OPTN Kidney Transplantation Committee
Meeting Summary
August 21, 2023
Teleconference

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

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 8/21/2023 to discuss the following agenda items:

1. Recap of Organ Allocation Simulation (OASIM) Discussions
2. Massachusetts Institute of Technology (MIT) Optimized Scenario Review and Discussion
3. Review Board Workgroup Recommendations

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

1. Recap of OASIM Discussions

Staff recapped previous Committee discussions in response to the OASIM results.

Presentation summary:

After reviewing the second round of the OASIM results in July, the Committee expressed interest in working with MIT to further optimize potential policy scenarios. Specifically, the Committee wanted to:

- Increase access for highly sensitized candidates (Calculated Panel Reactive Antibody (CPRA) 99.9+)
- Equalize access across CPRA groups
- Investigate minimizing median travel distance for pediatric candidates while maintaining access

Summary of discussion:

There were no questions or comments.

2. Massachusetts Institute of Technology (MIT) Optimized Scenario Review and Discussion

Staff recapped previous Committee discussions on priority for highly sensitized candidates and on minimizing organ distance traveled for pediatric patients.

Presentation summary:

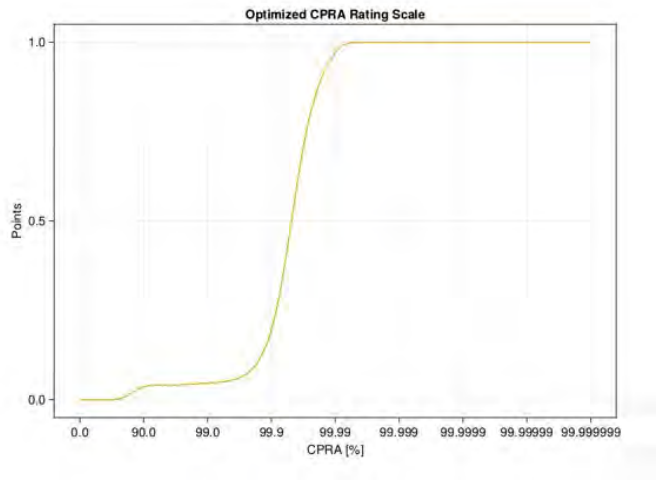
CPRA

OASIM results, which modeled current policy (as a reference) and four potential continuous distribution policy scenarios, showed a decrease in access for the highest sensitized patients across all continuous distribution scenarios compared to modeled current policy. This was particularly seen for patients with CPRA 99.9-100 percent. The Committee previously noted that drops for candidates with CPRA 80-99.5 percent – who currently have much higher access than other CPRA groups – were more tolerable in the interest of equalizing transplant rates across CPRA groups.

Initial efforts to achieve increased access for the highly sensitized candidates by MIT's optimization model included an attempt to increase the weight on CPRA. The model showed increases in transplant rate when increasing the weight from about 7 percent up to about 44 percent. However, MIT modeling showed that increased CPRA weights resulted in significant increases in transplant rates for CPRA 80-98 and 98-99.5 percent groups, who already have particularly high relative access in the modeled current policy.

Optimization modeling by MIT also included efforts to optimize a new CPRA rating scale, in order to achieve both of the Committees goals to 1) increase access for highly sensitized patients, and 2) equalize transplant rates across CPRA groups. The optimized rating scale is shown in **Figure 1.**

Figure 1: Optimized CPRA Rating Scale



The preliminary optimized CPRA rating scale results in minimal priority for candidates with CPRA 90-99.9, and then a steep increase in points for candidates with CPRA 99.9-99.99. Finally, those candidates with a CPRA of 99.99-100 percent receive the maximum number of points.

Using the optimized CPRA rating scale and a high weight (40 percent) on CPRA achieves maximum access for CPRA 99.9-100 while decreasing the differences between other CPRA groups. **Figure 2** shows preliminary transplant rates by CPRA.

Figure 2: Transplant Rates by CPRA *preliminary results*

Summary of Discussion:

One member asked if updating the CPRA rating scale and weight would impact the other outcomes currently being considered by the Committee. It was noted that high CPRA candidates are a small proportion of candidates. The Chair remarked that this modeling is based on historical data, but that it will be important to determine the implication on other outcomes. The Chair added that this rating scale would hopefully prevent drop in access for the most highly sensitized patients, and only an attenuated drop for the CPRA 80-98 percent and 98-99.5 percent patients. The Chair added that it will be important to message this decrease in transplant rate for these patients appropriately, as this decrease contributes towards increased equity across CPRA groups.

A member asked how this rating scale would translate for a currently listed patient, noting that this may not represent a larger number of patients. Staff explained that the model could produce a number of transplants to visualize the drop, but that the modeling is more helpful to understanding trends than discrete numbers. The Chair agreed that investigating the relative scales is helpful, but that the greater transplant community generally considers volumes more than trends. The Chair recommended the Committee review potential policies holistically in terms of volumes.

A representative of the Scientific Registry of Transplant Recipients (SRTR) expressed concern that the continuous distribution system would not prioritize the highest CPRA candidates as much as the current, classification-based system of allocation does. Staff explained that this rating scale was modeled with a 40 percent weight on CPRA. Between the rating scale and the high weight, the continuous distribution model is able to similarly prioritize the highest sensitized patients, ensuring they are at the top of the match runs they appear on. Another staff member emphasized that the weights could be balanced according to the Committee and community's preference.

One SRTR representative asked if the rating scale was optimized against one of the scenarios previously modeled by the SRTR, and staff confirmed this.

Presentation summary:

Pediatric Travel Distance

The Committee also expressed interest in understanding why OASIM results indicated high median travel distances for pediatric transplants, as well as exploring a potential policy that reduces median travel distance while still maintaining pediatric access.

Under current policy, pediatrics more than 250 nautical miles (NM) away are not as highly prioritized as pediatric candidates less than 250 NM away. In between these two groups, there are several types of adult candidates who have priority over pediatric candidates more than 250 nautical miles away. However, under the modeled continuous distribution scenarios, pediatric candidates are given a very high weight regardless of distances, resulting in pediatric candidates more than 250 NM away receiving similar priority to candidates within 250 NM of the donor hospital. In this instance, there are much fewer adult candidates prioritized ahead of any pediatric candidates.

To address the Committee's concerns, MIT investigated potential reduction in the weight assigned to pediatric candidates, to determine if a reduction in pediatric weight could result in similar or increased access to transplant for pediatric candidates relative to simulated current policy while still reducing median distance traveled. MIT's simulation efforts found that reducing the weight on the pediatric attribute from 15 percent to about 12 percent maintains a higher, similar access to transplant relative to simulated current policy, while substantially lowering median distance traveled from nearly 500 NM to about 300 nautical miles.

The OPTN Pediatric Committee provided feedback at their meeting on August 18th on the OASIM results, and particularly the median organ distance traveled for pediatric transplants modeled by the OASIM.

The Pediatric Committee had a mixed reaction to the possibility of a lower weight on the pediatric attribute, but supported improvements to screening tools for pediatric candidates, particularly on a candidate-specific level. The Pediatric Committee was supportive of increased access for pediatric candidates, but expressed concern for cold ischemic time, offer acceptance rates, and allocation efficiency based on the OASIM modeling results.

Summary of Discussion:

One member remarked that cold ischemic time is a more critical and important measure than distance, and that distance is less useful without the context of cold ischemic time. A representative of the Pediatric Committee agreed, and asked if the cold ischemic time could be extrapolated from modeled distances.

A representative of the Pediatric Committee asked how the slight reduction in weight on pediatric priority would impact transplant volumes, particularly for local transplant. Staff explained that the model did not project a significant difference in volume of local pediatric kidney transplants.

An SRTR representative noted that the simulations were run without offer filters, adding that offer filters may help programs reduce the number of offers they receive from greater distances. Staff responded that currently, offer filters does not include functionality to allow programs to build filters specific for pediatric candidates.

The Chair shared feedback gathered from the Pediatric Committee, noting that there was a general consensus that increased access for pediatric candidates is good, but that programs do not want to be overwhelmed with offers. The Chair continued that the Pediatric Committee emphasized the importance of efficiency at a program level, and noted that offer filters may not be effective without candidate-specific functionality. A representative from the Pediatric Committee noted that the considerations for each set of filters would differ on a candidate-basis, particularly as the pediatric population includes a wide range of unique and specific considerations. A representative of the Health Resources and Services Administration (HRSA) asked if updating offer filters is within scope, and staff noted that it could be.

The Vice Chair asked how many pediatric transplant programs are currently accepting offers from more than 250 nautical miles away. Staff noted that currently, there are not many pediatric transplants occurring outside of 250 nautical miles, but that this may be a function of current policy's prioritization of pediatric candidates within 250 nautical miles.

The Committee agreed to table this topic for future discussion in the interest of time.

3. Kidney Review Board Workgroup Recommendations

The Chair of the OPTN Kidney and Pancreas Review Boards Workgroup (the Workgroup) presented the Workgroup's recommendations for a Kidney Review Board in a continuous distribution framework.

Presentation Summary:

The Workgroup developed recommendations for kidney and pancreas review boards based on a cross organ framework with additional considerations for clinical and practical specifics of kidney transplant.

The Kidney Review Board will be chaired by a clinical member of the Kidney Transplantation Committee. If no member of the Kidney Committee can be found, a clinical member of another OPTN Committee with relevant expertise may take on this role. The Review Board leadership will be appointed and approved by the Kidney Committee. The Kidney Review Board will also have a Vice Chair who will become the next Review Board Chair, similar to current OPTN Committee leadership structure.

The Review Board Chair will have several responsibilities:

- Act as head of the Review Board
- Maintain awareness of cases and trends in cases, to be apprised if new policies may be necessary
- Chair the Appeal Review Body (ARB) and lead the ARB conference calls
- Act as a reviewer in the general review board pool, and review cases as assigned

The Review Board Vice Chair will back the Chair up in several of these responsibilities, and particularly be able to/responsible for:

- Act as a reviewer in the general review board pool, and review cases as assigned
- Attend ARB conference calls, and lead these calls in the case the Chair is not able or available
- Act as Review Board Chair, in the Chair's absence

Reviewers will be recruited via open call and programs may submit nominees if interested in participating. Programs may submit one reviewer and programs who submit nominees after the review board is full will be placed on a waiting list, to be called on if the pool is expanded or a reviewer needs to be replaced. The Workgroup determined regional representation was not necessary, as this is a national review board and clinical considerations would not change.

For Review Board member qualifications, the Workgroup recommends reviewers should be at least 5 years post-fellowship with direct transplant experience and actively working in transplant at an active transplant program. Transplant programs must ensure their nominees meet these requirements.

For pediatric review board members, the Workgroup recommends reviewers should be at least 5 years post-fellowship with direct transplant experience and actively working in transplant at an active transplant program with a pediatric kidney component. Additionally, pediatric reviewers should have worked with and/or performed at least two transplants on a pediatric patient in the last three years, at least one of which should be for a patient under the age of six years old or weighing less than 25kg at time of transplant. Review Board membership is a two-year commitment and the Kidney Review Board will have 40 members, with a minimum of one-third of reviewers having pediatric expertise.

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

- Medical urgency
- Safety net

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

A transplant program may submit an exception request for their candidate, including a justification narrative supporting their request. The request is then reviewed by the OPTN Organ Center, who redacts any personally identifiable information and then submits it to the Review Board. Once submitted, the Review Board system will assign the case to seven review board participants. Reviewers are selected with consideration for their expertise and case type, potential conflicts of interest, and then

at random based on reviewer case load. Reviewers with a conflict of interest will not be permitted to review that case.

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

The case will close when a majority approval or denial is met, or when the case reaches the end of the five day voting timeline, whichever is first. Votes are tallied using the Robert's Rules of Order definition of a majority ("simply more than half") to determine the case outcome of approved or denied. If a full majority vote is not achieved by the end of the case timeline, the case outcome will be determined by the majority of votes received. In the event of a tie, benefit will be given to the candidate and the exception approved. The transplant program will receive an appeal notification with the outcome of the exception request. Reviewers will have the opportunity to leave comments on cases that they have voted to approve and reviewers will be required to leave a comment explaining their decision to the program.

Edge case scenarios are highly unlikely, however, in the event that they do occur, it is necessary that the system knows how to act and operate. If seven available reviewers cannot be found in the system, the system will pull as many kidney-specific reviewers as possible. The minimum number of reviewers assigned to a case is two. Meaning, if at least two reviewers cannot be found, the system will default to an approval of the exception request. On a similar note, the minimum number of votes to consider a case denied is two votes. If two reviewers submit conflicting votes, the system will recognize the tie and default to an approval. If only one vote or no votes are submitted by the end of the case timeline, the system will default to an approval, as this is an insufficient number of votes to be considered a peer review.

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

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

Membership of the ARB is composed of members from the general Review Board pool, with a balance of pediatric and adult reviewers. A minimum of one-third and a maximum of half the ARB membership will have pediatric expertise. Membership on the ARB is considered a responsibility of joining the Review

Board. ARB members have a two-year commitment on the ARB. There will be 12 total ARB members, including the Chair and Vice Chair.

All members of the ARB are assigned to all second appeal cases, and expected to join the ARB call to review, discuss, and vote. Members are exempted from cases for which they have a conflict of interest. Cases will be reviewed in regularly scheduled calls and programs may opt to have a representative join the call to present the case and answer questions. The program representative will not be present for discussion and voting.

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

The minimum number of ARB reviewers required to discuss the case and submit a vote is three. If a minimum of three ARB reviewers cannot convene to vote before the end of the case timeline, the request will be approved by default. If a minimum of three votes are not submitted before the end of the case timeline, the request will be approved by default. Case outcomes will be decided by majority using the same Robert's Rules of Order, defined as "simply more than half." Ties at the ARB level will result in an automatic approval.

Summary of Discussion:

A member questioned the lack of regional representation and if that aligns with other organ-specific review boards. Staff responded the Workgroup discussed that each organ that already has a review board does not have regional balance but do have a system of rotating nomination that allows certain programs have access to terms on a rotating schedule. When the Workgroup discussed this, it was difficult to ensure all kidney programs had representation while maintaining a reasonable number of reviewers. The Workgroup Chair commented keeping the Review Board pool smaller allows reviewers to have more frequent reviews and gain experience. Additionally, since the exceptions are based on medical criteria, it should be consistent across the country.

A member expressed concern for potential misuse of exceptions if medically urgent cases are reviewed retrospectively. Staff commented the Committee can establish a threshold for transplant at denied status, at which case a program may be referred for MPSC review. Members were supportive of establishing a threshold. Another member asked if a dashboard or metrics would be made available to see case outcomes close to real time. Staff responded there are functionalities that currently exist for other organ types to allow programs to see their cases under review that may be able to be replicated. Additionally, the Committee would be able to monitor de-identified data on Review Board exception reviews and outcomes. The Chair and other members commented monitoring will be important. One member commented the Committee should be aware of introducing biases against programs when reviewing the data but agrees monitoring will be important.

Committee members supported the Workgroup's recommended framework pending additional discussions on monitoring and establishing a policy threshold for transplant at a denied status.

Upcoming Meetings

- September 18, 2023 – Conference Call

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Carrie Jadlowiec
  - Jason Rolls
  - Marian Charlton
  - Patrick Gee
  - Stephen Almond
  - Reza Saidi
  - Curtis Warfield
  - Eloise Salmon
  - Jesse Cox
  - John Lunz
  - Kristen Adams
  - Leigh Ann Burgess
  - Sanjeev Akkina
  - George Surratt
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
  - Nick Wood
  - Sommer Gentry
  - Tim Weaver
- **UNOS Staff**
  - Carlos Martinez
  - Thomas Dolan
  - Keighly Bradbrook
  - Kieran McMahon
  - Kayla Temple
  - Joann White
  - Kim Uccellini
  - Lauren Motley
  - Ross Walton
  - Ruthanne Leishman
  - Carly Layman
  - James Alcorn
  - Kaitlin Swanner
  - Rebecca Fitz Marino
- **Other**
  - Asif Sharfuddin
  - Caitlin Peterson
  - Namrata Jain