

**OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
February 28, 2022
Conference Call**

Peter Kennealey, MD, FACS, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 02/28/2022 to discuss the following agenda items:

1. Welcome and Review
2. Update on Focus Group Progress
3. Project Planning and Next Steps

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 Committee had no questions or comments.

2. Update on Focus Group Progress

The Workgroup received an update on the Histocompatibility, Administrative, and Informed Consent Focus Groups' discussions and recommendations.

Histocompatibility Focus Group discussion summary:

- Policies 13.5.A *Human Leukocyte Antigen (HLA) Typing Requirements for OPTN KPD Candidates* and 13.5.C *HLA Typing Requirements for OPTN KPD Donors* – the Histocompatibility Focus Group (the Focus Group) proposed no changes to these policies, as the implementation of the Update Human Leukocyte Antigen (HLA) Equivalency Tables project will update these policies for the inclusion of locus HLA-DPA1
- Policy 13.5.D *Responding to OPTN KPD Match Offers*– The Focus Group recommended reviewing the data regarding explanations of declines for unacceptable antigens to determine if this requirement is still needed. If this policy is still necessary, a regular review process should be established to continue monitoring the data, to ensure the policy is still relevant.
- Policy 13.7.B *Blood Type A, non-A1 and Blood Type AB, non-A1B* – The Focus Group recommended updated the antibody titer requirement to match the language in Kidney Policy 8.5.D *Allocation of Kidneys by Blood Type*, which requires transplant programs to establish their own written policy and reconfirm titers every 90 days.
 - Since that meeting, it was determined that these changes would have a system impact and require changes to data collection requiring approval from the Office of

Management and Budget (OMB). Staff recommends that this modification is separated into its own project since implementation timelines will be different.

- Policy 13.10 *OPTN KPD Crossmatching Requirements* – The Histocompatibility Committee has discussed this previously, and supported maintain the requirement for a physical crossmatch. The Focus Group agreed, and felt that the virtual crossmatching is not sensitive enough, and the investment of a physical crossmatch is valuable in the context of maintaining KPD chains.
 - The Focus Group discussed high resolution typing, and felt that requiring high resolution typing could considerably disadvantage smaller laboratories with limited access. The Focus Group also felt that high resolution typing isn't necessary if there is a physical crossmatching requirement.

Summary of discussion:

The Chair agreed that KPD policy regarding blood type A, non-A1 and blood type AB, non-A1B should match that in kidney policy. The Chair asked if that programming could be mapped into KPD. Staff explained that these system changes could be more complicated and typically require specific system changes, testing, and validation processes.

One member asked if current KPD policy sets a 90 day titer update requirement, and staff clarified that KPD anti-A titer policies do not set titer update requirements. The member noted that transplant hospitals typically vary in what titers they are willing to work with for ABO incompatible transplants, and that restricting titers to 1:8 excludes candidates from transplant programs willing to tolerate 1:16 with desensitization procedures. Another member agreed, adding that alignment with kidney anti-A titer policy would be critical to consistency and standardization. Another member agreed.

Staff clarified the programming impact of updating the titer policy would likely require this update to become a separate, individual project.

Administrative Policies Focus Group discussion summary:

- Policy 13.1 *Candidate Requirements for Participation* – the Administrative Focus Group (the Focus Group) discussed specifying that the candidate must be registered and active on the deceased donor waitlist in order to be active on the KPD waitlist, such that a candidate inactive on the deceased donor waitlist and unavailable for transplant must also be inactive in the KPD program. The Focus Group noted that there could be cases where it is appropriate for a candidate to be inactive on the deceased donor waitlist and kept active on the KPD waitlist. The Administrative Focus Group recommended maintaining the current language and instead update education and resources to clarify that candidates inactivated in DonorNet® are not automatically inactivated in KPD.
- Policy 13.11 *Receiving and Accepting KPD Match Offers* – The Administrative Focus Group recommended shortening the match offer response time deadline to one business day. The Focus Group felt that the KPD program should be more aggressive, and supported shortening deadlines over all.
 - The Administrative Focus Group recommended establishing a 60 day time frame deadline from match offer to transplant.
 - The Administrative Focus Group also recommended developing a scorecard for programs to indicate where the program did and did not meet deadline requirements.
- Policy 13.11.A *Requesting a Deadline Extension for a KPD Exchange* – The Focus Group discussed extension requests and ways to discourage over-reliance on extension requests. The Administrative Focus Group also recommended removing the final sentence from the policy

language, so that an extension request does not default to a denial of request if a transplant program does not respond.

Summary of discussion:

The Chair recommended adding a check box to the Waitlist, so that a coordinator updating a candidate's listing to Status 7 (inactive) could opt into similarly updating the candidate's KPD listing. Staff explained that, due to the KPD program's status as a pilot program, the KPD program must remain isolated from the other UNetSM applications. The Chair expressed support for adding education or a clarification to Waitlist that the KPD listing must be manually inactivated separately from the listing in Waitlist. The Chair noted that this will need to be explicit.

Informed Consent Policies Focus Group

- The Informed Consent Focus Group (the Focus Group) determined that no updates were necessary in Policy 13.3 *Informed Consent for KPD Candidates*
- Policy 13.4.B *General KPD Donor Informed Consent* – the Focus Group recommended including language to reference living donor informed consent policy, such that KPD programs are also required to consent KPD donors per the Living Donor Policy 14.3 *Informed Consent Requirements*
 - Policy 14.3 requires education on living donation and recipient processes, donor rights, information on psychosocial and medical evaluation requirements, disclosure of risks, and hospital specific transplant recipient outcomes and organ survival data
- Policy 13.4.C *Additional Requirements for KPD Donors* –The Focus Group recommended modifying the policy language to align with that of Policy 14.3, which includes wider language regarding potential financial risk
 - The Focus Group also recommended emphasizing the requirement for transplant hospitals to inform the paired donor of their right to withdraw at any time, potentially by requiring donor signature
- Policy 13.4.D *Additional Requirements for Non-Directed Donors (NDD)* – the Focus Group recommended including language to clarify additional requirements specified in 13.4.D applies only to non-directed donors entering the OPTN KPD Program
 - The Focus Group also recommended adding a cross reference in both Policy 13.4.D and Living Donor Policy 14.6.B *Placement of Non-directed Living Donor Organs*, to alleviate confusion as to which policies apply to KPD donors and non-KPD living donors
- Policy 1.2 *Definitions*, Definition of Bridge Donor – The Focus Group felt that the current language is unclear, and that specifying that a bridge donor continues a chain in a future match run is too prescriptive, as bridge donors may choose to donate to the deceased donor list
 - The focus group considered the following language: “A KPD donor at the end of a KPD chain who will be in future match runs”
- Policy 13.4.E *Additional Requirements for Bridge Donors*, Requirement 4 – the Focus Group agreed that it can be difficult to determine how long a bridge donor should expect to wait before undergoing surgery, particularly as it varies based on donor characteristics. The Focus Group recommended simplifying this policy to ensure the transplant hospital has explicit conversations with the bridge donor regarding expectations and informing the donor that they have the option to determine how long they are willing to wait

Summary of discussion:

One member remarked that tracking signatures can be difficult for documentation, particularly in terms of physical signatures. The member also pointed out that informed consent is an ongoing and

continuous process, and shouldn't be pinned down to one particular point in time. The member suggested documenting conversations with donors to ensure they are properly informed and aware.

3. Project Planning and Next Steps

The Workgroup reviewed the project timeline and next steps for the KPD policy review project.

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