

OPTN Kidney Transplantation Committee

Meeting Summary

April 1, 2022

Conference Call

Martha Pavlakis, MD, Chair

Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 4/1/2022 to discuss the following agenda items:

1. Estimated Post Transplant Survival (EPTS) and Kidney Donor Profile Index (KDPI) Mapping Tables
2. Continuous Distribution Discussion: Analytical Hierarchy Process (AHP) Exercise Results Overview
3. Continuous Distribution Discussion: Waiting Time
4. Continuous Distribution Discussion: Blood Type
5. Continuous Distribution Discussion: Longevity Matching
6. Continuous Distribution Discussion: Placement Efficiency

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

1. Estimated Post Transplant Survival (EPTS) and Kidney Donor Profile Index (KDPI) Mapping Tables

Kidney Donor Risk Index (KDRI) for each donor is converted to a KDPI percentage using a KDRI-KDPI mapping table, which is based on data from all kidney donors recovered in the previously calendar year. EPTS is similarly updated. Kidney allocation policy requires committee review and annual update of KDPI and EPTS mapping tables. The Committee reviewed changes in the reference donor and recipient populations in the last year, and voted to update the reference tables for KDPI and EPTS with data from the updated reference donor and recipient populations.

KDPI Data summary:

The updated KDPI cohort from 2021 is similar to 2020, with a small and steady increase in the KDRI distribution over time. This is essentially a steady decrease in donor quality as measured by KDRI over time. This shift is driven by a number of factors:

- Kidney donors have become slightly older on average
- Donor creatinine has steadily increased, with a slight dip between 2020 and 2021
- Proportion of kidney donors with a history of hypertension has been increasing, as well as history of diabetes
- The proportion of donation after cardiac death (DCD) donors has increased over time
- Proportion of donors recovered with Hepatitis C (HCV) has increased, with a slight dip between 2020 and 2021

Other factors used to measure KDRI that did not contribute to this trend include:

- Proportion of Black kidney donors has fluctuated over time but remain fairly consistent
- Donors who die of a Cerebrovascular Accident (CVA) or stroke have higher KDRI; however, the donor population with CVA as the cause of death has decreased over time

- Donor height has remained unchanged
- Donor weight has increased over time, though KDRI decreases as weight increases

These changes in KDRI to KDPI mapping is still relatively small year to year. The proposed new KDRI-to-KDPI mapping table follows these trends.

Summary of discussion:

The Chair remarked outside of the mapping tables, the KDPI calculation should be a future item of discussion within the Committee. A member commented that machine perfusion could have a dramatic impact on the risk index and recommended reviewing data on how many kidneys are perfused and that potential impact. The member further commented they expect the use of machine perfusion to increase. Another member commented there are additional areas that are changing such as the ability to treat hepatitis C patients and suggested the Committee should revisit those markers. The Vice Chair agreed there should be more Committee discussion on the parameters of KDPI as part of the development of Continuous Distribution for kidneys.

Vote:

The Committee voted unanimously to approve the new KDRI-to-KDPI mapping table based on the year 2021 reference population.

EPTS Data summary:

A candidate's EPTS score indicates the percentage of adult kidney candidates on the waiting list with a higher estimated post-transplant longevity, based on data from December 31 of the previous year. The EPTS score is used to confer priority on the waiting list.

There has been an increase in raw EPTS over time, meaning the threshold for the EPTS 20 percent or less priority has become slightly easier to meet. This shift is driven by:

- Candidates are older on average, with higher raw EPTS scores
- More candidates on the waiting list have diabetes

Center factors influencing raw EPTS calculation have opposed this trend:

- The proportion of candidates who have received prior transplant has decreased
- The average amount of time that candidates are dialyzed has decreased

Year to year, there is a small increase in the average raw EPTS. The 2021 data follows this trend, and adopting the new EPTS reference population will have implications for patients. Slightly more candidates would qualify for top 20 percent EPTS priority due to recalibration, as the raw EPTS score needed would increase from 1.5329 to 1.5351. Some candidates with an EPTS of 21 percent would see their score drop to 20 percent, giving them additional priority.

Summary of discussion:

The Chair commented the data presented would be interesting for the Committee to evaluate and wondered if the decrease in dialysis time reflects the new circles policy and broader sharing. A member asked if multi-organ transplant recipients are included in the data. Staff clarified anyone who is listed for a kidney is included in the cohort, including multi-organ candidates.

Vote:

The Committee voted unanimously to adopt the new EPTS mapping table based on the reference population snapshot of all adult kidney candidates on the waiting list on December 31, 2021.

2. Continuous Distribution Discussion: Analytical Hierarchy Process (AHP) Exercise Results Overview

The Committee reviewed an overview of the results from the kidney and pancreas AHP exercise from the winter 2022 public comment period. The AHP results are meant to be used as a tool to help inform the Committee's discussions on determining weights of attributes as part of the Continuous Distribution framework.

Participation in the two exercises was much larger than the participation rate in the lung AHP exercise, with the most participation from transplant hospital professionals. Participants were asked to compare two attributes, in the form of patient profiles, and determine the level of importance when compared to each other. In looking at the results for both kidney and pancreas, the level of importance placed on each attribute are fairly consistent across demographic groups. The Committee also reviewed Kidney Committee specific results.

Summary of Discussion:

The Chair commented it is interesting to see the patients and general public placed higher emphasis on prior living donors than other demographic groups and placed less weight on medical urgency. The Vice Chair wondered if there was a misunderstanding of what medical urgency referred to. A member commented they noticed the general public also placed more emphasis on longer waiting times and the OPO professionals placed more emphasis on very nearby candidates. Another member commented some patients may be valuing prior living donors over medically urgent candidates due to concern for their living donors potentially needing a kidney in the future.

Another member commented the results of the exercise show less emphasis on a very nearby candidate, which conflicts with feedback the Committee has received on placement efficiency after the implementation of the new circles policy. Staff agreed there was less emphasis placed on distance between donor and transplant hospital than expected, and was weighed lower than the lung AHP exercise. Staff also commented there are other considerations for placement efficiency the Committee should discuss outside of distance alone.

In reviewing the Kidney Committee's specific results, a member commented the definition of medically urgent in policy needs further refining to justify its high weight. The Vice Chair agreed and commented it will be important to define and verify a candidate's candidacy for medically urgent status. Staff commented this could be part of upcoming discussions on review boards as part of the development of the continuous distribution project.

3. Continuous Distribution Discussion: Waiting Time

The Committee discussed and finalized the rating scale recommendation for the waiting time attribute. To help inform discussion, the Committee reviewed current policy on waiting time and options previously discussed by the Kidney-Pancreas Continuous Distribution Workgroup (the Workgroup) and

their feedback. Additionally, the Committee reviewed feedback from Public Comment, the OPTN Ethics Committee, and the OPTN Patient Affairs Committee's (PAC) Patient and Donor Focus Group meeting.

Waiting Time Rating Scale: Summary of Previous Discussions and Public Comment Feedback

Current policy prioritizes candidates with higher waiting time, giving candidates unlimited points for each day of waiting time. Waiting times in the current system can vary significantly. For example, 2021 data indicates that the maximum waiting time on Kidney, Kidney-Pancreas, and Pancreas candidates is more than ten times the median waiting time.

When the Workgroup previously discussed the attribute, there was concern with establishing a ceiling for waiting time as it penalizes the rare candidates who have high waiting time. Workgroup members emphasized many candidates with substantial amounts of waiting time are due to access issues and the ability to backdate waiting time to start of dialysis attempts to address those disadvantaged patients. Other Workgroup members questioned if having a ceiling would promote placement efficiency as candidates with large amount of waiting time are also often highly sensitized and would receive a large amount of offers on a national level. The Workgroup also discussed whether there should be additional consideration for those candidates who qualify for waiting time based on dialysis, meaning those candidates who have been on dialysis longer receive greater points compared to those not on dialysis.

Public Comment showed support for considering GFR-qualified and dialysis waiting time differently, with support for weighting dialysis waiting time higher. There was also a recommendation to give points for pre-emptive listing to encourage pre-emptive transplant. There was general support for significant weighting of waiting time and for no limit to waiting time. However, there was some support for a rating scale that is linear to a curve after a specified threshold of waiting time.

The OPTN Ethics Committee discussed the attribute as well and questioned if waiting time is a surrogate for medical urgency or a factor of equity. An Ethics Committee member suggested use of a staggered rating scale, where different weights were used the more waiting time a candidate receives. The Ethics Committee also noted capping waiting time does not address unfair disadvantages with access to transplant.

The PAC's Patient and Donor Focus Group also supported treating dialysis-based waiting time differently, noting that dialysis is not a replacement for transplant. Focus Group members commented long waiting times and extended use of dialysis can increase a patient's medical complexity and impact their outcomes as a recipient. Some Focus Group members expressed concerns for organ utility, questioning if medically complex patients with long dialysis times would be the best longevity match. The Focus Group was also supportive of a linear to curve approach and recommended the waiting time threshold should be based to a degree on transplant survival benefit related to waiting time.

The Committee then reviewed two potential rating scale options:

- No ceiling: This approach would continue the linear function (i.e., each day of waiting time is worth the same amount) and allow candidates to receive an unlimited amount of waiting time points. The Committee should choose a threshold that captures most candidates in this approach. Candidates with a waiting time higher than this threshold would receive points greater than the weight assigned to this attribute. Candidates with less waiting time would naturally receive points less than the weight assigned to the attribute. This approach would allow the system to distinguish between candidates with any amount of waiting time. It would, however, create a small number of candidates who will receive more than 100 percent of the maximum weight for this attribute.

- Linear to curve: This approach allows the system to distinguish between candidates with extreme amounts of waiting time yet also retains the 0-100 rating scale. In this model, the Committee again chooses a threshold that will capture most candidates. Below that threshold, candidates receive waiting time in a linear fashion. Above that threshold, candidates will accrue points more slowly.

Summary of Discussion:

A member recommended the no ceiling approach as they believe it is the most equitable option. Another member commented there are assumptions within the community that long waiting times are due to medical complexity, and that medical complexity also means poorer outcomes. However, these assumptions are not validated and there are many other reasons candidates could have longer waiting times such as disparities in access to transplant. The member suggested possibly curving the number of points for candidates who don't have as much waiting time which could help address geographical variation. The Chair agreed early days of waiting time should count less, as well as non-dialysis waiting time. Another member agreed generally the longer candidates are on dialysis, the worse their health is but also recognized there is an ethical approach to pre-dialysis waiting time and points should be given for pre-dialysis waiting time as well.

Staff reminded the Committee that dialysis time is also a factor in the EPTS calculation, and that could account for potential negative impacts on outcomes. Staff recommended for the Committee to focus on the issue of access in discussing the waiting time attribute. The Vice Chair commented pre-dialysis candidates should not be penalized for having access to transplant, just like dialysis candidates should not be penalized for any lack of access. The Chair asked what the ethical justification would be for the linear to curve option. Staff suggested a justification for that scale could be autonomy and transparency. A member asked if both options could be modeled. Staff responded it would be possible to model both options but there are a limited number of scenarios that can be sent for modeling and recommended the upcoming sensitivity tool could help the Committee members see the difference between the rating scales.

The majority of Committee members supported modeling the no ceiling rating scale option for modeling.

4. Continuous Distribution Discussion: Blood Type

The Committee discussed and finalized the rating scale recommendation for the blood type attribute. To help inform discussion, the Committee reviewed current policy on blood type allocation and options previously discussed by the Workgroup and their feedback. Additionally, the Committee reviewed feedback from Public Comment.

Blood Type Rating Scale: Summary of Previous Discussions and Public Comment Feedback:

Kidney allocation currently classifies candidates according to compatible, incompatible, and permissible blood type matches, with prioritization for blood types O and B to provide equity in the system. In current kidney allocation, blood type O kidneys are reserved for blood type O recipients and blood type B kidneys are reserved for blood type B recipients because of biological disadvantages in finding compatible donors.

When the workgroup previously discussed this attribute, they acknowledged that the new framework would need to allow for compatibility while accounting for those disadvantaged blood types. In considering how to incorporate those, the Workgroup reviewed the use of a common scale developed for the Continuous Distribution of Lungs which put blood type and CPRA together. After reviewing data, the Workgroup considered whether certain blood types should have additional access to certain donor

kidneys, such as highly sensitized with blood type B. The Workgroup considered using a linear approach for the blood type rating scale, with candidates of each blood group receiving points equal to the blood groups' probability of incompatibility. The Workgroup also considered having a linear scale for blood type and aligning it with CPRA to allow for blood type O donor kidneys to go to non-O candidates in those rare situations of high sensitization. For example, a blood type O candidate with a CPRA of zero would receive 53 points for having blood type O and 0 points for their sensitization. However, a blood type AB candidate with a CPRA of 100 would receive 100 points due to their high sensitization and 0 points for blood type. In this situation, assuming all else is equal, the highly sensitized candidate would receive more priority than the blood type O candidate. The Workgroup ultimately didn't reach consensus on what rating scale to use and deferred a decision until review of public comment feedback.

Public Comment results showed support for prioritizing blood types O and B and for prioritizing non-A1/non-A1B kidneys to O and B candidates. Additionally, there was some support for allocating to A and B candidates with equal access between the two.

The Committee then reviewed two potential rating scale options:

- Screening: Use screening rules to replicate current policy in a points-based framework. The Committee would still consider a points-based rating scale to distinguish between compatible blood types on a match run.
- Points: Award points to candidates based upon their blood type and biological disadvantage. This approach would be like CPRA and the technique used in lung continuous distribution. Within a points-based framework, the Committee would decide upon either a linear or nonlinear approach for the rating scale.

To help aid discussion, the Committee briefly participating in a small AHP exercise specific to the blood type attribute. The AHP exercise used six patient profiles and asked the participant to compare two profiles at once and determine which one should receive the most priority. The Committee used the results as a jumping off point for discussion on whether to maintain current screening practices in kidney allocation.

Summary of Discussion:

The Chair commented that from the results of the exercise, it appears there is disagreement with the current screening policy and questioned if there was a mechanism for screening in the continuous distribution system. Staff responded there would still be screening for biologically incompatible candidates which could be extended for blood types O and B, but there could also be a more nuanced approach with the new system. Members commented they found the blood type specific AHP exercise challenging and were unclear what kind of donor offer they were considering in each scenario. Staff reiterated the Committee could explore a more nuanced approach with blood type specific points, unless the Committee wants to maintain screening. If the Committee chose to maintain screening, there should be a legal justification provided for screening off a compatible candidate.

The Chair commented not screening for blood type O donors to blood type O candidates would be difficult to justify as those candidates have such limited access. A member agreed the non-O blood type candidates should be screened off and commented there has been some experience with the OPTN Kidney Paired Donation Pilot Project (KPDPP) and matching O kidneys with non-O candidates and disadvantages to highly sensitized O candidates. The member commented further in their experience, O candidates are disadvantaged regardless of high sensitization.

Staff asked the Committee if there would be consideration for not screening B candidates off an O match run as B candidates are also disadvantaged. The Chair said that is important to remember blood

type B candidates are also disadvantaged and commented they would prefer to prioritize highly sensitized over O-ABDR mismatch candidates.

Staff reviewed potential blood type rating scale options for modeling. Staff informed the Committee if they decide to maintain screening for O and B candidates, rating scales would still need to be used to differentiate between candidates. Additionally, the Committee would need to discuss whether to keep existing O-ABDR mm prioritization on match runs. Staff reviewed a rating scale that includes both blood type and CPRA together.

A member commented there is a very small number of candidates that are highly sensitized and expressed concern for equating blood type to CPRA as it could further disadvantage O candidates. Staff commented points could be adjusted so O candidates have higher points to fall ahead of other blood type candidates. Staff further commented the Committee could decide to model a scenario with blood type points instead of screening. The Vice Chair commented any decision will need to be explainable to patients and the general public, and incorporating a new blood type framework may not be easily understood.

The Committee supported maintaining current blood type screening for modeling.

A member commented it would help discussion to have predictive data of outcomes for an option other than screening. The Chair commented the screening option could possibly be more nuanced in continuous distribution. Staff commented modeling could show how blood type will look with different weights. The Committee will continue discussions on blood type and how to incorporate O-ABDR mismatch into the rating scale.

5. Continuous Distribution Discussion: Longevity Matching

The Committee discussed and finalized the rating scale recommendation for the EPTS attribute. To help inform discussion, the Committee reviewed current allocation practices and options previously discussed by the Workgroup and their feedback. Additionally, the Committee reviewed feedback from Public Comment.

Longevity Matching Rating Scale: Summary of Previous Discussions and Public Comment Feedback:

Currently, EPTS is used to predict a candidate's projected longevity with a functioning kidney. EPTS works together with KDPI to match a kidney to a candidate and the top 20 percent KDPI kidneys are reserved for the top 20 percent EPTS candidates.

When the Workgroup previously discussed the attribute, they recognized the need for different allocation algorithms based on donor KDPI and expressed interest in expanding the KDPI/EPTS longevity matching past the top 20 to top 20 policy. The Workgroup ultimately didn't reach consensus and deferred a decision until review of public comment feedback.

Public Comment feedback also recognized kidney allocation should differ depending on the donor KDPI. Some commenters supported maintaining the top 20 to top 20 policy, while others supported an enhanced interaction between KDPI and EPTS.

The Committee then reviewed three potential rating scale options:

- Categorical: Replicate current policy in a points based framework.
- Curved: This approach would continue the practice of prioritizing low KDPI kidneys for candidates expected to have the best outcomes, and would have an extended curve for candidates in-between those extremes.

Summary of Discussion:

A member asked if there would be a negative impact to pediatric patients limited to 0-20 percent KDPI kidneys. Staff clarified pediatric candidates would still get pediatric priority.

A member commented they support the curved option as it supports prioritizing longevity over brevity. The Chair agreed and commented they support a rating scale that more accurately reflects outcomes. Another member commented they agree there should be some adjustments to the KDPI/EPTS relationship, but remembers there was contention within the kidney community on this issue when the current kidney allocation system was developed and recommended delaying the expansion of longevity matching in a future iteration of continuous distribution.

A member commented this decision still doesn't address the issue of KDPI and EPTS matching for pediatric candidates. Staff commented it would be possible to develop an EPTS calculation for pediatric candidates specifically. Another member commented the system has a responsibility to make the best use of donor kidneys, meaning kidneys with the highest expected longevity should be allocated to candidates with the longest expected survival.

The majority of the Committee supported modeling a curved longevity matching rating scale.

6. Continuous Distribution Discussion: Placement Efficiency

Staff introduced the topic of placement efficiency to be addressed in future Committee and Workgroup discussions.

Summary of Discussion:

A member commented proximity was the least prioritized of the attributes according to the AHP exercise results, but there should still be a difference in points or weight the further you get from the donor hospital. Another member commented within placement efficiency, there should be consideration for how allocation and placement practices relate to discards. Staff encouraged the Committee to also consider a difference in weights depending on the donor KDPI.

Upcoming Meetings

- April 18, 2022 – Teleconference

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Jim Kim
 - Vincent Casingal
 - Amy Evenson
 - Arpita Basu
 - Bea Concepcion
 - Caroline Jadlowiec
 - Deirdre Sawinski
 - Elliot Grodstein
 - Erica Simonich
 - Marilee Clites
 - Peter Lalli
 - Precious McCowan
 - Sanjeev Akkina
 - Stephen Almond
 - Nidyanandh Vadivel
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Grace Lyden
 - Jonathan Miller
 - Peter Stock
 - Bryn Thompson
 - Nick Wood
- **UNOS Staff**
 - Lindsay Larkin
 - Ross Walton
 - Kayla Temple
 - Amanda Robinson
 - Darren Stewart
 - James Alcorn
 - Jesse Howell
 - Joel Newman
 - Kaitlin Swanner
 - Kim Uccellini
 - Melissa Lane
 - Rebecca Murdock
 - Sarah Booker
 - Tina Rhoades
 - Sara Moriarty
 - Lauren Mauk
 - Alison Wilhelm
 - Chelsea Haynes