OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
November 15, 2021
Conference Call

Peter Kennealey, MD, FACS, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 11/15/2021 to discuss the following agenda items:

1. Review of Project Goals: Update KPD Policy
2. Review of OPTN KPD Policy and Potential Modifications

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

1. Review of Project Goals: Update KPD Policy

The Workgroup reviewed the main project goals.

Data summary:

The main goals of the Workgroup include:

- Removal of the KPD Operation Guidelines – approved by the OPTN Kidney Committee on October 18, 2021
- Review existing KPD policy to:
  - Ensure alignment with other OPTN policies
  - Identify areas in need of clarification
  - Identify potential items for future Workgroup projects

Summary of discussion:

The Workgroup had no questions or comments.

2. Review of OPTN KPD Policy and Potential Modifications

The Workgroup reviewed OPTN KPD policy and discussed potential modifications.

Data summary:

Potential modifications to policy range in size and data or information technology (IT) impacts. Smaller modifications are minor language changes with broad consensus, light data review, and input from other OPTN Committees as needed. Larger modifications include substantial language changes that require data report building and consultation with stakeholders and subject matter experts. Depending on resources required, these have the potential to become their own projects with separate workgroups. Data-related modifications include projects that would have an IT impact, require Data Advisory Committee processes, and could potentially require Office of Management and Budget (OMB) approval.

Policy 13.3: Informed Consent for KPD Candidates and 13.4 Informed Consent for KPD Donors apply for all KPD programs. All other sections of Policy 13 are specific to the OPTN KPD Program, and include requirements on candidate and donor participation, histocompatibility testing and crossmatching, matching processes including screening criteria, receiving and accepting offers, transportation, logistical requirements, etc.

Recommended modifications focus on OPTN KPD program specific policies, then move to broader informed consent policies. Modifications include staff recommendations based on alignment with other OPTN policies and feedback from program participants and recommendations submitted by the KPD Advisory Council.

Smaller recommended modifications for the Update OPTN KPD Policy Project include:

- 13.1 Candidate Requirements for Participation
    - Feedback to specify "registered as active or inactive on the deceased donor waitlist" and add new language to require candidates that are inactive on the waitlist and unavailable for transplant but also be inactive in the KPD program
- 13.3 Informed Consent for KPD Candidates 13.4 Informed Consent for KPD Donors
    - Recommendations to highlight and clarify that these policies apply to all KPD programs, with additional education efforts. This could utilize input and involvement from the Living Donor Committee to ensure alignment with current informed consent requirements in living donor policy
- 13.5 OPTN KPD Histocompatibility Testing
    - Human Leukocyte Antigen (HLA) requirements need to be updated. The Histocompatibility Committee should be requested to provide feedback and recommendations to ensure alignment with other HLA requirements
    - Policy currently specifies a physical crossmatch be performed as opposed to a virtual, and many centers don't do physical crossmatch until the final crossmatch. Policy doesn't specify that the initial crossmatch must be physical, but that is typically how it's interpreted. The KPD Advisory Council recommended removing the requirement for a physical crossmatch prior to scheduling recovery, as many centers have transitioned to virtual crossmatch
- 13.7.A: Blood Type and 13.7.B Blood Type A, non-A1, and Blood Type AB, non-A1B matching
    - These sections could benefit from OPTN Histocompatibility Committee input. Additionally, there have been requests to allow ABO mismatching
    - 13.7.B will need to be updated to align with Deceased Donor blood type policy, which has been updated since implementation of this policy
- 13.7.G OPTN KPD Waiting Time Reinstatement
- 13.10 OPTN KPD Crossmatching Requirements
- 13.11 Receiving and Accepting KPD Match Offers
    - Recommendation to tighten up deadlines for responsibilities upon receiving a KPD match offer. For example, adding an end date or shortening match offer response, which is currently 2 days.
    - Recommendations to reduce extensions

Larger modifications and potential new projects include:

- 13.7.E Donor Pre-Acceptance and Pre-Refusal and 13.7.F OPTN KPD Prioritization Points
    - There is currently a pilot project looking into prioritizing candidates based on likelihood to match. Research will be working on 2 year post-implementation evaluation to be

released in January, at which point the Workgroup could evaluate the current prioritization points, especially for pediatric and prior living donor candidates
- o Pre-acceptance and pre-refusal have been requested to be required for all candidates, not only highly sensitized candidates. Others disagree, as it can be time consuming and could be burdensome Depending on the modifications, this could become a larger project
- 13.8 Two and Three-Way Matches
  - o Recommendation to update the way two and three way matches operate
- 13.9.B Logistical Requirements for Donor Chains
  - o Recommendation to update logistical requirements to edit for efficiency. Depending on the level of updates, this could become a larger project

Data related modifications that could become part of a future data streamlining project include:

- 13.6.A Requirements for Match Run Eligibility for Candidates
  - o Recommendation to add a new section detailing a process for centers with prior living donor candidates, and create a process for centers to submit that information through the organ center to give a candidate prior living donor priority
- 13.6.B Requirements for Match Run Eligibility for Potential KPD Donors
  - o Advisory Council recommended mandatory updating of these requirements on an annual basis. There could be potential Information Technology (IT) programming with this recommendation

<u>Summary of discussion:</u>

The Chair remarked that the second requirement of 13.2, "potential KPD donors must… not be currently registered as a potential KPD donor for any other candidate registered in the OPTN KPD Program," is misleading and confusing in the case of non-directed donors, who don't have an intended recipient. Staff agreed that non-directed donors are not linked with any candidate, and noted that there is currently no issue with donors coming in with more than one candidate. Staff added that this requirement doesn't necessarily need to be removed or changed. A member commented that the current language implies that a potential living donor would need to be registered for one candidate, and altruistic (non-directed) donors wouldn't be registered with any candidate. The member suggested updating the policy language to "not currently registered as the potential donor for more than one candidate." The Chair agreed. One member expressed that further discussion is needed, noting that a well-worded and descriptive check box could ensure appropriate indication of prior living donor priority. A discrete field be important for data collection down the line, particularly if selecting "yes" prompted additional questions regarding when a kidney was donated and to which intended recipient. Staff shared that there is a system on the deceased donor side for verifying that the candidate was a prior living donor, which could be modeled in KPD to ensure a candidate is listed properly in KPD as well. The member agreed, pointing out that centers are familiar with the deceased donor candidate wait listing practices to verify the candidate was a prior living donor, and a streamlined process for all types of data systems could be advantageous here.

The Chair pointed out that virtual crossmatches are typically performed when the match run is created, then a physical crossmatch is performed in anticipation of a scheduled operation. The Chair continued that practices are ever changing, and asked the Workgroup whether the language of "physical crossmatch" and "final crossmatch" need to be specified. If technology improves with virtual crossmatching and the results become more heavily relied upon, another policy update could be indicated. The Chair recommended utilizing only "crossmatch." A member remarked that most labs will

perform virtual crossmatches if there is no concern about historical antibodies. The member continued that physical crossmatches are important for highly sensitized patients. The Chair agreed, and noted that whether or not policy mandates physical crossmatch, any updates to policy shouldn't need to be updated again later on. Another member agreed, pointing out that the policy intends to provide overarching guidance to centers without catering to individual preferences. The language of solely "crossmatch" assumes that a crossmatch is needed, and the assumption is that a center would perform a physical crossmatch if the patient is highly sensitized, per standard general practice. The member continued that as virtual crossmatch technology becomes more reliable and histocompatibility becomes more advanced, there is a high likelihood that some KPD transplants are performed without a physical crossmatch. The language of "crossmatch" includes the concept of crossmatch without limiting center practice and variability. The Chair agreed.

Staff pointed out that data streamlining updates could affect screening requirements.

The Chair asked for clarification on IT programming for recommended updates for 13.6.B, and Staff clarified that the system could require eligibility information to be updated within certain timeframes.

A member asked what would happen if a donor has been registered for a year without update to eligibility information, and if that donor profile expires or can still appear on KPD match runs. Staff responded that donors can still be matched, but end up needing updated testing, which prolongs time to match to surgery and increases the chance that something will occur that will cause an exchange to fall apart. The member remarked that mandating annual updating will need to be particular in terms of what information needs to be updated, so that requirements are not restrictive of current center practices.

The Chair commented that it would make sense to prescreen regardless of sensitization, as there are many scenarios where a candidate and donor would be poorly matched. A 25 year old candidate with a 0 percent calculated panel reactive antibody (CPRA) would not be likely to take a 60 year old donor kidney. Another member agreed, noting that this could reduce the likelihood of swap failures, particularly because of poor matching. The Chair noted that this would be important in conjunction with the prioritization points. The Chair pointed out that current KPD is incongruent with the new Kidney allocation system. The member agreed.

The Chair recommended eliminating restrictive requirements and policies in the updates to KPD policy project. The Chair pointed out that policy 13.8.B's requirement that "each matched donor recovery must be scheduled to begin within 24 hours at the start of the previous matched donor recovery" is not practical. The Chair remarked that there shouldn't be an update to policy with such high likelihood of violation, particularly with bridge donors. Staff remarked that this policy affects 2 and 3 way exchanges, which bridge donors are not a part of.

The Chair suggested discussing the smaller modifications first, and then working on the larger projects later on. The Chair asked how to best collaborate with the Histocompatibility Committee. Staff shared that leadership from relevant OPTN committees can join Workgroup calls as specific sections are discussed, such as Living Donor Committee representation in discussing informed consent.

The Chair remarked that updates to 13.7.E Pre-Acceptance and Pre-Refusal policies could be a paradigm shift for the OPTN KPD program and potentially a big undertaking, but based on feedback, be very feasible. The Chair continued that 13.8 Two and Three Way Matches and 13.9.B Logistical Requirements for Donor Chains projects could be developed in tandem as a medium sized project.

Staff shared that once the smaller modifications have been discussed and developed, prioritization of other projects can be discussed. Additional data needs could come out of the smaller modifications.

A member recommended that the Workgroup break up into smaller groups to tackle some of the smaller modifications, and then bring them back to the group at large. The Chair agreed with this suggestion.

Upcoming Meeting

December 13 – Teleconference

Attendance

- **Committee Members**
  - Peter Kennealey
  - Aneesha Shetty
  - Jim Kim
  - Justine Van Der Pool
  - Marion Charlton
  - Nancy Metzler
  - Stephen Gray
  - Valia Bravo-Egana
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Lindsay Larkin
  - Ruthanne Leishman
  - Anne McPherson
  - Jennifer Musick
  - Katrina Gauntt
  - Kayla Temple
  - Kerrie Masten
  - Leah Slife
  - Megan Oley
  - Meghan McDermott
  - Melissa Lane
  - Nicole Benjamin
  - Ross Walton