OPTN Kidney Transplantation Committee
Meeting Summary
October 11, 2023
In Person - Detroit, MI

Jim Kim, MD, Chair
Arpita Basu, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via in person in Detroit, Michigan on 10/11/2023 to discuss the following agenda items:

1. Welcome and Housekeeping
2. Recap Continuous Distribution: Progress thus Far, Modeling Updates, and Looking Ahead
3. Recap on Efficiency Task Force and Board Resolution
4. Public Comment Review
5. Data Review: Efficiency and Non-Use
6. Breakout Groups
7. Open Forum
8. Post-Implementation Monitoring: Establish Minimum Criteria to Require Renal Procurement Biopsy

The following is a summary of the Committee's discussions.

1. Welcome and Housekeeping

The Committee Chair and Vice Chair welcomed everyone to the meeting and shared ground rules for discussion. Staff shared objectives for the meeting as well as a staffing update.

Presentation summary:

Ground rules:

- Be engaged – everyone's perspectives are needed
- Participate in active listening and open dialogue
- Be solution focused
- Challenge assumptions and ideas, but not people – different backgrounds and experiences produce different values
    - Look for common ground on higher goals
    - If you dissent, speak up and explain the strengths of the alternative
- Make space and take space

Meeting objectives:

- Review progress thus far on the Continuous Distribution of Kidneys project
    - Committee's decisions thus far on rating scales, weights, and operational considerations
    - Recent Massachusetts Institute of Technology (MIT) optimization work, with updated rating scales for the calculated panel reactive antibody (CPRA) attribute
    - Public comment feedback

- Begin discussions to incorporate efficiency and utilization considerations in Kidney Continuous Distribution
    - Reducing non-use, reducing out of sequence allocation, and expedited placement for "hard-to-place" kidneys
- Open Forum
- Review 6-month post-implementation monitoring report for Biopsy Requirements

Summary of discussion:

There were no questions or comments.

2. Recap Continuous Distribution: Progress thus Far, Modeling Updates, and Looking Ahead

Staff provided an overview of the Committee's progress thus far on the Continuous Distribution of Kidneys effort, and briefly discussed the Committee's path forward. Representatives from MIT shared updates on recent modeling work related to pediatric travel distance and prioritization for highly sensitized candidates.

Continuous Distribution Overview:

The Kidney Committee's initial goal of this effort was to transition the current classification-based allocation system into a continuous distribution framework, with minimal disruption to the system. The Committee provided strong justification and rationale for recommendations deviating from current policy. The Continuous Distribution effort utilized the following guiding principles:[1]

- Utility – does the framework achieve the greatest good while reducing waste and promoting placement efficiency?
- Equity – does the framework achieve the most sustainable equitable allocation, and not further disadvantage vulnerable candidates?
- Transparency and Autonomy – is the framework easily understandable, and promote participation in shared decision making?

Thus far, in collaboration with the Organ Procurement Transplantation Network (OPTN) Pancreas Transplantation Committee, the Committee has:

- Identified and vetted 10 attributes across 5 goals
- Thoroughly discussed and established appropriate, data-driven rating scales for each attribute
- Released and reviewed a community-wide values prioritization exercise, additionally informed by organ procurement organization (OPO) and patient focus groups
- Established and tested donor modifiers, for more nimble kidney allocation
- Submitted the first modeling request, to gain an understanding of how a continuous distribution framework of kidney allocation may operate
- Intensive optimization work with MIT partners, to better understand how each attribute works with the others, and ultimately fine-tune weights
    - Included significant Committee discussion to determine modeling goals for each attribute
- Submitted and reviewed the second modeling request, utilizing optimized policy scenarios

[1] OPTN Ethics Committee, Ethical Considerations of Continuous Distribution in Organ Allocation White Paper, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/ethical-considerations-of-continuous-distribution-in-organ-allocation/

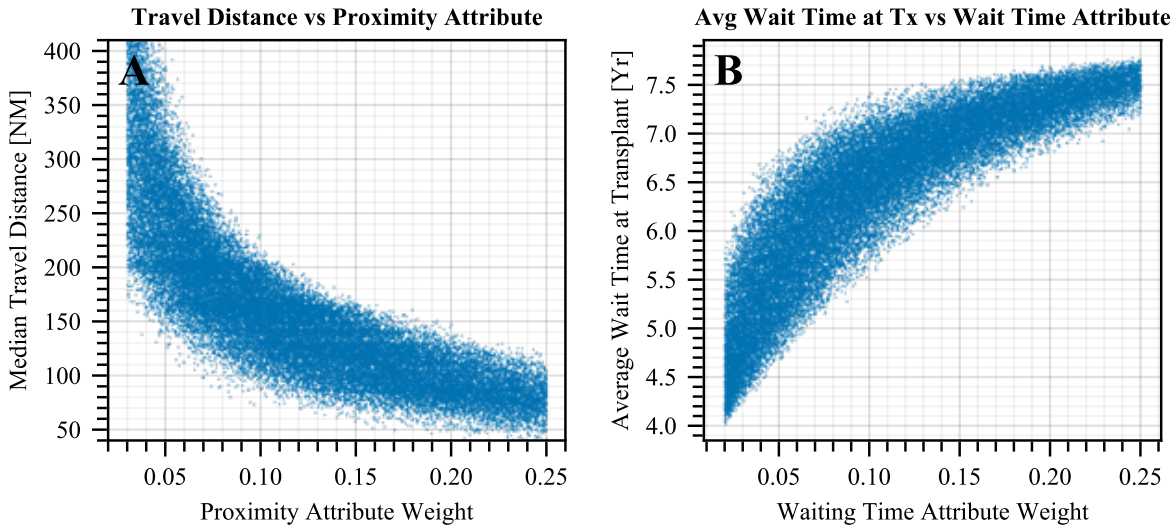
- Continued optimization and fine tuning discussions with MIT, based on Organ Allocation Simulation (OASim) modeling results
    - Focusing on access for high CPRA candidates and pediatric transplant rates and travel distances
- Developed and discussed a Kidney Review Board, to operate in a continuous distribution framework
- Developed and discussed solutions to several significant operational components, including:
    - Released organs
    - En bloc kidney allocation
    - Dual kidney allocation
    - Mandatory Kidney-Pancreas (KP) offers
    - Kidney minimum acceptance criteria screening tool (KiMAC)
    - National kidney offers
- Ongoing development of an updated definition for kidney medical urgency

<u>Continued MIT Optimization: Progress Update</u>

Previously, the Committee developed rating scales for each attribute, and was working to fine tune the weights assigned to each rating scale in order to optimally achieve the allocation system's goals. The rating scales create a set of sub-scores for each attribute; these sub-scores are weighted and combined in order to create an overall score for each candidate, based on the donor's characteristics.

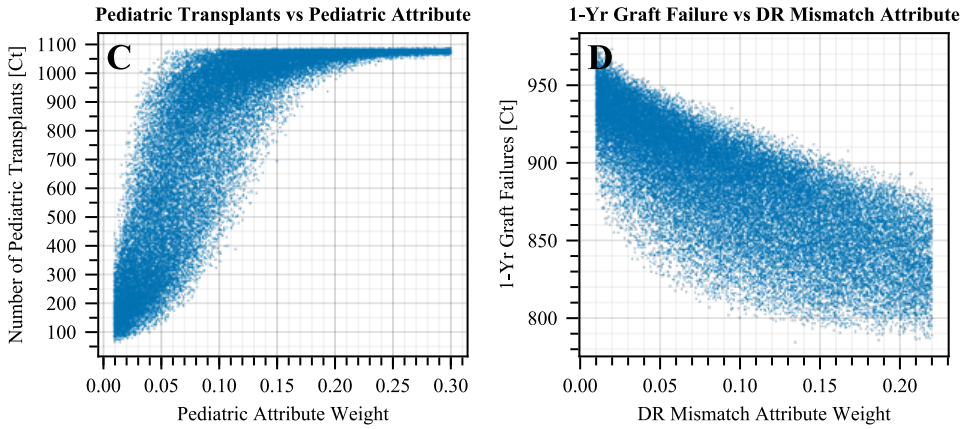
Using these rating scales, MIT was able to run simulations with 50,000 different combinations of attribute weights (each combination is known as a potential policy scenario). This allowed the effects of different weights for each attribute to be analyzed and understood. **Figures 1 and 2** show how generally, an increased weight on the proximity attribute results in a decreased median travel distance by generally prioritizing candidates closer to the donor hospital, and how an increased weight on the waiting time attribute results in a higher average waiting time at transplant by generally prioritizing candidates with longer waiting times.

Figure 1: Travel Distance vs Proximity Attribute Weight and **Figure 2: Average Waiting Time at Transplant vs Wait Time Attribute Weight**



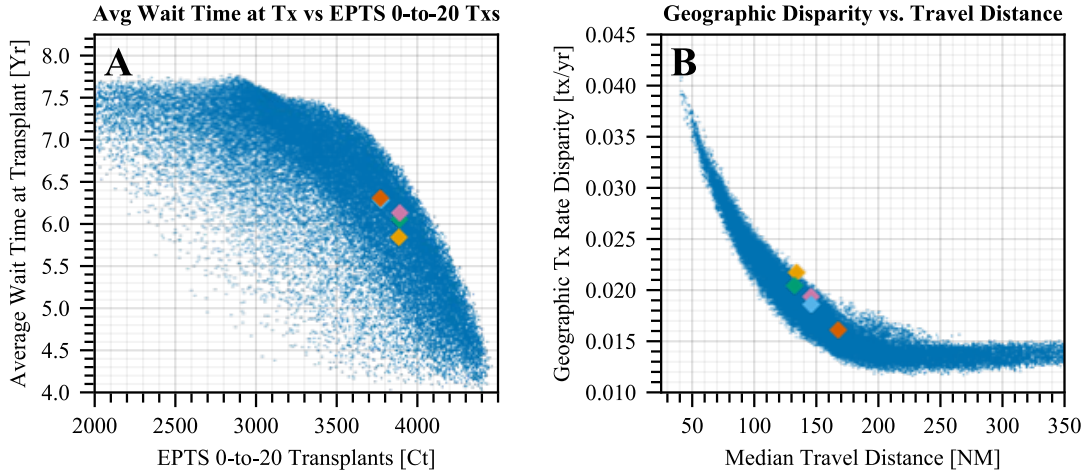
Similarly, attribute analysis allows the Committee to visualize the benefit of additional priority. **Figure 3** shows how increasing the weight on the pediatric priority attribute results in an increase in the number of pediatric transplants, but that these gains plateau at about 1100 transplants. The MIT representative described this as a thresholding effect, and noted that this also indicates that a high volume of pediatric transplants can be achieved across a number of different weight configurations. **Figure 4** shows how increasing the weight on the DR mismatch attribute produces a general trend towards reduced 1-year graft failure, but the spread of the scatter plot indicates that similar benefits can be achieved in a wider range of weights, depending on the weights assigned to other attributes.

Figure 3: Pediatric Transplants vs Pediatric Attribute Weight and **Figure 4: 1-Year Graft Failure vs DR-Mismatch Attribute Weight**



The MIT optimization process utilizes the goals established by the Committee in terms of desired outcomes to find a potential policy that best achieves all of these goals. This process also uses constraints to determine metrics that the optimized policy must meet – for example, the optimized policy must not result in fewer pediatric transplants than the current policy. These constraints can be modified based on what the Committee may be willing to tolerate – for example, the Committee may be comfortable with slight increases in travel distance. These variable constraints were set understanding that trade-offs exist between metrics. Specifically, maximizing one metric may prevent another metric from being able to be maximized. For example, **Figure 5** shows a trend between policies that increase the number of transplants for Estimated Post-Transplant Survival (EPTS) 0-20 patients resulting in a decreased average waiting time at transplant, meaning that fewer patients with long waiting times are transplanted. **Figure 5** demonstrates a trade-off between these outcomes. **Figure 6** shows how policies projected to increase median travel distance also project reduced geography disparity.

Figure 5: Average Waiting Time at Transplant by Count of EPTS 0-20 Transplants and **Figure 6: Geographic Disparity vs. Travel Distance**

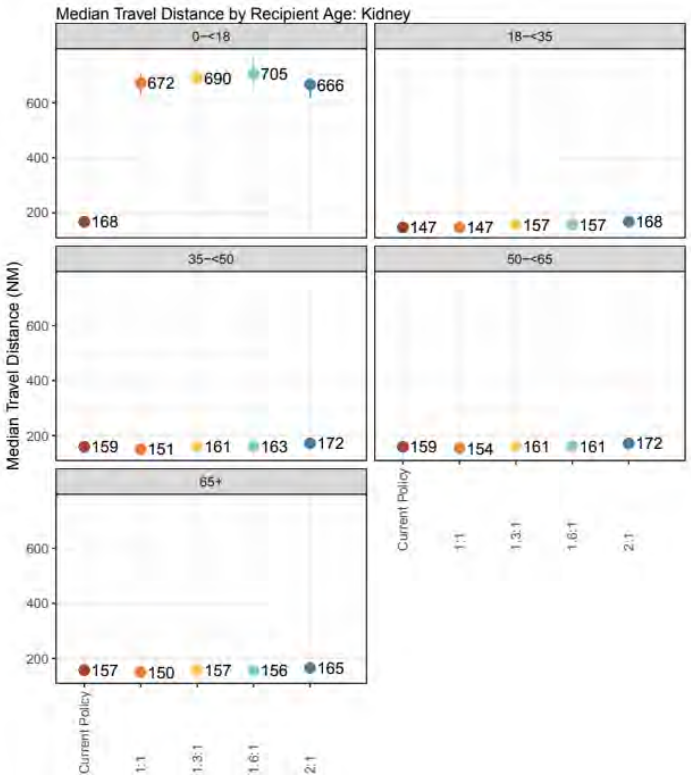


The Committee submitted four initially optimized policies for OASim modeling. The OASim results indicated two key areas of concern, specifically elevated pediatric travel distances and reduced transplant rates for candidates with CPRA 99.9-100 percent.

Elevated Pediatric Travel Distance

Figure 7 shows significantly increased travel distances for pediatric candidates in the continuous distribution scenarios modeled by the OASim, particularly compared to OASim modeling of current policy.

Figure 7: Median Travel Distance by Recipient Age[2]

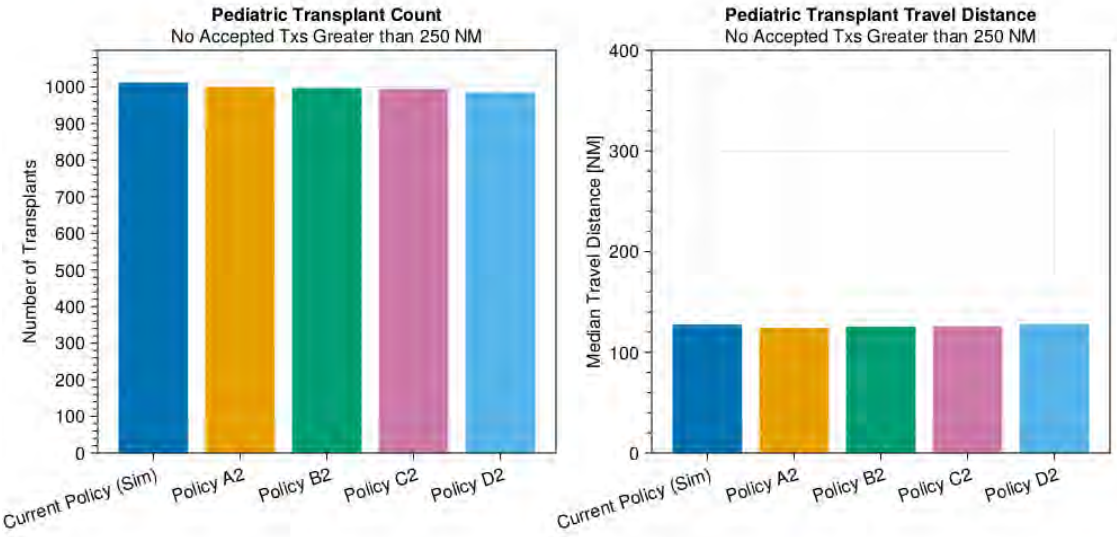


OPTN Pediatric Committee and Kidney Committee discussions noted that the simulated policies A1, B1, C1, and D1 show dramatic increases in median travel distances for pediatric candidates, and increasing numbers of long distance offers. It was also noted that the OASim models acceptance probabilities for long distance offers for pediatric candidates may be too high.

MIT performed additional analyses to determine if the volume of pediatric transplants could remain at its current level if the model did *not* accept the longer distance offers. **Figures 8 and 9** simulate that no program accepts any offers to pediatric candidates with a distance greater than 250 nautical miles. **Figure 8** shows that with this behavior modeled, the number of transplants does not decrease notably from current policy, and **Figure 9** shows that the median travel distance can be reduced to align with current pediatric transplant travel distances. The MIT representative explained that the pediatric attribute is weighted so highly that the number of pediatric transplants would remain the same, even if no program accepted these long distance offers. The MIT representative explained that the only question is whether the Committee would want to consider reducing pediatric priority to reduce the volume of long distance pediatric offers. Both the Kidney and Pediatric Committees discussed potentially reducing the weight on pediatric priority in order to reduce the number of long distance offers, but ultimately the Committee was divided on whether this was appropriate, particularly as it could reduce the number of pediatric transplants.

[2] https://optn.transplant.hrsa.gov/media/o52pegrg/kipacd_2023_01_analysisreport_2023_07_17.pdf

Figure 8: Pediatric Transplant Count and Figure 9: Pediatric Transplant Travel Distance



Reduced transplant rates for cPRA 99.9-100 percent candidates

Figure 10 shows reduced transplant rates for the most highly sensitized candidates in OASim modeling.

Figure 10: Transplant Rates by CPRA at Cohort Start

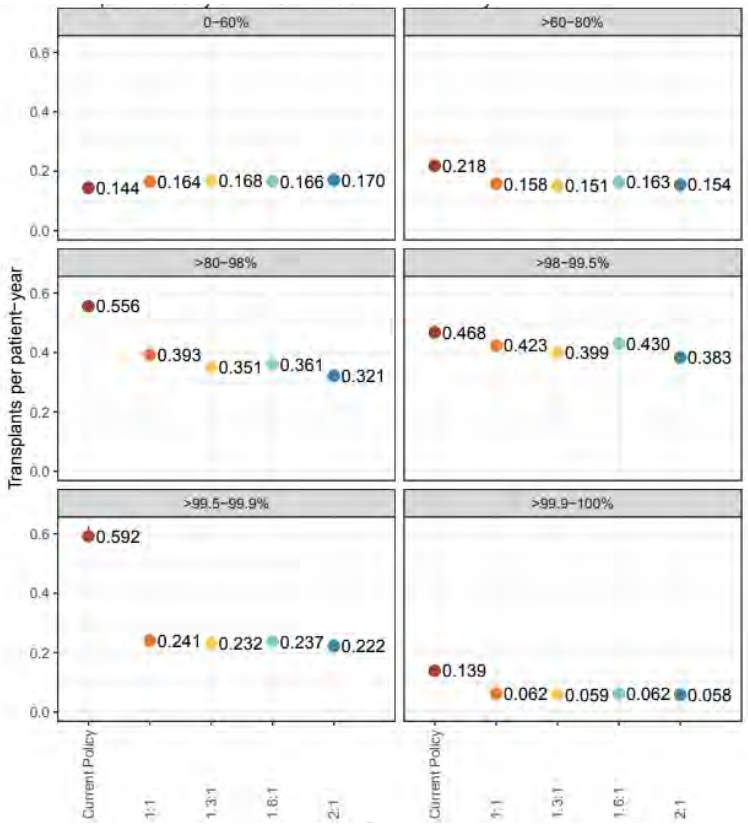
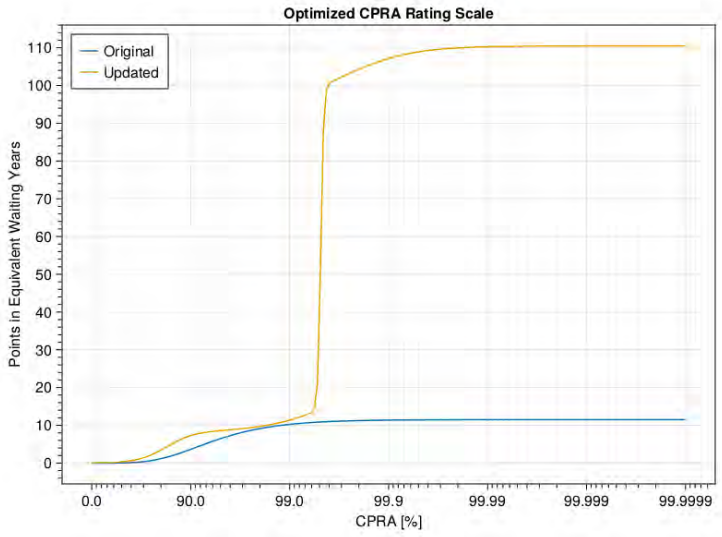


Figure 10 shows a decrease in transplant rate of a little over 50 percent for the CPRA 99.9-100 percent candidates. To address this, MIT optimized a new potential rating scale for the CPRA attribute, which

utilizes a much steeper curve to assign priority. This curve is shown below in **Figure 11,** in yellow, while the Committee's original CPRA rating scale is shown in blue**.**

Figure 11: Optimized CPRA Rating Scale



Further MIT Policy Optimization and Simulation

Using the goals discussed by the Committee, with updates for CPRA, MIT was able to optimize four new potential policy scenarios, updated from those scenarios the Committee submitted to the Scientific Register of Transplant Recipients (SRTR) in April. These policy scenarios and relevant weight combinations are shown in **Table 1**. The attributes underlined in **Table 1** are the attributes for which weights vary across policies A2, B2, C2, and D2.

Table 1: Policy Attribute Weights

Attribute	**Policy Attribute Weights**			
	Policy A2	Policy B2	Policy C2	Policy D2
Medical Urgency	0.096	0.096	0.096	0.096
DR Mismatch	0.010	0.010	0.016	0.030
Longevity Matching	0.055	0.064	0.043	0.042
Blood Type	0.093	0.093	0.093	0.093
CPRA	0.400	0.400	0.400	0.400
Prior Living Donor	0.096	0.096	0.096	0.096
Pediatric	0.100	0.100	0.100	0.100
Liver Safety Net	0.032	0.032	0.032	0.032

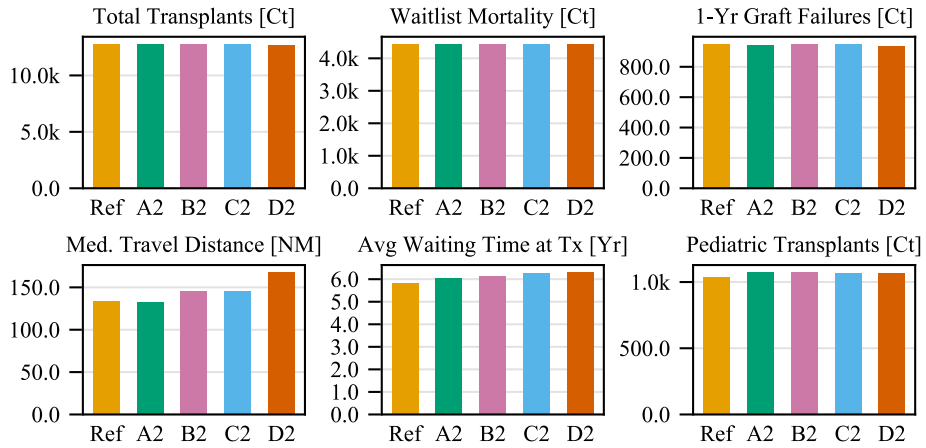
Waiting Time	0.039	0.041	0.049	0.051
Proximity Efficiency	0.079	0.069	0.075	0.059

MIT's optimization algorithm was set to minimize waitlist mortality, 1 year graft failure, blood type transplant rate disparity, geographic transplant rate disparity, and racial transplant rate disparity. The algorithm also set the following constraints:

- The number of pediatric transplants should be no less than current policy
- The number of CPRA 99.9-100 percent transplants should be no less than current policy
- The average waiting time at transplant should be no less than current policy
- The number of blood type B transplants should be no less than current policy
- For polices A2-D2, the constraint on distance is relaxed, allowing reduced geographic disparity
    - For A2, median travel distance should be no greater than current policy
    - For policies B2 and C2, median travel distance should be no greater than 110 percent of current policy
    - For D2, the median travel distance should be no greater than 125 percent of current policy
- For policies A2-D2, the constraint on volume of EPTS 0-20 transplants is reduced, allowing for increased number of transplants for candidates with long waiting times
    - For A2 and B2, the number of EPTS 0-20 transplants should be no fewer than current policy
    - For C2 and D2, the number of EPTS 0-20 transplants should be no fewer than 97 percent of current policy

All four of the policies modeled (A2, B2, C2, and D2) showed similar outcomes across all policies for number of transplants, waitlist mortality, and 1-year graft failure. The varying constraints on distance can be seen in increasing median travel distances in policies B2, C2, and D2. Similarly average waiting time at transplant increases as the constraints on EPTS 0-20 transplant volume are relaxed in policies C2 and D2. Pediatric transplant volume increases from A2 to D2 as the constraint on travel distance is relaxed. These metrics can be seen in **Figure 12**.

Figure 12: General Metrics



Geographic disparity was decreased by about 5 percent in policy A2, and B2 and C2 saw greater decreases, and D2 had the lowest geographic disparity measure. All of the policies similarly reduced

blood type disparities, and this is largely due to reducing the AB transplant rate to better align with transplant rates for other blood types. The CPRA transplant rate disparity is slightly improved in all of the modeled policies. There are improvements in racial transplant rate disparity across all of the modeled policies. The sex and ethnicity transplant rate disparities saw very small shifts. These metrics can be seen in **Figure 13**.

Figure 13: Transplant Rate Disparity Metrics

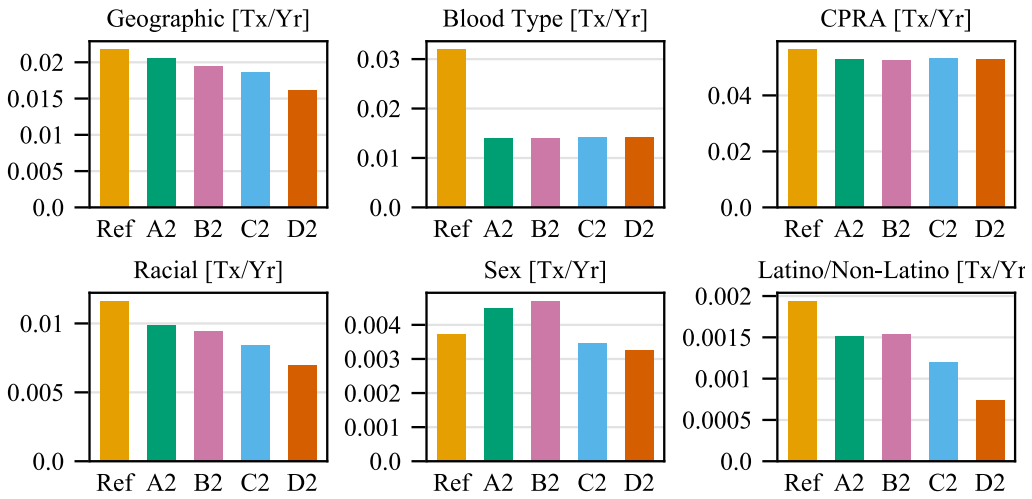
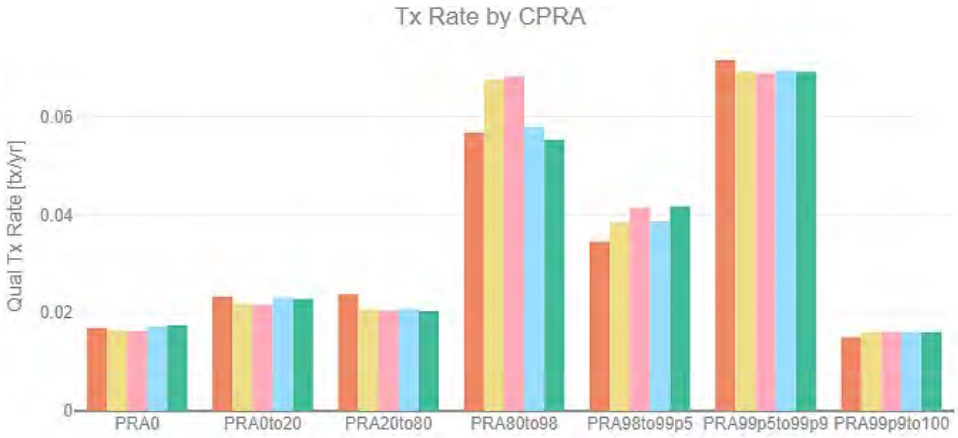


Figure 14 shows transplant rates by CPRA across the modeled policies. The continuous distribution policies are similar to current policy by design, based on limitations in modeling transplant rates across certain CPRA groups.

Figure 14: Transplant Rates by CPRA



Figures 5 and **6** show where the modeled current policy and modeled policies A2, B2, C2, and D2 fall on the trade off curves. Policies A2, B2, C2, and D2 largely met the Committee's goals, with a few nuances that may warrant further discussion, including distant pediatric offers and equalizing access across CPRA groups. Efficiency and utilization remains another area for discussion, particularly in understanding how continuous distribution may impact allocation and organ use, as well as allocation schema for high KDPI and "hard to place" kidneys.

<u>Summary of discussion:</u>

One member asked if MIT's models optimize a potential policy that aligns closely with the current system, which could prevent a dramatic shift post-implementation. The MIT representative responded that the current system does not utilize weights and so cannot be exactly mirrored in the continuous distribution framework, but that model could optimize for the outcomes of the current system. The member also noted that many of these outcomes are related, and that improving one outcome or metric may cause shifts in other metrics.

A member referenced **Figure 2**, noting that as weight for the waiting time attribute increases, the average waiting time increases. The MIT representative confirmed this, noting that this is a direct relationship. The member noted that an allocation with more emphasis on waiting time as a primary driver would be expected to have a decreased average waiting time. The MIT representative explained that increased "average waiting time at transplant" indicates that candidates who have waited longer are being transplanted. The MIT representative continued that each simulated policy is using the same population of candidates, so a decrease in the average waiting time at transplant would indicate that candidates who are waiting longer are not receiving the same number of transplants. The MIT representative added that over time, a policy that emphasizes waiting time may ultimately see a reduction in the average waiting time at transplant, particularly as those candidates with long waiting times are transplanted and the overall average waiting time of the candidate populations decreases. One member recommended reframing the Y-axis of **Figure 2** as the percentage of people with longer waiting times getting a transplant. The MIT representative agreed that may be more understandable.

A member asked if the Committee decided to leave the pediatric attribute at its current level of relative priority. The MIT representative confirmed that the new set of optimized policies modeled by MIT maintain similar results to those shown by the OASim, with a greater number of pediatric transplants occurring at increased distances. The MIT representative also explained that the probability of acceptance used in the OASim model was higher than can realistically be expected with respect to pediatric travel distances. The MIT representative explained that even if programs do not accept offers for pediatric candidates from such great distances, the overall pediatric transplant volume would be expected to remain high. The member emphasized that communication is key to ensuring programs and patients understand the modeled metrics. Staff agreed, and shared that the OPTN Pediatric Committee also discussed this at length, and was equally split on whether the pediatric attribute weight should be reduced to help reduce potential travel distance. Staff explained that pediatric candidates are currently highly prioritized, and that priority can really only be increased for pediatric candidates by offering those candidates kidneys from further away, although there are both allocation and efficiency concerns. The member also noted that monitoring will be important. The MIT representative also noted that the offer acceptance model could also be updated to more realistically reflect offer acceptance practices.

One member referenced the optimized rating scale, noting a large jump in priority at CPRA 99.5 percent. The member asked if this overcomes the relative advantage CPRA 99.5 percent candidates have in the current system, which rounds 99.5 percent up to 100 and provides the highest 100 percent CPRA priority to those candidates. The member explained that the 99.5 percent CPRA candidates then have a slight advantage compared to the CPRA candidates that have a CPRA of 99.9 and above, but are receiving the same priority. The member continued that having more discrete values and distinctions in priority for CPRA candidates 99.5-100 percent would improve equity between the very highly sensitized patients. The MIT representative explained that the simulators are limited in their accuracy when simulating transplant rate by CPRA, particularly because the highest sensitized population is so small. The MIT representative explained that the optimization algorithm attempted to equalize transplant rates across candidate CPRAs, but that the simulators themselves overestimate the transplant rate for certain CPRA groups, even when simulating historic policy. The MIT representative explained that this

provides a high level of uncertainty, and that this could cause an optimization algorithm to create a policy that could potentially result in reduced transplant volume for the highest sensitized candidates. Given this, the MIT representative explained that the optimized rating scale aligns very closely with the priority given in current policy. As a result, the model is not able to be optimized for equalizing access across CPRA groups, and thus CPRA 80-90 percent may still have relatively higher access. The MIT representative explained that this rating scale does differentiate between the 99.5 percent and 99.99 percent CPRA candidates, and has increasing priority from 99.5 percent to 99.99. The MIT representative explained that the MIT simulator shows increasing transplant rates for the 99.99 percent CPRA under optimized policy scenarios with this rating scale, compared to 99.5 percent CPRA group, which has slightly fewer transplants.

A member referenced Figure 5, asking if this indicates that increasing the number of EPTS 0-20 percent transplants performed will result in a lower average waiting time overall. The MIT representative explained that the greater number of 0-20 EPTS transplants performed in the system, the fewer candidates with long waiting times receive transplants. Staff explained that the Committee previously discussed this when considering expanding longevity matching, as increasing the volume of transplants for EPTS 0-20 candidates is in conflict with transplanting those candidates with extended waiting times, particularly because candidates with longer waiting times have higher EPTS scores. The member commented that KDPI and EPTS scoring systems are not yet sufficiently accurate for expanded longevity matching to be incorporated into allocation.

The Chair noted that the modeled current policies appear to reduce transplant rate disparities relative to the modeled current policy. The Chair asked if the geographic disparity measured differences in transplant rates across regions, or donor service areas (DSAs). The MIT representative confirmed that geographic disparity was measured by differences in transplant rates across DSAs.

One member expressed support for the modeled policy D2. The MIT representative noted that D2 produces the biggest improvements in equity, but that it makes bigger trade-offs in terms of distance and EPTS 0-20 transplant volume. The MIT representative noted that policy A1 doesn't change median travel distance, but still achieves a 5 percent improvement in geographic disparity. The member noted that the only downside to policy D2 is the increase in travel distance. Staff noted that this is correct, but that there are a number of immeasurable utilization and efficiency related concerns related to increasing the median travel distance, but that these concerns are not currently measurable the way equity-related metrics are. The member agreed that increased travel distance is often related to increased cold ischemic time, which can impact graft survival and delayed graft function, although this data is harder to find. Another member pointed out that the model assumes that the increased travel distances are feasible, and that the logistics are available for kidneys to travel that far in such instances. The member commented that there are limitations to transportation availability, and that the favorable equity outcomes may not play out in reality the same way, particularly if these outcomes are dependent on increased travel distances. One member commented that the increase in median travel distance of 20 nautical miles is minimal. . The Chair agreed that relaxed travel distance and EPTS 0-20 transplant volume constraints are expected to produce better outcomes in terms of equity. The Chair posed, from a quantitative perspective, what the optimal median travel distance is to ensure those equity gains can be achieved while balancing organ use and utility. A member remarked that the current allocation system resulted in increases in travel distances, which was followed by significant challenges in transportation, particularly with air transportation of organs. The member agreed that 20 nautical miles may be a small shift, but that this could still create transportation burden.

The Vice Chair asked if there is a sense of how much the increase in travel distance will impact cost. Staff explained that cost data is currently not collected, and so impact to cost cannot be modeled. One

member noted that the standard deviation of travel distance will likely be wider in D2, and that there may be edge cases where organs are travelling significantly. The member remarked that data spreads may be helpful. Another member remarked that travel distance is a proxy for cold ischemic time, and asked if MIT was able to model how increased travel distance maps to increased cold ischemic times. The MIT representative explained that cold ischemic time is not currently modeled by the OASim. Staff also noted that previous research has shown that travel distance is moderately correlated with cold ischemic time at best, and that distance traveled is not a perfect proxy. One member commented that distance traveled is impacted by the size of the DSAs involved in the organ allocation, noting that larger distances in the same DSA may be less complex than larger distances spanning across multiple DSAs. The member explained that there are inefficiencies in communication, organ hand-off, and organ import.

A member asked what the scope of the Continuous Distribution project is, noting that there may need to be separate projects related to efficiency to address these considerations. The MIT representative remarked that **Figures 12** and **13** present the high level results, but that the scope of the simulation study is to determine whether each policy meets the goals established by the Committee. The MIT representative added that the Committee has goals for the continuous distribution allocation framework that are not able to be modeled by the current simulators. The member also noted that the scale used to measure changes in transplant rate disparities, remarking that these improvements are relatively small.

One member noted that there are well founded concerns about efficiency and distance traveled, and recommended sharing deeper data regarding the minimum, maximum, and standard deviation for each policy, particularly with regard to distance traveled.

The Chair thanked the MIT team for their work, and noted that the goals of the Continuous Distribution project have shifted over time. The Chair explained that initially, the Continuous Distribution effort was geared towards transitioning to a continuous distribution framework, and recent shifts in the community have shifted the goals of the Continuous Distribution effort to consider non-use, utilization, and efficiency. The Chair remarked that efficiency hasn't been well defined yet, and that the Committee can help define this, particularly as the Committee begins to factor in operational and efficiency related considerations.

3. Recap on Efficiency Task Force and Board Resolution

Staff provided a recap on the OPTN Task Force on efficiency and the recent board resolution related to the Continuous Distribution of Kidneys and Pancreata project.

Presentation summary:

The OPTN Board of Directors approved the creation of a task force to study and improve the efficiency of organ usage and placement. The Task Force recognizes that attaining efficiency in allocation is a multi-faceted challenge impacting many factors, including policy changes, federal requirements, operational inefficiencies, data collection, behavioral variation, and travel/logistical considerations.

Recent discussion by the OPTN Board of Directors agreed that the greater transplant community is not currently prepared to transition to continuous distribution as the project has been developed at this point. The Board advised that the Kidney and Pancreas Committees should not plan to distribute the proposal during the next cycle, and instead ensure the proposal will incorporate the following considerations:

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

Moving forward, the Committee will continue developing the Continuous Distribution project:

- Continue modeling work with MIT and the Scientific Registry of Transplant Recipients (SRTR)
- Level set on what is currently included in the Continuous Distribution project and how it could impact or improve efficiency
- Evaluate with a refocus on efficiency gains
- Identify enhancements that may be included as part of the Continuous Distribution effort, or could be stand-alone projects
    - Ideas outside of the Kidney Committee's scope are also encouraged for consideration by the Task Force
- Discuss ideas to impact efficiency, specifically in the three areas delineated by the OPTN Board:
    - Non-use and non-utilization of kidneys and pancreata
    - Out of sequence allocation of kidneys
    - Consideration of expedited placement pathways for kidneys at high risk of non-use

Summary of discussion:

There were no questions or comments.

4. Public Comment Review

Staff provided an overview of public comments submitted regarding the Committee's *Request for Feedback on Efficiency and Utilization in Continuous Distribution of Kidneys and Pancreata*, including key themes. Staff also provided efficiency-related public comments and sentiments gathered from previous public comment cycle.

Presentation summary:

The *Efficiency and Utilization in Continuous Distribution of Kidneys and Pancreata Request for Feedback* (RFF) released for public comment July 27 through September 19, 2023. The RFF summarized and requested feedback on multiple operational aspects of Kidney and Pancreas allocation policy, including discussions by the Utilization Considerations, Review Boards, and Pancreas Medical Urgency Workgroups. The RFF includes detailed discussion of the Committees' work with MIT and discussions leading into the second modeling request. The RFF received 85 sentiments, with 30 written comments. The RFF was presented at 11 regional meetings, with focus on Dual Kidney, Mandatory KP allocation, and Pancreas Medical Urgency. The RFF was also presented to the OPTN OPO, Ethics, Transplant Administrators, and Transplant Coordinator Committees.

Public comments aligned with the following themes:

- General Support
    - Multiple OPTN Committees, OPOs, regions, societies, programs, and individuals expressed continued support for continuous distribution, particularly for improvement in equity
- En Bloc
    - Few comments related to en bloc allocation, but all were supportive of Committee's recommendation to utilize the en bloc coefficient in the KDRI allocation, to allocate en bloc kidneys based on their KDPI
- Released Organs
    - **Support for Committee's recommendation**, particularly for benefits to efficiency via increased weight on proximity efficiency and "carrying over" specific refusal codes
    - **Support for increased weight on proximity efficiency** → Reduce cold ischemic time

        - Recommendation to model released kidney weight
    - **Support for "carry over refusals" functionality** → reduce duplicative efforts and condense match run, with major benefits to allocation efficiency
        - Recommendation that *all* refusal codes carry over to reduce manipulation in refusal code selection
    - Multiple recommendations to incorporate policy-backed **transplant program back up** in cases with significant cold ischemic time, particularly consideration of logistical challenges
- Kidney Minimum Acceptance Criteria Screening Tool
    - **Support for recommended framework**, including applying the KiMAC at 8% of the match run
        - Some recommendation for applying KiMAC at the beginning of the match run, aligning with offer filters
        - American Society of Nephrology (ASN) recommendation to apply KiMAC only to the first 8% of the match run, as programs may be more selective with these candidates
    - Recommendation to require programs to update KiMAC response 2x a year, based on current acceptance practices
    - Recommendation to **simplify available screening tools** and nomenclature – one set of program-level, and one set of candidate-specific filters
    - Support for **further efforts to clearly define "hard to place" kidneys**
- Dual Kidney
    - **General emphasis on need to improve allocation for hard to place kidneys**, particularly during single kidney allocation processes and pathways
    - Support for data-driven modification to dual kidney allocation
    - **Mixed feedback regarding separate, dual kidney specific match run**
        - **Support for recommendation with efficiency considerations** + carry over refusal functionality
            - One recommendation for all refusal codes to be carried over to dual kidney match run
        - Support with recommendation for mandatory offer filters related to dual kidney, or else establish qualifying criteria for programs to qualify in order appear on dual kidney match run
        - **Concern for increased complexity and potential increase in offer volume**
            - ASN did *not* support carry over refusals for dual kidneys
        - **Recommendation for dual kidney allocation to occur from the single kidney match run**, such that programs can decline and indicate interest separately for single and dual kidney offers
    - Support for strict eligibility requirements to ensure single kidney offers are still made appropriately
    - **Limited support for dual kidney eligibility based on single kidney placement attempts**
        - Concern for cold ischemic time, variations in match runs across the country and based on donor factors
    - Significant support for incorporating **cold ischemic time considerations** in order to limit CIT for medically complex kidneys
    - **Some support for dual kidney eligibility based on donor criteria**
        - Recommendation that criteria is data based, using dual kidney characteristics and aggressive placement criteria

        - Donor after Circulatory Death (DCD), Expanded Criteria Donor (ECD), KDPI, Cold Ischemic Time (CIT), age, serology, Continuous Renal Replacement Therapy (CRRT) or Continuous Veno-Venous Hemodialysis (CVVH), diabetes and hypertension, anatomy, pump, and biopsy results
    - Recommendation that **highest KDPI kidneys may immediately be allocated as dual**
    - Some support for **OPO discretion** in dual kidney allocation; ASN less supportive of this
    - Limited support for requiring patient consent prior to appearing on dual kidney match run
- Mandatory KP Offers
    - Recommendation to consider **median waiting time for kidney-alone candidates**
    - Consideration for **higher morality rate** associated with Kidney-Pancreas candidates
        - Equity and utility for multi-organ candidates is particularly challenging
        - Consideration for **medically urgent KP** patients, with no vascular access or hypoglycemia unawareness
        - Support for ensuring **highly sensitized KP** candidates receive mandatory KP offers
        - Support for prioritizing **nearby candidates and reduced travel** for pancreas transplants
    - Concern for **prolonged allocation time** with combined kidney-pancreas
        - Challenges to pancreas recovery
    - Consideration for **pediatric kidney-alone candidates**
        - Support for allowing only one kidney from each donor to be allocated as part of multi-organ combination
        - Recommendations to further investigate impact of multi-organ allocation and impact on priority kidney-alone candidates
    - Consideration for multi-vis candidates, such as liver-pancreas-intestine candidates
- Composite Allocation Score and Modeling
    - **Support for increased transplant rate for pediatric candidates**
        - Need to capture nuances for pediatric candidates – size discrepancy, age-specific considerations, etc.
    - Concern for **significantly increased travel distances for pediatric candidates**
        - Limited capabilities in modeling acceptance behavior, especially at greater distances
        - Comment that increased distances may result in increased CIT, increased decline, reduced efficiency, and increased offer volume
        - Recommendation for candidate-specific pediatric offer filters
    - Concern for **limitations of OASim modeling** in predicting logistical impact of CD
        - Recommendation to monitor cost, non-utilization, etc.
    - Support for **priority for prior living donors, highly sensitized, and pediatric candidates**
    - Ethics Committee – **Imperative that CD does not widen disparities**
        - Support for increased equity by blood type, concern for decreased prior liver recipient transplant rates
    - Association of Organ Procurement Organizations (AOPO) – support for sufficiently high weight to be assigned to **placement efficiency**
- Task Force
    - Support for continued updates on continuous distribution and related efficiency work
    - Support for the task force, and continued opportunities to provide feedback

    - ASN highlighted the importance of increasing transparency and maintaining a commitment to equity in allocation in achieving efficiency
        - Recommendation to implement efficiency efforts prior to continuous distribution
- Other Efficiency Related Feedback
    - Support for many recommended efficiency and utilization considerations
        - AOPO – CD should aim to reduce variation in utilization of kidneys based on KDPI
    - Support for an operational philosophy that **avoids many large changes in allocation at once**
    - Recommendation to **investigate and understand the drivers for increase in non-use of kidneys**
        - **Lessons learned** from Lung Continuous Distribution, circles based kidney distribution, and non-use data to inform Kidney CD
        - Recommendation to **slow transition to CD** in order to incorporate increased efficiency
    - Support for task force and **general shift towards improving efficiency and addressing non-use**
        - Recommendation to reduce penalties for primary non-function to encourage use of medically complex organs
    - Several recommended focus areas related to efficiency and utilization:
        - **Dynamics and communication between OPOs + programs** throughout offer, recovery, and acceptance processes
            - Shared accountability between OPOs and programs
            - Clear requirements and responsibilities for programs for offer evaluation, back-up, etc.
        - Encouraging increased utilization of **virtual crossmatch**
        - **Improved offer environments** and reducing late night offers
        - Recommendation for **mandatory offer filters**, and **more dynamic offer filters**
            - Recommendation for candidate-specific offer filters, especially for pediatric candidates
        - Recommendation to **revisit and expand the KDPI calculation**
            - Particularly with respect to DCD status, medical history, AKI, etc.
        - Concern for **measurability of the capacity of current kidney transportation**, including commercial air travel

Efficiency was also a theme in previous public comment cycles:

- Significant number of comments related to efficiency; one commenter stated this should be first priority
- Concern for **increased distance** projected in OASIM
    - ASTS – programs should be required to adjust distance acceptable to their program
    - Distance is important factor for **CIT and DGF**
    - Consider **cost of travel and organ acquisition**
    - Need for a national transport system
- Proximity Efficiency weight and rating scale
    - Some comments supportive of proposed scale and increased weight
    - Suggest additional attributes for placement efficiency that are **more dynamic** based on organ quality and donor type

- Several comments highlighted challenges OPOs face in organ allocation and suggested:
    - Require transplant program's **full evaluation** of kidney offers; give more weight to provisional yes
    - **Require use of filters**; allow programs to set several different filters for various groups of patients
    - Consider consequences for **late turn downs**
    - Increase **virtual crossmatching**
    - **Minimum acceptance criteria** should be updated
    - **Dual kidney allocation** should be based on objective criteria
    - **En bloc criteria** should be based more stringently on size/age of the donor
- Several regions, committees, and OPOs concerned with **increase of out of sequence allocation, non-use rate, and CIT** of kidneys post-KAS250
- Support for increased weight on placement efficiency and logistics for **high KDPI kidneys**
    - Rec. to use predictive analytics and historical data to match hard to place organs more efficiently
- Recommendation to **standardize "hard to place" kidneys**
    - Hard to place, dual, and en bloc kidneys should be allocated in a way to minimize CIT
- Placement Efficiency
    - Consider **additional metrics for placement efficiency** (estimated CIT, population density, use of pumps, etc.)
    - Consider **geographic disparities** and rural programs
    - Need for more **system tools and resources** (offer filters, predictive analytics, etc.)
- Concern for **increasing non-use**, should be a top priority in CD
    - Better understanding of KAS250 and impact on transplant rates, non-use, and logistics before CD is implemented

Summary of discussion:

One member commented that appropriate patient education and awareness is critical. The member explained that patients can come in with pre-conceived notions that high KDPI kidneys are not good kidney offers, and that some patient-focused education can set the psychological stage for patients to decline kidneys that they may think are poor quality but may actually be appropriate and safe potential transplants. The member explained that for older patients, risk of waitlist mortality increases over time, and that "waiting for the perfect kidney offer" can be more harmful. The member continued that it's important for patients to understand the risks associated with any transplant, opportunity cost of declining a potential offer, and mortality of dialysis so that patients can understand the decisions they make with their care teams. The member continued that ideally patients understand that they may not receive a perfect kidney, but that they will hopefully receive a kidney that keeps them off of dialysis for at least five years. Another member agreed, noting that from a patient perspective, the patient conversations can often be overwhelming and overly clinical. The member noted that many patients just want to understand if the organ they are being offered is clinically appropriate for them. The member agreed that patient education and offer conversations need to improve, and should encompass all types of kidney transplant, including dual kidney transplant.

Another member shared their perspective as a patient, recounting a dual kidney offer they had received. The member explained that the education regarding dual kidney transplant was limited, and shared that the transplant had to be cancelled due to failure of one of the organs. The member remarked that particularly with patient education, there are patient organizations seeking partnership to disseminate this information to the public. The member continued that many patients don't know much about

transplant until they crash into dialysis, and that this information should be more widespread, not just for patients, but also for care partners and caregivers. The member added that the average kidney disease candidate does not understand transplant, and that it is important for patients to understand how the transplant system works and invest in it. The member expressed support for greater patient education and public awareness, also noting benefits to individual patient care.

The Chair remarked that from a transplant center perspective, programs have limited time with potential recipients prior to the transplant. The Chair noted that particularly in places with longer waiting times, programs may only interact with some patients once a year. The Chair explained that patient education needs to be multifaceted to be accessible, particularly across languages, backgrounds, cultures, and levels of education. The Chair continued that programs rely on dialysis centers, community nephrologists, social workers, and the community at large to provide most of the patient education. The Chair continued that programs provide educational opportunities, but ultimately may have a more limited reach. The Chair agreed patient and public education should be more highly emphasized, including basic transplant knowledge to the OPTN's ongoing work.

The Chair remarked that perspectives may vary regionally, across rural and urban areas, and across different patient populations with respect to placement efficiency and travel.

A member agreed that there is a need for greater collaboration with patient organizations, and recommended coordination with the Treatment Choice Learning Collaboration (TCLC) which is being run by the Center for Medicaid Services (CMS) and the Health Services Administration (HSA). The member explained that the TCLC are bringing OPOs, transplant programs, and histocompatibility labs to increase transplant of higher risk kidneys. The member noted that these organizations and collaboratives are out there, and that it is a matter of bringing these organizations together and coordinating the communication.

One member remarked that various educational materials exist across multiple organizations, and that it would be nice to have a central, unified location for well-vetted patient-specific education that could easily be accessed by all patients, both as physical and digital materials. The member continued that this education could lay out risks of kidney disease, relative risks of kidney transplant, and others. The member added that programs could be required to share this with their patients, or even that dialysis units could be required to share this information with patients.

A member asked how the 2019 Executive Order to Advance American Kidney Health interacts with the OPTN's work, particularly as it required increased kidney transplants, improved patient education, and greater use of home dialysis. Staff explained that this Executive Order also impacted CMS, dialysis centers, and many other health care institutions. Staff noted part of the Executive Order was to encourage and ensure dialysis centers are appropriately referring patients. Staff added that the OPTN Patient Affairs Committee has been involved in a number of patient educational efforts, and that the OPTN has a team of patient and donor family focused community administrators and patient services representatives.

One member asked if patient education will be discussed by the OPTN Board of Directors' Task Force on Efficiency. Staff responded that the Committee will be talking about patient education later in the meeting, and that the American Society of Nephrology emphasized shared decision making and patient empowerment in their public comment. Staff continued that this discussion can center on how patients and care teams can be connected in ways that patients are empowered, the organs are safely transplanted, and that the system efficiently and effectively serves the patients its built to serve.

The Vice Chair remarked that one of the biggest barriers to transplant is getting patients to a transplant center. The Vice Chair shared that transplant is discussed as an option to treat end stage renal disease

(ESRD), as well as dialysis. The Vice Chair continued that the way ESRD treatment should be discussed should view transplant as the primary treatment choice, and that dialysis can provide support in the meantime. One member explained that in the current framework, dialysis centers are not incentivized to refer patients to transplant. The member continued that this is particularly harmful to patients who may not have significant health literacy or are not well positioned to advocate for themselves, and that discussions relating to transplants can often make out transplant to be an infeasible option for many patients. The member added that there are many barriers to transplant itself, including obstacles such as limited support systems or lack of adequate insurance coverage. The member explained that there are distinct social groups of patients, splitting patients into those that prefer dialysis and have lived on dialysis for many years, and those patients who choose to pursue a transplant. The member explained that these dynamics can be overwhelming for patients.

One member remarked that the Executive Order also impacted OPOs and transplant programs in terms of improving performance and increasing transplant. The member continued that this Executive Order has driven many of the recent changes in the transplant community. The member added that patients are important achieving the goals set forth in the Executive Order, but that policies also need to drive change. The member remarked that the policy process is too slow to address the needs of OPOs, particularly in trying to meet the goals established by CMS, and that OPOs have to break policy as a result. The member added that particularly under the current kidney allocation policy, their OPO is exporting more than 80 percent of the kidneys procured to other DSAs, and that this has dramatically altered their allocation process. Another member commented that one issue with the bill is that it was trying to change too much too quickly, and threatened to quickly decertify more than half of OPOs, which would have caused a collapse of the transplant system. The member continued that this legislation was problematic. A member pointed out that in 2024, CMS will evaluate the performance of all OPOs and determine which OPOs may need to be decertified.

One member remarked on the misalignment in goals for OPOs and transplant program, and asked the Committee what feedback they have for the OPTN Board of Directors to help encourage alignment. A member commented that change, especially systemic change, takes time, and that holding one set of OPOs to a tight timeline without holding others transplant partners and organizations to that timeline creates friction, inefficiency, and frustration.

5. Kidney Committee Charge and OPTN Efficiency Portfolio

Staff presented a recap of the Kidney Committee's charge, and shared ongoing efficiency related work currently underway by other OPTN Committees.

Presentation summary:

The Kidney Transplantation Committee is charged with considering medical, scientific, and ethical aspects related to kidney organ procurement, distribution, and allocation. The Committee considers both the broad implications and the specific member situations relating to kidney issues and policies. The goal of the Committee's work is to develop evidence-based policies aimed at reducing the burden of renal disease in transplant patients (candidates and recipients), increasing kidney utilization, improving access to kidney transplantation as appropriate, and improving the health outcomes of kidney transplant recipients.

The OPTN Kidney Committee works in collaboration with other OPTN Committees, each of which has their own specific charge. New ideas and potential projects that may fall outside of the Kidney Committee's scope are referred to other OPTN Committees, including the OPTN Policy Oversight Committee, for their consideration. Other OPTN Committees are also currently undertaking efficiency related efforts:

- Data Advisory Committee
    - Update Non-Use Reason Field in UNet
    - Data Collection Addressing Late Organ Offer Turndowns
- Histocompatibility Committee
    - Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates
- Membership and Professional Standards Committee (MPSC)
    - OPO Performance Monitoring Enhancement
- Ad Hoc Multi-Organ Transplantation Committee
    - Identify Priority Shares in Kidney Multi-Organ Allocation
- Operations and Safety Committee
    - Redefining Provisional Yes and the Approach to Organ Offer and Acceptance
    - Collect Donor CRRT, Dialysis, and ECMO interventions Data
    - Optimizing Usage of Offer Filters
- Lung Transplantation Committee
    - Promote Efficiency of Lung Allocation
- OPO Committee
    - Modify Organ Offer Acceptance Limit

Summary of discussion:

There were no questions or comments.

6. Data Review: Efficiency and Non-Use

Staff presented a brief overview of high-level data related to kidney allocation efficiency, non-use, and out of sequence allocation (AOOS), as well as an overview of patient related education and communication regarding lung continuous distribution.

Presentation summary:

Community feedback has indicated that broader distribution in circles-based kidney allocation has resulted in more complex allocation, with increased travel distances, increased offer volume, and acceptances further down the match run. Feedback gathered in public comment included a call for efforts to standardize and define “hard to place” kidneys, with implications for allocation efficiency, including “expedited” allocation pathways or “recovery” allocation pathways in the context of late declines.

Figure 15: Non-use Rates for Deceased Donor Kidneys Recovered by KDPI and Policy Era

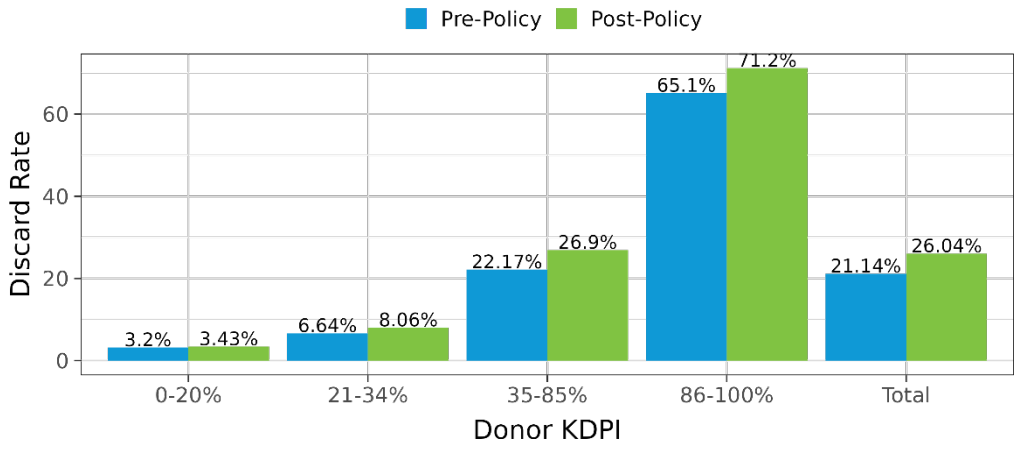
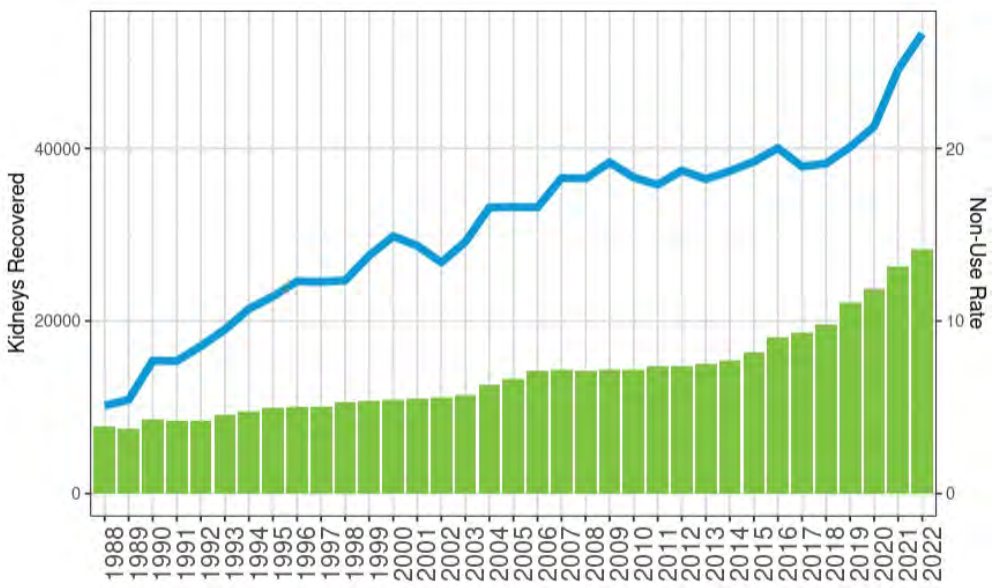
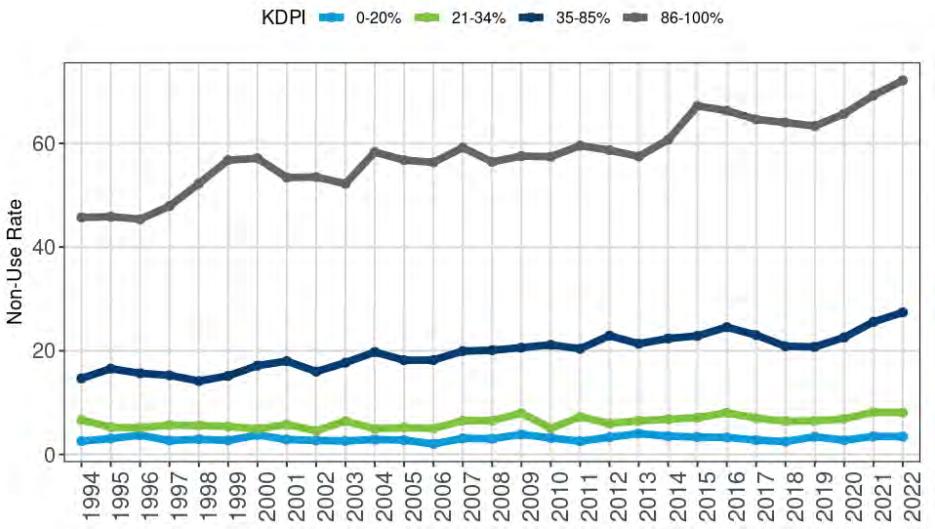


Figure 16: Deceased Donor Kidney Non-Use Rates Over Time



Non-use rate (y-axis on the right) overlaid with the **number of kidneys recovered** (y-axis on left)

Figure 17: Deceased Donor Kidney Non-Use Rates Over Time by KDPI



KDPI was not incorporated in the OPTN Donor Data and Matching System until 2012, so there is a larger proportion of donors for whom all of the necessary information to calculate KDPI was not present for, prior to 2017.

In 2022, non-use rates were 3.5 percent for donors with KDPI 0-20; 8.1 percent for donors with KDPI 21-34; 27.4 percent for donors with KDPI 35-85; and 72.1 percent for donors with KDPI 85-100.

Figure 18: Distance from Donor Hospital for Deceased Donor Kidney Transplants by Policy Era

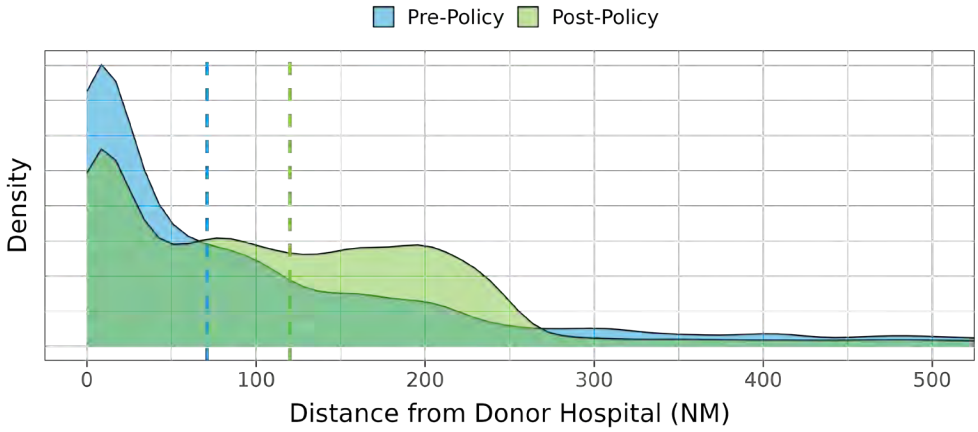


Figure 19: Cold Ischemic Time for Deceased Donor Kidney Transplants by Policy Era

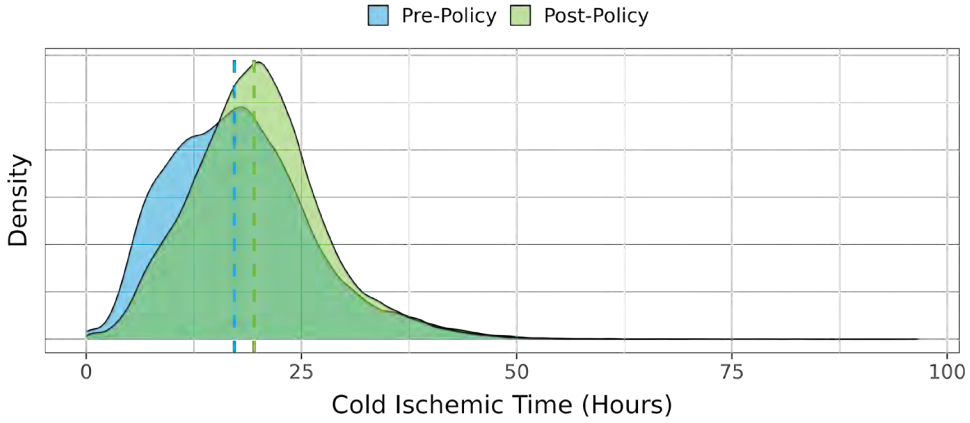


Figure 20: Distribution of Sequence Number of Final Acceptor for Kidney Match Runs by Policy Era

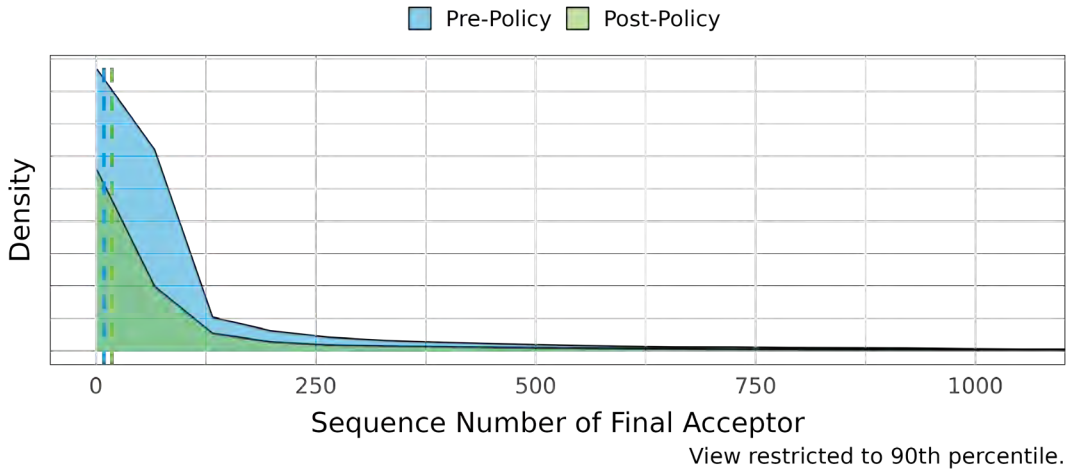


Figure 21: Offers per Active Patient Year for Kidney Match Runs by Policy Era

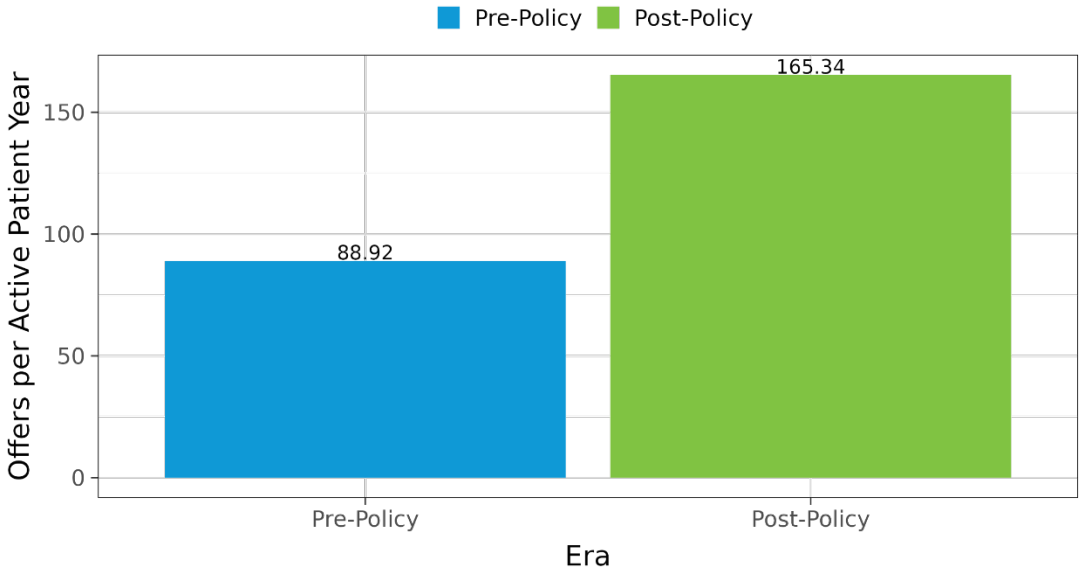


Figure 22: Non-Use Reasons Over Time

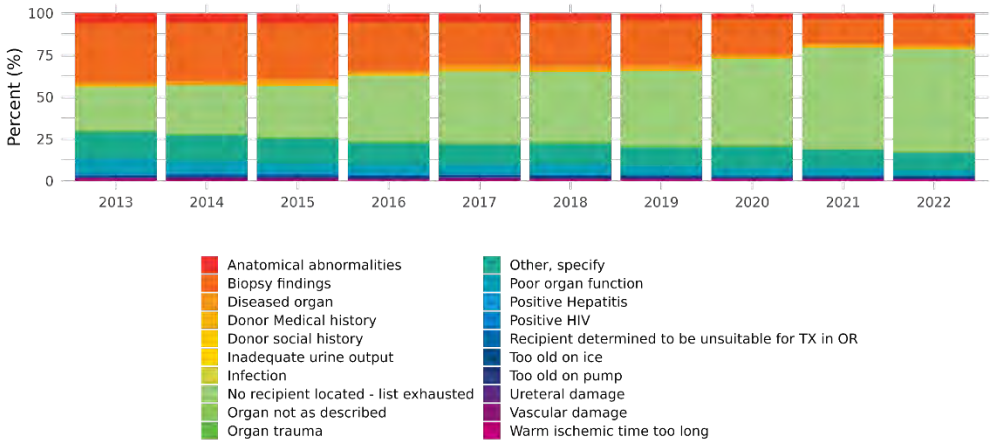
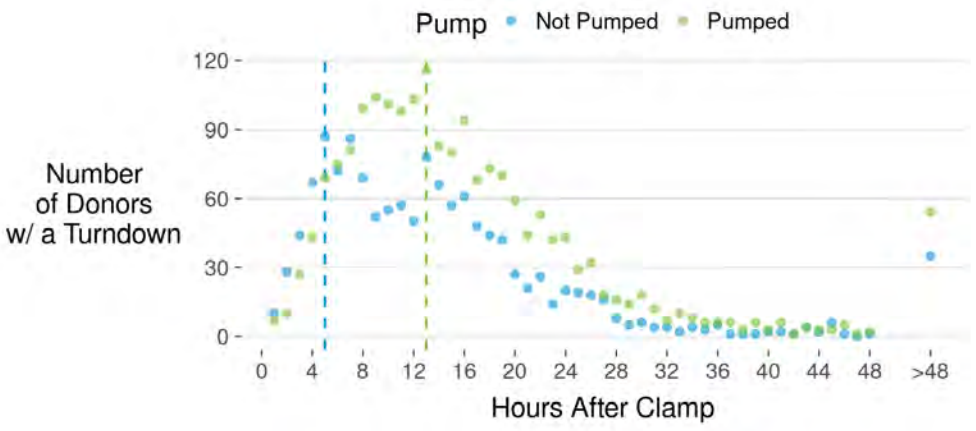
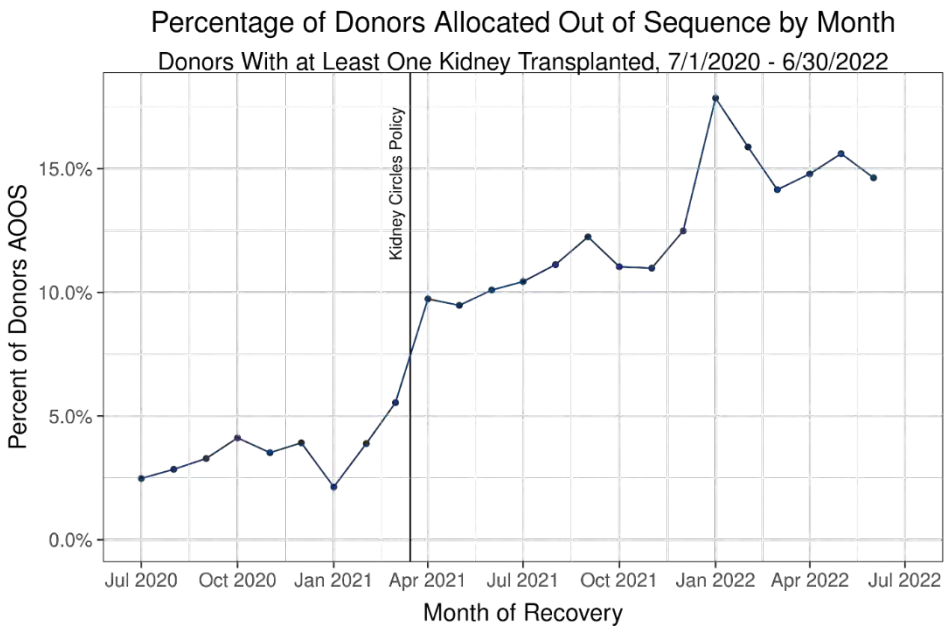


Figure 23: Late Turn Downs



Turn downs are most prevalent at 5 hours not pumped and 13 hours pumped.

Figure 24: Kidneys Allocated Out of Sequence



AOOS here is defined at the donor level, and not specific to kidney allocations out of sequence. The MPSC has observed a substantial increase in AOOS overall and for kidney. Prior to implementation of circles-based kidney allocation, 3-5% were generally allocated out of sequence. Since implementation, the percent of kidney donors who are allocated out of sequence has increased to 10-15% nationally.

Figure 25: Instances of Programs Indicating Provisional Yes and Later Declining by Policy Era

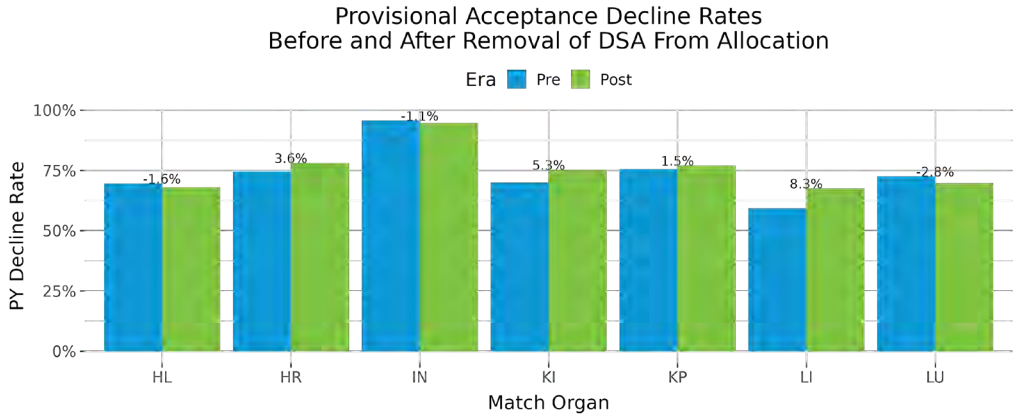
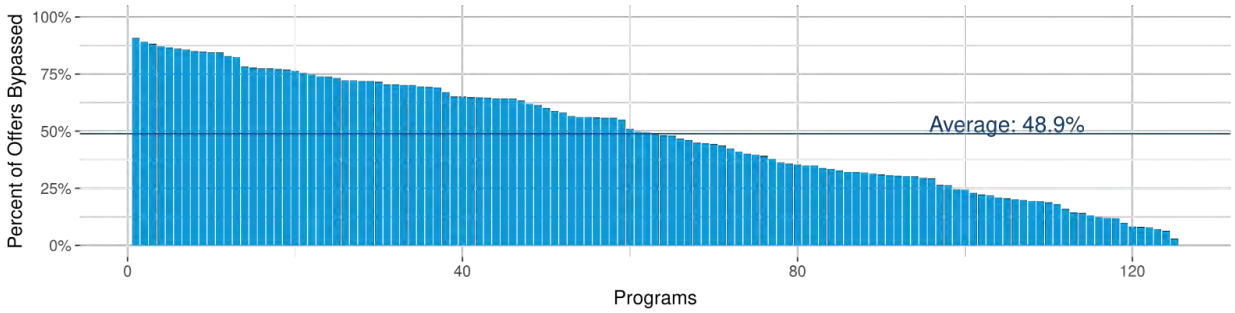


Figure 26: Percent of Offers Bypassed by the Offer Filters Tool



Shared decision making and effective communication was also discussed in public comment. The American Society of Nephrology (ASN) "identifying strategies to mitigate the growing number of organs that go unused, tackling the root causes of out of sequences offers… are all examples of efforts that will strengthen the transplant ecosystem over all… increasing transparency, particularly to patients, is likely to play a key role in achieving these objectives." This comment highlights a sense that shared decision-making, transparency, and patient empowerment are crucial to efficient and effective system geared towards patients. Current kidney policy incorporates shared decision making with respect to allocation of high KDPI kidneys, in that programs must obtain patient consent in order for patients to appear on match runs for donors with KDPI 86-100. Effective communication and education related to efficiency and allocation overall are also important. For example, lung continuous distribution included extensive patient-focused educational efforts and materials.

Summary of discussion:

The Vice Chair referenced **Figure 22**, asking how non-use reasons correlated with the quality of the organs being offered. Staff responded that this could potentially be broken out by KDPI, but that this may not be available for review today. Another member referenced **Figure 22**, expressing interest in further investigating organs not used for "no recipient located" to understand what the most frequent decline codes submitted for those organs were. The member explained that this could provide understanding if this was due to quality from the start, or if cold ischemic time increasingly becomes the most frequent refusal reason, and potentially provide insight into whether the organ may have been transplanted or if the organ was not medically appropriate for transplant. Staff noted that there is some research currently being undertaken to map refusal reasons to non-use reasons to determine if there are patterns.

One member asked if KDPI is calculated the same across years, with the same mapping table. Staff confirmed that KDPI was recalculated to the same mapping table across the years.

An SRTR representative remarked that not all kidneys are medically appropriate for transplant. The SRTR representative expressed surprise that programs are upset with increased offer volume, noting that more offers can lead to more transplants. The SRTR representative continued that part of the increase in non-use may be due to OPOs becoming more aggressive in the kinds of donors being pursued, and procuring increasingly medically complex organs. The SRTR representative concluded that it may not be appropriate to entirely attribute changes in non-use rate to changes in policy. A staff member agreed, noting that the Ex Oficio member has previously commented that while the non-use rate is too high, the appropriate non-use rate may not be 0 percent. Staff continued that the Committee and the community will need to determine what level of non-use is tolerable given the trends in donor characteristics and increasing risk of graft failure over time.

A member referenced **Figure 25**, remarking that late turn downs could be significantly reduced with enhanced offer filters. The member explained that the person taking primary call who receives an offer call may put in a provisional yes for everyone at their program without reviewing the offer, particularly if the offer is a back up offer with many programs ahead of them. At some point, the offer may become primary, and the program ends up declining for their program after reviewing the offer, but only once they are primary. The member explained that this is very inefficient, and that offer filters could help reduce offer volume for offers that the program would not consider. Another member remarked that many late turn downs are due to logistical reasons, particularly if there is limited flight availability. The member shared that their OPO will drive kidneys from Alabama to Ohio due to transportation issues. The member explained that logistics and outside factors could also impact late turn downs. Staff noted that there is not a high volume of kidneys with late turn downs.

7. Break Out Groups

The Committee broke out into four groups, with overarching key questions to consider as well as four focus areas.

Discussion questions:

Each group was asked to consider:

1. In your opinion, what are the largest pain points that you would like to see addressed by either this committee, the task force, or another committee?
2. What additional information would you need to understand and further investigate the problem(s) you identified above?
3. Has the committee discussed, have your read or do you have any ideas for how you might address the problem(s)

Group 1 focused on general allocation efficiency in continuous distribution, and also considered:

- Difficulties in allocating low and middle range (0-85 percent) KDPI kidneys
- Operational aspects (donor screening, visualizing and working with the match, dual kidney, released organs, etc.)
- What parts of the process increase allocation time and decrease efficiency?
- What parts of the process make it harder or easier to review an offer and accept a kidney quickly?
- Currently, candidates are ranked on match runs based on medical urgency, waiting time, priority statuses, and consideration of expected post-transplant survival, matching, and distance. How can new attributes, new donor modifiers, standardizing practices across OPOs and transplant programs, and improving match run workflow impact efficiency and non-use?

Group 2 focused on defining “hard to place” kidneys, and also considered:

- What makes a kidney “hard to place?” Consider also whether there is a lack of consensus around defining “hard to place” and the process of placement for hard to place kidneys
- How could a “hard to place” kidney be defined for the purposes of determining which kidneys may require placement through an expedited pathway?
- What clinical considerations are important to determining whether a candidate is an appropriate match for a “hard to place” kidney? What candidates are appropriate to accept these organs, and what characteristics do they share?

Group 3 focused on expedited kidney placement pathways, and also considered:

- How could an effective expedited kidney placement pathway operate? What are the key elements or considerations of such a pathway?
    - Consider screening and offer filters specific to "hard to place" kidneys, or prioritizing candidates differently for "hard to place kidneys" (longevity matching, reducing travel distance, etc.)
- How can equity in allocation be ensured in an expedited placement pathway?
- Alternate allocation pathways, such as dual kidney and released organ considerations, were already under discussion in Continuous Distribution of kidneys. How can these elements be incorporated or considered when discussing an expedited kidney placement pathway?

Group 4 focused on shared decision-making and communicating efficiency, and also considered:

- How should shared decision-making between patients and their transplant team be considered or expanded upon in future allocation policies?
    - Consider incorporating shared decision-making in continuous distribution, encouraging shared decision-making outside of continuous distribution, and patient education
- What are your thoughts on enhancing communication and education on continuous distribution, efficiency work, and allocation policy?
    - Consider what information patients need that other members may not need, what may be the best way to communicate with patients, and shared decision making materials and resources

Summary of discussion:

Group 1: Efficiency in Continuous Distribution

The Chair remarked that efficiency in continuous distribution is a broad topic encompassing many different considerations. The Chair shared that Group 1 discussed how other factors can play a role in efficiency, particularly across multiple stakeholders. The Chair explained that the initial goal of continuous distribution was to translate the current system to a more nimble, flexible framework, and now continuous distribution is expected to address and solve for efficiency. The Chair remarked that placement efficiency was a large discussion in the development of rating scales, and noted that the trade offs with increasing the importance of placement efficiency were difficult to balance, including longevity matching. The Chair remarked that difficulties in placement have to do with more medically complex kidneys. The Chair explained that it would be helpful to determine what information programs need to make a decision on an offer and ensure that information is packaged and available to programs when they need to make that decision.

The Chair added that programs, OPOs, and histocompatibility labs will need to partner with each other in order to ensure organ use and efficiency, particularly for medically complex organs. The Chair emphasized the benefits of virtual crossmatch, noting that eliminating the need for physical crossmatch prior to the transplant can encourage reduced cold ischemic time and post-clamp offer acceptance of organs for higher CPRA candidates. The Chair also noted that transportation is a current pain point, and plays a role in whether a program can accept an organ and whether a program can utilize the organ in a reasonable timeframe. The Chair added that each part of the procurement, allocation, transportation, and transplant process needs to be aligned, and that this requires coordination across stakeholders.

The Chair concluded that the Task Force will need to ensure appropriate coordination and strategy in planning to address inefficiencies across the transplant system. A member agreed, noting that there are many different pain points in the system, and that one of the large pain points lies in how many small factors become the "topic du jour," with smaller components addressed without a greater strategic

vision. The Chair agreed, noting that at some point projects need to be implemented in order to see and fully understand the changes. The Vice Chair agreed, and noted that the Task Force needs to develop an aligned definition of efficiency. The Vice Chair explained that efficiency is vague and expansive, and that an aligned definition of consensus would help improve strategic alignment in efforts across stakeholders. Another member agreed, adding that there are many different ideas addressing varying elements of efficiency, and that focused scope will be important for the Task Force to establish. One member agreed, adding that operational definitions are critical to appropriate project management, and that the Task Force needs to develop a project charter defining scope, objectives, key metrics, key stakeholders, and a timeline. The member added that this a project cluster, instead of a singular project, and that prioritizing those projects will be important. The Vice Chair noted that the Task Force may want to focus on smaller achievable efforts.

One member remarked that the OPTN has worked on many projects to improve efficiency, but that the fundamental infrastructure remains outdated and unsupported. The member continued that incremental changes to improve the allocation process may help, but ultimately will not solve logistical efficiency problems, including lack of access to logistics. The member added that there is limited and potentially insufficient data on this, and that many efforts may not fully operationalize due to limited infrastructure. The Vice Chair agreed, noting that the cost data is key to understanding the feasibility of increasing the median distance of travel in order to achieve equity gains. One member remarked that it's interesting to hear this discussed in terms of cost to the OPO, particularly when it is often billed back to the transplant program, or at least split with the transplant program. The member shared that their OPO split a 55,000 dollar plane ride with a transplant program accepting both kidneys from a donor for two candidates, because there were no other transportation options available. Another member agreed that this information should be reported on the cost report, and that there is a responsibility for appropriate use of tax dollars. The Vice Chair agreed, adding that high costs of transportation may prevent programs from pursuing or accepting some organs. A member added that there are other examples of cost considerations that need to be made. For example, pumping kidneys can result in slightly better outcomes if the organs are accepted; if the organs are not accepted, the OPO still has to pay the cost of pumping the organs. The member continued that if only one of 100 kidneys being pumped are transplanted because those kidneys are not really transplantable, then there needs to be a better way to distinguish and reduce wasted cost. Another member agreed that this is another aspect of infrastructural limitations – machine profusion is known to improve outcomes, but the current system doesn't support machine perfusion from a financial or resource perspective. The member remarked that machine perfusion has a known benefit, and that the system should be restructured to encourage its use.

A member of staff summarized discussion shared by the virtual attendees. Staff shared that the virtual group discussed potential definitions of efficiency, and identified that the key problem to be solved is organ non-use. The virtual attendees discussed how other efficiency metrics, such as median sequence number at acceptance, which can indicate the need for additional offering and additional time to offer. Staff shared that virtual attendees noted that it will be important to identify which organs are "hard to place" early in the allocation process in order to allow for appropriate use of expedited placement pathways. Staff shared that of the data points evaluated by the virtual attendees, that the system may be better able to handle distance and cold ischemic time, allowing allocation to prioritize shorter travel distance or programs to filter out far away offers with significant cold ischemic time. Staff continued that factors like high KDPI or "hard to place" may need an alternative approach to allocation, which could involve system changes to facilitate. Staff continued that virtual attendees expressed variation in OPO behavior, and that there is value in sharing, understanding, and analyzing this variation. Staff continued that "hard to place" kidney allocation may need additional standardization, including around

information availability and testing. Staff added that virtual attendees emphasized the pain points surrounding "hard to place" kidney allocation. Staff shared that the virtual attendees discussed offer filters, and the importance of offer filters capabilities in improving allocation efficiencies in a continuous distribution system, particularly with lessons learned from lung continuous distribution. One member added that virtual attendees agreed that defining efficiency is important, and considered a definition of efficiency based in allocating kidneys to the most appropriate patient at the appropriate program. The member remarked that this should be the underlying philosophy, but that there are many moving parts to ensuring the organs are allocated efficiently, equitably, and minimizing non-use.

The Chair remarked that there are many ongoing efforts, and that within each project, the Policy Oversight Committee has done great work to identify appropriate stakeholders and metrics. The Chair continued that there are many factors going into the continuous distribution framework, beyond just the composite allocation score that the Committee has been discussing – offer filters, mandatory kidney shares and multi-organ considerations, and other efforts will all influence kidney allocation prior to and in a continuous distribution framework. The Chair continued that these efforts are all intersecting without necessarily a unifying directive, and that this is an area the Task Force could help inform on. The Chair remarked that there should be a strategic project manager that can coordinate current and ongoing efforts and new efforts proposed by the Task Force. Another member agreed, noting that there is a need for greater coordination, particularly with the time it takes to finalize projects.

One member commented on decreasing non-use rates, noting that however "hard to place" kidneys are defined, "hard to place" kidneys could bypass the match run and be offered directly to more aggressive transplant centers. The member remarked that some programs are much more aggressive than others, and that it may not make sense to add more coal time in order to transport an organ to a program where it may not be utilized.

Group 2: Defining Hard to Place Kidneys

One member shared that when considering what makes a kidney "hard to place," Group 2 noted that while there are some more obvious characteristics like high KDPI, any characteristic at some point or in some combination can make a kidney "hard to place." The member explained that this makes it difficult to create a specific list of criteria to adhere to. The member provided an example of a low KDPI kidney that has gathered significant cold ischemic time – while initially the organ may not have been "hard to place," the cold ischemic time build up renders the organ "hard to place." The member continued that there is a need for flexibility in the definition of "hard to place," and that more granular criteria should potentially consider sequence number and cold ischemic time. The member referred to previously considered thresholds for applying the KiMAC, noting that these thresholds could be lowered to better define "hard to place" during placement. The member added that lower thresholds of number of candidates having declined could be used to trigger alternate allocation pathways. The member also noted that cold ischemic time should also be considered in combination with other factors, particularly as cold ischemic time can both impact and be impacted by logistical constraints. The member offered that lower cold ischemic times and lower sequence numbers could provide objective metrics for defining a "hard to place" organ.

A member agreed, adding that logistics can play a big role in how difficult an organ is to allocate, particularly for organs recovered in smaller towns or for programs in smaller towns attempting to accept organs. The member remarked that where the kidney is procured should factor into whether an organ is considered "hard to place," particularly if there are limited transportation options in that area.

One member remarked that, in considering which kidneys may require an expedited placement pathway, there are many different characteristics and considerations that may not independently define

a “hard to place” kidney, but may do so when in combination. The member commented that there may need to be more autonomy and trust in clinical decision making of the transplant center and the OPO as to whether an organ requires an expedited placement pathway.

One member remarked that it is difficult to directly determine which candidates may be more appropriate for “hard to place” kidneys, noting that this is a very nuanced answer depending on the program and the kidney characteristics. The member added that it would be difficult to appropriately build an algorithm that could prioritize appropriate candidates for a “Hard to place” organ because this consideration is so nuanced. The member continued that allocation does not take into account where a recipient is located in comparison to the transplant program, and that candidates who live 10 hours away from a transplant program are not feasibly going to be able to accept an organ with extended cold ischemic time. The member added that this has to be determined on a case by case basis.

A member shared that Group 4 discussed that there is not sufficient data to understand cold ischemia time and logistical impacts. The member continued that distance is a poor surrogate, and that there should be efforts to better capture that information. The member added that logistics are challenging in different ways for different parts of the country, and that having that information available by geographic region would be helpful. The member also noted that there may need to be variation within allocation based on what transportation is actually available. The member explained that donor hospitals at central transportation hubs have very different logistical options than donor hospitals in small towns. The member noted that these considerations are missing from the discussions about allocation due to lack of logistical data.

The Vice Chair asked if OPOs collect information regarding cold ischemic time based on how far the organ has to travel. Another member noted that some OPOs may collect this independently, but that this is not required for OPOs to collect.

One member offered that there could be some kind of model that could estimate based on general time of allocation and transportation – such as 5 hours of allocation, and 10 additional hours of cold ischemic time for additional connecting flights. The member continued that this could give a better sense of how feasible an offer is to accept. The member shared an example, noting that an offer from Florida with 13 hours of cold ischemic time may seem reasonable, but factoring in transportation and flights, the projected final cold ischemic time could be upwards of 30 hours. The member continued that this process may need to be modified depending on where the organs are located.

A member remarked that “hard to place” kidneys often need to be biopsied, and that programs do not submit an acceptance until they can review biopsy results. The member continued that it becomes very difficult to determine potential transportation pathways. Another member countered that there is criteria for when a biopsy should be performed. The member agreed, but that programs not submitting an acceptance until biopsy results are finalized can be problematic for determining logistics. The member added that sometimes, based on flight options, it can be easier and faster to transport the kidney further, and that there is limited predictability to this.

One member asked if giving OPOs more autonomy in the decision-making processes of allocating “hard to place” kidneys would help ensure increased organ use. Another member shared that their OPO places “hard to place” kidneys using an internal definition and based on the Recovery and Usage Maps (RUM) report. The member continued that their OPO evaluates the RUM report using the organs characteristics to create a nation-wide list of programs that have accepted similar kidneys. The member explained that using this list, their OPO will go back to the match run, and offer down the match run to candidates at those centers listed by the RUM report. The member noted that not all OPOs do that, but that this process allows their OPO to ensure the organ is placed and transplanted.

A member pointed out that transplant is a 24/7 operation, but that the transportation system used to ship kidneys does not. The member continued that this is a fundamental flaw in the system, and that there are no allocation changes that can address a lack of flight options. The member added that limited flight available, particularly at night, results in a significant portion of each week where transportation is simply unavailable. The member added that it is impossible to optimize other parts of the allocation system without addressing the logistical and transportation system limitations.

One member shared that a few OPOs are working on agreements with FedEx and UPS, because they are shipping on a 24/7 basis. The member agreed that there need to be more options than commercial flights, and shared that their OPO has previously worked with local reserve military bases on special cases. Another member agreed, noting that if there is investment in improving allocation, there needs to be investment in the logistical framework. One member added that this makes sense from an overall investment standpoint, noting that it is more expensive for the government to keep patients on dialysis long term than to transplant the patients. The member continued that prioritizing charter flights could help reduce non-use rates, and that reducing non-use rates even by 20 percent could result in significant healthcare cost savings for the federal government. Another member shared that charter flights have their own limitations, particularly with a lack of pilots.

The member continued that there is a cascading effect, where the more organs procured in the system, the greater strain on transplant surgeons, program resources, transportation resources, and OPO resources. The member added that the US transplant system has outpaced other countries' transplant systems in growth, and that this is the other side of that growth.

A member noted that previously, there were discussions expressing concerns about using alternate shipping agencies. Another member agreed, noting that carriers have lost organs before, and carriers need to ensure the organ's transportation is the highest priority and that organ tracking is incorporated. One member commented that organ transportation should be outsourced to an organization that specializes in transportation that is contracted to the OPTN and required to meet high standards. Another member remarked that the US military is the largest owner of planes and aircraft in the US, and although military pilots are available 24/7, the US military has not yet been officially contracted to fly most organs. The member shared that the US reserves near their OPO has agreed to scramble teams and fly organs on occasion, but that these conversations were at a local level under a significant time pressure. Another member remarked that there should be conversation between high level governmental leaders to establish reliable partnerships to ensure adequate organ transportation is available. One member added that this could be financially viable and ultimately generally reduce costs overall.

A member remarked that this is the right time to begin addressing non-use and logistical limitations, particularly with modernization initiatives. The member continued that transportation should be considered in these modernization initiatives, particularly to allow for a more centralized, strategic approach.

Staff noted that a number of these potential pathways to expand the capacity of organ transportation system have been discussed over the last few years, and that this would require a level of federal coordination and involvement beyond the scope of the OPTN.

Group 3: Expedited Kidney Placement Pathways

One member summarized the group's discussions, noting that Group 3 heavily discussed the offer filters functionality. Specifically, increasing the number and dynamism of offer filters available for use, such as age. A member explained that a spectrum of donor and candidate age, EPTS, and KDPI should be available as filtering criteria, allowing for more dynamic screening. The member added that there are

other critical medical attributes that should be considered, such as degrees of hypertension. Another member explained Group 3 agreed that the optimizing the offer filters tool and increasing its use would improve efficiency of the system. The Chair remarked that the characteristics for donors and recipients in the offer filters tool don't necessarily line up with what transplant programs are looking for. For example, programs may want to build filters specific to candidates over a certain age, particularly for medically complex or "hard to place" organs. The Chair noted that the candidate criteria should allow for thresholds both under or over a certain age. Another member agreed, noting that even now, filters won't stop a 65 year old kidney offer to a 30 year old candidate, which is not an offer that some programs would consider. A member of staff noted that candidate age over or under a threshold is an exclusion that will be programmed in to the offer filters tool with the most recent board approved enhancements. These enhancements also include additional donor factors such as serum creatinine. Staff asked Committee members to send along other recommendations for potential offer filters criteria.

Group 3 also discussed an accountability mechanism for transplant programs with respect to late turn downs. The member explained that this could work such that a program who has provisionally accepted an organ and puts in a late decline for the organ at a specific threshold (such as greater than 75 percent of offers) would then be required to under go an internal review. The member continued that the internal review would require that program to review and increase their offer filters usage. The member explained that this behavior results in unnecessary cold ischemic time for organs that the program would not end up transplanting. The member added that such a mechanism wouldn't flag if the program used the organ for a different recipient, only if the program's delayed review added unnecessary cold ischemic time to an organ.

The member shared that in considering distance from donor hospital, Group 3 noted that reducing distance from donor hospital is not necessarily important to quickly placing organs. The member explained that organs may need to travel to reach a program that would accept and transplant them.

One member shared that in considering expedited placement and equity, Group 3 discussed allowing the OPO and transplant centers to work together to place kidneys with the most appropriate, highly prioritized recipient. The member shared that their OPO utilizes the RUM report to hone in on the programs that are likely to accept a specific kidney based on the organ and donor characteristics, and working with those programs to ensure the most appropriate recipient at those programs receive the offer. Another member remarked that this process is aggressive, and backed with data from the RUM report. The member continued that each OPO has a different process, and that this variation could open the door for potential inequities based on standing relationships between OPOs and programs, even if not intentional. The member continued that it would be helpful for AOPO to release a recommended framework for aggressive allocation that utilizes a fair, data-backed process. The Chair agreed, adding that variation in OPO aggressive allocation policies ultimately contributes to inefficiencies. The Chair noted that some OPOs may not have the necessary resources to allocate in this way. Another member responded, noting that each OPO is trying to determine their own best practices, particularly with pressure from CMS to become a Tier 1 OPO. As a result, OPOs are developing their own processes for placing "hard to place" kidneys and defining "hard to place" their own way. The member continued that OPOs are looking for guidance on these processes, and added that the RUM report is effective because it matches the kidney characteristics to programs that have historically transplanted kidneys with those characteristics.

Group 4: Shared Decision Making and Communicating Efficiency

One member shared that in considering shared decision making, Group 4 discussed the complexity of patient education when a patient is initially added to the kidney waiting list. The member continued that

this can be overwhelming, and that patient education and shared-decision making should be simplified and accessible so that the patient can make an educated decision and the provider has an idea of what the patient is looking for. One such decision is whether the patient is looking for an organ with significant graft longevity, or is the patient hoping to get off of dialysis faster, and are more comfortable with a potentially shorter graft longevity to achieve that goal. Group 4 discussed this as a key decision and noted that should be a main element in patient education.

The member shared that Group 4 also discussed including the referring or general nephrologist in shared decision-making discussions, so that the patient's general nephrologist can understand the process, the patient's goals, and potentially act as a mediator or additional touch point for the patient. The member continued that it's likely the referring nephrologist has been following that patient for much longer than the transplant center, and may have a stronger relationship and more trust with that patient. The member added that this is a combination of patient, transplant program, and referring nephrologist.

The member shared that Group 4 discussed potential ways to utilize shared decision making in getting more organs transplanted and allocate more efficiency, such as incorporating increased risk for hepatitis B and hepatitis C, and dual kidney transplantation into shared-decision making processes.

In considering patient education, Group 4 commented on the overwhelm of information shared with patients during evaluation and listing. The member shared that Group 4 agreed that it is critical to provide information for patients to follow up with and refer to later. Group 4 discussed that it is important for patients to have access to the information they need and desire about transplantation and the process itself, particularly as it relates to any actions or decisions the patient may need to take. Group 4 agreed that patient education should be available in a variety of ways, allowing patients to learn visually, in conversation, or using a variety of materials, such as videos, literature, and more.

One member added that patient education should include offerings in multiple languages. The member added that community groups could also be involved in patient education and ensuring informed shared decision-making. The member explained that referring nephrologists may be too busy or otherwise unable to participate in that, and that this could be a gap that patient advocate groups could help fill.

8. Open Forum

The Committee held an open forum on discussion topics.

Summary of discussion:

One member remarked that they will bring this information back to the OPTN Board for consideration as well.

The Chair remarked that the OPTN site includes some patient education and engagement, and asked how comprehensive that information is and how many resources are put into it. Staff shared that currently, there are a number of patient education materials, and that UNOS and the OPTN produce educational materials and share them through a platform that is open and available to anyone for free. Staff continued that there is a lot of education in this platform for both patients and providers, and that there are a number of materials directly on the OPTN and UNOS site targeted towards patients. Staff continued that there is a team dedicated to developing educational materials, and that team works closely with patient community administrators and patient services teams. A member commented that the currently available educational materials have required a lot of effort, and recommended bringing forward all available patient education into one centralized location. The member continued that it would be helpful if the education was standardized and accessible, such that patients can easily find and access all the essential information about kidney transplant. Staff shared that the OPTN Patient Affairs

Committee has been working on an updated patient information letter that is now available on the OPTN site, and that this letter lists resources available to the patients. The resource does note that these resources may not be able to provide patient-specific medical information, but that it does provide a number they can call for general questions.

9. 6-Month Post-Implementation Monitoring: Establish Minimum Criteria to Require Renal Procurement Biopsy

The Committee reviewed the 6-month post-implementation monitoring report for the *Establish Minimum Criteria to Require Renal Procurement Biopsy* policy change.

Presentation summary:

The *Establish Minimum Criteria to Require Renal Procurement Biopsy* policy requires host OPOs to make a reasonable effort to perform a biopsy on kidney donors age 18 and older who meet the following criteria:

- Anuria, or a urine output of less than 100ml in 24 hours
- Donor has received hemodialysis or other renal replacement therapy during current hospital admission or in the course of donor management
- History of diabetes, or HbA1C of 6.5 or greater during donor evaluation or management
- KDPI greater than 85 percent at time of original match run
- Donor age 60 years or older
- Donor age 50-59 years, and meets at least two of the following criteria:
    - History of hypertension
    - Manner of death: cerebrovascular accident (CVA)
    - Terminal serum creatinine greater than or equal to 1.5 mg/dL

This cohort included all adult deceased kidney donors recovered in the United States between March 9, 2022 and March 5, 2023. The pre-policy era was defined as March 5, 2022 to September 5, 2022, and the post-policy era was defined as September 6, 2022 to March 5, 2023. Analysis of this policy is limited by the data collected in the OPTN Donor Data and Matching System, which does not include sufficient data collection related to donor use of dialysis or anuria to identify every donor that may meet the above criteria.

Conclusions:

- There has not been a drastic increase in the percentage of donors being biopsied
- There were small shifts in the type and characteristics of donors that have been biopsied
- Non-use has increased, although due to the shifting landscape of donors being recovered and biopsied, there is insufficient evidence to suggest biopsy status alone has increased non-use rates

Summary of discussion:

One member asked if biopsy and non-use rates were broken down by OPO, and staff responded that the scatter plots were broken down by recovering OPO, showing non-use rates and rates of biopsy. The member noted that certain OPOs have seen dramatic shifts in non-use rates, particularly in areas of the country where there are known risk factors. The member continued that their OPO was directly affected because of the new biopsy rates, where other OPOs were not as affected. The member added that the overall statistics may not seem like much, but the effect is stronger for certain OPOs. The member shared that their OPO is performing fewer biopsies in the post-policy era, and that their non-use rates have decreased. The member shared that neighboring OPOs following this policy have seen increased

biopsy rates and increased non-use, even of kidneys that were typically transplanted before. Staff shared that these rates are not adjusted by OPO. The member wondered why kidneys that were previously being placed and transplanted are no longer being transplanted. The Chair remarked that it is hard to know the outcomes, especially this early in the policy monitoring. The Chair continued that this policy provides standardization that will help to track and understand impact to outcomes as well.

The Chair remarked that regardless of biopsy, non-use rates increased, and that the largest jump was for the highest KDPI group, particularly for those kidneys that met criteria and were not biopsied. The Chair continued that the non-use rate increase may not be solely attributable to this policy. The Chair added that as programs get more data on the donors, this data will impact their decision to accept. The Chair continued that the data is not yet available to show impact of this policy to outcomes. The Chair remarked that it is difficult to make conclusions, particularly with a shifting transplant environment.

One member expressed support for standardizing biopsy performance. The member continued that there is still an issue with the quality of procurement biopsies, particularly frozen section biopsies read by pathologists with limited renal biopsy experience. The member recommended a more centralized approach to renal procurement biopsies. The member shared that some OPOs have been able to leverage a system where the biopsies are prepared as permanent sections by a physician's assistant and sent on to a group of renal-specific pathologists. The member continued that these OPOs are often still able to make this work even with remote and distant donor hospitals and recoveries. The member recommended a framework where each region had access to such a group of renal-pathologists, such that renal procurement biopsies were more reliable and generally better quality. The member also wondered if the biopsy sample preparation equipment could be more transportable, and the biopsy slides themselves digitally photographed such that the high resolution photographs could be sent and read by renal pathologists remotely. The Chair noted that previously, OPOs wanted to see renal procurement biopsy readings to be more centralized and standardized. The Chair continued that some OPOs previously argued that standardization of biopsy criteria is less meaningful without standardization of biopsy quality. The Chair agreed standardized biopsy reading is the next step.

One member remarked that the Banff pathology group made some effort to standardize liver pathology data and processes, and that something like this could be helpful for kidney biopsies as well. Another member agreed, noting that programs can have experiences where a transplanted kidney does not perform as expected, and that the post-transplant biopsy results differ greatly from the allocation procurement biopsy results.

A member remarked that initial standardization has been helpful, and that they are encouraged by the results thus far. The member continued that ongoing standardization of how the biopsy is processed, who performs the read, and having samples themselves be electronically available for programs to review would be the primary next steps. The member added that the biopsy reading is not always accurate, and that taking away concerns of reliability will help reinforce a program's decision to transplant or decline. The Chair agreed, noting that additional data regarding outcomes will also help support this. One member remarked that the increasing non-use rate for qualifying high KDPI kidneys where a biopsy was not performed may lead some to question if there is some component of those kidneys that may have been transplanted had a biopsy been performed and the desired information provided to evaluating programs. The member continued that this increase in particular is large. The Chair agreed, noting that programs may be less likely to accept a kidney where a biopsy was not performed, particularly if they had concerns.

One member asked if there is any data related to delayed graft function that could be evaluated. Staff noted that this was not evaluated in the six-month monitoring report, but could be evaluated in the future. Staff added that the *Standardize Kidney Biopsy Data Collection* proposal, which standardizes the

biopsy parameters that is reported, was only just implemented in September 2023. Staff shared that the Committee will be monitoring those results as well, and that this may provide additional insight into biopsy quality and the results themselves.

A member asked if there is any data investigating correlation between biopsy type and quality of the biopsy, particularly related to parameters considered for kidney transplant. One member responded that these findings are heterogeneous in terms of biopsy correlation with outcomes, even with a wedge biopsy, there is not necessarily a linear correlation between post-transplant outcomes and degree of glomerulosclerosis. The member clarified that timing is an issue, but that percutaneous biopsy could provide a solution to this, as opposed to a biopsy performed during organ recovery. Another member responded that there may be higher risks with a percutaneous biopsy prior to transplant. The member agreed that there is low incidence of risk, but that some donor hospitals may not perform them routinely, and that this risk is variable. The member continued that given the difficulty of obtaining and preparing a wedge biopsy sample at some smaller hospitals, it may be more difficult to get a pre-recovery native donor kidney biopsy. The member added that this could be different potentially with increased use of donor recovery centers and general biopsy standardization. The Vice Chair remarked that it can also be generally difficult to perform native kidney biopsies at transplant programs themselves, even just in scheduling the test. A member agreed that if there is a controlled center, it could be done potentially.

One member expressed support for increased standardization overall.

A member remarked that biopsies may be to OPOs' benefit in regards to CMS metrics. The member explained that showing reliable poor biopsy results, then the OPO should not be held responsible for an organ not being transplanted that was not transplantable to begin with. The member continued that the community would need to agree on the criteria, but that this could help. Another member commented that OPOs could use these biopsy parameters to determine whether or not to recover a kidney at all, particularly if the OPO performed a pre-transplant subcutaneous biopsy. A member remarked that this comes down to infrastructure considerations, noting that mandates of set criteria to biopsy kidneys does not necessarily mean that an OPO has the resources to perform the biopsies reliably and well. The member continued that the way an OPO looks at use or non-use may be different than how a transplant program assesses a kidney.

The Chair remarked that this discussion all relates to the general discussion of the day – no one thing will be the main solution to reducing non-use. The Chair continued that biopsy criteria is an example of standardization that can be evaluated and improved upon.

Next steps:

The Committee will continue monitoring the biopsy requirements policy.

Upcoming Meetings

- November 20, 2023 – Teleconference

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Sanjeev Akkina
  - Jason Rolls
  - Carrie Jadlowiec
  - Patrick Gee
  - Curtis Warfield
  - Stephen Almond
  - Eloise Salmon
  - John Lunz
  - Leigh Ann Burgess
  - George Surratt
  - Chandrasekar Santhanakrishnan
  - Charles Strom
  - Martha Pavlakis
  - Tania Houle
  - Aparna Sharma
  - Kristen Adams
  - Reza Saidi
  - Nidyanandh Vadivel
  - Jesse Cox
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Peter Stock
  - Bryn Thompson
  - Grace Lyden
  - Ajay Israni
  - Jon Miller
  - Nick Wood
- **UNOS Staff**
  - Lindsay Larkin
  - Kayla Temple
  - Carlos Martinez
  - Thomas Dolan
  - Keighly Bradbrook
  - Kieran McMahon
  - James Alcorn
  - Joann White
  - Kaitlin Swanner
  - Kelley Poff
  - Kim Uccellini
  - Laura Schmitt
  - Lauren Motley

    - Ross Walton
    - Ruthanne Leishman
- **Other**
    - Elijah Pivo
    - Dave Weimer