OPTN

Notice of OPTN Policy Change

Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements

Sponsoring Committee:	**OPTN Kidney Transplantation Committee**
Policies Affected:	***13.4.C: Additional Requirements for KPD Donors***
	13.6.B: Requirements for Match Run Eligibility for OPTN KPD Donors
	13.7: Re-Evaluation Requirements for OPTN KPD Donors
	13.8.B: Blood Type A, Non-A_1, and Blood Type AB, non-A_1B Matching
Public Comment:	**January 19, 2023 – March 18, 2023**
Board Approved:	**June 26, 2023**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Policy Change

The purpose of this proposal is to increase the number of transplants by improving the efficiency of the OPTN Kidney Paired Donation Pilot Program (KPDPP). This proposal will improve clarity and efficiency by aligning OPTN KPDPP blood type A, non-A1 and blood type AB, non-A1B matching eligibility requirements with those in OPTN kidney policy. These changes may also increase the number of matches certain blood type B and O candidates are eligible for and encourage increased transplants by expanding the number of eligible matches within the OPTN KPDPP candidate-donor pair population. Furthermore, this proposal will improve the efficiency of the KPD program and the quality of OPTN KPDPP matches by requiring annual donor re-evaluation, which will ensure donor information utilized in matches is up to date. Finally, both the donor re-evaluation requirement and the blood type matching policy alignments will have positive implications for living donor and recipient safety.

Proposal History

The OPTN KPD Workgroup re-formed in 2021 to review KPD policy and identify areas in need of clarification and alignment with current practices and other relevant parts of OPTN Policy. The Workgroup identified several appropriate policy modifications to improve KPD clarity and efficiency, which were included in the Board approved *Update KPD Policy Proposal*.[1] OPTN KPDPP blood type matching policy was also identified as an area in need of alignment and updating by the Workgroup. Furthermore, public comment feedback included several recommendations to require KPD donor re-evaluation. This proposal addresses this community feedback and the previously identified system

[1] OPTN Board of Directors Meeting Summary, December 5, 2022.

improvements by proposing the establishment of re-evaluation requirements and alignment of blood type matching policy with OPTN Kidney Policy.

The proposal received overall support across stakeholders during public comment. After reviewing community feedback, the Committee decided to expand the re-testing exception for donors with prior positive results to include hepatitis B and C antibody testing, remove the requirement to re-obtain the donor's signature, and expand proposed data collection removal to better align A2 and A2B blood type matching policy. The Committee also plans to incorporate a 90-day implementation period, in which donor re-evaluation requirements will be in place, but donor eligibility will not be immediately impacted upon implementation.

Summary of Changes

Align OPTN KPDPP Blood Type A, non-A1 and AB, non-A1B Matching

- The proposal aligns OPTN KPDPP blood type matching policy with that found in OPTN kidney policy by requiring programs to establish a written policy for transplanting A, non-A1 kidneys into blood type B and O candidates, and for transplanting AB, non-A1B kidneys into blood type B candidates, obtain consent from the candidates regarding their willingness to accept these kidneys, and confirm the candidates' eligibility every 90 days (+/- 20 days)

Establish Donor Re-Evaluation

- The proposal establishes a requirement for OPTN KPDPP donors to be re-evaluated annually in the following areas: informed consent, psychosocial, medical, transmissible and endemic disease screening, and related reporting requirements
- The proposal establishes logistics, timing, and notification requirements for this re-evaluation

Implementation

Programs participating in the OPTN KPDPP will need to develop a written policy regarding their program's titer threshold for transplanting blood type A, non-A1 donor kidneys into candidates with blood type B and blood type O, and for transplanting blood type AB, non-A1B donor kidneys into candidates with blood type B. Programs will need to obtain written consent from each eligible blood type B candidate regarding their willingness to accept a blood A, non-A1, or blood type AB, non-A1B kidney. Programs will also need to obtain written consent from each eligible blood type O candidate regarding their willingness to accept a blood type A, non-A1 kidney. Programs will need to confirm their candidates' eligibility to receive these offers and reconfirm the candidate's eligibility every 90 days (+/- 20 days).

Programs will need to train staff and familiarize themselves with the requirements for re-evaluation. Programs participating in the OPTN KPDPP will need to communicate with their candidate-donor pairs about the new requirement for annual re-evaluation and coordinate with these donors appropriately to ensure re-evaluation requirements are completed. Programs will need to report the date of completed re-evaluation to maintain the donor's eligibility to participate in KPD match runs. Policy effective date is pending implementation.

This proposal requires submission of OPTN data not presently collected, which will require a revision to the OMB-approved data collection instruments. The proposal will require IT implementation efforts to update the system to correspond to the changes proposed. Implementation of the proposed re-evaluation requirement will also include an initial implementation period of 90 days (three months), during which donor eligibility will not be impacted, but which will allow programs ample time to

coordinate upcoming re-evaluations. The OPTN will distribute educational materials and update current educational offerings for participating transplant programs.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

13.4.C Additional Requirements for KPD Donors

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
8. The possibility that the paired donor's kidney might not be transplanted, or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. The possibility that personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation related costs.
11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. That the paired donor may require re-evaluation
16. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

For initial evaluations of all donors, the paired donor's transplant hospital must obtain the paired donor's signature that confirms the donor has been informed that the paired donor may withdraw from participation in the KPD program at any time, for any reason.

For re-evaluation of OPTN KPD donors, the paired donor's transplant hospital must confirm the donor has been informed that the paired donor may withdraw from participation in the KPD program at any time, for any reason.

13.6 Matching within the OPTN KPD Program

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13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.5: Living Donor Blood Type Determination and Reporting* with the following modifications:
    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's blood type to the OPTN
    b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN, must compare the blood type from the two source documents, and separately report the potential KPD donor's blood type to the OPTN
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to *Policy 13.4: Informed Consent for KPD Donors*
3. The transplant hospital registering the potential KPD donor must complete the evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN:
    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information
        - Whether the potential KPD donor has signed an informed consent as required in policy
        - Whether the potential KPD donor has undergone all evaluations as required in *Policy 14: Living Donation*
        - Whether the potential KPD donor has had all cancer screenings as required in P*olicy 14: Living Donation*

- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:
   - The number of anti-hypertensive medications the potential KPD donor is currently taking
   - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
   - Creatinine clearance or glomerular filtration rate (GFR), date, and method
   - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
   - Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
   - Whether the potential KPD donor is willing to ship a kidney
   - Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
   - 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 the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

5. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reason for refusing offers
7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program
8. The transplant program has re-evaluated the potential KPD donor per *Policy 13.7: Re-Evaluation Requirements for KPD Donors* and reported to the OPTN the date of re-evaluation

13.7 Re-Evaluation Requirements for OPTN KPD Donors

Transplant programs must re-evaluate donors in the OPTN KPD Program annually. The donor's re-evaluation deadline is based on donor's date of registration in the OPTN KPD program or the date of the donor's re-evaluation, whichever is most recent.

Transplant programs will have 30 days after the donor's re-evaluation deadline to perform the re-evaluation. The paired donor's transplant hospital must report the date the donor re-evaluation was completed and any changes to the donor information reported per *Policy 13.6.B: Requirements for Match Run Eligibility for Potential Donors*. Failure to report date of completed donor re-evaluation by this time will render the donor ineligible to participate in match runs in the OPTN KPD program until a re-evaluation date is reported.

13.7.A Psychosocial Re-Evaluation Requirements for OPTN KPD Donors

A psychosocial re-evaluation of the OPTN KPD donor must be performed by the paired donor's transplant program per OPTN *Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements*.

13.7.B Medical Re-Evaluation Requirements for OPTN KPD Donors

A medical re-evaluation of the paired donor must be performed by a physician or surgeon experienced in living donation at the paired donor's transplant program. Documentation of the medical re-evaluation must be maintained in the donor medical record.

The medical re-evaluation must include *all* of the components in *Table 13-1* and *Table 13-2* below.

Table 13-1: Requirements for OPTN KPD Donor Medical Re-Evaluation:

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
General Donor History	1. A personal history of significant medical conditions, which include but are not limited to: o Hypertension o Diabetes o Lung disease o Heart disease o Gastrointestinal disease o Autoimmune disease o Neurologic disease o Genitourinary disease o Hematologic disorders o Bleeding or clotting disorders o History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. Evaluation for coronary artery disease
Kidney-specific Donor History	1. A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: o Kidney disease, proteinuria, hematuria o Kidney injury o Diabetes including gestation diabetes o Nephrolithiasis o Recurrent urinary tract infections
Social History	1. Occupation 2. Employment status 3. Health insurance status 4. Living arrangements 5. Social support 6. Smoking, alcohol and drug use and abuse 7. Psychiatric illness, depression, suicide attempts 8. Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
Physical Exam	1. Height 2. Weight 3. BMI 4. Vital signs 5. Examination of all major organ systems 6. Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
General laboratory and imaging tests	1. Complete blood count (CBC) with platelet count 2. Prothrombin Time (PT) or International Normalized Ratio (INR) 3. Partial Thromboplastin Time (PTT) 4. Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) 5. HCG quantitative pregnancy test for premenopausal women without surgical sterilization 6. Chest X-Ray 7. Electrocardiogram (ECG)
Other metabolic testing:	1. Fasting blood glucose 2. Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LCL cholesterol) 3. Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high-risk individuals
Kidney-specific tests	1. Urinalysis or urine microscopy 2. Measurement of urinary protein and albumin excretion 3. The following, if clinically indicated: o Urine culture o Measurement of glomerular filtration rate by isotopic methods or creatinine clearance calculated from a 24-hour urine collection o 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:	1. The paired donor's transplant hospital must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: o Cervical cancer o Breast cancer o Prostate cancer o Colon cancer o Lung cancer
Anatomic assessment	1. The following, if clinically indicated: o Whether the kidneys are of equal size o If the kidneys have masses, cysts, or stones o If the kidneys have other anatomical defects o Which kidney is more anatomically suited for transplant

The paired donor's transplant program must re-evaluate the donor for transmissible diseases per Table 13-2.

Table 13-2: Infectious Disease Testing Re-Evaluation Requirements:

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening:	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include all the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) 5. Hepatitis B surface antigen (HbsAg) 6. Hepatitis B core antibody (total anti-HBc) testing 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) 8. Hepatitis C antibody (anti-HCV) testing 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 10. Syphilis testing The donor does not need to be retested for the following infectious disease antibodies for which they have previously tested positive: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. Hepatitis B core antibody (total anti-HBc) testing 4. Hepatitis C antibody (anti-HCV) testing For tuberculosis (TB), the paired donor's transplant hospital must retest and follow protocol per *Policy 14.4: Medical Evaluation Requirements for Living Donors* 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.

13.7.C Informed Consent Requirements Upon Donor Re-Evaluation

Upon re-evaluation of the OPTN KPD donor, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of all of the requirements in *Policy 13.4.C: Informed Consent for KPD Donors*. The paired donor's transplant hospital must also confirm that the donor has been re-informed that they may withdraw from participation in the OPTN KPD program at any time, for any reason.

13.~~7~~8 OPTN KPD Screening Criteria

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13.~~7~~8.B Blood Type A, non-A1 and Blood Type AB, non-A1B Matching for Blood Type O and Blood Type B Candidates

~~In order for a blood type B candidate to be eligible to be matched to a blood type A, non-A_1 or blood type AB, non-A_1B potential donor, or for a blood type O candidate to be eligible to match to a blood type A, non-A_1 potential donor in the OPTN KPD Program, the candidate must meet *both* of these conditions:~~

~~1. The candidate must have an IgG antibody titer value less than 1:8~~
~~2. The candidate's transplant hospital must report to the OPTN the candidate's titer value and date of the test.~~

Kidneys from donors with blood types A, non-A_1 may be matched with candidates with blood type B or blood type O, and kidneys from donors with blood types AB, non-A_1B may be matched with candidates with blood type B, so long as *all* of the following criteria are met:

1. The paired candidate's transplant program establishes a written policy regarding its programs titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B and for transplanting blood type A, non-A_1 into candidates with blood type O.
2. The paired candidate's transplant program obtains written informed consent from the candidate regarding their willingness to accept a blood type A, non-A_1, or blood type AB, non-A_1B blood type kidney
3. The paired candidate's transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

Approved Modifications to OPTN KPD Data Collection

Data Element:	Current State:	Future State:
If the candidate is blood type B, is the candidate willing to accept an A2[2] or A2B donor?	Yes/No	Removed in Future state
If candidate is willing to accept an A2 or A2B donor, enter IgG antibody titer	1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, >1:64	Removed in Future state
If the candidate is O, is the candidate willing to accept an A2 donor?	Yes/No	Removed in Future state
If the candidate is willing to accept an A2 donor, enter IgG antibody titer	1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, >1:64	Removed in Future state
Titer date	MM/DD/YYYY	Removed in Future State
Does the candidate meet criteria for A2 or A2B (including patient consent)	Field does not exist	Yes/No
Donor re-evaluation completed and relevant changes reported as of:	Field does not exist	MM/DD/YYYY

[2] Note: A2 is used as shorthand for any blood type A subtype other A1 (i.e. non-A1, negative for A1). A2B is used as shorthand for any blood type AB subtype other than A1B (i.e. non-A1B, negative for A1B).