OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
May 16, 2022
Conference Call

Peter Kennealey, MD, FACS, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 05/16/2022 to discuss the following agenda items:

1. Welcome and Review
2. Update on Stakeholder Committee Feedback
3. Finalize Project Recommendations
4. Deadline Adherence and Accountability Discussions

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 OPTN Histocompatibility, Living Donor, and Transplant Coordinator Committees.

Summary of Feedback:

Patient Affairs Committee Feedback:

- Support for expanded financial risk disclosure, to align with OPTN Living Donor policy
- Recommendation to include disclosure of possible psychological outcomes
- Strong support to require programs to inform KPD donors that external resources may be available to defray costs
    - Recommended disclosure of other external resources for mental health and other issues living donors should consider prior to donation, such as updating life insurance policies
- Signatures acknowledging informed consent are important, as are documented ongoing conversations
    - Informed consent must occur well in advance of entering the OR, in which prospective donors are not under stress or otherwise distracted
- Informed consent and potential living donation conversations should include the possibility of becoming a bridge donor and related processes

Transplant Coordinator Committee Feedback:

- Shorter deadlines could be harmful to smaller centers who have limited staff dedicated to KPD
    - Recommendation to have coordinator staff who typically take deceased donor offers step in for KPD Offers
- Support for two business days between preliminary response and crossmatching agreements/donor records sharing
    - General support for shortened deadlines, including 60 days from match offer to transplant
- Agreement that non-response should default to an approval
- Recommendation to define appropriate exception requests so there are clear expectations
    - Recommendation to review trends for programs requesting extensions

Transplant Administrator Committee Feedback

- Support for shortened deadlines, with emphasis on accountability and expectations
- Support for 60 calendar days to transplant target, particularly with avenue for extension request
    - Concern that "deadline" connotes potentially heavy consequences, which could dis-incentivize participation in the OPTN KPD
    - Discouraged any kind of punitive action for programs who don't meet the deadline
- Recommendation to consult patients on their thoughts regarding these deadlines
- Support for updating the current extension request policy, such that a non-response defaults to an approval of the request

Summary of discussion:

The Chair noted that the proposed shortened deadlines are in alignment with current typical workflows, and that the coordinator feedback reflects this.

The Chair clarified that the match offer to transplant target should be 60 calendar days, not 60 business days.

A member expressed concern about the Transplant Coordinator Committee's recommendation to have deceased donor organ offer call staff take offers for KPD offers. The member explained that KPD requires a different skill set, and deceased donor call coordinators may not be familiar enough with KPD offers. The member pointed out that many centers use organ offer call services, and that coordinators on these services are not familiar enough with the patients to accept KPD offers. Staff noted that it would be difficult to write anything like that into a policy, but that stakeholder committee feedback includes considerations and recommendations on how a policy could work practically. Staff added that the Workgroup can document rationale for disagreement with those recommendations. The member remarked that the recommendation could work, but would need to be worded differently so that deceased donor call staff weren't specified. The member continued, recommending smaller programs have KPD-trained back up staff. Another member agreed, adding that the Transplant Coordinator Committee generally wanted to recommend that smaller programs that may be concerned about deadlines organize some sort of back up staff. Staff shared that the OPTN KPD Pilot Program (KPDPP) requires a primary and alternate contact, in case the primary is unavailable.

3. Finalize Project Recommendations

The Workgroup finalized their recommendations

Data summary:

The Workgroup discussed changes to 10 KPD policies:

- 1.2: Definitions (Bridge Donor)
    - Update language to be inclusive of Bridge Donor options
- 13.3: Informed Consent for KPD Candidates
    - Include specification that these policies apply to candidates in any KPD program
- 13.4: Informed Consent for KPD Donors
    - Include specification that these policies apply to donors in any KPD program
- 13.4.C: Additional Requirements for KPD Donors
    - Expand financial risk language to align with that in Living Donor policy
- 14.6.B: Placement of Non-Directed Living Donor Organs (Living Donor Policy)
    - Cross reference with 13.4.D Additional Requirements for Non-Directed Donors
        - Clarify this policy applies to non-directed donors entering KPD only
- 13.4.E: Additional Requirements for Bridge Donors
    - Simplify language, to ensure the program has explicit conversations with the bridge donor on expectations and informing the donor they have the option to determine how long they are willing to wait
    - Emphasize bridge donor may determine and revise the estimated amount of time they are willing to be a bridge donor
- 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates
    - Minor formatting corrections
- 13.7.G: Waiting Time Reinstatement
    - Minor language change, to align with kidney waiting time reinstatement Policy 3.6.B.i: *Non-function of a Transplanted Kidney*
- 13.11.A: Requesting a Deadline Extension for a KPD Exchange
    - Update policy such that a non-response by any transplant program in the exchange defaults to an approval of the request
- 13.11: Receiving and Accepting KPD Match Offers
    - Updated timelines recommended, to improve efficiency:
        - Within 1 business day of receiving match offer: report preliminary response
        - Within 3 business days of receiving match offer:
            - Agreement on contents in crossmatch kit, donor instruction, address for blood sample transport
            - Report agreed upon date of crossmatch to the OPTN
            - Make donor records accessible to candidate's transplant hospital, including serologic/nucleic acid testing (NAT) results, Public Health Service (PHS) risk criteria, and any additional records requested
        - Within 10 business days of receiving match offer:
            - Report to the OPTN the results of the crossmatch
            - Review the donor's records and confirm acceptance or report refusal of match offer to OPTN
        - Within 60 calendar days of receiving match offer: matched donor kidney recovery and matched candidate transplant

Summary of discussion:

13.4.D Additional Requirements for Non-Directed Donors and *14.6.B: Placement of Non-Directed Living Donor Organs*

The Chair asked for clarification on both non-directed donation policies. Staff explained that Policy 14.6.B: *Placement of Non-Directed Living Donor Organs* requires programs with a non-directed donor

donating to the deceased donor waiting list to contact the OPTN and request a match run to allocate the non-directed donor kidney. This requirement does not apply to non-directed donors in KPD programs. Staff explained that the recommendation is to add language to Policy 14.6.B to reduce confusion as to whether this applies to non-directed donors in KPD programs. This would mirror the current reference to Policy 14.6.B that exists in Policy 13.4.D: *Additional Requirements for Non-Direct Donors*.

One member asked if there is any requirement for non-directed donors to be educated on their donation options, including entering into a KPD program or donating to the deceased donor waiting list. The Chair remarked that there is a similar requirement in several places that living donors must be given a comprehensive understanding of what options they have as a potential donor, but that this may be a CMS requirement. Staff clarified that there is a requirement to educate potential non-directed donors on all of their donation options in KPD Policy 13.4.D: *Additional Requirements for Non-Directed Donors*. This policy requires the transplant program to document in the non-directed donor's medical record that the donor has been informed of all their donation options, including KPD, donating to the deceased donor waiting list, and any other options available to the donor.

13.4.E Additional Requirements for Bridge Donors

One member expressed support for increasing emphasis on the donor's willingness to wait, and noted that the donor's autonomy should be a priority.

13.7.G: Waiting Time Reinstatement

A member remarked that this is a simple, sensible change.

13.11: Receiving and Accepting KPD Match Offers

One member expressed support for the three business day, ten business day, and 60 day deadlines, but shared concerns about reducing preliminary offer response deadline to one business day. The member pointed out that there is very little redundancy, and programs with few KPD-trained staff may not be able to respond in time if the match offer was sent on a Friday. Another member agreed. Staff shared that the OPTN KPDPP doesn't run match runs on Fridays for that reason.

A member asked what the expected efficiency benefit would be from reducing the preliminary response deadline by one business day, emphasizing that this deadline could be a problem for smaller programs who only have one or two staff who oversee the KPD program. Another member remarked that this would be a bigger issue for smaller programs, and could discourage expansion of the OPTN KPDPP. A member shared their current KPD program is staffed only by them and their nurse coordinator, and that it could be difficult to respond in one business day if one person is out and the other is occupied with other responsibilities. This deadline could be hard for programs with limited KPD staffing.

One member shared that, as a patient in a KPD program, their coordinators neglected to upload the donor's scan imaging, resulting in nearly a two-year wait for the exchange. The member continued that there needs to be accountability for completing tasks required to qualify candidates for an exchange and move exchanges along towards recovery and transplant. Another member agreed.

Staff shared that, during the last meeting, the Workgroup was split between leaving the preliminary response deadline at two business days and reducing it to one business day. Staff added that this deadline is only for a preliminary response based on the given offer information, and does not include reviewing or obtaining renal imaging.

Staff asked the Workgroup how maintaining the preliminary response deadline at two business days from time of match offer would affect the other proposed deadlines. One member responded that the other deadlines are still appropriate if the preliminary response deadline is two business days. The

member noted that these deadlines are practical and appropriate, and should encourage timely completion of the exchange requirements. Another member agreed that the other deadlines are still appropriate. The Chair agreed.

Staff noted the Workgroup could ask for further feedback regarding this deadline during public comment. A member remarked that two business days to provide a preliminary response is reasonable, as long as there is accountability for programs to meet the deadline. Another member supported asking for specific feedback on these deadlines in public comment. The Chair agreed.

One member posed a hypothetical situation, where a research program dealing with a 1 business day deadline could have their own policy of always responding with "yes" preliminary responses and worry about submitting a decline later. The member noted that this could affect the efficiency of the process. Staff noted that some hospitals do provide fast preliminary yes responses, and go back to review donor information in its entirety later. A member remarked that this could be a function of a short deadline.

The Workgroup agreed to recommend a preliminary response deadline of two days from receipt of match offer.

4. Deadline Adherence and Accountability Discussions

The Workgroup discussed how to encourage greater deadline adherence and accountability in the OPTN KPDPP.

Summary of discussion:

Staff asked the Workgroup how the OPTN KPDPP can encourage greater accountability and adherence to the deadlines without consequences, and what incentives could be given.

One member recommended running a program-specific report for each transplant program, highlighting how timely the program was and how many match runs the program was involved in successfully resulted in transplant. The member recommended giving an efficacy score of the program's participation in the OPTN KPDPP. Staff shared that the KPD Advisory Council has discussed having some kind of score card to allow programs to see how they compare to others, but that there is limited information technology (IT) bandwidth to take on such a project right now. The member noted that this scorecard should not be punitive, or it risks discouraging growth in the OPTN KPDPP. Another member supported the use of scorecard to allow programs to see what deadlines they are meeting.

A member commented that transparency about performance without repercussions is important for transplant centers first starting in the KPD program to review and make changes. The member noted that most programs first enrolling in KPD see the value, but need the institutional support, as there is often very limited staffing dedicated to KPD. There is often little programmatic pressure or need to join a KPD program, and so any punitive actions tend to fall on the passionate individuals dedicated to making KPD work within their transplant programs. The member noted that punitive repercussions are not appropriate.

Staff noted that feedback on incentivizing better performance could be requested in the public comment proposal as well, particularly with focus on deadlines and efficiency. A member agreed with this recommendation, adding that this could encourage community support as well.

Attendance

- **Workgroup Members**
  - Peter Kennealey
  - Camille Rockett
  - JoAnn Morey
  - Justine Van Der Pool
  - Marian Charlton
  - Sanjeev Akkina
  - Vineeta Kumar
- **HRSA Staff**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Lindsay Larkin
  - Ruthanne Leishman
  - Kaitlin Swanner
  - Katrina Gauntt
  - Kim Uccellini
  - Meghan McDermott
  - Ross Walton