OPTN

Public Comment Proposal

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

OPTN Kidney Transplantation Committee

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

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Sponsoring Committee:	*Kidney Transplantation*
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Executive Summary

The OPTN's Kidney Paired Donation Pilot Program (KPDPP) has been operational since 2010 and is governed by *OPTN Policy 13: Kidney Paired Donation*. Kidney Paired Donation (KPD) is a process that matches one medically incompatible living donor-candidate pair with another, so the donor in each pair is medically compatible with the candidate in the other pair. By exchanging living donors, each candidate can receive a compatible transplant. These "exchanges" can consist of several candidate-donor pairs, creating KPD "chains."[1]

The OPTN Kidney Transplant Committee proposes the alignment of OPTN KPDPP blood type A, non-A1 and AB, non-A1B matching policy and establishing a new requirement for annual donor re-evaluation. The proposed changes will improve the efficiency of the OPTN KPDPP system, which may increase the OPTN KPDPP match success rate and may ultimately increase the number of transplants. The proposed changes have implications for improved living donor and recipient safety and equity in access across blood type. This proposal builds upon previous updates, alignments, and clarifications proposed in the *Update KPD Policy* proposal approved by the OPTN Board of Directors on December 6, 2022.

The first proposed change will align the OPTN KPDPP blood type A, non-A_1 and AB, non-A_1B matching policy with that in OPTN kidney policy. This alignment will provide clarity and improve general efficiency in the KPD system by allowing programs to consolidate their processes for candidate eligibility to receive A, non-A1 and AB, non-A1B offers on the deceased donor waitlist and the OPTN KPDPP. These alignments may expand access for some blood type O and B candidates at programs with less conservative titer policies, which could improve equity across blood types and increase the number of potential exchanges. In turn, this change may indirectly increase the OPTN KPDPP match success rate.

The Kidney Transplantation Committee is also proposing a new requirement for annual donor re-evaluation for donors participating in the OPTN KPDPP system. The proposed re-evaluation will include psychosocial, medical, and informed consent re-evaluation requirements. The proposed re-evaluation requirement aims to improve efficiency and match quality in the OPTN KPDPP, which will ultimately improve the match success rate and so increase transplants.

[1] Kidney Paired Donation, United Network for Organ Sharing. https://unos.org/transplant/kidney-paired-donation/

Purpose

The central purpose of this proposal is to increase the number of transplants by improving the efficiency of the OPTN KPDPP. 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. Furthermore, this proposal will improve clarity and efficiency by aligning OPTN KPDPP blood type A, non-A_1 and blood type AB, non-A_1B 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. Finally, both the donor re-evaluation requirement and the blood type matching policy alignments will have positive implications for living donor and recipient safety.

Background

The original OPTN KPD Workgroup (the Workgroup) formed in 2004 and developed a pilot national KPD program. This program, the OPTN KPDPP, became operational in 2010.[2,3] Over the last decade, the Workgroup has monitored the progress of the OPTN KPDPP, developing proposals to update policy as necessary to improve the success of the program.

The OPTN KPD Workgroup re-formed in 2021 with representation from the following OPTN Committees:

- Kidney Transplantation
- Living Donor
- Histocompatibility
- Minority Affairs
- Patient Affairs
- Transplant Coordinators
- Transplant Administrators

The Workgroup reviewed each section of *OPTN Policy 13: Kidney Paired Donation*, identifying areas in need of clarification and alignment with current practices and other relevant parts of OPTN policy. During this review, the Workgroup determined several policy modifications were appropriate to improve efficiency and clarity in KPD processes. Many of the identified improvements were included in the *Update KPD Policy Proposal*, which was approved by the Board of Directors in December, 2022.[4] OPTN KPDPP blood type A, non-A_1 and AB, non-A_1B matching policy was identified as an area in need of alignment, to improve overall efficiency, clarity, and consistency within OPTN policy. Other modifications were prioritized as future projects, as they necessitated data collection or additional resources. Subsequently, the Workgroup prioritized blood type A, non-A_1 and AB, non-A_1B matching policy alignment identified during the Workgroup's holistic review for the next round of updates.

[2] As a pilot, the OPTN KPDPP was governed by the official Operational Guidelines developed by the KPD Workgroup. These Operational Guidelines were not subject to the public comment process, and so allowed the KPD Workgroup the flexibility to adjust the rules and processes of the pilot program as necessary. In 2012, the KPD Workgroup began the process of revising and moving the KPDPP Operational Guidelines to OPTN Policy, in an effort to transition the program out of its pilot stage. The Operational Guidelines were revised a total of 10 times before their ultimate removal in October 2021, at the October 8, 2021 meeting of the OPTN Kidney Transplantation Committee.
[3]OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2021.
https://optn.transplant.hrsa.gov/media/4hzlnxhy/20211008_kidney_meeting_summary.pdf
[4] OPTN Board of Directors Meeting Summary, December 5, 2022.

In addition, this proposal incorporates the community feedback by proposing the establishment of re-evaluation requirements. Public comment submitted for the *Update KPD Policy Proposal* included several recommendations to require KPD donor information to remain up to date in order to improve the efficiency of the OPTN KPDPP system and the quality of information utilized in OPTN KPDPP matches.

Overview of Proposal

The Committee proposes two updates to OPTN KPDPP policy: the alignment of blood type A, non-A_1 and AB, non-A_1B matching eligibility requirements and the establishment of a requirement for annual donor re-evaluation.

OPTN KPDPP Blood Type A, non-A_1 and AB, non-A_1B Matching Alignments

The Committee proposes alignment of the OPTN KPDPP blood type A, non-A_1 and AB, non-A_1B matching eligibility requirements with those in OPTN Kidney Policy. Current OPTN KPDPP policy for A, non-A_1 and AB, non-A_1B matching includes a specific IgG antibody titer requirements. OPTN Kidney policy for deceased donor A, non-A_1 and AB, non-A_1B matching do not include a specific titer threshold and instead require programs to establish their own written policies for transplanting A, non-A_1 kidneys into blood type B and O candidates, and for transplanting AB, non-A_1B kidneys into blood type B candidates. Furthermore, OPTN KPDPP policy only requires the candidate's titer value and test date to be reported once, while general kidney A, non-A_1 and AB, non-A_1B matching policy requires the candidate's eligibility to receive such offers to be reconfirmed every 90 days (with a margin of 20 days). These alignments will improve general efficiency in the OPTN KPDPP system, as well as impact recipient safety and equity across blood type.

The Committee proposes the following new requirements for transplant programs for OPTN KPDPP candidate eligibility to receive A, non-A_1 and AB, non-A_1B offers. The transplant program must:

- Obtain written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or a blood type AB, non-A_1B kidney, and from each eligible blood type O candidate regarding their willingness to accept a blood type A, non-A_1 kidney
- Establish a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 kidneys into candidates with blood type B or O, and for transplanting blood type AB, non-A_1B kidneys into candidates with blood type B
- Confirm the candidate's eligibility every 90 days, plus or minus 20 days

Aligning these requirements will improve general efficiency in the OPTN KPDPP system by allowing programs to consolidate their processes for pursuing candidate eligibility to receive A, non-A_1 and AB, non-A_1B offers on the deceased donor waitlist and in the OPTN KPDPP. With alignment between OPTN kidney and KPD blood type A, non-A_1 and AB, non-A_1B matching eligibility requirements, programs can align their own policies regarding titer thresholds for transplanting blood type A, non-A_1 and AB, non-A_1B kidneys for candidates' deceased donor waitlist listing and OPTN KPDPP listing. This alignment of policies will increase efficiency for participating transplant programs and for the OPTN KPDPP as a whole.

Establishing a requirement for re-confirmation of the candidate's eligibility to accept blood type A, non-A_1 and AB, non-A_1B kidney offers also provides an additional measure for recipient safety, by encouraging the transplant program to continue engaging with the candidate regarding acceptance of these organs and continued testing of the candidate's titers.

Expanding Access and Blood Type A, Non-A_1 Matching for Blood Type O Candidates

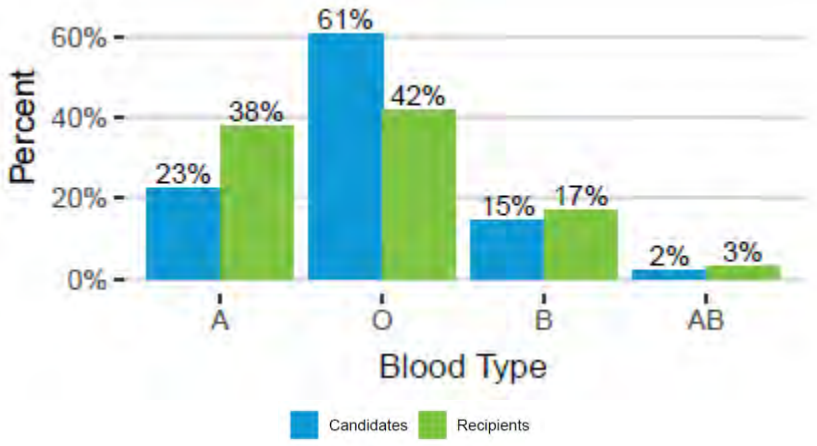
Current KPD A, non-A_1 and AB, non-A_1B matching policy allows blood type B and blood type O candidates to receive blood type A, non-A_1 offers, as long as they meet the eligibility requirements. Specifically, allocation for blood type A, non-A_1 and AB, non-A_1B donor kidneys in the OPTN KPDPP follows **Table 1.**

Table 1: Allocation of Blood Type A, non-A1 and Blood Type AB, non-A1B Donor Kidneys

Donors with:	Are matched to candidates with:
Blood Type A, non-A1	Blood types A, A1, or A, non-A1 Blood types AB, A1B, or AB, non-A1B Blood type O or B, if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A1 and Blood Type AB, non-A1B Matching*
Blood type AB, non-A1B	Blood types AB, A1B, or AB, non-A1B Blood type B, if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A1 and Blood Type AB, non-A1B Matching*

OPTN Kidney A, non-A_1 and AB, non-A_1B matching policy does *not* currently allow eligible O candidates to receive A, non-A_1 donor kidney offers. The Workgroup noted that O candidates are harder to match, as these candidates typically are only physiologically able to accept blood type O kidneys.[5] This disparity is reflected in transplant rates for the OPTN KPDPP – blood type O patients make up 61 percent of KPD candidates, but only 42 percent of the transplants, as show in **Figure 1.**

Figure 1: OPTN KPDPP Candidates and Recipients by Blood Type[6]



[5] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022: https://optn.transplant.hrsa.gov/media/i1rh1dx3/20221005-kpd-meeting-summary.pdf
[6] State of the KPD 10 Year Report, 2022

The Workgroup ultimately decided to recommend maintaining access to blood type A, non-A_1 donor kidneys for eligible blood type O candidates.[7] Maintaining this access will potentially encourage increased equity in access for blood type O candidates.

The proposed alignment in eligibility requirements to receive A, non-A_1 and AB, non-A_1B offers may also expand access for both blood type O and blood type B candidates. By removing the requirement for a specific titer threshold, some blood type O and B candidates listed at programs with less conservative titer policies may be eligible to receive A, non-A_1 and AB, non-A_1B offers that may not have been eligible to receive before, due to the specific titer requirement.[8] This expanded access for some candidates will encourage increased equity in access across blood types for blood type B and blood type O candidates. Furthermore, this expanded access will indirectly improve the match success rate, as the current pool of candidates are eligible to receive offers from more donors, increasing the number of potential viable matches and exchanges.

Modifications to OPTN KPDPP Blood Type A, non-A_1 and AB, non-A_1B Matching Data Collection

In order to ensure alignment with Kidney blood type A, non-A1 and AB, non-A1B matching policy and procedures in the OPTN Waitlist, the Committee proposes several modifications to data collection in the OPTN KPDPP system. This will include the removal of the data elements listed in **Table 2.**

Table 2: Data Elements Proposed for Removal from the OPTN KPDPP System

Data Element:	Response Options:
If the candidate is blood type B, is the candidate willing to accept an A2 or A2B donor?	Yes/No
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
Titer date	MM/DD/YYYY

The Committee proposes replacing the above elements with a single data element, to indicate whether the candidate meets their program's written criteria for accepting blood type A, non-A1 or AB, non-A1B. The full list of proposed modifications can be found in **Appendix A.**

OPTN KPDPP Donor Re-Evaluation Requirements

The Committee proposes a requirement for programs to re-evaluate their paired donor participants in the OPTN KPDPP on an annual basis. This requirement is specific only to paired donors participating in the OPTN KPDPP. This proposed re-evaluation includes informed consent, psychosocial evaluation, medical evaluation, and reporting requirements, each of which are expanded upon below. The Committee also proposes updates to informed consent requirements for KPD donors, to include informing the donors that they may be re-evaluated annually.

[7] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.
[8] Ibid.

Currently, the OPTN KPDPP program does not require transplant programs to re-evaluate their donors. As a result, donor information in the OPTN KPDPP system becomes outdated as changes in the donor's health and ability to donate occur, reducing the quality of the matches and ultimately, the success of these matches.[9] Furthermore, outdated donor information can prolong the period of time from match offer to recovery and transplant, as the donor needs to be fully re-evaluated before the exchange can move forward. Several aspects of the donor re-evaluation requirements below provide critical information regarding health factors which could impact a donor's decision to donate or their eligibility and candidacy for donation.[10] Requiring re-evaluation will not only ensure donor information is up to date, but will also ensure that only donors who are currently able to donate are active and participating in the OPTN KPDPP match runs.[11] Donors for whom a completed re-evaluation is not reported within the appropriate timeframe will be ineligible to participate in OPTN KPDPP match runs. These donors will remain ineligible until a date of completed re-evaluation is reported. The reported date of re-evaluation completion must be within the last 395 days to regain the donor's eligibility.

Establishing a requirement for regular donor re-evaluation will help to ensure that donor information utilized in match runs is up to date, which will increase the quality of the matches, increase the efficiency of OPTN KPDPP exchanges, and may increase the likelihood of match success.

Re-Evaluation Requirements: Informed Consent

The Committee proposes an update to OPTN Informed Consent *Policy 13.4.C: Additional Requirements for KPD Donors*, such that donors are informed that they may need to be re-evaluated. The Workgroup recommended this update, noting donors should understand that there may be a potential need for re-evaluation and that it may be a year or longer before they donate.

The Committee also proposes that transplant programs are required to re-inform and re-consent paired donors per OPTN *Policy 13.4.C: Additional Requirements for KPD Donors* upon re-evaluation. In recommending that programs re-obtain informed consent, the KPD Workgroup explained that it is important donors are regularly re-informed, in case of any changes to informed consent requirements. The Workgroup also emphasized that there is always a benefit to reviewing this information with donors, and that re-evaluation is a good opportunity to ensure donors are aware and fully informed.

As proposed, programs will need to obtain a signature reconfirming that the donor has been appropriately informed upon re-evaluation that they may withdraw from the program at any time, for any reason. This will help to ensure donors are appropriately informed and that they are still willing to participate in the OPTN KPDPP program.[12,13]

Re-Evaluation Requirements: Psychosocial Evaluation

The Committee proposes that programs must perform a full psychosocial re-evaluation per Living Donor *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. This will require that the psychosocial evaluation is performed by a psychiatrist, psychologist, masters prepared social worker, or licensed clinical social worker to evaluate all of the following:

[9] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022 https://optn.transplant.hrsa.gov/media/elegg2nd/20221018-kpd-meeting-summary.pdf
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] OPTN Kidney Paired Donation Workgroup Meeting Summary, November 30, 2022.

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome
2. An assessment of risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Service (PHS) Guideline*
3. A review of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the living donor understands the potential financial implications of living donation

The Workgroup determined that a full psychosocial re-evaluation is important to ensuring the donor is psychosocially still able to donate, as a lot can change in a donor's life over the course of a year.[14] Furthermore, OPTN *Policy 14.4.E: Living Donor Exclusion Criteria* requires programs to exclude any potential donors who have uncontrolled psychiatric conditions requiring treatment before donation, including any evidence of suicidality.

A psychosocial re-evaluation will help programs monitor donors' overall psychosocial health and ensure that the paired donor will still be able to safely donate without poor psychosocial outcome. Psychosocial re-evaluation will ensure the programs are able to address any concerns for donor candidacy and confirm that the donor remains able to donate. This will help ensure that only donors who are actively able to donate remain active and eligible to participate in KPD match runs.

Medical Re-Evaluation Requirements: General, Kidney-specific, and Social Donor History

The Committee proposes medical re-evaluation requirements similar to many of those laid out in *Policy 14.4: Medical Evaluation Requirements for Living Donors*. As such, the medical re-evaluation must be performed by the paired donor's transplant hospital and by a physician or surgeon experienced in living donation. The program will be required to maintain documentation of the donor's re-evaluation in the donor's medical record.

The proposed medical re-evaluation requirements include several general and kidney specific donor history requirements. The Workgroup determined these requirements based on those laid out in OPTN Living Donor *Policy 14.4: Medical Evaluation Requirements for Living Donors*. The general and kidney specific donor history requires are as follows:

[14] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.

- 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
    - Kidney disease, proteinuria, hematuria
    - Kidney injury
    - Diabetes including gestation diabetes
    - Nephrolithiasis
    - Recurrent urinary tract infections
- 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

In recommending the inclusion of these elements, the Workgroup determined that the above donor history information could potentially change over the course of a year, and that each of these components are critical to ensuring the paired donor's safety. Some elements provide insight to the donor's overall health, while others reflect kidney-specific concerns; each of these may affect the potential risk of donation to the donor and so impact the donor's decision to donate or general candidacy for donation. Diabetes, for example, could pose a long term risk to the donor's safety and so impact the donor's ability to safely donate, with implications for their candidacy for donation.[15]

Furthermore, several components – such as hypertension, diabetes, and potential infections – are also relevant to understanding potential risk associated for a potential recipient. Changes to kidney-specific donor history could reflect changes to the paired donor's general kidney function or kidney injury, and so may impact the paired donor's candidacy for donation in the interest of both donor and recipient safety and long term outcomes. For example, nephrolithiasis would be important to understanding potential risk of kidney stones for a potential recipient.[16]

The Workgroup discussed the potential to include family history and genetic kidney-specific disease history, but ultimately determined that these components should have been addressed on initial evaluation, and are not likely to change. The Workgroup determined that neither family history nor kidney-specific genetic disease need to be re-assessed.[17]

The proposed re-evaluation requirements also include several components regarding the donor's social history, based on the requirements for potential living donor evaluation found in *Policy 14.4: Medical*

[15] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[16] Ibid.
[17] Ibid.

Evaluation Requirements for Living Donors. The social history evaluation requirements for re-evaluation include:

- Occupation
- Employment status
- Health insurance status
- Living arrangements
- Social support
- Smoking, alcohol and drug use and abuse
- Psychiatric illness, depression, suicide attempts
- Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*

Changes to the above components of a donor's social history could impact a donor's ability to safely and securely donate. Certain aspects, such as the development of psychiatric illness, could affect the risk associated with donation, and ultimately impact the donor's decision to donate or general candidacy for donation. Changes to factors such as employment and health insurance status could preclude the donor from being financially or practically able to donate as well. This social information is important for the program to monitor, so that the donor does not remain active in the OPTN KPDPP program while they are unable to donate, as this prevents successful matches. Furthermore, changes to the risk criteria for acute HIV, HBV, and HCV provide important insight on potential risk of infection for both the donor and the potential recipient.[18]

Overall, the Workgroup recommended reassessing the donor's general, kidney-specific, and social history, in order to monitor potential risk to the donor, the donor's general ability to donate, and potential risk to the recipient.[19] Furthermore, understanding the donor's ability to donate will encourage programs to ensure that only donors currently able to donate are active in the OPTN KPDPP system. This will improve the overall quality of information utilized in the match runs, which will help to improve the success of OPTN KPDPP matches by ensuring only donors able to donate are identified for potential exchanges.

Medical Re-Evaluation Requirements: Physical Exam

In keeping with evaluation requirements posed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*, the Committee proposes several physical exam requirements for re-evaluation:

- Height
- Weight
- Body Mass Index (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

Workgroup discussion regarding physical exam requirements noted that these elements may vary widely over the course of a year, particularly weight and body mass index.[20] The Workgroup noted that

[18] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[19] Ibid.
[20] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022

all of the above elements are critical to understanding and monitoring the donor's overall health, and could implicate potential complications that may pose a risk to the donor's health and ability to donate.[21] For example, shifts in blood pressure or increases in weight can follow the development of hypertension and diabetes, which may complicate the paired donor's long term outcomes associated with donation, and ultimately their candidacy as a donor.[22] Re-evaluation of these elements will help programs ensure the donor is actively still eligible and able to safely donate, and so ensure that donors not currently able to donate are not active in the KPD system.

Furthermore, height, weight, and body mass index are all utilized in the OPTN KPDPP system to screen and match candidate-donor pairs. Changes to this information may impact the pool of candidates the donor is eligible to match with. Re-evaluation of this information will ensure donor information utilized by the OPTN KPDPP system is up to date, improving the overall quality of the matches and ensuring that candidates are not matched with donors they should have been screened for. This will help improve match success.

Medical Re-Evaluation Requirements: General Laboratory and Imaging Tests

The Committee proposes the following general laboratory and imaging test requirements for re-evaluation, in keeping with those requirements found in *Policy 14.4: Medical Evaluation Requirements for Living Donors*:

- 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)

The Workgroup determined that each of these elements provide valuable information on the donor's overall health and related ability to safely donate.[23] These tests can indicate potential health concerns that could pose a risk to a donor's health and long term outcomes, and ultimately prevent the donor from donation. For example, a positive pregnancy test would preclude donation for a period of time, and require the program to mark that donor as inactive.

The Workgroup discussed blood type and subtype as potential re-evaluation requirements, and determined that this would be unnecessary, as this information would not have changed after initial donor evaluation.[24]

Re-evaluation of these elements will help programs ensure the donor is healthy and able to safely donate. This will ensure that only donors actively able and eligible to donate are active in the OPTN KPDPP system.

[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Ibid.

Medical Re-Evaluation Requirements: Metabolic and Kidney-Specific Testing

The proposed re-evaluation requirements include the following metabolic and kidney-specific testing requirements, based on those found in *Policy 14.4: Medical Evaluation Requirements for Living Donors*:

- Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- 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
- Urinalysis or urine microscopy
- Measurement of urinary protein and albumin excretion
- As needed, based on relevant patient history and exam findings:
    - Urine culture
    - Measurement of glomerular filtration rate (GFR) by isotopic methods or creatinine clearance (CrCl) calculated from a 24-hour urine collection
    - Patients with a history of nephrolithiasis or nephrolithiasis (greater than 3 millimeters) identified on radiographic imaging must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine, and sodium
    - Perform anatomic assessment to determine:
        - 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

The proposed required metabolic tests are important to understanding the donor's health, particularly with respect to organ function and potential risk of diabetes. This information may impact a donor's ability and choice to donate, as well as their general donor candidacy, and is important to ensuring donor safety. Metabolic re-evaluation requirements will help programs to ensure that donors active in the KPD system are healthy and able to donate.

The proposed kidney-specific tests provide invaluable insight to the donor's renal health, with implications for the donor's health and donor candidacy and for potential risks to the recipient. The Workgroup agreed that urinalysis, urine culture, and measurements of urinary protein and albumin excretion were appropriate and effective screening tools to ensuring the donor's renal function remains stable and healthy. The Workgroup noted that the development of concerning results from these tests could indicate a need for further testing or intervention. Identifying such results is critical not only to the donor's health and the potential risk posed to the donor's long term outcomes, but also to understanding and preventing potential risks to the recipient's long term outcomes and graft function.[25]

The Committee proposes that programs perform a urine culture and re-evaluate GFR or CrCl only as needed, based on relevant patient history and exam findings.[26] Urine cultures are typically utilized to determine whether the donor has a bacterial infection present, and the Workgroup agreed that this may only be necessary if clinically indicated.[27] The Workgroup discussed the re-evaluation of GFR as a

[25] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[26] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[27] OPTN KPD Workgroup Meeting Summary, November 30, 2022.

potential requirement, but ultimately determined that this should only be performed if there is suspicion that the donor's renal function has declined, particularly as direct measurement of GFR and Creatinine Clearance is often invasive and cumbersome. The Workgroup noted that a donor with stable results on other kidney-specific tests likely has stable renal function, and so there may be no benefit to repeating the GFR or Creatinine Clearance test. However, the Workgroup agreed that programs should re-evaluate GFR if there is clinical indication for concern for the donor's renal function, particularly based on relevant exam findings and donor history, such as kidney injury. Changes in the potential donor's GFR or Creatinine Clearance could have implications for both donor safety and the donor's kidney function post-donation, as well as for the recipient's safety and the function of a potential graft.

Similarly, the Committee proposes that programs perform a 24-hour urine stone panel only as needed, based on relevant patient history and exam findings for patients with a history of nephrolithiasis or nephrolithiasis greater than 3 mm identified on radiographic imaging. The Workgroup noted that donors with a history of nephrolithiasis who have been cleared for donation after initial evaluation may not need a full 24-hour urine stone panel test unless the patient has recurrent stones or another clinical indication. The Workgroup agreed that patients with no prior history of kidney stones who are found to have kidney stones upon re-evaluation should undergo a 24-hour urine stone panel test, as the patients' relevant history and exam findings provide clinical indication. The Workgroup agreed that concerning findings on a urine stone panel test could have implications for donor safety and the donor's health outcomes post-donation, as well as for the recipient's safety and function of a potential graft.[28]

The Workgroup also considered recommending anatomic re-assessment, noting that donor anatomy is not likely to change significantly from the time of initial evaluation. The Workgroup agreed that anatomic re-assessment could be performed at a program's discretion based on initial assessment and changes in the donor's medical history, and would not need to be required. The Workgroup agreed that it could be sensible for a program to re-assess anatomy if there is some concern for recurrent stones or if there was a previously present renal cyst to follow up on. The Workgroup ultimately recommended that anatomic re-assessment remain at a program's discretion, based on the donor's relevant history and exam findings. The Workgroup noted that anatomic re-assessment could provide insight on the donor's overall health and the potential risks of donation posed to the donor's long term outcomes. Furthermore, changes to and overall donor anatomy are critical to understanding potential risk to the donor. Donor information gathered upon anatomic re-assessment could also impact the donor's preferences with respect to laterality for donation, and so affect the pool of candidates with whom the donor is eligible to match.

The Workgroup discussed the potential inclusion of a re-evaluation requirement related to polycystic kidney disease and other inherited renal diseases, but decided that these issues should have been addressed upon initial donor re-evaluation.[29] Furthermore, this information is not likely to have changed. The Workgroup agreed that, as long as the donor understands the increased risk related to family history of inherited renal disease, it is the program and the donor's decision to move forward with donation. The Workgroup ultimately decided not to recommend the inclusion of a re-evaluation requirement related to polycystic kidney disease or other inherited renal disease.[30]

[28] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[29] Ibid.
[30] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022

Medical Re-Evaluation Requirements: Cancer Screening

The Committee proposes requiring cancer screening upon donor re-evaluation, in alignment with the same requirements for cancer screening posed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*. This will require transplant programs to develop and comply with protocols consistent with the American Cancer Society (ACD) or the United States Preventive Services Task Force to screen for cervical cancer, breast cancer, prostate cancer, colon cancer, lung cancer. The Workgroup determined that cancer screening has implications for both the donor and recipient's safety. Cancer screening is important to determining the donor's health and general donor candidacy, as well as understanding potential risk for a recipient and ensuring recipient safety.[31]

The inclusion of cancer screening in donor re-evaluation will help to ensure that only donors eligible for donation are active in the KPD system and eligible to participate in match runs. This will improve overall KPD match quality, and so help to improve the success of OPTN KPDPP matches.

Medical Re-Evaluation Requirements: Transmissible and Endemic Disease Screening and Testing

The proposed re-evaluation includes requirements for programs to test for transmissible diseases in keeping with *Policy 14.4: Medical Evaluation Requirements for Living Donors*. This requires that infectious disease testing must be performed in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. The Committee proposes requiring that the following tests are performed upon re-evaluation:

- Cytomegalovirus (CMV) antibody
- Epstein Barr Virus (EBV) antibody
- Human Immunodeficiency Virus (HIV) antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination
- HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
- Hepatitis B surface antigen (HbsAg)
- Hepatitis B core antibody (total anti-HBc) testing
- Hepatitis B Virus (HBV) deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
- Hepatitis C antibody (anti-HCV) testing
- Hepatitis C Virus (HCV) ribonucleic acid (RNA) by nucleic acid test (NAT)
- Syphilis testing

The Committee proposes an exception to this requirement such that programs are not required to retest donors for CMV-antibody or EBV-antibody if the donor has previously tested positive, as the donor as already presented the risk of potential CMV transmission.[32] The Committee seeks community input on whether there are additional tests for which this exception should be applied.

The Workgroup determined that infectious disease testing is critical both to confirming donor health and eligibility, and to understanding potential risk to a recipient.[33] Changes to infectious disease results could impact a donor's decision to donate as well as impact their candidacy as a donor. OPTN *Policy 14.4.E: Living Donor Exclusion Criteria* excludes HIV positive donors from donation, unless the requirements for variance are met per *Policy 15.7: Open Variance for the Recovery and Transplantation*

[31] Ibid
[32] Ibid.
[33] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.

of Organs from HIV Positive Donors. Furthermore, positive infectious disease results have significant impact on potential risk to the recipient, and play a role in a candidate's donor selection. To this end, KPD screening and matching algorithms include several of the above infectious disease tests, including CMV, EBV, and HbsAg. The above infectious disease testing will ensure donor information utilized in the OPTN KPDPP system is accurate and up to date, which will improve the overall quality of OTPN KPDPP matches and help to increase the success of these matches.

The Committee also proposes requiring programs to re-screen and, as appropriate, test donors for tuberculosis (TB) and other endemic diseases per *Policy 14.4: Medical Evaluation Requirements for Living Donors* upon re-evaluation:

- For tuberculosis (TB), the paired donor's transplant hospital must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using either:
    - Intradermal PD
    - Interferon Gamma Release Assay (IGRA)
- 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

Tuberculosis and endemic disease screening and testing are helpful to understanding the donor's general health and are critical to understanding potential transmission risk to the recipient. The Workgroup agreed that re-evaluation is a critical opportunity to screen and test the donor for TB and endemic diseases, as positive test results could impact the donor's ability and eligibility to donate, as well as pose significant risk the potential recipient.

Donors with any kind of acute symptomatic infection are not eligible for donation per OPTN *Policy 14.4.E: Living Donor Exclusion Criteria*. Re-evaluating donors for the above transmissible diseases will allow programs to identify and address potential infections, and inactivate donors in the KPD system who are not actively eligible to donate due to infection. This will ensure that potential paired donors who are not eligible to donate are not identified as potential KPD matches.

Re-Evaluation Reporting Requirements

In order to ensure the donor information is appropriately updated, the proposed re-evaluation requirement will also include reporting requirements. The Committee proposes that programs must report any changes to the donor information reported in the OPTN KPDPP system per *Policy 13.6.B: Requirements for Match Run Eligibility for KPD Donors*. This information includes the following:

- Gender
- Height
- Weight
- Clinical donor information:
    - Number of anti-hypertensive medications that the potential KPD donor is currently taking
    - Systolic and diastolic blood pressure with date
    - Creatinine clearance or GFR, date, and method
    - Infectious disease results, including:
        - 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
- KPD status as active, inactive or removed

The above information are utilized in the OPTN KPDPP screening and matching algorithm, and changes to this information could impact the pool of candidates that the donor is eligible to match with. The Workgroup noted particularly that donor height, weight, and BMI are influential in a candidate's donor selection, as this information is closely related to organ size and can provide insight into potential future graft function. The Workgroup also determined that the clinical donor information and infectious disease testing results are particularly impactful for understanding potential risk to the candidate, and are critical elements of a candidate's donor selection.[34]

The paired donor's preferences, such as whether the donor is willing to ship a kidney, are typically gathered during informed consent conversations and the evaluation processes. The Workgroup noted that re-entry of donor preferences is not necessary if the donor's preferences have not changed upon re-evaluation.[35]

The Workgroup recognized that the above required reported donor information is more likely to change over the course of a year than the other donor information required by *Policy 13.6.B: Requirements for Match Run Eligibility for KPD Donors.* However, the Workgroup agreed that any changes to the donor information required in *Policy 13.6.B: Requirements for Match Run Eligibility for KPD Donors* should be reported.[36] As a result, the Committee proposes that any changes to the following donor information must also be reported:

- First and last name
- Social security number
- Date of birth
- Ethnicity
- Blood type
- Whether the potential KPD donor is a non-directed donor or a paired donor
- If a paired donor, the KPD candidate identification number of the paired candidate and the donor's relationship to the candidate
- Whether the potential KPD donor has signed an agreement to participate in the OPTN KPDPP, a release of protected health information, and an informed consent

[34] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[35] Ibid.
[36] OPTN Kidney Paired Donation Workgroup Meeting Summary, November 30, 2022.

- Whether the potential KPD donor has undergone all evaluations and cancer screenings as required in *Policy 14: Living Donation*.
- Donor human-leukocyte antigen (HLA) as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

The Workgroup noted that programs will not need to re-report elements that have not changed. For example, the Workgroup agreed that "donor is willing to participate in the OPTN KPDPP" does not need to be re-reported, as changes to a donor's willingness to participate would need to be reflected by their removal from the OPTN KPDPP system.[37]

Similarly, transplant programs will not be required to re-report that the donor has signed an informed consent. However, as noted above, programs will be required to obtain the donor's signature confirming that the donor has been re-informed that they may withdraw from participation in the OPTN KPDPP program at any time, for any reason.

Finally, the Committee also proposes the addition of a new requirement to *Policy 13.6.B: Match Run Eligibility Requirements for OPTN KPD Donors,* such that transplant programs must report the date that the donor's re-evaluation was completed and any changes were reported to the OPTN in order to maintain eligibility. In order to ensure this is properly reported, the Committee proposes the following new data element to be added to the OPTN KPDPP system:

- "Donor re-evaluation completed and relevant changes reported as of" – Month/Day/Year

This data element will be utilized by the OPTN KPDPP system to ensure only those donors who have been evaluated or re-evaluated in the last year remain eligible to participate in OPTN KPDPP match runs. Furthermore, this data element will allow the OPTN KPDPP system to utilize the donor's most recent date of re-evaluation to determine the donor's next re-evaluation date. The impact of this required reporting on donor eligibility is expanded upon in the next section.

Re-Evaluation Logistics, Timing, and Notification

The Committee proposes a requirement for programs to re-evaluate their paired donors annually. The donor's re-evaluation date is based on the date of the donor's initial addition to the OPTN KPDPP system or the most recent reported date of re-evaluation, whichever is more recent. The OPTN KPD Workgroup determined that yearly follow up for paired donors is appropriate, given that these donors have been previously evaluated and cleared for donation, and so are generally in good health.

The Workgroup agreed that programs should have completed re-evaluation within 30 days after the donor's annual re-evaluation date.[38] Implementation of the proposed re-evaluation requirement will include an eligibility component, such that programs will have until the end of 30 days after the donor's re-evaluation date to report the donor's re-evaluation. If a completion date for re-evaluation is not reported by the end of this 30 day period, the donor will become ineligible to participate in OPTN KPDPP match runs until the transplant program reports a date of completed re-evaluation. Completed re-evaluation dates older than 395 days from the day of reporting will not be considered valid to maintain the donor's eligibility to participate in OPTN KPDPP match runs.

[37] OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.
[38] Ibid.

The proposed re-evaluation requirement will also include an automated notification, which will be sent to the transplant program points of contact 60 days prior to a donor's upcoming re-evaluation date, and 90 days prior to the date at which the donor would become ineligible. The Workgroup noted that the advanced notice of a donor's upcoming re-evaluation window will allow programs ample time to coordinate with the donor to schedule all appropriate appointments and ensure that the re-evaluation requirements are completed in a timely manner.

The Workgroup discussed including a specification that an Independent Living Donor Advocate (ILDA) must be present for the donor's re-evaluation.[39] The Committee ultimately agreed that this specification was not necessary, as the requirement for an ILDA to present for any evaluation for donation, as written *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*, encompasses re-evaluation.

Policy Development Considerations

The proposed donor re-evaluation requirement will impact and potentially benefit a good portion of candidate-donor pairs in the OPTN KPDPP program. Variability in time to transplant is influenced by a number of patient factors, such as blood type and sensitization. Currently, about 38 percent of OPTN KPDPP candidates are highly sensitized, and have a calculated panel reactive antibody (CPRA) score of 80 percent or greater. Due to their sensitization, these candidates are medically compatible with fewer donors, and as a result, wait longer to find a match. As of November 2022, about 59 percent of eligible candidate donor pairs were still waiting after one year, and 38 percent were still waiting after two years in the OPTN KPDPP.[40] Based on this data, the proposed donor re-evaluation requirement may impact about 59 percent of candidate and donor pairs, and will provide benefit across all participants in the KPD system, as overall match quality is increased, with implications for increased likelihood of match success.

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) directed the OPTN to exercise oversight over living donation. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN 'to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule'. Furthermore, Congress modified NOTA in 2007 to permit human organ paired donation under the law,[41] and the current OPTN Contract requires the Contractor to "maintain KPDPP policies and develop new policies."[42] This project addresses living organ donors and candidates enrolled in kidney paired donation programs, including the KPDPP, by proposing specific requirements for re-evaluation and by establishing clear requirements for incompatible blood type matching.

[39] OPTN Kidney Paired Donation Workgroup Meeting Summary, November 30, 2022.
[40] OPTN Kidney Paired Donation Pilot Program Data Dashboard
[41] 42 USC §274e
[42] Organ Procurement and Transplantation Network; HHSH250201900001C, Performance Work Statement Task 3.4.3: Operate the OPTN Kidney Paired Donation Pilot Project (KPDPP)

Implementation Considerations

Member and OPTN Operations

This proposal will involve submission to the Office of Management and Budget (OMB), as well as information technology (IT) implementation efforts. Implementation of this proposal will involve standard educational and communication efforts.

This proposal is not anticipated to affect the operations of histocompatibility laboratories and organ procurement organizations (OPOs).

Operations affecting Transplant Hospitals

This proposal is expected to impact transplant program participants in the OPTN KPDPP.

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-A_1 donor kidneys into candidates with blood type B and blood type O, and for transplanting blood type AB, non-A_1B 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-A_1, or blood type AB, non-A_1B 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-A_1 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.

Operations affecting the OPTN

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

This proposal will involve information technology (IT) implementation efforts in the OPTN KPDPP system, including the removal of three data elements and the addition of two new data elements. IT implementation will also include efforts to adjust the criteria for donor eligibility, such that donors who do not have an appropriate re-evaluation date reported become ineligible to participate in match runs. Implementation of the donor re-evaluation requirement will include automated notification of a donor's upcoming re-evaluation date. For ABO changes, IT implementation will be comprised of efforts to ensure candidates, who have been confirmed as eligible per their program's written titer threshold policy to receive A, non-A1 and AB, non-A1B offers, are eligible for those offers in the OPTN KPDPP

system, as well as notification to transplant program when a candidate's eligibility to receive these offers must be reconfirmed.

Implementation of the proposed re-evaluation requirement will also include an initial implementation period, during which donor eligibility will not be impacted, but which will allow programs ample time to coordinate upcoming donor re-evaluations. The Committee seeks feedback from the community on the timing of this initial implementation period.

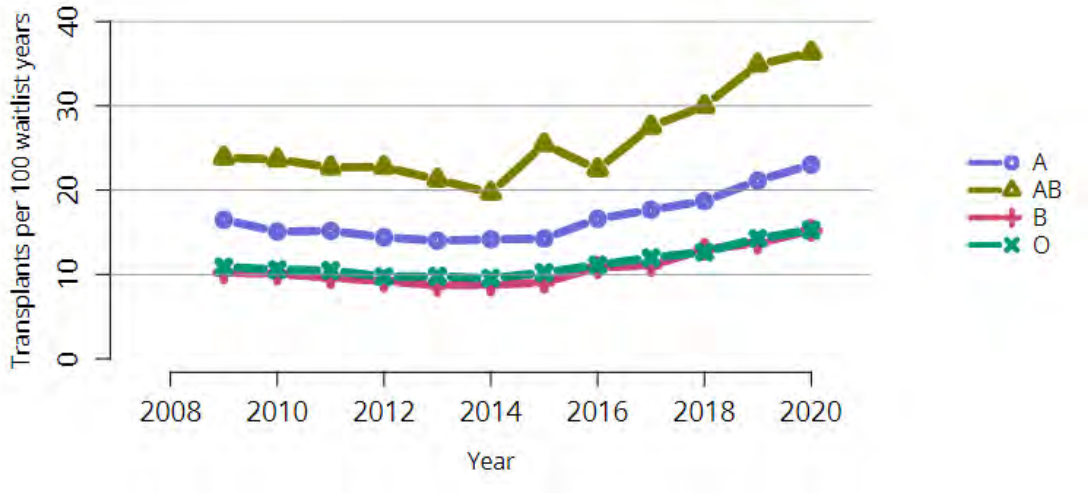
Feedback received on the proposed data elements, notification, and re-evaluation timing will be taken into consideration for final decisions on implementation efforts.

The OPTN plans to distribute educational materials and update current educational offerings for participating transplant programs will be updated appropriately. OPTN Policy will be updated, and a policy notice sent out to members.

Potential Impact on Select Patient Populations

This proposal has potential implications for blood type equity. The proposed policy alignments will remove specific IgG antibody titer thresholds for blood type O and B candidates to accept A, non-A_1 and AB, non-A_1B donor kidneys, and thus open up matching opportunities for candidates at programs with less conservative titer policies. Currently, blood type O accounts for 61 percent of all KPD candidates, but represents only 42 percent of transplants, as shown in **Figure 1** above.[43] While blood type B accounts for 15 percent of OPTN KPD candidates and 17 percent of OPTN KPD recipients, blood type B patients are overall harder to match and tend to have lower transplant rates.[44] Both blood type O and blood type B candidates generally have similar levels of access to transplant, as shown in **Figure 2.**[45]

Figure 2: Deceased Donor Kidney Transplant Rates Among Adult Waitlist Candidates by Blood Type[46]



[43] State of the KPD Report, 2022.
[44] Ibid.
[45] OPTN/SRTR 2020 Annual Data Report: Kidney, Lentine et al. https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16982
[46]OPTN/SRTR 2020 Annual Data Report: Kidney, Lentine et al. https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16982

Expanding matching opportunities for some blood type O candidates and blood type B candidates may reduce disparity in transplant rates across blood types.

This proposal also has implications for living donor and recipient safety. The proposed A, non-A_1 and AB, non-A_1B matching alignment will include a requirement for programs to establish a written policy regarding their own titer thresholds and require programs to confirm a candidate's eligibility every 90 days. These measures will help ensure the safety of the recipient.

The proposed re-evaluation requirements will also promote increased living donor safety via more regular communication and awareness of the donor's medical and psychosocial status. Re-evaluation of the donor will help programs monitor their donor's health and ability to donate, as well as ensure donors are aware of any risks or potential impacts to long term outcomes.

Projected Fiscal Impact

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories or OPOs.

Projected Impact on Transplant Hospitals

This proposal will affect transplant programs participating in the OPTN KPDPP program, and could potentially increase program burden by requiring donor re-evaluation on an annual basis. However, improving the quality and accuracy of information used to perform KPD matches will increase match success rates and reduce the number of broken chains and match failure. There may be minimal impact on transplant hospitals for training staff members and updating titer policies. Additionally, reconfirmation of blood type will result in minimal fiscal impact for transplant hospitals.

Projected Impact on the OPTN

The OPTN supported Committee and Workgroup meetings, as well as drafting, review, and revisions of proposed policy changes and data collection. This proposal will require IT implementation of additional data collection, notification, and eligibility requirements. This proposal will also require additional monitoring, educational efforts, and communication to members.

Post-implementation Monitoring

Member Compliance

The OPTN will continue to review the OPTN KPDPP requirements as outlined in policy. Site surveyors will review a sample of OPTN KPDPP medical records for documentation of written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or a blood type AB, non-A_1B kidney and will verify that the program has a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 kidneys into candidates with blood type B or O, and for transplant blood type AB, non-A_1B kidneys into candidates with blood type B.

Policy Evaluation

This policy will be formally evaluated approximately 1-year post implementation. The following metrics will be evaluated as OPTN KPDPP data become available and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy. Metrics will be split into

two categories; Section 1 will contain metrics concerning blood type policy alignments and Section 2 will contain metrics concerning donor re-evaluation efficiency. Data will be presented in tabular and graphical form as appropriate. Timeline is subject to change based on availability of data.

The following metrics and any others subsequently requested by the Committee, will be evaluated:

Section 1:

- Match rate (the number of matches divided by the number of matching opportunities)
- Transplant rates stratified by candidate ABO
- Distribution of candidate ABO
- Distribution of transplants by candidate ABO

Section 2:

- Match success rate (the proportion of matches that resulted in a transplant)
- Count of the utilization of the donor re-evaluation date field

Conclusion

The OPTN Kidney Transplant Committee proposes the alignment of OPTN KPDPP blood type A, non-A_1 and AB, non-A_1B matching policy and the establishment of a new requirement for annual donor re-evaluation. These proposed changes are specifically aimed at improving the efficiency of the OPTN KPD system, with implications on increasing the OPTN KPDPP match success rate and increasing the number of transplants. Furthermore, the proposed changes will provide benefits to improved living donor and recipient safety and may impact blood type equity in the OPTN KPDPP for blood type O and B candidates.

The proposed modifications will align OPTN KPDPP blood type A, non-A_1 and AB, non-A_1B matching requirements with those in OPTN Kidney policy. This alignment will provide clarity to programs and improve efficiency by allowing programs to consolidate their processes and policies for candidate eligibility to receive A, non-A_1 and AB, non-A_1B offers on the deceased donor waitlist and the OPTN KPDPP. These alignments may expand access for some blood type O and blood type B candidates at programs with less conservative titer policies, which could increase equity across blood types. Expanded access may also increase the number of potential exchanges within the OPTN KPDPP candidate and donor pool, and as a result, indirectly increase the match success rate.

The Committee also proposes a new requirement for annual paired donor re-evaluation for donors participating in the OPTN KPDPP. The proposed re-evaluation will include psychosocial, medical, informed consent, and reporting requirements. The proposed re-evaluation will emphasize components with implications for donor and recipient safety, as well as components impacting donor candidacy, selection, screening, and eligibility. The proposed re-evaluation requirement aims to improve efficiency and match quality in the OPTN KPDPP by ensuring donor information is accurate and up to date, with the ultimate goal of improving match success rate and increasing the number of transplants. The proposed re-evaluation will be required for transplant programs to maintain the paired donor's eligibility to participate in OPTN KPDPP match runs.

Considerations for the Community

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

1. Are the proposed psychosocial and medical re-evaluation requirements appropriate? Do any of the proposed re-evaluation requirements pose a burden on transplant programs, and if so, which?
2. Are there other additional medical or psychosocial elements that should be included for re-evaluation?
3. Should the infectious disease retesting exception apply to other tests that the donor has previously tested positive for, or just CMV antibodies and EBV antibodies? If so, which?
4. Should the donor's re-evaluation deadline be based on the date the donor was first registered in the OPTN KPDPP system, or the first date that the donor had an active status in the OPTN KPDPP system?
5. Is 60 days prior notice to the donor re-evaluation date sufficient, or should the notification be sent out earlier?
6. Is 90 days between notification and potential donor ineligibility date provide a sufficient amount of time to complete the donor's re-evaluation? Should this timeframe be shortened or extended?
7. Implementation of the donor re-evaluation requirement will include an initial implementation period in which donor eligibility will not be impacted. How long should this initial implementation period be?
8. Do you agree that aligning blood type A, non-A_1 and AB, non-A_1B matching requirements is appropriate?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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, child care 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

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.

13.6 Matching within the OPTN KPD Program

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 **Error! Reference source not found.**
        - 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 pair 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*
Physical Exam	1. Height 2. Weight 3. BMI 4. Vital signs

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
	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

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
	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 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 obtain a signature that confirms 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

13.~~7~~8.A Blood Type

The OPTN will only match candidates and potential donors who have identical or compatible blood types as defined in *Table 13-~~1~~3* below.

Table 13-~~1~~3: Allocation by Blood Type

Donors with:	Are Matched to Candidates with:
Blood Type O	Blood type O Blood types A, A_1, or A, non-A_1 Blood types B, AB, A_1B, or AB, non- A_1B
Blood Type A or A_1	Blood types A, A_1, or A, non-A_1 Blood types AB, A_1B, or AB, non- A_1B
Blood Type A, non-A_1	Blood types A, A_1, or A, non-A_1 Blood types AB, A_1B, or AB, non-A_1B Blood type **O or B** if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching*.
Blood Type B	Blood type B Blood types AB, A_1B, or AB, non-A_1B
Blood Type AB	Blood types AB, A_1B, or AB, non-A_1B
Blood Type A_1B	Blood types AB, A_1B, or AB, non-A_1B
Blood Type AB, non-A_1B	Blood types AB, A_1B, or AB, non-A_1B Blood type **B** if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching*.

13.~~7~~8.B Blood Type A, non-A_1 and Blood Type AB, non-A_1B 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-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. The paired candidate's transplant program establishes a written policy regarding its programs titer threshold for transplanting blood type A, non-A1 and blood type AB, non-A1B kidneys into candidates with blood type B and for transplanting blood type A, non-A1 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-A1, or blood type AB, non-A1B blood type kidney
3. The paired candidate's transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

13.~~7~~8.C Unacceptable Antigens

A transplant hospital must specify any unacceptable antigens it will not accept for its paired candidates using the process outlined in *Policy 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates*. The OPTN will not match the paired candidate with any potential KPD donor who has one of the candidate's unacceptable antigens entered as a human leukocyte antigen (HLA) value.

13.~~7~~8.D Candidate and Potential Donor Choices

A transplant hospital may specify criteria it will not accept for any of its KPD candidates as outlined in *Policy 13.6.A: Requirements for Match Run Eligibility for Candidates* or potential KPD donors as outlined in *Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors*. The OPTN will not match the KPD candidates with potential KPD donors who fall outside the specified criteria or potential KPD donors with KPD candidates who fall outside the specified criteria.

13.~~7~~8.E Donor Pre-Acceptance and Pre-Refusal

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must pre-accept or pre-refuse potential donors. The OPTN KPD candidate will only be matched with donors that are pre-accepted. If a donor is not pre-accepted, the donor will automatically be treated as pre-refused and will not be matched with the candidate.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital has the option to pre-accept or pre-refuse potential donors. These candidates will automatically be matched with all potential donors, unless the candidate's transplant hospital exercises the option to pre-refuse a potential donor.

13.~~7~~8.F OPTN KPD Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-~~2~~4: OPTN KPD Prioritization Points* when the OPTN identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN will then prioritize the set of exchanges with the highest total point value.

Table 13-~~2~~4: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is registered for the OPTN KPD program	.07 points for each day according to *Policy 13.~~7~~8.G: OPTN KPD Waiting Time Reinstatement*
Candidate is a 0-ABDR mismatch with the potential donor	10 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	75 points
Candidate and potential donor had a previous crossmatch that was one of the following: • Negative • Positive and acceptable with desensitization • Positive and acceptable without desensitization	75 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate is a prior living organ donor	150 points
Candidate ABO is O	100 points
Candidate ABO is B	50 points
Candidate ABO is A	25 points
Candidate ABO is AB	0 points
Paired donor ABO is O	0 points
Paired donor ABO is B	100 points
Paired donor ABO is A	250 points
Paired donor ABO is AB	500 points
Candidate CPRA is 0-19	0 points
Candidate CPRA is 20-29	5 points
Candidate CPRA is 30-39	10 points
Candidate CPRA is 40-49	15 points
Candidate CPRA is 50-59	20 points
Candidate CPRA is 60-69	25 points
Candidate CPRA is 70-74	50 points
Candidate CPRA is 75-79	75 points

If the:	Then the match will receive:
Candidate CPRA is 80-84	125 points
Candidate CPRA is 85-89	200 points
Candidate CPRA is 90-94	300 points
Candidate CPRA is 95	500 points
Candidate CPRA is 96	700 points
Candidate CPRA is 97	900 points
Candidate CPRA is 98	1250 points
Candidate CPRA is 99	1500 points
Candidate CPRA is 100	2000 points
Candidate is an orphan candidate	1,000,000 points

If a candidate has multiple paired donors with different blood types, then all of the candidate's matches will be awarded the priority point value associated with the paired donor whose ABO receives the fewest amount of points.

13.~~7~~8.G OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program with another living donor. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

1. Kidney graft removal within the first 90 days of transplant documented by a report of the removal of the transplanted kidney.
2. Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days after the candidate's kidney transplant.

KPD waiting time will be reinstated when the OPTN receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

13.~~7~~8.H Priority for Orphan Candidates

A candidate will be eligible for orphan candidate priority *only* if the candidate qualified for orphan status through participation in the OPTN KPD program. An orphan candidate will receive priority according to *Table 13-~~2~~4: OPTN KPD Prioritization Points*, even if the candidate has another willing living donor. The orphan candidate will retain this priority until the orphan candidate receives a kidney transplant. The orphan candidate can always refuse a match offer and retain orphan candidate priority.

13.~~8~~9 Two- and Three-Way Matches

13.~~8~~9.A Match Size

The OPTN will match KPD donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor (NDD) according to *Policy 13.~~9~~10: Donor Chains.*

13.~~8~~9.B Logistical Requirements for Two- and Three-Way Matches

In two-way or three-way exchanges in the OPTN KPD program, each matched donor recovery must be scheduled to begin within 24 hours of the start of the previous matched donor recovery. The donor surgeries in the exchange will begin only after all transplant programs agree to proceed.

13.~~9~~10 Donor Chains

13.~~9~~10.A Chain Size

In the OPTN KPD program there is no limit on the length of the KPD donor chains.

13.~~9~~10.B Logistical Requirements for Donor Chains

In OPTN KPD chains, each matched donor recovery must be scheduled to begin within 21 days from the date the matched donor's paired candidate receives a transplant. However, a KPD candidate-donor pair has the option to either have their surgeries begin within 24 hours of one another or refuse the match. Surgeries occurring within 24 hours would follow the same requirements as the two-way or three-way exchange according to *Policy 13.~~8~~9.B: Logistical Requirements for Two- and Three-Way Matches.*

13.~~9~~10.C Ending Chains

Transplant hospitals participating in OPTN KPD must follow the requirements for ending a chain according to *Table 13-~~3~~5* below.

Table 13-~~3~~5: Logistical Requirements for Ending Chains

If a chain begins that:	Then:
Does not include a match for an orphan candidate	The transplant hospital that entered the non-directed donor (NDD) can choose to *either*: • Allow the chain to continue through bridge donation, if the last paired donor in the chain is willing to be a bridge donor. • End the chain with a donation from the last paired donor in the chain to a candidate on the deceased donor waiting list at the transplant hospital that entered the NDD that started the chain.
Includes a match for an orphan candidate	The chain must end with a donation to the orphan candidate.

If the transplant hospital that entered the non-directed donor initially chooses to allow the chain to continue through bridge donation, the chain will extend until the transplant hospital reports to the OPTN that *one* of the following events has occurred:

- The bridge donor declines to donate
- The bridge donor donates to an orphan candidate
- The bridge donor donates to the deceased donor waitlist
- The transplant hospital that registered the bridge donor in the OPTN KPD program refuses to allow the donor to serve as a bridge donor

A transplant hospital that entered the non-directed donor can also request to end the chain with a donation to the deceased donor waiting list.

13.~~9~~10.D What to Do When a Chain Breaks

In the OPTN KPD program, a donor chain will proceed until a KPD candidate or matched donor refuses a match offer.

If a KPD candidate or matched donor in a chain refuses a match offer, then the matched donor at the end of the chain may donate to an orphan candidate, the deceased donor waiting list, or may be a bridge donor as outlined in *Policy 13.~~9~~10.B: Logistical Requirements for Donor Chains* and *Policy 13.~~9~~10.C: Ending Chains*.

13.~~10~~11 OPTN KPD Crossmatching Requirements

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.

3. Report all crossmatching results to the OPTN and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN that the review has occurred.

13.~~11~~12 KPD Match Offer and Transplant Timing Requirements

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

Table 13-~~4~~6: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN a preliminary response	2 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree in writing upon all of the following: • Contents required in the crossmatch kit • Instructions for the donor • Address at which to send the completed blood samples	3 business days of receiving the match offer.
The matched donor's transplant hospital	Report to the OPTN the agreed upon date of the crossmatch	3 business days of receiving the match offer.
The matched donor's transplant hospital	Make all of the following matched donor's records accessible to the matched candidate's transplant hospital: • Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital • Whether the matched donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline* • Additional records requested by the matched candidate's transplant hospital	3 business days of receiving the match offer.

The following members:	Must:	Within:
The matched candidate's transplant hospital	Report to the OPTN the results of the crossmatch	10 business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN	10 business days of the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree upon a date and time for the recovery of the matched kidney(s)	15 business days of receiving the match offer
The matched donor's transplant hospital and matched candidate's transplant hospital	Schedule both the recovery of the kidney from one of the matched donors in the exchange *and* the subsequent transplant of their matched candidate to occur	60 days of receiving the match offer

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

13.~~11~~12.A Requesting a Deadline Extension for a KPD Exchange

The transplant hospital may request an extension for any of the deadlines in Table 13-~~4~~6 by submitting a request in writing to the OPTN. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension within 2 business days. If all other transplant hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will be granted.

13.~~12~~13 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.1: Packaging and Labeling Requirements for Living Donor Organs and Extra Vessels*.

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.~~13~~14 Communication between KPD Donors and Recipients

The following rules apply to communication between KPD donors and matched KPD recipients that participated in an OPTN KPD program exchange. These rules do not apply to meetings between potential KPD donors and paired KPD candidates.

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the following conditions are met:

1. All the KPD donors and recipients participating in the communication agree on the conditions of the meeting or correspondence.
2. The meeting or correspondence occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. The transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

Appendix A: Proposed 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 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
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

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