

At-a-Glance

- **Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program**

- **Affected Policy:** Policies 13.4.4 (OPTN KPD Program Process Consents), 13.6.2 (Requirements for Match Run Eligibility for Potential Donors), 13.6.6.2 (Logistical Requirements), and 13.10 (Definitions)

- **Kidney Transplantation Committee**

The goal of this proposal is to increase matching opportunities in the OPTN KPD Program by allowing bridge donors (a donor who does not have a match identified during the same match run as his paired candidate) in the OPTN KPD Program. Currently, the OPTN KPD Pilot Program requires that donor chains end with a donation to a candidate on the deceased donor waiting list. As a result, donor chains could end when there may be the potential to extend the chain and transplant more candidates. Additionally, many transplant hospitals have expressed a desire for the OPTN KPD Program to include bridge donors. A secondary goal of this proposal is to increase participation in the OPTN KPD Program by providing more options for participating transplant hospitals. The proposed changes would allow potential donors who are not matched in the same match run as their paired candidates to enter a later match run to find a KPD match rather than donating to the deceased donor waiting list.

Note: These policies are also being proposed as new policies in the Proposal to Establish KPD Policy, which is also out for public comment in Spring 2012.

- **Affected Groups**

Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Living Donors

- **Number of Potential Candidates Affected**

This proposal will impact approximately 200 candidates currently in the OPTN KPD Pilot Program as well as any candidates who may join the OPTN KPD Program in the future.

- **Compliance with OPTN Key Goals and Final Rule**

The inclusion of bridge donors in the OPTN KPD Program addresses the OPTN key goal of increasing the number of transplants.

- **Specific Requests for Comment**

1. Should there be a limit on how long a bridge donor will be asked to wait in the OPTN KPD Program after his candidate receives a transplant?

Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program

Affected Policy: Policies 13.4.4 (OPTN KPD Program Process Consents), 13.6.2 (Requirements for Match Run Eligibility for Potential Donors), 13.6.6.2 (Logistical Requirements), and 13.10 (Definitions)

Kidney Transplantation Committee

Summary and Goals of the Proposal:

The goal of this proposal is to increase matching opportunities in the OPTN KPD Program by allowing bridge donors (a donor who does not have a match identified during the same match run as his paired candidate) in the OPTN KPD Program. Currently, the OPTN KPD Pilot Program requires that donor chains end with a donation to a candidate on the deceased donor waiting list. As a result, donor chains could end when there may be the potential to extend the chain and transplant more candidates. Additionally, many transplant hospitals have expressed a desire for the OPTN KPD Program to include bridge donors. A secondary goal of this proposal is to increase participation in the OPTN KPD Program by providing more options for participating transplant hospitals. The proposed changes would allow potential donors who are not matched in the same match run as their paired candidates to enter a later match run to find a KPD match rather than donating to the deceased donor waiting list.

Note: These policies are being proposed as new policies in the Proposal to Establish KPD Policy, which is also out for public comment in Spring 2012.

Background and Significance of the Proposal:

Background on the KPD Pilot Program

The OPTN began looking into a national kidney paired donation system in 2004, and the Kidney Transplantation Committee developed a proposal for a national kidney paired donation program. At the time, there was some ambiguity as to whether kidney paired donation constituted “valuable consideration” under the National Organ Transplant Act (NOTA). Therefore, the OPTN could not approve or implement a national kidney paired donation system. As a result, the KPD proposal was sent out for public comment in 2004 and 2006, but it was not sent to the OPTN/UNOS Board of Directors for consideration at that time. It was not until Congress clarified NOTA in 2007 to explicitly state that KPD did not constitute valuable consideration that the OPTN could move forward. In March 2008, the OPTN/UNOS Kidney Transplantation Committee voted to forward the original KPD proposal to the Board of Directors with minimal changes. In June 2008, the Board of Directors approved a proposal for a national KPD Pilot Program¹. This proposal, as sent out for public comment, allowed only two-way and three-way exchanges (See Figure 1); it did not include an option for non-directed donors (NDDs) and donor chains.

¹ To view the briefing paper for the KPD Pilot Program as approved by the OPTN/UNOS Board of Directors in June 2008, please go to http://optn.transplant.hrsa.gov/SharedContentDocuments/KPD_Briefing_Paper_508V.pdf

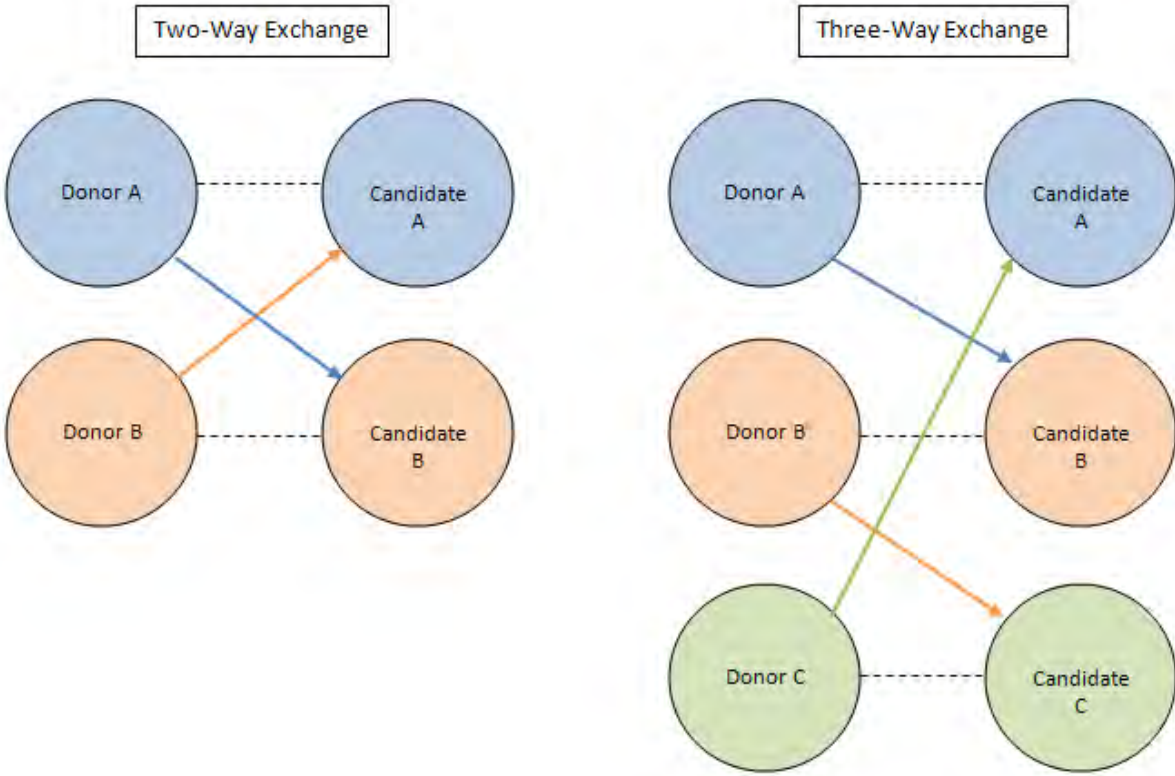


Figure 1: Diagrams on Two-Way and Three-Way Kidney Paired Donations

In the time since the original KPD proposal was sent out for public comment, advances have been made in the field of kidney paired donation. In October 2007, UNOS, as the OPTN contractor, sent out a request for information (RFI) on kidney paired donation. This RFI asked for information on software systems used to facilitate matching of potential kidney candidate/donor pairs. Nine groups responded, and presented to UNOS Staff, OPTN leadership, and consultants from Electronic Data Systems (EDS), an HP company, on February 4, 2008. Based on the presentations on February 4th, it was apparent that many kidney paired donation systems currently incorporate NDDs and donor chains and that the RFI presenters recommended including NDDs and donor chains in the OPTN National KPD system.

If an exchange is started from a NDD (often called an “altruistic” living donor; a living donor donating his/her kidney to any candidate in need of a kidney transplant), the last recipient will have a living donor who has not donated during the match cycle. This donor can either donate to the deceased donor list and close the chain (closed chain or “domino”)², or can become a “bridge donor” used to continue the chain in a subsequent match cycle (open chain)³(see Figure 2).

² Robert A. Montgomery et al., “Domino paired kidney donation: a strategy to make best use of live non-directed donation,” *Lancet* 368 (2006): 419-21.

³Michael A. Rees et al., “A non-simultaneous, extended altruistic donor chain,” *New England Journal of Medicine* 360 (2009): 1096-101.; Sommer E. Gentry et al., “The roles of dominos and non-simultaneous chains in kidney paired donation,” *American Journal of Transplantation* 9 (2009): 1330-1336.

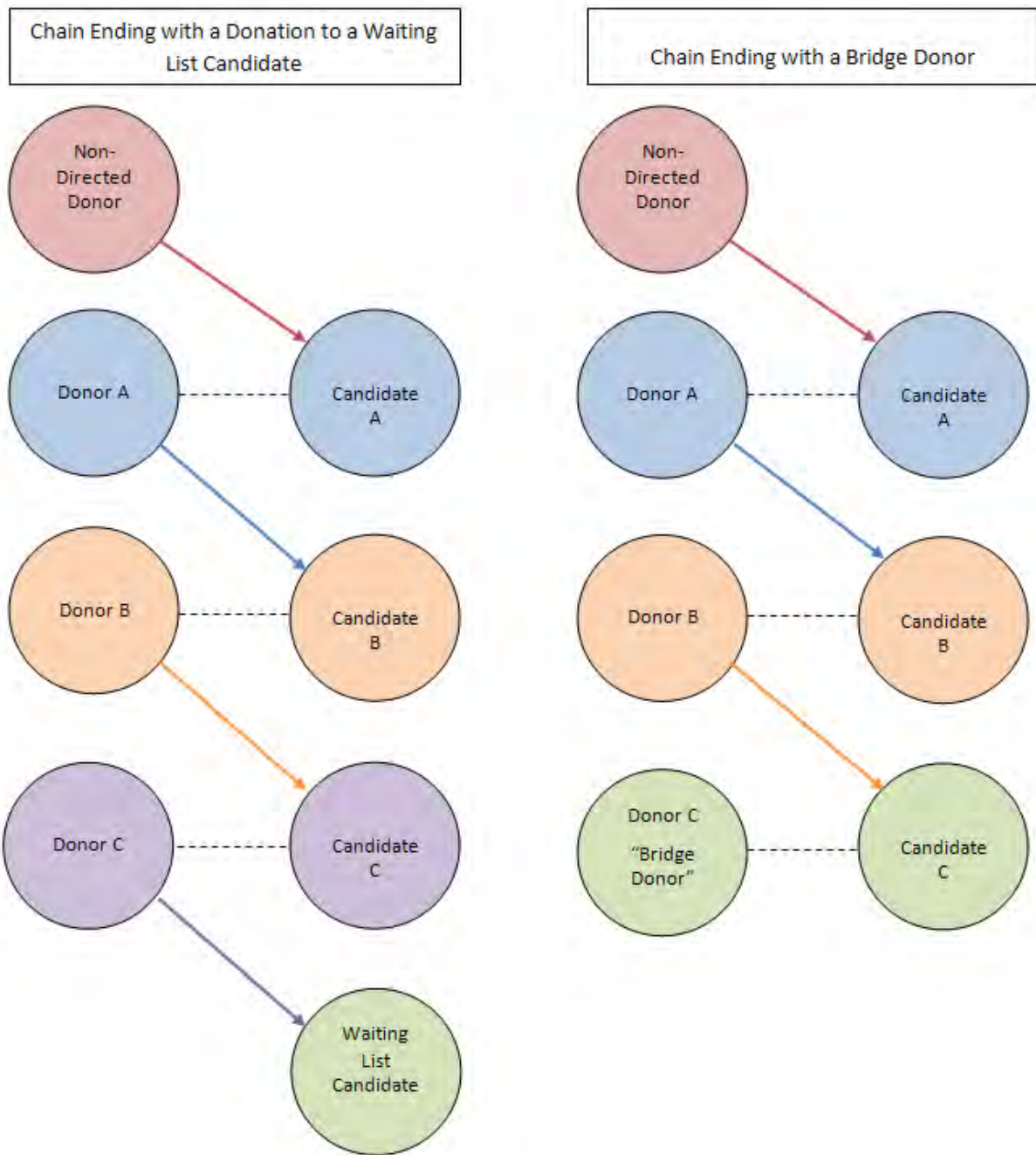


Figure 2: Diagrams on Donor Chains

The closed and open chain concepts and the incorporation of kidneys from NDDs were not included in the 2006 Kidney Paired Donation Proposal.

In June 2009, the Kidney Transplantation Committee distributed a proposal to include NDDs and donor chains in the OPTN KPD Pilot Program. At the time, the Living Donor Committee had the following concerns about the proposal:

The Living Donor Committee did not support this proposal. The Committee opined that open chains and/or bridge donors should not be included during the trial phase of the system. The Committee would support reconsideration of the use of open chains and bridge donors after a one-year trial period. The Committee did support the use of non-directed donors in closed chains if they are appropriately consented and evaluated. The Committee vote on the proposal as written was 10-Support, 13-Oppose, 0-Abstain.

As a result, the Kidney Transplantation Committee chose to remove the possibility of having bridge donors from the proposal at that time with the intent of continuing to discuss the Living Donor Committee's concerns. The Kidney Transplantation Committee did send a proposal to include NDDs and donor chains that end with a donation to waiting list candidate to the Board of Directors for consideration. In November 2010, the Board of Directors approved this proposal. In May 2011, donor chains were implemented in the OPTN KPD Pilot Program. In 2012, the Kidney Transplantation Committee also issued a proposal to establish KPD policy, which is out for public comment concurrent with this proposal. The policy language in this proposal modifies the policy language in the proposal to establish KPD policy.

The KPD Work Group of the Kidney Transplantation Committee has met twice a month beginning in July 2011 to develop KPD policy and to monitor OPTN KPD Pilot Program operations. The KPD Work Group includes Kidney Transplantation Committee representatives, Living Donor Committee representatives including a living donor, a Histocompatibility Committee representative, representatives from Members participating in the OPTN KPD Pilot Program, an OPO representative, and technical advisors who wrote the optimization algorithms used in the OPTN KPD Pilot Program. As the KPD Work Group examined the results of the OPTN KPD Pilot Program, they noticed that while donor chains were being identified, these chains never reached their full potential. A match would be refused at some point (also called a "chain break"), and the chain would end with a donation to a waiting list candidate even if the chain could be extended by entering the final donor in the next match run as a bridge donor. Even for chains that do reach their full potential with no refusals, bridge donors could still increase the number of transplants. Additionally, some donors stated a preference for being a bridge donor so that they could care for their intended candidates in their recovery period before donating rather than both the donor and the intended candidate recovering from surgery at the same time. Finally, some of the transplant community has been reluctant to participate or enter NDDs in the OPTN KPD Pilot Program because the program does not allow bridge donors. Based on these findings, the KPD Work Group began discussing the inclusion of bridge donors in the OPTN KPD Program.

The KPD Work Group decided to draft a public comment proposal to include bridge donors in the OPTN KPD Program. The KPD Work Group reviewed the Living Donor Committee's concerns about the 2009 donor chains proposal and developed specific informed consent requirements for bridge donors so that bridge donors would have multiple opportunities to decide whether to continue waiting as a bridge donor, donate sooner to the deceased donor waiting list, or decline to donate. The Work Group debated whether to set a maximum limit for how long a bridge donor would wait in the system. Ultimately, the Work Group decided to let each donor indicate how long he would be willing to be a bridge donor and to periodically offer the donor the opportunity to re-evaluate this decision.

In January and February 2012, the Kidney Transplantation, Living Donor, and Policy Oversight Committees reviewed the draft policy on bridge donors. The Living Donor Committee requested that the KPD Work Group require that the potential donor's Transplant Hospital inform potential bridge donors:

- that they may have to have another medical evaluation in the future and
- of the process for determining whether a potential donor will be a bridge donor.

The KPD Work Group agreed to this request, and these provisions are included in this proposal.

Both the Living Donor Committee and the KPD Work Group debated whether there should be a limit on how long the bridge donor waits. The consensus from both groups was to allow the potential donors to determine how long they would be willing to wait. The groups also considered whether the potential donors should state how long they would be willing to wait when they consent to being a bridge donor. The groups decided that the information may not be useful because the potential donors may change their minds at any point. Potential donors may state the amount of time they would be willing to wait up front, but the groups decided not to require that Transplant Hospitals obtain this information at the time of consent.

The Kidney Transplantation and Policy Oversight Committees did not have any suggestions for additional requirements to include in KPD policy regarding bridge donors. On February 6, 2012, the Kidney Transplantation Committee voted to send the KPD bridge donor policy language out for public comment. (18-Support, 0-Oppose, 0-Abstain)

Details of the Proposal

The Work Group agreed to the following requirements for donor chains in the KPD Pilot Program:

- A donor chain in the OPTN KPD Program may end with a donation to a waiting list candidate or a bridge donor.
- In order for a potential donor to be a bridge donor, the potential donor must consent to be a bridge donor at the following times:
 - Before the potential donor's Transplant Hospital enters that the potential donor is willing to be a bridge donor in the KPDSM application in UNetSM (typically at the time of informed consent to participate in the OPTN KPD Program),
 - When the potential donor is identified as a bridge donor in a chain, and
 - Every 3 months after match run in which the potential donor has been identified as a bridge donor.
- Each time the potential donor consents to be a bridge donor, the potential donor's Transplant Hospital must inform the potential donor that he may continue to be a bridge donor, donate to the waiting list, or decline to donate.
- The potential donor's Transplant Hospital must inform potential bridge donors:
 - that they may have to have another medical evaluation in the future and
 - of the process for determining whether a potential donor will be a bridge donor.
- The potential donor's Transplant Hospital may refuse to allow the potential donor to serve as a bridge donor.
- When a chain breaks, the final donor in the chain may become a bridge donor provided that they meet the bridge donor requirements defined in the policy.
- A donor choice will be added regarding whether the donor is willing to be a bridge donor.
- A transplant center choice will be added regarding whether the center that introduced the NDD requires a donor chain where the last living donor will donate to a patient on the waiting list of the center that introduced the NDD or is willing to take part in an chain the ends with a bridge donor where they are not guaranteed that any of their patients will "benefit" from the NDD.

Only the center that introduced the NDD needs to make this decision; the centers with the "middle" pairs in the chain are not affected by whether the chain is open or closed.

Supporting Evidence and Modeling:

In October 2010 through April 2011, data entry for the OPTN KPD Pilot Program included a question about whether potential donors would be willing to be bridge donors in order to assess interest in including bridge donors in the OPTN KPD Pilot Program. Of the 172 answers to this question for match-run eligible donors, 81% indicated that the potential donor would be willing to be a bridge donor.

Research by Ashlagi et al. also supports the inclusion of non-directed donors and chains in a KPD system.⁴

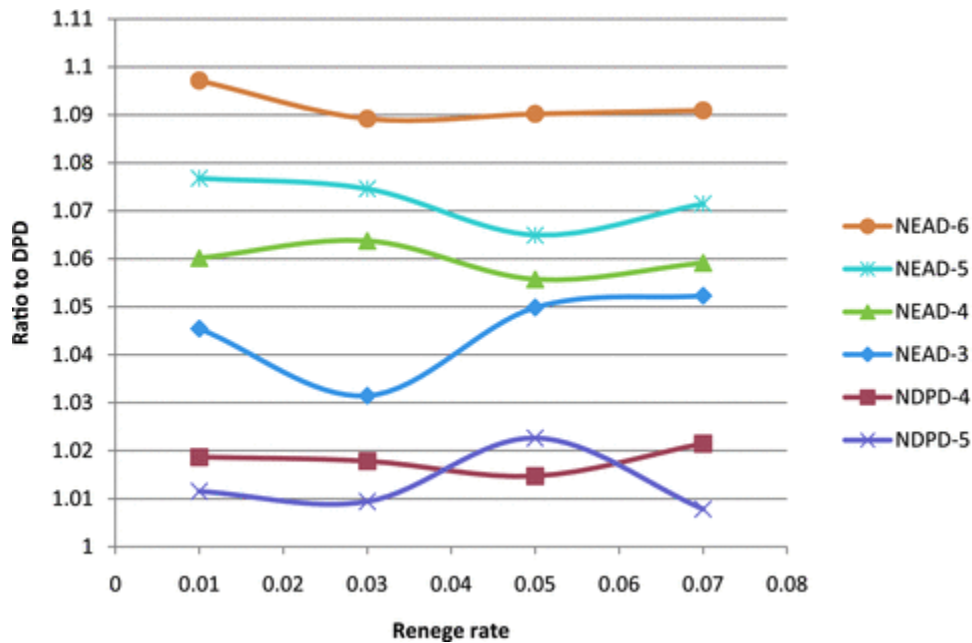


Figure 3: Comparing NEAD-k and NDPD-K policies to DPD, with sensitivity analysis on the renege rate from 0.01 to 0.07⁵

DPD (domino paired donation (“closed chains”)): each NDD initiates a chain of length at most 2, in which the last donor gives directly to a recipient on the waiting list.

NDPD-k (non-simultaneous long DPDs (“closed chains”)): each NDD initiates a chain of length at most k, in which the last donor gives directly to a recipient on the waiting list.

NEAD-k (non-simultaneous long NEAD (non-simultaneous extended altruistic donor) chains (“open chains”)): each NDD initiates a NEAD chain where in each period a chain of length at most k is found.

⁴ Itai Ashlagi et al., “Nonsimultaneous chains and dominos in kidney- paired donation revisited,” *American Journal of Transplantation* 11(2011):984-94.

⁵ Itai Ashlagi et al., “Nonsimultaneous chains and dominos in kidney- paired donation revisited,” *American Journal of Transplantation* 11(2011):984-94.

The bridge donor at the end of the previous chain becomes the NDD in a new chain in a subsequent match run.

Ashlagi et al. found that in simulations, both NDPD-k (which is already included in the OPTN KPD Program) and NEAD-k (which is proposed for inclusion in the OPTN KPD Pilot Program) yielded more transplants than simply using domino paired donation, since all curves lie entirely above 1 (Figure 3). While a reliable estimate of the true bridge donor renege rate is unavailable, experience in regional KPD programs suggests it is likely to be very low. In simulations that incorporated non-zero match failure rates to account for unexpected positive crossmatches, Ashlagi, et al, found that the expected benefit of NEAD chains relative to DPD remained relatively constant, even as the bridge donor renege rate was varied between 1% and 7% (Figure 3).

	DPD	NEAD-3	NDPD-4	NEAD-4	NDPD-5	NEAD-5	NEAD-6
Percentage of high PRA patients receiving transplants	6.4/87.1 (7.3%)	8.4/87.1 (9.7%)	7.5/87.1 (8.7%)	9.7/87.1 (11.2%)	7.6/87.1 (8.8%)	10.2/87.1 (11.7%)	10.6/87.1 (12.2%)
Percentage of high PRA recipients receiving transplants in chains	1/6.4(15.7%)	3.4/8.4 (39.7%)	2.3/7.5 (31.3%)	4.9/9.7 (50.2%)	2.8/7.6 (36.3%)	5.8/10.2 (57.1%)	6.6/10.6 (62.6%)
Percentage of recipients that are high PRA	6.6/58.3 (11%)	8.4/65.7 (12.9%)	7.5/62.3 (12.1%)	9.7/67.2 (14.5%)	7.6/61.3 (12.5%)	10.2/68.1 (15%)	10.6/68.2 (15.6%)
Ratio of blood type O patients that receive transplants	18.5/138.5 (13.4%)	21.2/138.5 (15.4%)	21.1/138.5 (15.3%)	23/138.5 (16.7%)	21.2/138.5 (15.3%)	23.7/138.5 (17.1%)	23.8/138.5 (17.3%)
Percentage of blood type O recipients receiving transplants in chains	2.7/18.5 (14.5%)	6/21.2 (28.4%)	5.7/21.1 (27.3%)	8.4/23 (36.5%)	6.5/21.2 (31.1%)	10.1/23.6 (42.7%)	11.8/23.9 (49.7%)
Percentage of recipients that are blood type O	18.5/58.3 (31.8%)	21.2/65.7 (32.4%)	21.1/62.3 (33.9%)	23/67.2 (34.3%)	21.2/61.3 (34.6%)	23.6/68.1 (34.7%)	23.9/68.2 (35%)

Figure 4: The first row shows for each policy the ratio between the number of high PRA (PRA>80%) recipients to the total number of high PRA patients that entered the pool. The second row shows the ratio between the number of high PRA recipients that were part of a chain to the total number of high PRA recipients (that were part of either a cycle or a chain). The third row shows ratio between the number of recipients that have high PRA to the total number of recipients. The 4th-6th rows are similar ratios for blood type O patients.⁶

⁶ Itai Ashlagi et al., "Nonsimultaneous chains and dominos in kidney- paired donation revisited," *American Journal of Transplantation* 11(2011):984-94.

Figure 4 shows that both NDPD (which is already included in the OPTN KPD Program) and NEAD (which is proposed for inclusion in the OPTN KPD Pilot Program) are expected to provide more transplants to highly sensitized and blood type O candidates than simply using domino paired donation.

Expected Impact on Living Donors or Living Donation:

This proposal requires KPD-specific informed consent for living donors participating in KPD who are willing to be bridge donors. Some Transplant Hospitals have not participated in the OPTN KPD Pilot Program or have not entered all possible donor-candidate pairs in the program. Therefore, this proposal could increase participation in KPD, which could increase living donation. Additionally, the inclusion of bridge donors could increase living donation by making more matches possible in the OPTN KPD Program.

Expected Impact on Specific Patient Populations:

This proposal has no known impact to specific patient populations. The overall OPTN KPD Program does increase access for highly sensitized candidates to receive a transplant by providing a larger pool of potential donors with whom they may match. By increasing matching opportunities, the inclusion of bridge donors could also increase access for highly sensitized and blood type O candidates.

Compliance with OPTN Key Goals and the Final Rule:

This proposal directly addresses the strategic plan goal to increase the number of transplants. By allowing bridge donors in the OPTN KPD Program, this proposal has the potential to increase the number of transplants by providing more opportunities for chains to be longer. For example, if a chain breaks, the last donor before the chain breaks can become a bridge donor and be entered in the next match run instead of simply donating to a candidate on the deceased donor list. This scenario could result in multiple transplants instead of one.

Plan for Evaluating the Proposal:

For the inclusion of bridge donors, the Kidney Transplantation Committee will consider the following information:

- **What questions or hypotheses are guiding the evaluation of the proposal?**
 - What proportion of centers who introduce NDDs to the KPD program allow the chain to end with a bridge donor? What proportion of centers require a chain that ends with a donation to a candidate on the waiting list?
 - How many bridge donors donated a kidney and started another chain?
 - What proportion of potential bridge donors choose not to donate? For those potential bridge donors who decline to continue with donation, at what point in the process is this decision made and why? When did the center learn of these potential bridge donors's decision to decline to continue? (For example, at the time a match offer was made, or did the donor contact the center and ask to be removed from the KPD program at some other time?)
 - How long do the potential bridge donors have to wait before KPD Program finds a match for the potential donor?
 - How many of the matches including NDDs were in chains with bridge donors?

- How many Transplant Hospitals join the OPTN KPD Program as a result of this policy?
- How many NDDs added to the OPTN KPD Pilot Program as a result of this policy?
- **Proposal Performance Measures:**
 - Percentage of centers that allow chains to end with a bridge donor
 - Percentage of centers that allow chains that end with a donation to a waiting list candidate but not chains that end with a bridge donor
 - Number of bridge donors who have donated their kidneys to start another chain
 - Rate of potential bridge donors who choose not to donate
 - For potential bridge donors who declined to continue with donation, the distribution of when the potential bridge donor declined to continue
 - For potential bridge donors who decide to donate to the deceased donor waiting list, the distribution of when the potential bridge donor decided to donate to the deceased donor waiting list
 - For bridge donors who donated, the distribution of when the bridge donor donated to a chain by blood type and location
 - Number of chains that end with bridge donors found in the OPTN KPD Program
 - Number of chains including bridge donors that resulted in transplants
 - Number of Transplant Hospitals that join the OPTN KPD Program before and after implementation of this policy
 - Number and rate of NDDs being added to the OPTN KPD Program before and after implementation of this policy

Time Line for Evaluation:

The Kidney Transplantation Committee will evaluate the program every 6 months for three years.

Additional Data Collection:

This proposal will require some additional data collection. Beyond what will already be collected for the KPD Pilot Program, the following data will be collected:

- Whether the donor is willing to be a “bridge donor”
- Whether the center that entered the NDD is willing to participate in an exchange that ends with a bridge donor

This additional data collection meets the data collection principle of developing transplant, donation, and allocation policies. This data is necessary so that the potential donors can stipulate the conditions under which they are willing to donate. This data facilitates the matching process for kidney paired donation.

Expected Implementation Plan:

The Board will consider this proposal in November 2012. If approved by the Board, the policy language will be effective pending programming.

If approved, Transplants Hospitals must receive consent from potential donors who are willing to be bridge donors at each of the following times:

- Before the potential donor is eligible for a KPD match run,
- When the potential donor is identified as a bridge donor in a chain, and

- Every 3 months after the match run in which potential donor has been identified as a bridge donor

Each time the potential donor consents to be a bridge donor, the potential donor’s Transplant Hospital must inform the potential donor that he may continue to be a bridge donor, donate to the waiting list, or decline to donate. Additionally, the potential donor’s Transplant Hospital must inform potential bridge donors that they may have to have another medical evaluation in the future and of the process for determining whether a potential donor will be a bridge donor.

This proposal does require programming in UNetSM to add the fields for the new bridge donor choices.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Members	E-newsletter	30 days after passed by Board
Website Enhancement	General public, members	Web-posting	After implementation date

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
Informed Consent Templates	Transplant surgeons, transplant coordinators	Posted in KPD SM application, member newsletter, and OPTN website	TBD

Compliance Monitoring:

During on-site reviews, the UNOS Department of Evaluation and Quality (DEQ) staff reviews and verifies donor recovery transplant centers’ policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.

During on-site reviews of bridge donors’ transplant centers, DEQ staff will verify that there is a record that the transplant center obtained consent to continue as a bridge donor from each bridge donor at each of the following times:

- Before UNOS was notified that the donor was willing to be a bridge donor
- After a match was been identified, but before the matched candidate received a transplant
- At least once every three months after the donor was identified as a match donor, until donation.

For each consent, DEQ staff will verify that there is documentation of that the potential bridge donor was informed that he has each of the following options:

- Option to continue to be a bridge donor
- Option to donate to the waiting list
- Option to decline to donate

This consent may be verbal as long as there is documentation of the conversation.

During on-site reviews of bridge donors' transplant centers, DEQ staff will also verify that there is a record that the transplant center informed each person reported as a potential donor of the factors listed in Policy 13.4.4.

Policy Proposal:

For the convenience of the reader, proposed policy language is underlined (example) and deleted language is struck through (~~example~~). Policy language that is proposed or deleted is in reference to a separate 2012 public comment proposal that creates Policy 13 and has not yet been adopted by the OPTN Board of Directors.

13.4.4 OPTN KPD Program Process Consents

The potential donor's Transplant Hospital must inform potential donors of the following elements of the OPTN KPD Program:

1. Potential donors do not choose with whom they match. A potential donor or a candidate may decline a match after it has been found.
2. Matching requirements in Policy 13.6.5 and Policy 13.6.6
3. Rules for when Members may facilitate meetings between donors and recipients in the OPTN KPD Program in Policy 13.9

The potential donor's Transplant Hospital must maintain documentation in the potential donor's chart that the potential donor has been informed of each element.

If the potential donor is willing to be a bridge donor, then the potential donor's Transplant Hospital must receive consent to be a bridge donor from the potential donor at each of the following times:

- Before the potential donor's Transplant Hospital reports to the OPTN Contractor that the potential donor is willing to be a bridge donor
- When a match has been identified in which the potential donor is a bridge donor and before the potential donor's matched candidate receives a transplant as part of the exchange in which the potential donor is a bridge donor
- Every three months after the match run in which a potential donor has been identified as a bridge donor until the potential donor donates, declines to be a bridge donor, or declines to donate

At each time, the potential donor's Transplant Hospital must inform the bridge donor that they may continue to be a bridge donor, donate to the waiting list, or decline to donate. The potential donor's Transplant Hospital must maintain documentation of these consents in the potential donor's chart.

Before the potential donor's Transplant Hospital reports to the OPTN Contractor that the potential donor is willing to be a bridge donor, the potential donor's Transplant Hospital must inform the potential donor:

- That the potential donor may need to have another medical evaluation at a future time
- Of the process for determining whether a chain ends with a bridge donor as defined in Policy 13.6.6.2

The potential donor's Transplant Hospital must maintain documentation in the potential donor's chart that it provided this information.

13.6.2 Requirements for Match Run Eligibility for Potential Donors

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

1. The potential donor's Transplant Hospital must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications
 - a. The potential donor's Transplant Hospital must report the potential donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential donor's actual blood type to the OPTN Contractor
 - c. The potential donor is not eligible for a KPD match run until the Transplant Hospital reports two identical blood types
2. The potential donor's Transplant Hospital must complete the informed consent process in Policy 13.3
3. The potential donor's Transplant Hospital must complete the medical evaluation process in Policy 12.3
4. The potential donor's Transplant Hospital must submit the required fields below to the OPTN Contractor
 - a. Donor Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Height and weight
 - Whether the potential donor is a non-directed donor;
 - If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate

- Whether the potential donor has signed an agreement to participate in the OPTN KPD Program
 - Whether the potential donor has signed a release of protected health information
 - Whether the potential donor has provided informed consent as required in policy
 - Whether the potential donor has undergone a medical evaluation as required in policy
 - Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status
- b. Clinical Information
- The number of anti-hypertensive medications the potential donor is on
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance, date, and method
 - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
- c. Donor Choices
- Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel
 - Whether the potential donor is willing to ship a kidney
 - Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain
 - Whether the potential donor and the Transplant Hospital are willing for the potential donor to be a bridge donor
- d. HLA
- HLA-A antigen typing
 - HLA-B antigen typing
 - HLA-Bw4 and –Bw6 antigen typing
 - HLA-Cw antigen typing
 - HLA-DR antigen typing
 - HLA-DR51, -DR52, and –DR53 antigen typing
 - HLA-DQ antigen typing
 - HLA-DR51, -DR52, and –DR53 antigen typing
5. The potential donor must be in an active status in the OPTN KPD Program
 6. The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program
 7. The potential donor’s Transplant Hospital must submit a response for all previous match offers for the potential donor in the OPTN KPD Program

8. The potential donor must not be in a pending exchange in the OPTN KPD Program.

13.6.6 Donor Chains

13.6.6.1 Chain Size

In the OPTN KPD Program, donor chains will be limited to 20 donor-candidate pairs.

13.6.6.2 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his or her paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. 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 candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain or with a 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 whether the chain must end with a donation to a candidate on the waiting list at that Transplant Hospital. In order for a potential donor to be a bridge donor, the potential donor's Transplant Hospital must receive consent from the donor to be a potential bridge donor as defined in Policy 13.4.4. The potential donor's Transplant Hospital may refuse to allow the potential donor to serve as a bridge donor at any point in the process.

13.6.6.3 What to Do When a Chain Breaks

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

If a candidate or potential 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 candidate or potential donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in Policy 13.6.6.2. may be entered in the next match run to repair the donor chain if *all* of the following conditions are met:

- ~~1. The operating room dates are not set for a chain at the time of the next match run~~
- ~~2. The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match~~
- ~~3. The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.~~

13.10 Definitions

- Bridge donor- a donor who does not have a match identified during the same match run as his paired candidate

- *Chain* – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate’s paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.
- *Exchange* – a set of matches that form a chain, a two-way exchange, or a three-way exchange.
- *Match* – a donor and his matched candidate
- *Match Run* – procedure used to generate a set of exchanges
- *Matched candidate* – the candidate that a KPD match run identifies as a potential recipient of a donor’s kidney
- *Matched donor* – a donor identified by a KPD match run as a potential donor for a candidate
- *Matched recipient* – a matched candidate that has received a transplant
- *Non-Directed Donor (NDD)* - a donor that enters KPD without a paired candidate
- *Other antibody specificities*- antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.
- *Pair* – a donor and his paired candidate
- *Paired candidate* – the candidate to whom a donor intended to donate his organ before entering into KPD
- *Paired Donation of Human Kidneys (KPD)* – the donation and receipt of human kidneys under the following circumstances:
 - An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.
 - A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
 - The first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.
 - If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
 - All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
 - Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.
- *Paired donor* – a donor who intended to donate his organ, before entering into KPD, to his paired candidate
- *Paired Recipient* – a paired candidate that has received a transplant
- *Three-way exchange*- a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.

- *Two-way exchange* – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.
- *Unacceptable antigens*- antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens.