OPTN Kidney Transplantation Committee
Meeting Summary
December 12, 2022
Conference Call

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

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 12/12/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Board Meeting Recap
3. Kidney Paired Donation (KPD) Proposal for Public Comment
4. Recap and Next Steps: Longevity Matching
5. Introduction and Discussion: Calculated Panel Reactive Antibodies (CPRA)

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

1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members, and shared that the upcoming in-person Committee meeting will take place in Houston, Texas.

Summary of discussion:

There were no questions or comments.

2. Board Meeting Recap

Staff and Committee Leadership provided the Committee with a brief overview of the December 5, 2022 OPTN Board of Directors meeting.

Presentation summary:

At their December 5, 2022 meeting, the Board of Directors voted unanimously to approve both the *Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations* (implementation scheduled for January 5, 2023) and *Update Kidney Paired Donation Policy* (implementation scheduled for February 1, 2023) proposals. Pre-implementation notice was sent to programs on December 6, 2022. Staff is currently developing resources and education for implementation of the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* proposal, including:

- FAQs for Transplant Professionals and Patients
- Professional Education for Programs with step by step instructions
- Candidate notification samples
- Attestation sample
- Report for programs

Summary of discussion:

A few Committee members volunteered to review educational resources for implementation of the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* proposal.

3. KPD Proposal for Public Comment

The Committee reviewed the *Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* proposal recommended by the OPTN KPD Workgroup, and voted to sponsor the proposal for public comment.

Presentation summary:

This proposal consists of two main parts: the first, to require annual donor re-evaluation, and the second, to align OPTN KPD blood type A, non-A1 and AB, non-A1B matching eligibility requirements with those in OPTN Kidney policy. This proposal will only affect the OPTN Kidney Paired Donation Pilot Program, or the OPTN KPDPP.

This proposal fit into the strategic goal of increasing the number of transplants. Requiring annual donor re-evaluation will support this goal by increasing the efficiency of the OPTN KPD program and improving the quality of OPTN KPD matches, and in so doing, increase the likelihood of match success. Aligning blood type A, non-A1 and AB, non-A1B matching eligibility requirements will support this goal by increasing efficiency and clarity in the OPTN KPD system and by expanding the donor pool for some blood type O and blood type B candidates.

Donor Re-Evaluation Requirement

Currently the OPTN KPDPP has no requirement for regular donor re-evaluation; as a result donor information in the OPTN KPD system becomes outdated, which reduces match quality, prolongs time between match offer and transplant, and reduces likelihood of match success. This matters particularly for the OPTN KPDPP, as 38 percent of OPTN KPD candidates are highly sensitized, and about 38 percent of candidate-donor pairs were still waiting after two years.

Establishing a requirement for annual donor re-evaluation will:

- Ensure donor information utilized in match runs is up to date
- Ensure that the donor pool participating in KPD match runs are actively able to donate
- Increase overall efficiency in the OPTN KPD system
- Improve the likelihood of match success

This proposal will establish a requirement for programs to annually re-evaluate OPTN KPD paired donors in order to maintain the donor's eligibility to participate in the OPTN KPD match runs. The re-evaluation requirements include informed consent, psychosocial evaluation, medical and social evaluation, and reporting requirements.

- Informed consent: programs will need to re-inform the donor per *Policy 13.4.C: Informed Consent for KPD Donors*, and obtain a signature from donors confirming they have been re-informed of their right to withdraw from participation at any time, for any reason
    - Policy 13.4.C: Informed Consent for KPD Donors will be updated to reflect that the donor may need to be re-evaluate
- Psychosocial evaluation: programs will be required to fully re-evaluate the donor's psychosocial health per Living Donor Policy 14.1: Psychosocial Evaluation Requirements for Living Donors
- Medical evaluation: programs will also be required to re-evaluate the donor's medical and social health, including:
    - General, kidney-specific, and social donor history – excluding genetic or family history
    - Physical examination

    - General laboratory and imaging tests
    - Metabolic testing
    - Kidney specific testing
    - Cancer screening
    - Transmissible and endemic disease screening and testing
        - CMV and EBV testing not required if previously positive
- Reporting requirements: programs must report to the OPTN any changes to the donor information required for match run eligibility as well as the date that donor re-evaluation was completed and relevant changes reported

The deadline for the donor's re-evaluation will be determined by whichever is most recent:

- The donor's date of registration in the OPTN KPD system
- The most recently reported date of completed re-evaluation

Programs will be notified of the donor's upcoming re-evaluation deadline 60 days prior to this date and will have up until 30 days after the donor's re-evaluation date to report a date of completed re-evaluation. Failure to report a date of completed re-evaluation after the 30 day window will result in the donor becoming ineligible to participate in OPTN KPD match runs. Donors will remain ineligible until their program reports a date of completed re-evaluation.

Blood Type Matching Policy Alignment

Current KPD policy is more stringent than Kidney policy, and sets specific anti-A titer requirements for candidate eligibility to accept A2 and A2B kidney offers. This alignment will:

- Improve general efficiency in the OPTN KPD system, by allowing programs to consolidate their processes for pursuing candidate eligibility to receive these offers
- Potentially increase matching opportunities for some blood type B and O candidates
- Require reconfirmation of candidate eligibility

This alignment will allow that kidneys from donors with blood types A, non-A1 may be matched with candidates with blood type B or blood type O, and kidneys from donors with blood types AB, non-A1B may be matched with candidates with blood type B, so long as all of the following criteria are met:

- Paired candidate's transplant program establishes written policy regarding titer threshold for these transplants
- Paired candidate's transplant program obtains written informed consent regarding willingness to accept blood type A, non-A1 or AB, non-A1B
- Paired candidate's transplant program must confirm candidate's eligibility every 90 days

<u>Summary of discussion:</u>

One member asked what current Kidney policy requires for blood type B candidates to opt in to receive blood type A, non-A1 and AB, non-A1B offers. Staff explained that current OPTN Kidney policy does not establish specific titer thresholds, and instead requires programs to establish their own written criteria regarding titer thresholds for transplanting A, non-A1 and AB, non-A1B kidneys into blood B candidates, obtain written consent from the patient regarding their willingness to receive and accept these offers, and reconfirm the patient's eligibility every 90 days. The member noted that specifying titer requirements is overly stringent, and agreed that it made sense to remove the specific titer thresholds from OPTN KPD Policy.

A member commented that they agree with the policy adjustments. The member noted that there are a lot of highly sensitized candidates in the OPTN KPDPP waiting for two years, and wondered if these candidates had been matched in that time period. The member asked, if that was the case, whether this proposal solves any issues preventing the candidate from being matched. Staff noted that candidate-donor pairs do match at two years in the OPTN KPDPP, and agreed that this proposal does not address every issue. Staff noted that the OPTN KPD Workgroup is proposing this with the idea that re-evaluation will reduce the chance that the donor is matched when the donor actually cannot donate. This proposal is intended to help prevent chains and exchanges from breaking. The member agreed, and expressed support for having up to date donor information.

The member shared that the OPTN KPDPP needs more major updates, and that the OPTN KPDPP could mirror some of the processes utilized by other KPD programs. The member suggested that a better process for a high CPRA candidate who has been in the KPD system for two years with a willing living donor would be to allocate a deceased donor kidney to that candidate and have the living donor donate to the list. The member added that living donation and deceased donation could be merged. The Vice Chair pointed out that the KPD Workgroup is currently working to update the OPTN KPDPP, particularly working through the policy language for areas of improvement and clarification. The Vice Chair agreed that more major updates are needed in the OPTN KPDPP, but added that this is one of the steps in the process to get there. Another member agreed. Staff shared that the Executive Committee has discussed longer term strategies and investment in the OPTN KPD program, and that the Board of Directors and the Health Resources and Services Administration are aware of these concerns.

The Vice Chair noted that this proposal makes sense, and that medical decisions regarding A, non-A1 and AB, non-A1B titer thresholds should be left up to programs.

One member asked if the donor re-evaluation requirement is aligned with other KPD programs' requirements. Another member noted that the proposed requirements are aligned with other programs, based on their experience.

The Committee voted unanimously in support of sponsoring the *Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* proposal for January 2023 public comment.

4. Recap and Next Steps: Longevity Matching

The Committee reviewed previous discussions regarding longevity matching in continuous distribution and received an update on next steps.

Presentation summary:

In the last few weeks, the Committee has discussed several options for the longevity matching attribute. The Committee is currently seeking Ethics Committee insight on the following questions:

- What should be the goal for the longevity matching attribute?
    - Achieve similar access for all Estimated Post Transplant Survival score (EPTS) groups?
    - Ensure access to transplant is similar to current policy (i.e. match lowest EPTS scores to lowest Kidney Donor Profile Index (KDPI) scores)
    - Increase access for specific EPTS groups? (ex. high EPTS scores to high KDPI scores)
    - Something else?
- Should any EPTS group have above average access?
- How should longevity matching be considered in comparison to other factors such as waiting time? Example: What if more equalized longevity matching results in longer waiting times for some EPTS groups?

Partners at the Massachusetts Institute of Technology will be building some trade-off curves to inform Committee discussion. Discussion will be revisited in an upcoming call.

Summary of discussion:

The Committee had no questions or comments.

5. Introduction and Discussion: CPRA

The Committee began discussions on the CPRA attribute rating scale.

Presentation summary:

Previously, the Kidney-Pancreas Continuous Distribution Workgroup agreed on a steep, non-linear scale for CPRA for both kidney and pancreas allocation, with a base of 100,000.

- The steep scale is intended to preserve priority for 99 and 100 percent CPRA candidates
- This attribute received a high value weight within both the kidney and pancreas AHP exercises
- Public comment feedback also showed support for a steep, non-linear scale and for high CPRA candidates to be given a heavy weight

In the modeling, CPRA weight ranged from 10 percent in the "Increased Longevity Weights" scenario to 15 percent in the "Combined AHP" and "High KDPI Efficiency Weights" scenarios. The Organ Allocation Simulator (OASIM) results showed:

- No substantial differences in the transplants rates for any of the CD policies compared to current policy for patients with CPRA less than 0.8
- For CPRA 0.8 to 0.98, transplant rates were notably lower for both the Increased Longevity Matching and All Donor Efficiency scenarios where the weight on CPRA was slightly lower, in comparison to current policy.
- For CPRA 0.98 to 1, all scenarios showed varying degrees of decreases in transplant rates as compared to current policy, with the largest decreases being seen in the All Donor Efficiency and Increased Longevity scenarios where less weight was placed on CPRA

Several questions were posed to help guide Committee discussion:

- What should be the goal for the CPRA attribute?
    - Achieve similar access for all CPRA groups (i.e. minimize the disparity between CPRA groups; i.e similar transplant rates across CPRA groups)
    - Ensure access to transplant is similar to current policy (i.e. CD does not make disparities in access to transplant worse than the current system)
    - Increase access (for example, transplant rates) for the very highly sensitized (CPRA > 98)
    - Something else?
- Should any CPRA group have above average access?
- Are any of the OASIM results concerning?
- Is there any additional information that would be helpful in making a decision on the weight or rating scale for the CPRA attribute?

Summary of discussion:

One member remarked that there is no reason why one CPRA group should have better access than the rest of the population. The member commented that the goal of this attribute should be restorative, to give harder to match candidates the same access as the rest of the transplant list. Other members agreed. The member noted that one could argue that higher CPRA candidates should have lower access on the basis of poorer graft survival, but that this doesn't seem appropriate in their opinion. The

member pointed out that current policy doesn't distinguish between CPRA 99.1 through 99.9 percent candidates, and that the Committee should try to be as granular as possible to ensure those candidates who really need that benefit receive it. Other Committee members agreed.

A member noted that what has been seen over the last eight years is that a lot of the 99.5 percent CPRA patients that have a rare chance of finding a donor are being transplanted at higher rates than other groups. The member noted that focus needs to be less on these candidates and more on the truly difficult to match candidates. The member pointed out that current policy gives CPRA 99.98 percent and CPRA 99.5 percent patients equal priority, and expressed support for distinguishing between those groups to give the highest CPRA, truly most difficult to match candidates, priority. The member added that the CPRA attribute is one component of the greater score, and that for these patients that realistically only have one donor offer in their potential life time, it will be important that the allocation system ensures these highest CPRA patients have access to that one donor kidney offer and are prioritized over other candidates regardless of other factors. Another member agreed.

One member expressed support for equalizing access to transplant across CPRA groups, noting that one group shouldn't have more or less access relative others if possible. The member noted that it will be challenging to develop the necessary mathematics to make that balance work, and that the Committee will need to determine where the necessary inflection points in the high CPRA ranges are. The member pointed out that it may be tenths of a point.

An SRTR representative asked if there is a standardized way to understand which patients are truly almost impossible to match beyond the CPRA number, noting that it's not always a perfect correlation. The SRTR representative commented that their program depends on their histocompatibility director to say whether it's a truly impossible match, as this guides whether their program accepts the organ or not. A member responded that there is currently a lot of discrepancy in how high the CPRA is versus the patients receiving acceptable offers. The member shared that some 99.98 percent CPRA patients receive two offers in two days, and that this shouldn't really be the case for a candidate with that high of a CPRA. The member explained that the current CPRA calculator is flawed, and that the newer CPRA calculator is set to go live soon, and will be truly more accurate about the patient's likelihood of receiving offers and compatibility. The member explained that the population statistics are better, and that the calculation itself will take into account for considerations. The member added that there is still some complexity where there are patients that may never get an offer, while others may have a better chance.

A member noted that access should be similar across CPRA groups, and wondered if there could be some kind of filter that would boost those highest CPRA, hardest to match candidates to the top of the match, without concern for the other factors. Another member noted that, similar to KDPI and EPTS, the Committee will need to work with the current version of the CPRA calculator until the newer one is implemented.

One member pointed out that the OASIM didn't look at these very highly sensitized patients, and that the Committee isn't able to differentiate how these different weights impact these groups as a result. The member noted that the next few iterations of modeling will need to focus on what happens with more granular CPRA categories at the high end, to understand how these weights do impact transplant rates for these groups. That will need to drive these decisions.

Staff summarized the Committee's discussion, such that the Committee aims to have priority for the highest sensitized, but that OASIM results were not granular enough amongst the highest CPRA groups.

One member pointed out that some patient are highly sensitized because they have already been transplanted, while other patients have not. The member asked if there is an ethical angle that could be

brought in with respect to those who have had a transplant versus those who haven't, to give priority to those candidates who have not been transplanted. The member asked if one group should have higher priority in the context of a limited resource, or if they should all be treated equally. The member acknowledged the difficulty of this question. Another member responded that, in their opinion, it comes down to medical need. The member continued that a prior transplant should not necessarily downgrade a patient's priority, as these patients are back in kidney failure and should have an equal chance at accessing transplant again. The member pointed out that some patients' transplants last only a few weeks or months, and that limited time out of kidney failure still results in increased sensitization. The member compared such a hypothetical patient to patients who have had a functioning graft for 20 years and now need a second transplant. A member agreed that, if the ethical question of prior transplant was in play, how long the graft survived would be an important consideration.

Staff noted that the current EPTS calculation utilizes prior transplant, so patients are affected by prior transplant in that way.

A member noted that, at the end of the day, the goal of transplant is to get patients off of dialysis, as time off of dialysis translates to greater lifespan. The member added that this goes back to some of the original tenets of continuous distribution. The member asked if the Committee is trying to equilibrate time off dialysis as a proxy of giving everyone an equal chance of a longer life.

Staff asked the Committee if they are comfortable with the steepness of the rating scale used in the modeling, which had a base of 100,000 and really only begins giving increased access at around 80 percent CPRA. This would be different from current policy. Staff noted that the Lung Committee utilized a CPRA curve with a base 100, which is less steep. Committee members expressed support for the base 100,000 CPRA curve that was used in the first SRTR modeling request. One member asked why Lung used a shallower curve, and another member clarified that one rationale for the base 100 CPRA curve is that, without a similar dialysis-like replacement for lung function, it is truly life-saving to provide additional priority in cases where patients don't have the same access.

6. Continuous Distribution Timeline Check-in

The Committee reviewed the timeline, and discussed best ways to encourage engagement and shared decision making.

Summary of discussion:

Staff asked the Committee how to best collect their thoughts to encourage and guide discussion. One member expressed support for receiving slides prior to the meeting, with highlighted areas for review and focus and specific items to review and consider ahead of the meeting. The member noted that surveys may not be easily completed on a weekly meeting schedule. Another member shared that keeping your camera on during the meeting is important, and encourages connection and engagement.

Upcoming Meetings

- December 19, 2022 - Teleconference

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Asif Sharfuddin
  - Bea Concepcion
  - Elliot Grodstein
  - Tania Houle
  - Caroline Jadlowiec
  - Jesse Cox
  - Marian Charlton
  - Marilee Clites
  - Oscar Serrano
  - Patrick Gee
  - Peter Lalli
  - Precious McCowan
  - Jason Rolls
  - Sanjeev Akkina
- **HRSA Representatives**
  - Jim Bowman
  - Adrienne Goodrich-Doctor
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Lindsay Larkin
  - Kayla Temple
  - Keighly Bradbrook
  - Kim Uccellini
  - Lauren Motley
  - Ross Walton
  - Ruthanne Leishman
  - Anne Paschke
  - Ben Wolford