OPTN | UNOS *Public Comment Proposal*

OPTN/UNOS Kidney Transplantation Committee

Revising Kidney Paired Donation Pilot Program Priority Points

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Executive Summary

This proposal seeks to improve how the OPTN Kidney Paired Donation Pilot Program (OPTN KPD) prioritizes candidate-donor matches identified in KPD exchanges (2-way, 3-way, and chains) to increase the likelihood of finding matches for difficult-to-match candidates. UNOS performs a match run on a regular basis to identify all possible exchanges. The match run often identifies more than one possible exchange for the same candidate-donor pair. Since each donor can only donate once, the OPTN KPD uses an optimization algorithm to select a single set of exchanges in which no pair is included more than once. The optimization algorithm searches for the combination of exchanges that maximizes the total number of "priority points" according to current OPTN KPD policy (Table 13-2).

As of June 16, 2015, the OPTN KPD system consisted of 56% of candidates with a calculated panel reactive antibody (CPRA) of greater than or equal to 80%, also known as highly sensitized candidates. A candidate with a CPRA of 80% is immunologically incompatible with 80% of donors making it difficult to find matches for these candidates. It is even more difficult to find matches for candidates with a CPRA of 98% or higher because these candidates are only compatible with about 2% of donors. Current policy does not take into account the vast difference in matching a candidate with a CPRA of 80% compared to one with a CPRA of 98% or higher.

Furthermore, seemingly easy to match candidates (e.g., non-O blood type with low level of HLA sensitization) that enter the OPTN KPD are often not receiving match offers. While these "easy to match" candidates may match with many potential donors, matches are seldom or never found because the candidate's paired donor is difficult-to-match due to non-O blood type or other factors. Currently, the optimization algorithm used to find OPTN KPD exchanges is based on a set of priority points that does not include either the candidate or paired donor's blood type, both of which affect the likelihood of a finding a match. The proposed revisions to the priority points include both a sliding point scale for CPRA and candidate and paired donor blood type to reflect the increased difficulty in matching candidates based on these traits. The proposal also includes other changes to the priority points intended to update a system developed in 2006.

As a part of the revision to the OPTN KPD priority points, the proposed policy changes will also provide a remedy for OPTN KPD candidates that are part of a failed exchange. A failed exchange happens when a KPD candidate does not receive a transplant after their paired donor has donated. This proposal refers to these candidates as "orphan candidates." The OPTN KPD does not currently have a remedy in place for failed exchanges outlined in policy. Although the OPTN KPD has not had any failed exchanges as of June 2015, this proposal outlines a remedy for failed exchanges in the event that one occurs.

The Kidney Transplantation Committee (Kidney Committee) and KPD Work Group believe that these changes will improve equity in access to highly sensitized candidates and pairs with difficult to match blood types by increasing the number of priority points given to these pairs and increase the number of transplants in the OPTN KPD by increasing the number of matches found.

Revising Kidney Paired Donation Pilot Program Priority Points

Affected Policies: Policy 1.2 Definitions, Policy 13.7 OPTN KPD Screening Criteria, Policy 13.8 Two-and Three-Way Matches, Policy 13.9 Donor Chains

Sponsoring Committee: Kidney Transplantation Committee

Public Comment Period: August 14 – October 14, 2015

What problem will this proposal solve?

This proposal seeks to improve how the OPTN Kidney Paired Donation Pilot Program (OPTN KPD) prioritizes candidate-donor matches identified in KPD exchanges (2-way, 3-way, and chains) to increase the likelihood of finding matches for difficult-to-match candidates.[1] UNOS performs a match run on a regular basis to identify all possible exchanges. The match run often identifies more than one possible exchange for the same candidate-donor pair. Since each donor can only donate once, an optimization algorithm (developed by Tuomas Sandholm, PhD, Carnegie Mellon University) is used to select a single set of exchanges in which no pair is included more than once. The optimization algorithm searches for the combination of exchanges that maximizes the total number of "priority points" according to current OPTN KPD policy (Table 13-2). Priority points are awarded to candidates and donors for various reasons, including "candidate is a 0-ABDR mismatch with the potential donor" (200 points), "candidate has a CPRA greater than or equal to 80%" (125 points), and "candidate is a prior living organ donor" (150 points). The points values help weight the optimization algorithm.

A March 2012 KPD Consensus Conference noted that centers may not enter their "easy to match pairs" in national KPD programs but instead reserve these pairs for KPD exchanges within their own centers.[2] When a pair pool consists of mostly "hard to match" (i.e. highly sensitized candidates or pairs with blood type O candidates and non-O donors), it is more difficult to find matches because the easy to match pairs are needed to match with the difficult to match pairs. Additionally, centers often wish to act in the best interest of their patients, so they may choose to do an internal (same hospital) exchange over a match with a sensitized candidate at another center. This increases the likelihood that the match proceeds to transplantation without confronting logistical or matching issues that may be present when an exchange involves candidates and donors from multiple transplant centers.

As of June 16, 2015, the OPTN KPD system consisted of 56% of candidates with a CPRA of greater than or equal to 80%, also known as highly sensitized candidates. A candidate with a calculated panel reactive antibody (CPRA) of 80% is immunologically incompatible with 80% of donors making it difficult to find matches for these candidates. It is even more difficult to find matches for candidates with a CPRA of 98% or higher because these candidates are only compatible with about 2% of donors. Current policy does not

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[1] For more information on kidney paired donation and the OPTN pilot program, see https://www.unos.org/donation/kidney-paired-donation/.

[2] Melcher ML, Blosser CD, Baxter-Lowe LA, Delmonico FL, Gentry SE, Leishman R, Knoll GA, Leffell MS, Leichtman AB, Mast DA, Nickerson PW, Reed EF, Rees MA, Rodrigue JR, Segev DL, Serur D, Tullius SG, Zavala EY, Feng S. "Dynamic Challenges Inhibiting Optimal Adoption of Kidney Paired Donation: Findings of a Consensus Conference." American Journal of Transplantation, 13 (2013): 851–860. Accessed on August 29, 2014. doi: 10.1111/ajt.12140

take into account the vast difference in matching a candidate with a CPRA of 80% compared to one with a CPRA of 98% or higher.

Furthermore, seemingly easy to match candidates (e.g., non-O blood type with low level of HLA sensitization) that enter the OPTN KPD are often not receiving match offers. While these "easy to match" candidates may match with many potential donors, matches are seldom or never found because the candidate's paired donor is difficult-to-match due to non-O blood type or other factors. Currently, the optimization process used to find OPTN KPD exchanges is based on a set of priority points that does not include either the candidate or paired donor's blood type, both of which affect the likelihood of a finding a match.

The current system includes points for 0-ABDR mismatches, CPRA greater than or equal to 80%, prior living organ donors, pediatrics, antibody specificities, geography (i.e. same region, DSA, or transplant hospital), and candidates' time spent waiting in the OPTN KPD. This proposal seeks to change how OPTN KPD optimizes the pair pool by revising the priority points schedule. This revision is intended to increase equity access in transplants facilitated through the OPTN KPD, in particular by identifying more matches for very highly sensitized patients (e.g., CPRA of 95%+) while also taking into account candidate and paired donor blood types. Transplanting more difficult-to-match pairs also has the potential to increase the number of matches found by mitigating against the KPD pool gradually becoming dominated by such difficult-to-match pairs. This proposal also prioritizes certain matches that are believed to have a low likelihood of being declined and thus are likely to result in a transplant. Optimizing in this way could reduce the match failure rate for existing and future candidates. In turn, a better match success rate may incentivize more transplant hospitals to participate by joining or entering more pairs into the OPTN KPD. As the match success rate increases, and more transplant hospitals participate, the OPTN KPD expects to facilitate an increased amount of transplants.

As a part of the revision to the OPTN KPD prioritization point system, the proposed policy changes will also provide a remedy for candidates that are part of a failed exchange. A failed exchange happens when a KPD candidate does not receive a transplant after their paired donor has donated. This proposal refers to these candidates as "orphan candidates." In June 2015, the OPTN Board of Directors approved KPD informed consent requirements with implementation on December 1, 2015. One of the requirements is for hospitals to inform KPD candidates and donors of each KPD program's remedy for a failed exchange and that the remedy does not include priority on the deceased donor wait list. The OPTN KPD does not currently have a remedy in place for failed exchanges outlined in policy. As of June 2015, the OPTN KPD has not had any failed exchanges and current policy decreases the possibility of a failed exchange because all exchange transplants occur either simultaneously (i.e. within a 24-hour period) or sequentially. *Policy 13.11 Transportation of Kidneys* and *Policy 16.2: Organs Recovered by Living Donor Recovery Hospitals* also provide requirements to reduce logistical issues that might prevent the timely receipt of the kidney. To build upon these existing preventative measures, this proposal outlines a remedy for failed exchanges in the event that one occurs.

Why should you support this proposal?
Changes to the OPTN KPD priority points are expected to increase equitable access to transplants, decrease match failure rates, and ultimately increase the number of transplants facilitated through the OPTN KPD. At the request of the KPD Work Group, UNOS research conducted sensitivity studies that demonstrated that incorporating pair characteristics (CPRA sliding scale, candidate ABO, and donor ABO) and streamlining the priority points table increased equity in match rates by increasing match opportunities for difficult to match pairs. Another study showed that prioritizing matches by pair

characteristics is expected to increase the number of matches in the long term.[3] By increasing the total number of matches, equity in the match rates, and match success rates, it is expected that more transplant hospitals may enter the OPTN KPD. Additionally, transplant hospitals already participating may increase the number of pairs they put into the OPTN KPD pair pool. In turn, this will increase the number of transplants overall.

Proposed Changes to OPTN KPD Priority Points and Policy

The following summarizes the proposed revisions to the OPTN KPD priority points table and policy:

- Maintain 100 base points for all matches
- Maintain existing points for prior living donor, pediatric, and waiting time
- Remove points for same region and same DSA
- Remove negative points for "all other antibody specificities"
- Reduce points for 0-ABDR mismatches
- Adopt a sliding scale for CPRA points
- Increase same-center points
- Award points for candidate and paired donor ABO
- Award points for previous negative or positive but acceptable crossmatches (with or without desensitization)
- Award points and create policy to prioritize orphan candidates in non-directed donor (NDD) chains

Remedy for Candidates in Failed Exchanges

As part of the Kidney Transplantation Committee's (Kidney Committee) proposal for Informed Consent for KPD, a Joint Societies Working Group (JSWG) provided recommendations regarding the development of informed consent policies for paired donors, candidates, and NDDs in KPD programs nationwide.[4] The JSWG recommended that KPD programs prioritize candidates in the event of a failed exchange, in which a paired donor donates but the paired candidate does not receive a kidney from their matched donor due to unforeseen circumstances. Although the Kidney Committee did not believe it was appropriate to require all KPD programs to employ the same remedy for a failed exchange, it did agree to adopt the JSWG recommendation to prioritize candidates in failed exchanges in the OPTN KPD. To build upon the existing policy previously mentioned that may limit the likelihood of a failed exchange, this proposal outlines a remedy including increased priority for candidates in failed exchanges in the event that one occurs.

Other Proposed Policy Changes

By introducing the remedy for a failed exchange, the KPD Work Group recommended revising additional sections of OPTN KPD policy to account for this remedy. The proposed changes include revisions to *Policy 1.2 Definitions* and *Policy 13.9 Donor Chains*. The proposal also includes revisions throughout *Policy 13 Kidney Paired Donation* to clarify existing policy. These proposed modifications are specific to the OPTN KPD and do not apply to any other KPD program.

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[3] Anderson, Ashlagi, et al, 2014, "A Simulation Study of Matching Strategies for UNOS KPD – technical report," unpublished. Additional information available upon request.

[4] http://optn.transplant.hrsa.gov/media/1114/01_kpd_informed_consent.pdf. Approved by the OPTN/UNOS Board of Directors on June 1-2, 2015.

How was this proposal developed?

The KPD Work Group distributed a Participation Barriers Survey to identify ways to increase the number of centers, pairs, and non-directed donors in the system. This survey was distributed to 1,350 transplant professionals across every OPTN-approved living donor program and received 543 responses. One common theme among the responses received was that the OPTN KPD needed to increase the number of match offers and match success rate. Additionally, 57% of survey respondents said that current incentives were insufficient for entering pairs they could match internally.

The KPD Work Group created the Design and Optimization Algorithm Subcommittee (DOAS) to explore refinements to the design of optimization algorithms used in the OPTN KPD to:

- Incentivize maximum participation
- Reduce match failure rates
- Promote fairness
- Increase the overall effectiveness of the program.

In 2013, DOAS began meeting to discuss potential changes to the optimization algorithm with the representation from the KPD Work Group, the Kidney Committee, and technical advisors from the Massachusetts Institute of Technology and Carnegie Mellon University.

Revisions to Priority Points

Technical advisors and the UNOS research department conducted multiple simulations and sensitivity studies to determine the optimal prioritizations scheme. DOAS considered two broad approaches before making its recommendations to the KPD Work Group:

Approach 1: Maintain the current framework for finding matches (a table of priority points and an optimization algorithm that maximizes the sum of points for each match run) but revising the point values in the following ways:
  o Removing several factors
  o Adopting a CPRA sliding scale
  o Prioritizing based on pair characteristics (i.e. paired donor ABO) instead of just candidate characteristics
  o Prioritizing matches with a prior negative (or acceptable) physical crossmatch
  o Ensuring that orphan candidates receive matches as soon as possible

Approach 2: Adopt a more sophisticated framework that would require a new optimization algorithm.[5] This alternative framework would include:

  o Forward-looking (i.e., "dynamic") matching, which attempts to maximize the number and types of matches found in the long run, not just in the current match run.
    ▪ Using this approach, the optimization algorithm would defer some matches that are available at the time of the match run to accommodate matching opportunities that may be available in the future to maximize the number and types of matches.
    ▪ It could also involve moving from a discrete match run cycle (e.g., twice per week) to a real-time approach in which matching possibilities are continuously searched for as candidates and donors are being added and removed from the system.

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[5] Dickerson, J. P., & Sandholm, T. (2015, October). FutureMatch: Combining human value judgments and machine learning to match in dynamic environments. In AAAI Conference on Artificial Intelligence (AAAI).

- "Failure-aware" matching, which explicitly takes into account the estimated success probability of each possible match in order to optimize the expected number of transplants, not just the expected number of matches.
- In this new paradigm, priority points could be "learned from the data" in order to achieve high-level committee goal(s) and updated periodically as the characteristics of the KPD pool change.

Ultimately, DOAS recommended pursuing Approach 1. Though the subcommittee is still interested in continuing to pursue Approach 2, it determined that more time is needed to fully evaluate the costs and potential benefits of adopting this approach. Further discussions are also needed to determine how to write OPTN policy language that explains how patients would be prioritized under this approach in a fully transparent way. Since its development in 2006, the current priority points table has become increasingly outdated and the subcommittee opted to propose Approach 1 now instead of waiting an unknown period before a proposal based on the alternate paradigm was ready.

Candidates in Failed Exchanges

Although there have not been any orphan candidates within the OPTN KPD, the KPD Work Group believes that it is critical to develop a solution so that candidates and participating hospitals have confidence in the program's attempt to find a remedy for these candidates if such an event were to occur. The KPD Work Group initially considered three different approaches in making its recommendations:

- Option 1: Manual Approach
    - Create a manual approach within the current operating system. If a non-directed donor chain began, UNOS staff would manually review the chain to see whether the chain could be closed with a donation to the orphan candidate.
- Option 2: Maximum Points Approach
    - Assign the maximum number of points to the orphan candidate (e.g., 1,000,000) so that the optimization algorithm would find the next available compatible match for the orphan candidate within a NDD chain. The system would stop the chain at the length necessary to remedy the orphan candidate, so even if a chain could potentially be longer, the system would truncate the chain to ensure the orphan candidate got a match.
- Option 3: Maximum Points Constrained to Shortest Chain
    - This more advanced approach would award the maximum (e.g., 1,000,000) points for matches to orphan candidates, but also modify the optimization algorithm to favor shorter orphan-ending chains as opposed to longer orphan-ending chains, since shorter chains are statistically more likely to result in the orphan candidate receiving a transplant. Consequently, this approach would prioritize, for example, a 2-link chain ending in an orphan candidate over a 4-link chain ending in that same orphan candidate.

The KPD Work Group also discussed whether orphan candidates could receive priority on the deceased donor kidney waiting list if they cannot find a match within the OPTN KPD. However, this idea would require changing policies within the Kidney Allocation System (KAS), which is outside the scope of this particular proposal.

The KPD Work Group favored the idea of adopting Option 2, with the plan of potentially adopting an alternative optimization algorithm (see Approach #2 above) that includes a "failure-aware" logic which would address the goals of Option 3. Therefore, this proposal does not require the shortest chain to be selected. Ultimately, the KPD Work Group believed that the policy language should be simple and that the goal of the policy is to provide a remedy for the orphan candidate to the extent possible, as soon as possible, within the system.

The KPD Work Group voted to send the proposal to the Kidney Committee for approval in May 2015. The Kidney Committee discussed the proposal in June 2015 and voted to send the proposal forward for public comment.

How well does this proposal address the problem statement?

The support for these revisions is largely based on the sensitivity study performed by UNOS research in April 2015. The sensitivity study re-optimized 136 historical OPTN KPD match runs from January 2013 – February 2015 to find 2-way, 3-way, and chain exchanges using 24 different priority point scenarios. This study aggregated the results across the 136 match runs with some candidates appearing in more than one match run. Scenarios included:

- a "no points" scenario in which all matches were weighted equally, which led the optimization algorithm to maximize the total number of matches found each time the match is run
- a "current policy" baseline, which included 200 points for 0-ABDR mismatches, 125 points for CPRA 80%+, etc.)
- 22 other scenarios involving the modification of point assignments for one or more factors (e.g., 125 points for CPRA 80%+ changed to a sliding scale), or the incorporation of points based on new factors (e.g., blood types)

The study compared the 22 various scenarios to the "no points" and "current policy" baseline scenarios and evaluated the results based on:

- the number and percentage of matches by candidate and pair characteristics
- the match "rate" (proportion of candidates for whom a match was found)
- the change in total number of matches found
- the impact of potential changes on equitable access for patients

The following is a summary of the data used to provide evidence supporting the proposed point values and policy changes.

Remove Priority Points Categories

O-ABDR Mismatch Points

OPTN policy awards 200 points for matches in which the candidate is a better HLA match with the donor (0-ABDR antigen mismatch). The sensitivity study found only three fewer 0-ABDR mismatches after removing the 200 priority points currently allotted to these matches. Another study also suggested that zero HLA mismatching does not offer a significant benefit in death censored graft or patient survival in non-related living donors.[6]

After discussing the results, DOAS recommended reducing this category to 10 points, which will mean this factor will have little impact and merely serve as a tiebreaker in case all else is equal.

Antibody Specificity Points

The current prioritization table (*OPTN Policy 13: Table 13-2*) subtracts 5 points for matches in which the candidate has a low or moderate level of sensitization that does not rise to the level of an "unacceptable antigen" to at least one of the donor's HLA antigens. These low or moderate-level sensitivities are called

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[6] Casey, M. J., Wen, X., Rehman, S., Santos, A. H., & Andreoni, K. A. (2015). Rethinking the advantage of zero-HLA mismatches in unrelated living donor kidney transplantation: implications on kidney paired donation. Transplant International, 28(4), 401-409.

A death-censored graft survival analysis is one that treats a graft as not having failed if a patient died but the graft was still functioning just before time of death.

"all other antibody specificities" in the OPTN KPD system.

DOAS recommended removing the -5 points for this category for three reasons. First, a KPD subcommittee devoted to streamlining KPD data collection previously recommended this information no longer be collected to reduce member data entry burden. Second, the sensitivity study showed that removal of this factor had zero impact on the types of matches found by the optimization algorithm. Finally, there is inconsistency among transplant hospitals in entering all other antibody specificities.

Change Priority Points Categories

Geography-Based Point Changes

Removing same-region and same-DSA points resulted in a modest increase in the percentage of interregional matches (from 84.6% to 88.6%). However, prior OPTN analyses showed that despite longer shipping distances and cold ischemic times, OPTN KPD transplants have had delayed graft function and graft survival rates comparable to other living donor kidney transplants.[7] In an effort to update and streamline the priority points table, DOAS recommended removing same-region and same-DSA points. Removing these points could also open up match possibilities for hard to match pairs.

Currently, the optimization algorithm awards 75 points to matches in which the candidate and matched donor are both registered at the same transplant hospital (25 for same hospital + 25 for same DSA + 25 for same region). DOAS considered substantially increasing the number of points for same-center exchanges to essentially guarantee that if a same-hospital match was possible, the optimization algorithm would select it. This was considered as a potential way to incentivize transplant hospital participation in the OPTN KPD by providing the "service" of finding internal (same hospital) matching opportunities that hospitals may not be already aware of. However, the sensitivity study found that while guaranteeing

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[7] Aeder, M., Stewart, D., Leishman, R., Sandholm, T., Formica, R. Early Outcomes of Transplant Recipients in the OPTN Kidney Paired Donation Pilot Program[abstract]. Am J Transplant 2014; 14(Suppl 3): 2229.

same-hospital matches approximately doubled the number of same-hospital matches, it created a sharp drop in the total number of matches found (**Figure 1**).[8]

**Figure 1: Impact of Geography-Based Point Changes
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)**

Geographical Proximity	Current Policy	No DSA or Regional Points	Guarantee Same Hospital Matches
Same hospital	5.1	4.2	11.4
Same DSA	3.0	1.8	2.1
Same Region	7.3	5.4	5.8
National	84.6	88.6	80.8
All	100.0	100.0	100.0
Total matches*	890	889	852
% change	-	-0.1%	-4.3%

DOAS discussed whether incentivizing centers to enter substantially more pairs into the OPTN KPD, by guaranteeing same-center matches, would offset the decrease in total matches. Ultimately, DOAS felt it was unrealistic to expect a behavioral change to compensate for this drop.[9]

DOAS felt that prioritizing same-center matches to some degree might reduce match failure rates, since same-center matches may be more likely to result in a transplant. Therefore, DOAS recommended increasing the same-center priority points from 25 to 75 points, which essentially offset the loss of points from removing same region/DSA. This recommendation is also consistent with the findings of the 2012 KPD Consensus Conference, which noted that "priorities for reducing distance between centers and prioritizing same center matches could be incorporated but should be deemphasized as they represent logistical rather than biological considerations."

Sliding Scale CPRA

According to current policy, candidates with CPRAs greater than or equal to 80% receive 125 points. This value does not take into account the vast difference in matching a candidate with a CPRA of 80% compared to one with 98% or higher. Adopting a sliding scale for CPRA values that takes into account the challenges of matching highly sensitized candidates would improve access to KPD for these hard to match candidates.

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[8] Since centers do not generally enter pairs that they could match internally, this increase in same-center matches was not caused by finding more exchanges that could take place entirely within the same center. Rather, the increases in same-center matches came from increases in (a) 3-way exchanges involving two pairs at one center and a third pair at another center and (b) internal (same-center) links of NDD chains.

[9] Additionally, 59.3% of the barrier survey respondents reported that changing the same center priority points will not change their behavior in entering pairs into the OPTN KPD they can match internally.

Although the sensitivity study evaluated three different sliding scales, DOAS ultimately recommended a CPRA sliding scale range of 0-2,000 points. **Figure 2** shows the difference between the current CPRA points and the proposed CPRA sliding scale CPRA points.

Figure 2: CPRA Scales

CPRA	Current Policy	Proposed CPRA Sliding Scale
0-19	0	0
20-29	0	5
30-39	0	10
40-49	0	15
50-59	0	20
60-69	0	25
70-74	0	50
75-79	0	75
80-84	125	125
85-89	125	200
90-94	125	300
95	125	500
96	125	700
97	125	900
98	125	1250
99	125	1500
100	125	2000

Figure 3 demonstrates the change in number of matches found by adopting this CPRA sliding scale.

Figure 3: Impact of CPRA Sliding Scale on Matches
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

CPRA	# Candidates*	% of Candidates	# Matches Found	
			Current Policy	CPRA Sliding Scale
0%	7,714	23.9	229	211
1-49%	2,767	8.6	178	175
50-79%	1,851	5.7	174	182
80-89%	1,467	4.5	117	98
90-94%	1,684	5.2	43	42
95-97%	2,068	6.4	39	39
98%	1,336	4.1	23	23
99%	3,507	10.8	31	39
100%	9,941	30.7	22	35
All	32,335	100.0	856	844

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

The study found that using this scale led to 60% more matches for candidates with 100% CPRA and 25% more matches for candidates with 99% CPRA. The study also found a 1% drop in the total number of matches. While increasing points may cause an apparent drop in matches in a static, retrospective study, dynamic studies have shown that finding transplants for hard to match candidates more quickly results in more total matches overall.[10]

This static sensitivity study also assessed whether a CPRA sliding scale would give *too much* priority to the very highly sensitized, but the study found that match rates (percentage of candidates that receive a

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[10] Anderson, Ashlagi, et al, 2014, "A Simulation Study of Matching Strategies for UNOS KPD – technical report," unpublished. Additional information available upon request.

match) for CPRA 100% would increase from 0.2% to 0.4% (see **Figure 4**), still much lower than other CPRA groups.

Figure 4: Impact of CPRA Sliding Scale on Very Highly Sensitized
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

CPRA	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy	CPRA Sliding Scale
0%	7,714	23.9	3.0%	2.7%
1-49%	2,767	8.6	6.4%	6.3%
50-79%	1,851	5.7	9.4%	9.8%
80-89%	1,467	4.5	8.0%	6.7%
90-94%	1,684	5.2	2.6%	2.5%
95-97%	2,068	6.4	1.9%	1.9%
98%	1,336	4.1	1.7%	1.7%
99%	3,507	10.8	0.9%	1.1%
100%	9,941	30.7	0.2%	0.4%
All	32,335	100.0	2.6%	2.6%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

Finally, the study assessed whether inequity would unintentionally increase for other patient populations by moving to a CPRA sliding scale (**Figures 5 and 6**).

Figure 5: Impact of CPRA Sliding Scale on Race/Ethnicity
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Race/Ethnicity	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy	CPRA Sliding Scale
White	21,045	65.1	2.5%	2.4%
Black	5,068	15.7	2.8%	2.8%
Hispanic	4,463	13.8	2.0%	2.2%
Asian	1,358	4.2	6.1%	6.2%
Other	399	1.2	1.8%	2.3%
All	32,333	100.0	2.6%	2.6%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

Figure 6: Impact of CPRA Sliding Scale on Age
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Candidate Age	# Candidates*	% of Candidates	Match rates (# matches / # candidates)	
			Current Policy	CPRA Sliding Scale
0-17	626	1.9	1.9%	0.8%
18-34	6,362	19.7	2.5%	2.5%
35-49	9,543	29.5	2.3%	2.2%
50-64	12,650	39.1	3.0%	2.9%
65+	3,154	9.8	2.9%	3.1%
All	32,335	100.0	2.6%	2.6%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

The study found that adopting a sliding scale had very little effect on match rates by race. There was also very little change across age groups; however, the results suggest a potential decrease in matches for pediatrics. Upon further review, the magnitude of this decrease appears to have been artificially inflated because many of the same candidates and donors appear multiple times in the study. The apparent decrease in matches for pediatric patients was driven by the absence of a match for one particular pediatric patient (when using the CPRA sliding scale) who happened to be matched four different times under the "current policy" scenario. The Kidney Committee weighed this evidence and agreed that though matches to pediatric patients may decline due to adoption of a CPRA sliding scale, the impact is expected to be small and increasing matching opportunities for very highly sensitized patients is important. If implemented, the Kidney Committee stressed the importance of monitoring pediatric access to KPD match offers in order to assess whether there is a greater effect than anticipated.

Results for the two other alternative sliding scales were very similar to the proposed sliding scale. The first alternative was derived using a similar, empirical approach as was used to develop the sliding scale used in deceased donor kidney allocation.[11] This first alternative awarded over 10,000 points to CPRA 100% patients but resulted in nearly identical results, highlighting that the potential impact of awarding points is limited. The second alternative sliding scale was similar to the proposed scale, but tempered at the extreme (e.g., CPRA 100% patients received 1,000 instead of 2,000 points); again, results were very similar to those with the proposed sliding scale, affirming the relative insensitivity of match rates to the specific sliding scale chosen.

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[11] Stewart D, Kucheryavaya, A., Reinsmoen, N., Friedewald, J. . Smoothing it Out: Creating a Sliding Scale for Assigning CPRA-Based Allocation Points [abstract]. Am J Transplant 2012; 12(Suppl 3): 338. 2012.

Add Priority Points Categories

Paired Candidate/Donor ABO Points

Prioritizing hard to match pairs by pair characteristics is important for creating fairness and equitable access and reducing pool degradation.[12] Pair pools degrade when easier to match pairs are transplanted first, leaving only a pool of hard to match pairs, which can lead to fewer matches in the future. A study performed for DOAS found that prioritizing patient CPRA without considering the related donor is not as effective as prioritizing the difficulty of matching a patient-donor pair. Either combining classical metrics (blood type, homozygous donors, and CPRA) or using a new metric (pair match power), prioritizes matches more efficiently and achieves a better outcome for the pair pool long term.

The existing priority points table does not include any points based on candidate or paired donor ABO. The proposed points for candidate ABO range from zero to 100 and for paired donor ABO from 0 to 500. The ordering of these point values was determined based on the degree of difficulty in matching these blood types.[13] The magnitude of these point values was determined after reviewing results from the sensitivity study, which compared results of three different point schedules for each of candidate and paired donor ABO.

As seen below in **Figure 7**, the sensitivity study found that prioritizing by candidate ABO modestly increased matching opportunities for blood type O candidates.

Figure 7: Impact of Candidate ABO Points
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Candidate ABO	# Candidates*	% of Candidates	# Matches Found		Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Candidate ABO Points (0-100 points)	Current Policy (0 points)	Candidate ABO Points (0-100 points)
A	5,965	18.4	266	255	4.5%	4.3%
AB	411	1.3	11	10	2.7%	2.4%
B	5,148	15.9	237	230	4.6%	4.5%
O	20,811	64.4	342	367	1.6%	1.8%
All	32,335	100	856	862	2.6%	2.7%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

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[12] Anderson, Ashlagi, et al, 2014, "A Simulation Study of Matching Strategies for UNOS KPD – technical report," unpublished. Additional information available upon request.

[13] Stewart, D., et al. "Exploring the Candidate/Donor Compatibility Matrix to Identify Opportunities to Improve the OPTN KPD Pilot Program's Priority Point Schedule." *TRANSPLANTATION.* Vol. 98. 530 WALNUT ST, PHILADELPHIA, PA 19106-3621 USA: LIPPINCOTT WILLIAMS & WILKINS, 2014.

Figure 8 shows that awarding points for candidate ABO changed the match rates very little by race/ethnicity.

Figure 8: Impact of Candidate ABO Points on Race/Ethnicity
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Race/ Ethnicity	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Candidate ABO Points (0-100)
White	21,045	65.1	2.5%	2.5%
Black	5,068	15.7	2.8%	2.9%
Hispanic	4,463	13.8	2.0%	2.0%
Asian	1,358	4.2	6.1%	6.1%
Other	399	1.2	1.8%	1.8%
All	32,333	100.0	2.6%	2.7%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

As shown in **Figure 9**, match rates based on age also changed very little. Although a slight decrease was noted for pediatric candidates, a subsequent review of these match runs showed that the magnitude of this effect was inflated by one pediatric candidate that appeared in multiple match runs.

Figure 9: Impact of Candidate ABO Points on Age
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Candidate Age	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Candidate ABO Points (0-100)
0-17	626	1.9	1.9%	1.4%
18-34	6,362	19.7	2.5%	2.5%
35-49	9,543	29.5	2.3%	2.3%
50-64	12,650	39.1	3.0%	3.1%
65+	3,154	9.8	2.9%	2.8%
All	32,335	100.0	2.6%	2.7%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

As shown in **Figure 10**, the sensitivity study yielded similar results for paired donor ABO points. Although the total number of matches was virtually unchanged, prioritizing by paired donor ABO could increase matching opportunities for candidates with non-O paired donor blood types.

Figure 10: Impact of Paired Donor ABO Points
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Paired Donor ABO	# Candidates*	% of Candidates	# Matches Found		Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Paired Donor ABO (0-500 points)	Current Policy (0 points)	Paired Donor ABO (0-500 points)
A	16,607	48.5	273	299	1.64%	1.80%
AB	1,454	4.2	5	6	0.34%	0.41%
B	5,939	17.4	215	213	3.62%	3.59%
O	10,226	29.9	363	340	3.55%	3.32%
All	34,226	100.0	856	858	2.50%	2.51%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

Additionally, **Figures 11 and 12** demonstrate that adding paired donor ABO points did not increase inequity among race/ethnic groups or age groups.

Figure 11: Impact of Paired Donor ABO Points on Race/Ethnicity
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)

Race/Ethnicity	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Paired Donor ABO (0-500 points)
White	21,045	65.1	2.5%	2.6%
Black	5,068	15.7	2.8%	2.8%
Hispanic	4,463	13.8	2.0%	1.9%
Asian	1,358	4.2	6.1%	6.3%
Other	399	1.2	1.8%	1.8%
All	32,333	100.0	2.6%	2.7%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

**Figure 12: Impact of Paired Donor ABO Points on Age
(Sensitivity Study performed on OPTN KPD Match Runs 1/2/2013-2/17/2015)**

Candidate Age	# Candidates*	% of Candidates	Match Rates (# matches / # candidates)	
			Current Policy (0 points)	Paired Donor ABO (0-500 points)
0-17	626	1.9	1.9%	1.9%
18-34	6,362	19.7	2.5%	2.3%
35-49	9,543	29.5	2.3%	2.4%
50-64	12,650	39.1	3.0%	3.0%
65+	3,154	9.8	2.9%	2.9%
All	32,335	100.0	2.6%	2.7%

* Sum of all candidates across all 136 match runs. Some candidates appeared in multiple match runs.

The results of the sensitivity study suggest that incorporating candidate and paired donor ABO points may increase matching opportunities for blood type O candidates and candidates with non-O paired donor blood types without affecting access to KPD match offers by candidate race/ethnicity or age.

Evaluating the Combined Impact of a CPRA Sliding Scale, ABO Points, and Other Changes

Included in the sensitivity study's 24 scenarios were six "composite" scenarios designed to assess the combined effect of modifying (or adding) priority point assignments for several factors simultaneously. One of these scenarios included the proposed CPRA sliding scale; the proposed candidate ABO points; the proposed paired donor ABO points; zero same-DSA or same-region points, as proposed; zero points for moderate-level (donor-specific) antibody specificities, as proposed; and zero points for 0-ABDR mismatches.

To assess the impact of the proposed points schedule on patient equity, match rates under this proposal were compared to the current policy scenario for 86 different pair types, each with differing candidate CPRA, candidate ABO, and paired donor ABO. These 86 pair types spanned the spectrum from very easy-to-match (e.g., candidate ABO=A, CPRA=1-49%, paired donor ABO=O) to most difficult to match (e.g., candidate ABO=A, CPRA=98-100%, paired donor ABO=AB).[14] Inequity in access to OPTN KPD matches was quantified by calculating the standard deviation of the match rates across the 86 pair types. The results showed that under a "no points" policy, the standard deviation was 7.41. The standard deviation decreased to 7.02 under the current priority points table, reflecting reduced inequity due to the 125 points for CPRA 80%+ candidates. The composite scenario that most closely mirrored the proposed policy resulted in a further decline in the standard deviation to 6.89, reflecting reduced inequity in match rates among pair types.

The Kidney Committee concluded that the reduction in equity is relatively small because the effect of awarding priority points is limited: more points cannot increase the number of matching possibilities between compatible donors and candidates, but it can only increase the odds that the optimization

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[14] "Distinguishing Easy from Difficult-to-Match KPD Candidates and Pairs Using Output from The Edgefinder Algorithm," analysis presented to DOAS, January 2014.

algorithm chooses such possibilities when multiple solutions are possible. Still, the Kidney Committee felt that this proposal is an important step updating a system that does not currently assess candidate and donor blood types and may not identify truly highly sensitized patients.

This sensitivity study has several limitations. First, the study evaluated the impact of priority point changes on the number of matches, not the number of transplants. Second, the study was a static, retrospective sensitivity study, not a dynamic simulation. A static approach cannot take into account compounded changes over time in the KPD pool that are due to matching and transplanting different patients under a new strategy. For example, prioritizing hard-to-match pairs may result in more matches and transplants for such pairs (who would be removed from the system), leading to a slightly easier-to-match pool and, thus, more future matches. A dynamic, forward-looking simulation (as provided to the subcommittee by Ashlagi, 2014) can demonstrate such an effect. Third, this study has limited ability to evaluate the impact of changing priority points on small subpopulations such as prior living donors.

Failure-Aware Matching Using Prior Crossmatch Information

Although DOAS recommended saving advanced failure-aware matching for future development, one area of basic failure-aware matching using prior crossmatch results from previous exchanges was identified to include in this proposal.[15] Occasionally, repeat matches are found for candidates with the same donor they previously matched with and reported to the OPTN a negative (or positive but acceptable) physical crossmatch. The match did not result in a transplant due to a non-crossmatch related reason, such as donor became unavailable, candidate became ill, or another match in the exchange was refused. Currently, the OPTN KPD optimization algorithm does not use this information. Positive crossmatch results account for over 30% of the match refusal reasons within the OPTN KPD. The subcommittee believed that a candidate-donor match that previously reported a negative or acceptable physical crossmatch would have a higher likelihood of being accepted and resulting in a transplant if the match were identified in a future match run. This form of basic failure-aware matching uses existing data to prioritize matches with a higher likelihood of success.

To gauge the magnitude of the potential impact of prioritizing such matches, DOAS requested data showing how many candidates and donors were currently still in the OPTN KPD system, had previously matched, and had reported a negative (or positive but acceptable) crossmatch result. As of April 13, 2015, 19 cases were present. Of these, 17 previously reported a negative crossmatch, while one reported positive but acceptable without desensitization, and one reported positive but acceptable with desensitization. The crossmatch was performed within the last six months for 12 of the 19 candidate-donor matches, while six were between 6 and 12 months old and one was more than a year old. Refusal reasons (e.g., "matched donor medical history") for three of these cases indicated the candidate would not be interested in a match with the donor in the future, leaving 16 cases of negative or acceptable crossmatches that could be prioritized by the optimization algorithm in future match runs.

Though the number of prior negative or acceptable crossmatches among candidates and donors still in the system is relatively small, the Kidney Committee wanted to account for this information and agreed that these matches should be prioritized to help reduce match failure rates. DOAS recommended that these matches receive the same priority as a moderately sensitized patient, and thus a value of 75 points was chosen to mirror the 75 points assigned by the new sliding scale to candidates with CPRA of 75-79. The monitoring of this proposal will assess the impact of prioritizing these matches and whether 75 points is appropriate or should be increased or decreased.

The Kidney Committee asked DOAS to consider adding a timeframe to the proposal to prevent matches

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[15] Dickerson, J. P., & Sandholm, T. (2015, October). FutureMatch: Combining human value judgments and machine learning to match in dynamic environments. In AAAI Conference on Artificial Intelligence (AAAI).

receiving priority points based on older, potentially outdated crossmatch results. Both DOAS and the KPD Work Group discussed adding a timeframe of 90 days, 6 months, or 1 year. However, DOAS and the KPD Work Group ultimately chose not to recommend specifying a timeframe because of the KPD histocompatibility requirements pending OPTN programming, which require transplant hospitals to update the list of unacceptable antigens every 90 days and report potentially sensitizing events. If a candidate develops donor-specific antibody sensitivities subsequent to a negative crossmatch, the reporting of the new antibody sensitivity(s) as an unacceptable antigen in the OPTN KPD system will preclude the candidate from matching with this particular donor in the future, regardless of whether prior negative crossmatch receives any priority points.

Orphan Candidates

As of June 16, 2015, the OPTN KPD has not had any failed exchanges where a donor donated but the paired candidate did not receive a kidney. However, as previously discussed, pending changes to the OPTN informed consent requirements will require transplant hospitals to inform KPD candidates and donors about the remedy for a failed exchange. This requirement does not mandate that KPD programs have a remedy for failed exchanges, only to inform patients of the remedy if one exists. If there is no remedy, then the transplant hospital must inform the candidates and potential donors that no remedy exists. Currently, the OPTN KPD falls into the latter category, because existing OPTN policy does not provide a remedy for failed exchanges within the OPTN KPD. The KPD Work Group believes that the OPTN KPD should have a remedy outlined in policy due to the serious nature of a failed exchange.

The KPD Work Group proposes adding a definition to OPTN policy to provide terminology for candidates that are part of a failed exchange. These candidates would be known as "orphan candidates." A candidate would be considered an orphan candidate if they did not receive a kidney transplant *for any reason* from the matched donor after the candidate's paired donor has donated. The KPD Work Group considered whether this definition should apply to any situation, or whether the circumstances surrounding why the paired candidate did not receive the kidney are relevant. Ultimately, the KPD Work Group decided that the definition should be simple and patient-centric: regardless of fault, the patient is still at a loss and requires a remedy. Therefore, fault will not play a role in determining whether a candidate is an orphan candidate.

Consistent with JSWG recommendation discussed earlier (see: Why should you support this proposal?), the KPD Work Group also recommended that orphaned candidates receive the highest priority within the OPTN KPD. DOAS ultimately recommended awarding the maximum of 1,000,000 points for orphan candidates to ensure that if possible, a match would be selected that could remedy the failed exchange. Other very high point values could have been chosen to achieve the same goal, but awarding 1,000,000 priority points is a mechanism to ensure that if it is possible to find a NDD or bridge donor chain that ends in the orphan candidate, the points-based optimization algorithm will choose that chain.

The KPD Work Group is also proposing to add the following stipulations to awarding these points:

1. Candidates will only receive these points if they were part of an OPTN KPD failed exchange. Candidates in failed exchanges from other KPD programs will not receive orphan status in the OPTN KPD.
2. The orphan candidate will receive these points even if they have another willing living donor. In the event that a candidate had more than one living donor, the KPD Work Group did not think that the orphan candidate should be required to use their second donor.
3. The orphan candidate will receive the priority points until they receive a kidney transplant.
4. The orphan candidate can always refuse a match offer and retain orphan candidate priority.

The Kidney Committee raised concerns about "cherry-picking" by allowing orphan candidates to refuse match offers and retain orphan candidate priority points. However, the KPD Work Group believed the high number of priority points that would guarantee a compatible match may not be the best match or even

feasible due to size, age of the donor, crossmatch results, etc., and that an orphan candidate should not be forced to accept a kidney just because it becomes available. Ultimately, the Kidney Committee agreed.

Maintain Existing Priority Points Categories and Values

Prior Living Donor and Pediatric Points

DOAS and the KPD Work Group discussed whether the points for prior living organ donors (150 points) or pediatric candidates (100 points) should be adjusted in light of the other changes made to the priority points, but decided not to make any changes to these categories. In relationship to other priority points categories, prior living organ donors and pediatric candidates will still receive more points than candidates with moderately high CPRAs, same-center matches (75 points), certain candidate and paired donor blood types, and candidates and potential donors with previous negative (or positive but acceptable) crossmatches. Additionally, OPTN KPD exchanges are identified and selected based on the combination of total points of all potential matches. A prior living organ donor or pediatric candidate can still receive additional points in other priority points categories.

Which populations are impacted by this proposal?

This proposal will impact all participants in the OPTN KPD, including currently participating transplant programs, candidates and donors, and any that may join the OPTN KPD in the future. As of June 2015, 150 living donor kidney transplant programs have agreed to participate in the OPTN KPDPP. Approximately 260 candidates and 280 donors currently appear in each semi-weekly OPTN KPD match run. Since 2010, over 1,300 different candidates have appeared in at least one match run.

Modifying the priority points table as proposed is expected to increase OPTN KPD matching opportunities for very highly sensitized patients (CPRA 99-100%), blood type O patients, as well as candidates with non-O paired donors. The impact of these changes is expected to be small or negligible for candidates of varying ages or races/ethnicities. The results of a sensitivity study evaluating the anticipated changes in access to OPTN KPD matches are provided in the preceding section of this document.

This proposal will have a significant impact on patients who, due to a failed OPTN KPD exchange, wind up without a transplant after their paired donor has donated. Though no such cases have occurred in the OPTN KPD thus far, other KPD programs have reported them. In the event that a candidate finds himself or herself in such a position in the OPTN KPD in the future, this proposal outlines the process that will be used to find a match for the "orphan candidate" as soon as possible.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* This proposal may increase the number of matches found and the number of transplants in the OPTN KPD. Positive changes in these two areas may incentivize more transplant hospitals to participate by joining or entering more pairs into the OPTN KPD. This proposal addresses two objectives of this goal: (1) to increase community participation in and transplants arranged through the OPTN KPD and (2) use data to improve the chance of timely offers of organs to centers and candidates most likely to accept.

2. *Improve equity in access to transplants:* This proposal provides greater equity in access to highly sensitized candidates and pairs with difficult to match blood types by increasing the number of priority points given to these pairs. It also improves access for candidates that find themselves "orphaned," having not received a kidney after their donor donated within a failed exchange.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no anticipated impact to this goal.

4. *Promote living donor and transplant recipient safety:* There is no anticipated impact to this goal.

5. *Promote the efficient management of the OPTN:* There is no anticipated impact to this goal.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

This policy will be evaluated approximately 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently requested by the Kidney Committee, will guide the evaluation of the proposal after implementation:

- Have matching opportunities and transplants increased for very highly sensitized patients?
- Have matching opportunities and transplants increased for blood type O patients as well as patients with a non-O paired donors?
- Have matching opportunities and transplants for other types of candidates, such as pediatrics or racial/ethnic minorities, been significantly impacted?
- Have match success rates – the proportion of match offers that are accepted and result in a transplant – increased?
- Have the number of centers, candidates, and donors actively participating in OPTN KPD match runs increased?
- Have any failed exchanges occurred, and if so, were matches and transplants found expediently for orphan candidates?

The following metrics, and any others subsequently requested by the Committee, will be evaluated to compare performance before vs. after the implementation of the new policy:

- The number of centers that signed the agreement to participate in the OPTN KPD
- The number of centers, candidates, and donors actively participating in match runs
- The number of matches found and transplants facilitated by the OPTN KPD
- The match success rate (# transplants / # matches found), overall and for matches with a prior negative (or acceptable) crossmatch. Analysis will be stratified by time since the prior crossmatch test was performed.
- The number and percentage of matches found, match rates (# matches / # matching opportunities), and transplants by candidate characteristics: age, CPRA, blood type, paired donor blood type, race/ethnicity, waiting time, prior living donor status
- The number and percentage of matches by geography: same-center, same-DSA, same Region, national.
- The number of failed matches and orphan candidates
- The distribution of time to match and time to transplant for orphan candidates after a failed exchange

How will the OPTN implement this proposal?

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in December 2015. If passed, the proposal would go into effect after implementing IT programming. UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). This proposal will require programming in UNet[SM], and the IT complexity for this proposal is large.

Upon Board approval, the OPTN will communicate these changes to members and provide educational materials as necessary. This proposal will continue to be monitored for instructional needs concerning policy or system changes that affect member processes.

How will members implement this proposal?

As required by *Policy 13.3 Informed Consent for KPD Candidates and Policy 13.4 Informed Consent for KPD Donors*, members participating in the OPTN KPD will need to learn the changes outlined in the proposal so that they may inform candidates and donors appropriately.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine site surveys of OPTN members. Any data entered in UNet℠ may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Language

1 **Policy 1: Administrative Rules and Definitions**

2 **1.2 Definitions**

3 **Bridge donor**

4 A Kidney Paired Donation (KPD) donor who does not have a match identified during the same match run
5 as the donor's paired candidate <u>and continues a chain in a future match run</u>.

6 **Chain**

7 A set of KPD matches that begins with a donation from a non-directed living donor to that KPD donor's
8 matched candidate. This candidate's paired living donor then donates to the KPD donor's matched
9 candidate. A chain continues until a living donor donates to <u>an orphan candidate,</u> a waiting list candidate<u>,</u>
10 or is a bridge donor.

11 **<u>Orphan candidate</u>**

12 <u>A KPD candidate who does not receive a kidney transplant from the matched donor for any reason after</u>
13 <u>the candidate's paired donor has donated.</u>

14 **13.7 OPTN KPD Screening Criteria**

15

16 **13.7.~~E~~ <u>F</u> OPTN KPD Prioritization Points**

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

21 **Table 13-2: OPTN KPD Prioritization Points**

If the:	Then the match will receive:
<u>Candidate is registered for the OPTN KPD program</u>	<u>.07 points for each day according to *Policy 13.7.G: OPTN KPD Waiting Time Reinstatement*</u>
Candidate is a 0-ABDR mismatch with the potential donor	~~200~~ <u>10</u> points
~~Candidate and potential donor are registered for the OPTN KPD program in the same region~~	~~25 points~~
~~Candidate and potential donor are registered for the OPTN KPD program in the same DSA~~	~~25 points~~
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	~~25~~ <u>75</u> points

If the:	Then the match will receive:
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 has a CPRA greater than or equal to 80%~~	~~125 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
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
~~Potential donor has at least one of the other antibody specificities reported for the candidate~~	~~- 5 points~~
Candidate is an orphan candidate	1,000,000 points

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13.7.F 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 Contractor 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 of the kidney transplant.

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

13.7.G 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: 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 Two- and Three-Way Matches

13.8.A   Match Size

The OPTN Contractor 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: Donor Chains.*

13.8.B   Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD program, all KPD donor surgeries involved in the exchange must begin within 24 hours and only after all donor surgeons involved in the exchange agree to proceed. each matched donor recovery must begin within 24 hours of the previous matched donor recovery in the exchange.

13.9 Donor Chains

13.9.A   Chain Size

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

13.9.B   Logistical Requirements

~~In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate must receive a kidney within 24 hours of the same day his paired KPD donor donates. A KPD candidate-donor pair will always have the option to have surgery on the same day. KPD donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.~~

~~A chain must end with a donation to a KPD candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor that started that chain or with a KPD bridge donor who will be included in a later match run. The transplant hospital that enters the NDD can choose whether the chain can end with a bridge donor or a donation to the deceased donor waitlist. The transplant hospital registering the potential KPD donor may refuse to allow the potential KPD donor to serve as a bridge donor at any point in the process.~~

In OPTN KPD chains, each matched donor recovery must be scheduled to occur 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 surgery 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.B: Logistical Requirements.*

13.9.C   ~~What to Do When A Chain Breaks~~ Ending Chains

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

Table 13-3: 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 Contractor that *one* of the following events has occurred:

1. The bridge donor declines to donate
2. The bridge donor donates to an orphan candidate
3. The bridge donor decides to donate to the deceased donor waitlist at the transplant hospital that entered the non-directed donor that began the chain
4. The transplant hospital that entered the non-directed donor requests to end the chain with a donation to the deceased donor waiting list
5. The transplant hospital that registered the bridge donor in the OPTN KPD program refuses to allow the donor to serve as a bridge donor

13.9.~~C~~D   What to Do When a Chain Breaks

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

~~If a KPD candidate or potential KPD donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a KPD candidate or potential KPD donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in *Policy 13.9.B: Logistical Requirements*.~~

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.B: Logistical Requirements* and *Policy 13.9.C: Ending Chains*.

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