

**OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
April 18, 2022
Conference Call**

Peter Kennealey, MD, FACS, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 04/18/2022 to discuss the following agenda items:

1. Welcome and Review
2. Update on Committee Feedback
3. Data Request – Decline due to Unacceptable Antigens
4. Rationale Discussion

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

1. Welcome and Review

The Workgroup reviewed the policy modification categories used to estimate project size and organize potential KPD policy modification projects.

Summary of discussion:

The Workgroup had no questions or comments.

2. Update on Committee Feedback

The Workgroup received an update on feedback provided by the Histocompatibility, Living Donor, and Transplant Coordinator Committees.

Summary of Feedback:

Histocompatibility Policies, Recommendations, and Topics:

- 13.5.A and 13.5.C: HLA Typing Requirements for OPTN KPD Candidates and Donors
- 13.5.D: Responding to OPTN KPD Match Offers
- Data Request Upcoming: Declines due to Unacceptable Antigens
- 13.10: OPTN KPD Crossmatching Requirements
- High Resolution Typing

Histocompatibility Committee feedback:

- Approval of maintaining requirement for a physical crossmatch
- Recommendation to provide guidance encouraging auto-crossmatching, to reduce potential for false positive physical crossmatch
 - This will likely be addressed in the Histocompatibility Committee's policy update project

Informed Consent Policies and Recommendations:

- 13.4.B: General KPD Donor Informed Consent

- 13.4.C: Additional Requirements for KPD Donors
- 1.2: Definitions (Bridge Donor)
- 13.4.E: Additional Requirements for Bridge Donors

Living Donor Committee Feedback:

- The modified definition of a bridge donor may be beneficial for increased clarity
- Agreed with aligning financial risk language in 13.4.E with that found in living donor policy
- Considered clarifying the role the matched candidate’s insurance plays in reimbursement, but decided that broadness provided by the language alignment is sufficient

Administrative Policies, Recommendations, and Questions:

- 13.1: Candidate Requirements for Participation
- 13.11: Receiving and Accepting KPD Match Offers – Shortening key deadlines
- 13.11.A: Requesting a Deadline Extension for a KPD Exchange

Transplant Coordinator Committee Leadership Feedback:

- 1 business day may not be an adequate amount of time to review an exchange and could result in programs defaulting to a provisional acceptance and subsequently declining
- 2 business days provides enough time to review clinical information in detail
- A scorecard could be helpful, but would need to be delivered in a non-punitive way
- A 60 day deadline from time of match offer to time of transplant is too long – 45 days is appropriate
- Over-use of exception requests could be discouraged by providing a guideline as to what type of exception requests are appropriate

3. Data Request – Decline Due to Unacceptable Antigens

The Workgroup discussed and voted to approve a data request on the decline due to unacceptable antigens data collected under the Policy 13.5.D.ii: *Responding to OPTN KPD Match Offers*.

Summary of data request:

Policy 13.5.D.ii : “When an OPTN KPD match offer is declined due to either a positive crossmatch or unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must submit a written explanation to the OPTN Contractor within 7 days after declining the offer”

- Follow up surveys collected to provide explanation regarding decline of a match due to positive crossmatch or unacceptable antigens
- The Workgroup recommended reviewing the data collected to determine if this requirement is still necessary, and if so, establish a regular review process

Request will evaluate refusal due to crossmatch follow up responses through the Match Decline Follow Up survey from KPDP transplant programs, beginning January 2016 through December 2021

The following metrics will be evaluated:

- The proportion of crossmatch declines based on
- The presence of multiple, lower level antibodies for which the corresponding antigens were not listed as unacceptable in the virtual cross match
- The presence of allele specific antibodies
- The distribution of the unacceptable antibodies or the allele specific antibodies identified in declines

- The proportion and count of the listed responses provided for candidate antibodies specific for those donor antigens
- The proportion of declines where the date for the serum sample screening with results reported at the time of the offer differed from the date of the serum sample which the decline is based on
- The proportion refusals where the unacceptable antigens were identified in an updated serum sample screening crossmatch from the original crossmatch provided at time of offer
- The distribution of refusals with donors prescreened and the pre-selected responses provided

VOTE:

The Workgroup unanimously approved the submission of the Decline due to Unacceptable Antigens Data Request.

4. Rationale Discussion

The Workgroup reviewed their proposed policy updates and discussed the rationale for each change.

Presentation summary:

The Workgroup has discussed minor updates to several policies, including:

- 1.2: Definitions (Bridge Donor)
 - Potential new language: “A Kidney Paired Donation (KPD) donor at the end of a KPD chain who will be in future match runs”
- 13.1: Candidate Requirements for Participation
 - Recommendation to maintain language and update education and resources to clarify candidates are not automatically inactivated in KPD
- 13.4.C: Additional Requirements for KPD Donors
 - Recommend alignment with living donor policies with respect to financial risk language
 - Emphasize the paired donor’s transplant hospital must inform the paired donor of the right to withdraw from participation in the KPD program at any time or any reason
- 13.4.D: Additional Requirements for Non-Directed Donors
 - Clarification that this policy applies to NDDs entering the OPTN KPD Program only
 - Recommendation to include cross reference to this policy in Policy 14.6.B: Placement of Non-Directed Living Donor Organs
- 13.4.E: Additional Requirements for Bridge Donors
 - Simplify the language so that policy ensures the program has explicit conversations with the bridge donor on expectations, and informing the living donor that they have the option to determine how long they are willing to wait
 - Maintain requirement for transplant hospital to document in the donor’s medical record how long the donor is willing to be a bridge donor
- 13.11: Receiving and Accepting KPD Match Offers
 - Shorten deadlines and establish a new deadline for time to transplant
- 13.11.A: Requesting a Deadline Extension for a KPD Exchange
 - A non-response to an extension request shouldn’t default to a denial of the request and termination of the exchange; a non-response should default to approval
 - Workgroup also discussed ways to discourage over-use of extension requests

Summary of discussion:

The Workgroup discussed whether non-responses should continue to result in an automatic denial of an extension request per Policy 13.11.A. Workgroup members commented a non-response could be for various reasons (ex. additional lab testing) and should default to an approval out of fairness to the patient.

The Workgroup then discussed the potential adjustments to response deadlines under Policy 13.11. The Chair commented the deadline adjustments are reasonable as current timelines in policy are too long. The Chair further commented it's important to keep both patients and the efforts of coordinators in mind when considering these adjustments. Another Workgroup member commented the deadlines as outlined in current policy are too long and the adjustments as proposed are sufficient. The member further commented the longer the timeline from start to finish is, the higher the chance of a KPD chain falling apart. Workgroup members agreed with adjusting the preliminary response deadline to one business day, agreement on crossmatching and other testing within three business days of receiving the match offer, and reporting of crossmatching results and acceptance or refusal of match within 10 business days. Additionally the Workgroup agreed the time from match to transplant should be 60 business days.

The Workgroup agreed with the adjustments to KPD informed consent policies and the adjusted definition of "bridge donor" under Policy 1.2. Additionally, the Workgroup agreed with simplifying language under *Policy 13.4.E: Additional Requirements for Bridge Donors* to ensure programs have explicit conversations with bridge donors on expectations and how long a donor can expect to wait vs. how long they are willing to wait before undergoing surgery. The Workgroup also agreed with maintaining the requirement for transplant programs to document how long the donor is willing to wait and any modifications as the donor may change their mind throughout the process.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
 - Peter Kennealey
 - Aneesha Shetty
 - Camille Rockett
 - Justine Van der Pool
 - Marion Charlton
 - Nancy Metzler
 - Valia Bravo-Egana
 - Vineeta Kumar
- **HRSA Staff**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Peter Stock
- **UNOS Staff**
 - Lindsay Larkin
 - Ruthanne Leishman
 - Meghan Oley
 - Kayla Temple
 - Ross Walton
 - Meghan McDermott
 - Anne McPherson
 - James Jobes
 - Jennifer Musick
 - Katrina Gauntt
 - Kerrie Masten
 - Leah Slife
 - Melissa Lane