Committee Update

Update on the Continuous Distribution of Kidneys, Winter 2025

OPTN Kidney Transplantation Committee

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Sponsoring Committee: Public Comment Period: Kidney Transplantation January 21, 2025 – March 19, 2025

Executive Summary

This paper provides an update to the community about the continuous distribution of kidneys project, including the OPTN Kidney Transplantation Committee's (the Committee) continued efforts to incorporate expanded efficiency objectives, with consideration for the balance in equity and utility in the match run order and operational aspects of allocation, such as expedited placement.

This paper includes updates on the Committee's progress towards expanded non-use and efficiency modeling capabilities, including next steps in collaboration with the Scientific Registry of Transplant Recipients (SRTR) and Massachusetts Institute of Technology (MIT) partners. This update further details the Committee's collaborative efforts to develop a kidney expedited placement policy, and requests feedback on potential principles of such an allocation pathway. This paper provides updates on the Committee's continued efforts to develop a preliminary, evidence-based definition of "hard to place" kidneys. Of note, this paper includes a thorough overview of the continuous distribution project as developed thus far, including a comprehensive appendix detailing the Committee's relevant discussions and decisions regarding each attribute, rating scales, and the various weight combinations the Committee's next steps towards finalizing the continuous distribution of kidneys project.

Background and Progress So Far

Overview

Continuous distribution is a points-based framework that assigns a composite allocation score (CAS) that considers all of candidate's characteristics, in context with several donor characteristics. The goal of continuous distribution is to replace the current **classification-based framework**, which draws hard boundaries between classifications in the current kidney allocation system, with a **points-based framework**, creating a holistic CAS that considers both candidate and donor characteristics and a consistent, cross-organ allocation framework. This score will be constructed with multiple attributes that align with NOTA and the OPTN Final Rule.¹ A more complete description can be found in **Appendix A**.

The Committee is tasked with developing a comprehensive proposal for the continuous distribution of kidneys, and has updated the community and requested feedback in collaboration with the OPTN Pancreas Transplantation Committee throughout project development.^{2,3,4,5,6,7} The two committees continue to inform each other of their respective efforts. The Committee will continue to work with the OPTN, SRTR, and contracted researchers as MIT to develop evidence-based rating scales and weights to define how points will be assigned to candidates with the CAS.

Attributes, Weights, and Rating Scales

Since the start of Kidney Continuous Distribution, the Committee identified 10 attributes (**Table 1**) across 5 goals, establishing empirically driven rating scales for each. A comprehensive description of the rating scales selected by the Committee for each attribute can be found in **Appendix B**.

In the fall of 2021, the Committee released and reviewed a community-wide values prioritization exercise, additionally informed by organ procurement organization (OPO) and patient focus groups.⁸ The Kidney and Pancreas Committees utilized the community's feedback to determine an initial set of weights, including donor modifiers, which allowed the Committee to increase the weight of certain attributes based on donor characteristics. The Committee submitted these weights and ratings as potential continuous distribution policies to the SRTR for an initial round of modeling in the Spring of 2022.⁹

After reviewing the results of the initial modeling request, the Committee began collaboration with MIT partners to further model and optimize potential continuous distribution policies. To achieve this, the

https://optn.transplant.hrsa.gov/media/npdlps1k/public-comment_kidney_cd-update_summer-24.pdf

⁷ OPTN Kidney and Pancreas Transplantation Committees, "Continuous Distribution of Kidneys and Pancreata Concept Paper." August 2021. https://optn.transplant.hrsa.gov/media/4776/continuous_distribution_of_kidneys_and-pancreata_concept_paper.pdf

⁸ OPTN Kidney Transplantation Committee Meeting Summary, April 8, 2022

 $^{^{\}rm 1}$ 42 U.S.C. Sec 273 et seq. and 42 C.F. R. part 121

² OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." July 2024 Public Comment.

³ OPTN Kidney and Pancreas Transplantation Committees, "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback." July 2023 Public Comment. <u>https://optn.transplant.hrsa.gov/media/445objk1/kipa_cd-rff_pcsummer2023.pdf</u> ⁴ OPTN Kidney and Pancreas Transplantation Committees, "Continuous Distribution of Kidneys and Pancreata Committee Update." Jan uary

²⁰²³ Public Comment. https://optn.transplantation Committees, "Continuous Distribution of Ridneys and Pancreata Committee Update." Jan uar 2023 Public Comment. https://optn.transplant.hrsa.gov/media/a5glt304/continuous-distribution-of-kidneys-and-pancreata-committeeupdate_pc-winter-2023.pdf

 ⁵ OPTN Kidney and Pancreas Transplantation Committees, "Update on Continuous Distribution of Kidneys and Pancreata." August 2022. https://optn.transplant.hrsa.gov/media/ha2mpuor/continuous-distribution-of-kidneys-and-pancreata_comm-update_summer-2022.pdf.
 ⁶ OPTN Kidney and Pancreas Transplantation Committees, "Update on Continuous Distribution of Kidneys and Pancreata." January 2022. https://optn.transplant.hrsa.gov/media/glhbtadp/continuous-distribution-of-kidneys-and-pancreata-request-for-feedback_winter-2022.pc.pdf

⁹ OPTN Kidney Transplantation Committee Meeting Summary, April 29, 2022

Committee developed key allocation objectives associated with each identified attribute; these goals were then used to determine a set of policies that may optimally balance all objectives for the allocation scheme. MIT's attribute analysis also allowed the Committee to visualize the relationship between attribute priority and potential outcomes. Based on the goals in **Table 1**, the Committee selected several optimized policies to submit to the SRTR for modeling. These discussions were outlined the Committee Update released for public comment in August 2023.¹⁰

Attributes	Goal	Modeling Objectives
Medical Urgency	Modical Urganov	Maintain high priority for medically urgent
Definition	Medical Orgency	patients, similar to current policy
DP Matching	Post-Transplant	Maintain similar priority to current policy;
	Survival	Minimize graft failure
		Match low KDPI kidneys to low EPTS candidates;
EPTS/KDPI ¹¹ Matching	Post-Transplant	Maintain transplant rates for EPTS 0-20;
	Survival	Equalize access for EPTS 21+
Blood Type	Candidate Biology	No decrease in access, especially for O and B
вюби туре	Candidate Biology	blood type candidates
	Candidate Biology	Equalize access across CPRA;
		Maximize access for CPRA 99.9+
Prior Living Donors	Patient Access	Maintain high priority, similar to pediatric access
Pediatrics	Patient Access	Maintain high priority, similar to prior living donor
		access
		Maintain similar priority to current policy for
Safety Net	Patient Access	kidney-after-liver, kidney-after-heart, and kidney-
		after-lung patients
Qualifying Time	Patient Access	Maximize median qualifying time at transplant
Provimity Efficiency	Placement Efficiency	Minimize distance traveled, especially for high
		KDPI kidneys;
		Relax constraint for pediatric and highly sensitized
		canuluates

Table 1: Kidney Allocation Objectives

The Committee continues to work with SRTR and MIT partners to finalize the components of the composite allocation score, including further optimization and modeling incorporating non-use metrics. These discussions are detailed below. A comprehensive list of the Committee's previously modeled weight combinations is detailed in **Appendix C**.

Operational Considerations

The Committee's modeling work was complemented by additional efforts to transition operational components of kidney allocation into a continuous distribution framework, including dual kidney

¹⁰ OPTN Kidney and Pancreas Transplantation Committees, "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback." July 2023 Public Comment.

¹¹ EPTS – Estimated Post-Transplant Survival; KDPI – Kidney Donor Profile Index

¹² CPRA – Calculated Panel Reactive Antibodies

allocation, released kidney allocation, en bloc kidney allocation, review boards, national kidney allocation, and the Kidney Minimum Acceptance Criteria (KiMAC) screening tool. The OPTN Kidney and Pancreas Committees collaborated in their efforts to develop solutions to transition several of these operational considerations, working together as the Utilization Considerations of Kidney and Pancreas Continuous Distribution and the Kidney and Pancreas Review Boards Workgroup.

The Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup's discussions were detailed in the Summer 2023 *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback*.¹³ With recent efforts towards expedited placement, detailed below, the Committee will reconsider potential approaches to several operational considerations, including dual kidney allocation, released kidney allocation, and the kidney minimum acceptance criteria screening tool. The Committee will continue to incorporate community feedback in the transition of these operational considerations.

The Kidney and Pancreas Review Boards Workgroup collaboratively developed frameworks for respective organ-specific review boards, which were endorsed by the Kidney and Pancreas Committees in 2023. The Kidney Committee endorsed this framework, outlined in the *Kidney Continuous Distribution Update, Summer 2024*,¹⁴ pending additional discussions on monitoring and the establishment of a policy threshold for transplant at a denied status.¹⁵

Efficiency in Continuous Distribution

On September 5, 2023, the OPTN Board of Directors (the Board) approved a resolution directing the OPTN Kidney Transplantation Committee (the Committee) and the Pancreas Transplantation Committee to incorporate the following goals into the existing Continuous Distribution project:¹⁶

- Decrease non-use/non-utilization of kidneys and pancreata
- Decrease out of sequence allocation of kidneys
- Consideration of expedited placement pathways for kidneys

Prior to this resolution, the primary goal of the Kidney Continuous Distribution project was to transition allocation to a points-based framework with minimal disruption to the kidney transplantation system. The resolution introduced new objectives into the project regarding non-use, allocation out of sequence, and expedited placement.¹⁷ The Committee's initial efforts to incorporate these objectives aimed to:

- Understand trends in non-use,
- Identify potential drivers,
- Define efficiency goals and associated metrics, and
- Develop a preliminary, data-driven definition of "hard to place" kidneys

¹³ OPTN Kidney and Pancreas Transplantation Committees, "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback." July 2023 Public Comment.

¹⁴ OPTN Kidney and Pancreas Transplantation Committees, "Continuous Distribution of Kidneys Update, Summer 2024." August 2024 Public Comment. https://optn.transplant.hrsa.gov/media/npdlps1k/public-comment_kidney_cd-update_summer-24.pdf

¹⁵ OPTN Kidney Transplantation Committee Meeting Summary, August 21, 2023

¹⁶ OPTN Board of Directors Meeting Summary, September 5, 2023.

¹⁷ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2024.

Within these efforts, the Committee identified further potential solutions to reduce non-use, both within and outside the scope of continuous distribution. Establishing efficiency goals allowed the Committee to visualize and target how their efforts will achieve the objectives established by the Board resolution. Finally, continued efforts to define "hard to place" kidneys support identifying those organs at increased risk of non-use, allowing the Committee to tailor approaches to improve likelihood of transplant for these organs, such as alternate and expedited allocation pathways. These discussions were detailed in the Committee's previous update to the community, alongside preliminary updates on the Committee's efforts towards expanded modeling capabilities to evaluate non-use and the development of expedited placement pathways for kidneys at risk of non-use.¹⁸ These efforts are further detailed below, including additional updates on the Committee's continued efforts to define "hard to place" kidneys.

Efficiency Modeling Updates

In February, the Committee submitted a request to the SRTR to assess the feasibility of modeling the impact of allocation policies on kidney and pancreas utilization with their allocation simulation model, known as the Organ Allocation Simulator (OASim).¹⁹ The Committee requested that SRTR assess whether it is possible to include the following metrics as modeled outcomes in future simulation requests, along with previous metrics:

- Utilization and non-use of deceased donor kidneys
- Timing and sequence number at acceptance
- Cold ischemic time
- Equity in access demographics of candidates accepting high KDPI kidneys

In November, the SRTR reported their efforts to incorporate these goals into the OASim to the Kidney and Pancreas Committees.²⁰ The SRTR evaluated combinations of seven potential sub-models for utilization and six potential sub-models for acceptance, eventually narrowing down to evaluate 9 different collections of sub-models (CSMs). Each CSM was assessed based on how closely the models' simulated data matched historical data. The SRTR evaluated each CSM against the historical data and each other across each of the Committee's research questions, and ultimately identified a set of sub-models, called *CSM: A*, which was best able to replicate historical data and answer the Committee's modeling questions. Figure 1 exemplifies one such modeling question, showing how the nine CSMs simulated the percent of organs not used as compared to historical policy.²¹

¹⁸ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." July 2024 Public Comment.

¹⁹ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024. <u>https://optn.transplant.hrsa.gov/media/nsxayk4u/final-</u>20240221-kidney-summary.pdf

²⁰ OPTN Kidney Committee Meeting Summary, November 18, 2024

²¹ "Continuous distribution – kidney and pancreas," OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuousdistribution/continuous-distribution-kidney-and-pancreas/.







CSM: A utilizes a center-level covariate, meaning the model recognizes variability in acceptance behavior by center, and allocation-related metrics, such as offer number, center number, and center rank.²² Offer number and center number both function as surrogates for time in the allocation process, with offers less likely to be accepted as time goes on and cold ischemic time accrues. While **CSM: A** slightly underestimates non-use of deceased donor kidneys overall (and therefore slightly overestimates kidney utilization), the sub-model accurately reflected trends in kidney non-use across sub-groups and did not result in any deficiencies in other simulated kidney metrics compared to OASim without utilization modeling. None of the models evaluated by the SRTR were able to adequately and reliably simulate cold ischemic time at acceptance or at transplant. The SRTR's full report on their efforts to evaluate utilization and efficiency sub-models can be found on the OPTN website.²³

Next Steps

The Committee will continue to collaborate with SRTR and MIT partners, utilizing expanded modeling capabilities to understand potential impacts of continuous distribution on non-use and optimize upon all the Committee's objectives (**Table 1**). MIT partners are working to incorporate utilization sub-models into the optimization system and will recommence optimization work and discussions with the Committee this spring.

As this work is happening, the Committee will consider potential modifications to the composite allocation score aimed at reducing non-use. The Committee preliminarily discussed several such modifications in October and will continue to explore into 2025. These discussions are outlined below.

²² Offer number – a potential transplant recipient's offer number is defined as one plus the number of non-bypassed potential transplant recipients with a lower sequence number

Center number – for a potential transplant recipient at offer number "x," the center number is the number of unique transplant centers represented by all potential transplant recipients with offer number less than or equal to x.

Center rank – a potential transplant recipient's center rank is their relative priority among non-bypassed potential transplant recipients at the same program. The potential transplant recipient with the lowest offer number at a transplant center has a rank of one, the potential transplant recipient with the second lowest offer number at a transplant center has a rank of two, etc. ²³ *Ibid.*

Composite Allocation Score: Efficiency Modifications

The Committee discussed several potential efficiency-specific modifications to the composite allocation score, thus impacting the order of the match run.²⁴ These changes include:

- Adjustments to the proximity efficiency rating scale,
- additional donor modifiers for "hard to place" kidneys,
- attribute-attribute interaction to more specifically incorporate distance,
- re-evaluating high KDPI consent for "hard to place" kidneys,
- inverse qualifying time for "hard to place" kidneys, and
- potential "likelihood of acceptance" attribute.

The Committee's discussions focused on narrowing down potential options, determining which modifications may warrant further consideration.

Update the Proximity Efficiency Attribute

This modification would alter the shape of the proximity efficiency rating scale to give increased priority to candidates closer to the donor hospital. The proximity efficiency rating scale previously developed by the Committee, shown in **Figure 2**, is a piecewise linear rating scale with a plateau in points out to 50 nautical miles (NM), a declining slope to 85% of points out to 250 NM, a steeper slope to 25% of points out to 500 NM, and from this point a much less steep slope out to 0% at 5181 NM.²⁵



Figure 2: Kidney Proximity Efficiency Rating Scale

This modification proposes a steeper decline in points for candidates registered at programs further from the donor hospital. Similar results could also be achieved through increasing the weight on proximity efficiency. The Committee noted public comment feedback showing support for reducing travel distance in kidney allocation, further noting that the 250 and 500 NM inflection points were data-driven inflection points built into the current, circles-based allocation.²⁶ The Committee will continue to

²⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

²⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

²⁶ Ibid.

consider potential modifications to the proximity efficiency weight and rating scale through optimization and modeling efforts.

Donor Modifiers for "Hard to Place" Kidneys

This modification to the composite allocation score would incorporate additional donor modifiers for kidneys considered "hard to place," such that candidates who are more likely to accept those kidneys – such as those registered at a program closer to the donor hospital – receive more points. The Committee has previously discussed and modeled donor modifiers for high KDPI kidneys (KDPI 86-100%), in order to prioritize candidates at programs closer to the donor hospital.²⁷ OASim modeling showed that high KDPI donor modifiers were effective to decrease travel distances for the highest KDPI kidneys, as shown by the simulated "High KDPI Efficiency" scenario in **Figure 3**.²⁸



Figure 3: Median Travel Distance by KDPI – KDPI 85-100%

Donor modifiers for high KDPI kidneys were also considered, to emulate current prioritization of pediatric and prior living donors, who do not currently receive priority for the highest KDPI kidneys, as these candidates are not typically an appropriate match for these medically complex kidneys with lower expected graft longevity.^{29, 30} Here, the Committee is currently considering utilizing donor modifiers to "turn off" priority for pediatric and prior living donors. In this case, using donor modifiers to "turn off" pediatric and prior living donor priority for high KDPI kidneys also improves offer efficiency for both OPOs and programs, as these candidates would not be expected to accept these offers due to candidate-donor matching considerations and their relatively high priority on lower KDPI match runs. In this case, the match run is organized to better prioritize candidates who are more appropriate matches

²⁷ Scientific Registry of Transplant Recipients, SRTR KI2022_01, October 20, 2022.

²⁸ Ibid.

²⁹ OPTN Policy 8.4.1: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%; 8.4.1: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but Less than 35%; and 8.4.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 35% and Less than or Equal to 85%.

³⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

for these organs, and thus more likely to accept them, reducing allocation time and enabling earlier placement and transplant. This modification would introduce additional donor modifiers to similarly improve the efficiency of "hard to place" kidneys, which may have more specific characteristics not accounted for in KDPI.³¹

The Committee considered additional donor modifiers for "hard to place" kidneys, but noted that this modification targets a similar profile of kidneys towards an expedited placement pathway. Considering this, the Committee agreed that expedited placement, depending on its structure, could more readily and flexibly achieve improved efficiency, placement, and utilization.³² The Committee also noted that expedited placement may be more effective than donor modifiers, particularly considering the potential efficiency benefits of default offer filters, which were implemented in November 2024.^{33,34}

Attribute Interaction with Distance

This modification would incorporate an interaction with distance to other attributes in the composite allocation score, such that candidate priority within that attribute is also stratified by distance. For example, the most recent OASim modeling results showed elevated travel distances for pediatric recipients across simulated continuous distribution policies compared to simulated current policy (**Figure 4**). This modification could modify the binary pediatric rating scale to stratify points more continuously, such that pediatric candidates registered at programs closer to the donor hospital receive additional priority compared to pediatric priority relative to adult candidates, but would modify the order of these highly prioritized pediatric candidates to support increased efficiency.



Figure 4: Median Travel Distance by Recipient Age: Kidney, Age 0-18 Years

³¹ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

³² Ibid.

³³ OPTN Operations and Safety Committee, *Optimizing Usage of Offer Filters*; approved June 26, 2023.

³⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024

The Committee questioned the benefit of this modification, noting that differences in relative priority of pediatric candidates on a match run should be based on equity-based factors, rather than distance. The Committee noted that, given the general high quality of kidneys allocated to pediatric patients, there may be minimal efficiency and non-use benefits to this modification. The Committee further noted concern that such a modification could potentially aggravate geographic waiting time disparities that may exist just based on geographic variation in donor availability. Members pointed out that some candidates may live greater distances from their program, and so the benefits of such a modification may be somewhat limited. The Committee noted that the kidneys typically offered to pediatric candidates are low KDPI and have a relatively low risk of non-use, and so the overall benefits to efficiency of this modification are limited. Members emphasized their previous discussions regarding elevated pediatric travel distance, including the decision to maintain high pediatric priority with the recommendation for programs to utilize offer filters and acceptance criteria to appropriately manage offers. Ultimately, the Committee agreed not to pursue this modification.

Re-Evaluate High KDPI Consent for "Hard to Place" Kidneys

OPTN Policy 5.3.C: *Informed Consent for Kidneys Based on KDPI Greater than 85%* requires programs to obtain written, informed consent from each candidate willing to receive offers to kidneys with a KDPI 86-100%. The Committee considered whether this policy could be updated to support increased shared decision-making for accepting high KDPI and "hard to place" kidneys, including alternative frameworks for matching kidneys based on both medical suitability and patient risk tolerance.

The Committee discussed the importance of widespread patient education, such that patients are informed about the relative risks and benefits of accepting a high KDPI kidney, particularly with consideration for the relative risk of remaining on dialysis for an extended period of time. The Committee noted knowledge gaps about transplant, including among community nephrologists, which can contribute to mixed messaging and misinformation to patients. Members agreed it is critical to ensure accessibility across languages, cultures, and reading levels. The Committee further pointed to limitations with KDPI as a predictive measure of graft survival and quality, which functions best to match those highest expected survival patients with highest longevity organs.

The Committee noted that the requirement's initial intent was to increase transparency and shared decision-making, but that the requirement for patient signature itself may have instead contributed to fear and stigma for high KDPI kidneys that may provide significant benefit to many patients. Members also questioned whether some patients are aware that *not* signing this form limits the offers they receive. The Committee instead considered alternatives, such as program attestation and documentation requirements related to patient education efforts. Members emphasized the importance of patient experience and risk tolerance in patient education, noting limitations of standardized education compared to understanding and meeting individual patient needs.

The Committee further discussed the relative risk of delayed graft function and graft longevity compared to extended time on dialysis, noting that this comparative data could be significantly beneficial to educate patients about the relative risk of accepting high KDPI organs. For example, Bui et al.'s 2019 study found that candidates may have increased survival benefit accepting a high KDPI kidney over remaining on dialysis, and Massie et al. confirmed that KDPI 81-100 kidneys have a lower mortality risk after 6-7 months and better survival after about 18-19 months than waiting for a lower KDPI



kidney.^{35,36} The Committee expressed interest in continuing to explore how patient preference and risk tolerance can be leveraged to support increased efficiency in allocation of "hard to place" and high KDPI kidneys.

Inverse Qualifying Time Priority for "Hard to Place" Kidneys

Historically, kidney allocation has ordered candidates from greatest to least waiting time, also known as qualifying time,³⁷ within classifications. Classifications are ordered based on other candidate and donor matching characteristics. The qualifying time rating scale developed by the Committee thus far, shown in **Figure 5**, similarly assigns an increasing number of points as candidate qualifying time increases. The Committee's qualifying time rating scale increases linearly with no ceiling, with the scale exceeding 100% of points beyond 10 years of qualifying time.



Figure 5: Sample Kidney Qualifying Time Rating Scale

This modification would invert the qualifying time rating scale for "hard to place" or high KDPI kidneys, in order to increase priority for candidates with less qualifying time for these organs. This concept is also known as "dealing from the bottom of the deck," and has been previously discussed amongst the kidney transplant community, including the American Society for Transplantation's (AST) Cutting Edge of Transplantation (CEoT) and in literature discussing potential methods to reduce non-use.^{38,39} This concept considers that candidates near the top of the match run for both high and low KDPI kidneys are more likely to have longer waiting times; these candidates' priority on all types of match runs may disincentivize acceptance of more marginal, higher KDPI kidneys. Furthermore, candidates with

https://www.myast.org/sites/default/files/Saturday_1400_Salon%20EF_Cooper.pdf. Accessed August 27, 2022

³⁵ Bui K, Kilambi V, Sanjay M. Functional-Status-Based Risk-Benefit Analyses of High-KDPI Kidney Transplant versus Dialysis. Transplant Int. 2019 Jul 31;32 (12): 1297-1312 https://pmc.ncbi.nlm.nih.gov/articles/PMC6874710/

³⁶Massie A, Luo X, Chow E, Alejo J, Desai N, Segev D. Survival Benefit of Primary Deceased Donor Transplantation with High-KDPI Kidneys. American Journal of Transplantation. 2014;14(10):2310–2316 https://pubmed.ncbi.nlm.nih.gov/25139729/

³⁷ Per OPTN Policy 8.3: Waiting Time, for candidates 18 and older, a candidate's qualifying time is based on the earliest of the following:

[•] The candidate's registration date with a glomerular filtration rate (GFR) or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min

The date after registration that a candidate's GFR or CrCl less than or equal to 20 mL/min

[•] The date that the candidate began regularly administered dialysis as an end stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting

³⁸ Cooper M: Regulatory and financial considerations that impact transplant center practice – What changes would increase transplantation? Cutting Edge of Transplantation presentation, February 2018.

³⁹ Stewart D, Tanriover B, Gupta G, Oversimplification and Misplaced Blame Will Not Solve the Complex Kidney Underutilization Problem. Kidney360. 2022 Dec; 3(12): 2143-2147

 $https://journals.lww.com/kidney360/fulltext/2022/12000/oversimplification_and_misplaced_blame_will_not.21.aspx$

extended qualifying times are more likely to have extended time on dialysis, and thus may be less medically compatible with more medically complex organs due to dialysis-related complications. For example, Aufhauser et al have shown that patients with <5 years, 5-9 years, and 10 or more years on dialysis prior to transplant had progressively decreased graft and patient survival.⁴⁰ Prioritizing these candidates (long-waiting time and potentially long-dialysis time) for the highest KDPI kidneys, for which these candidates may not be medically well-matched, could contribute to inefficiency in allocation, particularly as OPOs must offer sequentially to candidates unlikely to accept the organ. This inefficiency can increase cold ischemic time and potential ischemic damage, further increasing the risk of non-use for organs already at greater risk.

"Dealing from the bottom of the deck," or waiting time inversion, proposes to offer higher KDPI kidneys to candidates with less qualifying time. It may be more medically appropriate for such candidates to accept these kidneys due to less dialysis time. These candidates may also have greater incentive to accept due to relatively low priority on other organ match runs. Transplanting high KDPI kidneys has been similarly shown to benefit pre-dialysis candidates as well, and pre-emptively transplanted recipients of KDPI 86-100% kidneys have comparable outcomes to dialyzed recipients of KDPI 51-84% kidneys.⁴¹ Waiting time inversion could be achieved in a variety of ways, including a through use of a donor modifier, or by altering the waiting time rating scale based on donor KDPI. The mechanism by which waiting time inversion could be achieved, and the scope of kidneys for which it could be appropriate, will require further data and discussion.

The Committee emphasized the importance of careful consent and shared decision-making, reiterating the need for patient education and determining patient risk tolerance. The Committee also noted concern for potential impact to candidates in the middle range of waiting time who may have decreased priority for these organs. The Committee expressed interest in continuing to explore inverse waiting time, but note the importance of community support and consensus for a dramatic shift in allocation principles, even for kidneys at risk of non-use.

"Likelihood of Acceptance" Attribute

This modification would introduce a new attribute to the composite allocation score. This attribute would assign priority based on a program's history of accepting the organ being offered, utilizing the donor and organ specific characteristics. With this attribute, candidates would receive priority based on their program's likelihood of acceptance. The Committee could choose to limit the scope of this attribute to high KDPI and "hard to place" kidneys, and would need to determine an appropriate weight for this attribute.

The Committee noted that the OPTN Computer System has tools to understand program history of acceptance, including the Recovery and Usage Map (RUM) report and the offer filters models. However, the Committee expressed concern that such an attribute may perpetuate inequities by directing certain kidney offers to historically more aggressive programs, and that this trend would be perpetuated as more organs are received and transplanted. The Committee emphasized the importance of transparency, so that programs were aware of these offers. Members noted that this transparency may be critical to encouraging more programs to consider these organs. The Committee tentatively

⁴⁰ Aufhauser, et al. Impact of Prolonged Dialysis Prior to Renal Transplantation. Clin Transplant, 2018 Jun 25;32(6). https://pmc.ncbi.nlm.nih.gov/articles/PMC6023748/

⁴¹ Kadatz, et al. The Benefits of Preemptive Transplantation Using High-KDPI Kidneys. Clinical Journal of the American Society of Nephrology, 2023 May 18(5):634-643. https://journals.lww.com/cjasn/abstract/2023/05000/the_benefits_of_preemptive_transplantation_using.13.aspx

expressed interest in continued discussion on this attribute but emphasized concern from an equity and ethics perspective. The Committee's further discussions on this attribute, and other modifications, will engage the OPTN Ethics Committee.

The Committee will continue to discuss the above potential modifications, and those deliberations will be complemented, as is feasible, by optimization and modeling with MIT and SRTR partners, as noted above. The Committee will continue to update the community and seek feedback on efficiency and utilization-based modifications to kidney allocation.

Defining "Hard to Place"

In order to better address non-use and expedited placement, the Committee identified a need for a preliminary, consensus definition of kidneys that are "hard to place," and thus at increased risk of non-use. Developing this definition will support understanding of organs at increased risk of non-use and provide a data-informed standard to identify which kidneys may require alternate allocation pathways.⁴² The Committee's initial efforts to define "hard to place" were outlined in the *Continuous Distribution of Kidneys Update, Summer 2024* update paper, and the Committee's subsequent discussions and decisions are further expanded upon below.⁴³

After evaluation and discussion of literature and preliminary non-use data, the Committee decided to utilize a multi-pronged approach to define "hard to place," including clinical, allocation-based, and cold ischemic time indicators. This multi-pronged approach recognizes the dynamic relationship of logistical and clinical factors in contributing to non-use, particularly as clinical concern for graft function contributes to longer allocation times and late acceptance. Similarly, longer allocation times contribute to increased cold ischemic time, and thus clinical concern for ischemic damage and its impact to potential graft function.⁴⁴ This multi-pronged approach guided the Committee's discussions, allowing the Committee to identify potential indicators of difficulty in placement within the defined categories. With consideration for how the "hard to place" kidneys and predicted "hard to place" kidneys.⁴⁵ Here, the allocation-based and clinical criteria could be considered in combination to identify an organ as "hard to place" in real time, during allocation, while clinical criteria could help predict which organs may become hard to place. This delineation supports a definition of "hard to place" that incorporates both pre-recovery (predictive) and post-recovery (identified) characteristics.

"Hard to Place" Criteria

After considerable review of clinical, allocation, and cold ischemic time data and public comment feedback, the Committee narrowed down the following potential criteria to define "hard to place" for donors with KDPI 50% or greater. Committee discussions regarding each criterion are detailed below.

- Six hours of cold ischemic time
- Sequence 100, or offer 100
- Hypertension history greater than 5 years
- Donor age 60 or older

⁴² OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

⁴³ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." August 2024 Public Comment.

⁴⁴ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

⁴⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.



- Diabetes greater than or equal to 5 years
- Donation after Circulatory Death (DCD) donor
- Glomerulosclerosis greater than 10 percent on at least one kidney
- Use of continuous renal replacement therapy (CRRT) in donor management

The Committee agreed that each of these criteria alone may not be sufficient to define an organ as "hard to place" or at increased risk of non-use, and that the definition of "hard to place" should require multiple criteria to be met. The Committee submitted an additional data request exploring non-use and donor volumes for donors meeting varying levels of clinical criteria combinations. This request will also investigate how many donors meeting varying levels of criteria combinations also required more than 100 offers prior to placement. From this data, the Committee will be able to understand relative rates of non-use for donors meeting 1, 2, 3, 4, or 5 of the clinical criteria outlined above. The results of this request will support finalization of the "hard to place" definition.

Identified "Hard to Place" Criteria: Cold Ischemic Time and Allocation Indicators

Cold Ischemic Time

The Committee's initial discussions related to cold ischemic time as a factor in defining "hard to place" were detailed in the Summer 2024 update paper, specifically highlighting the dynamic effect of cold ischemic time on non-use both as a factor of allocation and clinical concern.⁴⁶ Specifically, medically complex organs may be more likely to be declined, requiring greater allocation efforts and increased allocation time, thus contributing to increased cold ischemic time and likelihood and severity of related ischemic damage.⁴⁷ Members discussed that a cold ischemic time threshold would need to account for the time required for OPOs to collect and report critical post-recovery organ information, particularly biopsy results and pump parameters. The Committee briefly considered alternative time thresholds based on time after post-recovery information becomes available, but noted that this could result in significantly increased complexity.⁴⁸ The Committee agreed that the cold ischemic time threshold incorporated into a definition of "hard to place" should reflect ample attempt at placement without success within the standard allocation framework.⁴⁹

Public comment feedback supported cold ischemic time as a factor in defining "hard to place," but noted that cold ischemic time alone is not sufficient to designate a kidney as "hard to place," citing variation in post-recovery evaluation and late declines.⁵⁰ Commenters generally supported a cold ischemic time threshold between 6 and 8 hours, noting that a higher threshold (such as 9-12 hours) is inadequate to accommodate allocation and transportation.⁵¹ Ultimately, the Committee agreed, supporting a cold ischemic time threshold of six hours post-cross clamp in the definition of "hard to place." The Committee noted that cold ischemic time is one criterion within the "hard to place" definition, and should be considered in context with other criteria.⁵²

⁴⁶ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." August 2024 Public Comment.

⁴⁷ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

⁴⁸ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

⁴⁹ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024

⁵⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024

⁵¹ Ibid.

The six hour cold ischemic time threshold is data-driven, referencing Wood et al.'s "Deviating from the Match Run to Save a Kidney" analysis, which evaluated how risk of non-use increases as cold ischemic time increases.^{53,54} This analysis demonstrated that non-use rates increased as cold ischemic times increased, with an inflection point around 5-6 hours post-cross clamp, overall and stratified by KDPI (**Figures 6 and 7**).⁵⁵

Figure 6: Kidney Non-Use Rate by Time from Cross Clamp⁵⁶ and Figure 7: Kidney Non-Use Rate by Time from Cross Clamp, Stratified by KDPI⁵⁷



There is precedent outside of the US for using 6 hours of cold ischemic time as a threshold, as expedited allocation is initiated in the United Kingdom once an organ accrues six hours of cold time.⁵⁸ Furthermore, this threshold includes transportation and logistics considerations, with Committee members noting that an organ accepted 6 hours post-recovery may still accrue 12-18 additional hours of cold ischemic time for transportation, particularly if allocation is occurring overnight, on the weekend, or a holiday.⁵⁹

Allocation Indicator: Sequence Number

The Update on Continuous Distribution of Kidneys, Summer 2024 paper introduced potential allocation thresholds based on number of candidate declines, or sequence number at offer, and number of program declines. Community feedback on potential allocation thresholds to define "hard to place" was mixed, with some support for the utility of declines as a relevant data point in understanding ease of

⁵⁴ Wood, et al. (2023). "Deviating from a Match Run to Save a Kidney." Presented at the 2023 American Transplant Congress. https://www.srtr.org/media/1677/wood_atc_2023_match_run_deviation.pdf
⁵⁵ Ibid.

⁵⁸ White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. Clin Transplant, 29(10), 872-881. https://pubmed.ncbi.nlm.nih.gov/26094680/

⁵³ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

⁵⁶ Wood, et al. (2023). "Deviating from a Match Run to Save a Kidney." Presented at the 2023 American Transplant Congress. https://www.srtr.org/media/1677/wood_atc_2023_match_run_deviation.pdf

⁵⁷ Ibid.

⁵⁹ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

placement, but concern that the specific sequence or center decline threshold itself is clinically arbitrary.⁶⁰ Critically, public comment feedback anecdotally acknowledged a "domino effect" phenomenon in organ allocation, such that some organs begin to increasingly accrue declines as more candidates and programs decline the offer.⁶¹ There was slightly greater support for use of an allocation threshold based on sequence number, or number of candidates declining, than number of program declines, with commenters citing that center declines are largely driven by individual surgeon behavior.⁶² Community feedback recommended a variety of different sequence number thresholds, ranging from 50 to 500.⁶³

Ultimately, the Committee opted to utilize 100 candidate declines, as indicated by no acceptance past sequence 100 or 100 offers, as a criterion within the "hard to place" definition. The Committee agreed that center decline may introduce too much complexity, as defining center decline itself requires complex consideration of multiple candidate types and the reasons for decline.⁶⁴ Members noted that sequence 100 is not a clinical threshold, but that there is precedent for identifying kidneys as "hard to place" by acceptance, or lack thereof, after sequence 100 within SRTR program performance metrics.⁶⁵ The Committee noted potential geographic variation within this criterion; in some regions, the first 100 sequences may represent 3 or fewer programs. The Committee agreed that sequence 100, in combination with cold ischemic time and clinical characteristics, is an appropriate factor in determining whether a kidney is "hard to place."⁶⁶ The Committee will continue to evaluate this criterion when reviewing the "hard to place" data request examining donor volumes and non-use based on the Committee's selected criteria.

Predictive "Hard to Place" Criteria: Clinical Indicators

In the spring, the Committee submitted an additional OPTN data request to better understand how interactions between criteria may impact risk of non-use. This request utilized two adjusted models – one overall and one stratified by KDPI group. The models utilized the following donor characteristics:

- Age (years)
- History of cancer
- History of cigarette use
- History of cocaine use
- History of drug use
- History of hypertension
- History of diabetes
- Duration of diabetes
- Insulin dependent diabetes
- Hepatitis C
- Hepatitis B
- DCD donor

- Serum creatinine
- Height
- Weight
- Body mass index (BMI)
- Cause of death
- Mechanism of death
- Blood type
- Birth sex
- Region, donor service area (DSA), and state
- COVID-19 status
- Pump status

⁶⁰ Ibid.

⁶¹ Ibid.

⁶² OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁶³ Ibid.

⁶⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁶⁵ Scientific Registry of Transplant Recipients, For Transplant Professionals: Offer Acceptance Tables. https://www.srtr.org/faqs/for-transplant-center-professionals/

⁶⁶ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.



- Biopsy status
- Public Health Service (PHS) increased risk status
- Cytomegalovirus (CMV) status

- Clinical infection
- Kidney donor risk index (KDRI)

The overall model identified the following criteria as independently and statistically significantly associated with increased risk of non-use:

- Terminal creatinine
- Presence of clinical infection in donor
- Mechanism of death unknown, or illdefined
- Kidney biopsy performed
- History of hypertension
- History of cigarette use, yes or unknown

- History of cancer, yes or unknown
- Hepatitis C positive
- Hepatitis B positive
- Duration of diabetes, unknown or greater than or equal to 5 years
- Donor age
- DCD donor
- Blood type AB

Table 2 summarizes the variables significantly associated with increased odds of non-use as identified by the KDPI-stratified model. A blank cell indicates that this variable was not significantly associated with non-use for that KDRI quartile.

Table 2: Summary of Significant Variables and Odds Ratios Associated with Increased Odds of Non-use in KDPI-Stratified Models

Variable	Third Quartile (KDRI 50-75) Adjusted Model	Fourth Quartile (KDRI 76-100) Adjusted Model
Terminal Creatinine (mg/dl)	1.36 (1.29, 1.43)	1.61 (1.47, 1.77)
Kidney Biopsied	2.08 (1.71, 2.53)	
Presence of Clinical Infection: No/Unknown	1.17 (1.01, 1.36)	1.5 (1.3 ,1.74)
History of Hypertension	1.18 (1.02, 1.37)	1.59 (1.35, 1.88)
History of Cigarette Use	1.27 (1.10, 1.47)	1.21 (1.05, 1.40)
Hepatitis C Positive		1.51 (1.12, 2.05)
Hepatitis B Positive	3.4 (1.74, 6.65)	13.17 (4.26, 40.71)
Duration Diabetes Unknown		1.58 (1.2, 2.09)
Duration Diabetes >= 5 yrs	2.15 (1.69, 2.73)	2.69 (2.22, 3.26)

Variable	Third Quartile (KDRI 50-75) Adjusted Model	Fourth Quartile (KDRI 76-100) Adjusted Model
Donor Age	1.03 (1.02,1.04)	1.08 (1.07,1.09)
DCD Donor	1.72 (1.48, 2)	1.84 (1.58, 2.14)
Blood type AB	1.67 (1.21, 2.3)	2.1 (1.41, 3.14)

Table 2 demonstrates subtle differences in donor factors associated with increased odds of non-use across the KDPI stratifications. Furthermore, this analysis showed that as KDRI increases, a greater number of donor factors are significantly associated with increased odds of non-use, indicating complexity and potential interaction in factors impacting potential non-use.

The Committee noted that the highest KDPI quartiles represented the greatest incidence of non-use, and decided to focus on the statistically significant donor characteristics identified within KDPI 50-75% and 76-100%.⁶⁷ The Committee discussed each characteristic in detail and determined whether the characteristic was appropriate and practical to include within a definition of "hard to place." The Committee's discussions regarding the following characteristics significantly associated with non-use are detailed below:

- Terminal creatinine
- Kidney biopsied
- No or unknown presence of clinical infection
- History of hypertension
- History of cigarette use
- Hepatitis B positive, Hepatitis C positive
- Diabetes, duration unknown, greater than or equal to 5 years
- Donor age
- DCD donor
- Blood type AB

Terminal Creatinine and Donor Use of CRRT

Members noted that creatinine trends are more useful and informative than terminal creatinine, and that terminal creatinine can be influenced by donor management practices, such as use of CRRT. The Committee agreed that terminal creatinine thresholds are less valuable in identifying organs as "hard to place," even though it was statistically significant.⁶⁸ The Committee noted that use of CRRT in donor management may be an appropriate surrogate for potential acute kidney injury or related damage instead of terminal creatinine. The use of CRRT in donor management was also recommended as a

⁶⁷ OPTN Kidney Transplantation Committee Meeting Summary, July 15, 2024.

⁶⁸ OPTN Kidney Transplantation Committee Meeting Summary, August 12, 2024.

potential factor of "hard to place" in public comment. The Committee supported the donor use of CRRT as a criterion to define "hard to place."⁶⁹

Kidney Biopsied and Glomerulosclerosis

For fourth quartile KDRI kidneys, biopsy had a protective effect on the odds ratio of non-use. This means that kidney biopsy minorly, but significantly, decreased the odds of non-use for these highest KDRI kidneys.⁷⁰ The Committee noted that many of these organs likely meet the criteria to require biopsy, and added that it may be necessary to specify relevant biopsy results within the definition of "hard to place."⁷¹

The Committee referenced further data which showed non-use rates of 59.63% for organs with a glomerulosclerosis score between 11-15%. Non-use rates were higher as glomerulosclerosis scores increased. The Committee supported the inclusion of glomerulosclerosis greater than 10% as a criterion to define "hard to place."⁷²

No or Unknown Presence of Clinical Infection

The Committee noted that "no or unknown presence of clinical infection" was not directly clinical nor logically relevant to risk of non-use, nor does lack of clinical infection inform on graft function. The Committee agreed not to include presence of clinical infection as a criterion for "hard to place."⁷³

History of Hypertension

The Committee requested additional data to further delineate history of hypertension by duration and compliance, noting that these factors may impact the relative risk of non-use. This follow-up analysis found that rates of non-use increase as history of hypertension increases:⁷⁴

- 16.33% for donors with no history of hypertension
- 35.41% for donors with a 0-5 year history of hypertension
- 48.66% for donors with a 6-10 year history of hypertension
- 54.21% for donors with a greater than 5 year history of hypertension
- 58.04% for donors with a greater than 10 year history of hypertension
- 46.75% for donors with a known history of hypertension but unknown duration
- 31.91% for donors with an unknown history of hypertension

This analysis did not show a clear relationship or trend between non-use rate and compliance with hypertension treatment; there was a non-use rate of 48.25% for compliant donors compared to 40.78% for noncompliant donors. Donors with unknown compliance had a non-use rate of 44.97%. The Committee said this may be due to the relative unreliability of data on hypertension treatment compliance, as this information is typically collected via donor risk assessment interviews as opposed to documented medical records.⁷⁵ The Committee noted that compliance is rarely meaningfully reliable in

⁶⁹ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁷⁰ OPTN Kidney Transplantation Committee Meeting Summary, July 15, 2024.
⁷¹ Ibid.

⁷² OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁷³ OPTN Kidney Transplantation Committee Meeting Summary, August 12, 2024.

⁷⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 28, 2024.

⁷⁵ Ibid.

offer evaluation and agreed that compliance should not be factored into the definition of "hard to place."76

The Committee compared hypertension durations of greater than 5 and greater than 10 years, and ultimately supported including history of hypertension greater than 5 years as a criterion to define "hard to place."77

History of Cigarette Use

The Committee remarked that history of cigarette use is likely related to non-use more as an indicator of overall donor health and lifestyle, and thus less directly informative to risk of non-use than other clinical criteria. The Committee agreed not to include history of cigarette use as a criterion for "hard to place." 78

Hepatitis B Positive and Hepatitis C Positive

Less than 1% of donors were hepatitis B positive in both KDPI quartiles, whereas 5.95% of donor with KDRI 76-100% were hepatitis C positive. The Committee noted that these characteristics represent a very small portion of the donor population, and advancements in hepatitis B and C treatments have significantly reduced risks to graft function for organs from such donors. The Committee agreed not to include hepatitis B and C positivity as criteria to define "hard to place."⁷⁹

History of Diabetes

Further analysis found that 5.91% of donors had diabetes for an unknown duration within the fourth KDRI quartile, while 17.89% of donors had diabetes for 5 years or more within the fourth KDRI quartile, and 7.66% of donors had diabetes for 5 years more within the third KDRI quartile.⁸⁰ The Committee agreed that the "unknown duration of diabetes" data point may be less reliable, and that this is relatively rare in the donor population. The Committee noted that extended diabetes history can impact potential graft function and contribute to increased risk of non-use and agreed that diabetes with a duration greater than or equal to 5 years is an appropriate criterion to define "hard to place."⁸¹

Donor Age

The Committee noted that donor age is clinically relevant to potential graft function, and that elevated donor age can contribute to increased risk of non-use. The adjusted model included donor age as a continuous variable and found increased odds of non-use as donor age increased. The median donor age for transplanted organs was 40 years, while the median donor age for non-used organs was 58. Non-use rates were 37.75% for donors aged 50-59, and 63.14 percent for donors aged 60 and older. The Committee noted donors aged 60 and older have very high rates of non-use and supported including a donor age threshold of 60 years and older as a criterion to define "hard to place."82

⁷⁶ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024.

⁷⁷ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024

⁷⁸ OPTN Kidney Transplantation Committee Meeting Summary, August 12, 2024. 79 Ibid.

⁸⁰ OPTN Kidney Transplantation Committee Meeting Summary, July 15, 2024. ⁸¹ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁸² OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024.

DCD Donor

Further analysis found that 46.72% and 46.29% of donors were DCD in the third and fourth KDRI quartiles, respectively.⁸³ In 2023, DCD donors had a non-use rate of 33.87%, compared to 23.06% for donation after brain death (DBD) donors.⁸⁴ The Committee noted that DCD status is clinically relevant to graft function and risk of non-use⁸⁵ and agreed that DCD status should be considered as a criterion within the definition of "hard to place."⁸⁶

Blood Type AB

The Committee noted that blood type AB is relatively rare compared to other blood types, and match runs are typically relatively short for blood type AB donors.⁸⁷ As a result, blood type AB candidates tend to have shorter waiting times.⁸⁸ The Committee noted that the small populations of medically compatible patients and shorter overall waiting times for this candidate population may drive more selective behavior amongst transplant programs, thus contributing to increased non-use of blood type AB organs. The Committee agreed that non-use related to AB blood type cannot be addressed via increased efficiency or expedited placement. With this in mind, the Committee determined that blood type AB is not an appropriate donor characteristic to include in the definition of "hard to place."⁸⁹

Next Steps

The Committee noted the benefit of relative simplicity in a preliminary definition of "hard to place." Specifically, the Committee has highlighted comprehensibility for OPOs, transplant programs, and patients in order to ensure the definition is practically useful and able to be consistently, transparently, and effectively applied.^{90,91} The Committee cited similarly simple initiation criteria for expedited placement in the European and United Kingdom transplant systems.^{92,93} While the preliminary definition developed by the Committee is relatively simple, members emphasized the benefit of continued iteration of the "hard to place" definition. The Committee expressed support for developing a predictive model utilizing several donor and organ criteria with weighted coefficients. This predictive model could be used to generate a score calculating an organ's risk of non-use. The Committee noted that such a model could potentially incorporate the interactions between variables that often contribute to acceptance decisions, and thus may more accurately capture an organ's risk of non-use.⁹⁴ While the Committee acknowledges the potential benefits of such a predictive model in defining "hard to place," the Committee also recognized that this approach would require intensive modeling efforts and

⁸³ OPTN Kidney Transplantation Committee Meeting Summary, August 12, 2024.

⁸⁴ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

⁸⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

⁸⁶ Ibid.

⁸⁷ OPTN Kidney Transplantation Committee Meeting Summary, July 15, 2024.

⁸⁸ OPTN National Data; Kidney Competing Risk Median Waiting Time to Deceased Donor Transplant For Registrations Listed: 2003-2014. https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

⁸⁹ OPTN Kidney Transplantation Committee Meeting Summary, July 15, 2024.

⁹⁰ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

 $^{^{91}}$ OPTN Kidney Transplantation Committee Meeting Summary, August 18, 2024

⁹² White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. Clin Transplant, 29(10), 872-881.

⁹³ Assfalg, et al. (2023). Rescue Allocation Modes in Eurotransplant Kidney Transplantation: Recipient Oriented Extended Allocation Versus Competitive Rescue Allocation – A Retrospective Multicenter Outcome Analysis. Transplantation.

⁹⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 28, 2024.

resources, and could potentially extend continuous distribution and expedited placement timelines. The Committee supported future pursuit of such efforts to iterate on the "hard to place" definition.⁹⁵

As mentioned above, the Committee submitted a final "hard to place" OPTN data request in November, evaluating donor volumes and understanding non-use rates across various combinations of clinical criteria.⁹⁶ The request will also investigate donor volumes of donors with more than 6 hours of cold ischemic time without placement of one or more donor kidneys and where one or both kidneys are placed at offer number > 100. Data collection on use of CRRT on donors is pending implementation⁹⁷ and therefore will not be captured in the data request. The Committee will review the results of this data request and determine the number of criteria necessary to be met in order for donor kidneys to be considered "hard to place." These discussions will finalize the definition of "hard to place" kidneys, and the Committee will recommend this definition for consideration by the OPTN Kidney Expedited Placement Workgroup as potential expedited placement initiation criteria.

Kidney Expedited Placement

Kidney Expedited Placement Workgroup Background and Scope

The Kidney Expedited Placement Workgroup (hereafter, the Workgroup) was formed to address the OPTN Board directive to incorporate kidney expedited placement frameworks into the Continuous Distribution proposal. The Workgroup, which was first introduced in the *Continuous Distribution of Kidneys Update, Summer 2024*, is composed of members from the OPTN Kidney Transplantation, Transplant Coordinators, Operations and Safety, OPO, and Ethics Committees ⁹⁸

Prior to September 2024, this Workgroup worked closely with the OPTN Expeditious Task Force and the Rescue Allocation Pathways Workgroup to develop protocols within the *Expedited Placement Variance* policy. This variance policy aimed to test and compare potential expedited placement protocols utilizing a small portion of the donation and transplant community, thus allowing the OPTN to understand the impact of a potential policy ahead of national implementation.⁹⁹ Previously, the Workgroup studied expedited placement via a literature review and developed an expedited placement framework to be submitted for consideration as a protocol under the *Expedited Placement Variance* policy. The Workgroup's literature review and identified key considerations are expanded upon in the Committee's previous update.¹⁰⁰ The Workgroup's previous discussions towards the development of an expedited placement framework are detailed below.

On August 30, 2024, HRSA submitted a critical comment to the OPTN regarding allocation out of sequence.¹⁰¹ This critical comment directed the OPTN to delay implementation of protocols under *Expedited Placement Variance* policy "given that the issues of concern raised in this critical comment could be experienced by OPTN members not participating in" the variance.¹⁰² However, the OPTN has continued interest in expedited placement, with public comment feedback largely supportive of a

⁹⁵ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024

⁹⁶ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024

⁹⁷ "Deceased Donor Support Therapy Data Collection," OPTN, Policy Notice, https://optn.transplant.hrsa.gov/media/lpgbo2mr/policynotice_osc_donor-support-therapy_data-collection.pdf.

⁹⁸ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." August 2024 Public Comment.

⁹⁹ OPTN Executive Committee, "Expedited Placement Variance." December 22, 2023 – January 21, 2024 Special Public Comment.

¹⁰⁰ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." August 2024 Public Comment.

¹⁰¹ HRSA Critical Comment to the OPTN concerning "expedited" allocation of organs. August 30, 2024.

https://optn.transplant.hrsa.gov/media/q2qiywew/08302024-aoos-critical-comment-letter-to-optn-508.pdf ¹⁰² Ibid.

standard, transparent, and effective expedited placement pathway, particularly for "hard to place" kidneys and kidneys at increased risk of non-use.¹⁰³

In October, the Kidney Committee unanimously supported pursuit of a national kidney expedited placement policy utilizing the Workgroup's previous discussions towards developing such frameworks.¹⁰⁴ Specifically, the Committee supported developing an expedited placement policy to operate in the current circles-based kidney allocation system, preceding the continuous distribution proposal. Separating the expedited placement project from the continuous distribution proposal allows the community to review and provide comment on these two major shifts in allocation separately. Furthermore, this allows an expedited placement pathway to be released for public comment and implemented separately from the continuous distribution timeline. The Committee plans to update the expedited placement pathway to accommodate points-based allocation as part of the continuous distribution proposal.

The Kidney Expedited Placement Workgroup has begun to transition their expedited placement framework to inform a national policy and is aiming to release the proposal for public comment during the Summer 2025 public comment cycle.¹⁰⁶ Key components of this framework and the Workgroup's discussions are outlined below.

Expedited Placement Framework: Key Components

The Kidney Expedited Placement Workgroup's literature review evaluated several expedited placement frameworks and concepts.¹⁰⁷ The Workgroup's initial discussions utilized the Euro-Transplant (ET) system's Recipient Oriented Allocation pathway (REAL) as a model for kidney expedited placement in the United States, noting the REAL pathway's success in balancing transparency, equity, accountability, and efficiency.¹⁰⁸ The REAL system utilizes elements of simultaneous offering, candidate submission, system-imposed evaluation time limits, and standard allocation candidate prioritization to achieve this.¹⁰⁹

The framework discussed by the Workgroup thus far would also entail simultaneous offer evaluation and candidate submission. The framework further aims to maintain equity by utilizing the initial match run order to determine candidate priority. The Workgroup is also considering incorporating program qualification criteria based on donor-specific acceptance history to more effectively offer each organ to programs with a demonstrated history of acceptance for certain donor and organ types. Finally, the Workgroup highlighted the importance of expectations of higher standards for programs and OPOs within an expedited placement process, with specific expectations related to donor information sharing, virtual crossmatching, and more. Each of these elements are expanded upon below.

¹⁰⁴ Ibid.

¹⁰³ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

¹⁰⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2024.

¹⁰⁶ OPTN Kidney Expedited Placement Workgroup Meeting Summary, November 4, 2024.

¹⁰⁷ OPTN Kidney Committee, "Continuous Distribution of Kidneys Update, Summer 2024." July 2024 Public Comment.

¹⁰⁸ OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024.

¹⁰⁹ Assfalg, et al. (2023). Rescue Allocation Modes in Eurotransplant Kidney Transplantation: Recipient Oriented Extended Allocation Versus Competitive Rescue Allocation – A Retrospective Multicenter Outcome Analysis. Transplantation.

Simultaneous Offering and Candidate Submission

The Workgroup particularly supported the simultaneous offering and candidate submission aspects of the REAL allocation system.¹¹⁰ The framework discussed by the Workgroup aims to recreate these aspects, such that programs have the same period of time to evaluate an offer and designate candidates for whom they would accept the organ offer.¹¹¹ The Workgroup highlighted the benefits of simultaneous offer evaluation, noting increased efficiency and decreased allocation time achieved by condensing evaluation across all potential accepting programs within the European system.¹¹² These benefits are further supported within the literature; Mankowski et al found that simultaneous offering methods, as opposed to sequential offering, increased the number of kidneys accepted and reduced overall allocation times, even for high KDPI kidneys.¹¹³ Additional programming may be required to ensure feasibility of simultaneous notification for OPOs.¹¹⁴

The Workgroup supports a 90-minute evaluation period, slightly longer than the 60 minutes given during the European Transplant system's REAL protocol. The Workgroup noted that the additional time may be necessary to allow programs to evaluate their lists, complete virtual crossmatches, and contact patients for initial screening.¹¹⁵

The Workgroup's discussions emphasized a key point of tension in simultaneous evaluation, such that too many programs receiving a simultaneous offer can contribute to offer evaluation overwhelm and burnout. Furthermore, simultaneous evaluation and candidate selection by multiple programs will inherently result in program resources spent towards evaluating and preparing for an offer the program does not ultimately receive. The Workgroup noted that simultaneous offering blocks should maintain a reasonable transplant program volume, to better manage overwhelm and mitigate unnecessary loss of offer evaluation resources.¹¹⁶ The Workgroup considered program resources, noting the need to monitor and measure potential cost to programs.¹¹⁷

In considering candidate selection, the Workgroup discussed a framework that allows programs to designate up to 3 candidates for whom they would accept the organ. It was noted that limiting the number of candidates a program may designate can help reduce and manage the number of resources spent evaluating each individual expedited offer. The Workgroup noted that minimum candidate submission requirements may not be appropriate, particularly with consideration for smaller programs and for donors with rarer blood types.¹¹⁸ Critically, programs would not be required to designate any candidates, and could choose to decline the offer outright.

The Workgroup emphasized the importance of patient education with expedited placement offers, particularly as these offers may have a lower likelihood of becoming primary.¹¹⁹ Members noted that programs should discuss these offers with patients as back up offers, to reduce confusion and potential disappointment. While members noted that programs will know best how to appropriately educate and

¹¹⁰ OPTN Kidney Transplantation Committee Meeting Summary, May 29, 2024.

¹¹¹OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

¹¹² OPTN Kidney Transplantation Committee Meeting Summary, May 29, 2024.

¹¹³ Mankowski, et al. (2019). Accelerating kidney allocation: Simultaneously expiring offers. Am J Transplant, 19(11), 3071-3078.

https://pubmed.ncbi.nlm.nih.gov/31012528/

¹¹⁴ OPTN Kidney Transplantation Committee Meeting Summary, July 8, 2024.

¹¹⁵ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024.

¹¹⁶ OPTN Kidney Transplantation Committee Meeting Summary, May 29, 2024.

¹¹⁷ Ibid.

¹¹⁸ OPTN Kidney Transplantation Committee Meeting Summary, November 4, 2024.

¹¹⁹ OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024

communicate with their individual patients, the Workgroup included specific expectations regarding patient education in the program expectations outlined below.¹²⁰ The Workgroup noted that patient education regarding potential expedited placement offers is critical to patient autonomy and shared decision-making, and further supports increased efficiency as patients consider their willingness to accept expedited placement offers.¹²¹

The Workgroup recommended that programs consider maintaining a pre-identified list of candidates who may be medically and logistically appropriate matches for expedited kidney offers. This practice would support early and iterative patient education, as well as improve efficiency for programs evaluating expedited offers and determining which candidates to designate. This practice would also support program resource management and potentially reduce evaluation burnout.¹²²

Transparency and Equity: Candidate Prioritization

The Workgroup agreed that priority candidates should receive standard allocation offers prior to initiation of expedited placement, to ensure equity in access for these candidates. High priority candidates were identified as those candidates who are 98-100% CPRA, prior living donor, medically urgent, or 0-ABDR mismatch. It was noted that ideally, allocation has progressed past these candidates before expedited placement can be initiated.¹²³

The Workgroup also supported prioritizing which candidate ultimately receives the organ based on designated candidate's ranking on the original match run, noting that this ensures equity, transparency, and consensus in the expedited placement process.¹²⁴

Transparency and Effective Offering: Program Qualification Criteria

The Workgroup agreed that transparency, objectivity, and consistency in determining which programs receive expedited placement offers is critical for ensuring equity. The Workgroup discussed several potential methods for determining program qualification criteria based on acceptance history, including the recovery and usage map (RUM) report, program offer acceptance ratios, and offer filters program acceptance behavior models.¹²⁵

Several members expressed support for a framework without program qualification criteria, at least for programs within 250 nautical miles, ensuring smaller programs have the opportunity to grow.¹²⁶ The Workgroup noted challenges associated with this, particularly as program-dense areas may see more than 40 programs within 250 nautical miles.¹²⁷ The Workgroup considered the feasibility of such a large volume of programs simultaneously evaluating an offer, noting lower odds of receiving the final organ offer and potential offer evaluation burn out.¹²⁸ The Workgroup noted that offer filters will also support effective offering and increased efficiency in expedited placement.¹²⁹

¹²⁰ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 5, 2024.

¹²¹ OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024

¹²² OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024.

¹²³ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 19, 2024.

¹²⁴ OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024

¹²⁵ Ibid. ¹²⁶ Ibid.

¹²⁷ OPTN Kidney Expedited Placement Workgroup Meeting Summary, July 8, 2024

¹²⁸ Ibid.

¹²⁹ OPTN Kidney Expedited Placement Workgroup Meeting Summary, June 10, 2024.

The Workgroup seeks feedback on the appropriate volume of programs evaluating an offer simultaneously, as well as feedback on whether the expedited placement pathway should incorporate program qualification criteria.

Accountability: OPO and Program Expectations

The Workgroup's discussions supported a clear set of expectations for programs and OPOs utilizing expedited placement, noting that these standards can encourage alignment between OPOs and programs and help ensure smooth operation of the expedited placement pathway.

The Workgroup has discussed several potential recommendations and expectations for programs evaluating expedited placement offers. One such recommendation encourages programs to designate a general list of candidates who may be medically well matched and logistically appropriate to accept expedited placement offers. Other recommendations include ensuring appropriate patient education, consent, and notification both prior to and during offer receipt. The Workgroup also considered recommendations related to evaluation, such as encouraging programs to designate candidates they are willing to transplant based on virtual crossmatch results alone and to perform general patient screening to ensure wellness, availability, and interest in accepting the offer. The Workgroup has also considered a potential recommendation for programs to prepare a backup candidate to accept the organ, in the event a primary recipient is unable to be transplanted.¹³⁰

The Workgroup also considered potential recommendations and expectations for OPOs making expedited placement offers. The Workgroup noted that OPOs generally meet most of these recommendations, but emphasized their importance to rapid allocation.¹³¹ These recommendations include encouraging OPOs to share as much clinical relevant donor and organ information as possible, as quickly as possible, including making efforts to ensure biopsy results are available within 6 hours of cross clamp when possible.¹³² This recommendation included consideration for early upload of the anatomy sheet, as well as recommendations to take images of the front, back, and aortic patch of the kidneys.¹³³ The Workgroup also discussed pump practices, with a recommendation for OPOs to make efforts to pump these organs, or else communicate plans to pump or not pump upfront. The Workgroup noted that pumping may not be possible, appropriate, or in the best interest of placing the organ in every situation, and that pumping should not take precedence over timely transportation. Finally, the Workgroup discussed a recommendation that OPOs may notify programs about a donor's potential or pending qualification for expedited placement prior to initiation of the pathway.¹³⁴

These recommendations remain in development, and the Workgroup will continue to determine whether certain expectations should be considered policy requirements versus general guidance.

Next steps

The Workgroup will continue to develop the expedited placement framework, including discussions on initiation criteria, programming and notification requirements, potential program qualification criteria, potential data collection, incorporation of and impacts to dual kidney and released kidney allocation, and more. Public comment and community feedback will continue to inform these discussions, as well

¹³⁰ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 5, 2024.

¹³¹ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 5, 2024.

¹³² OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 19, 2024.

¹³³ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 5, 2024.

¹³⁴ OPTN Kidney Expedited Placement Workgroup Meeting Summary, August 5, 2024.

as the Kidney Committee's discussions towards defining "hard to place" kidneys as the Workgroup works towards their Summer 2025 target date. Of note, the OPTN Ethics Committee is developing a white paper regarding the ethical considerations of expedited and out of sequence allocation.¹³⁵ When completed, the Kidney Expedited Placement Workgroup will review this white paper and discuss relevant ethical considerations into the development of the kidney expedited placement framework, as well as continue collaboration with OPTN Ethics Committee representatives on the Workgroup.

Looking Ahead

The Kidney Committee will continue finalizing the continuous distribution policy, including discussions related to efficiency modifications, further modeling and optimization for reduced non-use, and finalizing operational aspects of kidney allocation. These operational components include modifications to the medical urgency definition, kidney review board finalization, transition considerations for dual and released kidney allocation, kidney minimum acceptance criteria screening tool modifications, and establishing continuous distribution based multi-organ thresholds. The Committee will continue working towards the establishment of an expedited placement pathway as a separate project, with a goal of sending out a proposal for public comment in Summer 2025. The Kidney Expedited Placement Workgroup may also need to consider potential impacts to dual and released kidney allocation, in both current and continuous distribution kidney allocation.

The Kidney Committee will finalize the definition of "hard to place," and hand this off for consideration by the Kidney Expedited Placement Workgroup as expedited placement initiation criteria. The Committee will transition discussions towards efficiency modifications in the winter and spring of 2025, working up to continued optimization work with MIT. Throughout 2025, the Committee will aim to finalize the kidney composite allocation score, including submission of a 3rd OASim modeling request with efficiency-inclusive optimized policies and metrics. The Committee will also aim to finalize the medical urgency definition and related Kidney Review Board considerations, and finalize operational considerations related to the kidney minimum acceptance criteria screening tool in continuous distribution, dual kidney allocation, and released organ allocation. Finally, through the end of 2025, the Committee will work to finalize the overall continuous distribution proposal, including kidney expedited placement and multi-organ allocation.

NOTA and Final Rule Analysis

The Committee submits this update under the authority of NOTA, which requires the OPTN to "establish...medical criteria for allocating organs,"¹³⁶ 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."¹³⁷ 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

 ¹³⁵ OPTN Ethics Committee Meeting Summary, October 16, 2024. <u>https://optn.transplant.hrsa.gov/media/jxsntide/20241016_ethics-meeting-summary.pdf</u>
 ¹³⁶ 42 U.S.C. §274(b)(2)(B)

¹³⁷ 42 CFR §121.4(a)

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."¹³⁸ While this update will not immediately result in an allocation policy change, the concepts presented in this paper:

Are based on sound medical judgment:¹³⁹ The construction of the individual rating scales and weights of the kidney composite allocation score are based on objective data, including analysis of OPTN data, peer-reviewed literature, simulation modeling, and mathematical optimization. Similarly, the "hard to place" definition and expedited placement pathway under development are based on data and peer-reviewed literature. The Committee will rely upon these data as well as their own clinical experience and judgment to finalize proposals for upcoming policy changes.

Seek to achieve the best use of donated organs:¹⁴⁰ The kidney continuous distribution policy under development would continue to give priority to candidates who meet policy criteria for medical urgency. The Committee will consider the potential impact of an expedited placement pathway on medically urgent candidates before submitting a policy proposal for public comment.

Are specific for each organ:¹⁴¹ In this case, kidney.

Are designed to avoid wasting organs:¹⁴² The new metrics incorporated into the SRTR modeling and upcoming mathematical optimization will help the Committee to assess the impact of potential continuous distribution policies on kidney non-use.

Are designed to...promote patient access to transplantation:¹⁴³ The Committee aims to ensure similarly situated candidates have equitable opportunities to receive an organ offer through inclusion of biological disadvantage attributes such as blood type and CPRA, and patient access attributes such as prior living donor status, pediatric status, safety net priority, and waiting time.

Are designed to...promote the efficient management of organ placement:¹⁴⁴ The Committee is considering several approaches to promoting efficiency in kidney placement, including the weight on the placement efficiency rating scale; donor modifiers to increase the weight on placement efficiency for the highest KDPI kidneys; development of an expedited placement pathway for "hard to place" kidneys; and potential additional attributes that could be added to the composite allocation score for efficiency.

Not be based on the candidate's place of residence or place of listing, except to the extent required¹⁴⁵ for efficient placement of kidneys.

Consider whether to adopt transition procedures:¹⁴⁶ 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

¹³⁸ 42 CFR §121.8(a)
¹³⁹ 42 CFR §121.8(a)(1).
¹⁴⁰ 42 CFR §121.8(a)(2)
¹⁴¹ 42 CFR §121.8(a)(4)
¹⁴² 42 CFR §121.8(a)(5)
¹⁴³ 42 CFR §121.8(a)(5)
¹⁴⁴ 42 CFR §121.8(a)(5)
¹⁴⁵ 42 CFR §121.8(a)(8)
¹⁴⁶ 42 C.F.R. §121.8(d)

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 Committee will continue discussions on transition procedures as the project progresses.

Conclusion

This paper provides an update to the community about the continuous distribution of kidneys project, including the OPTN Kidney Transplantation Committee's (the Committee) continued efforts to incorporate expanded efficiency objectives, with consideration for the balance in equity and utility in the match run order and operational aspects of allocation, such as expedited placement.

Specifically, this update summarizes and seeks relevant feedback on the Committee's recent efforts to expand non-use and efficiency related modeling capabilities, establish a pathway for the expedited placement of "hard to place" kidneys, and further develop a preliminary, data driven definition of "hard to place." This paper also provides an overview of the Committee's next steps towards finalizing the Continuous Distribution of Kidneys project. Finally, the appendix paper also provides a comprehensive, collected overview of the Committee's relevant discussions and decisions regarding each attribute, rating scales, and various weight combinations the Committee has considered to date.

Considerations for the Community

The Committee seeks feedback regarding the following continuous distribution topics and questions:

- Which, if any, of the following efficiency modifications do you support including in kidney continuous distribution? Are there additional considerations or concerns the Committee should examine regarding these potential modifications?
 - Adjustments to the proximity efficiency rating scale
 - Additional donor modifiers for "hard to place" kidneys
 - Attribute-attribute interaction incorporating distance
 - Re-evaluating high KDPI consent for "hard to place" kidneys
 - Inverse qualifying time for "hard to place" kidneys
 - "Likelihood of acceptance" attribute
- Do you support the factors identified by the Committee to develop a preliminary definition of "hard to place?"
 - Are there additional factors for the Committee to consider?
 - Are there any factors that should be removed from this definition?
- Please provide feedback on the expedited placement framework, either with individual elements or overall, currently in development by the Kidney Expedited Placement Workgroup:
 - Should the framework use historical organ offer acceptance patterns to qualify transplant programs to participate in expedited placement?
 - Which expectations for transplant programs and OPOs should be written into an expedited placement policy, as opposed to guidance?

Appendix A: 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.¹⁴⁷

Figure 1 shows how allocation goals combine into a composite allocation score (CAS).¹⁴⁸ 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 2 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.

 $^{^{\}rm 147}$ 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.

¹⁴⁸ Continuous Distribution of Kidneys and Pancreata Concept Paper, OPTN Kidney and Pancreas Transplantation Committees, August 2021.





Figure 2: Example of a Composite Allocation Score Match Run¹⁴⁹

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.¹⁵⁰ In **Figure 2**, 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.

¹⁴⁹ 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.

¹⁵⁰ 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.

Appendix B: Attributes and Rating Scales

To date, the Committee has identified 10 attributes across the five continuous distribution goals of medical urgency, post-transplant survival, reducing biological disadvantages, improving patient access, and improving efficiency of organ placement. This appendix includes an overview of each attribute and the most updated rating scale developed for each attribute. These attributes and rating scales are summarized in **Table 1**.

Attributes	Goal	Rating Scale	
Medical Urgency	Medical Urgency	Binary	
HLA Matching	Post-Transplant Survival	0, 1, or 2 DR Mismatch	
Longevity Matching	Post-Transplant Survival	0-20% EPTS Priority for 0-20%	
		KDPI Kidneys	
Blood Type	Candidate Biology	Current Screening and	
		Candidate-per-Donor Points	
CPRA	Candidate Biology	Optimized, Steep Non-Linear	
		Curve	
Prior Living Donors	Patient Access	Binary	
Pediatrics	Patient Access	Binary	
Safety Net Kidney	Patient Access	Binary	
Waiting Time	Patient Access	Linear, Exceeds 100% Beyond	
		10 Years	
Proximity Efficiency	Placement Efficiency	Piecewise Linear	

Table 1: Kidney Continuous Distribution Attributes and Rating Scales

Goal: Medical Urgency

Attribute: Kidney Medical Urgency

The current kidney allocation system prioritizes medically urgent candidates, defined as those candidates who have lost or face imminent loss of dialysis access. These candidates currently receive priority via the "medically urgent" classification, as well as additional points within this classification for time at status. The kidney medical urgency attribute is the sole attribute in the medical urgency goal.

The Kidney Committee's Kidney Medical Urgency Workgroup considered minor modifications to the kidney medical urgency definition in OPTN Policy *8.5.A.i: Kidney Medical Urgency*, to support straightforward qualification for medical urgency in cases of loss of dialysis, and use of review board exception request pathways for other potentially medically urgent cases.¹⁵¹ The Committee will continue this effort as they work to finalize the continuous distribution proposal.

Rating Scale: Binary

The Kidney Medical Urgency attribute will utilize a binary rating scale, as candidates either meet the definition of medical urgency and thus qualify to receive priority, or otherwise are not considered

¹⁵¹ OPTN Kidney Medical Urgency Workgroup Meeting Summary, August 14, 2023.

 $https://optn.transplant.hrsa.gov/media/rt2gcn0w/20230814_kidney-medical-urgency-wg-summary.pdf$

medically urgent. Candidates who met the medical urgency definition will receive 100% of possible medical urgency points. The incoming Kidney Review Board will review medically urgent cases individually, and determine whether the candidate qualifies as medically urgent per the definition established in OPTN Policy *8.5.A.i: Kidney Medical Urgency*.

Goal: Post-Transplant Survival

Attribute: Human Leukocyte Antigen (HLA) Matching

Current kidney allocation prioritizes 0-ABDR mismatch in combination with CPRA, estimated posttransplant survival (EPTS), pediatric status, and distance from the donor hospital across several classifications. Current policy also awards candidates points for being a 0-ABDR mismatch, as well as level of DR-mismatch. HLA matching is prioritized in kidney allocation due to proven impacts to improved patient and graft outcomes when candidates and donors are well matched, particularly at the A, B, DQ, and DR locus.

The Workgroup discussed matching at the A, B, DR, and DQ loci, and evaluated these loci as part of their data request investigating the impact of HLA Matching on Graft Failure in Kidney Transplant Recipients. The results of this request found that mismatches at the DR locus are most strongly associated with hazard of graft failure. Compared to two DR-mismatches, one DR mismatches was associated with a 10.7% lower hazard of any-cause graft failure, and having zero DR mismatches was associated with a 15.4% lower hazard of any-cause graft failure.

Rating Scale: DR-Mismatch

The Kidney-Pancreas Continuous Distribution Workgroup recommended awarding points based on level of DR-mismatch, and developed a rating scale derived on the associated effects of DR mismatch on longevity. Candidates receive 100% of potential HLA-matching points for a zero DR-mismatch, 70% of points for one DR-mismatch, and zero points for two-DR mismatches. This rating scale is demonstrated in **Figure 2**.



Figure 2: Kidney HLA Matching Rating Scale

Attribute: Longevity Matching

Current kidney allocation priorities candidates with EPTS 0-20% for kidneys with KDPI 0-20%, also known as top 20-top 20 matching. The EPTS score is used to predict a candidate's projected longevity with a functioning graft post-transplant, while the KDPI score aims to estimate the quality of deceased donor kidneys relative to other recovered kidneys. Pediatric candidates do not currently receive an EPTS score, though they are currently highly prioritized for KDPI 0-20 kidneys as well.

Longevity matching was first incorporated into the kidney allocation system to reduce unrealized graft years and reduce returns to the waitlist for younger candidates and recipients, thus improving post-transplant outcomes.

Rating Scale: KDPI and EPTS Matching

The Committee explored several rating scales expanding the scope of longevity matching in continuous distribution, including a continuous longevity matching scale that simulated lower transplant rates for 35-50 year old candidates and increased graft failure rates in older kidney recipients. Public comment feedback on expanded longevity matching was mixed, with commenters noting the limitations of EPTS and KDPI. Due to this lack of clear community consensus and potentially major shifts in transplant distributions, the Committee decided to utilize a rating scale mirroring the current top 20-top 20 EPTS/KDPI matching. Thus, the longevity matching rating scale assigns 100% of the longevity matching points to EPTS 0-20% candidates for KDPI 0-20% organs.

Goal: Reducing Biological Disadvantages

Attribute: Blood Type

Kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with prioritization for blood types O and B to provide equity in the system.¹⁵² In current kidney allocation, blood type O kidneys are reserved for blood type O recipients because of biological disadvantages in finding compatible donors.¹⁵³

Rating Scale: Screening and Blood Type Compatibility Points

The Kidney Committee supported maintaining current blood type screening rules, to ensure access to transplant for blood type O and blood type B candidates who may have increased difficulty finding a medically compatible donor compared to other blood types. The blood type rating scale will also assign candidates points based on their probability of compatibility. This is done by calculating the volume of candidates per compatible donor utilizing current policy's blood type screening rules. For example, a larger number of candidates per donor indicates increased competition for a compatible organ, and potentially decreased access to transplant; in this case, the candidates with a higher candidate-perdonor value blood type would receive greater priority.

¹⁵² OPTN Policy 8.5.D: Allocation of Kidneys by Blood Type as of October 7, 2021.

¹⁵³ Based on OPTN Data as of April 23, 2021.

Attribute: Calculated Panel Reactive Antibody (CPRA)

Current kidney allocation policy prioritizes candidate sensitized through classifications and using points within classifications. This prioritization grants harder to match candidates increased priority for those donors that may be medically compatible, as these candidates are expected to rarely receive a potentially compatible offer. Current allocation policies prioritize the most highly sensitized candidates (100% CPRA) on a national level, and CPRA 99% and 98% candidates within 250 nautical miles. Current policy also assigns candidates points, to prioritize candidates within classifications, based on level of sensitization. These points are currently assigned on an exponential scale, with a maximum of 202.10 points for 100% CPRA candidates.

Rating Scale: Optimized Curve

The Committee's initial exponential rating showed a decrease in access for the most highly sensitized patients across all continuous distribution scenarios, particularly for candidates with a CPRA of 99.9% or greater. To address this, the Committee worked with MIT to optimize a new CPRA rating scale accounting for steep differences in likelihood of matching across CPRA groups The new optimized CPRA rating scale assigns some priority for candidates with CPRA 90-99.90%, with a steep increase in priority for candidates with CPRA 99.99-100% receive the maximum number of potential CPRA points. The optimized CPRA rating scale is shown in **Figure 3**.



Figure 3: Optimized CPRA Rating Scale

Goal: Improving Patient Access

Attribute: Safety Net Kidney (Prior Liver, Heart, or Lung Recipient)

Current policy prioritizes kidney-after-liver, kidney-after-lung, and kidney-after-heart priority to qualifying candidates via a specific prior liver, heart, or lung classification. This priority is also called "safety net kidney" priority. In order to qualify for safety net kidney priority, candidates must meet the requirements laid out in Policy 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List, Policy 8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List, and Policy 8.4.H: Prioritization for Lung Recipients on the Kidney Waiting List.

Rating Scale: Binary

The Committee supports a binary rating scale for this attribute, such that qualifying candidates receive 100% of potential safety net kidney points, and non-qualifying candidates receive zero points.

Attribute: Pediatric Priority

Current kidney allocation prioritizes pediatric kidney candidates in specific pediatric classifications for kidneys with a KDPI of 34or less.

Rating scale: Binary

The Committee supports a binary rating scale for pediatric priority, such that candidates registered prior to their 18th birthday, and candidates 18 and older at time of registration receive no pediatric priority points. The Committee plans to expand pediatric prioritization for donors with a KDPI between 35-85%, particularly as some small, younger donors who may be appropriate pediatric size matches may have KDPI scores higher than 34%.

Attribute: Prior Living Donor Priority

Current kidney allocation grants all prior living donors priority on the kidney match run, with the exception of vascularized composite allograft (VCA) and domino living donors. The OPTN Ethics and Living Donor Committees have noted both ethical and legal justifications for prior living donor priority across all organ types, regardless of the organ donated.¹⁵⁴

Rating Scale: Binary

The Committee supports a binary rating scale, such that prior living donors will receive 100% of prior living donor priority points, and non-prior living donors receive no prior living donor points.

Attribute: Qualifying Time

Current kidney allocation policy prioritizes qualifying time via points, which sort candidates within classifications. Candidates receive points in a linear fashion, such that each additional day of waiting time is worth the same as any other additional day.

Rating Scale: Linear, Exceeds 100% Beyond 10 Years

The Kidney Committee supports a linear rating scale with no ceiling, noting that this option is the most equitable for candidates with substantial waiting times who may have had issues in accessing

¹⁵⁴ OPTN Living Donor Committee. 2021, 12 May. Living Donor Committee Meeting Summary.



transplant.¹⁵⁵ After reviewing data on the average waiting times for kidney candidates showing that 90 percent of candidates have waiting times less than 10 years, the Kidney Committee determined that candidates would receive 100 percent of qualifying time points at 10 years of waiting time. Because this rating scale has no ceiling, candidates may receive more than 100 percent of qualifying time points if their waiting time surpasses 10 years. This is demonstrated in **Figure 4**.



Figure 4: Kidney Qualifying Time Rating Scale

Goal: Improving the Efficiency of Organ Placement

Attribute: Proximity Efficiency

The OPTN Final Rule requires that geographic proximity may only be considered to the extent necessary to satisfy other requirements in the Final Rule, including efficient management of organ placement and the avoidance of futile transplants due to increased ischemic time.¹⁵⁶

Rating Scale: Piecewise Linear

The Committee supports a piecewise linear rating scale, with 100% of proximity points assigned through the first 50 nautical miles (NM) around the donor hospital, 85% of points at 250 NM from the donor hospital, 25% of proximity points at 500 NM, and 0% of points at 5181 NM. The proximity efficiency rating scale is demonstrated in **Figure 5**.

¹⁵⁵ Meeting summary for April 1, 2022 meeting, OPTN Kidney Transplantation Committee ¹⁵⁶ 42 CFR 121.8(a)(8).







Appendix C: Modeling Goals and Recently Optimized Weights

Previously, the Committee established the following goals for optimization of policies:

- Minimize waitlist mortality
- Minimize 1-year graft failure
- Minimize blood type transplant rate disparity
- Minimize geographic transplant rate disparity
- Minimize racial transplant rate disparity
- Minimize sex transplant rate disparity
- Constrain pediatric transplants to no less than current policy
- Constrain CPRA 99.90-100% transplants to no less than current policy
- Constrain average waiting time at transplant to no less than current policy
- Constrain blood type B transplants to no less than current policy
- Constrain median travel distance:
 - Policy "A2"¹⁵⁷ no greater than current policy
 - Policy "B2" no greater than 110% of current policy
 - Policy "C2" no greater than 110% of current policy
 - Policy "D2" no greater than 125% of current policy
- Constrain EPTS 0-20% transplants:
 - Policy "A2" no less than current policy
 - Policy "B2" no less than current policy
 - Policy "C2" no less than 97% of current policy
 - Policy "D2" no less than 97% of current policy

The Committee will revisit these goals and establish new goals related to non-use and efficiency as they continue modeling and optimization utilizing the new sub-models.

The relevant weight combinations for the above goals are shown in **Table 3**. The underlined attributes are the attributes for which weights vary across the optimized policies, as the Committee had set out to balance varying constraints on distance and EPTS 0-20 transplant volume.

Attribute	Policy A2 Weights	Policy B2 Weights	Policy C2 Weights	Policy D2 Weights
Medical Urgency	0.096	0.096	0.096	0.096
DR Mismatch	0.010	0.010	<u>0.016</u>	0.030
Longevity Matching	0.055	0.064	0.043	0.042
Blood Type	0.093	0.093	0.093	0.093
CPRA*	0.400	0.400	0.400	0.400
*New rating scale				
Prior Living Donor	0.096	0.096	0.096	0.096

Table 3: Re-Optimized Policy Scenarios

¹⁵⁷ Here, "A2," "B2," "C2," and "D2" are the given names of each potential policy. The initially optimized policies utilized names "A-D;" they have been renamed "A2-D2" to refer to re-optimization with updated CPRA rating scales and related adjustments.



Attribute	Policy A2 Weights	Policy B2 Weights	Policy C2 Weights	Policy D2 Weights
Pediatric Priority	0.100	0.100	0.100	0.100
Prior Liver, Heart, or	0.032	0.032	0.032	0.032
Lung Recipient				
<u>Waiting Time</u>	0.039	0.041	0.049	<u>0.051</u>
Proximity Efficiency	0.07 <u>9</u>	0.069	0.075	0.059