kidney allocation, utilizing a separate dual kidney specific match run?
- Do you support the proposed efficiency considerations of the dual kidney match run? Are there other considerations that should be incorporated, including "carrying over" certain refusals and increased weight on placement efficiency?

    - Do you support the refusals recommended to be carried over as found in **Appendix A**?
- How should policy define when an OPO may begin allocating kidneys as dual? Should this definition be based on donor criteria, on a requirement to offer the kidneys as single first, or a combination of the two?
    - If the dual kidney eligibility requirement is based on offering the kidney as single first, what percentage of the single kidney match run should receive and decline the primary kidney offer before the OPO may move to dual kidney allocation?
    - If the dual kidney eligibility threshold is based on criteria, which criteria should be incorporated?
- Should programs be required to obtain patient consent prior to opting candidates into receiving dual kidney offers?

En Bloc Kidney Allocation

- Do you support the Committee's recommendations on en bloc kidney allocation?

Facilitated Pancreas

- Do you have any feedback specific to facilitated pancreas?
- Do you support the recommendation of maintaining the 250NM distance for both the qualifying criteria and when facilitated pancreas bypasses are applied?
- Do you support the proposed qualifying criteria (increasing the number of pancreata transplanted from more than 250 NM from 2 to 4)?

Mandatory KP Offers

- What candidate characteristics should be considered in determining the mandatory KP shares threshold?

Pancreas Medical Urgency

- Do you support the inclusion of an exception-based medical urgency attribute for pancreas?
- What clinical considerations should be considered in defining greater medical urgency among pancreas and KP candidates?

Appendix A: Carry Over Refusals

The OPTN Kidney Committee is considering a new system functionality to "carry over" refusals from an original single kidney match run to dual kidney or released kidney match runs. This functionality is discussed in detail above. The following tables present the full list of refusal codes under consideration, including recommendations on whether the code should be "carried over" and rationale for these recommendations. **Tables 10-17** detail the recommendations for refusal codes under consideration to be carried over to released kidney match runs. **Tables 18-25** detail recommendations for refusal codes under consideration to be carried over to dual kidney match runs. In the Carry Over columns, "Yes" indicates "yes, carry refusal over" and "No" indicates "no, do not carry refusal over."

Table 10: Released Organs "Carry Over" Refusal Codes Considerations – Donor and Candidate Matching

Code	Refusal Reason	Description	Rationale	Carry Over?
700	Donor age	Donor age is not clinically suitable for potential transplant recipient (PTR)	Will not change when organ is released	Yes
701	Organ size, specify** **(Program given an optional text field to provide detail)	Donor organ expected to be too large or small for PTR	Will not change when organ is released	Yes

Table 11: Released Organs "Carry Over" Refusal Codes Considerations – Organ Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
710	Organ preservation: unacceptable method or findings	Method or findings of organ preservation does not meet acceptable criteria (pump pressures, pumping issue, not pumped, on pump, etc.)	Will not change when organ is released	Yes
711	Organ anatomical damage or defect	Surgical damage, non-surgical trauma, diseased organ, organ vasculature, en bloc kidneys or any other anatomical reason	Will not change when organ is released	Yes

Code	Refusal Reason	Description	Rationale	Carry Over?
712	Actual or projected cold ischemic time too long	The actual or projected cold ischemic time is too long for the organ	If the organ is in a different location, the project cold ischemic time may be different	No
713	Warm ischemic time too long	The warm ischemic time is too long for the organ	Will not change when organ is released	Yes
714	Biopsy not available	Organ biopsy results are not available or a biopsy was not performed	Potentially, the previously accepting center performed its own biopsy, and results are now available	No
715	Biopsy results unacceptable	Organ biopsy results do not meet acceptable criteria	Unlikely to change when organ is released	Yes
716	Organ specific test results not available, specify** **(Program given an optional text field to provide detail)	Organ specific test not done or results not available at time of organ offer (e.g. HIC NAT testing, cardiac catheter results, etc.) Do not use for unavailable biopsies	Will not change when organ is released	Yes
717	Unacceptable organ specific test results, specify ** **(Program given a required text field to provide detail)	Organ specific test results do not meet acceptable criteria (e.g., lowPaO2, high creatinine, low ejection fraction, or imaging findings). Do not use for biopsy results that are unacceptable.	Will not change when organ is released	Yes

Table 12: Released Organs "Carry Over" Refusal Codes Considerations – Candidate Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
720	Candidate temporarily medically unsuitable	Potential recipient temporarily too sick, medically contraindicated, or not optimized to attempt transplant	Unlikely to change when organ is released	Yes

Code	Refusal Reason	Description	Rationale	Carry Over?
721	Candidate transplanted or pending transplant	PTR has been transplanted, a transplant is in progress, or another offer is being considered	Rare, but possible, that the candidate's previous offer fell through	No
722	Candidate's condition improved, transplant not needed	PTR's condition has improved and transplant is currently unnecessary	Unlikely to change when organ is released	Yes
723	Candidate requires different laterality	PTR requires organ of a different laterality (e.g. right lung is specified)	Unlikely to be relevant, and unlikely to change when organ is released	Yes
724	Candidate requires multiple organ transplant	PTR requires a multiple organ transplant (e.g. heart offered without kidney)	Will not change when organ is released	Yes
725	Epidemic/Pandemic – Candidate	PTR related epidemic/pandemic reason (e.g., the candidate has a potential exposure, is symptomatic, is being tested, or has a positive test result). If the PTR is making the decision to refuse offers due to the pandemic, please select 'Candidate refused' as the refusal reason for the offer	Unlikely to change when organ is released	Yes
726	Candidate temporarily ineligible due to insurance or financial issue	PTR is temporarily ineligible for transplant due to insurance or financial related reasons	Unlikely to change when organ is released	Yes
727	Candidate unavailable	PTR is unavailable (e.g. traveling) or could not be contacted	Possibility that patient could not be reached before, and is now able to be contacted by the transplant program	No

Code	Refusal Reason	Description	Rationale	Carry Over?
728	Candidate refused	PTR refused the offered organ	Candidate response unlikely to change when organ is released	Yes

Table 13: Released Organs "Carry Over" Refusal Codes Considerations – Histocompatibility Related

Code	Refusal Reason	Description	Rationale	Carry Over?
730	No candidate serum for crossmatching	No candidate serum is available for crossmatching	Unlikely to change when organ is released	Yes
731	No donor cells/specimen for crossmatching, or no time for crossmatch	No donor cells or specimen for crossmatching or no time to complete a crossmatch	More donor specimen may have become available – may logistically be possible to get the specimen where it wasn't before. Post-recovery, there may also be nodes available.	No
732	Positive physical crossmatch	Physical crossmatch result between donor and PTR is positive	Will not change when organ is released	Yes
733	Positive virtual crossmatch/unacceptable antigens	Virtual crossmatch result between donor and PTR is positive or PTR has donor-specific antibodies that are considered contraindications to transplant	Will not change when organ is released	Yes
734	Number of HLA mismatches is unacceptable	Number of HLA mismatches between donor and PTR is unacceptable	Will not change when organ is released	Yes

Table 14: Released Organs "Carry Over" Refusal Codes Considerations – Disease Transmission Risk

Code	Refusal Reason	Description	Rationale	Carry Over?
740	PHS risk criteria or social history	PHS risk criteria for donor or other reasons related to social history. If a candidate refuses the offer for PHS risk criteria, please select 'Candidate refused' as the refusal reason for the offer.	Will not change when organ is released	Yes
741	Positive infectious disease screening test: CMV, HBV, HCV, etc.	CMV, HBV, HCV, HIV, HTLV, VDRL, etc. donor testing is positive	Will not change when organ is released	Yes
742	Donor infection or positive culture	Donor has an active infection or positive culture results (e.g. meningitis)	Will not change when organ is released	Yes
743	Malignancy or suspected malignancy	A malignancy or potential malignancy is suspected with the organ	Will not change when organ is released	Yes
744	Epidemic/Pandemic – Donor	Donor related epidemic/pandemic reason. This may include reasons such as donors with high exposure risk, no testing available, positive or indeterminate test results, or if a different specimen type is preferred	Will not change when organ is released	Yes

Table 15: Released Organs "Carry Over" Refusal Codes Considerations – Donor Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
750	Donor medical history, specify* *(Program given a required text field to provide detail)	Donor medical history is not clinically suitable for PTR	Will not change when organ is released	Yes
751	Donor instability/high vasopressor usage	Donor has prolonged hemodynamic instability and/or requires high vasopressor use	Will not change when organ is released	Yes
752	Prolonged downtime/CPR	Donor has experienced prolonged downtime and/or CPR	Will not change when organ is released	Yes
753	DCD donor neurological function/not expected to arrest	DCD donor has high neurological function and is not expected to arrest in time	If organ is released, the DCD donor will have arrested in time despite expectation	No
754	VCA graft appearance or quality, specify ** **(Program given an optional text field to provide detail)	VCA graft is unsuitable due to appearance or quality reasons such as incompatible skin tone, tattoos, scars, bruising, ecchymosis, hematoma, etc.	Not relevant to Kidney	N/A

Table 16: Released Organs "Carry Over" Refusal Codes Considerations – Logistics

Code	Refusal Reason	Description	Rationale	Carry Over?
760	Resource time constraint (OPO, TXC, donor hospital, etc.)	Time constraint for transplant imposed by the OPO, TXC, donor hospital, etc.	These logistical constraints may not apply post-recovery, or else may have changed	No
761	Donor family time constraint	Time constraint imposed by the donor family	Organ is already recovered; logistical constraint no longer applies	No
762	Recovery team availability	Recovery team or local recovery team is unavailable to perform procedure (heavy workload, etc.)	Organ is already recovered; logistical constraint no longer applies	No
763	Transplant team or transplant facility availability	Transplant team is unavailable to perform transplant procedure (heavy workload, etc.)	This may have changed in time between refusal and organ being released	No
764	Transportation availability	Transportation for the organ cannot be obtained	If the organ is in a different location, transportation may become available	No
765	Exceeded policy defined response time (OPO only)	Response was not received from the center within the time period specified in policy	Candidate should not be disadvantaged, and should be given the opportunity again	No

Table 17: Released Organs "Carry Over" Refusal Codes Considerations – Other

Code	Refusal Reason	Description	Rationale	Carry Over?
790	Disaster Emergency Management Consideration	Use only in the event of a natural disaster, regional emergency, etc. that is affecting the operations or recovery of organs	Rarely used – issue may be resolved by time of released organ match Disaster is often represented in more granular refusal reasons	No

Code	Refusal Reason	Description	Rationale	Carry Over?
798	Other, specify** **(Program given a required text field to provide detail)	Use only when the reason does not fit the other refusal reasons available. Provide a detailed description of the reason the organ is being refused.	While there is no way to be consistently sure of the reason being entered in real time, anecdotal feedback notes that this code is often being used instead of more appropriate refusal reasons listed above. The Kidney Committee agreed that, because the released kidney offer is such a similar offer, it would be appropriate to carry over these refusals.	Yes

In reviewing the carry over refusal code considerations, it is important to note that the Utilization Considerations Workgroup and Kidney Committee are considering updates to the "donor refusal" functionality. Specifically, these updates would allow a program to "opt out" of receiving future dual kidney offers from a specific donor for all of their candidates. These updates are further described above, in the *Dual Kidney* section.

Table 18: Dual Kidney "Carry Over" Refusal Codes Considerations – Donor and Candidate Matching

Code	Refusal Reason	Description	Rationale	Carry Over?
700	Donor age	Donor age is not clinical suitable for PTR	May be considered differently in context of dual offer	No
701	Organ size, specify**	Donor organ expected to be too large or small for PTR	May be considered differently in context of dual offer	No

Table 19: Dual Kidney "Carry Over" Refusal Codes Considerations – Organ Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
710	Organ preservation: unacceptable method or findings	Method or findings of organ preservation does not meet acceptable criteria (pump pressures, pumping issue, not pumped, on pump, etc.).	May be considered differently in context of dual offer	No
711	Organ anatomical damage or defect	Surgical damage, non-surgical trauma, diseased organ, organ vasculature, en bloc kidneys or any other anatomical reason	May be considered differently in context of dual offer. The injury could be mediated or mitigated by the second kidney	No
712	Actual or projected cold ischemic time too long	The actual or projected cold ischemic time is too long for the organ	May be considered differently in context of dual offer. More nephron mass may mitigate the cold ischemic damage, and may increase the CIT tolerance. On the other hand, cold time will affect all nephrons.	No
713	Warm ischemic time too long	The warm ischemic time is too long for the organ	May be considered differently in context of dual offer	No
714	Biopsy not available	Organ biopsy results are not available or a biopsy was not performed	May be considered differently in context of dual offer	No
715	Biopsy results unacceptable	Organ biopsy results do not meet acceptable criteria	May be considered differently in context of dual offer	No

Code	Refusal Reason	Description	Rationale	Carry Over?
716	Organ specific test results not available, specify**	Organ specific test not done or results not available at time of organ offer (e.g. HIC NAT testing, cardiac catheter results, etc.) Do not use for unavailable biopsies	May be considered differently in context of dual offer. Programs may have refused before some test results become available. Patient should be given the option.	No
717	Unacceptable organ specific test results, specify *	Organ specific test results do not meet acceptable criteria (e.g., lowPaO2, high creatinine, low ejection fraction, or imaging findings). Do not use for biopsy results that are unacceptable.	May be considered differently in context of dual offer	No

Table 20: Dual Kidney "Carry Over" Refusal Codes Considerations – Candidate Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
720	Candidate temporarily medically unsuitable	Potential recipient temporarily too sick, medically contraindicated, or not optimized to attempt transplant	Not expected to change when offer is dual	Yes
721	Candidate transplanted or pending transplant	PTR has been transplanted, a transplant is in progress, or another offer is being considered	Rare, but possible, that the candidate's previous offer fell through	No
722	Candidate's condition improved, transplant not needed	PTR's condition has improved and transplant is currently unnecessary	Not expected to change when offer is dual	Yes

Code	Refusal Reason	Description	Rationale	Carry Over?
723	Candidate requires different laterality	PTR requires organ of a different laterality (e.g. right lung is specified)	Code is unlikely to be used for a kidney patient, and is not relevant to kidney, particularly dual kidney	No
724	Candidate requires multiple organ transplant	PTR requires a multiple organ transplant (e.g. heart offered without kidney)	Will not change when offer is dual	Yes
725	Epidemic/Pandemic – Candidate	PTR related epidemic/pandemic reason (e.g., the candidate has a potential exposure, is symptomatic, is being tested, or has a positive test result). If the PTR is making the decision to refuse offers due to the pandemic, please select 'Candidate refused' as the refusal reason for the offer	Not expected to change when offer is dual	Yes
726	Candidate temporarily ineligible due to insurance or financial issue	PTR is temporarily ineligible for transplant due to insurance or financial related reasons	Not expected to change when offer is dual	Yes
727	Candidate unavailable	PTR is unavailable (e.g. traveling) or could not be contacted	Possibility that patient could not be reached before, and is now able to be contacted by the transplant program	No
728	Candidate refused	PTR refused the offered organ	May be considered differently in context of dual offer. Patient should be given the choice again	No

Table 21: Dual Kidney "Carry Over" Refusal Codes Considerations – Histocompatibility Related

Code	Refusal Reason	Description	Rationale	Carry Over?
730	No candidate serum for crossmatching	No candidate serum is available for crossmatching	Not expected to change when offer is dual	Yes
731	No donor cells/specimen for crossmatching, or no time for crossmatch	No donor cells or specimen for crossmatching or no time to complete a crossmatch	Unlikely, but possible that more donor specimen may have become available, and it may logistically be possible to get the specimen where it wasn't before. Furthermore, there may be nodes available post-recovery.	No
732	Positive physical crossmatch	Physical crossmatch result between donor and PTR is positive	Will not change when the offer is dual	Yes
733	Positive virtual crossmatch/unacceptable antigens	Virtual crossmatch result between donor and PTR is positive or PTR has donor-specific antibodies that are considered contraindications to transplant	Will not change when the offer is dual	Yes
734	Number of HLA mismatches is unacceptable	Number of HLA mismatches between donor and PTR is unacceptable	Will not change when the offer is dual	Yes

Table 22: Dual Kidney "Carry Over" Refusal Codes Considerations – Disease Transmission Risk

Code	Refusal Reason	Description	Rationale	Carry Over?
740	PHS risk criteria or social history	PHS risk criteria for donor or other reasons related to social history. If a candidate refuses the offer for PHS risk criteria, please select 'Candidate refused' as the refusal reason for the offer.	Risk is not expected to be reduced with dual kidney offer	Yes
741	Positive infectious disease screening test: CMV, HBV, HCV, etc.	CMV, HBV, HCV, HIV, HTLV, VDRL, etc. donor testing is positive	Risk is not expected to be reduced with dual kidney offer	Yes
742	Donor infection or positive culture	Donor has an active infection or positive culture results (e.g. meningitis)	Risk is not expected to be reduced with dual kidney offer	Yes
743	Malignancy or suspected malignancy	A malignancy or potential malignancy is suspected with the organ	Risk is not expected to be reduced with dual kidney offer	Yes
744	Epidemic/Pandemic – Donor	Donor related epidemic/pandemic reason. This may include reasons such as donors with high exposure risk, no testing available, positive or indeterminate test results, or if a different specimen type is preferred	Risk is not expected to be reduced with dual kidney offer	Yes

Table 23: Dual Kidney "Carry Over" Refusal Codes Considerations – Donor Specific

Code	Refusal Reason	Description	Rationale	Carry Over?
750	Donor medical history, specify*	Donor medical history is not clinically suitable for PTR	May be considered differently in context of dual offer	No

Code	Refusal Reason	Description	Rationale	Carry Over?
751	Donor instability/high vasopressor usage	Donor has prolonged hemodynamic instability and/or requires high vasopressor use	May be considered differently in context of dual offer	No
752	Prolonged downtime/CPR	Donor has experienced prolonged downtime and/or CPR	May be considered differently in context of dual offer	No
753	DCD donor neurological function/not expected to arrest	DCD donor has high neurological function and is not expected to arrest in time	May be considered differently in context of dual offer	No
754	VCA graft appearance or quality, specify **	VCA graft is unsuitable due to appearance or quality reasons such as incompatible skin tone, tattoos, scars, bruising, ecchymosis, hematoma, etc.	Not relevant to kidney match runs	N/A

Table 24: Dual Kidney "Carry Over" Refusal Codes Considerations – Logistics

Code	Refusal Reason	Description	Rationale	Carry Over?
760	Resource time constraint (OPO, TXC, donor hospital, etc.)	Time constraint for transplant imposed by the OPO, TXC, donor hospital, etc.	These logistical constraints may not apply post-recovery, or else may have changed	No
761	Donor family time constraint	Time constraint imposed by the donor family	Organs are already recovered; logistical constraint no longer applies	No
762	Recovery team availability	Recovery team or local recovery team is unavailable to perform procedure (heavy workload, etc.)	Organs are already recovered; logistical constraint no longer applies	No
763	Transplant team or transplant facility availability	Transplant team is unavailable to perform transplant procedure (heavy workload, etc.)	This may have changed in time between single-kidney refusal and dual kidney offer	No

Code	Refusal Reason	Description	Rationale	Carry Over?
764	Transportation availability	Transportation for the organ cannot be obtained	The transportation considerations and constraints may be different for the dual kidney offer	No
765	Exceeded policy defined response time (OPO only)	Response was not received from the center within the time period specified in policy	Candidate should not be disadvantaged, and should be given the opportunity again	No

Table 25: Dual Kidney "Carry Over" Refusal Codes Considerations – Other

Code	Refusal Reason	Description	Rationale	Carry Over?
790	Disaster Emergency Management Consideration	Use only in the event of a natural disaster, regional emergency, etc. that is affecting the operations or recovery of organs	This could resolve between original offer and dual kidney offer	No
798	Other, specify*	Use only when the reason does not fit the other refusal reasons available. Provide a detailed description of the reason the organ is being refused.	While there is no way to be consistently sure of the reason being entered in real time, anecdotal feedback notes that this code is often being used instead of more appropriate refusal reasons listed above. The Kidney Committee agreed that, because dual kidney presents a very different offer than the initial single kidney offer, this refusal code should *not* be carried over.	No

Appendix B: Other Efficiency Efforts

Broader distribution in circles-based allocation has increased match run complexity, impacting allocation efficiency.[179,180,181] Screening tools are critical to enable allocation efficiency in order to ensure organ utilization. Several efforts are underway to improve system efficiency, including an ongoing effort to redefine provisional yes, proposals to optimize the usage of Offer Filters, predictive analytics, and biopsy data reporting standardization.[182,183,184] The Utilization Considerations Workgroup considered these efforts in their discussions across operational topics, in order to leverage existing and imminent system functionalities to optimize recommended solutions. The Committees will similarly consider these efforts as they discuss and finalize the transition of operational topics to a continuous distribution framework.

Offer Filters

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 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 "hard to place" organs. The OPTN Operations and Safety Committee's January 2023 *Optimizing Usage of Offer Filters* proposal aims to increase the utilization of the kidney Offer Filters tool and would increase the number of transplants by getting to organ offer acceptance faster. The proposal is undergoing Board review. If approved, additional information will be available. In their discussions regarding dual kidney offers, the Utilization Considerations Workgroup made a recommendation to the Operations and Safety Committee regarding the use of "dual kidney" as a potential filtering criterion, such that programs could build dual-kidney specific filters.[185] The Operations and Safety Committee agreed with this recommendation, and incorporated dual kidney as a filtering criterion.[186] The Committees will continue to consult with the Operations and Safety Committee for additional input on how the tool may be incorporated into and optimized for the continuous distribution framework.

Predictive Analytics

The development of kidney and pancreas continuous distribution has also coincided with the testing and release of the Donor Predictive Analytics (DPA) tool. The DPA tool was released to all kidney transplant programs in January 2023, and aims to support programs in the critical decision to accept or decline an organ offer.[187] The DPA tool provides supplemental predictive analytical data regarding time to next offer as well as the candidate's predicted survival over the next three years without a transplant. Programs are able to consider the DPA data, which supplements existing data, research, and clinical judgement. The DPA tool not only aims to improve waitlisted patient and transplant recipient outcomes, but in supporting the offer decision process, aims to encourage utilization of kidneys.[188]

[179] Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report. July 1, 2022.
[180] *Perspective on the Complex Kidney Underutilization Problem*. Darren Stewart, Bekir Tanriover, Gaurav Gupta. Kidney360 Oct 2022.
[181] OPTN Organ Procurement Organization Committee Meeting Summary, September 8, 2021.
[182] Redefining Provisional Yes and the Approach to Organ Offers Concept Paper, OPTN Operations and Safety Committee, August 2022.
[183] *Optimizing Usage of Kidney Offer Filters Concept Paper*, OPTN Operations and Safety Committee, August 2022.
[184] *Optimizing Usage of Kidney Offer Filters Proposal,* OPTN Operations and Safety Committee, January 2023.
[185] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, October 12, 2022.
[186] OPTN Operations and Safety Committee Mandatory Usage of Offer Filters Workgroup Meeting Summary, October 24, 2022.
[187] OPTN predictive analytics launched to all kidney transplant programs, UNOS News Bureau; January 26, 2023.
[188] OPTN predictive analytics project to launch education in December 2022, is intended to increase organ utilization, UNOS News Bureau, October 19, 2022.

Biopsy Data and Reporting Standardization

The *Standardize Kidney Biopsy Reporting and Data Collection* policy update is set to be implemented later this year, in September 2023.[189] This policy change will standardize biopsy reporting and data collection, as well as provide data elements with which an OPO may provide specific biopsy characteristics critical to informing offer evaluation. This policy change will support allocation efficiency by streamlining the reporting of biopsy results and encourage utilization by minimizing the need for transplant hospitals to perform their own deceased donor kidney biopsy analyses. The Kidney Committee and Utilization Considerations Workgroup are current considering leveraging these incoming data elements as they work to finalize a proposed dual kidney allocation policy in a continuous distribution framework.[190]

The Committees welcome feedback on how to best operationalize current and incoming efficiency efforts and solutions in the continuous distribution framework.

[189] "Standardize Kidney Biopsy Reporting and Data Collection," Policy Notice, OPTN: https://optn.transplant.hrsa.gov/media/tz1ffmdo/data-change_stand-kid-bpsy-rprting-and-data-collec_kid.pdf
[190] OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup Meeting Summary, January 11, 2023

Appendix C: Background on Continuous Distribution

Continuous distribution is a points-based framework that assigns a composite allocation score (CAS) that considers all of a candidate's characteristics, in context with several donor 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 holistic CAS. This score would be constructed with multiple attributes that align with NOTA and the OPTN Final Rule.[191]

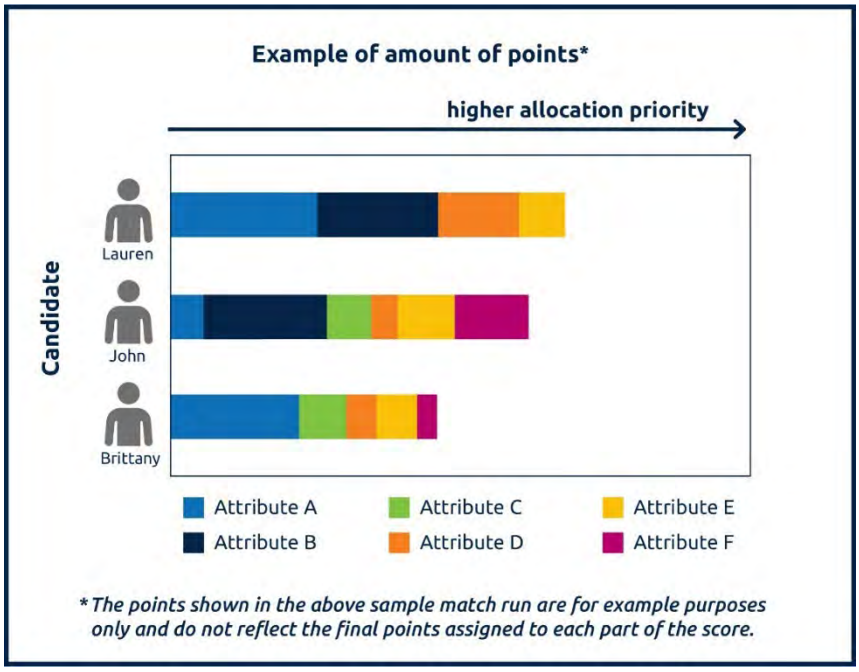
Figure 11 shows how allocation goals combine into a composite allocation score (CAS).[192] Within each goal, the Committees have identified different attributes. Candidates will be assigned a certain number of points for each attribute, which will then be combined to create sub-scores that align with the different goals, which are then weighted against each other to create the overall CAS. 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.

Figure 11: Components of Composite Allocation Score (CAS)

Figure 12 shows how potential kidney, pancreas, or kidney-pancreas (KP) composite allocation scores could function. Candidates would receive points for each of the different attributes used for prioritization. The amount of points given to each candidate would depend upon the candidate's unique situation, donor characteristics, the rating scale for that attribute, and the amount of weight given to that attribute.

[191] 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.
[192] *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

Figure 12: Example of a Composite Allocation Score Match Run[193]



The maximum amount of points given for any attribute is determined by the weight given to that attribute, as well as any applicable donor weight modifiers.[194] In **Figure 12**, the amount of points given to a candidate varies depending upon the candidate's specific circumstances. In comparison, the current classification-based system prioritizes all patients in a higher classification ahead of candidates in a lower classification, regardless of other considerations. A continuous distribution framework will eliminate hard boundaries between classifications existing in the current system. Candidates will receive points for various attributes and all of these attributes can be considered together as part of a CAS. A candidate's CAS, based on both candidate and donor characteristics, will determine their priority on each match run.

[193] 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.
[194] For more information on potential composite allocation score attributes, weights, and donor modifiers, refer to *Continuous Distribution of Kidneys and Pancreata Committee Update,* OPTN Kidney and Pancreas Transplantation Committees, August 2022.