At-a-Glance

Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy

- **Affected/Proposed Bylaws and Policy:** Bylaws Appendix E.5.F: Kidney Paired Donation (KPD) and Appendix E.5.G: Required Living Donor Protocols; and Polices 13.7.E: Prioritization Points, 13.7.F: OPTN KPD Waiting Time Reinstatement, 13.10: Crossmatching Protocol, 13.11: Transportation of Kidneys, and 13.12: communication between KPD Donors and Recipients.

- **Kidney Transplantation Committee**

  In June 2014, the OPTN/UNOS Board of Directors approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP). Though the "pilot" label will not be removed until the Board's decision is approved by the Health Resources and Services Administration (HRSA), the Kidney Committee believes it is appropriate to continue to transition sections of the operational guidelines into OPTN policy. Including these sections in OPTN policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN. Other sections of the operational guidelines were previously transitioned to OPTN policy in November 2012 and June 2014.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Social Workers
  KPD Candidates
  Living Donors
  KPD Contacts

- **Number of Potential Candidates Affected**
  This proposal will have a minimal but positive effect on all candidates and donors participating in the KPDPP, because it does not significantly change the way in which the KPDPP currently operates but will make the KPDPP more efficient.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal meets the OPTN Key Goal to "increase the number of transplants" by "increasing the number of organ donors" and "facilitating matching of willing donor and recipient pairs among different transplant centers."

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Kidney Transplantation Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

In June 2014, the OPTN/UNOS Board of Directors approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP). Though the "pilot" label will not be removed until the Board's decision is approved by the Health Resources and Services Administration (HRSA), the Kidney Committee believes it is appropriate to continue to transition sections of the operational guidelines into OPTN policy. Including these sections in OPTN policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN. Other sections of the operational guidelines were previously transitioned to OPTN policy in November 2012 and June 2014.

These sections both aim to make the KPDPP's matching process more efficient, by ensuring that transplant hospitals respond to offers and perform exchange responsibilities in a timely fashion, and by requiring the pre-selection of donors for sensitized candidates in order to avoid futile match offers.

Background and Significance of the Proposal:

The Donor Pre-Select Requirements and the KPD Contact Responsibilities are both sections in the KPDPP Operational Guidelines.[1] Since November 2012, when the first operational guidelines were transitioned into policy, the KPDPP has been governed by both the operational guidelines and policy. The OPTN/UNOS Board of Directors, in June 2014, voted to remove the pilot label from the OPTN/UNOS KPD program to make the OPTN/UNOS KPD program permanent. As a permanent function of the OPTN/UNOS, the KPD program will ultimately be governed solely by OPTN/UNOS policies and bylaws.

Many sections of the operational guidelines have already transitioned to policy, including Prioritization Points (June 2014), Matching Within the OPTN KPD Program (November 2012), Transportation of Kidneys (November 2012) and Rules for When Donors and Recipients Can Meet (November 2012). Converting the guidelines to policy permits the OPTN to monitor compliance with the policies, and also commits the OPTN to transparency and public participation by submitting all future policy changes through the public comment process. As the guidelines become policy, the public will not only have input in how the KPDPP operates, but it will also be able to access the governing rules in one location.

[1] http://optn.transplant.hrsa.gov/resources/KPDPP.asp

The Kidney Committee proposes converting the Donor Pre-Select Requirements and KPD Contact Responsibilities to policy with minimal changes, so the overall impact of the transition will be small. However, transitioning the guidelines to policy will make the KPDPP even more transparent and easier to navigate.

Donor Pre-Select Requirements

In March 2012, a Consensus Conference convened "to address the dynamic challenges and complexities of KPD that inhibit optimal implementation."[2] KPD exchanges involve multiple candidates, multiple donors, and often require multiple transplant hospitals to cooperate in order to successfully recover kidneys and transplant all candidates in the exchange. Because "a match offer that falls through late in the process disrupts multiple potential transplants and incurs additional, potentially avoidable, costs," the Consensus Conference recommended that "recipient centers should preselect acceptable donors to increase the percentage of viable match offers."

The KPD Work Group quickly worked to implement a solution based on the Consensus Conference findings to reduce the number of turn-downs due to unacceptable antigens. In May 2012, the Work Group began developing a donor pre-select mechanism for the KPDPP. The tool would allow a transplant center to preview potential donors with whom their candidates might match. Entering a pre-acceptance allows the candidate to potentially match with that donor; however, the transplant center is not committing to accepting any future match offers. Entering a refusal prevents the candidate from matching with that donor in future match runs.

The KPD Work Group additionally established a calculated panel reactive antibody (CPRA) threshold at which candidates would only match with donors that had been pre-accepted. Based on data provided by UNOS staff, explained in more depth in the Supporting Evidence section below, the KPD Work Group determined that candidates with a CPRA of 90% or higher must use the donor pre-select tool to pre-accept or pre-refuse all donors with whom they may potentially match. The candidate will not match with any donor that is not pre-accepted. Transplant hospitals entering candidates in the KPDPP are encouraged to use this tool for candidates with any CPRA, but it is only mandatory for those candidates with a CPRA greater than or equal to 90%.

As explained in the June 2013 Kidney Committee Board Report[3], the KPD Work Group and Kidney Committee considered various options regarding the donor pre-select tool:

> The Workgroup recommended those donors who are a zero antigen mismatch be excluded from the 90% threshold requirement. This would add complexity to the programming requirements and significantly delay the donor pre-select tool from going live. Of the over 200 matches offered in the OPTN KPDPP thus far, only 1 offered has been a zero antigen mismatch. We could have this added, pending programming at a later date and continue to collect data on the number of zero mismatches offered.
>
> The group also recommended that the data be provided to transplant programs to explain why the pre-select tool is important.

[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

[3] http://optn.transplant.hrsa.gov/CommitteeReports/board_main_KidneyTransplantationCommittee_6_26_2013_20_18.pdf (visited on August 14, 2014).

> Finally, the Workgroup recommended use of this tool for candidates listed with a lot of lower level unacceptable antigens.
>
> The KPD Workgroup considered not requiring the donor-preselect for any candidate or for candidates with a CPRA >=80%. However, given the data, the KPD Workgroup thought requiring candidates with a CPRA of >=90% had the most potential to significantly decrease the match decline rate.

In January 2013, the Kidney Committee voted to incorporate the Donor Pre-Select Requirements into the KPDPP Operational Guidelines. In June 2014, the KPD Work Group determined that the Donor Pre-Select Requirements should be transitioned to policy without any changes, and in August 2014, the Kidney Committee agreed.[4]

KPD Contact Responsibilities

The March 2012 Consensus Conference also provided helpful recommendations regarding the responsibilities of those people coordinating KPD exchanges, noting:

> The KPD process is highly complex, requiring extensive coordination between multiple coordinators, nurses and physicians at multiple programs. As a result, standardization of the content and timing of communication is paramount to maximize the confidence of all involved parties. Prompt responses to match offers should be required.

Previous versions of the Operational Guidelines delegated a number of responsibilities to the KPD Contact at each transplant hospital, but did not specify the timeframes in which the contact must act. The lack of deadlines created delays in the exchange process and kept potential donors and candidates out of subsequent KPD matching opportunities, as candidates and donors in pending exchanges are not eligible to appear in subsequent match runs. The KPD Work Group determined that it should establish firm deadlines with tangible consequences, namely, that the exchange will be terminated if the deadlines are not met. The KPD Work Group supported the concept of incorporating timelines, but stressed the importance of granting exceptions for extenuating circumstances.

The Work Group ultimately sent a proposal to the Kidney Committee in April 2014 to change the operational guidelines to include deadlines for certain actions between match offer and transplant. The proposal also included a section permitting extensions and outlining the process for requesting one. In order to streamline the extension process, the Work Group members determined that requests for extensions should be sent by the transplant program to the OPTN, which in turn will distribute the request to all others in the exchange. After review, the transplant programs involved in the exchange will submit their approval or denial of the extension to the OPTN, which will then notify the requesting transplant program of the decision.

[4] See *Policy 13.7.E: Donor Pre-Select*, below.

The Work Group sent the following proposed deadlines to the Kidney Committee for consideration:

Actor	Action	Deadline
Each transplant hospital that received a match offer	Enter preliminary response in the KPD system	2 business days of receiving offer
Matched donor's transplant hospital	Provide matched candidate's transplant hospital with the name and location of where the crossmatch kit is to be sent.	1 business day of receiving notification of exchange acceptance
Matched candidate's transplant hospital	Report results of the crossmatch to the OPTN contractor	13 days of receiving notification of the exchange acceptance
Matched donor's transplant hospital	Make all donor records accessible to the matched candidate's transplant hospital	2 days of receiving notification of exchange acceptance
Matched candidate's transplant hospital	Review the donor records and report a final acceptance/refusal to the OPTN Contractor	13 days of receiving notification of exchange acceptance

Figure 1: March 2014 KPD Work Group Proposal for Deadlines for KPD Contact Responsibilities for Operational Guidelines

The Kidney Committee reviewed the recommendations on April 7, 2014. The Committee modified the proposed deadlines to be "business days," with the exception of the deadlines for performing the crossmatch and reporting the results, and for reporting a final acceptance or refusal, which would both remain 13 days from notification of exchange acceptance. The Kidney Committee also clarified the language to ensure that the requirement to "make available" donor records does not mean the donor's hospital must ship the records. The Kidney Committee voted to adopt the proposed guidelines, effective September 1, 2014.[5]

As the KPDPP moved closer to permanence, the KPD Work Group evaluated which Operational Guidelines should be transitioned into policy. The KPD Work Group recognized the importance of putting the deadlines into policy, as they are crucial to ensuring the efficiency of the KPDPP's exchange process. The Work Group also suggested removing KPD contact responsibilities within operational guidelines that would be redundant with other policies, or that are no longer in practice.

The Kidney Committee again reviewed the KPD Work Group's recommendations on August 4, 2014. The Kidney Committee approved the Work Group's proposal, with a few minor modifications. It determined that "business days" should apply to every deadline for KPD contacts to achieve consistency. To the same end, the Kidney Committee agreed to change the deadline for the matched candidate's transplant hospital to provide the matched donor's hospital with the contents required for the crossmatch kit and the address at which to ship the blood samples from one day to two business days.

[5] Alcorn, James. "Changes to OPTN Bylaws and Policies from actions at June Board of Directors Meeting." Policy Notice. July 23, 2014. http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-24-2014.pdf. Accessed on August 28, 2014.

The Kidney Committee also added a step that was missing from the KPD Work Group's proposal. The new step creates a five business day deadline for the matched donor's transplant hospital to send the completed blood samples to the matched candidate's hospital. Without this step, the matched candidate's transplant hospital would have been held to a deadline that would be potentially impossible if it did not receive the blood sample from the matched donor's transplant hospital in ample time. The Kidney Committee determined that five business days is a reasonable deadline for this step and reflects common practice. The Kidney Committee debated whether to require overnight shipping for the blood sample. It ultimately decided not to include the requirement, as there may be extenuating circumstances in which the matched donor, or the matched donor's transplant hospital, could not ship the blood sample overnight. However, the Kidney Committee stressed that overnight shipping is very important, and transplant hospitals should ship overnight when possible. Additionally, the matched candidate's transplant hospital could specify in its crossmatch instructions to the matched donor hospital that the blood sample must be shipped overnight.

Lastly, the Kidney Committee retained the extension request process in the proposed policy to allow for flexibility in the exchange process. Transplant hospitals involved in an exchange have the option to allow an extension, or to refuse it so that all the candidates and donors involved in the exchange can be available for the next match run.[6]

On August 4, 2014, the Kidney Committee voted to send this proposal for public comment. (10 support, 0 oppose, 0 abstentions).

Supporting Evidence and/or Modeling:

The supporting evidence for the Donor Pre-Select was previously reported extensively in the Kidney Committee's June 2013 report to the Board of Directors[7]:

> Over 90% of match offers are declined [between October 27, 2010 and May 2, 2012]. 20% of matches have not reported a refusal reason. 40% might have accepted the match, but the exchange was terminated by another pair.
>
> Of the remaining 40% of refused matches:
> • 33% refused due to an actual or virtual positive crossmatch
> • 7% due to "candidate involved in a pending exchange" (with another program)
> • 60% due to various other donor or candidate reasons including: Donor unacceptable due to age, weight, size, medical history etc.
>
> When a match is declined, the remaining matches in that exchange are frequently terminated as well, increasing the overall decline rate.
>
> […]

[6] See *Policy 13.11: Receiving and Accepting KPD Match Offers*, below.

[7] http://optn.transplant.hrsa.gov/CommitteeReports/board_main_KidneyTransplantationCommittee_6_26_2013_20_18.pdf. Accessed on August 28, 2014.

> Although candidates are given a variety of choices to rule out donors prior to matching, donors frequently fall just outside the acceptable limit. For example, a candidate can set a maximum BMI of 35 and therefore match with a donor with a BMI of 34.9, in which the candidate may decline. In addition, a candidate may decline for a combination of donor characteristics, in which they would not decline on one characteristic independently. For example, a candidate may set a minimum CrCl of 80 and willing to accept a 65 year-old donor with a CrCl of 80, but the 32 year-old donor with a CrCl of 80 would be unacceptable and declined.
>
> […]
>
> The refusal reasons by candidate sensitivity level were analyzed… to see if a large percentage of refusals (due to virtual or actual positive crossmatch) were occurring for highly sensitized candidates.
>
> The crossmatch-related refusal rate showed an increasing trend by CPRA, from 3.8% for CPRA=0% to over 25% for CPRA>90%.
>
> In addition, as the number of "all other antibody specificities" increased, the crossmatch refusal rate also increased.
>
> When candidates with a CPRA of 90-100% and candidates with 10 or more antibody specificities are analyzed together, the crossmatch refusal rate was 81.8%.
>
> Given this information the KPD Workgroup supported a recommendation to require programs with candidates with a CPRA of 90% or higher to use the Donor Pre-select tool. These highly sensitized candidates would only match if a donor is pre-accepted; candidates with CPRA less than 90% would still be allowed to match with any donors that were not pre-refused (including those that were neither pre-accepted nor pre-refused). The Workgroup will start with 90% as the threshold required in the automated KPD solution and monitor outcomes.[8]

The KPD Work Group and Kidney Committee continue to monitor the impact of the donor pre-select tool and the CPRA threshold. Both groups are satisfied with its success thus far, and therefore recommend transitioning the Donor Pre-Select Requirement, as written in Operational Guidelines, into OPTN policy without modification.

The deadlines for KPD contact responsibilities were decided upon based primarily on anecdotal evidence. The members of the KPD Work Group and Kidney Committee have participated in numerous KPD exchanges, both within and outside the KPDPP, and determined that the deadlines proposed are reasonable based on common practice. Data were presented to the Work Group showing that 92% of match offers received responses within two days, supporting

[8] For the complete data report, see the Appendix.

the proposed preliminary match response deadline. As the deadlines did not become effective in KPDPP operational guidelines until September 1, 2014, the KPD Work Group has not yet monitored their effect.

Expected Impact on Living Donors or Living Donation:

This proposal will affect living donation with respect to those parties involved in the OPTN KPDPP. The proposed policies, currently in operational guidelines, make the KPDPP more efficient, so more matches are found and proceed to transplant in a timely manner.

Expected Impact on Specific Patient Populations:

No known impact to specific patient populations.

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

This proposal meets the OPTN Key Goal to "increase the number of transplants" by "increasing the number of organ donors," and "facilitating matching of willing donor and recipient pairs among different transplant centers." The proposal helps facilitate the matching of willing donor and recipient pairs by making the process for doing so within the KPDPP more efficient.

Plan for Evaluating the Proposal:

The KPD Work Group will continue to monitor the efficacy of the donor pre-select tool, in particular by reviewing match success rates and refusal reasons for matched candidates with CPRA of 90% or higher.

In addition, the KPD Work Group will monitor the frequency of match offers being automatically declined due to exceeding the allowable response time of 2 business days. The KPD Work Group will also review the distribution of days between:

- the date of preliminary acceptance notification and the crossmatch date
- the date of preliminary acceptance notification and the date the crossmatch results are reported to the OPTN contractor
- the date of the preliminary acceptance notification and the date of final exchange acceptance or refusal
- the date of the match run and the date of transplant

Additional Data Collection:

No additional data collection is required with this proposal.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect September 1, 2015. Modifications to the KPD Operational Guidelines would be made at the same time.

Upon implementation, the Donor Pre-Select tool will continue to operate as it currently does. Transplant programs must therefore pre-accept any potential donors shown for candidates with a CPRA greater than or equal to 90 percent to potentially receive an offer from that donor. Any

donors that are not pre-accepted will be treated as pre-refused. Candidates do not receive offers from pre-refused donors. Pre-refusals and pre-acceptances may be entered for candidates with a lower CPRA; while doing so is not mandatory, it will make the match process more efficient.

Every transplant program participating in the KPDPP must appoint a KPD contact and alternate, and report their contact information to the OPTN contractor. The KPD contact must become familiar with all of the deadlines triggered by the receipt of a match offer or exchange acceptance so that exchanges in which their candidates or donors are participating do not terminate due to missed deadlines.

Communication and Education Plan:

This proposal will continue to be monitored for instructional needs. We may offer an instructional program in summer 2015 that will clarify for members updates to KPD policy and the KPD system. Any instructional methodology will allow a question and answer segment.

Upon board approval, we will communicate these changes to members and make educational materials available online.

- Policy notice on OPTN website
- OPTN news item(s)
- Presentation at Regional Meetings
- Formal training (if needed, summer of 2015)

Compliance Monitoring:

Members will be expected to accurately report data based upon the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet℠ may be subject to OPTN review, and members are required to provide documentation as requested.

Policy and Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

E.5 Kidney Transplant Programs that Perform Living Donor Recovery

A kidney recovery hospital is a designated kidney transplant program that performs the surgery to recover kidneys from living donors for transplantation. Kidney recovery hospitals must meet all the requirements of a designated kidney transplant program as outlined above and must also have:

1. Protocols and resources in place for performing living donor evaluations.
2. Surgical resources on site for open or laparoscopic living donor kidney recoveries.

Some pediatric living donor or kidney paired donation transplants may require that the living organ donation occurs at a hospital that is separate from the approved transplant hospital.

A. Potential Living Donor Medical Evaluation

The kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor.

B. Psychological Assessments

The kidney recovery hospital must have the clinical resources to perform a psychosocial assessment of the potential donor's ability to make an informed decision. This psychosocial assessment should also confirm that the evaluation and donation are completely voluntary.

C. Independent Donor Advocate

The kidney recovery hospital must have an Independent Donor Advocate (IDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the potential living donor. The IDA must be independent of the decision to transplant the potential recipient and follow the Protocols that outline the duties and responsibilities of the IDA as described in *OPTN Policy 12.0*.

The goals of the IDA are:

- To promote the best interests of the potential living donor.
- To advocate the rights of the potential living donor.
- To assist the potential living donor in obtaining and understanding information about the consent process, evaluation process, surgical procedure, as well as the benefit of and need for follow-up care.

D. Primary Open Living Donor Kidney Surgeon

A Kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of an accredited American Society of Transplant Surgeons (ASTS) fellowship with kidney certification.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon or First Assistant. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

E. Primary Laparoscopic Living Donor Kidney Surgeon

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon or first assistant. Seven of these nephrectomies must have been performed as the primary surgeon, and this role should be documented by a letter from the fellowship program director. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

F. Kidney Paired Donation (KPD)

~~Members~~Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate ~~kidney paired donation~~KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.
4. ~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules (Operational Guidelines). Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

G. Required Living Donor Protocols

Kidney recovery hospitals must develop protocols that address:

1. The living donation process
2. Duties for the Independent Donor Advocate (IDA)
3. Medical evaluations
4. Informed consent

The requirements for these protocols are described in detail in *OPTN Policy ~~12~~14.0*.

13.7 KPD Screening Criteria

13.7.E Donor Pre-Select

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must use the Donor Pre-Select Tool to pre-accept or pre-refuse potential donors. The OPTN KPD candidate can only be matched with donors that are pre-accepted.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital may use the Donor Pre-Select Tool to pre-accept or pre-refuse potential donors. The OPTN KPD candidate can be matched with all donors that are not pre-refused.

13.7.~~E~~F Prioritization Points

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

Table 13-2: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is a 0-ABDR mismatch with the potential donor	200 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate is a prior living organ donor	150 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 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 points
Potential donor has at least one of the other antibody specificities reported for the candidate	- 5 points

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 ~~on~~ 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. 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.

13.10 Crossmatching ~~Protocol~~ Requirements

The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the OPTN KPD program before the matched KPD donor's recovery procedure.

~~The transplant hospital registering the potential KPD donor is responsible for arranging shipment of the potential KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.~~

The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.

13.11 Receiving and Accepting KPD Match Offers

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

Table 13-2: Timelines for Performing Responsibilities upon Receiving a KPD Match Offer

Upon receipt of a match offer in the OPTN KPD program, the following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report a preliminary response to the OPTN Contractor	2 business days of receiving the match offer.
The matched candidate transplant hospital	Provide the matched donor's transplant hospital with contents required in the crossmatch kit, instructions for the donor and the address at which to send the completed blood samples.	2 business days of receiving notification of preliminary offer acceptance.
The matched donor transplant hospital	Send the completed blood samples to the address specified by the matched candidate's hospital.	5 business days of receiving the information about the contents required for the crossmatch kit and instructions for the donor and the address at which to send the completed blood samples.
The matched donor transplant hospital	Make all of the matched donor's records accessible to the matched candidate's transplant hospital. The matched donor's records must include any updated serology and NAT testing results, and must indicate whether the matched donor is increased risk according to the PHS Guidelines.	2 business days of receiving notification of preliminary exchange acceptance.
The matched candidate transplant hospital	Report the results of the crossmatch to the OPTN Contractor	13 business days of receiving notification of preliminary exchange acceptance.

Upon receipt of a match offer in the OPTN KPD program, the following members:	Must:	Within:
The matched candidate transplant hospital	Review the matched donor's records and report a final acceptance or refusal of the match to the OPTN Contractor	13 business days of notification of preliminary exchange acceptance.

If the matched candidate and matched donor transplant hospitals do not meet the deadlines specified above, then the exchange will be terminated, unless all transplant hospitals in the exchange agree, before the deadline expires, to extend the deadline. The transplant hospital requesting the extension must submit the request in writing to the OPTN Contractor explaining the reason for the request and include the new requested deadline date.

Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. The transplant hospitals in the exchange will have 1 business day to respond to the request for extension. If all other transplant hospitals in the exchange agree to the extension, it will be granted and the exchange will not be terminated. If any of the transplant hospitals in the exchange fail to respond to the request for extension within 1 business day of receiving the request, the request will not be granted. If the extension request is submitted before the deadlines specified in Policy 13.10, the exchange will not terminate until the resolution of the extension request or until the deadline is reached, whichever comes first.

13.1~~1~~2 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.2: Organs Recovered by Living Donor Recovery Hospitals*.

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

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

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

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

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

13.1~~2~~3 Communication between KPD Donors and Recipients

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

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

1. All the KPD donors and recipients participating in the communication agree on the conditions of the meeting or correspondence.
2. The meeting or correspondence occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. The ~~T~~transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

FINAL REPORT

OPTN KPD MATCH OFFER OUTCOMES AND REFUSAL REASONS, BY CANDIDATE CPRA

FOR KPD MATCH RUNS: OCT 27, 2010 – MAY 2, 2012

Prepared for:
Kidney Paired Donation Work Group
Teleconference Meeting
July 13, 2012

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BACKGROUND/PURPOSE

As of May 2, 2012, 19 transplants have been facilitated through the OPTN KPD Pilot Program (KPDPP). A large percentage of the candidates that have been entered into the national system are considered "difficult to match" – either blood group O, highly sensitized (e.g., CPRA>=80%), or both. Nonetheless, matches have frequently been found for high CPRA candidates in the OPTN KPDPP. However, many of these matches have not led to transplant, for a variety of reasons: patients involved in a pending match in another KPD program; patients refusing the donor due to donor characteristics; and refusals due to positive crossmatches or unacceptable donor antigens.

Due to the apparent high rate of exchanges falling apart due to unexpected positive crossmatches and/or unacceptable donor antigens, the KPD work group is interested in having KPD programs pre-accept or pre-refuse donors that may potentially match with their candidates in a future KPD match run. The work group has discussed the idea of making donor pre-screening mandatory for certain candidates based on CPRA, since higher CPRA candidates are generally associated with higher refusal and positive crossmatch rates.

To better understand the relationship between KPD match refusal rates/reasons and candidate CPRA, as well as to possible help establish a CPRA threshold for requiring donor pre-screening, the KPD work group has requested an analysis of KPD match refusal rates and reasons by candidate CPRA.

WORK PLAN ITEM ADDRESSED

Implement a kidney paired donation pilot program and begin to match pairs of donors and recipients in 2010. Develop and issue for public comment proposed interim policies for kidney paired donation.

COMMITTEE REQUEST

Tabulate the number of refusals, refusal rates, and refusal reasons by candidate CPRA for all KPD match runs for which enough time has lapsed to collect match response (accept/refuse) data.

DATA AND METHODS

This analysis is based on the data collected to operate the OPTN KPDPP since the inception of the program through June 13, 2012. Outcomes of match offers for match runs #1-20 (Oct 27, 2010 – May 2, 2012) are included. Match runs after May 2, 2012 could not be included since match offer response data was still in the process of being collected when this analysis was performed.

CPRA is based on the unacceptable antigens provided by the center for the purpose of screening off unwanted KPD match offers. The CPRA is based on the unacceptable antigens for each candidate as of the time candidate eligibility is determined prior to each KPD match run. In addition

to unacceptable antigens, centers can also list "other antibody specificities," which represent donor antigens that alone would not rule out transplantation, but in combination may result in a positive crossmatch. These "undesirable" antigens do not preclude the KPD system from matching candidates with donors; however, the optimization algorithm downweights such matches to decrease the likelihood of selecting them for inclusion in a potential KPD exchange.

After each match run, match offer(s) were sent to each transplant center having KPD candidate(s) involved in a 2-way or 3-way exchange, or non-directed donor (NDD) chain, as determined by the KPD optimization algorithm. Centers have the opportunity to initially refuse the offer or preliminarily accept it. If they preliminarily accept, they may later refuse after a crossmatch has been performed. Even if the center submits both a preliminary and final acceptance of match offer and schedules an OR date, it is still possible that such a match offer could end up not resulting in a transplant due to unforeseen circumstances. For both the preliminary and the final refusal, centers have the opportunity to provide both a primary and secondary reason; typically, however, only a primary reason is provided. Centers can select a one of the available refusal codes (e.g., "Matched donor: Weight") or write-in a custom reason by selecting "Other, specify."

Each of the 218 KPD match offers was classified as into one of the following four categories, based on the outcome of the offer:

(1) transplant,
(2) transplant pending,
(3) "exchange fell through," or
(4) match refusal.

The "match success rate" is simply the number of matches that resulted in a transplant divided by the total number of matches.

Matches in which the "exchange fell through" are cases in which a center may have been willing to accept a donor on behalf of their KPD candidate but was unable to accept because other matches in the exchange were refused, preventing the entire exchange from proceeding to transplant. Any match offer that a center refused for a reason other than "exchange fell through" (including those identified from the "Other, specify" text) was considered a "match refusal."

Crossmatch-related refusals are a subset of the match refusals. They include any match for which either the preliminary or final response (either primary or secondary reason) included one (or more) of the following four refusal codes:

- 2001 - Donor: Crossmatch unacceptable
- 2080 – Matched Donor: Candidate antibodies against donor antigens are unacceptable
- 2302 – High CPRA
- 2306 – Positive Crossmatch

In addition, refusals were considered crossmatch-related if the "Other, specify" text contained verbiage clearly consistent with crossmatch or unacceptable antigens; for example, "recipient had DSA's" was considered crossmatch-related.

The crossmatch-related refusal rate is the number of crossmatch-related refusals divided by the total number of match offers.

For nearly 15% of match offers, the transplant center did not provide a reason for refusal. It is possible that some of these refusals were related to a positive crossmatch or unacceptable antigens.

Table 4 shows the frequency of all refusal reasons provided by users. Matches with multiple refusal reasons among preliminary/final and primary/secondary fields were included once for each distinct reason; hence, the total number of refusal reasons (238) in Table 4 exceeds the number of match offers (218) shown in Tables 1-3. The "Other, specified" text responses have been redacted to remove individual and institutional identifiers, as applicable.

A small number, 9, of the KPD matches were the result of "repairing" a NDD-chain. In these cases, the exchange fell apart due to one or more match refusal(s) early in the chain. With KPD Work Group approval, UNOS staff was able to "repair" the chain by find a compatible candidate further down in the chain that matched with a refused donor earlier in the chain. These repairs are likely to have a higher success rate, since they are screened ahead of time during communication with the transplant centers prior to actually making the offers. (Note: Per KPD Work Group guidance, UNOS staff is no longer repairing broken chains.)

This analysis excluded match offers to the final candidate in an NDD chain; these are candidates on the deceased donor waitlist and not necessarily in the KPD system.

Sample sizes are small, so apparent differences in rates may be exclusively or predominantly due to random variability and thus should be interpreted cautiously. However, statistical analyses were conducted to test the hypotheses that there is no relationship between the crossmatch-related refusal rate and CPRA. Logistic regression was used for these analyses, with CPRA a continuous independent variable, as well as a categorical variable; in both cases, p-values (based on the likelihood ratio test) were similar. A similar logistic regression analysis was also conducted for the association between the crossmatch-related refusal rate and the number of other antibody specificities. The 95% confidence interval cited in the results is derived using the Wilson/Score-based methodology for binomial proportions.

RESULTS

Table 1 shows that the overall match success rate – the number of match offers that resulted in a transplant divided by the total number of match offers – was 7.4%. Though there is no discernible trend in the match success rate with respect to CPRA, this is likely an artifact of a small sample size (N=16 transplants). It is possible that a relationship between CPRA and the match success rate exists, but with only 1-3 transplants in many of the CPRA groups, much of variation seen in the match success rates (for example, the 20% rate for the CPRA of 80-89 group) is likely due to random variability and not a real phenomenon.

However, the rate of offers being refused due to a crossmatch-related issue does appear to be a function of candidates' CPRA. Though the overall rate of refusing for crossmatch-related reasons was 14.7%, the rate was 34.8% and 25.8% for candidates in the CPRA 90-95 and 96-100 groups, respectively. In spite of the limited sample sizes, the relationship between CPRA and the crossmatch-refusal rate is statistically significant ($p<0.01$).

Based on the relationship between the crossmatch-related refusal rate and CPRA in Table 1, for subsequent analyses CPRA was broken into the following three groups: 0, 1-89 and 90-100.

Table 2 shows a higher crossmatch-related refusal rate for candidates with a large number of "other antibody specificities." For those with 10 or more undesirable antigens listed in the OPTN KPD system, the crossmatch-related refusal rate was 52.4%. The relationship between the number of other antibody specificities and the crossmatch-refusal rate is also statistically significant ($p<0.01$).

For candidates with CPRA of 90-100 and with 10 or more other antibody specificities, the estimated refusal rate due to crossmatch-related reasons jumped to 81.8% (**Table 3**). Though this rate is based on a fairly small sample size (9 refusals out of 11 match offers), a 95% confidence interval for the true rate is (52.3%, 94.9%) suggests that the true crossmatch-related refusal rate for these candidates, at a minimum, exceeds 50%.

Table 4 shows all reported refusal reasons provided during the first 20 OPTN KPDPP match runs, including "Other, specify" reasons provided in free form text by users. The most prevalent reason was actually not a refusal reason at all: the center intended to accept, but was unable to because another match in the exchange was refused and thus the entire exchange fell through. Table 4 also shows that cross-match related reasons are disproportionately represented among the match offers to candidates with CPRA of 90-100.

Table 1: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate CPRA
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
CPRA								
0	79	9	1	11.5%	41	28	3	3.8%
1-49	32	1	0	3.1%	12	19	6	18.8%
50-79	38	1	0	2.6%	19	18	5	13.2%
80-89	15	3	0	20.0%	5	7	2	13.3%
90-95	23	1	0	4.3%	6	16	8	34.8%
96-100	31	1	0	3.2%	13	17	8	25.8%
All	218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Match Success Rate = (# Transplants / # Match Offers)
Exchange Fell Through: Match May Have Been Accepted but Had to be Refused due to Other Match(es) Falling Apart
Crossmatch-Related Refusal: Refused due to Positive Crossmatch, Unacceptable Antigens, or DSA's
Based on OPTN KPD data as of June 13, 2012

Table 2: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate # Other Antibody Specificities
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
# Other Antibody Specificities								
0	178	13	1	7.3%	79	85	18	10.1%
1-9	19	3	0	15.8%	12	4	3	15.8%
10+	21	0	0	0.0%	5	16	11	52.4%
All	218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Match Success Rate = (# Transplants / # Match Offers)
Exchange Fell Through: Match May Have Been Accepted but Had to be Refused due to Other Match(es) Falling Apart
Crossmatch-Related Refusal: Refused due to Positive Crossmatch, Unacceptable Antigens, or DSA's
Based on OPTN KPD data as of June 13, 2012

Table 3: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate CPRA & Other Antibody Specificities
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

		Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
CPRA	**# Other Antibody Specificities**								
0	**0-9**	75	9	1	12.2%	38	27	3	4.0%
	10+	4	0	0	0.0%	3	1	0	0.0%
1-89	**0-9**	79	5	0	6.3%	34	40	11	13.9%
	10+	6	0	0	0.0%	2	4	2	33.3%
90-100	**0-9**	43	2	0	4.7%	19	22	7	16.3%
	10+	11	0	0	0.0%	0	11	9	81.8%
All		218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Match Success Rate = (# Transplants / # Match Offers)
Exchange Fell Through: Match May Have Been Accepted but Had to be Refused due to Other Match(es) Falling Apart
Crossmatch-Related Refusal: Refused due to Positive Crossmatch, Unacceptable Antigens, or DSA's
Based on OPTN KPD data as of June 13, 2012

Table 4: OPTN KPD System Match Offer Refusal Reasons by Candidate CPRA
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	CPRA						All	
	0		1-89		90-100			
	N	%	N	%	N	%	N	%
Refusal Reasons								
2081: Accepted but exchange fell through	31	37.3	26	28.0	14	22.6	71	29.8
Not reported	17	20.5	12	12.9	6	9.7	35	14.7
2082: Matched donor not considered because exchange fell through	10	12.0	7	7.5	4	6.5	21	8.8
2311: Other specify	5	6.0	11	11.8	3	4.8	19	8.0
2080: Matched Donor: Candidate antibodies against donor antigens are unacceptable	2	2.4	7	7.5	9	14.5	18	7.6
2001: Donor: Crossmatch unacceptable	1	1.2	6	6.5	6	9.7	13	5.5
2083: Candidate involved in a pending exchange	0	0	7	7.5	1	1.6	8	3.4
2604: Candidate ill, unavailable, or temporarily unsuitable	3	3.6	2	2.2	2	3.2	7	2.9
2002: Matched Donor: Number of HLA mismatches unacceptable	1	1.2	0	0	3	4.8	4	1.7
2023: Candidate already received transplant	1	1.2	1	1.1	2	3.2	4	1.7
2606: Matched Donor refused candidate	1	1.2	1	1.1	1	1.6	3	1.3
2603: Candidate refused	0	0	1	1.1	1	1.6	2	0.8
2012: Donor: Other specify	1	1.2	0	0	1	1.6	2	0.8
2006: Matched Donor: Weight	1	1.2	0	0	1	1.6	2	0.8
2607: Matched Donor ill, unavailable, or temporarily unsuitable	1	1.2	1	1.1	0	0	2	0.8
2404: Intended donor ill, unavailable, or temporarily unsuitable	1	1.2	1	1.1	0	0	2	0.8
2307: Candidate cannot be contacted	0	0	0	0	1	1.6	1	0.4
reason for match refusal is chain fell through	0	0	1	1.1	0	0	1	0.4
The reason for not accepting is positive crossmatch for another recipient in this swap.	0	0	1	1.1	0	0	1	0.4
BP	0	0	0	0	1	1.6	1	0.4
One of the other candidate s centers declined to accept the donor due to BMI.	0	0	0	0	1	1.6	1	0.4
Donor was declined by other center.	0	0	1	1.1	0	0	1	0.4
2004: Matched Donor: Distance for donor kidney to be shipped too far for candidate	0	0	0	0	1	1.6	1	0.4
New antibody that is unacceptable to this donor was discovered since entering.	0	0	0	0	1	1.6	1	0.4
Never crossmatched but after diluting recipient serum, revealed more DSA than previously thought.	0	0	1	1.1	0	0	1	0.4

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Matches with Multiple Refusal Reasons (Preliminary, Final/Primary, Secondary) Included Once for Each Distinct Reason
Free-form Refusal Reasons ('Other: Specify') Redacted to Omit Individual and/or Institutional Identifiers
Based on OPTN KPD data as of June 13, 2012

Table 4: OPTN KPD System Match Offer Refusal Reasons by Candidate CPRA
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	CPRA						All	
	0		1-89		90-100			
	N	%	N	%	N	%	N	%
The recipient had DSA's	0	0	0	0	1	1.6	1	0.4
2019: Kidney: Organ anatomical damage or defect	0	0	1	1.1	0	0	1	0.4
candidates donor was requested tohave an open nephrectomy and refused	0	0	1	1.1	0	0	1	0.4
2608: Donor cannot be contacted	1	1.2	0	0	0	0	1	0.4
2007: Matched Donor: ABO	0	0	0	0	1	1.6	1	0.4
2022: Insurance Issues	0	0	0	0	1	1.6	1	0.4
2005: Matched Donor: Age	0	0	1	1.1	0	0	1	0.4
2009: Matched Donor: Medical history	1	1.2	0	0	0	0	1	0.4
matched donor at XXXX-TX1 already invovled in another exchange.	1	1.2	0	0	0	0	1	0.4
candidate receiving a transplant from a compatible daughter	1	1.2	0	0	0	0	1	0.4
3 renal arteries	0	0	1	1.1	0	0	1	0.4
size mismatch	1	1.2	0	0	0	0	1	0.4
2018: Kidney: Size	1	1.2	0	0	0	0	1	0.4
paired donor inactive	0	0	1	1.1	0	0	1	0.4
candidate found another living donor	0	0	1	1.1	0	0	1	0.4
kidney abnormality	1	1.2	0	0	0	0	1	0.4
All	83	100.0	93	100.0	62	100.0	238	100.0

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Matches with Multiple Refusal Reasons (Preliminary, Final/Primary, Secondary) Included Once for Each Distinct Reason
Free-form Refusal Reasons ('Other: Specify') Redacted to Omit Individual and/or Institutional Identifiers
Based on OPTN KPD data as of June 13, 2012