OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
November 30, 2022
Conference Call

Marion Charlton, RN, SRN, CCTC, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 11/30/2022 to discuss the following agenda items:

1. Finalize KPD Blood Type Alignment and Donor Re-Evaluation Project
2. KPD Priority Points Monitoring Report

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

1. Finalize KPD Blood Type Alignment and Donor Re-Evaluation Project

The Workgroup reviewed their project to align OPTN KPD pilot program (OPTN KPDPP) A, non-A1 and AB, non-A1B matching policies and establish a requirement for donor re-evaluation. The Workgroup discussed finalized the project to send to the Kidney Committee for approval.

Project summary – Blood Type Alignments:

This project will align KPD 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 will:

- Maintain allowance for O candidates to receive A, non-A1 offers if they meet requirements in *Policy 13.7.B: Blood Type A, non-A1 and Blood Type AB, non-A1B Matching*
    - O candidates experience the most disparity in transplant rates in the OPTN KPDPP, with 61 percent of KPD donors being blood type O, and only 42 percent of KPD recipients being blood type O
- Potentially expand matching opportunity for some blood type B and blood type O candidates

Currently, KPD policy is more stringent than Kidney policy, and sets specific anti-A titer requirements for candidate eligibility to accept A2 and A2B kidney offers. However, there is variability in what centers accept in terms of titer value, and some programs are more aggressive than others.

The new, proposed policy would allow kidneys from donors with blood types A, non-A1 may be matched with candidates with blood type B or blood type O, and kidneys from donors with blood types AB, non-A1B may be matched with candidates with blood type B, so long as all of the following criteria are met:

1. Paired candidate's transplant program establishes written policy regarding titer threshold for these transplants
2. Paired candidate's transplant program obtains written informed consent regarding willingness to accept blood type A, non-A1 or AB, non-A1B
3. Paired candidate's transplant program must confirm eligibility every 90 days (+/- 20 days)

Summary of discussion:

The Workgroup agreed the effort to align A, non-A1 and AB, non-A1B matching policies was clear and made sense. There were no additional questions or comments.

Project summary – Donor Re-Evaluation Requirement:

Current policy does not require regular re-evaluation of KPD donors, resulting in outdated information being utilized to run KPD match runs. Outdated information results in reduced likelihood of match success, resulting in broken chains and exchange failure. Furthermore, there was support for requirement for regular testing for donors and candidates in public comment, to improve efficiency.

This proposal would require annual re-evaluation and communication with KPD donors, with implications for both match success rate and program efficiency.

- Programs in the OPTN KPDPP will need to re-evaluate their donors annually, including informed consent, psychosocial, medical evaluation, and reporting requirements
    - Donor re-evaluation date based around the donor's KPD anniversary (date added to the KPD system)
    - Programs have a 60 day window, with 30 days prior to donor evaluation date and 30 days after evaluation date to complete the evaluation
- Proposal includes an update to informed consent requirements for KPD donors, such that programs must informed donors that they may require re-evaluation

The proposal will require programs to complete a full psychosocial re-evaluation required per *Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements*.

The proposal will also require programs to complete a medical evaluation, including:

- General donor history assessment:
    - A personal history of significant medical conditions, which include but are not limited to:
        - Hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer including melanoma
    - History of infections
    - Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication
    - Allergies
    - Evaluation for coronary artery disease
- Kidney-specific donor history assessment:
    - A personal history of significant medical conditions, which include but are not limited to, kidney specific personal history including:
        - Kidney disease, proteinuria, hematuria, kidney injury, diabetes including gestation diabetes, nephrolithiasis, recurrent urinary tract infections
- Social history assessment, including:
    - Occupation
    - Employment status
    - Health insurance status
    - Living arrangements
    - Social support
    - Smoking, alcohol and drug use and abuse
    - Psychiatric illness, depression, and suicide attempts
    - Risk criteria for acute HIV, HBV, and HCV infection according to the US PHS Guidelines

- Physical exam, including:
    - Height
    - Weight
    - BMI
    - Vital signs
    - Examination of all major organ systems
    - Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
- General laboratory and imaging tests:
    - Complete blood count (CBC) with platelet count
    - Prothrombin Time (PT) or International Normalized Ratio (INR)
    - Partial Thromboplastin Time (PTT)
    - Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
    - HCG quantitative pregnancy test for premenopausal women without surgical sterilization
    - Chest X-Ray
    - Electrocardiogram (ECG)
- Metabolic testing:
    - Fasting blood glucose
    - Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LCL cholesterol)
    - Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals
- Kidney-specific testing:
    - Urinalysis or urine microscopy
    - Measurement of urinary protein and albumin excretion
    - The following, if clinically indicated based on history and exam findings:
        - Urine culture
        - Measurement of glomerular filtration rate by isotopic methods or creatinine clearance calculated from a 24-hour urine collection
        - Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine, and sodium
- Cancer screening:
    - Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:
        - Cervical cancer
        - Breast cancer
        - Prostate cancer
        - Colon cancer
        - Lung cancer
- Anatomic assessment, if clinically indicated:
    - Whether the kidneys are of equal size
    - If the kidneys have masses, cysts, or stones
    - If the kidneys have other anatomical defects
    - Which kidney is more anatomically suited for transplant
- Infectious disease testing, if the donor has not previously tested positive for any of the below:

    - CMV (Cytomegalovirus) antibody
    - EBV (Epstein Barr Virus) antibody
    - HIV antibody (anti-HIV)/ HIV Ag/Ab combination
    - HIV ribonucleic acid (RNA) NAT
    - Hepatitis B surface antigen (HbsAg)
    - Hepatitis B core antibody (total anti-HBc)
    - HBV deoxyribonucleic acid (DNA) NAT
    - Hepatitis C antibody (anti-HCV)
    - HCV ribonucleic acid (RNA) NAT
    - Syphilis
- Tuberculosis and endemic disease testing and screening
    - For tuberculosis (TB), living donor recovery hospitals must retest and follow protocol per OPTN Living Donor Policy 14.4: Medical Evaluation Requirements
    - Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation

Summary of discussion:

The Chair noted that, often, a donor is evaluated months ahead of the recipient being ready to enter the KPD system. The Chair asked if the donor re-evaluation date should be based on the date of initial donor evaluation instead of the date of entry into the KPD system. Staff explained that the OPTN KPDPP system does not currently capture the date the donor was initially evaluated, but that the date of entry into the KPD system is a proxy of this. The Chair agreed.

Staff asked the Workgroup if urine culture should be required on re-evaluation, or if urine culture should only be required if there is clinical concern. The Chair remarked that urine culture should only be required for re-evaluation if there is clinical concern. The Workgroup agreed.

The Workgroup achieved consensus that urine culture should only be performed on re-evaluation if clinically indicated.

Staff explained that previously, the Workgroup had agreed that infectious disease tests did not need to be repeated for those tests that a donor had previously tested positive. Staff asked the Workgroup if the previously positive exception applies for all infectious disease tests, or just some of the tests. The Chair explained that a donor with a positive HbsAg test would not have remained a candidate as a donor, and continued that donors should be retested for all HIV, Hepatitis B, and Hepatitis C tests. The Chair continued that Syphilis should also be re-tested at re-evaluation.

Staff asked the Workgroup if the previously positive exception only applied to anti-CMV and anti-EBV tests. The Chair agreed that donors will need to be retested for all tests, unless they were previously positive for CMV and EBV, and then the donor does not need to be retested for the specific test for which they were previously positive. Other members agreed.

Staff asked if HIV would need to be retested if the donor was previously positive. The Chair explained that viral load would be critical to understand. Another member agreed.

One member wondered if the previously positive exception for anti-CMV and anti-EBV made testing requirements more complicated, and if these tests should just be required for previously-positive donors anyway. Staff asked if it was necessary for these tests to be redone for previously positive donors if these donors are typically retested prior to recovery anyway. Another member pointed out that CMV and EBV would not prevent donation, but simply need to be tested prior to recovery to understand post-

transplant transmission risk. The Chair agreed, adding that this would also affect the education for the recipient.

The Workgroup achieved consensus that donors previously positive for CMV and EBV do not need to be retested upon re-evaluation for the test for which they had a positive result. The Workgroup agreed that all other proposed tests will be required upon re-evaluation for all donors.

The Workgroup agreed that tuberculosis and endemic disease screening and testing will need to be included and required for re-evaluation.

Project summary – Donor Re-Evaluation Requirements:

The proposed project also includes informed consent requirements, such that Programs will be required to maintain documentation in the donor's record that it has informed the paired donor of all of 13.4.C: Informed Consent for KPD Donors upon re-evaluation. Furthermore, as proposed, programs will also be required to obtain a signature from the paired donor reconfirming their interest in continuing in the KPD program.

- The informed consent changes going to the Board of Directors for approval in December require programs to initially obtain a signature confirming the donor has been informed of their right to withdraw from participation at any time, for any reason

The Workgroup specified that the program must report changes to the following donor information upon re-evaluation:

- Gender
- Height
- Weight
- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic BP measurements with date (either 24 hour monitoring or 2 measurements)
- Creatinine clearance or GFR, date, and method
- The following infectious disease testing results:
    - Anti-CMV
    - EBV
    - HbsAg
    - Anti-HbcAb
- The following donor choices:
    - Whether the donor would be willing to travel and to which transplant hospitals or the distance willing to travel
    - Whether the donor is willing to ship a kidney
    - Whether the donor is willing to donate a left kidney, right kidney, or either
    - Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
    - Whether the potential KPD donor and transplant hospital are willing for the potential KPD donor to be a bridge donor
- The date the donor re-evaluation was completed and above relevant donor information updated in the OPTN KPD system

Summary of discussion:

Staff asked the Workgroup if they would prefer to maintain the requirement that transplant programs obtain a signature from the donor confirming they are still interested in participating in the OPTN KPDPP, or if they would rather require programs to obtain a signature confirming the donor has been re-informed of the right to withdraw at any time, for any reason. Staff noted that feedback from the *Update Kidney Paired Donation Policy* proposal recommended emphasizing donor autonomy in policy language and requirements, and noted that as is, this requirement could be interpreted as a binding agreement. The Chair agreed that the signature confirming interest in participating in the OPTN KPDPP could be seen as a binding agreement. The Chair expressed support for instead requiring programs to obtain a signature confirming the donor has been re-informed of the right to withdraw, in the interest of consistency and emphasis on donor autonomy.

The Workgroup achieved consensus that programs should be required to obtain a signature from the donor confirming the donor has been re-informed of their right to withdraw from the OPTN KPDPP at any time, for any reason.

Staff asked the Workgroup if they would prefer to specifically list which pieces of information the program should report changes for, or if the policy should instead require programs to report any changes to the information reported for match run eligibility, per *Policy 13.6.B: Requirements for Match Run Eligibility for KPD Donors*. The Chair expressed support for requiring programs to report any changes to information previously reported in the KPD system, per *Policy 13.6.B: Requirements for Match Run Eligibility for KPD Donors.* Another member agreed.

Staff noted that previously, the Workgroup expressed support for proposing additional data collection, such that programs report the date donor re-evaluation was completed and all relevant changes to donor information reported in the OPTN KPD system. The Chair expressed support for including this as proposed data collection. Another Workgroup member agreed.

Staff asked the Workgroup if the re-evaluation requirement should impact the donor's eligibility to match in the OPTN KPD system. Staff noted that there may not be sufficient information technology implementation resources to include this, but asked the Workgroup if this would be preferable to include, if feasible. The Chair remarked that an eligibility component would be important to the success of this policy change, and would ensure that the donor information used in OPTN KPD match runs is up to date. The Workgroup agreed that, if feasible, an eligibility component should be included, such that a donor with an overdue re-evaluation is not eligible to participate in OPTN KPD match runs until a date of re-evaluation is reported. The Workgroup agreed that, if this is not feasible, the requirement for donor re-evaluation should still move forward, though the benefits may be diminished.

The Chair remarked that the re-evaluation requirement should also include an Independent Living Donor Advocate (ILDA) requirement, as initial evaluation does. Staff noted that this is part of Living Donor policy, but could be included in the re-evaluation requirement. The Chair explained that ILDA requirements are separate from psychosocial evaluation requirements, but are critical to ensuring there is no coercion. The Workgroup agreed that re-evaluation should include requirements for an ILDA per *policy 14.2: Independent Living Donor Advocate Requirements*. Staff asked if the psychosocial evaluation should still be included, and the Chair agreed that psychosocial re-evaluation should be included in re-evaluation requirements.

2. KPD Priority Points Monitoring Report

The Workgroup reviewed the results of the two-year post-implementation monitoring report for the Updated OPTN KPD Priority Points policy.

Presentation Summary:

The OPTN KPDPP is open to all OPTN-approved living donor kidney transplant programs. The OPTN KPDPP facilitates about 40-50 transplants a year, which dropped to about 20 a year during the COVID-19 pandemic. Matches are run once a week, and were run once every two weeks during the COVID-19 pandemic. The matching algorithm searches for two-way, three-way, and chain exchanges.

In 2019, the OPTN implemented a new policy to update how priority points are awarded in KPDPP match runs, with several goals:

- Increase the likelihood of finding matches for highly sensitized candidates and pairs with difficult to match blood types
    - Adopted a sliding scale for calculated panel reactive antibodies (CPRA) points
    - Add priority points for candidate blood type (ABO)
    - Add priority points for paired donor ABO
- Add a remedy for orphan candidates who are part of a failed exchange
    - Award orphan candidates the maximum possible amount of priority points, ensuring that the optimization algorithm will find the next available compatible match in a non-directed donor chain
- Remove priority points based on donor service area (DSA)
    - Removed priority points for candidates in the same DSA or administrative region as donors

The cohort utilized for this monitoring report is split into three groups:

- Pre-policy: October 22, 2017 – October 23, 2019
- Post-policy, pre-COVID: October 24, 2019 – March 12, 2020
    - March 13, 2020 – COVID-19 declared a national emergency in the US
- Post-policy, COVID – March 13, 2020 – October 24, 2021

Metrics evaluated and summarized results include:

- Orphan candidates
    - The OPTN KPDPP has not had any failed exchanges resulting in an orphan candidate
- Participation in OPTN KPDPP match runs
    - There were an average of 182 candidates participating in match runs in the pre-policy era, which dropped to 151 in the post-policy, pre-COVID era. This dropped sharply in March of 2020 before gradually recovering
    - Center participation reflected a similar trend, with 60 centers in the pre-policy era, participation dropping to 53 centers in the post-policy, pre-COVID era, and then dropping sharply in March of 2020 before gradually recovering
- Match and match rates
    - In March 2020, the OPTN KPDPP switched from weekly match runs to match runs every two weeks in response to the drop in participation during the COVID-19 pandemic. The program returned to weekly match runs in November of 2021
    - Fewer matches found post-policy – with 815 match offers in the pre-policy era and a total of 436 match offers in both post-policy eras combined
    - Match rate significantly increased in both post-policy eras relative to pre-policy
        - Match rate, the proportion of match opportunities that resulted in a match
- The proportion of matches for type O candidates increased slightly post-policy
    - Match rate for type O candidate also increased post-policy, though not statistically significant

    - Match rate for type AB candidates also increased post-policy, though interpretation is challenging due to the small number of matches for AB candidates
- The proportion of matches for pairs with an AB donor has increased noticeably from 2.4% of matches pre-policy to around 4 or 6 percent post-policy
    - Matches for pairs with O donors have also increased
    - Match rates for pairs with an AB donor increased in both post-policy eras relative to pre-policy, from 1.41 percent to roughly 3.6 percent post-policy and pre-COVID and 2.4 percent post-policy, COVID
- Proportion of matches for candidates in the 80-89, 90-97, and 98-100 percent CPRA groups increased in the post-policy pre-COVID era, but decreased against in the post-policy, COVID era
    - Similarly, the match rates for candidates in the 80-89, 90-97, and 98-100 percent CPRA groups increased post-policy in the pre-COVID era, then decreased in the COVID era
- There were no matches for candidates receiving priority as prior living donors in post-policy eras and only 7 in the pre-policy era, though candidates receiving prior living donor priority points were entered in match runs 294 times in the pre-policy era and a total of 48 times post-policy.
- Match outcomes:
    - The transplant rate in the pre-policy era was 10.6 percent with 86 of the 815 matches resulting in a transplant.
    - The transplant rate in the post-policy pre-COVID era was similar at 10.6 percent
    - The transplant rate during the COVID era was lower at just 7.1 percent with 21 matches resulting in a transplant.
    - In the pre-policy era there were 10 matches where the candidate and donor had a prior negative or acceptable crossmatch. There were also 3 in the post-policy pre-COVID era and 9 in the COVID era.
        - Around 30 percent of these matches resulted in transplants across the eras
    - Proportion of national share type transplants increased from the pre-policy era to the post policy eras from 67.5 percent to around 71 percent and 84 percent of transplants in the post-policy eras

Though interpretation of the post-policy COVID-era data is challenging due to the impact the pandemic has had on the KPDPP, two years of data suggest that although there were no notable change in the matches/match rate for highly sensitized candidates. The policy is having the intended effect of increasing matches/match rates for type O candidates and pairs with type AB donors.

Summary of discussion:

Staff asked the Workgroup if they had any questions or comments about the results of the two-year post-implementation monitoring report. The Chair noted that they did not have any comments, but that it may take a little time to digest and mull over the results of the report.

The Workgroup had no additional questions or comments.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Marian Charlton
  - Stephen Gray
  - Aneesha Shetty
  - Erica Seasor
- **HRSA Staff**
  - Marilyn Levi
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Alina Martinez
  - Katrina Gauntt
  - Kim Uccellini
  - Megan Oley
  - Ross Walton
  - Ruthanne Leishman