

Committee Update

Continuous Distribution of Kidneys Update, Summer 2024

OPTN Kidney Transplantation Committee

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Continuous Distribution of Kidneys Update, Summer 2024

Sponsoring Committee: *Kidney Transplantation*
Public Comment Period: *July 31, 2024 – September 24, 2024*

Executive Summary

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

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

This paper provides an update to the community about the continuous distribution of kidneys effort, including incorporating the Board’s efficiency objectives, as the Committee works to strike the critical balance between ensuring equity and utility.

Prior to the Board resolution, the Committee had been working to finalize weights and rating scales across 10 attributes. This update contains these discussions, as well as discussions related to continued modeling and optimization efforts, including efforts to expand modeling capabilities to include non-use and efficiency metrics. This paper also includes Committee discussions related to investigating non-use, identifying key drivers of non-use, establishing specific goals to define efficiency in continuous distribution, and developing a data-driven definition of “hard to place” kidneys. The update details the efforts of the Kidney Expedited Placement Workgroup, which is working towards the development of an expedited kidney placement policy. The Committee’s collaboration with the OPTN Expeditious Task Force on Efficiency on a range of efficiency and utilization goals, including expedited placement, is also detailed within this paper. Finally, this paper concludes with an overview of next steps for the continuous distribution of kidneys effort.

Background and Progress So Far

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 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 C**.

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} The two committees continue to inform each other of their respective efforts. The Committee has been and will continue to work with the OPTN, Scientific Registry of Transplant Recipients (SRTR), and contracted researchers from the Massachusetts Institute of Technology (MIT) to develop evidence-based rating scales and weights.

Since the start of Kidney Continuous Distribution, the Committee has identified 10 attributes (**Table 1**) across 5 goals, establishing empirically driven rating scales for each. 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.⁷ 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 Committees submitted these weights and rating scales as potential continuous distribution policies to the SRTR for an initial round of modeling in the Spring of 2022.⁸

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 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, which were submitted to the SRTR for modeling. These discussions were outlined in

¹ 42 U.S.C. Sec 273 et seq. and 42 C.F. R. part 121

² OPTN Kidney and Pancreas Transplantation Committees, "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback." July 2023 Public Comment. <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/efficiency-and-utilization-in-kidney-and-pancreas-continuous-distribution-request-for-feedback/>

³ OPTN Kidney and Pancreas Transplantation Committees, "Continuous Distribution of Kidneys and Pancreata Committee Update." January 2023 Public Comment. https://optn.transplant.hrsa.gov/media/a5glt304/continuous-distribution-of-kidneys-and-pancreata-committee-update_pc-winter-2023.pdf

⁴ 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

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

⁶ 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

⁷ OPTN Kidney Transplantation Committee Meeting Summary, April 8, 2022.

⁸ OPTN Kidney Transplantation Committee Meeting Summary, April 29, 2022.

the Committee Update released for public comment in August of 2023. The Committee’s optimized weights can be found in **Appendix B**.

Table 1: Kidney Allocation Objectives

Attributes	Goal	Modeling Objectives
Medical Urgency Definition	Medical Urgency	Maintain high priority for medically urgent patients, similar to current policy
DR Matching	Post-Transplant Survival	Maintain similar priority to current policy; Minimize graft failure
EPTS/KDPI ⁹ Matching	Post-Transplant Survival	Match low KDPI kidneys to low EPTS candidates; Maintain transplant rates for EPTS 0-20; Equalize access for EPTS 21+
Blood Type	Candidate Biology	No decrease in access, especially for O and B blood type candidates
CPRA	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
Safety Net	Patient Access	Maintain similar priority to current policy for kidney-after-liver, kidney-after-heart, and kidney-after-lung patients
Qualifying Time	Patient Access	Maximize median qualifying time at transplant
Proximity Efficiency	Placement Efficiency	Minimize distance traveled, especially for high KDPI kidneys; Relax constraint for pediatric and highly sensitized candidates

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 allocation, released kidney allocation, national kidney allocation, and the Kidney Minimum Acceptance Criteria Screening tool. With the September 5, 2023 Board resolution, the Committee shifted their efforts to incorporate new efficiency and non-use goals into the Continuous Distribution project. The Committee’s modeling, optimization, and operational efforts are described within this section below. The Committee’s incorporation of the 2023 Board resolution, including approaches to defining non-use and efficiency goals, defining “hard to place,” and consideration of expedited placement of kidneys, are described in later sections of this paper.

Modeling and Optimization

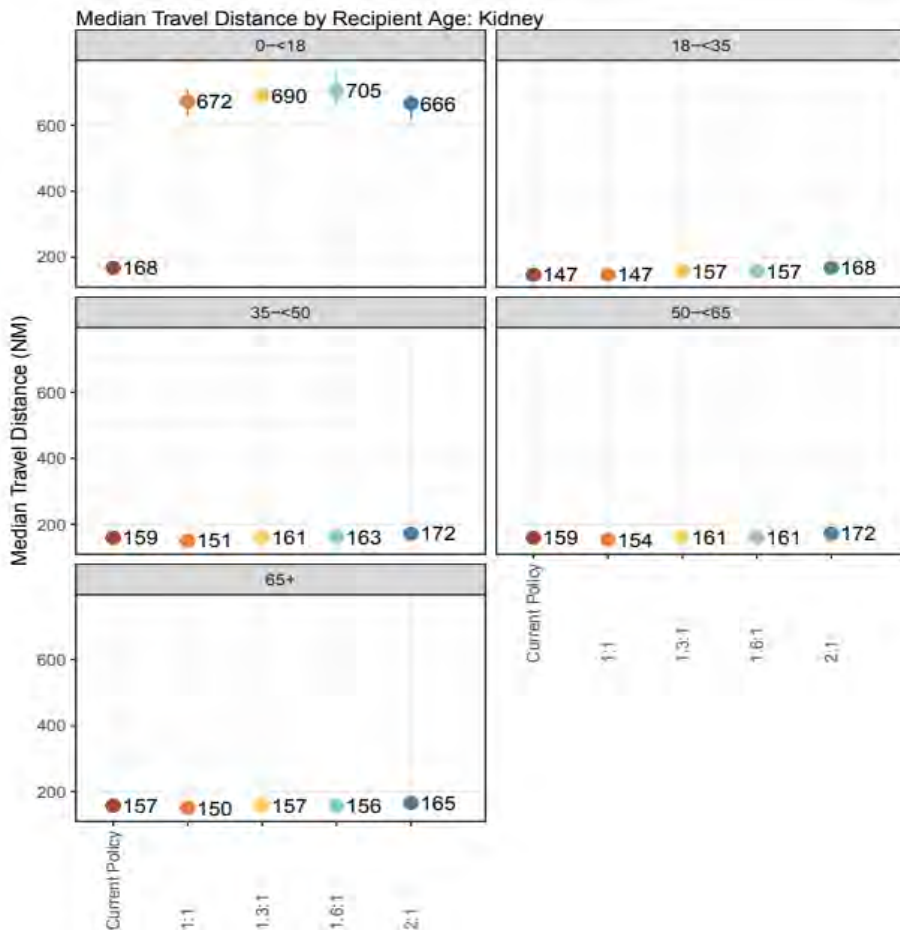
The Committee identified two key areas of concern upon reviewing the results of the second SRTR modeling request, specifically, increased travel distances for pediatric recipients and reduced transplant rates for the most highly sensitized candidates (CPRA 99.9-100 percent).

⁹ EPTS – Estimated Post-Transplant Survival; KDPI – Kidney Donor Profile Index

Reducing Pediatric Travel Distance

The SRTR’s modeling results for the optimized continuous distribution scenarios showed increases in pediatric access, but significantly increased travel distances for organs offered to pediatric candidates, particularly compared to the modeling of current policy (**Figure 1**). Both the OPTN Pediatric Transplantation (Pediatric Committee) and Kidney Committees noted that the SRTR models may be utilizing overly optimistic acceptance probabilities for long distance offers to pediatric candidates, and that programs may be realistically much less likely to accept offers from such great distances. The Pediatric Committee expressed concern for potentially dramatic increases in pediatric travel distances, noting anticipated corresponding increases in offer volumes and general inefficiency due to increased travel, including increased cold ischemic time.

Figure 1: Median Travel Distance by Recipient Age¹⁰

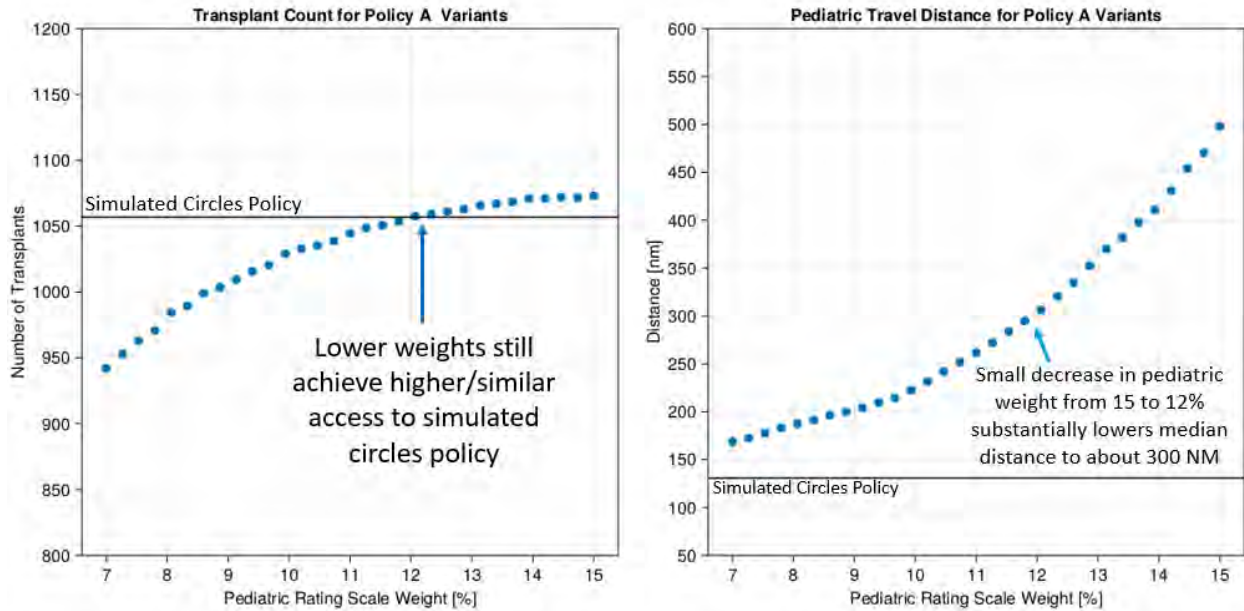


To investigate potential solutions to reduce travel distance, MIT performed additional analyses, including simulating reduced pediatric priority weight and adjusting acceptance models to account for lower likelihood of acceptance of long distance offers for pediatric candidates. MIT’s analysis found that reducing the pediatric attribute’s weight from 15% to about 12% maintains higher or similar level of

¹⁰ Scientific Registry of Transplant Recipients, “Kidney Pancreas 2023 Allocation Simulation Analysis Report.” July 11, 2023. https://optn.transplant.hrsa.gov/media/052pegrg/kipacd_2023_01_analysisreport_2023_07_17.pdf

access to transplant relative to current policy, while substantially lowering median distance traveled from 500 nautical miles (NM) to about 300 NM (Figure 2 and 3).¹¹

Figure 2: Number of Pediatric Transplants by Pediatric Priority Weight and Figure 3: Distance Traveled for Pediatric Recipients by Pediatric Priority Weight



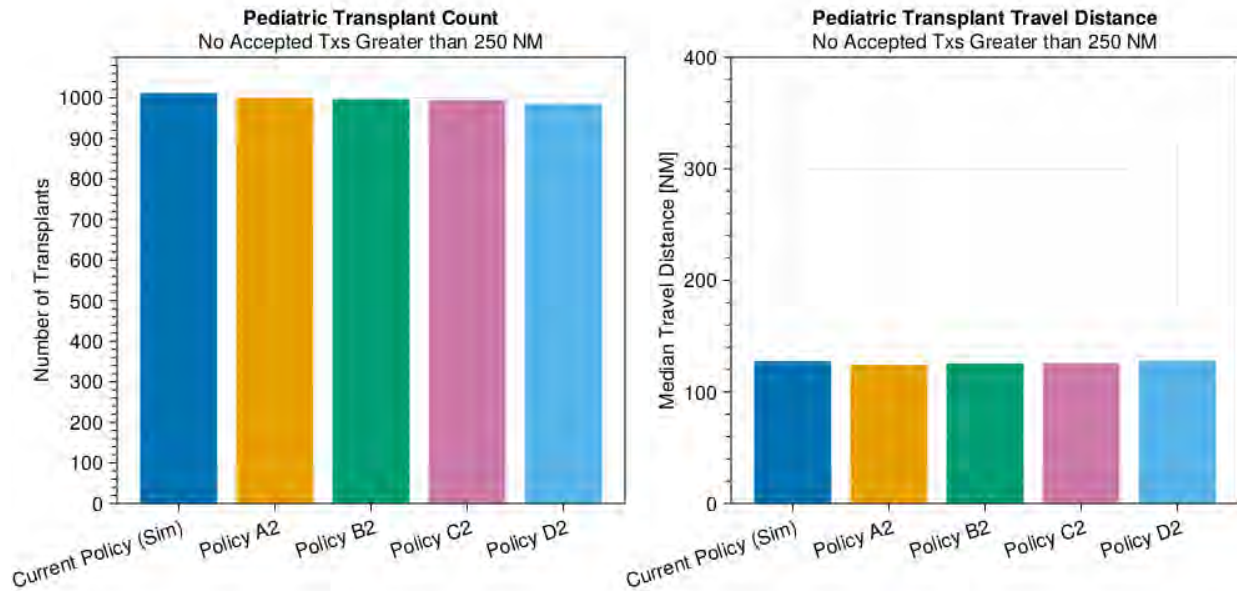
MIT’s second analysis addressing pediatric travel distances simulated the same continuous distribution scenarios, this time utilizing an acceptance model such that no program accepts any offers to pediatric candidates with a distance greater than 250 nautical miles. This simulation showed that the number of transplants does not decrease notably from current policy for any of the modeled scenarios, but that median travel distances can be reduced to align with current pediatric transplant travel distances.

Figures 4 and 5 illustrate these results. These analyses indicate that optimized policies have assigned such a high weight to pediatric priority that pediatric access can only be expanded by increasing priority for longer distance offers. Thus, these analyses also indicate that the only way to reduce pediatric travel distances is to reduce the weight on pediatric priority.¹²

¹¹ OPTN Kidney Transplantation Committee Meeting Summary, August 21, 2023. <https://optn.transplant.hrsa.gov/media/3p1d0uwp/20230821-kidney-committee-meeting-summary.pdf>

¹² OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023. <https://optn.transplant.hrsa.gov/media/5txmsrnz/20231011-kidney-committee-meeting-summary.pdf>

Figure 4: Pediatric Transplant Count by Policy Scenario, with No Acceptance for Pediatric Recipients Beyond 250 NM and Figure 5: Pediatric Transplant Travel Distance by Policy Scenario, with No Acceptance for Pediatric Recipients Beyond 250 NM



The OPTN Pediatric Committee expressed concern that lower weight for pediatric patients could reduce their priority, but supported increased screening options for pediatric candidates, particularly on a candidate-specific level.¹³ In consideration of Pediatric Committee feedback, the Committee opted not to reduce the pediatric priority attribute’s weight, noting concern for the potential to reduce the overall volume of pediatric transplants.¹⁴ The Committee commented that if pediatric weight remains the same, pediatric programs will need to utilize offer filters and candidate acceptance criteria to maximize efficiency in managing offers to pediatric patients.¹⁵ The *Optimizing Usage of Offer Filters* proposal will incorporate updates to the Offer Filters system to allow programs to make pediatric-specific filters.¹⁶ This proposal has not yet been implemented. The Committee is seeking community feedback on whether the pediatric attribute weight should be slightly reduced to achieve more reasonable median travel distance for pediatric recipients.

¹³ OPTN Pediatric Transplantation Committee Meeting Summary, August 18, 2023. https://optn.transplant.hrsa.gov/media/4qupezrk/20230818_pediatic_summary.pdf

¹⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

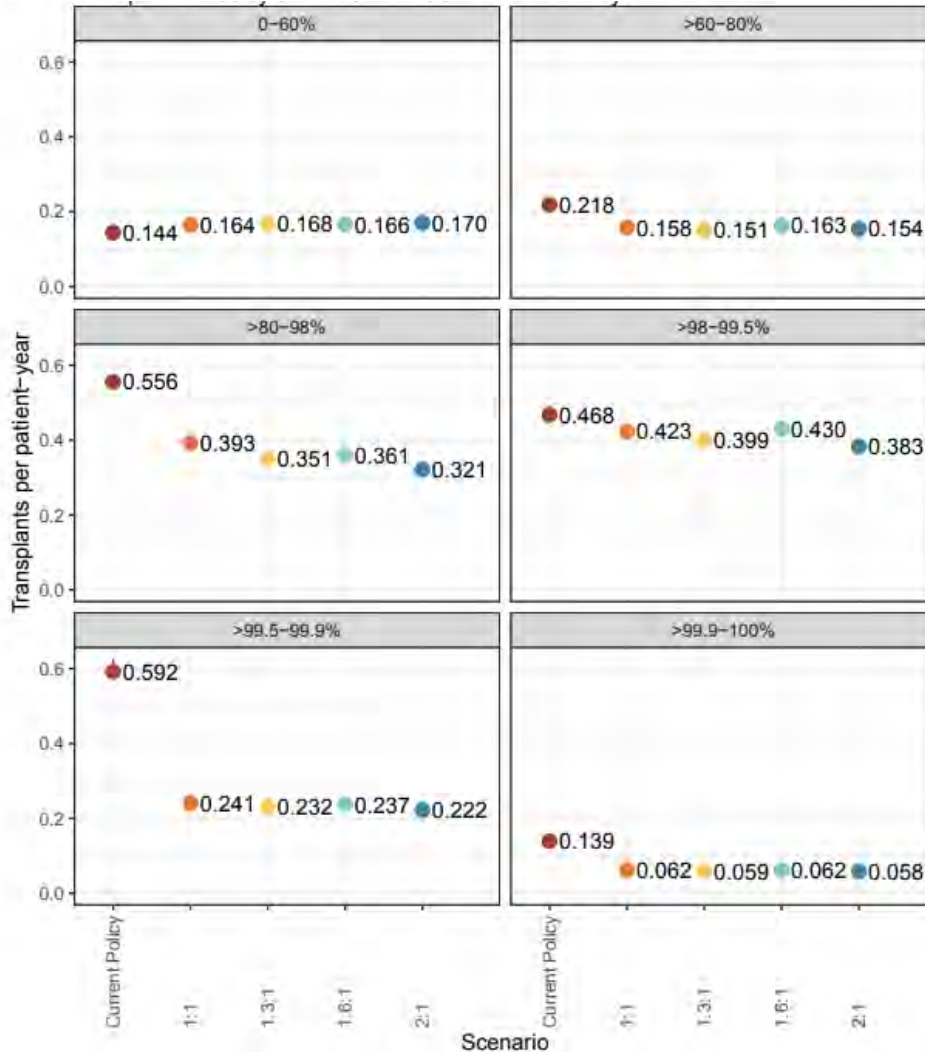
¹⁵ OPTN Kidney Transplantation Committee Meeting Summary, August 21, 2023

¹⁶ OPTN Operations and Safety Committee, *Optimizing Usage of Offer Filters*. Approved June 2023. https://optn.transplant.hrsa.gov/media/xdvgftub/osc_offer-filters_policy-notice_jun-2023.pdf

Ensuring Access for CPRA 99.9% and Greater

OASim results showed a decrease in access for the most highly sensitized patients across all continuous distribution scenarios compared to modeled current policy, particularly for patients with CPRA 99.9% or greater, as shown in **Figure 6**.

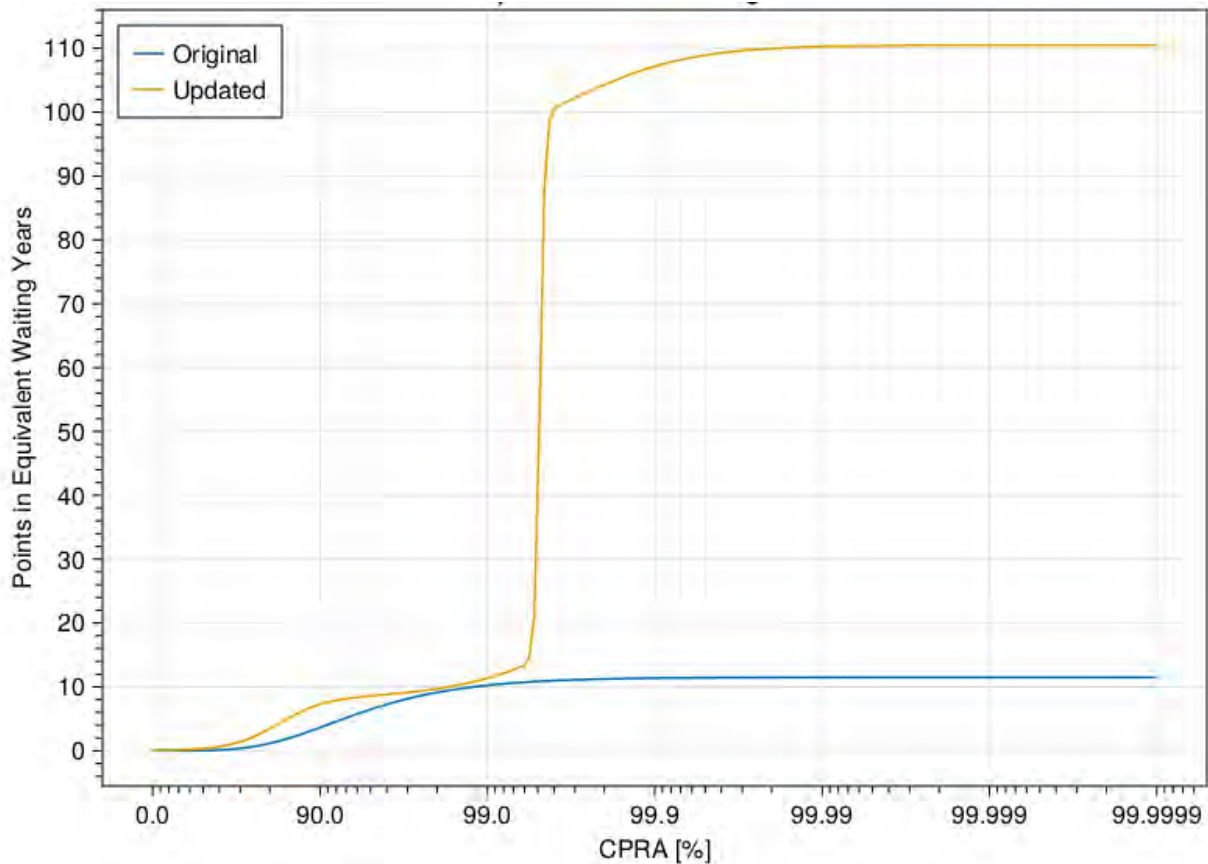
Figure 6: Transplant Rates by CPRA at Cohort Start by Policy Scenario



In consideration of potential solutions to address this, MIT’s optimization model simulated increased weight for the CPRA attribute, as well as a new, optimized CPRA rating scale aimed at achieving both of the Committee’s allocation objectives for the CPRA attribute. MIT’s model showed increased transplant rates for the most highly sensitized when increasing the CPRA attribute weight from 7% to 44%. These increases were complemented by significant increases in transplant rates for CPRA 80-98% and CPRA 98-99% groups, which have relatively high access in modeled current policy compared to other CPRA

groups. To address this, MIT optimized a new CPRA rating scale, shown in **Figure 7**, which accounts for steep differences in clinical access (likelihood of matching) across CPRA groups.¹⁷

Figure 7: Optimized CPRA Rating Scale



MIT's modeling utilizing the new optimized CPRA rating scale showed some priority for candidates with CPRA 90-99.90%, and a steep increase in priority for candidates with CPRA 99.90%-99.99%. Those candidates with a CPRA 99.99-100% receive the maximum number of points. MIT simulated this optimized rating scale with a high CPRA attribute weight and found that this rating scale achieves maximum access for the most highly sensitized while decreasing differences between other CPRA groups. It is important to note that simulators are limited in accuracy with respect to CPRA, as the population of the most highly sensitized is very small. As a result, simulators will inherently overestimate the transplant rate for certain CPRA groups. The optimized rating scale addresses this by aligning closely with priority given in current policy, which maximizes access for the most highly sensitized.

The Committee agreed that decreased access for CPRA 80-98% and 98-99% groups is tolerable in the interest of equalizing transplant rates across CPRA groups. The Committee supported the optimized rating scale, noting that this scale will help ensure the most highly sensitized candidates maintain their high priority on match runs for the few donors with whom they are a match.¹⁸

¹⁷ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

¹⁸ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

Further Policy Optimization

The initial optimized policy scenarios utilized the Committee’s initial CPRA rating scale; the incorporation of the new rating scale for CPRA required re-optimization of weights to ensure the Committee’s modeling goals can be achieved. MIT collaborators incorporated the optimized CPRA rating scale to optimize four new potential continuous distribution scenarios. These newly optimized policy scenarios can be found in **Appendix B**, and identified below as A2, B2, C2, and D2. The newly optimized policy scenarios utilized the same optimization constraints for waiting time, longevity matching, and proximity that were incorporated in the initial optimized policy scenarios.¹⁹

MIT’s simulation of the newly optimized policies showed similar outcomes across all policies for number of transplants, waitlist mortality, and 1-year graft failure. The newly optimized policies achieve similar variations in median travel distance, geographic disparity, waiting time at transplant, and EPTS 0-20 transplant volume as achieved by the initial optimized policies. The newly optimized policies resulted in similarly reduced blood type disparities, racial transplant rate disparities, and shifts in sex and ethnicity transplant rate disparities, as shown in **Figure 8**.

Figure 8: Transplant Rate Disparities by Optimized Policy

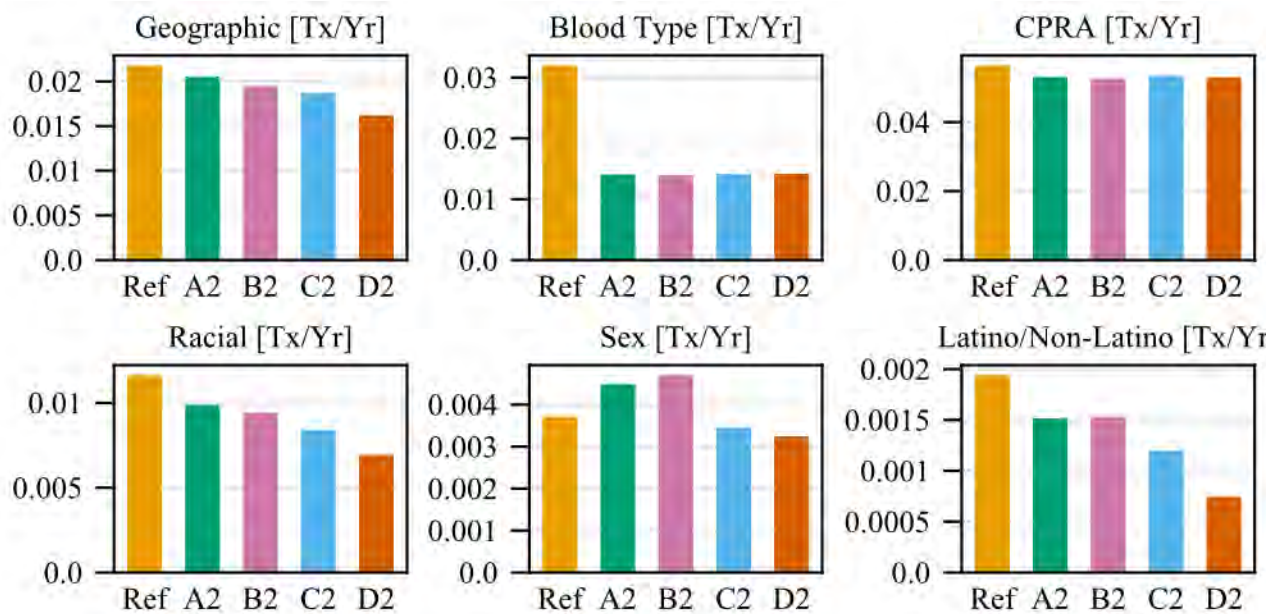


Figure 8 shows transplant rate disparities modeled for the current policy and four newly optimized policy, named A2, B2, C2, and D2. “Ref” refers to current policy, which is used as a reference. From right to left, top to bottom, the disparities metrics measured include geographic disparity, blood type disparity, CPRA disparity, racial disparity, sex disparity, and ethnicity disparity. Here, a shorter bar indicates a potential improvement in equity. Please note the relative scale of each graph.

The CPRA transplant rate disparity is slightly improved across all newly optimized policies, with the newly optimized policies demonstrating similar transplant rates across CPRA groups to current policy by

¹⁹ For more information on the development of the initial policy scenarios, please refer to the July 2023 *Continuous Distribution of Kidneys and Pancreata Committee Update*, linked here: https://optn.transplant.hrsa.gov/media/gh4lcghi/kipa_cd-oasim-resource_pcsummer2023.pdf

design, due to previously discussed limitations in modeling transplant rates across CPRA groups (Figure 9). MIT’s simulation shows that policies A2, B2, C2, and D2 met the Committee’s goals, with discussion still open for distant pediatric offers and equalizing access across CPRA groups.²⁰ The Committee seeks community feedback on these considerations, particularly with respect to reducing pediatric travel distances.

Figure 9: Transplant Rate by CPRA Group



Efficiency and Utilization in Modeling

The Committee continues to work with the SRTR and MIT to investigate and expand modeling capabilities with respect to efficiency and utilization. In February, the Committee submitted a request to the SRTR to update their model, known as the Organ Allocation Simulator (OASim), to incorporate utilization-related research questions.²¹ These questions ask the OASim to demonstrate how the proposed policies impact the following additional focus areas (along with previous metrics):

- Utilization and non-use of deceased donor kidneys
- Timing and sequence number at acceptance, including modeled increases in organs accepted after sequence 100
- Cold ischemic time
- Equity in access – demographics of candidates accepting high KDPI kidneys

The SRTR will report back to the Committee on the feasibility of incorporating these research questions into the OASim, with consideration for the model’s overall accuracy and accuracy with respect to individual non-use questions.²²

²⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

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

²² *Ibid.*

Operational Considerations

The OPTN Kidney and Pancreas Committees have also collaborated in their efforts to develop and transition operational considerations outside of the composite allocation score, working together as the Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup 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*.²³ The Committee will continue to incorporate community feedback in the transition of these operational considerations, including finalized solutions for released kidney allocation, the kidney minimum acceptance criteria screening tool (KIMAC), and dual kidney allocation.

The Kidney and Pancreas Review Boards Workgroup collaboratively developed frameworks for respective organ-specific review boards and forwarded the recommendations to the Kidney and Pancreas Committees for endorsement. The Kidney Committee supported this Review Boards framework, outlined in **Appendix B**, pending additional discussions on monitoring and the establishment of a policy threshold for transplant at denied status.²⁴

Efficiency in Continuous Distribution

Committee Approach to Non-Use

On September 5, 2023, the Board approved a resolution (the resolution) directing the Kidney and Pancreas Committees to incorporate the following goals into the Continuous Distribution project:²⁵

- Decreased non-use/non-utilization of kidneys and pancreata
- Decreased out of sequence allocation of kidneys
- Consideration of expedited placement pathways for kidneys at high risk of non-use

Prior to the Board resolution, the primary goal of the Kidney Continuous Distribution effort was to transition allocation to a points-based framework with minimal disruption to the kidney transplantation system. The resolution introduced new objectives into the Continuous Distribution effort regarding non-use, allocation out of sequence, and expedited placement.²⁶

The Committee's initial discussions to incorporate these objectives aimed to understand trends in non-use and identify drivers of non-use. These discussions emphasized the breadth and complexity of non-use, noting many potential drivers of non-use that may require multiple approaches and solutions, including those out of the scope of the Continuous Distribution project. In consideration of this, the Committee's identification of potential drivers of non-use also included the development of several recommendations for consideration by the OPTN Task Force, which are detailed below.

The Committee's discussions to understand non-use informed their approach to incorporate the Board resolution's goals into the existing Continuous Distribution effort. This approach outlined two key foundational tasks:

²³ OPTN Kidney and Pancreas Transplantation Committees, "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback." July 2023 Public Comment.

²⁴ OPTN Kidney Transplantation Committee Meeting Summary, August 21, 2023.

²⁵ OPTN Board of Directors Meeting Summary, September 5, 2023. https://optn.transplant.hrsa.gov/media/cr5ft5sj/20230905_board-of-directors_meeting-summary.pdf

²⁶ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2024.

1. Develop Continuous Distribution-specific efficiency goals and considerations, including metrics
2. Develop a data driven, consensus definition of “hard to place”

Defining efficiency goals and specific associated metrics allow the Committee to communicate how their efforts will address decreasing non-use and allocation out of sequence within a Continuous Distribution system. Furthermore, a consensus definition of “hard to place” will allow the Committee to identify which organs may be at increased risk of non-use and develop approaches to improve likelihood of transplant, including alternate and expedited allocation pathways.

The Committee’s discussions to address the Board directive, including understanding and identifying drivers of non-use, defining and incorporating specific efficiency goals, developing a data driven definition of “hard to place” kidneys, and collaboratively exploring a kidney expedited placement pathway, are detailed below.

Collaboration with the OPTN Expeditious Task Force on Efficiency

The OPTN Board resolution was approved shortly before the OPTN Board of Directors’ creation of the OPTN Expeditious Task Force on Efficiency (the Task Force). The Task Force was created to study, evaluate, and make recommendations on ways to increase the number of donated organs used for transplant and to increase the efficiency of the organ placement process. Given the alignment between the Task Force’s goals and those specified in the OPTN Board directive, the Committee has collaborated and coordinated with the OPTN Task Force as it works to incorporate and consider these efficiency goals. Both the Committee and the Task Force have been kept abreast of each other’s respective efforts and progress. The Committee received Task Force updates, and similarly shared updates on their work with the Task Force, including the results of the Committee’s preliminary data request investigating the current state of non-use and clinical characteristics associated with non-use. One member of the Kidney Committee is also a member of the Task Force, and the Committee’s visiting Board Member for the 2023-2024 session has participated in both Kidney Committee and Task Force discussions.

While the Committee remains focused on items within the scope of Continuous Distribution, the Committee’s discussions regarding efficiency and drivers of non-use included a number of recommendations and considerations for the OPTN Task Force to contemplate. The Committee also provided feedback to the Task Force on the *Expedited Placement Variance* policy proposal, as well as the first protocol submitted under this variance policy, the *Accelerated Placement of Hard-to-Place Kidneys* protocol.^{27,28} The Committee’s recommendations were developed during early discussions to understand drivers of non-use and identify potential solutions. The Committee’s recommendations and further collaboration with the Task Force are detailed in the sections below.

Kidney Continuous Distribution Efficiency Components Prior to Board Resolution

Prior to the Board resolution, proximity efficiency and donor modifiers were the primary efficiency-specific elements impacting the allocation algorithm. The proximity efficiency attribute prioritizes candidates based on distance to the donor hospital, with increasing distance decreasing priority, utilizing as piece-wise linear rating scale. The rating scale has a relative decrease in priority changing based on the distances at which the organ would be expected to drive or fly, or if the organ is in the “uncertainty zone,” where either driving or flying may be appropriate. Donor modifiers allow the weights of different attributes to vary based on donor characteristics. This includes increasing the weight on proximity

²⁷ OPTN Kidney Transplantation Committee Meeting Summary, January 19, 2024.
https://optn.transplant.hrsa.gov/media/0rkba3co/20240119_kidney_summary.pdf

²⁸ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024.

efficiency for high KDPI kidneys in order to reduce travel distance, while reducing priority for pediatric candidates and prior living donors for high KDPI kidneys. The Committee notes that it is expected that pediatric and prior living donor candidates are not expected to accept these organs, as these candidates are highly prioritized on lower KDPI matches.

Other operational components impact allocation efficiency in the continuous distribution framework, including dual kidney allocation, released kidney allocation, modification to national kidney offer requirements, kidney minimum acceptance criteria screening (KiMAC) and other filtering tools.²⁹ Dual Kidney allocation provides an alternate allocation pathway for high KDPI and other “hard to place” kidneys.³⁰ Released kidney allocation provides a released organ “rescue” allocation pathway.³¹ As previously described in the *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback*, released kidney allocation in continuous distribution may incorporate additional functionalities to reduce duplicative offers in allocating released organs.³² The Committee also agreed to remove the requirement for OPOs to turn over allocation of kidneys more than 250 nautical miles away from the donor hospital to the OPTN Organ Center. OPOs would still be able to request assistance at their own discretion. As part of this transition, the Committee plans to update the KiMAC screening tool by streamlining the screening criteria and automating application of the screening tool in the OPTN Donor Data and Matching system.³³ As a result of changes to allocation policy, offer filters, candidate specific waitlist acceptance criteria, and predictive analytics would also be impacted. The Committee continues to work towards finalizing these operational components.

In evaluating the efficiency-specific components of Kidney Continuous Distribution, the Committee agreed that incorporation of the Board’s efficiency goals will require modifications to the composite allocation score, potentially developing new attributes, and the provision of additional operational considerations, including expedited placement.³⁴

Understanding Non-Use and Identifying Potential Drivers

The Committee’s initial discussions to understand non-use included a brief data review, including:³⁵

- Non-use and efficiency metrics from the circles-based kidney allocation monitoring report
- Non-use rates over time by KDPI
- Non-use reasons over time
- Late turn downs and cold ischemic time trends
- Trends in allocation out of sequence
- Offer filters use

The Committee’s discussions were later supplemented by an extensive literature review and an in-depth data report describing distributions of donors over time and 2022 non-use rates by donor characteristics.^{36,37} This data report also evaluated match runs to determine whether certain donor

²⁹ OPTN Kidney and Pancreas Transplantation Committees, “Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback.” July 2023. https://optn.transplant.hrsa.gov/media/4450bik1/kipa_cd_rff_pcsummer2023.pdf

³⁰ OPTN Policy 8.5: Allocation of a Both Kidneys from a Single Deceased Donor to a Single Candidate.

³¹ OPTN Policy 8.7: Allocation of Released Kidneys.

³² OPTN Kidney and Pancreas Transplantation Committees, “Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback.” July 2023.

³³ *Ibid.*

³⁴ OPTN Kidney Transplantation Committee Meeting Summary, September 18, 2023.

<https://optn.transplant.hrsa.gov/media/w2hivxhq/20230918-kidney-committee-meeting-summary.pdf>

³⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

³⁶ Dolan, Bradbrook, and Martinez, “Hard to Place Kidneys Data Request.” OPTN Kidney Transplantation Committee, February 21, 2024

³⁷ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

characteristics are associated with allocation further down the match run, indicating more effort and difficulty in placement for those characteristics.³⁸ The bibliography for the Committee’s literature review can be found in **Appendix D**.

The Committee’s data review confirmed the trend in increasing non-use, particularly between 2020 and 2023 (**Figure 10**). Kidneys with KDPI 35-85% and 86-100% particularly saw increases in non-use, as shown in **Figure 11**.

Figure 10: Non-Use Rate of Deceased Donor Kidneys Recovered in the United States by Recovery Year³⁹

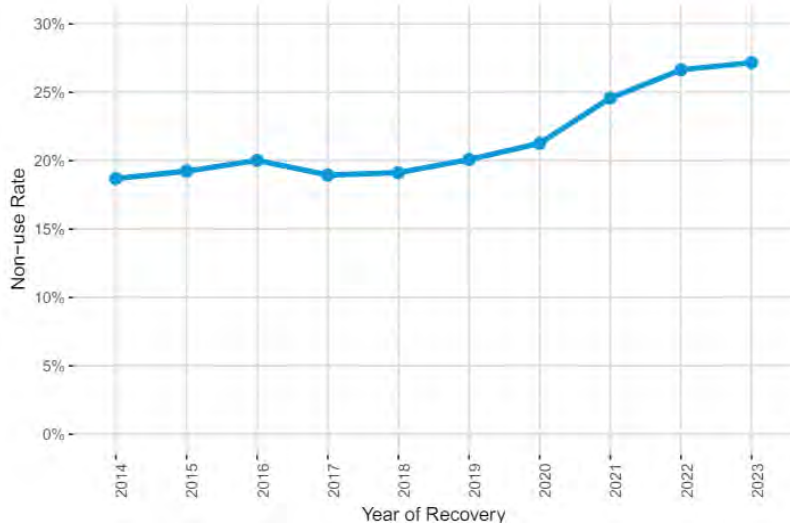
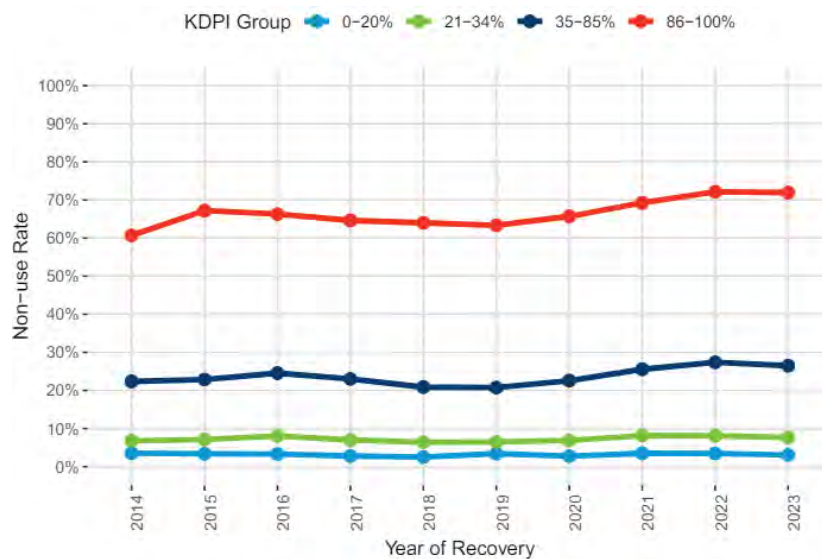


Figure 11: Non-Use Rate of Deceased Donor Kidneys Recovered in the United States by Recovery Year and KDPI Group⁴⁰



³⁸ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

³⁹ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

⁴⁰ *Ibid.*

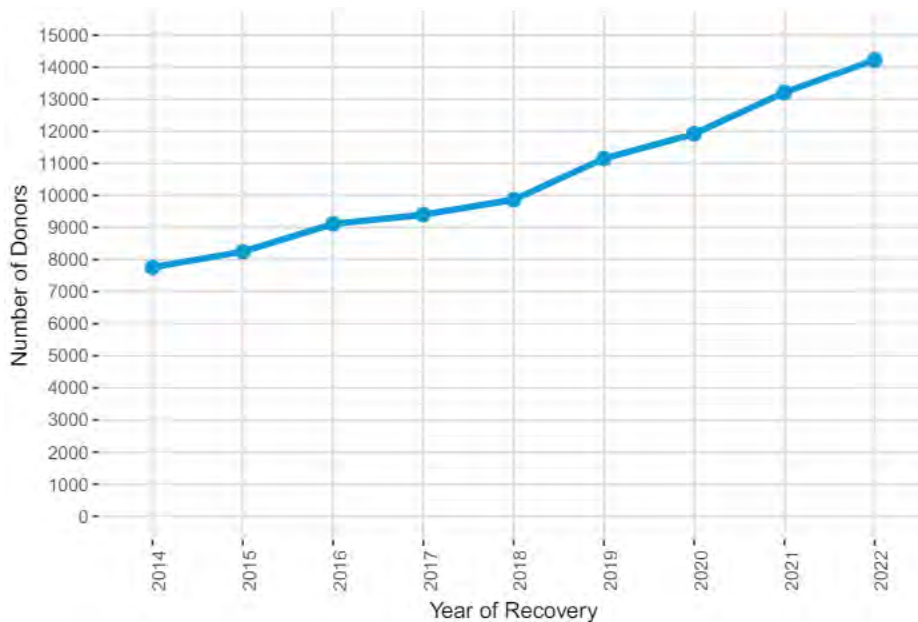
The Committee identified several potential drivers of non-use, recommendations, and options to address these drivers, in addition to several key considerations. The Committee emphasized the complexity of non-use, noting that addressing some drivers may be out of the scope of the Continuous Distribution effort, allocation policy, the Kidney Committee, and in some cases, the OPTN.⁴¹ The drivers and considerations identified and detailed below include:

- Shifting donor populations
- Allocation inefficiency
- Offer evaluation inefficiency
- Logistics
- Stakeholder coordination
- Shared decision making

Shifting Donor Populations

The Committee pointed to recent shifts in OPO practices, as OPOs have worked to increase the organ supply.⁴² **Figure 12** demonstrates the consistent increase in kidneys recovered, year over year.⁴³

Figure 12: Number of Deceased Donor Kidneys Recovered in the United States by Recovery Year



In response, the Committee noted that OPOs have begun to pursue increasingly medically complex donors, and that often these medical complexities contribute to concerns for graft function and longevity.⁴⁴ The Committee referenced Stewart et al.’s study “Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States,” which found that increases in non-use rates

⁴¹ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁴² Ibid.

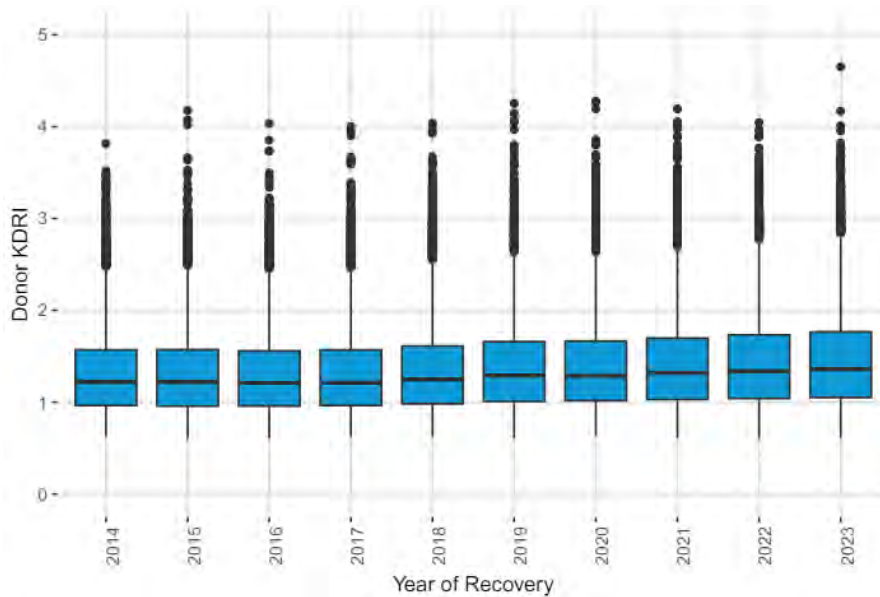
⁴³ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

⁴⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

in the early aughts could largely be attributed to shifting donor populations, with medically complex organs being recovered at greater rates than transplanted.⁴⁵

The Committee remarked that similar shifts in the donor population could be contributing to non-use rates, as OPOs recover more medically complex kidneys than programs may be comfortable transplanting.⁴⁶ The Committee’s data review identified trends in the donor population that may support this, with the donor population becoming older, with greater incidence of cancer history, hypertension history, and diabetes history. **Figure 13** demonstrates the steady increase in donor KDRI over time, with median donor KDRI reaching a high of 1.360 in 2023.⁴⁷

Figure 13: Distribution of Deceased Kidney Donors Recovered in the United States by Recovery Year and Donor KDRI⁴⁸



Specifically, the following shifts in the donor population occurred between 2014 and 2023:⁴⁹

- Proportion of donors aged 50 years or older increased from 32.6% to 39.9%
- Proportion of donors with a history of cancer increased from 2.8% to 3.8%
- Proportion of donors with a known history of hypertension increased from 30.6% to 37.1%
- Proportion of donors with a history of diabetes increased from 9.66% to 14.41%
- Proportion of DCD donors increased from 16.5% to 36.3% of donors

The Committee’s literature review found some of these specific donor characteristics to be consistently associated with non-use, including age, hypertension, diabetes, BMI, and other factors.^{50,51,52} OPTN data

⁴⁵ Stewart, et al. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation*, 101(3), 575-587. <https://pubmed.ncbi.nlm.nih.gov/27764031/>.

⁴⁶ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁴⁷ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

⁴⁸ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024.

⁴⁹ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024.

⁵⁰ Mohan, et al. (2018). Factors leading to the discard of deceased donor kidneys in the US

⁵¹ Cohen, et al. (2019). Kidney allograft offers: Predictors of turnaround and the impact of late organ acceptance on allograft survival.

⁵² Massie, et al. Improving distribution efficiency of hard-to-place deceased donor kidneys: predicting probability of discard or delay.

also demonstrates greater non-use rates for donors and organs with many of these clinical characteristics. In 2022, the non-use rates for these characteristics were:⁵³

- 43.89% for donors aged 50-64 in 2022 was 43.89%,
- 70% for donors aged 65 and older
- 47.43 % for donors with a history of cancer had a non-use rate, compared to 25.76% for donors without a history of cancer
- 45.24% for donors with a history of hypertension, compared to 15.85% for donors without a history of hypertension.
- 53.94% for donors with a history of diabetes, compared to 22.56% for donors with no history of diabetes.

The Committee expressed support for developing a data-driven definition of “hard to place” to identify those organs at increased risk of non-use, which may require alternate allocation pathways. The Committee considered the challenges to such a definition, noting that combinations of clinical factors could result in a “hard to place” organ given the introduction of logistical difficulties and cold ischemic time. The Committee agreed that, there may be instances where an organ does not immediately meet a definition of “hard to place,” but due to rare medical or logistical complexities, ultimately requires alternate allocation pathways to ensure utilization.⁵⁴ The Committee’s discussions and efforts to develop a definition of hard to place are detailed below.

Allocation Efficiency

The Committee discussed opportunities to improve efficiency in allocation and offer evaluation processes. The Committee highlighted increasing benefits from improved efficiency as the number of organs recovered and being offered increases, particularly in consideration of medically complex organs.

The Committee remarked that program resources must also match growth in organ recovery in order to sustain greater system growth.⁵⁵ The Committee discussed:

- Variation in OPO behavior
- Availability, timing, and reporting of donor and organ information
- Sequential allocation and offer evaluation
- Match run order: balancing equity and utility

Variation in OPO Behavior

The Committee recommended that the Task Force evaluate and analyze variation in OPO allocation practices, to better address and orient efficiency solutions that either address the challenges driving this variation or that allow for adequate flexibility for OPOs to address these challenges themselves. Members noted that potential drivers for variation in OPO and transplant program behavior may be due to geography and variations in donor and patient populations, particularly in the specific needs and demographics of certain populations. For example, some regions have significantly greater population density, while other regions or programs may have a greater proportion of candidates that live several hours away from their transplant programs. Variations in geography and population demographics can present specific and unique logistical challenges that may necessitate variation in behavior.⁵⁶

⁵³ Dolan, Bradbrook, and Martinez, “*Hard to Place Kidneys Data Request*.” OPTN Kidney Transplantation Committee, February 21, 2024.

⁵⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

Availability, Timing, and Reporting of Organ and Donor Information

The Committee remarked that there are variations in the timing, availability, and reporting of donor and organ information critical to evaluating organ offers. The Committee noted that this is particularly true of post-recovery information, including biopsy, anatomy, and pump information. The Committee's *Standardize Biopsy Reporting and Data Collection* proposal attempted to address this. The OPTN OPO Committee's *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection* also aims to improve donor information sharing, particularly for DCD donors. The Committee emphasized the benefit of standardization to efficiency of organ allocation and offer evaluation, recommending that the Task Force consider incorporating increased standards for OPOs in donor testing and information sharing, including timing. The Committee remarked that biopsy performance is one area that could benefit from increase standardization in practices, particularly with ensuring the quality of procurement biopsy readings. The Committee recommended that the Task Force encourage coordination between OPOs and pathology partners to expand access to tele-pathology services, such that procurement biopsies are able to be rapidly read by renal pathology experts. The Committee noted that this would increase the reliability of procurement biopsies and thus improve offer decision-making. The Committee recommended that the Task Force investigate similar opportunities to improve post-recovery information quality and sharing practices, including consideration for coordination of resources between OPOs.⁵⁷

The Committee remarked that biopsy, pump, and post-clamp information gathering can contribute to accumulation of cold ischemic time, and that these practices should be evaluated for their necessity, reliability, and effectiveness against contribution to risk of non-use.⁵⁸ While the proportion of kidneys biopsied has stayed about the same over time, with only slight increases from 2018 to 2019, the OPTN as a whole is recovering more donors, meaning that the absolute volume of biopsy is also increasing. In 2022, biopsied kidneys had a non-use rate of 40.2%, compared to just 7% of kidneys not biopsied.⁵⁹ In 2019, Lentine et al demonstrated that biopsy was associated with an increased rate of non-use at each KDPI level, although this was most pronounced for low KDPI kidneys.⁶⁰ In this article, Lentine et al discussed the limited reliability of procurement results, with limitations stemming from variation in slide preparation technique and quality, as well as the expertise of the pathologist reading the biopsy.⁶¹ The distribution of glomerulosclerosis scores for biopsied kidneys has stayed about the same over time, and the majority of biopsied kidneys (60%) score between 0-5% glomerulosclerosis. About 15% of kidneys have glomerulosclerosis scores higher than 16%. **Figure 14** shows the distribution of non-use rates for biopsied kidneys based on percent glomerulosclerosis, with high rates of non-use associated with organs scoring more than 6% glomerulosclerosis.

⁵⁷ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

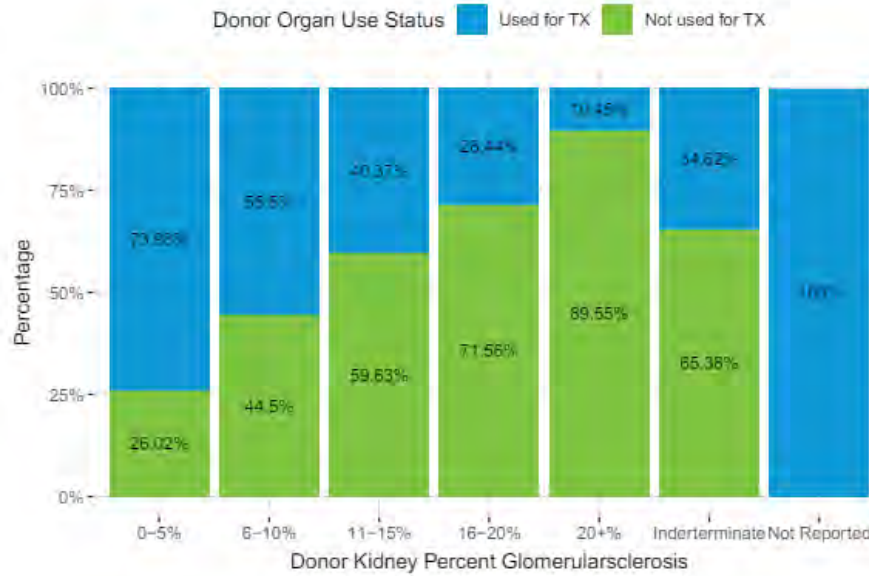
⁵⁸ *Ibid.*

⁵⁹ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

⁶⁰ Lentine, et al. (2019). Variation in use of procurement biopsies and its implications for discard of deceased donor kidneys recovered for transplantation. *Am J Transplant*, 19 (8), 2241-2251. <https://pubmed.ncbi.nlm.nih.gov/30809941/>

⁶¹ *Ibid.*

Figure 14: Percentage of Deceased Donor Kidneys Recovered in the United States in 2022 by Donor Organ Percent Glomerulosclerosis and Donor Organ Use Status⁶²



Sequential Allocation and Offer Evaluation

The Committee considered sequential allocation, noting the impact of current practices in offer evaluation. Members of the Committee noted that many programs may not fully evaluate an offer until the offer is primary for one of their candidates, and that delayed evaluation in a sequential allocation system results in accumulation of cold ischemic time, particularly as many programs await post-recovery information to make final acceptance or decline decisions.⁶³ As cold ischemic time accrues, the Committee noted that the organ becomes increasingly more difficult to place, with fewer programs able to accept and transport the organ within a reasonable cold ischemic time window. The Committee has recommended that notification of post-clamp information availability to all programs either evaluating or with a provisional yes could support earlier evaluation of organ offers, even if the program has not yet received the primary offer.⁶⁴ Further discussions on how offer evaluation inefficiency contributes to allocation inefficiency and potential impacts to non-use are described in the following section.

The Committee evaluated benefits of simultaneous allocation systems, including discussion of the Mankowski et al. (2019) study on simultaneous expiring offers, which found that simultaneous offering can increase acceptance rates and decrease cold ischemic time.⁶⁵ The Committee disagreed with Mankowski’s evaluation of impact to program resources, noting that the authors’ projected offer volume increases could greatly overwhelm programs, with negative impacts to evaluation times.⁶⁶ The Committee will continue consideration of simultaneous offering over sequential offering in the

⁶² Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

⁶³ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁶⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁶⁵ Mankowski, et al. (2019). Accelerating kidney allocation: Simultaneously expiring offers. *Am J Transplant*, 19(11), 3071-3078.

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

⁶⁶ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023

development of an expedited placement pathway, as described in the *Kidney Expedited Placement Workgroup* section below.

Match Run Order: Balancing Equity and Utility

The Committee agreed that the allocation algorithm and resulting match run order can also impact allocation efficiency. The Committee considered how improved matching and prioritization of longevity matching in the match run could improve allocation efficiency. The Committee pointed out that increased candidate screening and filtering can prioritize more appropriate candidates for specific organs, with benefits to allocation efficiency. The Committee expressed that higher KDPI kidneys, or kidneys with increased risk of non-use and shorter expected graft longevity, may require alternate allocation algorithms that prioritize different types of candidates than lower KDPI kidneys with greater expected graft longevity.

With this in mind, the Committee remarked that the balance of utility and equity maintained in an allocation algorithm may need to emphasize utility more significantly for those organs that have an increased risk of non-use. One article by Stewart et al. considered that alternate prioritization, such as prioritizing patients with less waiting time for the highest KDPI kidneys, may help support increased acceptance, and thus allocation efficiency and utilization, for these organs.⁶⁷ The Committee noted that longevity matching, organ mass and recipient matching, and placement efficiency must be cautiously considered regarding impacts to equity.⁶⁸ The Committee will continue to discuss potential modifications to the continuous distribution allocation algorithm, including modifications to attribute weights and rating scales, as well as consideration for new efficiency rating scales.

The Committee also considered that alternate allocation pathways may be necessary to ensure placement of kidneys at increased risk of non-use, in alignment with the Board resolution.⁶⁹ The Committee remarked that standardization and consensus in a definition of “hard to place,” particularly to ensuring the community has a clear understanding of which organs may require alternate approaches to allocation. The Committee emphasized the importance of balancing standardization – with benefits to transparency and equity – and efficiency, noting that adequate flexibility and clinical discretion may be necessary to ensure placement and use.⁷⁰

Offer Evaluation Inefficiency

Offer evaluation inefficiencies are closely tied to allocation inefficiencies, as delays in program evaluation can significantly contribute to increased cold ischemic time, and thus increased risk of non-use, particularly in a sequential allocation system.⁷¹ The Committee noted that program evaluation delays may in part be due to significant offer volumes. The Committee pointed out that offer filters reduces the volume of offers that a program would not accept, ultimately reducing burn out for offer-evaluating personnel and allowing programs to focus resources towards thorough evaluation of offers the program would accept. The Committee expressed support for expansion of offer filters criteria, including the number and dynamism of offer filters available for use. The Committee significantly emphasized the potential power of offer filters to improve efficiency, both for OPOs in allocation and for

⁶⁷ Stewart, et al. (2022). Oversimplification and Misplaced Blame Will Not Solve the Complex Kidney Underutilization Problem. *Kidney360*, 3(12), 2143-2147. Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9802557/>

⁶⁸ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023

⁶⁹ *Ibid.*

⁷⁰ *Ibid.*

⁷¹ Stewart, et al. (2023). Beyond Organ Donation to Organ Utilization in the USA. *Curr Opin Organ Transplant*, 28(3), 197-206. <https://pubmed.ncbi.nlm.nih.gov/36912063/>

transplant programs in offer volume management. The Committee’s recommended expansion of offer filters included age and longevity matching filters, as well as greater inclusion of clinical information, such as more detailed biopsy results, serum creatinine, and consideration of multiple clinical factors in context with each other. The Committee also noted that offer filters could create separate filters for medically complex or “hard to place” organs. The Committee particularly emphasized the screening benefits of incorporating better candidate and donor matching into the offer filters system. Adequate uptake of offer filters, either voluntary or mandatory, would ensure OPOs are making offers only to candidates at programs that would accept similar organs, thus reducing unnecessary offers that will be declined. This would reduce overall allocation time by reducing evaluation time from programs that ultimately will not accept the organ. The Committee also noted that this ensures efficiency is achieved equitably, as there is no disadvantage to candidates being bypassed for offers that their programs would not consider accepting on their behalf.⁷²

The Committee also noted that program reliance on physical crossmatch can contribute to extended evaluation time, allocation delays, and late declines, and that increased use of virtual crossmatch could reduce this reliance. The Committee pointed out that eliminating the need for physical crossmatch prior to transplant can encourage reduced cold ischemic time and post-clamp offer acceptance. The Committee recommended that the Task Force consider standardizing widespread utilization of virtual crossmatch.⁷³

The Committee discussed offer timing, and the impact that this has on risk of non-use. Cohen et al. (2019) found a higher rate of non-use and increased decline when an organ was offered over the weekends.⁷⁴ Similarly, Narvaez et al (2018)’s study also found that timing of offer can increase risk of non-use, including offers sent late at night.⁷⁵ The Committee noted that offer timing is known to be relevant for clinicians, and could also impact patients as well, positing that some patients may be less likely to accept a potentially increased risk offer if the offer is made late at night.⁷⁶ The Committee acknowledged that OPOs are constrained in their ability to control offer timing, particularly related to late night and weekend offers. Committee members also noted that weekend and late-night offer timing may be impacted by increased limitations in transportation availability at those times.⁷⁷

Logistics

The Committee highlighted the great impact of transportation limitations on the performance of transplant system, and recommended that challenges to transportation may be best resolved by engaging stakeholders beyond the OPTN.⁷⁸ The Committee explained that kidney transportation is severely limited, with transplant operating 24 hours a day, 7 days a week, but without similar levels of transportation availability. Limitations in flight and transportation availability may present an insurmountable barrier to offer acceptance, and potentially, transplantation. The Committee noted that this impacts both the efficiency of the system and increases risk of non-use, but also reduces the equity of the system, as programs are forced to decline offers for higher ranking candidates due to infeasibility

⁷² OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁷³ *Ibid.*

⁷⁴ Cohen, et al. (2019). Kidney allograft offers: Predictors of turndown and the impact of late organ acceptance on allograft survival. *Am J Transplant*, 18(2), 391-401. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5790617/>.

⁷⁵ Narvaez, et al. (2018). Hard-to-place kidney offers: Donor and system level predictors of discard. *Am J Transplant*, 18(11), 2708-2718. <https://pubmed.ncbi.nlm.nih.gov/29498197/>.

⁷⁶ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁷⁷ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

⁷⁸ OPTN Kidney Transplantation Committee Meeting Summary, November 20, 2023. <https://optn.transplant.hrsa.gov/media/vfdmfand/20231120-kidney-committee-meeting-summary-1.pdf>

of transport and ultimately safe transplant. Wang et al (2022) demonstrated that availability of direct flights was a driver in kidney-sharing across OPTN regions, with the introduction of a new airline route increasing the number of shared kidneys by 7.3% in donor service area and region-based kidney allocation.⁷⁹

The Committee pointed out that there are insufficient data to understand and evaluate the impact of transportation availability in real time, and recommended that the Task Force similarly investigate ways to access greater transportation data. The Committee discussed OPO engagement with alternative shipping companies and local reserve military bases, and recommended that the Task Force consider engagement with such stakeholders to improve transportation availability. The Committee offered that engaging the United States Department of Defense to utilize military reserve resources to transport organs may end up reducing overall government costs, particularly in reducing the number of patients on dialysis by increasing access to transplant.⁸⁰ The Committee concluded that transportation limitations should be considered with stakeholders beyond OPTN membership, to allow for a more effective, centralized, and strategic approach, but that this is ultimately beyond the Committee's scope, and may be beyond the OPTN's purview.⁸¹ The Committee will also consider how to incorporate greater consideration for travel feasibility into the continuous distribution effort.

The Committee pointed to limited organ perfusion incentives as another example of infrastructural limitations. Members emphasized that pumping kidneys can improve post-transplant outcomes and limit cold ischemic damage, but that reimbursement policies for organs that are not accepted may discourage OPOs from utilizing pump perfusion.⁸² Furthermore, perfusion machines are not easily transported via planes, further limiting their use. The Committee recommended that the Task Force consider and advocate for structural and resource changes that support use of machine perfusion.

Stakeholder Coordination

The Committee highlighted the interdependence of the transplant process, and the importance of ensuring all stakeholders are aligned throughout the candidate listing and management, donor referral and management, organ procurement, allocation, transportation, and transplant process. Members explained that this interdependence requires that all stakeholders must be equally accountable to ensuring and enacting greater system change.⁸³ Specifically, the Committee expressed concern that as OPOs recover more organs from more medically complex donors, existing program performance and survival metrics may discourage programs from accepting and transplanting potentially riskier, more medically complex offers. The Committee noted that there are gaps in the community's understanding of risk adjustment in program metrics, and that this may generate program concern for the impact of transplanting kidneys at increased risk of graft failure – and thus increased risk of non-use. Members agreed that stakeholder performance metrics and incentivization should ensure increases in volume of organs recovered also translates to increases in organ acceptance and transplant.⁸⁴

⁷⁹ Wang, et al. (2022). Does Transportation Mean Transplantation? Impact of New Airline Routes on Sharing of Cadaveric Kidneys. *Management Science*, 68(5), 3660-3679.

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3582675#:~:text=We%20estimate%20the%20introduction%20of,the%20introduction%20of%20new%20routes.

⁸⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁸¹ *Ibid.*

⁸² Ghoneima, et al. Outcomes of Kidney Perfusion Techniques in Transplantation from Deceased Donors: A Systematic Review and Meta-Analysis. *J Clin Med*, June 2023; 12(12): 3871. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10298857/>

⁸³ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

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

The Committee recommended that the Task Force engage stakeholders beyond OPTN members to encourage greater coordination and cohesion in driving increased system efficiency. Towards this end, the Committee also recommended that the Task Force consider developing a definition of efficiency, and identify specific efficiency goals, as well as consideration for how those goals may impact various stakeholders. The Committee emphasized that transplant system growth must be matched by growth in the system's capacity across stakeholders to ensure that system growth is realized, with direct impacts for increasing access to transplant for patients.⁸⁵

Shared Decision Making

The Committee discussed the variety of candidates waiting for a kidney, noting that there are many candidates who may be interested and willing to accept a kidney with shorter projected graft longevity in order to end reliance on dialysis sooner. Mehrotra et al.'s "Patient Preferences for Waiting Time and Kidney Quality" (2022) study demonstrated that the average respondent was willing to forgo 4.5 years of graft function for a 2 year reduction in waiting time, accepting that a kidney transplant provided at least 6.5 years of total graft function.⁸⁶ The Committee remarked that system efficiency could be improved by matching patient risk tolerance and organ risk profiles, prioritizing such candidates for lower projected longevity organs, that maybe more likely to be at risk of non-use.⁸⁷ The Committee noted that this prioritization could increase allocation efficiency by prioritizing candidates more likely to accept the organ, and that this could reduce risk of non-use and potentially improving outcomes for these organs by reducing cold ischemic time. Members emphasize that a patient's willingness to accept a lower graft longevity kidney is a key decision, which may shift over the course of a patient's time waiting, and that this should be considered by the patient, the patient's transplant and personal care team.⁸⁸

The Committee emphasized the importance of shared decision making in reducing non-use, as well as the importance of adequate patient education to ensure informed decision making. The Committee agreed that patient education can be overwhelming, and that patient education should be simplified and accessible as much as possible to ensure informed decision making. The Committee recommended that patient education should be easily referred to later, include resources across learning styles, and be accessible in multiple languages. To help facilitate patient education, the Committee recommended that the Task Force consider incorporating the patient's greater care team into shared decision-making efforts, including referring nephrologist, to ensure the patient has many touch points for information. The Committee pointed out that many patients may have a stronger relationship and more trust with their referring nephrologist, particularly if this nephrologist has been managing the patient's kidney care for an extended period of time.⁸⁹ The Committee will continue to consider how shared decision-making can be leveraged to increase access to transplant for patients by evaluating their risk tolerance when considering potential transplant with US Public Health Service (US PHS) increased risk kidneys, medically complex or hard to place organs, high KDPI, and dual kidneys.

⁸⁵ OPTN Kidney Transplantation Committee meeting summary, October 11, 2023.

⁸⁶ Mehrotra, et al. (2022). Patient Preferences for Waiting Time and Kidney Quality. *Clin J Am Soc Nephrol*, 17(9), 1363-1371. <https://pubmed.ncbi.nlm.nih.gov/35985699/>.

⁸⁷ OPTN Kidney Transplantation Committee Meeting Summary, December 18, 2023.

https://optn.transplant.hrsa.gov/media/dc5eiowc/20231218_optn_kidney_meeting_summary-1.pdf

⁸⁸ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁸⁹ *Ibid.*

Efficiency Goals and Considerations

The Ethical Considerations of Continuous Distribution white paper defines equity, utility, transparency, and autonomy as the major guiding principles for the development of Continuous Distribution.⁹⁰ Specifically, a continuous distribution allocation system should achieve equitable allocation without disadvantaging vulnerable candidates; achieve the greatest good while reducing waste and promoting placement efficiency; be easily understandable; and promote participation in shared decision making. With consideration for these principles, the Committee developed the following efficiency goals and considerations through extensive discussion regarding potential drivers of non-use, metrics to measure efficiency in an allocation system, and identifying considerations for ensuring sustainable success in efficiency in a continuous distribution system. Specifically, the Committee aims to:⁹¹

- Improve allocation efficiency, with the goals of reducing non-use and allocation out of sequence
- Maintain or improve post-transplant outcomes and waitlist mortality
- Increase incorporation of shared decision-making in the allocation system
- Understand and incorporate transportation as a balancing factor in equity and utility
- Accommodate shifting program practices, for sustainable growth of the transplant system

The Committee's goals and relevant metrics are included below.

Improving Allocation Efficiency

The Committee agrees that the structure and order of allocation can influence allocation efficiency and thus impact non-use. The Committee's approach to improving allocation efficiency thus aims to incorporate both modifications to the overall allocation algorithm and provide alternate allocation pathways for hard to place organs.⁹² The Committee explained that more efficient allocation would result in earlier acceptance, lower cold ischemic time at acceptance, and lower cold ischemic time at transplant, with adequate consideration for feasibility of transportation.⁹³ The Committee noted that improved allocation efficiency could be measured in reduced cold ischemic times, reduced number of offers required to place an organ, and reduced allocation out of sequence.⁹⁴

The Committee also noted that an efficient allocation system leverages more effective offers, achieved by more effective filtering and an allocation algorithm that equitably allocates each organ to the most appropriate patient whose program will accept the offer.⁹⁵ More efficient allocation thus results in fewer offers necessary to secure organ acceptance and transplant.⁹⁶ The Committee continued that improved efficiency in allocation will require appropriate consideration and allocation pathways for organs at increased risk of non-use.⁹⁷ The Committee noted that the incorporation of these pathways should render allocation out of sequence unnecessary, as even medically complex kidneys are able to be expeditiously placed and transplanted. Reduced allocation out of sequence is a measurable goal and indicator of an effective allocation system.

⁹⁰ OPTN Ethics Committee, *The Ethical Considerations of Continuous Distribution White Paper*, February 2022.

⁹¹ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024

⁹² OPTN Kidney Transplantation Committee Meeting Summary, March 18, 2024.

⁹³ *Ibid.*

⁹⁴ OPTN Kidney Transplantation Committee Meeting Summary, November 20, 2023

⁹⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

⁹⁶ OPTN Kidney Transplantation Committee Meeting Summary, January 19, 2024

⁹⁷ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

Maintaining or Improving Post-Transplant Outcomes and Waitlist Survival

The Committee agreed that efficiency in Continuous Distribution and increased utilization of kidneys at risk of non-use should aim to maximize survival benefit and realize increases in use without significant negative impact to patients and recipients, as measured in waitlist mortality and post-transplant outcomes.⁹⁸ The Committee noted that transplant programs are measured on specific patient and graft survival metrics, and are entrusted in ensuring the safety of their patients, both listed and transplanted.⁹⁹

Expanding Shared-Decision Making

The Committee emphasized the importance of shared decision making in supporting increased access to transplant for patients and increased utilization of kidneys at risk of non-use.¹⁰⁰ The Committee acknowledged the importance of understanding patient preferences and willingness to accept organs with specific risk profiles, specifically kidneys with shorter expected graft longevity, in order to end reliance on dialysis sooner.¹⁰¹ The Committee referenced literature emphasizing the survival benefit for patients who are transplanted earlier, with less dialysis time, as opposed to those patients who are transplanted with greater time on dialysis.¹⁰² The Committee remarked that while kidneys at increased risk for non-use may not be appropriate for all potential transplant recipients, the organs may be appropriate and provide great benefit for many candidates. The Committee noted that it is important to ensure patients and their care teams are informed and empowered in accepting organs that may be at increased risk of non-use, with understanding of all potential risks and benefits.¹⁰³ OPTN Policy captures some aspects of shared decision-making currently, by requiring programs to obtain written consent from patients in order to opt those patients into appearing on KDPI 86-100 match runs.¹⁰⁴ The Committee hopes to expand opportunities for shared decision-making, and will continue to incorporate these considerations.

Understanding the Impact of Transportation on Equity and Utility

As the Committee has evaluated continuous distribution modeling results indicating increased travel distances, the Committee has also considered how limitations in transportation availability may impact the feasibility of modeled equity gains. The Committee emphasized that limitations in transportation render some organ offers infeasible, with programs having to decline on behalf of higher ranking candidates due to lack of transportation logistics to support the organ's travel.¹⁰⁵ The Committee agreed that transportation limitations must be appropriately considered when understanding the feasibility of improvements in equity associated with increased travel distances, particularly in evaluating modeling.¹⁰⁶ The Committee identified a critical lack of transportation data, particularly in a format that would allow more direct incorporation into allocation.¹⁰⁷ Similarly, this lack of data makes measurability

⁹⁸ OPTN Kidney Transplantation Committee Meeting Summary, January 19, 2024

⁹⁹ *Ibid.*

¹⁰⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

¹⁰¹ OPTN Kidney Transplantation Committee Meeting Summary, December 18, 2023

¹⁰² Jay, et al. "Survival Benefit in Older Patients Associated with Earlier Transplant with High KDPI Kidneys." *Transplantation*. April 2017; 101(4): 867-872. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5292097/>.

¹⁰³ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹⁰⁴ OPTN Policy 5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85%

¹⁰⁵ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023.

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

of this goal difficult. The Committee will continue discussing transportation and incorporate these considerations as they discuss modifications to allocation algorithm.

Accommodate Changing Program Acceptance Behavior

Finally, the Committee emphasized the importance of developing efficiency solutions that accommodate shifting program practices, such that programs are not always held to only receiving offers aligning with their historical acceptance patterns. The Committee noted that more efficient allocation and increased transplantation of kidneys at risk of non-use will encourage shifting acceptance patterns across the greater transplant system, particularly as programs and care teams share best practices to support increased organ longevity and improved recipient outcomes.¹⁰⁸ Improved efficiency should support sustainable, equitable growth in volume of transplants.¹⁰⁹ Shifting program acceptance behavior may be reflected in greater overall acceptance of medically complex organs, including the number of programs accepting these organs.

The Committee’s efforts to finalize the Continuous Distribution project will aim to achieve these goals, as well as the previously defined goals of Continuous Distribution, to ensure the development of an allocation system that appropriately balances utility, equity, transparency, and autonomy while reducing non-use and inefficiency.

Defining Hard to Place

In order to address non-use and expedited placement, the Committee highlighted the need to identify those kidneys that are “hard to place” and thus at increased risk of non-use. The Committee agreed that a data-driven, consensus definition of “hard to place” will ensure an established standard in which kidneys are described when talking about organs at increased risk of non-use, as well as provide data-based standardization in identifying which kidneys may require alternate allocation pathways. A standard definition of “hard to place” may further support wide-spread efficiency conversations, and allow the Committee, the OPTN Task Force, and the community to more directly evaluate and address the factors resulting in an increased risk of non-use. Previous public comment feedback expressed support for a standard definition for “hard to place” kidneys.¹¹⁰ It is important to note that the Committee aims to develop a *preliminary*, evidence-based definition for “hard to place” kidneys, such that the definition can be modified based on its application.¹¹¹

Multi-Pronged Definition

Initial discussions to define “hard to place” focused on pre-cross clamp and post-cross clamp distinctions, noting that there may be instances where an organ should be identified as hard to place both prior to and after recovery. The Committee’s discussions included both clinical indicators and allocation indicators, such as number of programs having declined, and the Committee noted that the latter may be more useful. After further evaluation and discussion of literature and data regarding non-use, the Committee determined that the definition of “hard to place” kidneys should be multi-faceted, with consideration for how logistical and clinical factors can result in difficulty in placement.¹¹² The Committee also noted dynamic relationship of cold ischemic time as both a clinical and logistical factor,

¹⁰⁸ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2023.

¹⁰⁹ *Ibid.*

¹¹⁰ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2023

¹¹¹ OPTN Kidney Transplantation Committee Meeting Summary, January 19, 2024

¹¹² OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

with clinical concern for graft function contributing to longer allocation times and late acceptance, and longer allocation times contributing to increased cold ischemic times and resulting clinical concern for graft function.¹¹³

The Committee noted that a multi-pronged definition of “hard to place” may be more flexible, potentially allowing an organ to be identified as “hard to place” regardless of timing or organ recovery. On the other hand, the Committee noted that a multi-pronged definition of “hard to place” should also be flexible enough to capture those organs that may have limited obvious clinical concerns, but may have become hard to place due to cold ischemic time accrual or logistic reasons. A multi-pronged definition of “hard to place” may better capture the dynamic risk of non-use over time as organs are allocated, which can help ensure those organs in need of alternate allocation pathways. Furthermore, a multi-pronged, flexible definition of “hard to place” that captures multiple aspects of risk of non-use may better accommodate variation across regions, donor populations, and geography.¹¹⁴ The Committee’s discussions regarding individual nuances of a multi-pronged definition are described below:

- Clinical
- Allocation and Logistical
- Cold Ischemic Time

Defining “Hard to Place:” Clinical Factors

The Committee evaluated a number of donor and organ characteristics in consideration of potential clinical factors to define “hard to place.” The following characteristics were shown to have increased rates of non-use, particularly compared to the 2022 overall non-use rate of 26.65%, including:^{115,116}

- KDPI greater than 80% - non-use rate greater than 50%
 - KDPI 70-79% - non-use rate of 38.82%
 - Compared to KDPI 60-69% - non-use rate of 27.53%
- Donor age 65 and older – non-use rate of 70.02%
 - Donor age 50-64 – non-use rate of 43.89%
 - Median age of non-used organs – 56 years
- Donor history of cancer – non-use rate of 47.43%
 - Compared to no history of cancer – non-use rate 25.76%
- Donor history of hypertension – non-use rate 45.24%
 - Compared to no history of hypertension – non-use rate 15.85%
- Donor history of diabetes – non-use rate of 53.94%
 - Donor history of diabetes greater than 5 years – non-use rate of 61.15%
 - Donor history of diabetes greater than 10 years – non-use rate of 62.92%
 - Donor history of diabetes, duration unknown – non-use rate of 56.01%
 - Compared to no history of diabetes – non-use rate 22.56%
- DCD donor – non-use rate of 33.87%
 - Compared to DBD donor – non-use rate of 23.06%
- Cerebrovascular Accident (CVA) – non-use rate 40.74%
 - Compared to other – non-use rate 34.3%; anoxia – non-use rate of 24.52%

¹¹³ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹¹⁴ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024

¹¹⁵ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹¹⁶ Dolan, Bradbrook, and Martinez, “Hard to Place Kidneys Data Request.” OPTN Kidney Transplantation Committee, February 21, 2024

- Unknown presence of clinical infection – non-use rate of 95.14%
 - Less than 1.36% of donors have an unknown presence of clinical infection
- Donor history of cigarette use – non-use rate of 38.17%
 - Compared to no history of cigarette use – non-use rate 22.79%
- Donor organ pumped – non-use rate of 31.23%
 - Compared to not pumped organs – 22.71%
- Donor organs biopsied – non-use rate of 40.17%
 - Donor organs not biopsied – non-use rate of 7.54%
- Glomerulosclerosis greater than 11% - non-use rate greater than 50%

Several of these characteristics were found to be similarly associated with non-use and late acceptance in multiple articles reviewed by the Committee.^{117,118,119} The Committee also noted that the literature found that a greater number of non-use characteristics correlated to an increased risk of non-use.¹²⁰ The Committee cited Mohan et al, which found that donors with more than one risk characteristic had a 1.41 increase in the odds of non-use, while donors with more than 5 risk characteristics had a 21.42 increase in odds of non-use.¹²¹

The Committee also considered several donor characteristics for which there is limited data, such as proteinuria and anatomical considerations.¹²² The Committee noted that proteinuria is somewhat unreliable, particularly as urinalysis samples are often taken after catheters are placed. Furthermore, there is variation in OPO testing for proteinuria. Due to concerns for reliability and inconsistency, the Committee decided not to include proteinuria in the definition.¹²³ Anuria was similarly considered, but ultimately not included due to inconsistency in collection.¹²⁴ The Committee also acknowledged that there is currently little data collection in the OPTN Donor Data and Matching system regarding kidney anatomy.¹²⁵ However, the Committee also referred to an article by Narvaez et al, which found that many predictors of non-use lose significance when more granular data points such as anatomy, histopathology, disease, and cancer transmission are assessed.¹²⁶ The Committee seeks community feedback on the incorporation of anatomy characteristics into the definition of “hard to place.”

The Committee discussed incorporating pump parameters in a definition of “hard to place,” noting nuances and variation in pump parameters based on different machines and variation in pump practices and availability. Members noted that different pump machines may have different parameters, and that this variation creates inconsistency in pump criteria. The Committee also emphasized variation in OPO pump practices and availability. Several Committee members also noted that pumping can introduce

¹¹⁷ Mohan, et al. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int.*, 94(1), 187-198. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6015528/>

¹¹⁸ Cohen, et al. (2019). Kidney allograft offers: Predictors of turndown and the impact of late organ acceptance on allograft survival. *Am J Transplant*, 18(2), 391-401. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5790617/>

¹¹⁹ Massie, et al. Improving distribution efficiency of hard-to-place deceased donor kidneys: predicting probability of discard or delay. *Am J Transplant*, 10(7), 1613-1620. <https://pubmed.ncbi.nlm.nih.gov/20642686/>

¹²⁰ Mohan, et al. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int.*, 94(1), 187-198.

¹²¹ *Ibid.*

¹²² OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹²³ OPTN Kidney Transplantation Committee Meeting Summary, March 18, 2024

¹²⁴ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

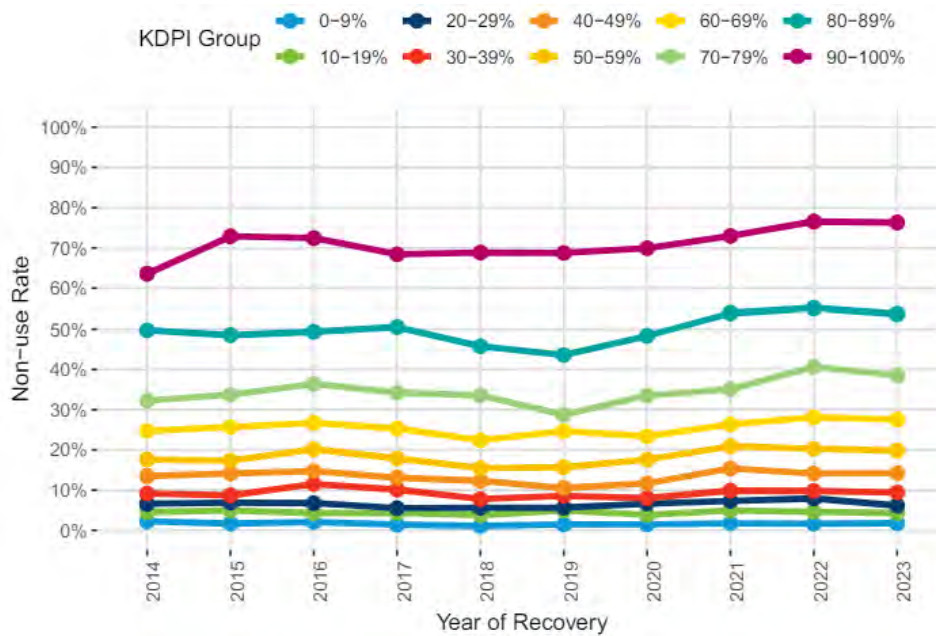
¹²⁵ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024.

¹²⁶ Narvaez, et al. (2018). Hard-to-place kidney offers: Donor and system level predictors of discard. *Am J Transplant*, 18(11), 2708-2718. <https://pubmed.ncbi.nlm.nih.gov/29498197/>

delays in post-recovery allocation, particularly as it can take several hours of pumping before pump numbers are accurate and reliable.¹²⁷

The Committee considered whether clinical criteria should be stratified by KDPI, noting that lower and medium KDPI kidneys have lower risk of non-use as well as fewer non-use risk characteristics, and so may require definitions of hard to place that lean more on post-clamp information, particularly those not incorporated into the KDPI calculation. The Committee also considered that higher KDPI kidneys have such high non-use rates (**Figure 15**), that it may be appropriate for these kidneys to meet fewer clinical criteria to be considered “hard to place,” allowing for earlier initiation of expedited placement. Members supported a definition of “hard to place” that ensured high KDPI kidneys may be allocated via an expedited placement pathway prior to organ recovery.¹²⁸

Figure 15: Non-use Rate of Deceased Donor Kidneys Recovered in the US by Recovery Year and KDPI Deciles, 2014-2023¹²⁹



¹²⁷ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024

¹²⁸ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹²⁹ Dolan, Bradbrook, and Martinez, "Hard to Place Kidneys Data Request." OPTN Kidney Transplantation Committee, February 21, 2024

In consideration of how interactions between criteria may impact non-use, the Committee submitted an additional data request in June, utilizing an adjusted model to understand the impacts of these donor characteristics to non-use in relation to each other.¹³⁰ The model will utilize the following variables, with one overall model and another model stratified by KDPI group:

- 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
- 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
- Pumping status
- Biopsy status
- PHS increased risk status
- Cytomegalovirus (CMV) status
- Clinical infection
- Kidney Donor Risk Index (KDRI)

The Committee will review the results of the adjusted model and finalize the clinical definition of “hard to place” this summer. The Committee seeks community feedback on these characteristics, their interaction, and whether a clinical criterion for “hard to place” should be stratified by KDPI, particularly in the context of a multi-pronged definition of “hard to place.”

Defining “Hard to Place:” Allocation and Logistical Factors

The Committee considered logistical and allocation indicators of increased risk of non-use, including transportation availability, candidate decline threshold, and center decline threshold. The Committee noted that allocation thresholds are particularly impactful indicators of risk of non-use, as they specifically indicate difficulty in placement by establishing points at which lack of placement is concerning.¹³¹ Massie, et al.’s model to predict probability of non-use found that donors in the “hard to place” threshold were more likely to have a higher number of patient-level refusals and a higher number of center-level refusals.¹³² Given the increase in non-use reasons attributed to “match exhausted – no recipient found” (**Figure 16**), allocation thresholds may help encourage early intervention for organs with a significant number of declines. The Committee noted that continued allocation efforts past certain thresholds essentially summarize the complex combination of clinical and logistical factors that contribute to an individual organ’s risk of non-use.¹³³

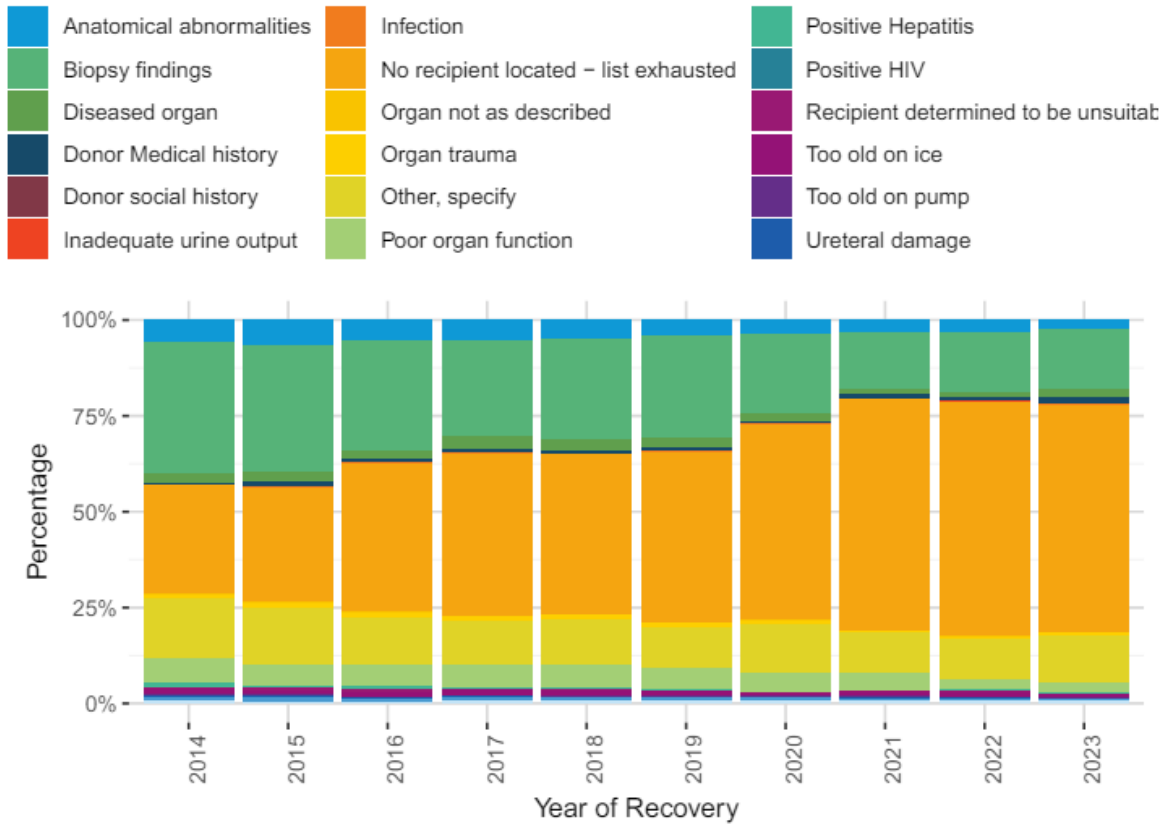
¹³⁰ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

¹³¹ OPTN Kidney Transplantation Committee Meeting Summary, March 18, 2024.

¹³² Massie, et al. Improving distribution efficiency of hard-to-place deceased donor kidneys: predicting probability of discard or delay. *Am J Transplant*, 10(7), 1613-1620. <https://pubmed.ncbi.nlm.nih.gov/20642686/>

¹³³ OPTN Kidney Transplantation Committee Meeting Summary, March 18, 2024

Figure 16: Distribution of Deceased Donor Kidneys Recovered in the US by Recovery Year and Donor Organ Reason for Non-Use



The Committee acknowledged that there is limited data regarding transportation availability that could support clear and specific transportation-related criteria. The Committee agreed that transportation is nuanced, and transportation availability is impacted by distance to the nearest airport, the size of that airport, cargo hours, time of day, and even time of day, week, or even year.^{134,135} The Committee noted that a simple cold ischemic time threshold may be more appropriate, or else incorporating OPO discretion in determining when transportation availability is so limited that expedited placement may be necessary. The Committee expressed support for increased data collection regarding transportation and transportation availability.¹³⁶

The Committee considered establishing a candidate decline threshold based on sequence number, such that a kidney or kidneys would be considered hard to place once all candidates up to a specific sequence number had declined the organ. The Committee noted that a simple sequence number may not be adequate to capture difficulty in placement, particularly considering there are regions of the country where one transplant program may account for many, if not all, of the initial hundred or so candidates on the match run. The Committee agreed that a decline from 1 program for the first 100 candidates on a match run does not necessarily indicate difficulty in placement the same way that a decline for 100

¹³⁴ Cohen, et al. (2019). Kidney allograft offers: Predictors of turndown and the impact of late organ acceptance on allograft survival. *Am J Transplant*, 18(2), 391-401.

¹³⁵ Narvaez, et al. (2018). Hard-to-place kidney offers: Donor and system level predictors of discard. *Am J Transplant*, 18(11), 2708-2718.

¹³⁶ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

candidates from 15 or 20 centers may. Furthermore, utilizing a sequence number-based decline threshold would include declines for candidate-specific issues, such as candidate illness or unavailability, and this does not necessarily indicate difficulty in placement.¹³⁷ The Committee noted similar challenges in utilizing a candidate decline threshold based on percentage of the match run, such that the organ would be considered hard to place if a percentage of candidates had declined. In consideration of these nuances, the Committee agreed that number of centers having declined may be more specific and indicative of difficulty in placement and increased risk of non-use. The Committee noted that a sequence number threshold is more likely to be influenced by candidate-specific issues, while a center decline threshold may be impacted by program risk aversion in acceptance practices.¹³⁸ The Committee noted, however, that a sequence number threshold is simple and understandable, and noted precedent in the SRTR’s definition of “hard to place” based on non-acceptance within the first 100 sequences.¹³⁹ The Committee is seeking community feedback on the inclusion of a sequence number-specific allocation threshold to define “hard to place.”

The Committee noted that center decline thresholds may also be limited in their ability to indicate difficulty in placement or risk or non-use. Members shared that while some programs may have protocols where the program declines for all candidates based on specific criteria, other programs may consider the offer for some patients up until a specific cold ischemic time threshold. For example, one program may never accept offers from donors over 60 years old with a history of hypertension, while another program may consider such offers if the cold ischemic time is less than 10 hours. The Committee pointed out that multiple center declines may not occur until late in the allocation process.¹⁴⁰

Defining Center Decline Thresholds

In discussing how to define “center decline,” the Committee noted that there may be a critical mass of patients at a center for which the center has declined that may be appropriate.¹⁴¹ The Committee reviewed match run data evaluating the distribution of center declines utilizing four potential center decline definitions:

- Range refusals – defined as when a transplant hospital enters a decline response simultaneously for multiple candidates on the match run. For the purposes of this request, a center was defined as having a center decline for the range refusal definition if it submitted one or more range refusals
- Center decline greater than 50% - defined as a program submitting a decline for 50% or more of the program’s candidates on the match run
- Center decline greater than 75% - defined as a program submitting a decline for 75% or more of the program’s candidates on the match run
- Center decline 100% - defined as a program declining for all of the program’s candidates appearing on the match run

¹³⁷ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹³⁸ *Ibid.*

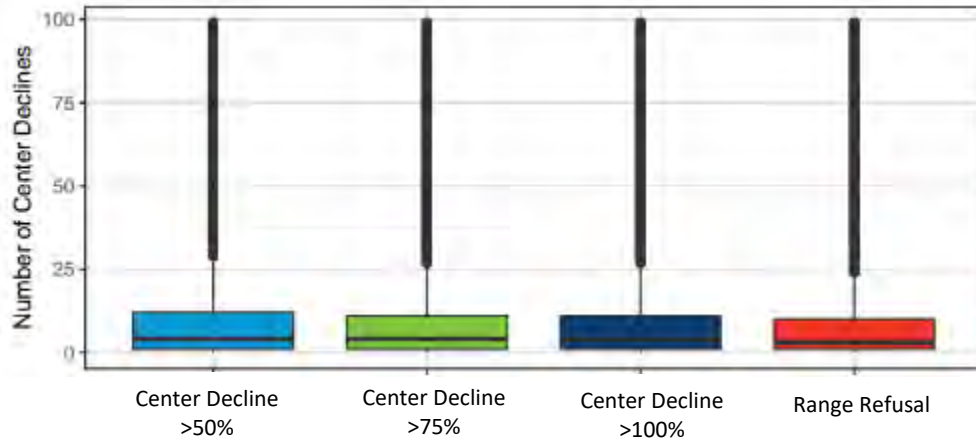
¹³⁹ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

¹⁴⁰ *Ibid.*

¹⁴¹ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

The Committee found that the distribution of center declines across match runs was similar across the definitions, as shown in **Figure 17**. It is important to note that the data cohort utilized to evaluate match runs for center declines consisted of all deceased donor kidney matches within a final acceptance in 2023.

Figure 17: Distribution of Center Declines by Definition Across Match Runs



In consideration of these data, the Committee expressed support for utilizing a definition of center decline based on a program declining for 100% of their candidates appearing on the match run. The Committee noted that a program that is thoroughly evaluating an offer may decline for a proportion of their candidates – even a large proportion – and still be interested in accepting the organ for a minority of their eligible patients. For example, a program may decline for their first 75 candidates of their 100 candidates on a match run, but may be interested in receiving the offer for their 76th candidate at a later sequence, for example. The Committee noted that the 50%, 75% and range refusal definitions of center decline may not necessarily indicate clinician concern or disinterest in acceptance that would result in difficulty in placement or increased risk of non-use.¹⁴²

The Committee considered additional nuances in how to determine the number of full center declines that should be used to define “hard to place.” As shown in **Figure 17** and **Table 2**, match run analysis shows that, on average, 3-4 centers enter a full center decline.¹⁴³

Table 2: Distribution of Center Declines by Definitions Across Match Runs

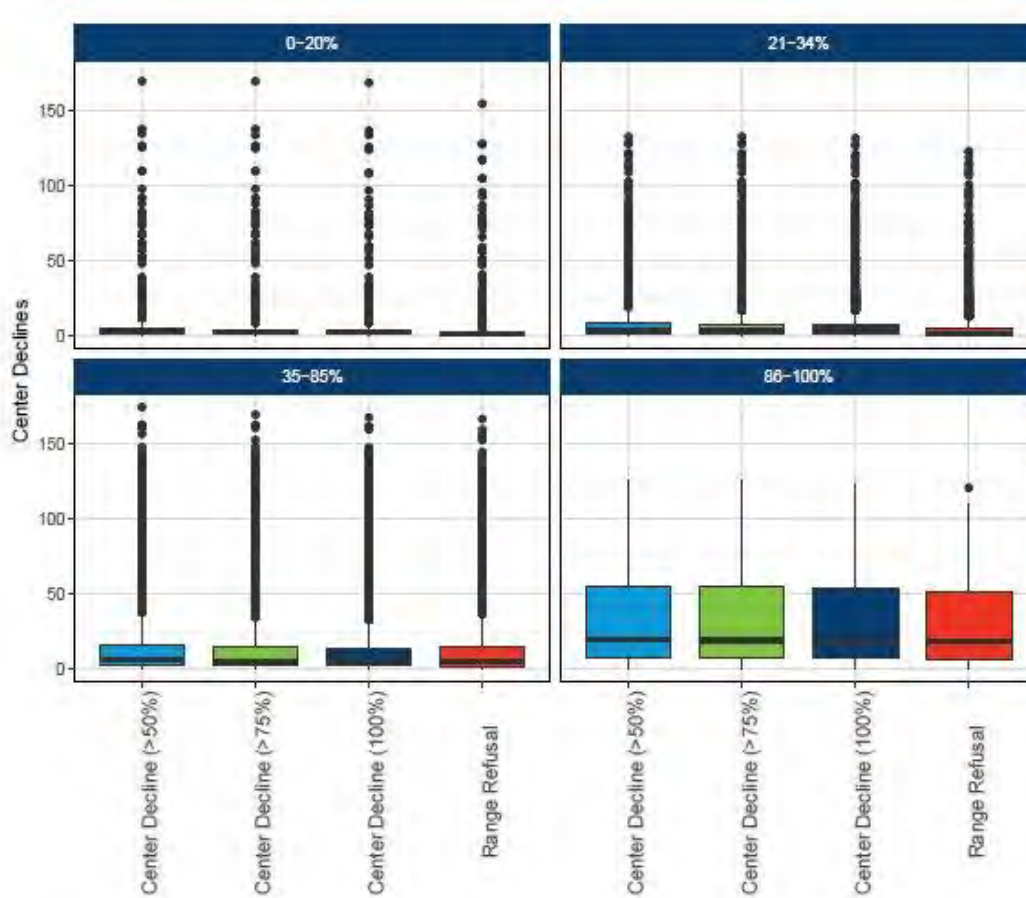
Center Decline Definition	Minimum	Q1	Median	Q3	Maximum
Center Decline (>50%)	0	2	4	13	175
Center Decline (>75%)	0	1	4	12	170
Center Decline (100%)	0	1	4	11	169
Range Refusal	0	1	3	11	167

¹⁴² OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024

¹⁴³ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024

Furthermore, higher KDPI was associated with a higher number of center declines, with a median of 18 centers inputting a full center decline for KDPI 86-100% match runs, as shown in **Figure 18**.

Figure 18: Distribution of Center Declines by Definition and KDPI



The Committee noted that the center decline threshold definition may need to take other factors into consideration, noting that a specific number of center declines may not indicate difficulty in placement for match runs with fewer programs within 250 nautical miles.¹⁴⁴ The Committee remarked that the center decline threshold may need to consider variation in transplant program density, but that this could potentially overcomplicate the definition of hard to place.¹⁴⁵

The Committee seeks community feedback on incorporating allocation thresholds into a definition of hard to place, including thresholds based on sequence number and center declines. The Committee will continue to consider allocation thresholds as it works to develop a definition of “hard to place.”

Defining “Hard to Place:” Cold Ischemic Time

The Committee identified the dynamic effect of cold ischemic time on risk of non-use, and agreed that cold ischemic time should be incorporated into the definition of hard to place. The Committee described

¹⁴⁴ OPTN Kidney Transplantation Committee Meeting Summary, March 18, 2024.

¹⁴⁵ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

how medically complex organs may require greater allocation efforts and time before offer acceptance, with increased allocation time generally contributing to increased cold ischemic time.¹⁴⁶ This increased cold ischemic time only compounds clinical concern for a graft’s longevity. The Committee noted that increased cold ischemic time during allocation can provide additional constraints to feasibility of acceptance, as some programs may not be able to transport an already cold organ within a reasonable and safe amount of time. In this way, cold ischemic time can both reflect and contribute to logistical challenges that may increase risk of non-use and difficulty of placement. Members emphasized that increased cold ischemic time generates clinical concern even for kidneys with long expected graft longevity and low KDPI.¹⁴⁷

The Committee discussed whether cold ischemic time thresholds should consider the impact of offer timing, noting the logistical challenges and increased risk of non-use found to be associated with weekend and late-night offers.¹⁴⁸ The Committee determined that incorporating multiple cold ischemic time thresholds would need to consider adjustments for timing, geography, and transportation limitations, for which there is limited data. The Committee agreed that this level of granularity reduces the effectiveness of a definition of hard to place, and noted that a simpler cold ischemic time threshold may be more appropriate.¹⁴⁹

With consideration of existing literature on the topic, the Committee initially discussed that a cold ischemic time threshold of 6 hours may be an appropriate threshold.¹⁵⁰ The Committee referenced the United Kingdom model of expedited allocation, which utilizes a cold ischemic time threshold of 6 hours.¹⁵¹ To further support their discussion, the Committee also reviewed Wood et al.’s “Deviating From the Match Run to Save a Kidney,” which evaluated directly how risk of non-use increases as cold ischemic time increases utilizing an updated cohort of deceased donor kidneys recovered between January 1, 2023 and January 1, 2024.¹⁵² This analysis found that the non-use rate increased as cold ischemic time increases, with a sharp inflection point at around 2-3 hours post-cross-clamp, as shown in **Figure 19**.¹⁵³

¹⁴⁶ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

¹⁴⁷ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024.

¹⁴⁸ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024.

¹⁴⁹ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024

¹⁵⁰ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

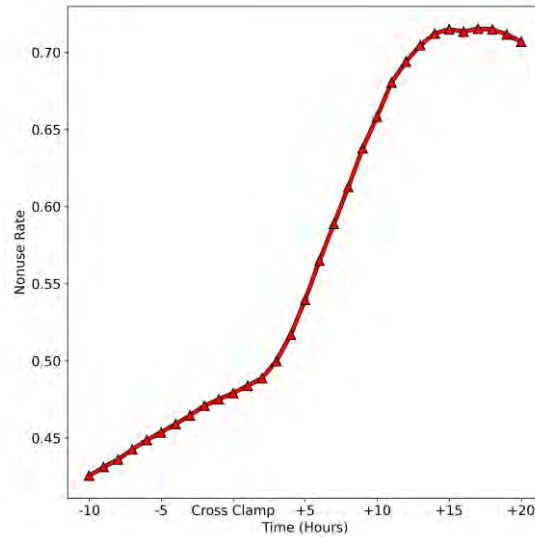
¹⁵¹ White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. *Clin Transplant*, 29(10), 872-881.

¹⁵² 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

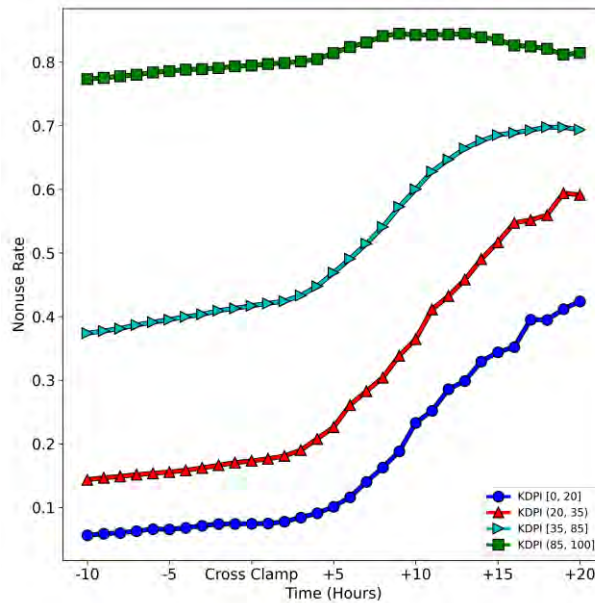
¹⁵³ *Ibid*.

Figure 19: Kidney Non-Use Rate by Time from Cross Clamp



The authors repeated this analysis, stratifying by KDPI, and found a similar inflection point between 3-5 hours post-cross clamp, as shown in **Figure 20**.¹⁵⁴ This analysis showed that increased cold ischemic time is associated with increased risk of non-use even for low KDPI kidneys. Furthermore, some organs, including high KDPI kidneys, have consistently high rates and risk of non-use even early in allocation.¹⁵⁵

Figure 20: Non-Use Rate by Time from Cross Clamp, Stratified by KDPI



¹⁵⁴ Wood, et al. (2023). "Deviating from a Match Run to Save a Kidney." Presented at the 2023 American Transplant Congress.

¹⁵⁵ *Ibid.*

The Committee considered the inflection point for increased risk of non-use at about 5 hours of cold ischemic time, noting that this inflection point applies regardless of KDPI. In consideration of cold ischemic time and risk of non-use for low KDPI kidneys, the Committee pointed out that low KDPI kidneys without an acceptance by 5 hours of cold ischemic time may have other clinical concerns not captured in KDPI, such as acute kidney injury, donor use of dialysis, or anatomical issues, that have contributed to lack of acceptance.¹⁵⁶ The Committee noted that, particularly for low KDPI kidneys, lack of organ acceptance at even low cold ischemic times may be indicative of serious clinical concern and greater risk of non-use.¹⁵⁷

The Committee agreed that the data supported a cold ischemic time threshold of 5 hours, but expressed concern that this may be too early to trigger expedited placement, especially for middle and lower KDPI organs.¹⁵⁸ Members noted that 5 hours post-cross clamp could trigger expedited allocation even before post-recovery information, such as biopsy or pump numbers, have become available. This could be particularly true for organs recovered at more rural donor hospitals. The Committee agreed that this information is often critical to making final acceptance decisions, and that expedited placement allocation should not precede final decisions in standard allocation. The Committee noted that the definition of “hard to place” should ensure that there has been adequate attempt at placement, with out success, in the standard allocation framework.¹⁵⁹

The Committee considered alternatives to a single cold ischemic time threshold, noting that potentially, there could be separate thresholds depending on whether the organs will be biopsied. Members noted that, for organs not awaiting post-recovery information sharing, programs should be finalizing acceptance or decline decisions by 6 hours of cold ischemic time. In consideration of a cold ischemic time threshold to define hard to place for organs not biopsied, the Committee supported a 6-hour threshold.

The Committee considered a time threshold based not on cold ischemic time, but on a specific time threshold for allocation after post-recovery information becomes available. Members discussed that this could work such that an organ could be considered hard to place some number of hours after final post-recovery information is available. In this scenario, members considered the complexity of pumping, noting that it may be necessary to delineate a set number of hours after which pump numbers are considered finally available. The Committee pointed out that this could be difficult, particularly given the variation in pump practices, use of different pump devices, and timeframes required before pump numbers can be considered accurate and reliable for evaluation. Members agreed that this could greatly increase the complexity of the definition of hard to place.¹⁶⁰

The Committee seeks community feedback on incorporating cold ischemic time into the definition of “hard to place,” including how to set the cold ischemic time threshold and whether a stand-alone cold time threshold is appropriate.

¹⁵⁶ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024.

¹⁵⁷ OPTN Kidney Transplantation Committee Meeting Summary, May 20, 2024.

¹⁵⁸ *Ibid.*

¹⁵⁹ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

¹⁶⁰ OPTN Kidney Transplantation Committee Meeting Summary, June 10, 2024.

Key Considerations

The Committee has iterated the importance of ensuring the definition of “hard to place” is simple and understandable for OPOs, programs, and patients, in order to ensure usefulness of the definition and consistency and effectiveness of the definition’s application. The Committee referenced the European and United Kingdom transplant systems, which utilize relatively simple criteria to initiate expedited placement allocation, noting that these systems were able to ensure utilization of these organs.^{161,162} While the Committee considered more complicated interactions between clinical and allocation criteria, members noted that an understandable and straightforward definition will ensure greater consistency and transparency, particularly in consideration of expedited placement pathways.¹⁶³

The Committee agreed that standardized definitions should incorporate a level of clinical discretion when applied practically to the allocation system; for example, there may be instances where an organ does not immediately meet a definition of “hard to place,” but due to medical or logistical complexities, ultimately requires alternate allocation pathways to ensure utilization. The Committee emphasized the importance of balancing standardization and benefits to efficiency, with adequate flexibility and clinical discretion.¹⁶⁴

Kidney Expedited Placement

In order to address the OPTN Board directive to consider incorporating a kidney expedited placement framework, the Committee sponsored the OPTN Kidney Expedited Placement Workgroup (the Workgroup). This Workgroup is composed of members from the OPTN Kidney Transplantation, Transplant Coordinators, Operations and Safety, OPO, and Ethics Committees. The Workgroup will work closely with the OPTN Expeditious Task Force and the Rescue Allocation Pathways Workgroup towards the ultimate development of a kidney expedited placement policy.

Toward this goal, the OPTN Expeditious Task Force and Executive Committee developed the *Expedited Placement Variance* policy. The variance policy created new opportunities to test and compare potential expedited placement protocols utilizing a small portion of the transplant community, allowing the OPTN to understand the impact of a potential policy ahead of full implementation. The OPTN Task Force’s Rescue Allocation Pathways Workgroup is responsible for reviewing, modifying, monitoring, and evaluating these protocols as they are submitted, iterated upon, and implemented.

In support of developing an expedited placement pathway, the Workgroup’s main work includes the following:

- Perform a literature review of expedited placement, to understand the strengths, weaknesses, and lessons learned from various expedited placement protocols across multiple organs and transplant systems
- Develop expedited placement variance protocol(s) for submission to the Task Force’s Rescue Allocation Pathways Workgroup
- Provide feedback and maintain awareness of approved variance protocols and their results

¹⁶¹ 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*.

¹⁶² 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.

¹⁶³ OPTN Kidney Transplantation Committee Meeting Summary, February 21, 2024

¹⁶⁴ OPTN Kidney Transplantation Committee Meeting Summary, October 11, 2024.

- Develop potential frameworks for policy and systems implementation of successful expedited placement variance protocol(s)
- Consider other alternate allocation pathways in Continuous Distribution, such as dual kidney

The Workgroup’s collaboration and coordination with the OPTN Task Force will facilitate more rapid development of a kidney expedited placement pathway in OPTN Policy. The Workgroup’s literature review and early collaboration with the OPTN Task Force are detailed below.

Expedited Placement Literature Review

The Workgroup reviewed several articles and monitoring reports, examining seven different expedited placement policies across multiple organs and transplantation systems. The Workgroup’s literature review examined the following expedited placement pathways:

- United Kingdom’s Initial “Rescue Allocation” Scheme¹⁶⁵
- United Kingdom’s Fast Track Kidney Allocation Scheme (FTKAS)¹⁶⁶
- Eurotransplant’s Recipient Oriented Extended Allocation (REAL)¹⁶⁷
- Eurotransplant’s Competitive Rescue Allocation (CRA)¹⁶⁸
- United States’ Kidney Accelerated Placement (KAP)¹⁶⁹
- United States’ Expedited Liver Placement¹⁷⁰
- United States’ Facilitated Pancreas^{171, 172}

A more extensive description of each of the above expedited placement pathways can be found in **Appendix E**. The Workgroup’s discussions, specifically focusing on effective key components and lessons learned from these expedited placement frameworks are summarized below. The Workgroup identified the following key considerations based on their protocols review:

- **Timing:** Reducing overall allocation time is necessary to effectively expedite placement
 - Expedited placement processes should be initiated adequately early in allocation
 - Specific and shortened timeframes for multiple points in allocation and evaluation process can reduce delays
 - Simultaneous offering and evaluation to reduce allocation time, if utilizing appropriately sized offer batches
 - Notification of post-clamp information should be sent simultaneously to all evaluating programs immediately upon availability
- **Effective Offering** – qualification criteria for programs to receive expedited offers should include sufficient historical evidence of acceptance for the type of organ being offered

¹⁶⁵ 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/>

¹⁶⁶ *Ibid.*

¹⁶⁷ 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*. <https://pubmed.ncbi.nlm.nih.gov/38073036/>

¹⁶⁸ *Ibid.*

¹⁶⁹ Noreen et al (2022). “Kidney Accelerated Placement Project: Outcomes and Lessons Learned.” *Am. J. Transplant*. 22(1): 210-221. <https://pubmed.ncbi.nlm.nih.gov/34582630/>

¹⁷⁰ OPTN OPO Committee Expedited Liver Placement Pathway 1 Year Post Policy Implementation Monitoring Report. October 15, 2022.

¹⁷¹ OPTN Policy 11.6: *Facilitated Pancreas Allocation*

¹⁷² OPTN Pancreas Committee: ‘Facilitated Pancreas Allocation’ part of the Eliminate DSA and Region in Pancreas Allocation 2-Year Post-Implementation Monitoring Report. July 10, 2023

- Qualifying criteria should be such that programs demonstrate a pattern of acceptance for the type of organ(s) being offered through the pathway
- Qualifying criteria should consider multiple organ and donor characteristics, including in the context of cold ischemic time
- Effective offering and evaluation requirements must consider program resources
- **Flexibility** – Expedited placement initiation should incorporate a level of clinical and logistical discretion
 - Multiple pathways may allow the transplant system to accommodate a variety of allocation situations more flexibly
- **Transparency and equity** must remain critical components of allocation, standard or expedited
 - Patient awareness of expedited placement should be prioritized, particularly as it relates to the likelihood of receiving potential offers
- **Outcomes** for organs offered through expedited placement pathways should be evaluated in the context of organs of similar quality

Timing

The Workgroup agreed that effective expedited placement pathways reduce cold ischemic time, particularly cold ischemic time, accumulated during post-recovery allocation.¹⁷³ Greater cold ischemic time is associated with worse transplant outcomes, and has been shown to increase the risk of non-use.¹⁷⁴ The Workgroup noted that early initiation of expedited placement processes can be a crucial way to reduce cold ischemic time.¹⁷⁵ The Workgroup pointed to an early initiation time point in the European Recipient Oriented Extended Allocation (REAL) and the United Kingdom (UK) Fast Track Kidney Allocation Scheme, which were able to effectively increase utilization of qualifying organs offered through these pathways.^{176,177}

In support of initiating expedited placement protocols early, the Workgroup supported including clinical criteria in initiation criteria, as well as cold ischemic time and allocation-based (such as number of centers declining or sequence number) criteria. The Workgroup added that post-clamp information, such as biopsy, anatomy, and pump, should also be considered in clinical criteria utilized to initiate expedited placement.¹⁷⁸

The Workgroup evaluated simultaneous and sequential offering methods and remarked on the benefits of simultaneous offering to reducing overall allocation time by aligning offer evaluation timeframes. Under the European “REAL” system, all programs in the region are notified of the organ offer and given 60 minutes to evaluate the offer and designate potential recipients.¹⁷⁹ The Workgroup noted that

¹⁷³ OPTN Kidney Expedited Placement Workgroup Meeting Summary, April 29th, 2024.

https://optn.transplant.hrsa.gov/media/otldt/htm/20240429_kidney-ex-placement-wg-summary_final.pdf

¹⁷⁴ Lum, et al (2023). Cold Ischemia Time, Kidney Donor Profile Index, and Kidney Transplant Outcomes: A Cohort Study. *Kidney Med*, 5(1): 100570.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9827060/#:~:text=We%20examined%20the%20outcomes%20of,the%20quality%20of%20the%20kidney.>

¹⁷⁵ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁷⁶ White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. *Clin Transplant*

¹⁷⁷ 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*.

¹⁷⁸ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁷⁹ 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 synchronizes offer evaluation across programs, which can substantially reduce post-clamp allocation time and thus overall cold ischemic time. The Workgroup compared the “REAL” model to the OPTN Liver Expedited Placement pathway, which maintained the sequential primary offering mechanism, and noted that sequential evaluation of organ offers can increase cold ischemic time, reduce the number of offers made and evaluated within a period of time, and may prevent effective expedited placement of an organ.^{180,181}

The Workgroup emphasized the importance of appropriately sizing simultaneous offer batches, citing the relative resource intensity of evaluation and potential disappointment factor for programs who have prepared candidates but ultimately do not receive the primary offer.¹⁸² The Workgroup referenced an article by Mankowski et al (2019), which found that simultaneous “batch” offering can be effective, but could also significantly increase offer volume for programs overall.¹⁸³ Workgroup members noted that immediate, rapid, and resource-intensive offer evaluation for expedited offers should be pre-empted by early notice as much as possible, such that programs are able to begin evaluation earlier in the process. The Workgroup noted that thorough and rapid offer review is a standard expectation for programs for any offer, but that early notification can reduce resource burden, and thus potential for program burnout, particularly in instances where programs may fully mobilize to accept but not receive the organ. Members agreed that additional accountability for programs could be achieved via clearly designated, shortened time intervals or by asking programs to indicate which patients they would accept the organ for. Members also noted that clarity, transparency, and fairness in expedited allocation processes – such that the primary offer is given to the highest ranked candidate as opposed to the fastest responding program – may help to reduce program burn out.¹⁸⁴

The Workgroup noted that clear, specific expectations regarding information sharing and offer evaluation for both OPOs and transplant programs could also reduce allocation delays, both in standard and expedited allocation schemes. Furthermore, the Workgroup recommended that immediate and simultaneous notification of availability of post-clamp organ information to all interested programs, regardless of simultaneous or sequential offering, can synchronize offer evaluation and reduce overall post-recovery allocation time. The Workgroup noted that, at this point, evaluation should be rapid and immediate, as programs are no longer awaiting further information from the OPO to determine clinical suitability.¹⁸⁵

Similar to Committee discussions, the Workgroup also noted that post-clamp information gathering can contribute to accumulation of cold ischemic time. Several members agreed that post-clamp organ testing practices should be evaluated for necessity, reliability, and effectiveness, against contribution to risk of non-use for a particular organ.¹⁸⁶

¹⁸⁰ OPTN Policy 9.10: Expedited Liver Offers

¹⁸¹ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁸² *Ibid.*

¹⁸³ Mankowski, et al. (2019). Accelerating kidney allocation: Simultaneously expiring offers. *Am J Transplant*, 19(11), 3071-3078. <https://pubmed.ncbi.nlm.nih.gov/31012528/>

¹⁸⁴ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁸⁵ *Ibid.*

¹⁸⁶ OPTN Kidney Expedited Placement Workgroup, April 29th, 2024.

Effective Offering

The Workgroup compared models allowing programs to opt-in to receiving expedited offers, with those utilizing qualifying criteria to determine which program eligibility to receive expedited offers. Ultimately, the Workgroup agreed that qualifying criteria may be most appropriate in the context of expedited kidney allocation, particularly as this ensures critical allocation time is not spent making offers to programs that would not accept such an organ based on its characteristics.¹⁸⁷ The Workgroup discussed several potential qualifying criteria, noting sufficient historical acceptance thresholds, with consideration for specific clinical characteristics.¹⁸⁸

Both the OPTN Liver Expedited Placement policy and the United Kingdom's FTKAS utilize an opt-in model for programs interested in receiving expedited offers.^{189, 190} Regarding the opt-in model utilized in the OPTN Liver Expedited Placement pathway, the Workgroup noted that more than 60% of candidates opted in as eligible to receive expedited offers, despite the majority of programs and candidates never accepting such offers. The OPTN OPO Committee provided feedback that this opt-in model resulted in OPOs having to make offers to programs that would not accept them, ultimately delaying allocation and increasing the risk of non-use for those livers.¹⁹¹ The Workgroup remarked that opt-in alone can reduce the effectiveness of offering, with OPOs making offers that programs evaluate but ultimately do not accept, and thus increase the number of offers being made, increasing overall allocation time and risk of non-use. The Workgroup noted that the opt-in model utilized in the UK's FTKAS still allowed for increased utilization of these organs, but that the UK system is significantly smaller than the United States system, with less than 30 transplant centers within the UK system, compared to more than 200 in the US.¹⁹² Furthermore, White et al. emphasized variation in transplant program awareness of the scheme, and that 75 percent of organs offered through the FTKAS were accepted by 5 of 10 participating programs.¹⁹³

The Workgroup agreed that qualifying criteria should be based on historical program acceptance patterns, such that programs receiving expedited offers have demonstrated a pattern of acceptance for the clinical characteristics of the organ being offered. Specifically, the Workgroup noted that the organ's characteristics should be considered in context with each other when determining whether the organ aligns with program's historical behavior, including consideration for cold ischemic time. The Workgroup noted that the offer filters model could provide a good foundation for understanding program acceptance patterns and determining acceptance thresholds.¹⁹⁴

The Workgroup noted that qualifying criteria should be clear and objective in order to ensure transparency, for both programs and patients. Furthermore, objective criteria based on program acceptance ensures equity of an expedited placement system, such only those candidates whose program would not accept the offer are those bypassed by the expedited placement system.¹⁹⁵

¹⁸⁷ OPTN Kidney Expedited Placement Workgroup, April 29th, 2024.

¹⁸⁸ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁸⁹ 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.

¹⁹⁰ OPTN OPO Committee Expedited Liver Placement Pathway 1 Year Post Policy Implementation Monitoring Report. October 15, 2022.

¹⁹¹ OPTN OPO Committee Meeting Summary, October 16, 2022.

¹⁹² OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁹³ White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. Clin Transplant

¹⁹⁴ OPTN Kidney Expedited Placement, May 13th, 2024.

¹⁹⁵ *Ibid.*

Finally, the Workgroup agreed that expedited placement pathways and qualifying criteria should be flexible enough to account for shifting program behavior. The Workgroup noted that previously non-qualifying programs should be able to become eligible by demonstrating increased acceptance of clinically concerning organs. The Workgroup noted that qualifying criteria should consider acceptance behaviors based on clinical characteristics in combination with various cold ischemic time thresholds and distances.¹⁹⁶

The Workgroup reiterated that offer evaluation resources must also be managed efficiently, and that large volumes of offers that the program will not have an opportunity to accept could result in program burnout. The Workgroup warned that this could negatively impact the success of an expedited placement pathway and the system as a whole as it impacts a programs' ability to evaluate offers adequately, thoroughly, and rapidly. The Workgroup emphasized that clarity, transparency, and fairness in expedited allocation processes and expectations are important to ensuring offers are made and evaluated effectively, for OPOs and transplant programs.¹⁹⁷

Flexibility

The Workgroup emphasized that flexibility will be key to ensuring expedited placement is effective at reducing non-use, particularly given the wide range of allocation situations and reasons an organ may have an increased risk of non-use.¹⁹⁸ The Workgroup remarked that clinical discretion should be incorporated into the criteria utilized to initiate expedited placement, similar to that incorporated in the UK Fast Track Kidney Allocation and Eurotransplant REAL schemes. The Workgroup noted that clinical and logistical discretion will ensure expedited placement is feasible in every scenario where it may be necessary.

The Workgroup expressed support for the Eurotransplant system of expedited placement, which utilizes two non-standard expedited placement pathways. If an organ cannot be placed through standard allocation, it may be allocated via the REAL system; if the organ still cannot be placed through REAL or there are significant time constraints and risk of non-use, the organ can be allocated via the CRA system.¹⁹⁹ The Workgroup noted that this tiered system provides a higher level of flexibility, which can reduce non-use by accounting for a greater range of allocation scenarios. The Workgroup noted that multiple methods of expedited placement may be more complex and less comprehensible, particularly for patients.²⁰⁰

Transparency and Equity

The Workgroup emphasized the importance of ensuring transparency and equity around expedited placement pathways. Members agreed that at least initially, expedited allocation must balance offering effectively to those candidates and programs that will accept the offer, but maintain equitable priority of candidates receiving those offers. To achieve this, the Workgroup recommends utilizing the match run to determine candidate priority.²⁰¹

¹⁹⁶ OPTN Kidney Expedited Placement Workgroup, May 13th, 2024.

¹⁹⁷ *Ibid.*

¹⁹⁸ OPTN Kidney Expedited Placement Workgroup, April 29th, 2024.

¹⁹⁹ 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.

²⁰⁰ OPTN Kidney Expedited Placement Workgroup, Meeting Summary, May 13th, 2024.

²⁰¹ OPTN Kidney Expedited Placement Workgroup, Meeting Summary, May 13th, 2024.

The Workgroup also touched on the importance of ensuring patient understanding of expedited placement pathways. This is particularly true of any system where programs are asked to identify and prepare candidates to receive an offer that may not ultimately result in a transplant for that candidate. Members noted that these situations can be emotionally taxing, and it is important for patients to understand how these offers work.²⁰²

Outcomes

The Workgroup noted that clinical considerations should be incorporated into analysis and monitoring outcomes for organs allocation via expedited pathways. Organs requiring placement through such pathways may have clinical characteristics associated with shorter expected graft longevity, greater risk of delayed graft function, or greater risk of graft failure, that may have made these organs less likely to be accepted in standard allocation.²⁰³

Collaboration with the OPTN Expeditious Task Force for Efficiency

The Workgroup’s literature review and subsequent discussions were shared with the OPTN Task Force, including the Task Force’s Rescue Allocations Pathways Workgroup. The Rescue Allocations Pathways Workgroup can utilize these considerations as they continue to approve, modify, monitor, and evaluate expedited placement protocols tested under the *Expedited Placement Variance* policy, implemented in April of 2024. The Workgroup has also provided feedback on the first expedited placement variance protocol, *Accelerated Placement of Hard-to-Place Kidneys*, with consideration for the Workgroup’s previous literature review.

The Workgroup plans to submit a variance protocol for the expedited placement of kidneys for review by the Rescue Allocations Pathway Workgroup this summer.

Looking Ahead: Project Plan

The Committee will continue their efforts to:

- Develop a data driven definition of “hard to place” kidneys, including evaluating association and interaction of clinical donor and organ criteria with non-use
- Address and finalize several operational considerations, including released organs, kidney minimum acceptance criteria screening, dual kidney, and an updated definition kidney medical urgency definition
- Explore enhanced non-use and efficiency modeling capabilities with SRTR and MIT partners, and
- Consider modifications to the allocation algorithm, including new efficiency attributes, adjustment and re-optimization of weights, and revisions to attribute scales

The Kidney Expedited Placement Workgroup will continue to work towards submission of an expedited placement protocol for consideration by the OPTN Rescue Allocations Pathways Workgroup.

The Committee will continue coordination and collaboration with the OPTN Task Force and other OPTN collaborating committees on their efforts to incorporate efficiency goals. The Committee will also

²⁰² OPTN Kidney Expedited Placement Workgroup, Meeting Summary, May 13th, 2024.

²⁰³ *Ibid.*

continue to update the community and the OPTN Board of Directors on the progress of the Continuous Distribution project and efficiency and non-use related directives.

NOTA and Final Rule Analysis

The Committees submit this update under the authority of NOTA, which requires the OPTN to "establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,"²⁰⁴ 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."²⁰⁵ The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."²⁰⁶ While this Request for Feedback will not immediately result in an allocation policy change, this request will aid in the development of future allocation policy for all kidneys and pancreata in a continuous distribution framework that meets the criteria above. This effort will also impact equitable allocation through examining the appropriate balance between priority for single and multi-organ candidates as well as exploring medical urgency priority for patients waiting for a pancreas. As continuous distribution seeks to consider candidate and donor characteristics holistically, each item discussed above may impact the candidate's placement on any given match run.

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.²⁰⁷ Prior to adoption of any allocation policies, the OPTN will determine whether any candidates will be treated less favorably under the future policy, and if there is a need for transition procedures for those candidates or others. This would allow members and patients time to prepare for these changes. The Committees will continue discussions on transition procedures as the project progresses.

Conclusion

This Committee update details the Kidney Committee's continued efforts to develop the continuous distribution of kidneys project, including the incorporation of new efficiency objectives regarding decreasing non-use, decreasing allocation out of sequence, and expedited placement of kidneys.

Specifically, this update summarizes Committee discussions investigating non-use, identifying key drivers of non-use, establishing continuous distribution-specific efficiency goals, and developing a data-

²⁰⁴ 42 U.S.C. §274(b)(2)(B)

²⁰⁵ 42 CFR §121.4(a)

²⁰⁶ 42 CFR §121.8(a)

²⁰⁷ 42 CFR §121.8(d)(1)

driven definition of “hard to place” kidneys. This paper also details the efforts of the Kidney Expedited Placement Workgroup, which is working towards the development of a kidney expedited placement policy. The Committee’s collaboration with the OPTN Expeditious Task Force on expedited placement and a range of efficiency topics and goals is also detailed within this paper. Finally, this update also describes the Committee’s discussions regarding continued modeling and optimization efforts, including efforts to expand modeling capabilities to include non-use and efficiency metrics.

Considerations for the Community

The Committee encourages all interested individuals to comment on this paper in its entirety. The Committee also welcomes specific feedback on the following questions:

Modeling and Optimization

- In the most recent round of modeling, OASim modeling suggested that median travel distance for pediatric candidates could be over 650 nautical miles for each simulated continuous distribution policy.²⁰⁸ Do you feel that it is appropriate to slightly reduce the weight of pediatric priority, in order to reduce median travel distances within a more feasible range?
 - If not, do you feel that offer filters and candidate acceptance criteria screening will be adequate to help programs manage offers from greater distances?
 - If not, do you feel that the pediatric rating scale should be modified or updated, to stratify pediatric priority by distance?
- Do you support the updated optimized CPRA rating scale that ensures access for the most highly sensitized candidates?

Defining Hard to Place

- Do you support a multi-pronged approach to defining hard-to-place kidneys, such that a kidney may be considered “hard to place” by meeting clinical criteria, allocation thresholds, and/or a cold ischemic time threshold?
- **Clinical Criteria:**
 - Do you support stratifying clinical criteria by KDPI, such that a donor with a lower KDPI may need to meet multiple clinical criteria to be considered “hard to place?”
 - Do you have any feedback or recommendations on whether anatomy characteristics should be incorporated in a definition of “hard to place?” If so, which anatomy characteristics?
- **Allocation thresholds:**
 - Do you support a “hard to place” allocation threshold based on number of programs having responded with a total center decline, defined as declining for all candidates at the program?
 - Are there other potential allocation-specific thresholds that the Committee should consider with respect to defining “hard to place?”
- **Cold ischemic time thresholds:**
 - Do you support the inclusion of a stand alone cold ischemic time threshold, such that an organ would be considered “hard to place” once it reached a specific cold ischemic time, regardless of other characteristics or progression of allocation?

²⁰⁸ Scientific Registry of Transplant Recipients, “Kidney Pancreas 2023 Allocation Simulation Analysis Report.” July 11, 2023. https://optn.transplant.hrsa.gov/media/052pegrg/kipacd_2023_01_analysisreport_2023_07_17.pdf

- If not, should cold ischemic time be included in conjunction with clinical or allocation characteristics? How should this be achieved?
- Do you support the use of a cold ischemic time threshold of 5 hours, based on SRTR data analyzing increasing risk of non-use past 5 post-cross clamp?
- Are there other potential considerations and options for cold ischemic time that the Committee should consider with respect to defining “hard to place?”

Expedited Placement

- Specifically, do you have any recommendations, or support recommendations discussed here, on how to achieve effective offering, appropriate timing, reducing cold ischemic time, maintaining flexibility, and ensuring transparency and equity in expedited placement?

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.²⁰⁹

Figure 21 shows how allocation goals combine into a composite allocation score (CAS).²¹⁰ 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 21: Components of Composite Allocation Score (CAS)

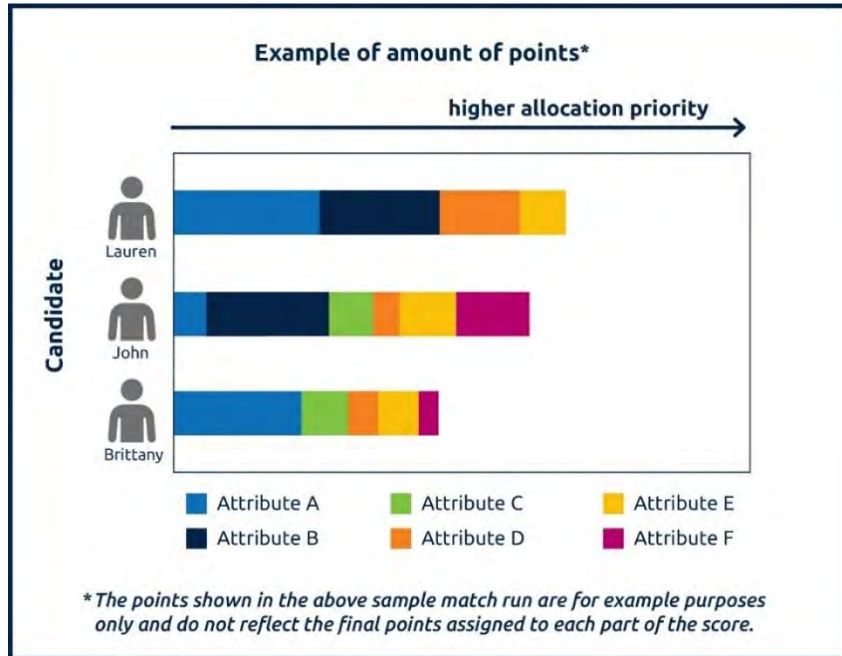


²⁰⁹ 42 U.S.C. Sec. 273 et seq. and 42 C.F.R. part 121.

²¹⁰ *Continuous Distribution of Kidneys and Pancreata Concept Paper*, OPTN Kidney and Pancreas Transplantation Committees, August 2021.

Figure 22 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.

Figure 22: Example of a Composite Allocation Score Match Run²¹¹



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.²¹² In **Figure 12**, the amount of points given to a candidate varies depending upon the candidate's specific circumstances. In comparison, the current classification-based system prioritizes all patients in a higher classification ahead of candidates in a lower classification, regardless of other considerations. A continuous distribution framework will eliminate hard boundaries between classifications existing in the current system. Candidates will receive points for various attributes and all of these attributes can be considered together as part of a CAS. A candidate's CAS, based on both candidate and donor characteristics, will determine their priority on each match run.

²¹¹ 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.

²¹² 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: Re-Optimization Goals and Weights

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 – 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 B – no less than current policy
 - Policy C2 – no less than 97% of current policy
 - Policy D2 – no less than 97% of current policy

The relevant weight combinations 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.

Table 3: Re-Optimized Policy Scenarios

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

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 Lung Recipient	0.032	0.032	0.032	0.032
<u>Waiting Time</u>	<u>0.039</u>	<u>0.041</u>	<u>0.049</u>	<u>0.051</u>
<u>Proximity Efficiency</u>	<u>0.079</u>	<u>0.069</u>	<u>0.075</u>	<u>0.059</u>

Appendix C: Kidney Review Board Framework

The Kidney Committee has expressed support for the following Kidney Review Board framework, pending additional discussions on monitoring and establishing a policy threshold to limit transplant at a denied status.

Kidney Review Board Structure:

Review Board Leadership

The Kidney Review Board will be led by a Chair and a Vice Chair. The Chair and Vice Chair will be appointed by the Kidney Committee.

The Chair and Vice Chair will be clinical members of the Kidney Committee. If no clinical member of the Kidney Committee is willing or able to lead the Review Board Workgroup, a clinical member of another OPTN Committee with relevant Kidney expertise may fulfill this role. Similar to Committee Leadership structure, the Vice Chair will serve as the next Review Board Chair. Both the Chair and Vice Chair position have a year-long term, with the Vice Chair becoming Chair as a two-year commitment.

The Review Board Chair will have several responsibilities, and act as head of the Review Board. In this capacity, the Chair will be responsible for hearing concerns from reviewers or submitting programs, and may reach out to review board members to address inappropriate reviewer comments or provide education. The Review Board Chair will also be able to approve the removal of non-responsive reviewers. The Review Board Chair will act as a liaison between the Review Board and the Committee, maintaining awareness of cases and trends in cases and remaining apprised of whether new policies may be necessary. The Review Board Chair will also serve as Chair to the appeal review body (ARB) and will be responsible for leading the appeal review body calls. In this capacity, they will be responsible for guiding conversation and maintaining a working knowledge of OPTN Policies and Guidance documents. Finally, the Review Board Chair will also act as a reviewer in the general review board pool, and review cases as assigned. The Review Board Chair will be considered a representative of their program.

The Review Board Vice Chair will back the Chair in all of these responsibilities. The Vice Chair may act as the Review Board Chair in the Chair's absence. The Vice Chair will also particularly be responsible for attending appeal review board calls, and being prepared to lead these calls in the case the Chair is not able or available. The Vice Chair will also reach out to review board members to educate where appropriate. Finally, the Vice Chair of the Review Board will act as a reviewer in the general review board pool, and will be expected to review cases as assigned.

Review Board Membership

To begin, the Kidney Review Board (the Review Board) will be composed of 40 members. Review Board membership will not be included in the operational guidelines, in order to allow for flexibility and later modification if necessary. At minimum, at least one third of the review board membership should have pediatric expertise.

Review Board participants will be recruited via an annual open call for nominations. Programs may submit one reviewer nominee if interested, and membership will be filled on a first come, first serve basis. Programs who submit nominees after the Review Board is full will be kept on a waiting list, to be

called on if the pool is expanded, or a reviewer steps down or otherwise needs to be replaced. The Workgroup determined that regional representation was not necessary, as this is a national review board and clinical considerations would not vary by region.

The Review Board Workgroup is recommending the following review board member qualifications. These qualifications will not be monitored, but are guidance for programs submitting nominees. Review Board member qualifications include:

- Reviewers should be at least 5 years post-clinical fellowship with direct kidney transplant experience
- Reviewers should be working in transplant at an active kidney transplant program

Pediatric Review Board member qualifications include:

- Reviewers should be at least 5 years post-fellowship with direct transplant experience
- Reviewers should be actively working in transplant at an active transplant program with a pediatric kidney component
- Pediatric reviewers should have worked with and/or performed at least 2 transplants on a pediatric patient in the last three years
 - At least one should be for a patient under the age of 6 years old or weighing less than 25kg at time of transplant

Review board membership is a 2-year commitment. Half of the Review Board membership will roll off each year, and the call for reviewer nominations will happen annually. Upon initiation of the Review Board, the second half of respondents to the open call for nominations will have a single year term on the board. Upon call for nominations, programs who have just had representatives roll off will be allowed to submit a nominee again, in consideration of potentially limited number of programs with pediatric expertise. However, nominees who have just rolled off or from programs who have had representation recently roll off will not be prioritized, unless there are limited nominees or appropriate representation must be obtained (such as ensuring pediatric reviewers are represented).

Case Review:

Pediatric and Adult Case Reviews

Exception requests submitted on behalf of adult patients will be reviewed by review board participants with adult expertise. If a full set of adult reviewers cannot be found, the case review will be filled in with available pediatric kidney reviewers. Exception requests submitted on behalf of pediatric candidates will be reviewed by review board participants with pediatric expertise. If a full set of pediatric reviewers cannot be found, the case review will be filled in with available adult kidney reviewers. Reviewers have the option to excuse themselves from a case if they do not feel comfortable reviewing and voting.

Potential Exception Requests and Review Timing

Exceptions are attribute-based, candidate-specific, and submitted prior to the time of match run. Exception requests are submitted to shift a candidate's position on a rating scale, in order to grant a candidate more points for that specific attribute. Exceptions do not change the weight of the attribute, nor the importance of that attribute relative to other attributes.

The Review Board Workgroup identified that exception requests may be submitted for the following attributes:

- Medical urgency
- Kidney after liver safety net

Exception requests regarding medical urgency will be reviewed retrospectively, meaning the candidate will receive the benefit of the exception prior to and during case review. All other exception requests will be reviewed prospectively, meaning the candidate does not receive the benefit of the exception until the request is approved.

The Review Board Workgroup identified that exception requests were *not* appropriate for the following attributes:

- DR Matching
- Longevity: Kidney Donor Profile Index (KDPI) versus Estimated Post-Transplant Survival (EPTS)
- Blood type
- Calculated panel reactive antibody (CPRA)
- Prior living donor priority
- Pediatric priority
- Waiting time
- Proximity efficiency

Case Review Workflow

Exception request submission and case review will follow the below workflow:

A transplant program may submit an exception request for their candidate, including a justification narrative supporting their request. The request is then reviewed by the OPTN Organ Center, who redacts any personally identifiable information and then submits it to the Review Board.

Once submitted, the Review Board system will assign the case to 7 review board participants. Reviewers are selected with consideration for their expertise and case type, potential conflicts of interest, and then at random based on reviewer case load. Reviewers with a conflict of interest – such as working at or having permissions at the submitting center – will not be permitted to review that case.

Upon submission and assignment of the case, a five calendar day clock starts on the case. Day of submission is considered day zero. Reviewers will have three days (until midnight on day three) to review the case and submit a vote. If a reviewer does not vote within three days, they will be replaced by another reviewer, also assigned at random. The Review Board system will send email notifications to participants when the case is assigned to them, to remind the participant on day two, and to alert a participant that the exception case has been reassigned due to lack of voting. If they are not able to vote, participants may request that the case be reassigned to another randomly selected participant. Participants are also able to mark themselves as out of office to prevent case assignments.

The case will close when a majority approval or denial is met, or when the case reaches the end of the five day voting timeline, whichever is first. Votes are tallied using the Robert's Rules of Order definition of a majority – “simply more than half” – to determine the case outcome of approved or denied. In

example, the case may close on day three if 4 of 7 reviewers have voted to approve the case. If a full majority vote is not achieved by the end of the case timeline, the case outcome will be determined by the majority of votes received. For example, if three reviewers have voted to approve and two have voted to deny the exception request by the end of day five, the case will close at the end of day five with an approval. In the event of a tie, benefit will be given to the candidate and the exception approved. The transplant program will receive an appeal notification with the outcome of the exception request.

Reviewers will have the opportunity to leave comments on cases that they have voted to approve. Reviewers will be required to leave a comment explaining their decision to the program.

Case Review: Edge Cases

The following scenarios present edge cases which are highly unlikely. However, in the event that they do occur, it is necessary that the system knows how to act and operate.

If seven available reviewers cannot be found in the system, the system will pull as many kidney-specific reviewers as possible. The minimum number of reviewers assigned to a case is two – if at least two reviewers cannot be found, the system will default to an approval of the exception request.

On a similar note, the minimum number of votes to consider a case denied is two votes. If two reviewers submit conflicting votes – one to approve and one to deny – the system will recognize the tie and default to an approval. If only one vote or no votes are submitted by the end of the case timeline, the system will default to an approval, as this is an insufficient number of votes to be considered a peer review.

Appeal Process

If an exception request for medical urgency (retrospectively reviewed) is denied, the transplant program will have to remove the patient from the status or submit an appeal within 5 days of the denial notification. If an exception request for a prospectively reviewed attribute is denied, the transplant program will may submit an appeal within 5 days of the denial notification. Once the appeal is submitted, the 5 day case review starts over again. The first appeal is reviewed by the participants that denied the initial request, along the same review timeline as the initial review. Upon this appeal, programs will have the opportunity to submit additional information in their justification narrative, addressing comments received upon the initial denial.

Second Appeal Review Body

If the first appeal is also denied, programs will be given one more opportunity to appeal. Programs will again have 5 days from notification of the first appeal's denial to downgrade their patient or submit an appeal. The second appeal will be reviewed by the Kidney Appeal Review Body (ARB). The ARB will have 14 days from assignment to review, meet via conference call to discuss, and vote on the case – if the case is not voted on by the end of the 14 day period, the request will be approved by default.

Membership of the ARB is composed of members from the general Review Board pool, with a balance of pediatric and adult reviewers. A minimum of 1/3rd and a maximum of ½ the ARB membership will have pediatric expertise. Membership on the ARB is considered a responsibility of joining the Review Board. ARB members have a two year commitment on the ARB, and half of the ARB will roll off every year. There will be 12 total ARB members, including the Chair and Vice Chair.

All members of the ARB are assigned to all second appeal cases, and expected to join the ARB call to review, discuss, and vote. Members are exempted from cases for which they have a conflict of interest.

Cases will be reviewed in regularly scheduled calls, which will occur biweekly – if there are no cases to review, the call will be canceled. For now, scheduling and meeting cadence will not be incorporated into the operational guidelines. Programs may opt to have a representative join the call to present the case and answer questions, but a program representative is not required to join in order for the case’s review to move forward. The program representative will not be present for discussion and voting.

The Kidney Review Board Chair and Vice Chair will be voting members of the ARB, and will be expected to join all calls. The Chair will have the responsibility of leading the ARB call, maintaining a working knowledge of OPTN Policies and Guidance and guiding conversation along those policies and guidelines. If the Chair has a conflict of interest or is otherwise unable or unavailable to lead the call or case review, the Vice Chair will be expected to lead in their stead. If the Chair *and* Vice Chair are unavailable, a present member of the ARB may volunteer to lead the call, with a vote of approval from other present ARB members. If no volunteer steps forward to lead the call, the call and case review will be rescheduled.

The minimum number of ARB reviewers required to discuss the case and submit a vote is three. If a minimum of three ARB reviewers cannot convene to vote before the end of the case timeline, the request will be approved by default. If a minimum of three votes are not submitted before the end of the case timeline, the request will be approved by default.

Case outcomes will be decided by majority using the same Robert’s Rules of Order, defined as “simply more than half.” Ties at the ARB level will result in an automatic approval.

Appendix D: Kidney Non-Use Literature Review

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Appendix E: Expedited Placement Pathways

The Workgroup’s literature review examined the following expedited placement pathways, each of which are described below:

- United Kingdom’s Initial “Rescue Allocation” Scheme²¹³
- United Kingdom’s Fast Track Kidney Allocation Scheme (FTKAS)²¹⁴
- Eurotransplant’s Recipient Oriented Extended Allocation (REAL)²¹⁵
- Eurotransplant’s Competitive Rescue Allocation (CRA)²¹⁶
- United States’ Kidney Accelerated Placement (KAP)²¹⁷
- United States’ Expedited Liver Placement²¹⁸
- United States’ Facilitated Pancreas^{219, 220}

United Kingdom – Initial Rescue Allocation and Fast Track Kidney Allocation Scheme (FTKAS)

The United Kingdom’s initial rescue allocation scheme was initiated once 5 centers had declined the kidney(s) for donor- or organ-related reasons. The kidney would then be offered to alternative centers who had previously opted in to receive “rescue offers.” These offers were made to sequentially based on the rank order of these program’s patients based on the allocation algorithm, which resulted in increased CIT.²²¹

In 2012, this initial rescue allocation scheme was replaced by the Fast Track Kidney Allocation Scheme, or FTKAS. In order to be eligible for FTKAS, kidneys from donation after brain death (DBD) donors had to meet at least one of the following criteria:²²²

- Kidney deemed unsuitable for transplant by the Specialist Nurse – Organ Donation (SNOD), or member of the procurement team
- Kidney has been declined by 5 programs for donor- or organ-related reasons
- 6 hours of cold ischemic time has elapsed without offer acceptance

Kidneys from DCD donors must meet at least one of the following similar criteria:²²³

- Kidney deemed unsuitable for transplant by SNOD or member of the procurement team

²¹³ 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/>

²¹⁴ *Ibid.*

²¹⁵ 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*. <https://pubmed.ncbi.nlm.nih.gov/38073036/>

²¹⁶ *Ibid.*

²¹⁷ Noreen et al (2022). “Kidney Accelerated Placement Project: Outcomes and Lessons Learned.” *Am. J. Transplant*. 22(1): 210-221. <https://pubmed.ncbi.nlm.nih.gov/34582630/>

²¹⁸ OPTN OPO Committee Expedited Liver Placement Pathway 1 Year Post Policy Implementation Monitoring Report. October 15, 2022.

²¹⁹ OPTN Policy 11.6: *Facilitated Pancreas Allocation*

²²⁰ OPTN Pancreas Committee: ‘Facilitated Pancreas Allocation’ part of the Eliminate DSA and Region in Pancreas Allocation 2-Year Post-Implementation Monitoring Report. July 10, 2023

²²¹ 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/>

²²² *Ibid.*

²²³ *Ibid.*

- Kidney has been declined by 3 programs for donor- or organ-related reasons
- 6 hours of cold ischemic time has elapsed without offer acceptance

The FTKAS-eligible kidney is offered simultaneously to all programs who had previously opted in to receive FTKAS offers. From the FTKAS offer notification, centers have 45 minutes to review donor and organ information and indicate acceptance or decline. At the end of the evaluation period, the kidney is offered to the highest ranking patient and center, based on the initial allocation algorithm.²²⁴

Eurotransplant – Recipient Oriented Allocation (REAL) and Competitive Rescue Allocation (CRA)

The Eurotransplant (ET) system utilizes two different methods of rescue allocation to encourage utilization of transplantable organs. Competitive Rescue Allocation (CRA) has been in use since 1996, and provides a more aggressive allocation pathway. The Recipient-Oriented Allocation scheme was implemented alongside CRA in 2012 to provide increased transparency, accountability, and efficiency of rescue allocation processes. Typically, organs not placed through standard allocation are then offered via REAL. CRA is typically only initiated when an organ cannot be allocated in REAL, or in instances where allocation time is extremely limited, such as cases of unstable donors and long cold ischemic times.²²⁵

In order to initiate REAL, at least one of the following criteria must be met:²²⁶

- Rejection of the offered graft for all recipients of 5 programs for donor- or organ-related medical reasons during standard allocation
- Lack of acceptance of the graft from a donor 65 years or older, 5 hours after procurement
 - If the donor is younger than 65 years, a logistical reason is also necessary
- Logistics preventing timely transplant, causing increased cold ischemic time
- Impending loss of the organ for transplant

Once REAL is initiated, the ET system contacts all programs in the region or country where the organ is located to notify them of the REAL offer. Within the ET online application, each program is able to see a list of their potential recipients and their respective ranking in standard allocation. Programs may select up to 3 designated recipients for whom they would accept this offer. Programs must designate their recipients within 60 minutes, or 30 minutes in Germany, in order to be eligible to receive the primary offer. At the end of the 60 minute evaluation period, the ET offers to organ to highest ranked designated candidate, based on the standard allocation ranked.²²⁷

If the organ cannot be allocated in REAL, the ET may initiate CRA. In CRA, the organ is offered to at least three programs simultaneously. The first program to accept the offer will receive the organ. This program may choose to transplant the organ to any of the ABO-compatible candidates listed at their

²²⁴ 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/>

²²⁵ 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*. <https://pubmed.ncbi.nlm.nih.gov/38073036/>

²²⁶ *Ibid.*

²²⁷ *Ibid.*

program. The program may decide to assign the graft according to standard allocation or other predetermined internal rules.²²⁸

United States – Kidney Accelerated Placement (KAP)

The Kidney Accelerated Placement (KAP) project was a study performed to test a potential expedited kidney placement policy between July 18, 2019, and July 15, 2020. This project utilized a bypass functionality to expedite kidney allocation, with bypasses applied to programs based on previous acceptance behavior.

In order to qualify for KAP, the following criteria must have been met:

- Deceased donor 18 years of age or older
- KDPI greater than or equal to 80% at time of match run
- Kidney(s) declined by all local and regional candidates, with allocation reaching national classifications

OPTN Policy at that time required that OPOs hand off national kidney allocation to the OPTN Organ Center. With this in mind, all KAP kidneys were allocated via the OPTN Organ Center.

Once allocation reached national classifications, the Organ Center utilized the KAP tool to apply bypasses to non-KAP-qualifying programs. The Organ Center then continued sequential allocation through the match run. If the kidneys were not placed via KAP, the bypasses were removed, and offers were made sequentially, in rank order, to the remaining candidates at non-KAP-qualifying programs.

Instead of a static list of qualifying programs, program eligibility to receive KAP offers was determined based on each donor's characteristics. The characteristics considered include donor KDPI, age, peak serum creatinine, history of diabetes, history of intravenous drug use, and DCD status. In order to be eligible for KAP offers for a certain donor, programs must have accepted and transplanted at least one kidney with similar or worse donor characteristics within the prior two years. Critically, KAP accounted for shifting program behaviors. Programs were able to increase KAP offer eligibility by accepting and transplanting similarly modeled kidneys from local and regional offers.

United States – OPTN Liver Expedited Placement Policy

The OPTN Liver Expedited Placement policy establishes a policy-approved pathway for OPOs to allocate livers that have been declined late in allocation or recovery. OPOs are permitted, but not required, to utilize this pathway if criteria have been met. An OPO may expedite liver allocation once all of the following criteria have been met:

- Organ recovery has begun, or for DCD donors, withdrawal of life-sustaining mechanical support has been initiated
- The primary accepting liver transplant hospital has notified the OPO that the primary candidate will no longer accept the liver offer
- The OPO has reported the following to the OPTN:
 - Date and time of organ recovery initiation, or for DCD donors, withdrawal of life-sustaining support
 - Date and time the OPO was notified of the accepting liver transplant hospital's decision to withdraw acceptance

²²⁸ 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*. <https://pubmed.ncbi.nlm.nih.gov/38073036/>

- Reason for primary offer refusal

The expedited liver placement pathway operates as a bypass functionality on the original match run. Once the above criteria have been met, the OPO may utilize the expedited placement functionality to apply bypasses to candidates who are not eligible to receive expedited placement offers. The OPO may notify any number of programs of the expedited offer as they choose; however, the OPO must still sequentially according to the match run when making the primary offer. Transplant programs have 30 minutes from notification to determine acceptance or refusal for the candidate receiving the offer. At the end of 30 minutes, the OPO must place the liver with the highest ranking candidate with a provisional yes.

In order for a liver candidate to become eligible to receive expedited offers, the candidate's transplant program must individually opt-in each candidate. To do this, the program must agree to accept a liver recovered by any procurement team, and report expedited-liver specific acceptance criteria for each candidate, including:

- Minimum and maximum acceptable donor age
- Maximum acceptable body mass index (BMI)
- Maximum acceptable distance from donor hospital
- Minimum and maximum acceptable donor height
- Acceptable percentage of macrosteatosis
- Minimum and maximum acceptable donor weight

United States – OPTN Facilitated Pancreas Policy

The OPTN Facilitated Pancreas policy allows, but does not require, OPOs to expedite placement of isolated pancreata if the pancreas has not been accepted within 3 hours of scheduled organ recovery. Facilitated pancreas operates as a bypass functionality. Once the time threshold has been reached, the OPO may utilize the facilitated pancreas functionality to automatically apply bypasses to pancreas-alone candidates registered at non-qualifying programs more than 250 nautical miles away from the donor hospital. OPOs are required to continue to follow the match run during facilitated pancreas allocation.

Programs qualify to receive facilitated pancreas offers if the program has transplanted at least two deceased donor pancreata from donor hospitals more than 250 nautical miles away in the last two years. Pancreata transplanted as part of a kidney-pancreas or multi-organ transplant are counted towards facilitated pancreas qualification. Qualifying programs who do not wish to receive facilitated pancreas offers must explicitly opt out.