OPTN Kidney Transplantation Committee
Meeting Summary
January 27, 2023
Houston, TX

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

Introduction

The Kidney Transplantation Committee (the Committee) met in Houston, TX on 1/27/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Continuous Distribution Discussion: Recap
3. Continuous Distribution Discussion: Optimized Scenarios and Breakout Groups
4. Public Comment Presentation: Expand Required SLK Allocation
5. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation
6. Open Forum

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. Continuous Distribution Discussion: Recap

Staff presented a summary of the goals of the Continuous Distribution project and a recap of the Committee's discussions so far.

Presentation summary:

The goal of the Kidney Committee is to transition the current classification system into a continuous distribution framework system. For those recommendations that are not aligned with current policy, the Committee is asked to provide strong justification and rationale. The first iteration of Continuous Distribution is meant to incorporate current policy requirements with minimal changes. Items that may require new or additional policy considerations, or substantial changes that would require additional review and modifications to current policy would be included in future iterations of the project.

The Committee was encouraged to consider utility, equity, transparency, and autonomy as guiding principles when considering the new framework. These principles are informed by the OPTN Ethics Committee's 2021 paper "Ethical Considerations of Continuous Distribution in Organ Allocation".[1]

[1] OPTN Ethics Committee, "Ethical Considerations of Continuous Distribution in Organ Allocation," 2021 https://optn.transplant.hrsa.gov/media/mjzfpb3h/ethical-considerations-of-continuous-distribution-in-organ-allocation_whitepaper.pdf

The Committee also reviewed the attributes, rating scales, and weights included in the first Organ Allocation Simulator (OASIM) request, and key takeaways from the report.

- Expanding and increasing weight on longevity matching showed:
    - Lower transplant rates in 35-50 year old candidates
    - Post-transplant graft failure rates lower in 18-34 and 35-49 year olds at one and ten years
    - Increased graft failure rates in older kidney recipients
- Median travel distance increased in all scenarios
    - Increasing proximity efficiency weight does reduce this, but also reduces transplant rate for CPRA greater than 98 percent
    - Increasing the donor modifier for high KDPI kidneys reduces the median travel distance for those kidneys
    - Pediatric candidates saw largest increase in median distance, likely due to pediatric priority weight
- Transplant rates
    - Lower for Black candidates and those on dialysis five or more years in scenarios where less weight was placed on qualifying time
    - Varied by OPTN region
    - Decreased for highly sensitized in scenarios where less weight was placed on calculated panel reactive antibody (CPRA) attribute

The Committee also reviewed a summary of the Committee's discussions thus far.

- Concern for increased travel distance
    - Especially for pediatric candidates in longevity matching scenario
    - Kidney Committee consensus: no more than 50 percent of Kidneys should go more than 500 nautical miles (NM)
- CPRA
    - CPRA groups should have equal access, and there should be priority for highest sensitized
- Longevity Matching
    - Should not decrease transplant rate for estimated post-transplant survival score (EPTS) 0-20 candidates
    - Concern for middle EPTS ranges; There should be similar transplant rates across EPTS's
    - EPTS and the Kidney Donor Profile Index (KDPI) need to be revisited (future project)

Summary of discussion:

There were no questions or comments.

3. Continuous Distribution Discussion: Optimized Scenarios and Breakout Groups

The Committee was provided with three optimized policy scenarios to review in breakout groups. The breakout groups then reported out on their discussions and staff summarized key points.

Presentation summary:

The Committee was provided with three mathematically optimized policy scenarios to include:

- Scenario One - "No worse" scenario: This scenario was optimized to do "no worse" than current policy across waitlist mortality, graft failure, pediatric transplant rate, geographic disparity, blood type disparity, CPRA disparity, racial disparity, and travel distance.

- Scenario Two - MIT optimized scenario: This scenario was optimized to give primary priority for waitlist mortality, graft failure, pediatric transplant rate, geographic disparity, blood type disparity, CPRA disparity, racial disparity. This scenario also relaxes the constraint on travel distance.
- Scenario Three - Optimized for distance: This scenario was optimized to give primary priority for travel distance and secondary priority for waitlist mortality, graft failure, pediatric transplant rate, geographic disparity, racial disparity and blood type disparity. Additionally, CPRA disparity was constrained to be "no worse" than current policy.

Staff also oriented the Committee to the various metrics included with the scenarios and how those are defined:

- Waitlist mortality rate: Calculated as the number of deaths on the waiting list divided by the total amount of time on the waiting list (active or inactive) within the simulation period.
- Graft failure count: Calculated as the number of graft failures within a year after transplant.
- Active transplant rate: Calculated as the number of transplants divided by the total amount of time on the waiting list in active status for registrations ever waiting during the simulation period.
- Listed transplant rate: Calculated as the number of transplants divided by the total amount of time on the waiting list (active plus inactive) within the simulation period.
- Qualifying transplant rate: Calculated as the number of transplants within the simulation period divided by the total amount of qualifying time (including dialysis time) for patients who were ever waiting during the simulation period.
- Median distance: The median distance (in nautical miles) from the transplant hospital to donor hospital for all recipients transplanted within the simulation period.
- Distance 25th percentile: The 25th percentile of the distribution of distance between transplant hospital and donor hospital for all transplants performed in the simulation period. 25 percent of all transplants will occur within this distance.
- Distance 75th percentile: The 75th percentile of the distribution of distance between transplant hospital and donor hospital for all transplants performed in the simulation period. 75 percent of all transplants will occur within this distance.
- Qualifying time at transplant: The total qualifying time (includes dialysis time) for all candidates who received a transplant.
- Average qualifying time at transplant: The average qualifying time for all candidates who received a transplant.
- Median qualifying time at transplant: The median qualifying time for all candidates who received a transplant.
- Transplant rate disparity: The highest transplant rate minus the lowest transplant rate over several groups of candidates. For example, the ABO transplant rate disparity is the highest minus lowest transplant rate between blood type A, B, O, and AB candidates.
- Geographic disparity: Because there are so many groups to compare, we use the average difference in transplant rate between geographic regions rather than just the highest minus lowest.
- Median KDPI: Median KDPI of donor kidneys transplanted within the study period.

Committee members were asked to split into groups and discuss the three policy scenarios. For each scenario, Committee members were encouraged to consider the following questions as well as any other observations:

- Will the policy increase travel distance? If so, is the increase tolerable?
- Does the policy increase any disparities (sex, ethnicity, race, geographic, blood type)?
- Does the policy maintain appropriate pediatric priority?
- How far are organs traveling to pediatric candidates? Is this tolerable?
- How does the policy affect access for the highest sensitized? Is this change tolerable?
- Does the policy take into account the utility of the system?

Summary of discussion:

The Committee reconvened to discuss takeaways from their breakout group discussions on each scenario.

Group One → Scenario One – "No Worse" Scenario Feedback and Key Takeaways:

Overall, the group thought the outcomes presented in this scenario were favorable. Group members commented the scenario gives priority as a whole to all patients with respect to proximity, but there may be benefit for subgroups in terms of weights. Group members commented there should be emphasis on proximity, but that this could possibly be relaxed for highest sensitized.

Members commented in reviewing data, having an absolute number reference for volume would be helpful in decision making. Looking at fairness in access for highly sensitized, there are nuances in the 98 to 100 ranges, and it would be worthwhile to break that down further into more granular categories. Members asked if adjusting the steepness of the CPRA rating scale would impact this. Staff responded that is another parameter that could be optimized. Staff also clarified the scenarios depicted use one year's worth of patient data to create the simulations.

One member commented that access to transplant should be evenly distributed across CPRA groups, which would require that the highest sensitized candidates have high priority and appropriate access to the very rare donor kidney they are able to match with. The member further commented adding more weight to CPRA or increasing the steepness of the rating scale curve may not be able to address this. Another member agreed candidates of all CPRA levels should have similar access, and noted that the highest sensitized would be difficult to mathematically describe because they are so rarely able to match with an appropriate donor kidney. Members also commented the new CPRA calculator was just implemented the day before and its effects are yet to be known, but that this calculator is expected to be more accurate in predicting and representing a patient's likelihood to find a medically suitable HLA-match in the general donor population.

Group Two → Scenario Two – MIT Optimized Scenario Feedback and Key Takeaways:

Group members commented the Committee should develop the best scenario possible for the first iteration of project with the awareness that the system can be further refined. Group members commented it will be important to remind the community continuous distribution will be an ongoing effort.

Overall, the group thought the scenario addressed equity fairly well. The group commented the scenario equalizes access to transplant across CPRA groups better than current policy. The group also noted the scenario shows a potential decrease in access for Asian candidates but that it is unclear why this is. The scenario maintains pediatric priority, though it predicts kidneys are traveling farther for those candidates under 18.

A member questioned if predicted distance for pediatric candidates should be as much of a concern. The Vice Chair responded this has been a concern from the Pediatric Committee in reviewing the results of the first OASIM report. The Vice Chair pointed out that results show increasing priority for pediatric

candidates results in a potential increase in travel distance. However, modeling does not account for acceptance behavior. A member commented they agree travel distance should not be as large of a concern for pediatric candidates, and would be in favor of giving transplant programs the opportunity to decide whether or not to accept the offer. Another member agreed. The member further commented increasing distance also increases access for this candidate population. The member wondered if allowing for priority for pediatric candidates at a greater distance would help those candidates gain access to organs that may otherwise be allocated to multi-organ transplant centers.

The Chair agreed with the points raised, and commented it is important to make the distinction that access for pediatric candidates should not get worse, which may mean travel distance increases. Another member commented pediatric candidates are typically matched with lower KDPI kidneys, which generally can tolerate higher cold ischemic times and so travel longer distances than higher KDPI kidneys can. Other members agreed.

Group Three → Scenario Three – Optimized for Distance Scenario Feedback and Key Takeaways:

Group members observed that the scenario decreased the CPRA transplant rate disparity, and also had an impact on sex disparity but were unable to tell why. This group also a projected increase in travel distance for pediatric candidates and agreed this should not be as large of a concern. An OPO representative member agreed and commented the lower KDPI kidneys are not as difficult to place.

Similar to Group One, this group would also like to see more granular data for the highest sensitized and also noticed a decrease in transplant rate for Asian candidates. However, the group commented this scenario does a better job of balancing out overall racial disparity.

Group members also observed the scenario shows a change in sex disparity, with an increase for males and a decrease for females. Members commented that may be due to sensitization. The Chair also wondered if this was relative to their representation on the wait list.

The Vice Chair commented that the results of these scenarios and most modeling are projected over a short distance after general implementation. The Vice Chair explained that it may difficult to differentiate which of these outcomes are potentially immediate bolus effects and what the longer term outcomes will be. Staff agreed modeling cannot account for how metrics will level out eventually and reiterated modeling does not predict behavior.

Summary

Staff summarized key takeaways and goals for desired outcomes. The Committee confirmed the following key points for an acceptable policy scenario:

- Establish a tolerable threshold for median travel distance; relax constraint for pediatric and highly sensitized candidates
- Agreement for maintaining pediatric priority
- Support more equity across CPRA groups; desire for more granularity in highest CPRA groups
- Highest CPRA candidates may be difficult to account for in the system
- Support for minimized disparities in all categories
- Interest in relative volumes and in qualifying time metrics (as opposed to active time)
- It is difficult to assess utility through modeling

<u>Next Steps</u>

Staff and MIT representatives will use feedback from the Committee's discussion to optimize additional scenarios further. The Committee will discuss scenario weights and revisit the longevity matching rating scale in a future meeting.

4. Public Comment Presentation: Expand Required SLK Allocation

The Chair of the OPTN Ad Hoc Multi-Organ Transplant Committee presented the *Expand Required Simultaneous Liver-Kidney Allocation* proposal currently out for public comment.

Presentation summary:

The Chair of the Ad Hoc Multi Organ Transplant Committee presented the *Expand Required Simultaneous Liver-Kidney Allocation* proposal to the Committee and requested feedback.

Summary of discussion:

Committee members commented they support the proposal's goal to ensure there is consistency in MOT policies. Regarding what OPOs should do after completing required SLK offers, Committee members felt the originally offered kidney should not default to another MOT combination and kidney-alone candidates should be considered. Furthermore, consideration should be given to medical need of kidney-alone candidates as well as pediatric candidates.

5. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation

The Chair of the OPTN Ad Hoc Multi-Organ Transplant Committee presented the *Identify Priority Shares in Kidney Multi-Organ Allocation* concept paper currently out for public comment.

Presentation summary:

The Chair of the Ad Hoc Multi Organ Transplant Committee presented the *Identify Priority Shares in Kidney Multi-Organ Allocation* concept paper to the Committee and requested feedback.

Summary of discussion:

Committee members supported the concept of prioritizing kidney-alone candidates or limiting the number of kidneys going to MOT combinations in general. Committee members commented medical need should be a consideration, and kidneys should be prioritized for those candidates who are medically urgent and would not survive without a kidney transplant. Committee members also commented kidney-alone pediatric candidates should receive priority compared to MOT candidates. Additionally, members commented simultaneous kidney-pancreas should be considered separately from other organ combinations (ex. simultaneous liver-kidney or heart-kidney).

There was also support for cases where one kidney is used for an MOT transplant, reserving the second kidney for a kidney-alone candidate. A member commented an increase in MOT transplant candidates dramatically affects the kidney-alone candidates, even with safety net rules.

Members also commented the decision on how the organ combinations are allocated should not be left to OPO's. Committee members suggested reviewing data on how many donor kidneys are allocated as pairs for MOT transplant versus a single kidney.

6. Open Forum

The Committee held an open forum on discussion topics.

Summary of discussion:

Committee members discussed one of the National Academies of Sciences, Engineering, and Medicine (NASEM) report recommendations to eliminate pre-dialysis wait time for kidney allocation. The Chair commented before the kidney allocation system changes in 2014, Region 1 only based wait time on dialysis, which resulted in candidates being referred for transplant late. The Chair commented pre-dialysis wait time should not be eliminated, but there should be consideration for disparities in access to

the wait list. Another member agreed there are disparities in who receives pre-dialysis wait time but that should be addressed in other ways. Members discussed possibly giving candidates on dialysis more priority than pre-dialysis candidates. For example, one day of dialysis wait time would be weighted more than a day of pre-dialysis wait time. Members commented this type of differentiation would be arbitrary and difficult to justify, unless it could be informed by data on advanced kidney disease stages. A member commented that data shows there is a large mortality benefit for pre-dialysis transplants, though a lot depends on the characteristics of the individual patient.

Patient representative members commented in their experience, they were not told about the possibility of pre-dialysis listing until they were already on dialysis or until they were listed for subsequent transplants. The members agreed with the previous statements on patients having better outcomes and quality of life if they are transplanted preemptively.

Another member suggested allowing for backdating pre-dialysis wait time prior to listing date, similar to dialysis wait time. The member commented this could address the issue with late referral for transplant and doesn't take away the importance placed on pre-dialysis listing. The Chair suggested there would still need to be an element of continuity in the criteria to initiate wait time to ensure the patient has chronic kidney disease vs. an acute kidney injury resulting in a low eGFR for example.

The Chair asked if any members were in support of the NASEM recommendation to eliminate pre-dialysis wait time. The Committee unanimously disagreed with the NASEM recommendation. Members further commented the removal of pre-dialysis wait time removes the incentive to refer patients to transplant earlier. Another member commented the issue isn't with preemptive listing, but with access to transplant consultation.

Upcoming Meetings

- February 6, 2023 – Conference call

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Jason Rolls
  - Arpita Basu
  - Steve Almond
  - Caroline Jadlowiec
  - Jesse Cox
  - Elliot Grodstein
  - Asif Sharfuddin
  - Beatrice Concepcion
  - Marilee Clites
  - Precious McCowan
  - Pete Lalli
  - Patrick Gee
  - Sanjeev Akkina
  - Tania Houle
  - Chandrasekar Santhanakrishnan
  - Jesse Cox
  - Kristen Adams
  - Nidyanandh Vadivel
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
  - Peter Stock
  - Sommer Gentry
  - Ryutaro Hirose
- **UNOS Staff**
  - Lindsay Larkin
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Thomas Dolan
  - Kim Uccellini
  - Alex Carmack
  - Amber Fritz
  - Ben Wolford
  - James Alcorn
  - Kaitlin Swanner
  - Krissy Laurie
  - Lauren Motley
  - Matt Cafarella

    - Ross Walton
    - Sara Moriarty
    - Shelby Jones
    - Tina Rhoades
- **Other**
    - Eli Pivo
    - Lisa Stocks