OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
June 17, 2022
Conference Call

Peter Kennealey, MD, FACS, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 06/17/2022 to discuss the following agenda items:

1. Update KPD Policy Project Overview
2. KPD Deadlines Data Review
3. Update KPD Policy Proposal Preview: Public Comment Questions

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

1. Update KPD Policy Project Overview

Staff provided an overview of the Update KPD Policy Project.

Presentation summary:

The Update KPD Policy project will align *OPTN Policy 13: Kidney Paired Donation* with other OPTN policies, clarify language and requirements, and bring deadlines and administrative requirements up to date with current practices.

During the development of this project, the Workgroup has sought feedback from identified OPTN Committee stakeholders, including:

- Transplant Administrators Committee
- Transplant Coordinators Committee
- Patient Affairs Committee
- Living Donor Committee
- Histocompatibility Committee

The KPD Workgroup identified, discussed, and finalized recommended changes, which were officially endorsed by the OPTN Kidney Committee to be released as a proposal for the August 2022 public comment cycle.

In total, the Workgroup has discussed changes to 10 KPD policies:

- 1.2: Definitions (Bridge Donor)
- 13.3: Informed Consent for KPD Candidates
- 13.4: Informed Consent for KPD Donors
- 13.4.C: Additional Requirements for KPD Donors
- 14.6.B: Placement of Non-Directed Living Donor Organs (Living Donor Policy)
    - Reference with 13.4.D Additional Requirements for Non-Directed Donors
- 13.4.E: Additional Requirements for Bridge Donors

- 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates
- 13.7.G: Waiting Time Reinstatement
- 13.11: Receiving and Accepting KPD Match Offers
- 13.11.A: Requesting a Deadline Extension for a KPD Exchange

The Workgroup has proposed updated KPD deadlines, to improve efficiency:

- Within 2 business days of receiving match offer: report preliminary response
- Within **3 business days** of receiving match offer, reduced from 4 business days:
    - Agreement on contents in crossmatch kit, donor instructions, 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/NAT testing results, PHS risk criteria, and any additional records request
- Within **10 business days** of receiving match offer, reduced from 15 business days:
    - 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:

There were no questions or comments.

2. KPD Deadlines Data Review

Staff presented data related to KPD timelines, match refusal, and match success for the OPTN KPDPP.

Data summary:

To support the proposal, OPTN Research Staff compiled data related to KPD timelines, match refusal, and match success. The cohort utilized in this analysis were candidates and donors participating in the OPTN KPD Pilot Program (KPDPP) between January 1, 2016, and December 31, 2021.

The following key data points were presented:

- Median time to transplant remained around 62-72 days until 2020
    - Maximum days between match run and transplant saw an upward trend between 2016 and 2021
    - 2021 median time to transplant was 87 days
- Most refusals submitted are within 2 business days of the match offer
    - Late refusals occurring 15 business days after the match run make up the smallest proportion
- 25% of offers refused after 2 business days took over 31 days from match run to report a refusal
    - Of the 380 refusals received at least 2 business days after the match run, 11% occurred 60 days or more after the match offer was sent
- 25% of offers refused after 15 business days took over 68 days from match run to confirm refusal
    - Median time to refusal for these offers has remained between 36 and 52 days
- 'Donor Related,' 'Candidate Related,' and 'Other' reasons for refusal increased in proportion as the time to refusal increased
    - "Donor Related" was the leading offer refusal reason in both time frames

- Match success rate was highest in 2019 at 12.2%
    - 11.4% of candidates entered into KPD between October 2010 and December 2020 were transplanted in the OPTN KPDPP
    - 22.7% of candidates transplanted in other KPD program, 18.2% received DD transplant

Candidate-related refusal reasons include:

- Candidate ill, unavailable, or temporarily unsuitable for transplant
- Candidate involved in pending exchange with another KPD program
- Candidate already transplanted, transplant in progress, or other offer being considered
- Candidate death
- Candidate's condition improved, transplant not needed

Donor-related refusal reasons include:

- Paired donor ill, unavailable, or temporarily unsuitable for transplant
- Paired/Matched donor declined to donate
- Organ specific and donor-specific clinical refusals (medical history, test results, etc.)
- Other – paired donor pregnancy, travel, illness
- Match timing too long; donor refused to donate on the exchange timeline, and donated to the waitlist

Other refusal reasons include:

- Mostly N/A
- Donor unsuitable for waitlist
- Non-directed donor not able to donate until later
- Organ and donor-specific medical changes
- Logistical difficulties

Summary of discussion:

The Chair expressed surprise at the median and maximum time to refusal, remarking that 18 days is too long of a timeline. Staff explained that there are outliers in the data. The Chair wondered if the longer time to refusal is because the programs needed to mail images and discs with donor information before reviewing. The Chair commented that these refusal timeframes seem to be far outside what should be considered a standard refusal timeline.

One member asked if there are recurring centers who submit refusals so late. Staff responded that the data would need to be analyzed, but anecdotally this problem isn't unique to only a few programs.

The Chair remarked that this refusal data supports the need for information to be easily and quickly transferred between programs. The Chair continued that this technology is available, and would significantly enhance facilitation of the KPD processes and potentially eliminate late refusals.

One member expressed support for the proposed 60 day timeline from match offer to recovery and transplant, adding that the longer the time from match run, the greater the risk that something happens to the candidate or donor that prevents the fulfillment of the exchange. Reducing the time between match offer and transplant will reduce that risk. Another member agreed, noting that the 60 day timeline makes sense.

A member wondered if more parallels can be drawn in the deceased donor offer process. The member explained that, if a deceased donor offer is accepted and the kidney shipped, a center can only refuse the kidney late for certain reasons without being penalized. If the offer is accepted, the assumption is

that the anatomy has been approved based on the information provided. The member continued, noting that it seems inappropriate to decline for donor anatomy at 30 days from time of match offer. The member wondered if there could be a policy to outline the reasons that an organ could be refused late, to reduce inappropriate late refusals. Staff shared that the Workgroup could submit a data request, to review refusal data more granularly and determine which reasons are occurring most commonly. Staff explained that some refusals could be avoided with pre-screen, as some hospitals will consistently decline donors with certain characteristics. A member agreed that the Workgroup should dig deeper into refusal reasons data.

One member asked how median time to transplant compares between the OPTN KPDPP and other KPD systems. Another member responded, noting that another KPD system has a significantly shorter time from match offer to transplant, about three weeks. The member explained that, if a program can't schedule a surgery within three weeks, then the programs will consider alternate dates within a week or so of the original target surgery date. Otherwise, the match is terminated. Another member remarked that a three week timeline puts a lot of pressure on the participating transplant programs to ensure everything is appropriately aligned. If the surgeon is going to decline, the decline needs to be reported within two weeks. The member noted that a 60 day timeframe provides more leeway for programs to decline later in the process. Another member pointed out that there are fines associated with maintaining deadlines in other KPD systems.

The Workgroup agreed that a 60 day timeline from match offer to time of transplant and recovery is still appropriate.

3. Update KPD Policy Proposal Preview: Public Comment Questions

The Workgroup discussed several questions to pose in the public comment proposal.

Summary of discussion:

The Chair remarked that a two business day preliminary response timeline is appropriate, particularly with time zone changes. The Chair continued that one business day can be tricky for KPD programs with less KPD-specific staff.

The Chair commented that renal images should be available at the time of offer, so that the offer receiving program can review the donor's chart and make a real decision, similar to a deceased donor kidney offer. Another member agreed, reiterating that the full information should be available at time of offer. The Chair remarked that this could improve the efficiency of acceptance and refusals. Staff shared that there is currently no place within the OPTN KPD Computer System to upload renal images. The ability to make these images available is important to consider when discussing policy requirements regarding information sharing. Staff noted that there is the capability to upload the medical record. The Chair remarked that the inability to upload renal images themselves, as exists in the OPTN Donor Data and Matching System, is a hurdle to efficiency in the KPD system, and forces programs to make a decision without accurate and complete information early on, only to have to refuse later when the full information is made available.

One member recommended creating a requirement to have the donor chart complete and uploaded when entering the donor and candidate pair into the OPTN KPD Computer System. Staff explained that this could be a policy change. The member emphasized that this information is important to have upfront. The Chair agreed, noting that otherwise, the work to upload and share the donor information has to be done twice. Members agreed that most programs want to be able to review as much donor information as possible on receiving the match offer, particularly renal images. Members agreed that making the complete donor medical record and renal images available at time of match offer would

improve system efficiency significantly. One member pointed out that renal imaging is a big reason for match offer decline. The Chair agreed, remarking that the imaging is critical to offer evaluation, and that neither the donor surgeon nor recipient surgeon can make clear, informed decisions without understanding the anatomy.

A member emphasized the importance of safeguards in the system if renal images are required upfront. The member explained that administrative lapses, such as a coordinator forgetting to upload donor renal images, could prevent a candidate from receiving offers in the system. The Chair agreed, noting that such a scenario could pose a disadvantage to candidates. One member remarked that requiring information upfront would allow for some degree of quality control and management of what donor information is shared. The member explained that having a list of required information when adding candidates and donors will allow for fewer administrative mistakes at a center level. Staff clarified that the OPTN KPDPP reaches out to programs who have candidate-donor pairs that are inactive due to missing data. If the data is not entered, the OPTN KPDPP program will contact the program directly to ensure the issue is addressed. Staff explained that there is a system in place to notify if donor information is not uploaded. One member expressed support for this system.

One member recommended that pertinent donor information, such as history of hypertension, be clearly outlined within the donor record, to ease offer review.

<u>Finalized Questions for Public Comment Feedback:</u>

1. Are the proposed deadlines appropriate? Do the deadlines provide sufficient time to perform the required tasks and review the match offer? Is the 60 day deadline from time of match offer to schedule recovery and transplant appropriate?
2. Should the deadline for the provision of a preliminary response be shortened to 1 business day from receipt of match offer, or is 2 business days more appropriate?
3. How can over use of extension requests be discouraged? How can better performance be incentivized in the program?
4. Are the offer review and matched donor information sharing requirements still appropriate? Should additional clinical donor information, such as renal imaging, be specified as required donor information made accessible to the matched candidate's transplant hospitals within the three business day deadline?
5. Should the entire donor's evaluation record, including renal images, be available in the OPTN KPD System at time of match offer?
6. Should policy specify that transplant programs obtain a signature from bridge donors confirming informed consent and the estimated period of willingness to be a bridge donor?

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Peter Kennealey
  - Aneesha Shetty
  - Camille Rockett
  - Justine van der Pool
  - Marian Charlton
  - Nancy Metzler
  - Stephen Gray
  - Valia Bravo-Egana
  - Vineeta Kumar
- **HRSA Staff**
  - Vanessa Arriola
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kayla Temple
  - Katrina Gauntt
  - Ruthanne Leishman
  - Kerrie Masten
  - Stryker-Ann Vosteen