At-a-Glance

- **Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation Pilot Program**

- **Affected Program: Kidney Paired Donation Pilot Program**

- **Kidney Transplantation Committee**

- This proposal would allow non-directed (or altruistic) living donors to participate in the Kidney Paired Donation Pilot Program. Also, this proposal would include donor chains as a matching option in the program in addition to two-way and three-way matching.

- **Affected Groups**
  Kidney transplant surgeons
  Kidney transplant coordinators
  Nephrologists
  Kidney candidates
  Potential living donors

- **Specific Requests for Comment**
  Please consider and comment on the entire proposal.

Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation Pilot Program

Affected Program: Kidney Paired Donation Pilot Program

Kidney Transplantation Committee

Summary and Goals of the Proposal:

Currently, the Kidney Paired Donation (KPD) Pilot Program only allows potential living donors with incompatible potential recipients to participate. Potential non-directed (or altruistic) living donors (those who are not linked to an incompatible potential recipient) have no way to enter the program. Also, candidate/ donor pairs can only be matched in groups of two or three, and all donor nephrectomies in the group must occur simultaneously. This proposal would allow potential non-directed living donors (NDDs) to participate in the KPD Pilot Program and add donor chains as an option in the system. A donor chain occurs when a NDD gives a kidney to a recipient whose living donor in turn gives a kidney to another recipient and continues the chain. This proposal would allow two types of donor chains: open and closed. Closed chains start with a NDD and end with a donation to a recipient on the deceased donor waiting list. Open chains start with a NDD and end with a potential bridge donor who will start another segment in the open chain. In open chains, the bridge donor nephrectomy does not occur at the same time as the other living donor nephrectomies. Donor chains have the potential to increase the number of transplants in a KPD system.

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 never sent to the OPTN/UNOS Board of Directors for consideration. 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 with minimal changes. In June 2008, the Board of Directors approved a proposal for a national KPD Pilot Program[1]. This proposal, as sent out for public comment, allows only two-way and three-way exchanges (See Figure 1); it did not include an option for NDDs and donor chains.

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[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://www.unos.org/CommitteeReports/board_main_KidneyTransplantationCommittee_6_23_2008_16_51.pdf

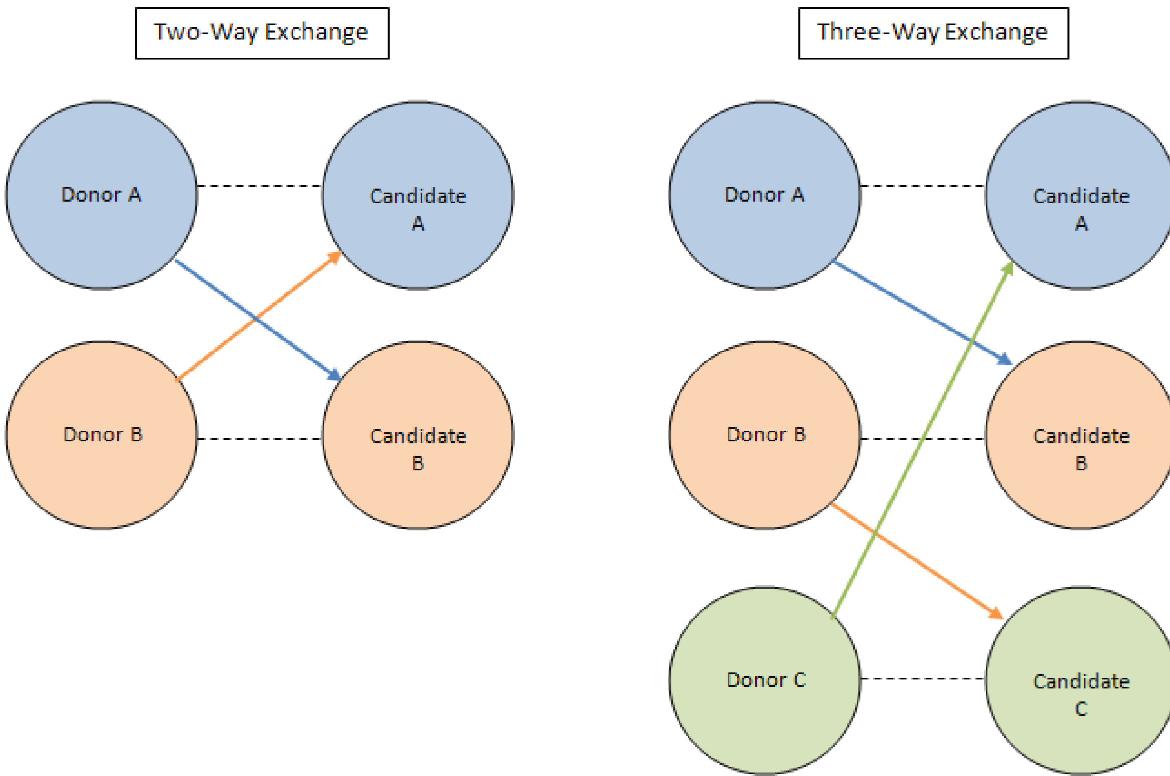

Figure 1: Diagrams on Two-Way and Three-Way Kidney Paired Donations

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 Electronic Data Systems (EDS, an HP company) consultants 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 these systems would look for the inclusion of these features in a national 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(s) 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 (start the next "segment") in a subsequent match cycle (open chain)[3](see Figure 2). In order to continue these open chains, programs have used strategies such as only ending an open chain with a recipient who has more than one potential living bridge donor, as it is less likely that one of two or more potential living donors will be unable to donate in the future. Programs may also prefer for

[2] Montgomery, R.A. et al. (2006). Domino paired kidney donation: a strategy to make best use of live non-directed donation. *Lancet*, 368(9533): 419-21.
[3] Rees, M.A. et al. (2009). A non-simultaneous, extended altruistic donor chain. *New England Journal of Medicine*, 360(11): 1096-101.; Gentry, S.E., Montgomery, R.A., Swihart. B.J., and Segev, D.L. (2009). The roles of dominos and non-simultaneous chains in kidney paired donation. *American Journal of Transplantation,* 9: 1330-1336.

the potential bridge donor(s) to be a person with a favorable blood type for donation, such as Type O or A.

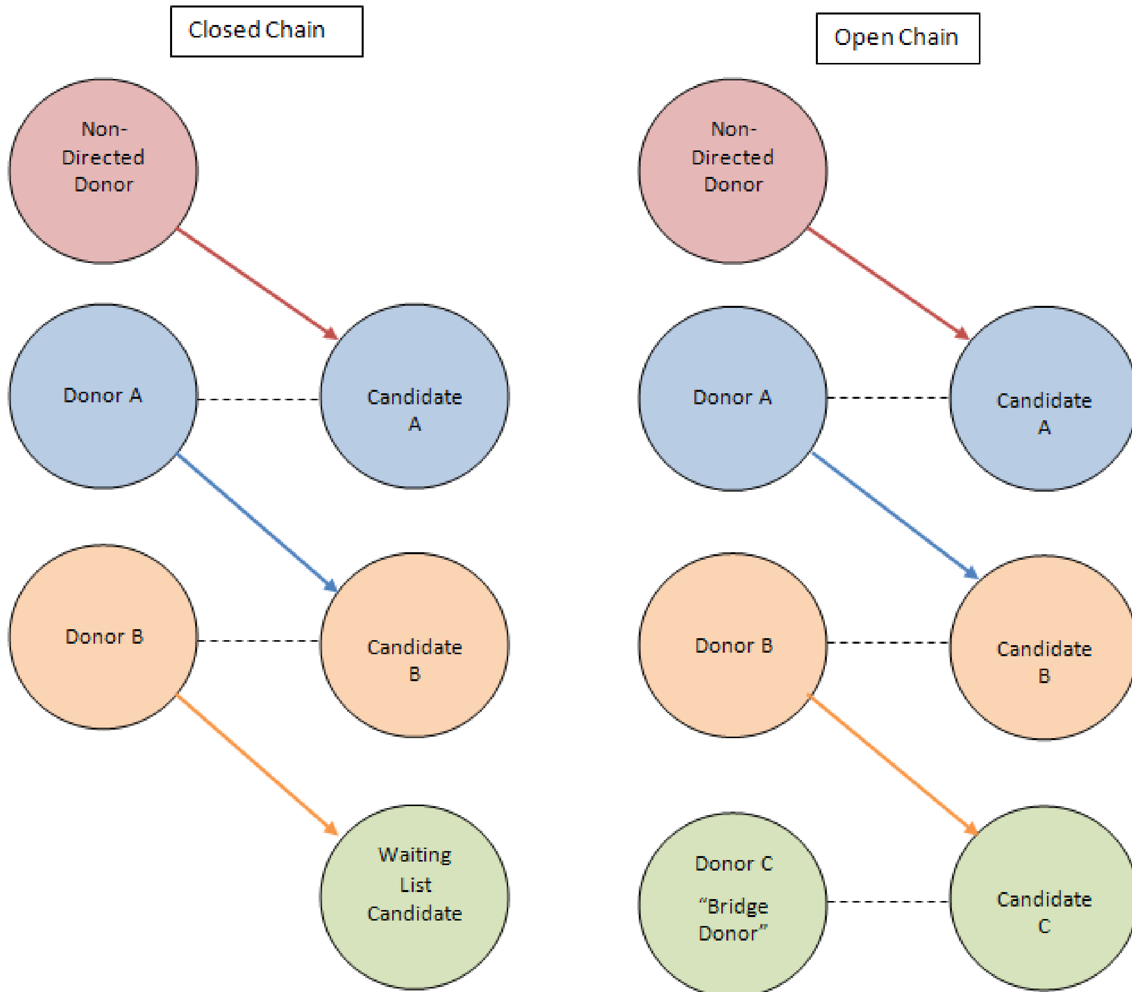

Figure 2: Diagrams on Closed Chains and Open Chains

The closed and open chain concepts and the incorporation of kidneys from NDDs were not included in the 2006 Kidney Paired Donation Proposal. Since these features are substantially different than the original proposal and incorporate NDDs, these concepts are being sent out for public comment separately.

Details of the Proposal

On April 22, 2008, the Kidney Paired Donation Work Group met to discuss how to incorporate donor chains and NDDs into the KPD Pilot Program. The Work Group agreed to the following definitions and requirements for donor chains in the KPD Pilot Program:

- Closed chains start with a NDD and end with a simultaneous donation to a list recipient. Open chains start with a NDD and end with a potential bridge donor who will start another segment in the open chain at a later date.
- The term "segment" will be used for parts of open chains that occur at different times (rather than clusters or any other term). Every donor operation in a given segment will occur at the same time, though possibly at different hospitals.

- For closed chains, the chain size will be limited to three incompatible pairs. A closed chain with three incompatible pairs means that four transplants take place. A closed chain with a size of three would include a NDD, three donor/candidate pairs, and a list recipient. Closed chains may also involve only two incompatible pairs, or only one incompatible pair. Closed chains can involve multiple hospitals.
- For closed chains, all donor surgeries must occur at the same time.
- For closed chains, the list recipient should be from the waitlist of the center that entered the NDD.
- For open chains, the segment size will be limited to three incompatible pairs. An open chain with a size of three would include a NDD and three donor/candidate pairs. One of the donors from the candidate/donor pairs would be the potential bridge donor and not donate until a later time (the next segment). Three transplants would take place simultaneously in this case. Open chains may also involve only two incompatible pairs, or only one incompatible pair.
- For open chains, all donor surgeries for each segment must take place at the same time, except the potential bridge donor, and subsequent segments initiated by that bridge donor will occur at a different time.
- A donor choice should be added regarding whether the donor is willing to be a bridge donor. If the donor is willing to be a bridge donor, the donor must have an appropriate final imaging study (bilateral renal arteriogram, CT arteriogram or MR arteriogram) *prior to the match run* in addition to all other potential living donor evaluation requirements.
- A center choice should be added regarding whether the center that introduced the NDD is willing to take part in an open chain (where they are not guaranteed that any of their patients will "benefit" from the NDD) or requires a closed chain (where last living donor will donate to a patient on the waiting list of the center that introduced 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.
- The potential bridge donor will be entered into three consecutive match cycles after the potential bridge donor's intended candidate has received a transplant. If the potential bridge donor has not been matched by this time, the bridge donor <u>and</u> the center that evaluated the non-directed donor that started the chain can elect to have the potential bridge donor continue to participate in match runs, or either the potential bridge donor <u>or</u> the center that evaluated the NDD can elect to have the potential bridge donor donate to the deceased donor list. After six match cycles after the potential bridge donor's intended candidate has received a transplant, the potential bridge donor will be asked to donate to the deceased donor waiting list. The potential bridge donor can choose to donate to the DD list or leave the program at any time.
- There are no required characteristics for the living donor kidney that is sent to the deceased donor list.
- A deceased donor will not be used to start chains in the KPD Pilot Program at this time.

If the transplant center is willing to participate in a closed chain or an open chain, the candidate/donor pair will have the option to participate in a closed chain or an open chain. If a pair is unwilling to participate in a chain, they will only be matched in two-way or three-way matches. The requirements for the informed consent and medical evaluation of potential living kidney donors will apply to NDDs as well as potential living donors that are part of a candidate/donor pair. These requirements are consistent with the processes outlined in the Living Donor Committee's "The Resource Document for

Informed Consent of Living Donors[4]" and "Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols.[5]"

Points for Closed and Open Chains

The optimization protocol for matching candidate/donor pairs maximizes the quantity and/or quality of potential transplants according to the priorities assigned. For example, it is possible to assign priority only for the highest number (i.e., quantity) of matches (potential transplants) that can be accomplished. It is also possible to assign priority to different types of candidates or matches. The optimization algorithm uses these priority points to select the "best" matching (i.e., the set of matches with the highest points value). In the KPD proposal approved by the Board of Directors in June 2008, the points values were set to maximize the number of transplants while allowing for some priority for specific populations and types of matches, as shown in Figure 3:

Priority Points Per Candidate As approved by the Board of Directors in June 2008	
Base match per candidate (based on 200 points for a 2-way match)	100 points
Zero antigen mismatch with the matched donor	200 points
Highly sensitized candidate (CPRA ≥80%)	125 points
Prior living donor status of the candidate	150 points
Pediatric candidate (age <18 years)	100 points
Waiting time accumulated within the KPD program	50 points per cycle
Geographic proximity with the matched donor (i.e. transplant center, local, regional)	75,50,25 points, respectively

Figure 3: Priority Points Per Candidate

The points system for closed and open chains is based on the 200 points value for a match between two incompatible pairs (100 points for each candidate from an incompatible pair who is transplanted) approved in the 2008 KPD proposal. For both open and closed chains, 100 points will be assigned for each candidate from an incompatible pair who is transplanted as part of the segment of that chain. Neither the waiting list candidate (for a closed chain) or the bridge donor (for an open chain) will be assigned any points. If there are three incompatible pairs in a segment, then the segment will be assigned 300 points minus 10 points. The weight of -10 points increases the likelihood of picking segments with two incompatible pairs over segments with three incompatible pairs if the number of total transplants is the same in both scenarios (e.g. three groups of two incompatible pairs is preferred over two groups of three incompatible pairs). Smaller segments are preferable at this point in time because existing KPD groups report that logistical complexities increase as the number of incompatible pairs in a segment increase. Figures 4 and 5 illustrate the possible points for different closed and open chain segments.

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[4] http://www.unos.org/ContentDocuments/Guidance_for_the_Informed_Consent_of_Living_Donors_11508.pdf

[5] http://www.unos.org/ContentDocuments/Program_Specific_Living_Kidney_Donor_Med_Eval_Protocols.pdf

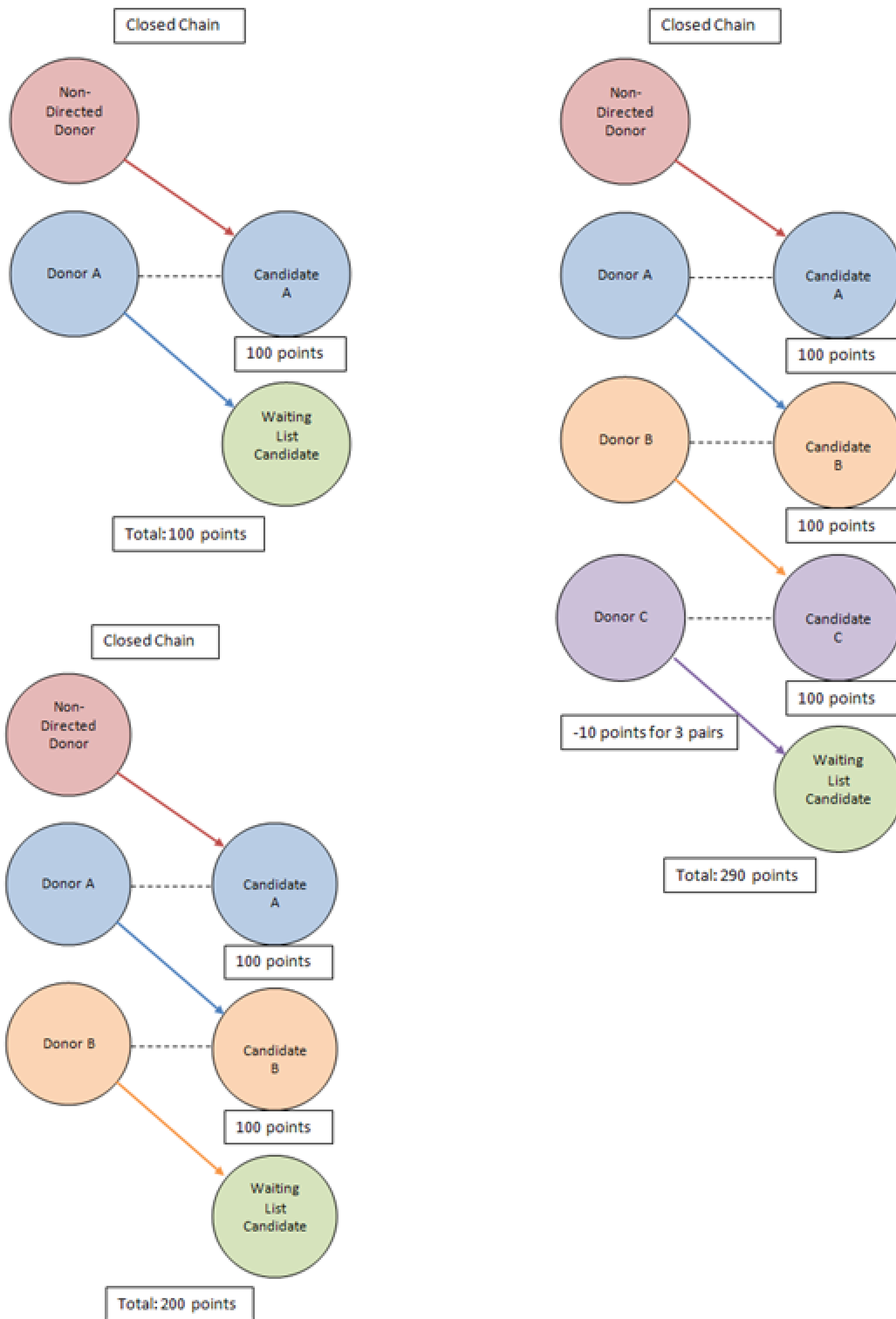

Figure 4: Diagrams of Possible Points for Closed Chains

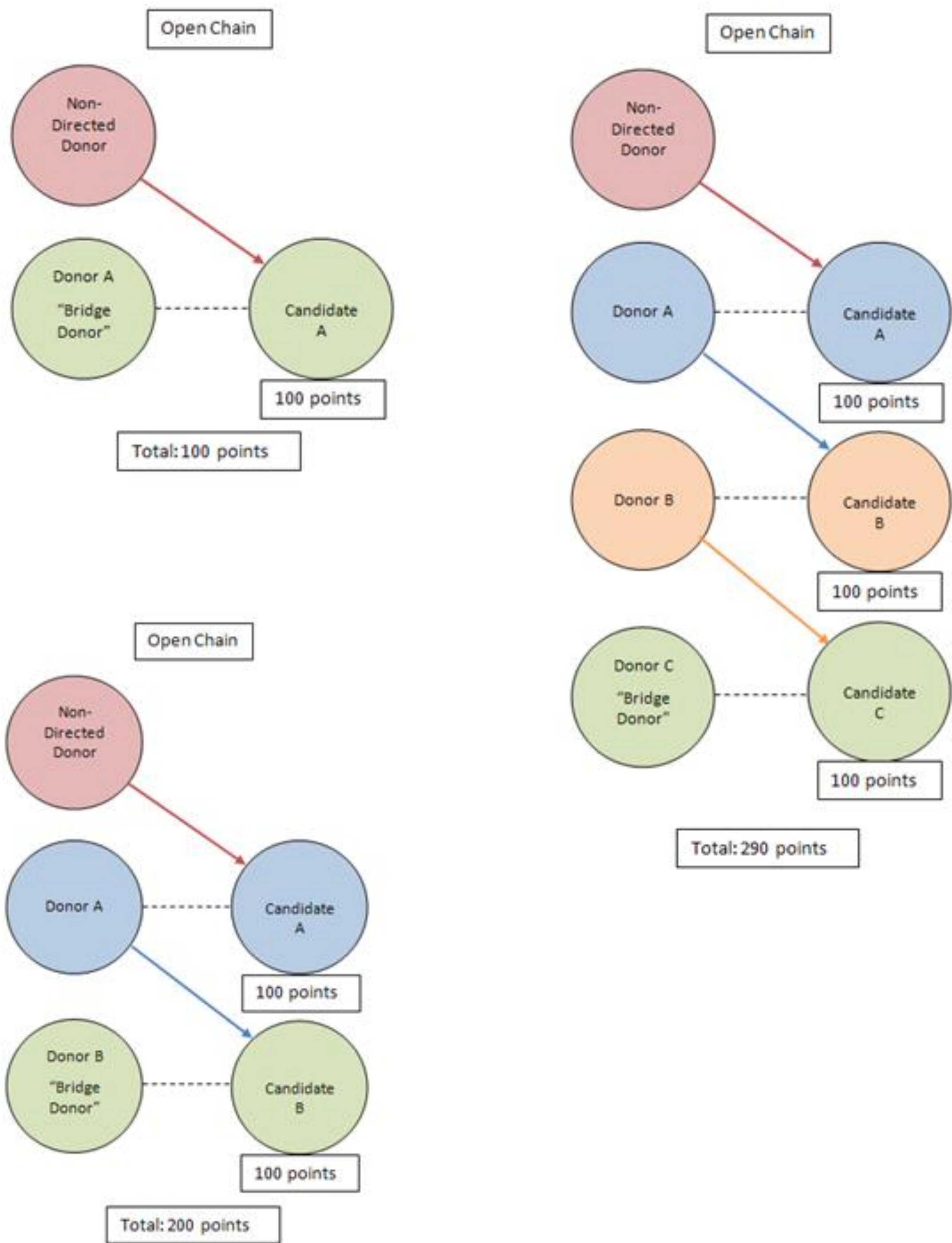

Figure 5: Diagrams Possible Points for Open Chains

Changes to the KPD Pilot Program Based on the Addition of Donor Chains

- The match cycle timeline of 4 match cycles per year with 3 match runs per match cycle will be changed to 12 match runs per year. Allowing pairs to enter the system at the beginning of any

match run rather than just the beginning of a match cycle will give the potential bridge donors more opportunities to match in any given match run. The goal is for potential bridge donors to wait less time to be able to enter a match run after the intended candidate has received a transplant and to find a match once entered in a match run.

- If the match cycles are eliminated, the waiting time points must be adjusted because they are currently based on the match cycle. Instead of pairs accruing 50 points per match cycle, the pairs will accrue 2 points per match run. A larger number of points would mean that waiting time would quickly become the largest determinant of matches, which was not the original intent of the KPD Pilot Program.
- A base value of 290 points will be assigned to a 3-way exchange (100 points for each candidate in an incompatible pair and -10 points for three pairs being involved) to be consistent with the points system for donor chains.

On January 27, 2009, the Kidney Transplantation Committee reviewed a draft of this proposal. The Committee unanimously voted to send the proposal out for public comment pending review by the Living Donor Committee.

On February 23, 2009, the Living Donor Committee discussed this proposal. Some Living Donor Committee members voiced concerns about marketing to or encouraging potential non-directed living donors to participate in paired donation. There was concern that a potential non-directed donor could be told that he/she will actually be helping not just one but multiple ESRD patients by donating to the Kidney Paired Donation system.

Using bridge donors in paired donation was another area of concern for the Living Donor Committee. The Committee asked how the system will prevent dropout among bridge donors. The Committee also inquired if the the psychosocial outcomes for bridge donors who proceed with donation could be worse than those of other paired (or unpaired "regular") donors. The Living Donor Committee supported sending the proposal out for public comment. (24-Support, 1-Oppose, 1-Abstain)

The Kidney Paired Donation Work Group met on April 27, 2009, to finalize this proposal and to discuss the feedback from the Living Donor Committee. The Work Group debated how to weight bridge donors versus waiting list candidates. Members of the Work Group commented that chains often end with AB blood type donors, who are hard to match, and suggested assigning weights to the bridge donor based on blood type. The Work Group also suggested that after three months, the center that evaluated the non-directed donor and the bridge donor should have the choice to stay in the system, donate to the deceased donor waiting list, or be removed from the system, rather than automatically asking the donor to donate to the deceased donor waiting list.

The Work Group addressed concerns about the proposal from the Living Donor Committee. The Living Donor Committee asked about marketing to or encouraging potential non-directed living donors to participate in paired donation. There was concern that a potential non-directed donor could be told that he/she will actually be helping not just one but multiple ESRD patients by donating to the Kidney Paired Donation system. The Work Group noted that this information would be disclosed because all available information should be communicated. The Work Group agreed that it would be important to disclose all advantages and disadvantages of all the options. Using bridge donors in paired donation was another area of concern for the Living Donor Committee. The Living Donor Committee asked how the system will prevent dropout among bridge donors. The Work Group noted that this concern had been addressed by having the option to donate to the deceased donor after three months as a bridge donor.

Also, donors should have a full work-up including final imaging before being considered as a bridge donor to reduce the likelihood of not being able to donate for medical reasons. There is no way to eliminate the possibility of a bridge donor choosing not to donate. Living donors may decide to leave of the program at any time. The Committee also inquired if the psychosocial outcomes for bridge donors who proceed with donation could be worse than those of other paired (or unpaired "regular") donors. Members of the Work Group commented that the rewards the donor feels are directly related to how the intended recipient fared. The Work Group agreed that psychosocial outcomes should be closely monitored as the program moves forward.

Supporting Evidence and/or Modeling:

On April 22, 2008, the KPD Work Group reviewed simulation data comparing donor chains, two-way matches, and three way matches. The Work Group discovered that, in general, chains are better direct allocation of the NDD kidney to the waiting list.[6]

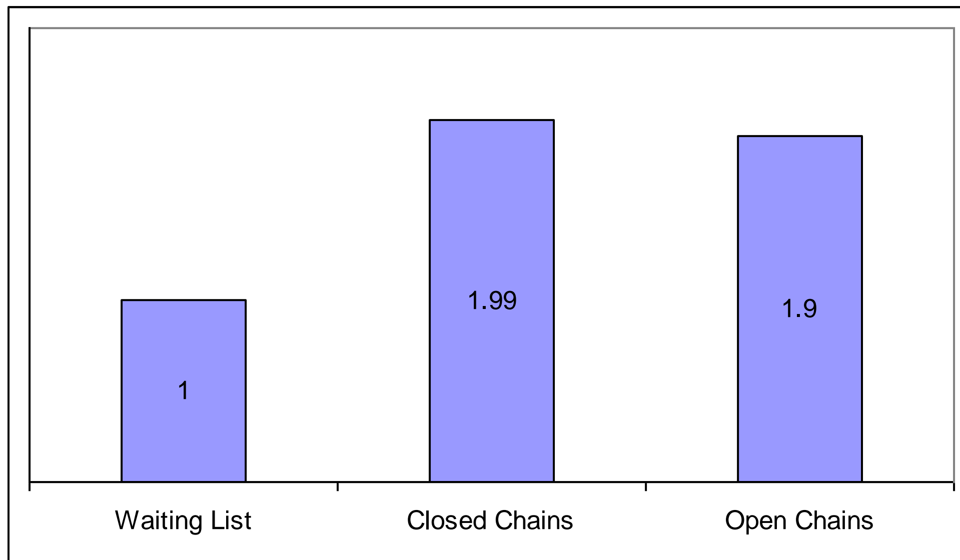

Figure 6: Number of Transplants Facilitated by a NDD[6]

Figure 6 shows the ratio of the number of transplants that each NDD facilitates when using NDDs in open chains and closed chains compared to the number of transplants achieved when NDDs give directly to the deceased donor waiting list. This figure compares the increase in transplants attributable to a single NDD under the various strategies.

These data indicate that including chains in a KPD system has the potential to increase the number of transplants that can be performed. In fact, it is likely that more than 50% of KPD transplants performed in recent years have involved chains.

Additionally, the advantage of chains is greater when there are fewer pairs entering the pool, such as at the beginning of a KPD Program.

[6] Gentry, S.E., Montgomery, R.A., Swihart. B.J., and Segev, D.L. (2009). The roles of dominos and non-simultaneous chains in kidney paired donation. *American Journal of Transplantation,* 9: 1330-1336.

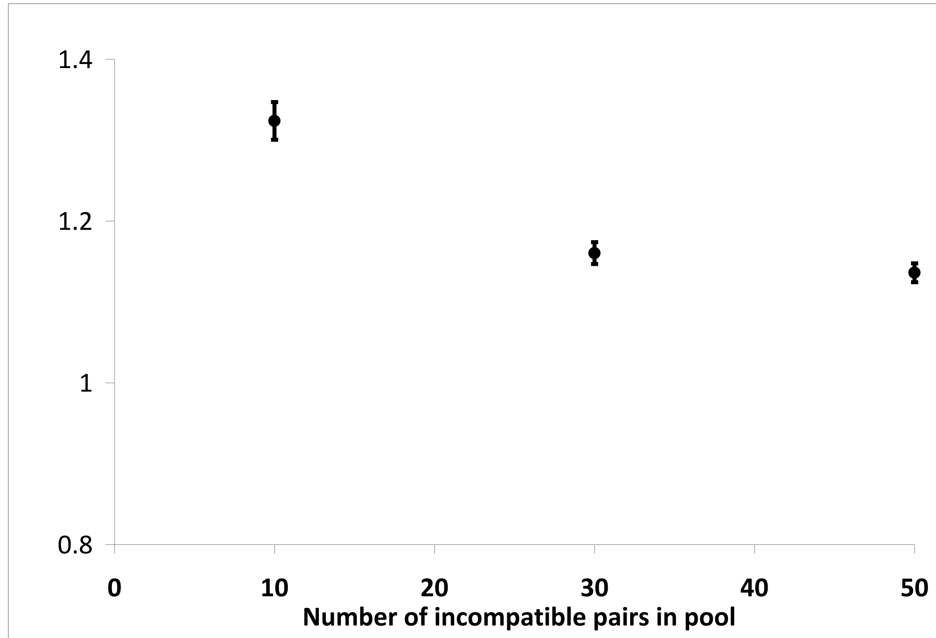

Figure 7: Ratio of the Number of Transplants Facilitated by NDDS for Varying Pool Sizes[6]

Figure 7 shows the ratio of the total number of transplants achieved using NDDs in chains to the number of transplants achieved when NDDs give directly to the deceased donor waiting list for varying numbers of incompatible pairs in the pool. The numbers of transplants include both recipients of incompatible pairs and recipients on the deceased donor waiting list.

Finally, given that current KPD programs allow chains, it is unlikely that there will be participation in the KPD Pilot Program unless similar options are implemented. Therefore, the Committee has agreed that chains should be included in the KPD Pilot Program and implemented at the same time as the previously approved portion of the KPD Pilot Program in order to receive the greatest advantage of the chains.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal directly addresses the strategic plan goal relating to the donor shortage. This goal states that the OPTN will support the HHS Program Goals and maximize the number of donors and transplants. By allowing NDDs in the KPD Pilot Program, this proposal has the potential to increase the number of living donors by giving NDDs the opportunity to donate to a national system. Beyond just giving their own kidney, these living donors can start a donor chain, which creates more flexibility in the matching process for the KPD Pilot Program. The additional flexibility of donor chains can increase the number of donors and kidney transplants in the KPD Pilot Program, especially at the beginning of the program.

Plan for Evaluating the Proposal:

Specifically for the inclusion of NDDs and donor chains, the Committee will consider the following information:

- **What questions or hypotheses are guiding the evaluation of the proposal?**
    - How many NDDs are registered in the program?
    - How many matches include NDDs?

- How many NDDs have donated their kidneys through the KPD Pilot Program?
- What proportion of centers who introduce NDDs to the KPD program allow open chains? What proportion of centers insist on a closed chain so that a kidney comes back to their deceased donor list eventually?
- How many bridge donors donated their kidneys and started another chain?
- What proportion of potential bridge donors choose not to donate? At what point in the process do these potential bridge donors who decline to continue do so, and why? When did the center learn of these potential bridge donor'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 the next segment?
- How many of the matches including NDDs were open chains? Closed chains?
- How many transplants occurred as part of a chain started by a NDDs?
- How many more transplants occurred because of the inclusion of NDDs and donor chains?

- **Proposal Performance Measures:**
  - Number of NDDs registered in the program
  - Number of matches including NDDs
  - Number of NDDs who have donated their kidneys through the KPD Pilot Program
  - Percentage of centers that allow open chains
  - Percentage of centers that allow closed chains but not open chains
  - 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, 5th, 25th, 50th, 75th, and 95th percentiles of when the potential bridge donor declined to continue
  - For bridge donors who donated, 5th, 25th, 50th, 75th, and 95th percentiles of when the bridge donor donated to the next segment of the chain by blood type and location
  - Number of open chains found in the KPD Pilot Program
  - Number of closed chains found in the KPD Pilot Program
  - Number of open and closed chains that resulted in transplants
  - Number of matches found using chains compared to simulation data of how many matches would be found using only two-way and three-way matching

Also, the impact of NDDs and donor chains will be included in the evaluation of the full KPD Pilot Program. The plan for evaluating the proposal for the full program as set forth in the June 2008 KPD Pilot Program briefing paper is below.

- **What questions/hypotheses are guiding the evaluation of the proposal?**
  - How many centers are participating in the system?
  - How many pairs are registered in the system?
  - How many matches are made through the system?
  - How many matches made through the system proceed to transplant?
  - What are the characteristics of potential candidates and potential donors?
  - What are the characteristics of actual candidates and actual donors?

- What are the characteristics of matched pairs that do not proceed to transplant?
- What are the patient and graft survival outcomes for the transplants facilitated through the system?

- **Pilot Program Performance Measures:**

Once experience with the KPD Pilot Program yields information sufficient to begin assessment of performance, the following measures will be evaluated to determine if the system is achieving its objective of increasing transplant opportunities for kidney candidates:

- Number of living donors and candidates registered in the KPD Pilot Program
- Number of centers participating in the KPD Pilot Program
- Number of match cycles run
- Number of transplants facilitated by the KPD Pilot Program overall
- Number of transplants, by candidate ABO, candidate calculated panel reactive antibody (CPRA) level, by candidate age, and by candidate diagnosis
- Percent of matched pairs that proceed to transplant
- Percent of matched pairs that have crossmatch results within the specified timeframe
- Number of matched pairs that refuse the match before a crossmatch is run and associated refusal reasons
- Patient and graft survival rates, rates of delayed graft function (not as a primary end point, but to evaluate impacts from the system overall)
- Living donor outcomes
- Number of match cycles that have been performed since any changes to the Operating Guidelines have been made (measure of stability)

- **Time Line for Evaluation**

As soon as sufficient time has passed after implementation of the pilot program, the Kidney Transplantation Committee will evaluate the program every 6 months for the first three years of the pilot program and recommend appropriate adjustments to the system. The Kidney Transplantation Committee will share data on the KPD system with the Living Donor Committee and the Patient Affairs Committee.

In its evaluation, the Kidney Transplantation Committee will consider when it is reasonable to write policy language for the national KPD system. The Kidney Transplantation Committee will take into account both the stability of the pilot program and pilot program performance measures described above. The stability of the pilot program can be assessed by investigating the number of match cycles that have been performed since any changes to the Operating Guidelines have been made and by the percent of transplant centers that are able to complete all the requirements for the KPD match within the specified timeframe. After three match cycles have been run, the Kidney Committee will re-evaluate how it will measure whether the pilot program has met its objectives and when it is appropriate to transition from a pilot program to a national program with policy language. More information on the implementation of this program can be found in the Expected Implementation Plan section.

Additional Data Collection:

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

- Whether the center is willing to participate in an open or closed chain exchange

- Whether the donor is a NDD
- Whether the donor is willing to be 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 and so that the candidates can specify in which types of paired exchange they are willing to participate. This data facilitates the matching process for kidney paired donation.

Expected Implementation Plan:

If approved, the inclusion of NDDs and donor chains will be implemented simultaneously with the already approved portion of the KPD Pilot Program. The expected implementation plan for the full program as set forth in the June 2008 KPD Pilot Program briefing paper is below.

Phase 1:
UNOS staff and the Kidney Transplantation Committee will develop operational guidelines for the KPD Pilot Program that will clearly explain all the rules and protocols for the program. These operational guidelines will include at least:

- Requirements for participation
- Data entry requirements
- Crossmatching protocol
- Staffing recommendations/ primary transplant center contact
- Rules for when participants can meet
- Informed consent requirements
- Histocompatibility testing requirements
- Living donor evaluation recommendations
- Prioritization points
- Match cycle timeline
- Rules for the shipping of kidneys

Phase 2:
While the system is being programmed, transplant centers will be able to apply to participate in the pilot program of KPD. Centers that wish to participate must have approval by UNOS to perform kidney transplants and, when applicable, living donor kidney transplants. Also, centers must designate one representative who can be the single point of contact for KPD and who is willing to participate in regular conference calls to discuss the operations of the KPD system. The KPD Financial Subcommittee will continue to meet to address financial barriers to participation in the KPD system.

Phase 3:
Once the system is programmed, the centers participating in the pilot will be able to enter pairs into the system. Centers will have at least two months to enter pairs before the first match. Conference calls to discuss data entry and to prepare for the match process will begin in this phase.

Phase 4:
The first match will be run after centers have entered the pairs. Conference calls with center representatives will continue. Adjustments may be made to this system in this time frame. The Kidney

Transplantation Committee, Living Donor Committee, and Patient Affairs Committee will discuss the KPD system and any recommended adjustments at least once a year during the pilot program.

Phase 5:
Once the pilot has shown the best way to run the KPD system, the Kidney Transplantation Committee will draft policy language for the KPD system to be sent out for public comment and Board approval. The pilot study will end when this policy language is approved.

Communication and Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding the approval of including NDDs and donor chains via the Policy Notice that follows each Board meeting. Additional details regarding the final implementation date will be sent to members through a UNet^{SM} System Notice.

Additionally, the inclusion of NDDs and donor chains will be included in all educational materials for the KPD Pilot Program. The Kidney Paired Donation Education Subcommittee is developing educational material for both potential participants and professionals. The subcommittee plans to use the following media to educate the public and the transplant community about the Kidney Paired Donation Pilot Program:

- Brochures
- List of frequently asked questions
- Articles in the UNOS Update
- Website
- Presentations at OPTN/UNOS regional meetings
- Presentations at meetings of national organizations involved in transplantation
- Kidney Paired Donation Telephone Line
- Policy Notice
- System Notice
- DVD on Kidney Paired Donation
- E-mails from UNOS Communications

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Members	E-mail	30 days after passed by Board
UNOS Update Article	Members	Print	1-3 months after implementation
System Notice	Members	Through UNet	Implementation Date
Website Enhancement	General public, members	Web-posting	prior to implementation date

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Online Tutorial	UNet users	Online PowerPoint presentation	TBD
Professional Brochure	Kidney transplant surgeons, transplant coordinators	Brochure	TBD
Donor/ Candidate Brochure	Potential living donors, kidney candidates	Brochure	TBD
DVD	Potential living donors, kidney candidates	DVD	TBD
Informed Consent Guidelines	Transplant surgeons, transplant coordinators	Guidelines posted on website	TBD

Monitoring and Evaluation:

UNOS will monitor participating kidney programs for compliance with the operational guidelines developed for the KPD system and all applicable OPTN/UNOS policies and bylaws.

How members will be expected to comply with this pilot program:

In addition to the requirements for the previously approved portion of the KPD Pilot Program, transplant centers will be expected to:

- Follow all living donor evaluation and consent requirements set forth in the KPD Pilot Program Operational Guidelines for all living donors, including NDDs
- Document whether candidate/donor pairs are willing to participate in donor chains and whether the potential living donor is willing to be a bridge donor
- Submit documentation upon request
- Comply with all OPTN/UNOS requests related to the implementation, execution, monitoring, and analysis of the KPD Pilot Program

How UNOS will evaluate member compliance with this pilot program

UNOS currently monitors transplant center compliance with applicable OPTN/UNOS policies and bylaws during site surveys of transplant centers. UNOS staff forward potential violations of OPTN/UNOS policies and bylaws to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

Upon implementation of a national kidney paired donation (KPD) Pilot Program, UNOS staff would incorporate monitoring for applicable requirements into routine reviews of transplant centers with participating KPD programs. As the KPD Pilot Program develops, UNOS staff will assess the need for additional monitoring efforts. UNOS staff will communicate more detailed information to members, specific to complying with the KPD Pilot Program, closer to implementation.

Policy or Bylaw Proposal:

There is no policy or bylaw language for the KPD Pilot Program. If approved, information on the inclusion of donor chains and NDDs will be included in the program materials.