# OPTN Kidney Transplantation Committee
# Meeting Summary
# October 14, 2022
# Chicago, IL

**Martha Pavlakis, MD, Chair**
**Jim Kim, MD, Vice Chair**

## Introduction

The Kidney Transplantation Committee (the Committee) met in Chicago, IL to discuss the following agenda items:

1. Welcome and Announcements
2. Vice Chair Opening and Process
3. Proposal: Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations
4. Review of Public Comment Feedback for Kidney-Pancreas Continuous Distribution and One Year Monitoring Report Committee Updates
5. Massachusetts Institute of Technology (MIT) Modeling Trade Off Curve Presentation

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

## 1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members and facilitated a round of introductions for everyone attending in person and virtually.

Summary of discussion:

There were no questions or comments.

## 2. Vice Chair Opening and Process

Staff announced there will be a Committee Vice Chair vacancy in 2023 and presented an overview of the Vice Chair selection process.

Summary of discussion:

There were no comments or questions.

Next Steps:

The application period for the Vice Chair position will be open until November 1, 2022.

## 3. Proposal: Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

The Committee discussed public comment feedback and post-public comment recommendations for the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* proposal.

Presentation summary:

The proposal was released for public comment from August 3, 2022 to September 28, 2022. The proposal received 199 comments, including 41 substantive, written comments. This includes six comments from OPTN Committees and five comments from stakeholder organizations and societies.

The proposal presented the modification of waiting time for Black kidney candidates affected by race based eGFR calculations not as a requirement, but as a voluntary opportunity for transplant programs. The most frequent feedback received on this proposal was that submission of eGFR waiting time modifications on behalf of affected candidates should be mandatory for all transplant programs. Respondents who supported this theme expressed the importance of ensuring more equity for every qualifying candidate, not just those registered at transplant programs that take the opportunity to participate.

Feedback on the proposal also indicated support for increased transparency through clear communication with patients regarding this policy. Input also suggested notifying those patients who qualified for an eGFR modification. Input that responded to the Committees' request for feedback about educational resources suggested that both transplant programs and patients will seek guidance on the eGFR waiting time modification process.

The proposal received mixed feedback regarding the recommended 365 day timeframe for submission of eGFR modifications. Some responses indicated support for the proposed timeframe, while others suggested that it should be longer that 365 days, shorter than 365 days, or that there should be no timeframe.

The majority of respondents supported the proposed scope which included both pre-dialysis and dialysis candidates. Some feedback indicated support for limiting the scope to only the eGFR or creatinine clearance criteria candidates.

Finally, the proposal received some feedback suggesting that its implementation could contribute to an increase of administrative burden and challenges.

The Reassess Race in eGFR Workgroup met on October 11 after public comment closed to discuss potential post-public comment changes. Their recommendations were as follows:

- Mandate eGFR wait time modifications
- Require programs submit an attestation to the OPTN at the conclusion of their review and submission of modifications
- Supported proposed scope of both pre-dialysis and dialysis candidates
- The Workgroup was split between recommending a 365 day or 6 month time frame
- Require programs to send a patient notification

Summary of discussion:

*Optional vs. Mandatory Modifications and Monitoring*

The Chair commented the Workgroup initially moved forward with an optional pathway and public comment showed an overwhelming support for a mandatory policy. Members supported the recommendation to make the policy mandatory. Some members expressed concern for the administrative burden of monitoring compliance as it will be challenging for programs. Members commented programs may make all reasonable efforts but may not be able to locate prior documentation for some candidates. The Chair recognized there are likely situations where a candidate's prior documentation cannot be found and commented programs should attest to their efforts. A member suggested including information in the attestation detailing the number of candidates reviewed and the result of those reviews to demonstrate they completed their assessment. Another member asked if the OPTN could supply a list of candidates to each center. The Chair commented the OPTN is working on providing a tool. However, adding increased complexity to the tool would likely delay implementation of the policy. Staff further commented the OPTN is working on tools

and education to provide to transplant programs to help guide them through the assessment and modification process.

A member commented the administrative burden is dependent on scope of candidates who are eligible, and the inclusion of dialysis candidates would be more challenging for programs. Another member suggested a directive for programs to review their own lists initially, and then have the OPTN provide a list of candidates for whose waiting time was not adjusted to for programs to provide explanations as to why they were not adjusted.

Some members discussed the idea to apply a blanket amount of time to all Black candidates. Another member commented by reviewing individual candidates, some candidates may be missed due to unavailability of data. The Chair commented this was discussed previously and an issue with applying a blanket amount of time is it would be arbitrary and may create further disparities elsewhere, so would be difficult to justify. A member commented transplant programs may not be aware of the amount of time a candidate could potentially gain back, and informing programs of the impact this can have on qualifying candidates could incentivize them to fully assess their lists. Staff further commented post-public comment changes must be based on what was proposed and public comment received otherwise it is not legally justifiable. Applying a blanket amount of time to candidates would require another round of public comment. The Chair commented another round of public comment would further delay the restoration of waiting time for those impacted candidates.

The Committee was informally polled and was in support of a policy mandate and an attestation requirement.

*Scope*

A member commented the broader scope is the right thing to do, but in practical application will be difficult due to lack of available data for dialysis candidates. A patient member asked for an example of how this may impact a patient. The Chair gave an example of a pre-dialysis patient who came to transplant program for evaluation and there was a delay in listing due to the use of a race-based calculation, but could have begun accruing waiting time if a race-neutral calculation had been used. A more difficult example would be a dialysis patient who is referred to a transplant program and began accruing waiting time based on their dialysis start date. The transplant program may not have access to those pre-dialysis lab values. A member commented delayed referral for transplant affected them personally and asked how this proposal would help those types of patients. The Chair clarified delayed referral to transplant is a much broader disparity issue that should also be addressed, but this proposal has a limited focus on those impacted by the use of the race-inclusive eGFR calculation. A member expressed concern for allowing backdating of time for Black dialysis candidates as backdating for eGFR values is not part of current policy and would not be an opportunity available for all dialysis candidates. The Chair commented the proposal is limited to the Black candidate population because it is addressing a disparity that has existed based on race-inclusive calculations. The Chair recognized other disparities exist, but this policy proposal is focused on the use of the Black race variable in eGFR calculations and further suggested the Committee should not hold a proposal to fix one disparity because other disparities exist.

A member who would specifically be in the qualifying population asked if it is inclusive of multiracial candidates. The Chair commented the proposal refers to if the Black race variable in the eGFR calculation was applied to the candidate.

Committee members discussed a scenario of a candidate who provides documentation of an earlier qualifying eGFR value that shows both race-inclusive and race-neutral eGFR values below 20 mL/min. As proposed, the candidate would qualify for a wait time adjustment. Members commented if the

proposal's intent is to fix a disparity due to the use of the race-inclusive variable, the eGFR values should span from above 20 mL/min with a race-inclusive value and below 20 mL/min with a race-neutral value.[1] A member commented this will be a rare scenario for dialysis candidates and expressed concern for the amount of administrative burden this may have and the potential for transplant programs to not review their lists thoroughly due to that burden.

A member commented they have a large list of Black candidates and requiring transplant programs to reach out to reach out to referring nephrologists for prior lab values will be a large lift for program staff. A member recommended transplant programs request patients to acquire their own documentation. The Chair commented partnering with patients is important but it should not be solely the responsibility of the patient.

A member asked if this policy would apply to candidates yet to be listed. The Chair clarified programs are required to use a race-neutral calculation as of July 1, 2022.

A member recommended limiting the scope of qualifying candidates to just pre-dialysis listed candidates as they have established transplant program care. The Vice Chair commented that was part of the original discussion in development of the proposal, but as discussions developed the scope was broadened to have the most impact and benefit for the affected population.

A patient member commented they would propose including both types of candidates in the mandatory policy as in their experience, Black candidates do not receive as much education or access for pre-dialysis listing. The patient member recognized the administrative burden on hospitals but recommended the Committee consider the bigger picture of making a difference for this population.

The Committee was informally polled on whether they would recommend a broader (pre-dialysis and dialysis) or more narrow scope (pre-dialysis). The Committee was split with a slight majority supporting the broader scope.

A member commented in current policy dialysis candidates are able to backdate their waiting time to the start of dialysis, and pre-dialysis candidates cannot backdate their waiting time prior to their listing date. Therefore, the member suggested limiting the scope to pre-dialysis candidates as a "safety net" to be able to backdate waiting time already exists for dialysis candidates.

A member asked for clarification on whether any eGFR below 20 mL/min would qualify for the adjustment or if it must span from above 20 mL/min with a race-inclusive value and below 20 mL/min with a race-neutral value. Staff answered as proposed, the policy language does not specify the eGFR values must span 20 mL/min. Members recommended clarifying in the policy language to define eligible candidates, that the eGFR values should span from above 20 mL/min with a race-inclusive value and below 20 mL/min with a race-neutral value. The Committee felt this language should be clarified to keep with the spirit of the proposal to tie the wait time modification eligibility directly to the use of the race-based variable in the eGFR calculation.

*Timeframe*

A member suggested mandating review of pre-emptive candidates and leaving the review of dialysis candidates as optional. The member further commented a 365 day timeframe may limit the program's thorough review of their candidates and may end up not helping those candidates fully.

Some members commented 365 days may be too long, and a more limited scope should shorten that timeline. The Chair asked if six months would be reasonable if the scope were broader than pre-

[1] Reference OPTN Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older.

emptive. A member suggested having different timeframes for different program sizes. Other members responded the size of the program may not necessarily correlate to the amount of administrative staff available.

A member asked what the timeframe pertains to. Staff clarified that as currently drafted, the timeframe would be specific to the requirements of the program to follow the policy requirements and the patient eligibility for modification does not sunset.

Committee members commented the timeframe recommendation would be dependent on the scope of eligible candidates. The Committee also considered recommending different timeframes for review of pre-emptive vs. dialysis candidates. A member commented shortening the timeframe would help these candidates sooner. Members also commented a timeframe of one year may be a better timeframe since the resources of the programs and their volume of candidates are unknown. Members felt the 365 day time frame would give more flexibility for the program to complete their review.

Recognizing transplant programs may have difficulty locating the required documentation for all of their eligible candidates, members also recommended monitoring data on related wait time adjustments after the policy is implemented to determine impact of the policy. Upon review of this data, members suggested the Committee could pursue a subsequent project to further address other potentially affected candidates.

*Patient Notification*

A member commented transplant programs should be responsible for notifying patients of the policy, but patients should provide the relevant documentation to the programs to apply for wait time modification as they have more direct relationships with their prior medical teams. A patient member asked if dialysis facilities would be required to provide documentation. A member commented the transplant system does not have oversight over dialysis facilities, and the information required would be from before a candidate was put on dialysis. The patient member commented candidates may not know how to locate this documentation or where to find it. A member responded transplant programs could help guide candidates.

The Committee discussed whether pre-eGFR modification eligibility patient notification should be required. The Committee supported requiring pre-eGFR modification eligibility patient notification for those candidates registered as Black or African American. The Committee also supported the patient notification including detail of the policy and what the program is required to do. Some members also supported programs include language to encourage patients to locate their lab documentation. Committee members also suggested providing recommendations and best practices for language to include through education.

Some members commented there should also be a post-review notification to the reviewed candidates letting them know the results of the review. Other members commented requiring a second notification would increase the administrative burden on programs.

<u>Next steps:</u>

The Minority Affairs Committee will be discussing the public comment feedback and post-public comment changes on October 17. The Kidney Committee will continue their discussions and finalize recommendations on October 24. The *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* recommendations will be presented to the Board of Directors in December.

**4. Review of Public Comment Feedback for Kidney-Pancreas Continuous Distribution and One-Year Monitoring Report Committee Updates**

Staff gave a presentation on feedback received during Public Comment on the *Kidney-Pancreas Continuous Distribution* paper and regional meeting feedback on the *Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report* Committee updates.

Presentation summary:

The continuous distribution update received 32 public comments from individuals, committees, regions, and other stakeholders. Commenters expressed overall support for the continuous distribution project. Additional comments were organized into the following themes:

AHP Values Prioritization Exercise

- Concerns regarding participation in exercise; results in underrepresentation of certain groups
- Flaw of value-based exercise is the assumption these are all high quality kidneys

Modeling

- Support on modeling efforts; more data analysis/modeling are needed to address this complex topic
- Consideration for pediatric and sensitized candidates
- Support for increased weight on placement efficiency and logistics for high KDPI kidneys
- Support and suggest use of predictive analytics, based on historical data, to match place organs more efficiently

Medical Urgency

- Current definition is subjective
- Consider setting an upper limit of expected Medical Urgency candidates a year (ex. 0.5 percent or less of waiting list); evaluate programs that list more than the limit set
- Post-transplant survival
- Consideration for an allocation policy that is focused not just on waitlist mortality but also on long-term post-transplant outcomes
- Consider graft survival well beyond year 1 in addition to raw transplant numbers, rates, and waitlist mortality

HLA Matching

- Opposition to a model where DR matching is attributed more percentage points than CPRA
- Reconsideration for DR antigen mismatches in CD
- DR matching should be encouraged (as long as it does not limit access to minority populations)
- Longevity Matching (KDPI and EPTS)
- Consideration to using a gradient for KDPI and not a hard cutoff at 85 percent
- Support for continuous longevity matching approach
- Agreement in giving pediatric candidates low KDPI kidneys (ex. current pediatric priority)
- Blood Type and CPRA
- The CPRA scale should be created to allow equal access, but not more rapid access for sensitized patients
- Support for proposed point system for ABO; Suggestion to intermix A and B candidates for A donor kidneys

Pediatric Candidates

- Support for prioritization of pediatric candidates based on their age and time of registration
- Support for inclusion of pediatric donor kidneys with a KDPI 35-85 percent for pediatric candidates
- Consider how EPTS will be incorporated for longevity matching (this has not been applied to children before)
- Interest in interaction between kidney-pancreas and kidney allocation and how it may impact pediatric access

Prior Living Donor Priority

- Support for providing prior living donors priority to all living donors
- Concern that prior living donors may not see the same priority in continuous distribution

Safety Net

- Support for safety net patient access to top 20 percent KDPI for candidates with EPTS top 20 percent

Waiting Time

- Support for waiting time rating scale being kept linear
- Support for keeping non-dialysis waiting time accumulation

Dual, En Bloc, and Marginal Kidneys

- Consider standardization around hard to place kidneys
- Pediatric en bloc kidneys/pancreas transplant should occur as they have in the past
- Hard to place, dual, and en bloc kidneys should be allocated in a way to decrease CIT

Placement Efficiency

- Consider additional metrics for placement efficiency (Ex. estimated cold ischemic time (CIT), population density, use of pumps, etc.)
- Consider geographic disparities and rural programs
- Support for proposed proximity efficiency rating scale for kidney
- Need for more system tools and resources
- Ex. offer filters, predictive analytics, etc.

Other Comments

- Support for the development of review boards

Additionally, regional meeting attendees provided the following feedback on the *Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report*:

- Satisfaction in the improvement among minorities and CPRA candidates
- Various factors could be attributed to increase in transplants outside of the policy change
- Concern for discard rate; should be a top priority in continuous distribution project
- Consider collecting more granular data on discards
- There should be better understanding of the circles policy and the effects on transplant rates, discards, and logistics before continuous distribution is implemented
- Any lessons learned from the circles policy should be considered and incorporated in development of continuous distribution

<u>Summary of discussion:</u>

There were no questions or comments.

Next Steps:

The Committee will revisit and continue to consider public comments in developing the continuous distribution proposal.

## 5. Massachusetts Institute of Technology (MIT) Modeling Trade Off Curve Presentation

The Committee received a presentation from MIT representatives on their modeling efforts.

Presentation summary:

The main purpose of this analysis is to use mathematical optimization and artificial intelligence to inform continuous distribution policy development. Previously, MIT has published research on optimizing both Kidney (2013) and Liver allocation (2019). The OPTN Lung Transplantation Committee also collaborated with MIT to apply this methodology in the development of Lung Continuous Distribution. This presentation introduced the methodology at a high level and provided some interim results for Kidney continuous distribution.

This analysis's main goal is to help the Committee hone-in on attribute weights in developing the next KPSAM modeling request. Discussions today will focus on analysis related to pediatric weight and proximity weight. MIT also seeks feedback on what additional results could be useful.

At a high-level, this methodology involves augmenting KPSAM with artificial intelligence in order to quickly and accurately predict outcomes. Instead of specifying certain weights to predict outcomes, this tool allows the Committee to shift focus by utilizing the desired outcomes to determine the most effective weights to achieve those outcomes. This is possible through "instantaneous" predictions, which can efficiently search through potential policy options. Tweaking the desired outcomes allows for tradeoff analysis:

- For example: transport distance and broad distribution versus access. As access increases and disparities decreases, transportation distances also increase

Example Scenario:

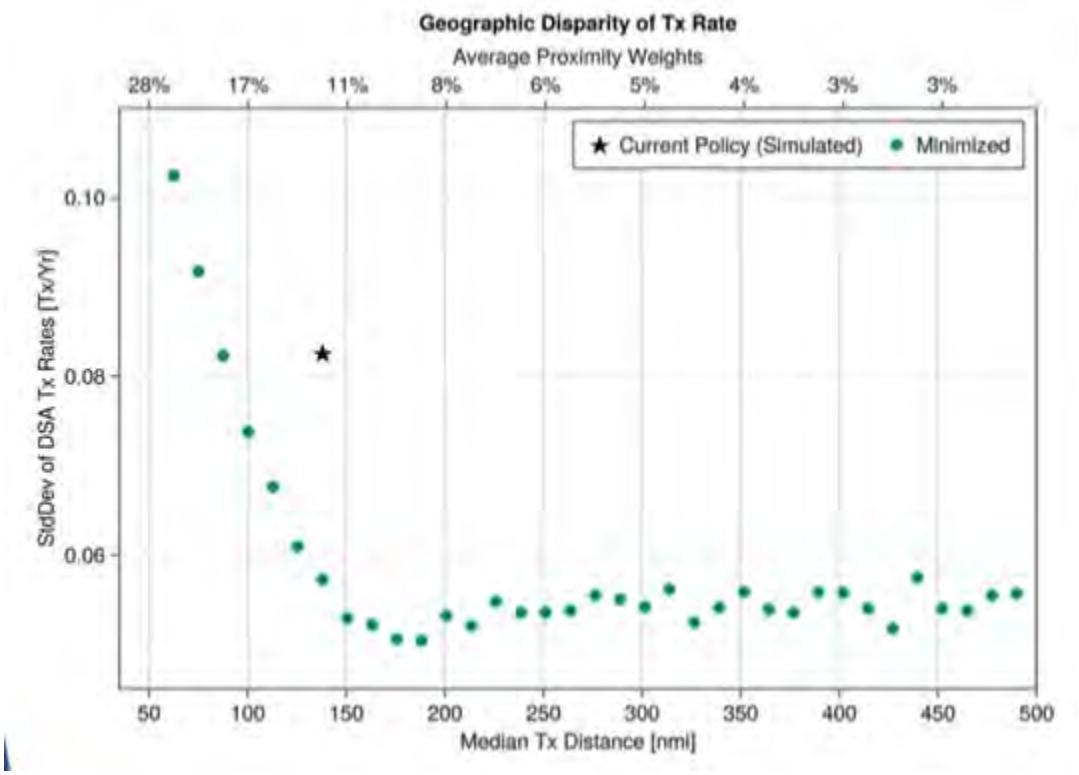
- Begin with an objective: minimizing or maximizing an outcome → minimize geographic transplant rate disparity
- Specify constraints on other outcomes relative to current policy → no loss of placement efficiency, no increase in transplant rate disparities by blood type, no decrease in transplant rate, and no increase in waitlist mortality
- Optimization will consider the objective and constraints, and provide a set of recommended weights (known as policies) to achieve these outcomes
    - These policies can be fed back through KPSAM to confirm that this policy achieves what we set out to achieve

This process can generate tradeoff curves to understand how geographic disparities trade off with placement efficiency

- Disclaimers:
    - Using KPSAM 2019, with the same 2017 cohort of patients
    - Small population weights (medically urgent, kidney after liver safety net, and prior living donor) are being held constant
- Charted on a graph:
    - Y axis – metric of transplant rate disparity across donor service areas (DSA)

    - X axis – plotting the median transport distance that different policies result in, and their related proximity weight
- Current simulated policy achieves roughly a median transplant distance of 150 nautical miles (NM) and a standard deviation of 0.08 in terms of transplant rate disparity across DSAs
- Example simulated policy, designed to minimize geographic transplant rate disparity: reduced transplant rate disparity by about 20 percent (0.06), with no increase to transport distance
- Trade off curve: what if you were willing to allow distance to increase, or wish to further reduce transport distance? What impact does that have on geographic disparity?
    - See **Figure 1** for several potential policy options, which hold other constraints constant (no increase in waitlist mortality, etc.)

**Figure 1: Geographic Disparity in Transplant Rate by Median Transplant Distance**




You can see an inflection point at a distance of 150 NM, with a proximity weight of about 10 to 15 percent. This analysis shows that a weight greater than 15 percent will result in increased disparities geographically. **Figure 1** only shows the proximity weight. **Figure 2** illustrates the range of outcomes as other weights are also manipulated.

**Figure 2: Range of Geographic Disparity in Transplant Rate by Median Transplant Distance**

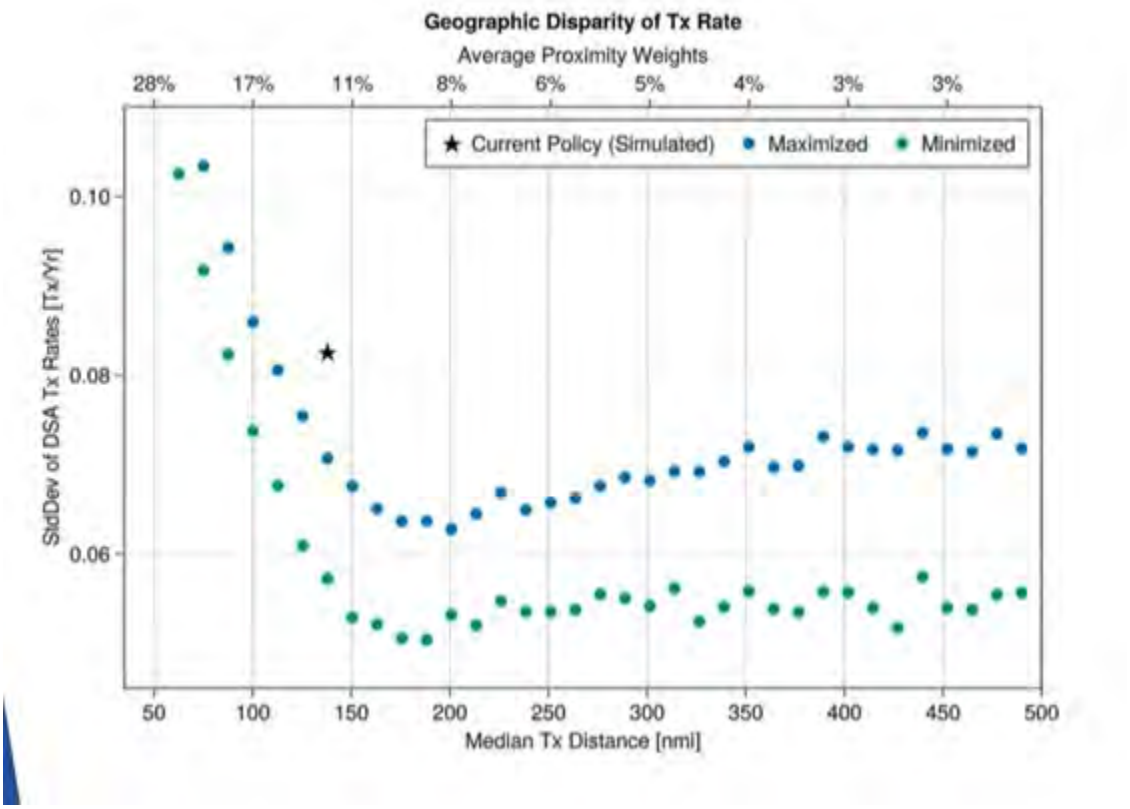



**Figure 2** shows that if a proximity weight of roughly 10 percent is chosen, this analysis suggests that the standard deviation of transplant rates across DSAs will vary between 0.05 and 0.07, depending on the other weights chosen. **Figure 2** shows that a proximity weight of less than 10 percent provides a sense of possibilities for the disparity across DSAs.

Summary of discussion:

One member noted that both policies use the same median transportation distance, but there is a large difference in geographic disparity. What did you use to reduce the score? An MIT representative explained that the current policy does not use the continuous distribution framework, and that the continuous distribution framework itself is more powerful with more degrees of freedom that allows certain outcomes to be achieved. The MIT representative continued that the gains occur across all fronts because the continuous distribution framework allows a greater degree of freedom and flexibility. The MIT representative noted that optimization is a sophisticated tool, and can search the policy space to pick the combination of weights to minimize disparities.

The Chair summarized the presentation, noting that each dot represents a different policy, and that this model allows the Committee to see the benefits and consequences of increasing certain weights, including where the benefits stabilize. The Chair continued that **Figure 2** allows the Committee to see the way that other aspects of the policy or other attribute weights may impact these outcomes. The representative from MIT agreed, noting that **Figure 2** can give the potential range of outcomes as well.

One member noted that in an ideal world, the policy would be right at zero. Staff agreed, noting that these models also show that the ideal world is impossible, but that the system can be optimized to

minimize disparities and minimize shipping kidneys. Staff continued that this will allow the Committee to have further conversations about potential trade-offs involved with other weights.

One member pointed out that the minimum and maximum trade off curves seem to parallel each other, and asked if it was expected that the curves would come out to the same inflection point. The MIT representative explained that this was not necessarily expected, and does not always occur. The MIT representative continued that continuous distribution is a complex policy with each attribute acting as a "dial". Each of these "dials" can be tweaked and alter the outcomes.

A member remarked on the idea of working backwards from desired outcomes, and asked if the Committee could define some ideals, such as reducing discrepancies, increase graft longevity, and then maximize five or six main goals. The MIT representative agreed that this was possible, noting that one reasonable constraint for the example presented is that the standard deviation of transplant rates across geography should not be more than 0.07. The analysis allows that number to be quantified. Utilizing these constraints, the system will produce a set of weights to produce the outcomes desired.

An SRTR representative asked if, in this example, the constraint was on median distance or that the proximity weight was what was on the top panel. The MIT representative explained that the constraint is on distance in the example plot, and the top of the graph shows the average weight to achieve that distance.

One member noted that their region has provided a lot of feedback on linear distance not necessarily accounting for all transportation efficiency, as some airports may be more accessible and better traveled than others, etc. The member asked if this model can account for a more complex measure of transportation efficiency. The MIT representative explained that this analysis does not account for this, but that previous analyses have included robustness checks and metrics for percentage of organs flown. The MIT representative explained that, in those analyses, the inflection point of the curve was roughly the same. The member explained that lungs typically are transported via private jets, while kidneys are transported via commercial airline, meaning that raw distance may not match up as well with these deviations.

Another member asked if there was any kind of data built from calculating potential routes between all potential donor hospitals and all transplant centers. Staff explained that this is not available, and that there was an outside analysis done for Liver transportation that Lung was able to adapt and utilize in building their placement efficiency considerations. Staff noted that Kidneys travel differently, and that an algorithm for that at this point is not available.

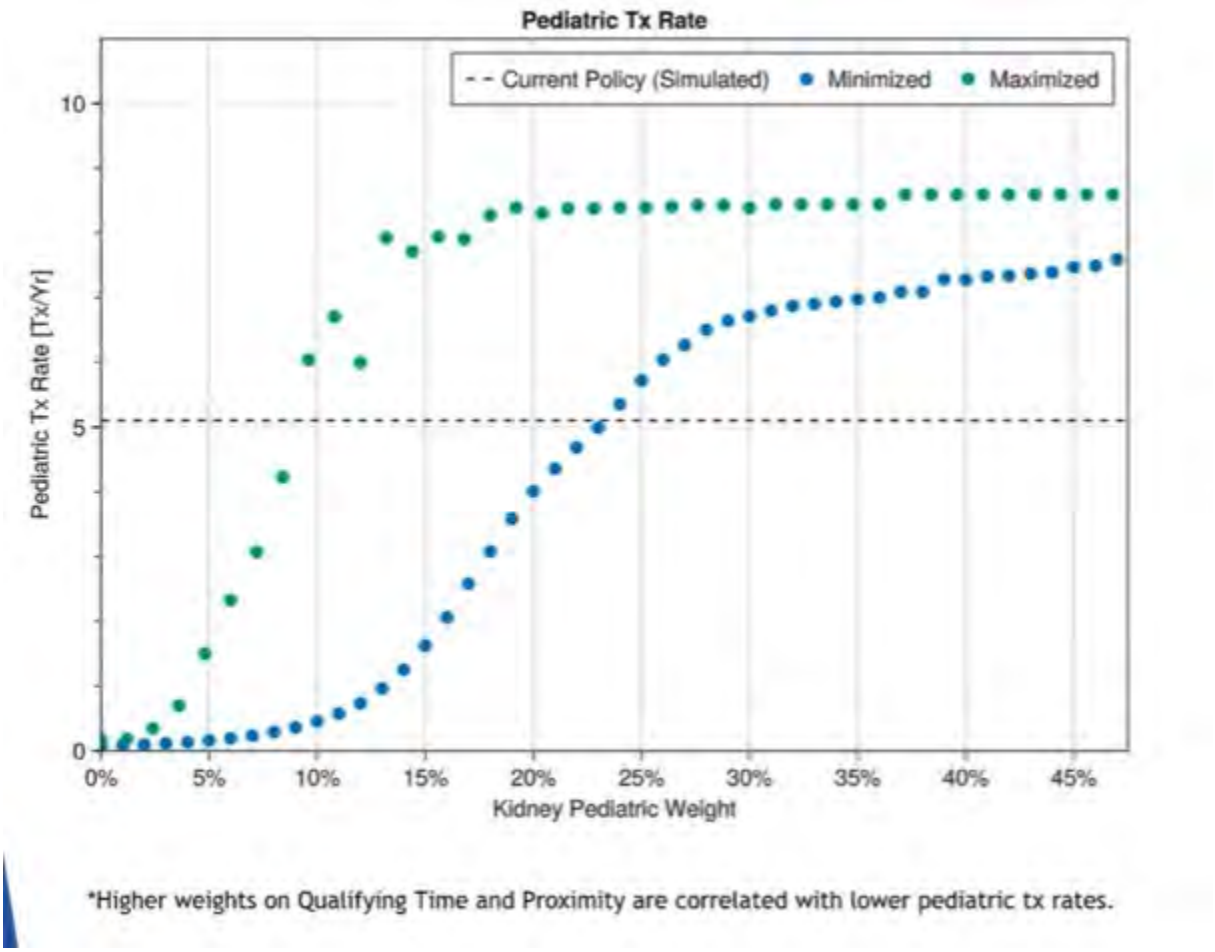
The Vice Chair pointed out that roughly 250 NM was distance at which it would be typically flown or driven. Staff agreed, sharing that the Committee spent some time discussing at what distance a kidney is likely to be flown versus the distance a kidney is definitely going to be flown. At that time, the Committee noted that this will vary based on where in the country the center is, the time of day, whether or not it's a weekend, weather, and the cargo hours at nearby airports. Staff continued that the Committee ultimately determined a simpler model is more appropriate.

The MIT representative explained that the analysis done by MIT measured proximity efficiency through median transplant distance, but that they would be glad to hear other suggestions to further analyze this trade off.

<u>Presentation summary:</u>

Pediatric Weight Selection – instead of looking at a tradeoff between two outcomes, **Figure 3** looks at that impact of choosing a certain percentage.

**Figure 3: Pediatric Transplant Rate**




Current policy is shown using the horizontal line, which represents the current policy's pediatric transplant rate, according to the simulator. This is a reference point.

The minimized curve is made of dots, each of which represents a minimized policy corresponding to one of these percentages. So if there is 20 percent pediatric weight, all of the other weights are selected in such a way that it minimizes the pediatric transplant weight. This shows that, no matter what weight you select for the other attributes, the pediatric transplant rate will be above that. This allows for a robust policy. Looking at the 20 percent, you are guaranteed that no matter what happens with the other weights, the simulator does not predict a pediatric transplant rate of less than four.

The maximized curve makes the assumption that other weights are selected to maximize the pediatric transplant rate as much as possible. On this curve, around the 24 percent pediatric weight, you are basically guaranteed to have a higher transplant rate predicted by the simulator, no matter the weights chosen for other attributes.

**Figure 3** shows that the number of pediatric transplants could be nearly doubled, according to the simulator.

Summary of discussion:

The Chair pointed out that **Figure 3** shows an example where the minimized curve presents a very steep incline early on, whereas the maximized curve is a steady slope up. The Chair continued that there is a

bigger difference between the two, as compared to **Figure 2** where they were mirrored in shape and only slightly separate. The Chair asked why one would be tight and parallel while others would be disparate. The MIT representative noted that this is difficult to answer, because there are a lot of factors in play. The MIT representative continued that changing the other weights, such as the proximity weight, will change the outcomes for pediatric candidates.

One member noted that, at a given weight, the curves narrow, and so despite optimizing other factors, the new policy would not disadvantage children in a large way. An MIT representative noted that this is similar to **Figure 2**, where there was a possible range of outcomes when thinking about a particular way. The MIT representative explained that, between 10 and 15 percent pediatric weight, this analysis shows that highest pediatric transplant rates can be achieved *if the other weights are chosen to maximize pediatric access*. The MIT representative explained that **Figure 3** shows that a high pediatric transplant rate can be achieved by a weight of at least 10 percent if other weights are chosen appropriately, or else by choosing a high weight, such as 30 or 35 percent, at which point the emphasis is so high that the other weights do not matter. The MIT representative noted that **Figure 3** also shows that pediatric weight is not the only factor impacting pediatric access – other weights matter. The MIT representative continued that, for **Figure 2,** the proximity efficiency weight was the main impact on transplant rates across DSAs. **Figure 3** suggests, however, that other factors are at play, such as proximity.

One member noted that these graphs are single factor, and asked if there is a visual way to show the opportunity costs of making different changes on pediatric transplant rate, to give a sense of what is being balanced. The member also asked if there is a way to put caps on the lowest or highest of other weights. The MIT representative explained that a baseline can be established and graphs built to communicate these tradeoffs. The member explained that the distance applies to all cases, but since pediatric populations are so small, little will change, while proximity and distance affects all kidneys. The MIT representative explained that the more constraints are applied, the tighter the curves will be, because there is less room to maneuver and less flexibility with other outcomes.

Another MIT representative noted that the small populations are why prior living donor, kidney after liver safety net, and other populations were held constant, because changing those weights won't have a significant impact on the rest of the outcomes. The MIT representative explained that it is helpful to limit the number of factors fluctuating and being evaluated at once.

<u>Presentation summary:</u>

**Figure 4** shows disparity in active wait time for transplant, with standard deviation across DSA on the Y axis and median transplant distance on the X access. This shows a similar curve to **Figure 2**, where increased median transplant distance will potentially reduce disparities.

**Figure 4: Geographic Disparity of Active Wait Time Per Transplant**

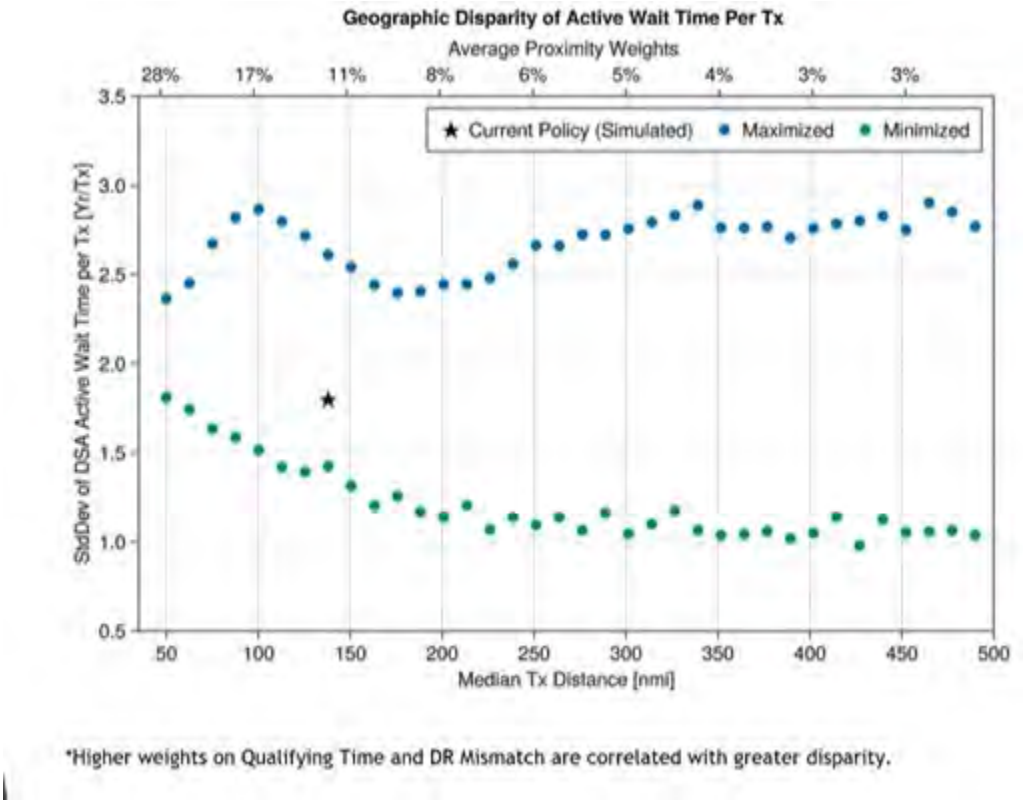



**Figure 4** shows maximized and minimized curves that are not parallel, however. The maximized curve shows that this can still result in worsened geographic disparities. Certain metrics are more complicated than others. Percentages alone may not be sufficient. The star represents the current policy.

The MIT team also developed a preliminary interactive tool where specific outcomes and weights are selected, and the impact evaluated. The tool is still in development and not yet fully functional. Eventually, users will be able to select their X axis and their Y axis to try to determine potential impact and the best weights.

Summary of discussion:

One member expressed excitement about the tool, and noted that it seems that median transplant distance remains a tight and cohesive band, no matter the weights on other attributes. An MIT representative explained that the example tool mirrors **Figure 2**, just including a great variety of points that were not filtered. The MIT representative explained that, per **Figure 2**, as proximity weight changes, the standard deviation of transplant disparities across DSAs doesn't vary by much. The curves were parallel and near, meaning that proximity weight is a key driver of the disparity, as indicated by the narrow band.

The Chair explained that in current policy, the vast majority of kidneys are allocated within 250 NM. The Chair asked if it was possible to show that proximity weight can be tweaked such that kidneys do not travel as far, because they may not need to go out to 250. The Chair noted that the example tool shows that the curve flattens well before 250 NM, and the Committee may be able to determine that the

benefit of broader sharing is achievable with kidneys traveling more within a 180 nautical mile radius. The MIT representative noted that this potentially is possible, but that there are other outcomes that may be affected, not just disparities. The MIT representative noted that potentially, you could show that these organs may not need to travel quite as far. Staff explained that the Lung Committee saw this in their modeling. Staff continued that continuous distribution does not necessarily mean broader distribution, but instead means smarter distribution. In Lung Continuous Distribution, more medically urgent patients would have a bigger circle, while less urgent patients would have more localized distribution. Staff continued that this could happen for kidney – highly sensitized patients may have a larger circle, while patients with less waiting time and low sensitization may have a smaller, more localized allocation circle.

The Chair noted that there has been criticism that continuous distribution will increase the travel distance further, and that the response is not to change how kidneys are allocated, just to transition, but this modeling shows that the continuous distribution system may be much smarter.

An SRTR representative emphasized that it is critical that the Committee determine what metrics of disparity they want to use. If the metric of disparity is a standard deviation of transplant rates by geography, it will look like a very different curve than if you used difference in wait times by geography. The SRTR representative noted that one curve will be much wider with a larger range and more scatter, because those metrics are very different. The SRTR representative continued that the Committee can constrain the policy optimizer to say that pediatric transplant rates should not decrease, distances generally should not increase beyond current travel, and there should be no increase in geography disparity. The MIT group can use these constraints to narrow the policy scatter and model more effectively. An MIT representative added that this may also hold true for proximity efficiency, in that median transplant distance may not be the only metric of proximity efficiency.

One MIT representative noted that the policy optimizer will vary the percentages applied to the predefined rating scales. The MIT representative continued that altering the rating scales could also alter the outcomes. The MIT representative explained that proximity efficiency is based on a piecewise linear rating scale based on distance; if instead the proximity was based on ischemic time, this would alter the outcomes of the model. The MIT representative noted that this would likely be harder to design.

Presentation summary:

MIT representatives showed a draft “Policy Analyzer” tool, which showed the weights and histograms of how well the 50,000 policies perform for each metric. These metrics include transplant rate, median transplant distance, post-transplant years, pediatric transplant rate, waitlist deaths, and graft failures. The histograms show a curve of how well the 50,000 randomly generated policies perform. For post-transplant years, you can see, if randomly generating a policy, the average would be somewhere near the peak. Each histogram has a different looking curve. The histograms on the rate also show transplant disparities, including blood type, CPRA, geographic disparities, sex, race, and ethnicity.

Summary of discussion:

One member asked if the draft tool showed the current policy. The MIT representative responded that the policy shown is the second model run that the SRTR was asked to simulate. Another MIT representative explained that the Policy Analyzer tool can be used to predict how easily a particular policy would do. A user can change the weights and see the impact across outcomes. The MIT representative commented the tool is still in development, but that the idea is that this tool would allow each policy to be quickly analyzed. Given certain weights, one could see the performance of a particular policy relative to several outcomes at once.

Staff added that this tool will be extremely helpful, particularly showing the impact of altering the weights on other inputs and outputs. One member asked if this tool will be available for public use. The MIT representative shared that this tool will be publically available once it is fully developed.

The Chair asked if the SRTR had an estimate as to when the MIT group will have access to the post-circle policy data, noting that this tool is based on older data. An MIT representative explained that this tool utilizes the 2017 cohort, and the acceptance model and outcome models were from the 2019 KPSAM. The MIT representative noted that there has not yet been talk of updating this. The Chair pointed out that acceptance patterns have changed, and asked when that would be updated by the SRTR. An SRTR representative explained that the simulation request currently underway utilizes an updated model and updated cohort, and once complete, will be shared with the MIT team. An MIT representative explained that there are a lot of steps required before the SRTR can fully share the data with the MIT team, and that once this data is shared, the MIT team can perform the analysis. The MIT team added that there may also be clearance involved in what data can be shared with the Policy Analyzer and policy evaluation tools. The MIT representative noted that the aggregate level data should be okay, and that appropriate dissemination is currently being planned.

An MIT representative reiterated that the goal of this discussion is to familiarize the Committee with what the MIT group is capable of analyzing and upcoming tools, and invite the Committee to request analyses that may be useful.

One member noted that these tools and analyses make the complex system much more understandable. The member noted that there were big asks in what measure of disparity the Committee wants to use and whether there were any other factors that should be considered.

The Chair noted that discard rates are not included because it is too complex a measure to predict, but that distance travel is an imperfect proxy for discard rate in that the longer a kidney travels, the less likely it is to be used. The Chair explained that many community members ask how the new system will address the discard rate, and that this is challenging to answer.

A member suggested that waiting time could be used as a driving factor, noting that waiting time could act as a proxy for many other factors. If discard rates increase, so will waiting time, and if waiting time is minimized, one would assume that the rest of the factors are playing a role. The member noted that how quickly a patient can get transplanted is what really matters, and that might be the safest guiding principle. The Vice Chair agreed, noting that waiting time is the biggest factor of disparity. The member noted that geographic disparity is based on how long people are waiting. Another member commented that patients really care about how quickly they can be transplanted and their life expectancy. The Vice Chair added that the Committee is trying to reduce the disparity around waiting time, and that is the ultimate goal.

One member noted that age disparities are not included here. The member recalled the LYFT proposal, including concerns regarding age disparities. The member asked if there was a reason that age disparities weren't included in the Policy Analyzer. An MIT representative explained that their group has not yet made a deliberate choice with regards to excluding or including certain metrics, and that age disparity could easily be analyzed. Another MIT representative explained that pediatric and adult disparities are included so far.

An MIT representative pointed out that one analysis could examine the percentage of high EPTS patients that receive low KDPI organs, and how age disparities are impacted that way. A member agreed that is a good secondary outcome to examine. The member shared that it does happen that older, less healthy patients end up receiving very young and healthy organs that may have better utilization in younger patients. The member expressed support for a move towards more continuous longevity matching. The

member asked if appropriate matching and reduced age disparity via KDPI and EPTS matching could be a secondary goal or constraint.

One member expressed concern that 99.9 percent CPRA patients currently have distinct allocation classifications and related priority that separate them from the rest of the population. The member explained that these classifications will not exist in continuous distribution, and shared that CPRA needs to be weighted in such a way that those patients still receive high priority regardless of other considerations. The member asked if something like that could be included in the analysis, where the goal is to ensure these high CPRA patients have appropriate access to the one or few organs that they will ever receive an offer for. The MIT representative explained that the pediatric case is an example of group for whom boosted access is the goal. The MIT representative continued that this same concept would be applied in trying model boosted access for high CPRA candidates and medically urgent candidates. The MIT representative noted that CPRA is a little different because the goal is to level the playing field between candidates of all CPRAs, such that patients across the range of CPRA values all have the same access. The MIT representative continued that this would be a disparity versus a priority.

One member disagreed, noting that the goal is to provide more access to highly sensitized patients, so that higher CPRA patients have increased priority. The MIT representative explained that the concept is the high CPRA patients are given enough of a boost in points so that the effect is that they have an equal chance of being given a kidney. Other members agreed. One member explained that the goal would be, whether you have 0 percent CPRA or 100 percent CPRA, you have a good a chance of receiving an organ offer. The member continued that the 99.9 or 99.5 percent CPRA aren't being specifically targeted – instead all candidates, regardless of their CPRA, have a chance at receiving an organ. Another member confirmed that the highest priority should still be given to the highest CPRA candidates. Staff clarified that the highest CPRA patients would receive more points for the CPRA attribute than a patient with a lower CPRA due to their decreased access overall, such that the transplant rate becomes similar across CPRA.

Next Steps:

The Kidney and Pancreas Committees will continue review of MIT results along with the KPSAM modeling results once available. The Committee will continue to identify important metrics to include as part of MIT mathematical optimization.

**Upcoming Meetings**

- October 24, 2022 - Teleconference

**Attendance**

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Beatrice Concepcion
  - Jesse Cox
  - Patrick Gee
  - Precious McCowan
  - Sanjeev Akkina
  - Stephen Almond
  - Asif Sharfuddin
  - Chandrasekar Santhanakrishnan
  - Jason Rolls
  - Marian Charlton
  - Marilee Clites
  - Arpita Basu
  - Caroline Jadlowiec
  - Kristen Adams
  - Elliot Grodstein
  - Peter Lalli
  - Tania Houle
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Grace Lyden
  - Ajay Israni
  - Bryn Thompson
  - Jonathan Miller
  - Caitlin Nystedt
  - Jon Snyder
  - Nick Wood
  - Ryo Hirose
  - Ryan Follmer
- **UNOS Staff**
  - Lindsay Larkin
  - Sarah Booker
  - Kim Uccellini
  - James Alcorn
  - Carson Yost
  - Joann White
  - Kelley Poff
  - Kieran McMahon
  - Ross Walton
  - Krissy Laurie
  - Lauren Motley
  - Rebecca Murdock

    - Roger Brown
    - Ruthanne Leishman
    - Sara Moriarty
    - Susan Tlusty
    - Tamika Qualls
    - Thomas Dolan
    - Tina Rhoades
- Other
    - Elijah Pivo
    - Nikos Trichakis