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

Marion Charlton, RN, SRN, CCTC, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 10/18/2022 to discuss the following agenda items:

1. New Project Development: Require Donor Re-evaluation and Notification
2. Discussion: *Update Kidney Paired Donation Policy* Post-Public Comment Changes

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

1. New Project Development: Require Donor Re-Evaluation Notification

The Workgroup discussed the second aspect of their new project, establishing a requirement for programs to regularly re-evaluate their paired donors.

Presentation Summary:

The project currently in development by the Workgroup includes A, non-A1 and AB, non-A1B matching policy alignments as well as the establishment of donor re-evaluation requirements.

This project will align OPTN *Policy 13.7.B: Blood Type A, non-A1 and Blood Type AB, non-A1B Matching* policy with that in Kidney *Policy 8.5.D: Allocation of Kidneys by Blood Type*. This alignment will still maintain A, non-A1 matching opportunities for blood type O candidates. Current KPD policy is more stringent than Kidney policy, and sets specific anti-A titer requirements for candidate eligibility to accept A, non-A1 and AB, non-A1B kidney offers. There is typically variability in what some centers will accept in terms of titer values. This will potentially expand matching opportunities for some blood type B and blood type O candidates.

This project will also establish requirements for programs to regularly re-evaluate donors. Current KPD policy does not require this; as a result, donor and candidate information in the OPTN KPD system becomes outdated, reducing the quality of the matches and the success of these matches. There was support for a requirement for regular testing for donors and candidates in public comment. This project would include a system enhancement to send out an email notification to programs with participating pairs of an approaching deadline to re-evaluate their paired donor. This project would require regular re-evaluation and communication with KPD donors, with implications for both match success rate and program efficiency.

The Workgroup has several decisions to make with respect to what should be proposed, including:

- How regularly should donors be re-evaluated?
    - 38 percent of candidates have a CPRA greater than or equal to 80 percent
    - 57 percent of candidate-donor pairs are still waiting after 1 year, 38 percent of candidate-donor pairs are still waiting after 2 years

    - The Chair has recommended that donors are re-evaluated annually, with a 60 day window around the donor's KPD anniversary to allow programs time to perform the evaluation.
- What should be required upon re-evaluation? Several policies govern general KPD and living kidney donor re-evaluation, including:
    - 13.5.C: HLA Typing Requirements for OPTN KPD Donors
    - 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors
    - 14.1: Psychosocial Evaluation Requirements for Living Donors
    - 14.4: Medical Evaluation Requirements for Living Donors
    - 14.4.B: Additional Requirements for the Medical Evaluation of Living Kidney Donors
    - 14.4.E: Living Donor Exclusion Criteria

Summary of discussion:

One member agreed that annual re-evaluation within a 60 day window makes sense. Another member agreed, noting that potential donors are generally healthy people and would not likely need more frequent follow up.

Psychosocial Re-evaluation Requirements

Staff shared that the Workgroup Chair recommended that a full psychosocial re-evaluation be completed, as these conversations are important to capturing potential changes in a donor's list that could prevent them from safe donation. A member agreed that a full psychosocial re-evaluation, per *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*, would be appropriate, particularly as a lot can change over a year for potential donors. The member added that this seems to be particularly true in the last few years. Another member agreed.

Medical Evaluation Requirements and General Donor History

Staff shared that the Chair recommended that aspects from nearly every category of OPTN *Policy 14.4 : Medical Evaluation Requirements for Living Donors* be re-evaluated, with the exception of family history, as this will not likely change over the course of a year and may not be necessary. The Chair also recommended that all bullets for "general donor history" but "general family history, including cancer and coronary artery disease" are included in the re-evaluation requirements, noting again that family history is not likely to change much over a year. The Chair noted that the other elements of general donor history, particularly including the development of hypertension and diabetes and monitoring of potential infections, will be critical to ensuring the donor is able to safely donate and important to understanding the risk associated for a potential recipient. A member agreed, sharing that their program mostly sees large changes in weight and related complications, such as metabolic disorders, when re-evaluating their potential donors.

Social History

Staff noted that many of these questions are included in the psychosocial evaluation, and such aspects, particularly employment and health insurance, may be important for a transplant program to gauge, as they impact a donor's ability to donate safely and securely. One member agreed that it would be important for a transplant program to follow this information, but that it does not have any impact on potential risk to the recipient. The member noted that it may not be necessary for the program to complete a social history re-evaluation, with the exception of risk criteria.

Staff shared that the OPTN KPD Pilot Program (OPTN KPDPP) does have incidences where donors experience changes in health insurance and employment status that preclude them from being able to donate. Staff shared that the Chair had expressed that it would be important for the transplant

programs to monitor these aspects, as they impact the donor's actual ability to donate. Staff added that changes in the donor's ability to donate are not always communicated upfront to the transplant hospital, and that these changes can result in unsuccessful matches as the transplant program learns post-match that the donor is no longer able to donate. One member agreed, and suggested including the "social history" evaluation requirement, for consistency and monitoring a potential donor's candidacy for donation.

Physical Exam and General Laboratory and Imaging Tests

Staff shared that the Chair supported transplant center re-evaluation of physical exam requirements, including height, as younger donors could still experience shifts in height, and these changes can affect the BMI of the donor. A member agreed, noting that shifts in height, weight, BMI, and the donor's vital signs would be important to understanding and monitoring the donor's health and any potential risks posed to the donor for donation and the recipient.

Staff shared that the Chair supported including most requirements from the "general laboratory and imaging tests" section, with the exception of blood type and subtyping, as this is not likely to change. Staff continued that the Chair thought that these would be important to know for general donor health monitoring, but that the Chair requested specific input on the value of a chest x-ray or electrocardiogram (ECG). A member agreed that these requirements made sense, and recommended that potential donors being re-evaluated also receive a chest x-ray and ECG, as this could provide important information on the donor's health. The member agreed that blood type and subtyping does not need to be retested.

Transmissible Disease Testing and Endemic Disease Screening

Staff shared that the Chair noted that infectious disease testing would be important to understanding potential risk to the candidate, but that it did not make sense to re-test the donor for any infectious disease test they had already tested positive for. Several members agreed. One member pointed out that it would be important to know if the donor sero-converted, particularly for CMV and EBV, as these could impact potential risk to the recipient. Staff pointed out that the OPTN KPD matching system considers CMV and EBV status when determining which donor-candidate pairs are eligible for exchange with other donor-candidate pairs, and so ensuring this information is accurate is important to ensuring match success.

One member added that infectious disease results particularly highlight risk to the potential recipient, particularly as not all candidates will be willing to accept an organ from a Hepatitis C or Hepatitis B positive donor. The member continued that these results may impact the decision process and potentially the role of the donor.

Staff shared that the Chair felt it made sense to have programs engage with donors and ask questions about potential exposure to endemic transmissible disease, at least to have an understanding of risk to the candidate. Staff asked the Workgroup for their thoughts, and if this would be considered information critical to understanding potential risk to the recipient. One member noted that this would be information critical to understanding potential risk to the candidate or recipient, and asked if there was an expanded requirement in OPTN Policy. Staff clarified that presented policy requirement for endemic transmissible disease is that in OPTN Living Donor Policy, so transplant centers need to determine if their donor is at increased risk and screen appropriately. Staff clarified that this requirement would be for programs to identify donors at risk for infection of TB and endemic disease and test appropriately. Staff noted that this information is also required in the OPTN KPD system.

One member asked if there is a time requirement for checking living donor serologies, expressing concerns for in-window serology conversion. Staff clarified that for many of the infectious diseases listed, there is a requirement to test within 28 days prior to recovery. Staff noted that infectious disease testing is done both when the donor is entered into the OPTN KPD system and prior to the donation surgery. The member remarked that it made logistical sense to require infectious disease testing as part of re-evaluation, particularly because it could break the chain to find out later that the donor is positive for one of the infectious disease.

Cancer Screening

Staff shared that the Chair felt that cancer screening would be critical to the donor's health and ability to donate, as well as risk to the candidate. A member agreed, adding that this is a reasonable requirement, with implications both for the donor and recipient's health and safety.

Kidney-Specific Donor and Family History

Staff asked the Workgroup about requirements for kidney-specific donor and family history as potential re-evaluation requirements, noting that evaluation for genetic disease and family history would already have been completed and those results would not likely change over a year. A member agreed that it would be reasonable to check for a personal history of significant medical conditions, including kidney disease, proteinuria, hematuria, kidney injury, diabetes, nephrolithiasis, and recurrent urinary tract infections. The member continued that it is reasonable to assess these in the interest of reassess donor candidacy based on changes in kidney function or injury. The member added that diabetes poses a long term risk to the donor's safety, as well as potential risk to the recipient safety. The member noted that nephrolithiasis can be determined from a renal ultrasound, and that this is a reasonable re-evaluation requirement. The member continued that this would be important for the recipient's awareness of potential kidney stones. The member added that recurrent urinary tract infections would be important to understanding the donor's health and candidacy for donation. The member remarked that evaluation of these elements would be important to ensuring donor safety and recipient safety, particularly as it relates to potential impacts on their outcomes.

One member remarked that family history does not need to re-evaluated, as this will have been evaluated upon the donor's entry to the KPD program and is not likely to change over the course of a year.

Kidney-Specific Physical and Metabolic Testing

One member remarked that all of the tests under "kidney specific physical and metabolic testing" would be important not only for understanding donor candidacy, but also to ensuring donor safety. The member added that, from a one year standpoint, there may not be a huge difference to the recipient. Another member agreed.

Kidney-Specific Testing

Staff shared that the Chair of the Workgroup recommended that urinalysis, urine culture, measurement of urinary protein and albumin excretion, and GFR or CrCl would be appropriate for understanding the donor's general health and ability to donate, without requiring too invasive or complicated a test. One member agreed that urinalysis, urine culture, and urinary protein and albumin excretion measurements would be easy to test, not inconvenient to the donor, and are good screening tools to see if there are any concerns that may require further testing or to be addressed further. The member noted that these tests provide insight to the donor's general health and candidacy as a donor.

A member suggested that GFR or CrCl measurement should not be mandatory for re-evaluation, but that it could be an option if the program feels the need to re-evaluate that test based on the results of the urinalysis, urine culture, and urinary protein and albumin excretion measurements. The member continued that if those three tests look stable, there may not be a need to repeat the GFR or CrCl test, and thus the GFR or CrCl measurement may not be necessary every year. Staff asked if GFR or CrCl should be performed only as needed dependent on other changes to the donor history. The member agreed, noting that it would only make sense to perform the GFR measurement again if there is a suspicion of reduced GFR. The member recommended using language such as "re-evaluate GFR or CrCl based on relevant history and exam findings," adding that relevant history could include kidney injury. The member noted that there would not likely be a big change in renal function if the donor has been relatively stable from one year to the next, and it may not be worth repeating the test if not clinically indicated.

One member remarked that the requirement regarding polycystic kidney disease or other inherited renal disease and the 24 hour urine stone panel may not be necessary for re-evaluation. The member explained that the transplant program would have had to develop and comply with their written protocol for polycystic kidney disease and inherited renal disease as indicated by family history upon the donor's first evaluation, and so that information is not likely to have changed. Another member remarked that, as long as the donor understands the increased risk related to family history of inherited renal disease, it should be up to the donor to decide. The member agreed that this conversation should have been addressed in the initial assessment.

A member remarked that, for patients with a history of nephrolithiasis, if the initial evaluation cleared those patients for donation in the first case, it may not be necessary to re-test a 24-hour urine stone panel unless the patient has recurrent stones. The member noted that the 24-hour urine stone panel would only be required if there is relevant history and exam findings that clinically indicate the need for it, and that this test should only be re-performed as needed. The member provided an example: if the patient didn't initially have kidney stones and kidney stones are found upon ultrasound at the re-evaluation, this could be an appropriate time to perform a 24 hour urine stone panel, with relevant history and exam findings providing clinical indication.

Staff summarized discussion, noting that the workgroup seems to support requiring urinalysis, urine culture, and measurement of urinary protein and albumin excretion upon re-evaluation, while measurement of GFR or CrCl and a 24 hour urine stone panel would only be required as needed, based on relevant history and exam findings. Staff continued that the polycystic kidney disease and other inherited renal disease protocol compliance would only be optional, based on the donor's decision. One member noted that the conversations regarding polycystic kidney disease and inherited renal disease should have been completed initially, upon initial evaluation, and this would not change. The member explained that the polycystic kidney disease and inherited renal disease is not necessary and doesn't make sense as a re-evaluation requirement. Another member agreed, noting that the increased risk just needs to be explained to the donor, and that this needs to have been done when initially evaluated.

Anatomic Assessment

Staff shared that the Chair noted that the anatomic assessment may not necessarily need to be fully re-evaluated, as this would not likely change much. A member agreed, noting that anatomic re-assessment should be optional at the transplant center's discretion, not required. The member continued that it may make sense to re-assess anatomy if there is a clinical indication of concern for recurrent stones or there was a previous renal cyst to follow up on. The member continued that these things would be clinically indicated and require a repeat ultrasound or CT scan. The member added that anatomic reassessment should be at the program's discretion based on initial assessment and changes in medical

history over the year, and that this would mostly be done to monitor donor safety and candidacy and understand potential risks to the recipient.

Informed Consent

The Workgroup considered if it should be required for donors to be re-consented per *Policy 13.4.C: Informed Consent Requirements for KPD Donors*.

Staff shared that the Chair felt that programs should re-consent the donor fully per Policy 13.4.C: Informed Consent Requirements for KPD Donors, as there is a benefit to reviewing that information. The Chair also noted that it would be important to know if there were any changes to the paired donor's preferences. One member agreed, adding that it is helpful for a donor to hear this information again, to remind them of what is involved and to ensure any changes in the informed consent are appropriately captured. The member continued that it is always a good idea to ensure donors are aware.

Staff asked if the informed consent requirements should be updated as well, such that donors are made aware that they may need to be re-evaluated. One member remarked that the informed consent requirements should be updated to reflect that the donor may need to be re-evaluated, and that this will also make the donor aware that it may be a year or longer before they actually donate. Another member agreed.

Re-evaluation reporting requirements

The Workgroup considered which aspects of Policy *13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors* are appropriate for re-evaluation.

One member agreed that programs should report if the donor's height, weight, gender, or BMI have changed, adding that this will impact donor selection and the pool of candidates that the donor could match with. Staff pointed out that height and weight affect matching, and that BMI is used in screening, and so changes to this information may change the pool of candidates that donor is eligible to match with.

Staff asked if programs should reconfirm the donor's willingness to participate, and noted that the PHI release would not need to be signed again. A member noted that donors who choose not to participate in the KPD program any longer will make that known to their candidate and transplant program. The member continued that there is no need for re-entry if the candidate remains willing.

Staff asked if Policy should require a signature to confirm the donor is still willing to participate, and to confirm consent. The Workgroup agreed that the program will need to reconfirm the donor's willingness to participate with a signature.

One member noted that changes to clinical donor information should be reported in the KPD system, particularly as they impact matching and screen, and the potential pool of eligible candidates that donor could match with. The member continued that any changes to infectious disease testing results should also be reported.

Staff shared that the information reported under donor choices is typically gathered during informed consent conversations, and noted that the Chair recommended that any changes to these preferences be reported in the KPD system. Staff continued that the Chair noted that willingness to donate right or left kidney may not change over a year. One member pointed out that preference to donate the left or right kidney could very well change from year to year, particularly if one kidney has a cyst or some similar anatomical concern. The member added that, while anatomic re-assessment is optional, centers should report any changes to donor preference.

Tracking and notification

The Workgroup considered when notification for the upcoming re-evaluation period should be sent to programs and how re-evaluation should be tracked and monitored.

Staff shared that the Chair recommended the notification email be sent 60 days prior to the donor's KPD anniversary, which is 30 days prior to the start of the evaluation window, which would give programs ample time to set up the necessary appointments and get in touch with the donor. One member expressed support for this notification timeline, adding that 30 days advanced notice should be sufficient time for programs to schedule all of the appropriate appointments. The member added that with the advanced notice, programs should be able to perform this re-evaluation well within the proposed evaluation window of 60 days.

One member expressed support for including a data element to track donor re-evaluation, noting that this would allow for better monitoring of the policy and allow for the system to know how recent the donor's last evaluation was. The member noted that this would be useful, particularly as the date of re-evaluation the next year could be based on the date of the most recent re-evaluation. Another member expressed support for some kind of tracking data element, agreeing that this would improve monitoring.

Staff asked the Workgroup if they would still recommend this project to the Kidney Transplantation Committee for approval without a data field to track last re-evaluation. The Workgroup agreed that the data element to track last evaluation, while helpful, was not critical to establishing a requirement for re-evaluation.

2. Discussion: *Update Kidney Paired Donation Policy* Post-Public Comment Changes

The Workgroup continued discussions on post-public comment changes for the *Update Kidney Paired Donation Policy* proposal.

Presentation summary:

Previously, the Workgroup determined that an additional deadline should be created as part of the *Update KPD Policy Proposal*, to require programs to agree upon a recovery date within 25 calendar days.

- In the OPTN KPD, initial discussions to choose 2 potential OR dates are held between 4 to 6 business days after time of match offer
- Should the deadline to finalize the date for OR be made tighter, and in line with the other offer review deadlines (IE 15 business days from time of match offer)?

Summary of discussion:

Staff shared that the Chair recommended shortening the proposed deadline to agree upon a recovery date to 15 business days. This would put the deadline to agree upon a recovery date about 5 business days after the crossmatch results reporting date. One member expressed support for the deadline, noting that this will encourage programs to begin planning for the recovery and transplant as those crossmatch results come back, and will encourage increased efficiency.

A member agreed that shortening the deadline to 15 business days makes sense, as the longer time between match offer and transplant increases the chances that a candidate has a sensitization event which could alter the crossmatch results and prevent the fulfillment of the exchange.

One member expressed support for switching the deadline from a calendar day timeline to a business day timeline, noting that this improves consistency.

The Workgroup agreed to alter their recommended post-public comment change, noting that the proposed deadline for programs to agree upon a recovery date should be 15 business days.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Sanjeev Akkina
  - Stephen Gray
  - Valia Bravo-Egana
  - Erica Seasor
  - Sergio Manzano
- **HRSA Staff**
  - James Bowman
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Meghan McDermott
  - Alina Martinez
  - Katrina Gauntt
  - Kerrie Masten
  - Kim Uccellini
  - Megan Oley
  - Ross Walton
  - Ruthanne Leishman
  - Steve Wendt