OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
October 5, 2022
Conference Call

Marion Charlton, RN, SRN, CCTC, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 10/05/2022 to discuss the following agenda items:

1. Update KPD Policy: Public Comment Review
2. Discussion: Post-Public Comment Changes
3. New Project Idea

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

1. Update KPD Policy: Public Comment Review

Staff reviewed public comments and sentiment received on the *Update KPD Policy* proposal.

Presentation summary:

The proposal was supported across OPTN regions, stakeholders, and member types. In addition to support for the proposal, some substantive comments were submitted via the OPTN website. Comments were divided into the following themes:

Timelines and efficiency

There was general support for reduced timeframes and increased efficiency, as well as reduction to potential for and number of delays to an exchange. Some members expressed concern for administrative burden and a smaller program's ability to meet proposed deadlines. Additionally, there was overall support for maintaining the two business day preliminary response deadline as members felt this was sufficient time to adequately review and respond to offers.

There was general support for the 60 day deadline from match offer to transplant and recovery, with some stakeholders commenting the 60 day deadline was too long and others commenting it was too short. There was concern raised for requiring the surgeries to occur within a specific timeframe as it may be interpreted as pressure on the donor and does not allow flexibility in the case of an operating room being unavailable. Some commenters provided recommendations to require the surgery to be scheduled within 60 days or to require all programs in the exchange to agree upon a surgery date within a certain time frame.

Bridge donors, signatures, and informed consent

There was general support for increased emphasis on donor autonomy, as well as increased communication and patient understanding by allowing donors to make a determination of their own willingness to wait as a bridge donor.

The proposal received mixed feedback regarding the requirement for transplant programs to obtain a signature from the bridge donor on their willingness to wait. Commenters raised concerns that requiring a signature from a bridge donor on estimated willingness to wait could be interpreted as binding, rather than altruistic and voluntary. Further, there was concern a signature could be counter intuitive as informed consent is an ongoing, continuous conversation. Some recommendations included not requiring programs to obtain a signature from bridge donors and rather to confirm assessment of and education to the donor on bridge donation, and document that these conversations occurred. Additionally, commenters recommended transplant programs should be encouraged to establish and maintain a bridge donor policy that works for their program, patients, and providers.

There was general support for expanded language regarding financial risk and improved clarity in KPD informed consent policies. Some commenters recommended adding additional clarity to informed consent for bridge donors to review additional options if they choose not to continue in a KPD exchange. Another commenter recommended requiring transplant programs to disclose the presence of multiple KPD programs.

Program performance and extension requests

There was support for tighter deadlines with commenters noting this will improve efficiency of the OPTN KPD Pilot Program. Some commenters cautioned against making the OPTN KPD Pilot Program specific policies overly prescriptive so as not to disincentivize programs to participate.

There was overall support for proposed updates to the extension request policy. Some commenters also provided recommendations to reduce potential over-use of extension requests to include consideration for a maximum duration for the extension or a maximum of extension requests a program can submit.

Donor information sharing

There was overall support for standardizing proposed KPD information necessary for evaluation including support for requiring a donor's renal imaging to be shared and available to the match candidate's transplant hospital. Commenters also recommended making clinical donor information and evaluation records available at the time of preliminary offer and to require programs to maintain updated testing while pairs are active in the KPD registry.

Summary of discussion:

The Chair commented the proposal received excellent feedback. There were no additional questions or comments.

2. Discussion: Post-Public Comment Changes

Based on feedback received through public comment, the Workgroup discussed options for potential post-public comment changes to the proposal.

Summary of discussion:

The Workgroup first discussed the proposed timelines. Workgroup members agreed to maintain the two business day deadline for a preliminary response from offer as it was supported in public comment. Regarding the 60 calendar day deadline from match over to recovery and transplant, the Workgroup discussed the possibility of changing the requirement to instead agree upon a surgery date within 30 days. A member agreed with the recommendation to require decision on a surgery date within 30 days to promote efficiency, however was not supportive of removing the 60 day deadline to have the surgery itself. The member commented having a deadline for the completion of transplant reduces the chances of it being canceled due to other factors. The member suggested requiring the programs to agree on a

surgery date within 30 days, and then complete the transplant within the next 30 days. However, the member did recognize the concern for donor autonomy with requiring a specific transplant timeframe. Other members commented a deadline of 30 days to schedule the surgery would be too long and suggested shortening to 15 days after receiving crossmatch results, and then an additional 45 days to complete the surgery. Members commented 15 days from time of crossmatch may be difficult for small programs, and recommended a deadline of 25 days from time of match offer. The Workgroup supported a deadline to agree on a surgery date within 25 days of match offer.

The Workgroup discussed the proposed 60 day deadline to complete the transplant. A member commented a concern for extending the deadline provides opportunity for factors, such as a sensitization event, to complicate the exchange. The member commented the longer the timeframe, the higher the possibility of events that may cancel the exchange. The Chair commented they would support the 25 day deadline to agree upon a surgery date and within 60 days the transplant must be scheduled. The Workgroup supported this recommendation.

The Workgroup then discussed the proposed signature requirement for bridge donors. Based on public comment feedback, the Workgroup agreed to remove the proposed requirement for a bridge donor signature. Regarding options for bridge donors, Workgroup members supported requiring a conversation with those donors about available options should they choose to not donate to a KPD exchange.

The Workgroup also agreed with the recommendation to add "The below requirements apply to candidates participating in KPD programs unless otherwise specified" language to Policies *13.3: Informed Consent for KPD Candidates*.

3. New Project Idea

The Workgroup reviewed and discussed two potential new projects.

Presentation summary:

As part of the development discussions of the *Update KPD Policy* proposal, the Workgroup identified a new project aligning Policy *13.7.B: Blood Type A, non-A1 and Blood Type AB, non-A1B Matching* with the requirements outlined in Policy *8.5.D: Allocation of Kidneys by Blood Type*.

Current KPD policy sets specific anti-A titer requirements for candidate eligibility to accept A2 and A2B kidney offers. There is variability in what programs accept in terms of titer values. Current kidney policy requires programs obtain written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A1 or blood type AB, non-A1B type kidneys. Kidney policy also requires programs establish a written policy regarding its program's titer threshold for transplanting blood type A, non-A1 and blood type AB, non-A1B kidneys into candidates with blood type B. The transplant program must also confirm the candidate's eligibility every 90 days.

Another potential project that was suggested in public comment was to require programs to regularly re-evaluate donors. Current KPD policy does not require this and donor and candidate information in the KPD system becomes outdated, reducing the quality and success of these matches.

Summary of discussion:

The Workgroup supported a new project to require donor re-evaluation. The Chair commented this is crucially important to match offers.

For the blood type policy alignment project, the Workgroup supported including blood type O candidates into the requirements as these candidates are often disadvantaged in KPD. Members asked if

“written informed consent” language excludes consent submitted electronically. Staff commented they will clarify and follow-up on a future meeting as “written” may be a surrogate for “documented”. The Workgroup supported the eligibility confirmation window of every 90 days.

The Workgroup supported sending both projects to the OPTN Kidney Transplant Committee for endorsement.

Upcoming Meeting

- October 18, 2022

Attendance

- **Workgroup Members**
  - Marian Charlton
  - Aneesha Shetty
  - Stephen Gray
  - Valia Bravo-Egana
- **HRSA Staff**
  - James Bowman
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Meghan McDermott
  - Megan Oley
  - Katrina Gauntt
  - Ruthanne Leishman
  - Jennifer Musick
  - Ross Walton
  - Alina Martinez