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This report reflects the work of the OPTN/UNOS Kidney Transplantation Committee during October 2013-April 2014.

Action Items

1. **OPTN Kidney Paired Donation (KPD) Pilot Program Prioritization Points**
   
   **Public Comment**  Spring 2012
   
   The Board is asked to approve policy language that converts into OPTN policy the existing OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) Operational Guidelines section regarding candidate prioritization points.
   
   **RESOLVED, that Policy 13.7.E (Prioritization Points) is modified, as set forth in Exhibit A, effective September 1, 2014.**

2. **KPD Program Permanency**
   
   **Public Comment**  n/a
   
   The Board is asked to approve the removal of the “pilot” label from the OPTN/UNOS Kidney Paired Donation Pilot Program, based on the progress of the program since its first match run in October, 2010 as described in Exhibit B. Removal of the pilot label reflects the stability and success of the OPTN/UNOS KPD program, and symbolizes the OPTN’s commitment to continue to meet the demand for kidney transplants by providing another method of identifying and matching kidney transplant candidates with donors.
   
   **RESOLVED, that the pilot label is removed from the OPTN/UNOS Kidney Paired Donation Pilot Program, and the program is a permanent function of the OPTN, effective pending HRSA’s approval.**

Committee Projects

3. **Simultaneous Liver Kidney (SLK) Allocation**
   
   **Public Comment:**  Fall 2015 (estimated)
   
   **Board Review:**  Spring 2016 (estimated)
   
   The Committee continues to discuss whether policies are needed for simultaneous liver kidney allocation. In April 2014, UNOS staff presented the results of data requested by the Committee in August 2013. The Committee requested data on the following:
   
   - Clinical information for SLK recipients at time of transplant for transplants performed since 2005, including percent on dialysis, time on dialysis (<6 months, 6+ months),
creatinine values, primary diagnoses for kidney and liver transplants, donor quality (KDPI), MELD by creatinine, and sensitization level (PRA/CPRA).

- Number of listings for kidney after liver transplant for each year since 2005 by region and Donation Service Areas (DSA); and distribution of time between the liver and subsequent kidney listings including the proportion with kidney listings within certain time period (e.g., within one and three years) after the liver transplants, stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nephrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
- Number of kidney transplants after liver transplants each year since 2005 by region and DSA; and distribution of time between the liver and subsequent kidney transplant including the proportion with kidney transplants within certain time period (e.g., one and three years) after the liver transplants, separately for deceased and living donor transplants, and stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nephrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
- 25th and 50th percentiles of times to transplant for registrations waiting for kidney after liver and for registrations waiting for kidney with no previous liver transplants by blood type. Explore the feasibility of computing percentiles of time to transplant for each blood type, by region and DSA (feasibility may be limited by sample size).

The results were summarized as follows:

- Among 3,431 SLK recipients during 1/1/05-6/30/13, 510 (15%) did not receive pre-transplant dialysis and had a serum creatinine of <2.5 mg/dl at transplant, which would suggest that some of these patients may not have needed a kidney.
- Of the 510 SLK recipients with no pre-transplant dialysis and a serum creatinine of <2.5 mg/dl, 237 (46%) received a KDPI <35% kidney, which suggests that kidneys utilized in SLK transplants also tended to have a lower KDPI scores. Since pediatric kidney candidates are prioritized to receive kidneys from donors with age<35 (KDPI<35 in the new Kidney Allocation System), SLK transplants in which the kidney was not needed may disproportionately affect pediatric access to kidneys.
- On average, 200 patients were listed per year for a kidney transplant during 1/1/05-6/30/13 after a solitary liver transplant; the median time to listing for these patients was about 9 years for those with a kidney diagnosis of CNI nephrotoxicity, 6.5 years for hypertensive nephrosclerosis, 5 years for type 2 diabetes, and 11 months for hepatorenal syndrome; additionally, only 19% were listed within a year of the liver transplant.
- On average, there were 120 kidney transplants (including both deceased and living donor) performed per year during 1/1/05-6/30/13 after a solitary liver transplant; the median time to kidney transplant was 10 years for those with a kidney diagnosis of CNI nephrotoxicity, 7 years for hypertensive nephrosclerosis, 6 years for type 2 diabetes, and 2 years for hepatorenal syndrome; additionally, only 9% were transplanted within a year of the liver transplant.
- The 25th percentile of times to deceased donor kidney transplant tended to be lower for registrations added to the waiting list during 2003-2008 after a previous liver transplant as compared to those added to the waiting list during the same time period without a previous liver transplant.
After reviewing this data, many of the Kidney Committee members voiced support for creating qualifying criteria for SLK candidates in combination with a safety net that would prioritize liver alone recipients who continue to experience kidney failure after transplant. The Committee recently formed an SLK workgroup with the Liver and Intestinal Transplantation, Ethics, and Minority Affairs Committees to discuss the problem further and recommend new policies for SLK allocation.

4. **Addressing Geographic Disparities in Kidney Allocation**

   **Public Comment:** Spring 2016 (Estimated)
   **Board Review:** Fall 2016 (Estimated)

The Committee continues to review data to determine what metric should be used to best assess geographic disparity in kidney allocation. The Committee plans to explore a variety of options while also considering any lessons learned as the Liver and Intestinal Transplantation Committee releases a concept document for liver redistricting.

The Geographic Disparities Subcommittee met in February and March to review results of data requested at the August 2013 in-person meeting. The subcommittee presented the results of the data review and the decisions made thus far at the April in-person committee meeting.

The Committee reviewed the following data by (deidentified) DSA:
- Offer rate per 100 active patient years
- Transplant rate per 100 active patient years
- Supply/demand ratio (where supply reflects quality of organs and demand represents waiting list population)
- Median time to transplant (competing risks method)

In addition, offers, transplants, and “supply” were calculated for three different donor groups:
- All deceased kidney donors
- Deceased kidney donors with KDPI greater than or equal to 85%
- Deceased donors with KDPI greater than or equal to 85% and non-DCD

The Committee also reviewed data to determine whether to use an incident (newly listed) or prevalent (entire list) patient population to define the denominators of the offer rate, transplant rate, and supply to demand ratios. As a result of assessing changes to both the numerators and denominators of these ratios, the Committee considered six different types of transplant rates, six different types of offer rates, and twelve different types of supply v. demand metrics, for a total of 24 different metrics. In addition, the Committee reviewed an analysis of the median (and 25th percentile) times to transplant by DSA.

In addition to quantifying the degree of DSA-to-DSA variability by each of the 24 ratios, the correlation between each metric and all others was evaluated to determine which choices — e.g., changes to numerator vs. changes to denominator — would have a larger effect on the optimization modeling to be used for determining new districts. If two metrics are highly correlated, the decision of which one to use would have relatively little impact compared to the choice between two metrics that are weakly correlated or uncorrelated.
The key findings from the review are as follows:

- There is huge variation in access to kidneys across DSAs for all of these metrics.
- The results suggest that case-mix differences (e.g., DSA’s with higher proportion of sensitized candidates) may explain at least some of this variability, in particular in offer and transplant rates.
- It is often impossible to estimate median times to transplant due to fewer than 50% of candidates being transplanted in certain DSAs as well as competing risks (e.g., removal from the waiting list for death and other reasons).
- Excluding lower quality kidney donors had very little impact on the rank ordering of DSA’s by either offer rates, transplant rates, or supply-to-demand ratios.
- The following decisions are expected to have a much larger impact on the development of new districts based on mathematical optimization:
  - Including all or only recently listed patients (incident v. prevalent waiting list)
  - Including all or only active patients
  - The class of metric to use (offer rates, transplant rates vs. supply-to-demand ratios)

After reviewing these data, the Committee decided to include all kidney donors (no exclusion of DCD or high KDPI donors) for supply-to-demand, offer rates, and transplant rates. The Committee also decided to include only active patients. The Committee is leaning toward an incident-based metric in order to avoid overcompensating for historical, accumulated disparities, but the members agreed that any such time period should be made prior to announcement of any new redistricting proposal to avoid gaming. There was some concern that, depending on how recent the incident population is, it may take a substantial amount of time to resolve inequities.

The Committee continues to discuss concerns that using a transplant rate metric does not account for variation in center acceptance practices. Similarly, the Committee is concerned that, no matter the metric selected, it will likely be difficult to account for behavioral changes and OPO performance. The Committee’s preference is to reassess geographic disparity after implementation of the new Kidney Allocation System (KAS), which is expected to have at least some effects on the geographic distribution of kidneys. The Committee has also expressed the importance of having some flexibility in periodically reassessing any metric selected and recalibrating geographic boundaries if necessary.

5. National Standard for Marking Organ Laterality

Public Comment: Spring 2015 (Estimated)
Board Review: November, 2015 (Estimated)

The incorrect marking of kidney laterality was the third highest ranking failure on the Failure Modes Effects and Criticality Analysis (FMECA) conducted by Northwestern University as part of the Electronic Tracking and Transport Project. In February, the Committee was tasked with making recommendations on whether there should be uniform guidance or policy on marking kidney laterality. The Committee has assigned a subcommittee to discuss the issue. The subcommittee expects to report recommendations to the full Committee in fall 2014, with an expected public comment date of spring 2015 (if the subcommittee determines that policy changes are needed).
6. **KPD Informed Consent Guidelines to Policy**

*Public Comment:* Spring, 2012 (First round)

*Public Comment:* Fall, 2014 (Estimated)

*Board Review:* June, 2015 (Estimated)

Informed consent for KPD was originally included in the March, 2012 *Proposal to Establish Kidney Paired Donation (KPD) Policy*, but the section was removed before the proposal was recommended to the Board of Directors in November, 2012. A Joint Societies Work Group (JSWG) formed to address informed consent for KPD, and sent its finalized recommendations to the Joint Societies Steering Committee in October, 2013. *(Exhibit C)* The Joint Societies Steering Committee approved the JSWG recommendations without modification in March, 2014.

The KPD workgroup (KPDWG) reviewed the recommendations during on April 25, 2014. The KPDWG agrees with the components of the JSWG proposal, but recommended that the Kidney Committee distribute the proposal for another round of public comment because it is substantively different than the original informed consent policy proposal. The KPDWG also recommended that the Kidney Committee incorporate a modified version of the JSWG proposal into the KPDPP Operational Guidelines, so that there are updated KPD informed consent guidelines until the Board of Directors approves the KPD informed consent policy proposal.

7. **Converting KPD Operational Guidelines to OPTN Policies and Bylaws**

*Public Comment:* Fall, 2014 (Estimated)

*Board Review:* June, 2015 (Estimated)

The KPDWG is examining the extent to which the current Operational Guidelines should be converted to OPTN policy. Some sections of the Operational Guidelines, such as the prioritization points are presently before the Board of Directors for approval, while others, such as the histocompatibility section, was distributed for public comment in Spring, 2014. Other sections, such as donor pre-select, KPD contact responsibilities, and information sharing between transplant centers, will be distributed for public comment in Fall, 2014 to be included in the OPTN policies and bylaws. The KPD logistical deadlines, explained in more detail below, will also be included in the public comment proposal. Once all of the Operational Guidelines are incorporated into OPTN policies and bylaws, the Operational Guidelines will be eliminated. All future changes to KPD policies and bylaws will follow the OPTN policy development process, from public comment to Board approval.

The KPDWG voted on March 25, 2014 to approve a proposal to incorporate logistical deadlines into the current KPD Operational Guidelines in order to accelerate the exchange process from the time an exchange is first identified until the exchange is complete. Requiring programs to perform their respective responsibilities within a shorter time frame will benefit candidates because candidates and potential donors are ineligible to participate in a match if they are involved in a pending exchange. If a transplant program does not meet the deadlines set forth in the newly approved guidelines, then the exchange will be terminated so that all candidates and donors involved can be eligible for the next match run. The KPDWG also included a procedure for requesting an extension, so that an exchange will not terminate if all other participants agree to the extension.
The proposal was sent to the Kidney Committee, which approved the proposal on April 7, 2014. (Exhibit D) The changes will be effective September 1, 2014.

8. **Revising KPD Priority Points**

*Public Comment: Spring, 2015 (Estimated)*  
*Board Review: November, 2015 (Estimated)*

Members of the Design and Optimization Algorithm Subcommittee (DOAS) continue to perform optimization studies to help the KPDWG determine whether and how to modify the prioritization algorithm for the KPDPP in the future. The KPDWG has received updates on the results of these simulations throughout 2014, and will use the results to inform the decision regarding whether to first pursue small-scale changes to the current optimization scheme and prioritization points schedule, or whether to significantly overhaul the way in which the KPDPP system identifies matches. DOAS has also reviewed data on zero HLA mismatching and is debating the role HLA mismatching should play in future prioritization of KPD candidates. Any proposed changes should incentivize transplant programs to enter their living donor pairs into the KPDPP, and should identify more matches that ultimately proceed to transplant in a manner that is fair and transparent.

9. **Allowing Deceased Donor Chains in the KPDPP**

*Public Comment: Fall, 2015 (Estimated)*  
*Board Review: June, 2016 (Estimated)*

The KPDWG is exploring the potential of allowing deceased donor chains in the KPDPP. Permitting a deceased kidney donor to initiate a chain in the KPD system would potentially increase the number of kidney transplants overall, without decreasing the number of donors available for the deceased donor waiting list. There are a number of ways in which a deceased donor kidney could initiate a chain. Due to the laws regarding valuable consideration and allocation, staff for the KPDWG are discussing possible options for this project within those legal constraints.

10. **Living Donor Match Runs When Candidate and Donor Are in Different DSAs**

*Public Comment: n/a*  
*Board Review: June, 2015*

The Kidney Committee previously agreed that a “permanent fix” is needed for situations in which a donor’s chain-ending kidney donation is allocated to a KPD candidate transplant hospital in a DSA that is different from the donor’s hospital, or a KPD candidate transplant hospital wants to “backup” a living donor kidney that is being imported from a different DSA. Currently, computer programming does not allow a transplant center, OPO, or the Organ Center to run a match run when the donor recovery hospital is in one DSA and the transplant recipient hospital is in another DSA; however, a manual work-around has been established. The manual solution is successful, as members have not been requesting help in these situations since it was established.
The Kidney Committee previously voted to send this project idea to the Policy Oversight Committee (POC) for consideration in Fall, 2013. Though the POC approved the project, the KPDWG and Kidney Committee did not send the project to the POC for ongoing approval during the Spring, 2014 review cycle because it is not currently a priority amongst the other projects. The KPDWG will work with the Living Donor Committee while developing this project.

Committee Projects Pending Implementation

11. Revised Kidney Allocation System (KAS)

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<tr>
<th>Public Comment:</th>
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<td>Board Approval:</td>
<td>June, 2013</td>
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<tr>
<td>Implementation:</td>
<td>The revised KAS will be implemented in two main phases through a series of system programming releases throughout 2014. The project is projected to be fully implemented by December 2014.</td>
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The Estimated Post-Transplant Survival (EPTS) calculator, released on March 20, 2014, was the first of these releases. The EPTS calculator can be used to evaluate how various patient characteristics, like an increase in time on dialysis or a prior transplant, will impact a patient’s EPTS score. In the revised system, candidates with an EPTS score of 20% or less will have increased priority for receiving kidney offers when the donors kidney donor profile index (KDPI) is also 20% or less. The EPTS calculator is displayed in UNet and on the OPTN website. Between March 20-April 24, 2014, there were 411 visits to the calculator via UNet and 1,873 page views to the calculator on the OPTN website.

On May 27, 2014, a second set of programming changes will be released in UNet that will display an EPTS landing page and data fields to allow programs to add and confirm candidate information eventually used to calculate EPTS scores (age, diabetes diagnosis, time on dialysis, and prior solid organ transplants). The Committee requested that kidney programs be given approximately six months to update data prior to full implementation of the revised KAS.

A number of tools are being programmed in the system to help ease the data and compliance burden for kidney programs. Programs will be able to upload and update data in bulk or within each individual candidate record. A third programming release (planned for early July) will provide kidney programs with reports that flag missing or unconfirmed data on their candidates. With regard to donor acceptance criteria, the system will default candidates added prior to May 27, 2014 with certain maximum KDPI acceptance criteria based on the Standard Criteria Donor (SCD) and Expanded Criteria Donor (ECD) criteria selected in the current UNet system. If a current candidate has consented to accept an ECD kidney, UNet will default to a maximum KDPI of 100%. If a current candidate has not consented to accept an ECD kidney, UNet will default the KDPI maximum to 85%. Programs will have the ability to select different maximum KDPI scores and will be able to differentiate between maximum KDPI criteria for local v. non-local offers, as well as zero mismatch v. non-zero mismatch offers.

The system will also display a number of references to assist programs with accuracy of data. For example, if the candidate received a prior organ transplant in the U.S., UNet will display a list of these transplants according to what was previously reported by OPTN members. UNOS staff worked with CMS to obtain data on dialysis start date information.
previously reported in the CMS database. If a reliable dialysis start date can be found for
the candidate (based on Social Security Number and other information), the system will
display the date as a reference for the program. If the program selects a dialysis start date
that matches the CMS data provided, the program will not need to provide additional
documentation for the purposes of UNOS site visits.

There will also be tools that will allow programs to assess how the new allocation system
changes will affect prioritization for candidates on their list prior to implementation.
Programs will receive a ‘Priority Points Report’ in the system that will display how each of
the candidates on their list will rank under the new system when calculating total points
(including those for waiting time points, CPRA, etc.) along with the EPTS score calculated
for each. This points report will give programs a snapshot of how the candidates at their
own program rank, but it is limited to the specific program and will not account for all local,
regional, and national candidates.

The Committee continues to work with UNOS staff to release a number of educational
offerings to help transplant programs, OPOs, and histocompatibility laboratories prepare for
implementation of the new system. Thus far, UNOS staff has worked in conjunction with the
Committee to release the follow education products:

- “Introduction to the Kidney Allocation System” podcast (released February 2014)
- “What referring physicians need to know” recorded webinar (released February
  2014)
- “Basic preparations” webinar (released March 2014)
- “Virtual town hall meeting on the new kidney allocation system” (held in March
  2014)
- “Resources for creating protocols and processes” webinar (held in April 2014)
- Frequently Asked Questions (FAQ) document
- Member checklist

The Committee has collaborated with a number of other OPTN/UNOS committees as part of
these educational efforts, including the Transplant Administrators, Minority Affairs, and
Patient Affairs Committees. The Committee leadership presented an overview of the new
allocation system and basic preparation information at the UNOS Transplant Management
Forum (TMF) in April 2014 and presentations are scheduled for the World Transplant
Congress (WTC), the NATCO annual meeting, and the American Society for
Histocompatibility and Immunogenetics (ASHI) annual meeting later this summer. UNOS
staff is also planning to hold a number of system trainings in advance of the upcoming
programming releases to help programs navigate the system changes. Resources for
patients will be released in summer 2014.

Upon implementation, all variances will be eliminated along with the current payback
system.

**Implemented Committee Projects**

**12. The Kidney-Pancreas (KIPA) Waiting Time Projects**

*Board Approval:* n/a
*Implementation:* March 19, 2014
In March, UNOS implemented programming to allow kidney and kidney-pancreas programs to update and modify waiting time criteria (creatinine clearance, GFR, and dialysis date) on behalf of their candidates. Prior to this implementation, programs had to submit work orders to the Organ Center in order to modify the criteria. This change was intended to better prepare the system for the upcoming KAS. There have been no post-production issues and the change has been working as intended.

Other Committee Work

13. Kidney Waiting Time Modifications

During the period from October 2013-March 2014, the Organ Center modified waiting time for 66 kidney candidates.

Meeting Summaries

The Committee held meetings on the following dates:

- December 9, 2013
- April 7, 2014
- May 19, 2014

Meetings summaries for this Committee are available on the OPTN website at: http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=89.
# Proposal to Convert Prioritization Points from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN/UNOS Policy

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Title: Proposal to Convert Prioritization Points from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy

Sponsoring Committee: Kidney Transplantation Committee

Summary and Goals of the Proposal:

This proposal converts the existing OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) Operational Guidelines section regarding prioritization points into OPTN policy. Including the prioritization points in OPTN policy is consistent with the principles of transparency and public participation that are the hallmarks of the KPDPP and the OPTN.

Though the KPD Work Group (KPDWG) and OPTN Kidney Transplantation Committee both recognize that changes are needed in the way candidates and matches are prioritized in the KPDPP, they expressed unanimous support for addressing the current policy gap, which is presently silent with respect to prioritization of matches in the KPDPP. Moving the current priority points from operational guidelines into policy is intended to be an interim solution. The KPDWG and its Design and Optimization Subcommittee (DOAS) are actively investigating a variety of potential improvements to the way matches are found in the program, including changes that address concerns raised after this priority points schedule was distributed for public comment in 2012. The committee anticipates developing and distributing a new proposal to revise the way matches are prioritized in the near future.

Background and Significance of the Proposal:

In March 2012, the Kidney Transplantation Committee (Kidney Committee) distributed for public comment the Proposal to Establish Kidney Paired Donation (KPD) Policy. Among other topics, the proposal included a Prioritization Points section. The proposal specified the characteristics of matches that receive points, and included proposed language regarding waiting time accrual and reinstatement for KPD candidates. (Appendix A – policy language distributed for public comment in March 2012).

The proposed priority points were based largely on the work previously described in the June 20, 2008 Proposal for a National kidney Paired Donation (KPD) Pilot Program:

The optimization protocol for matching donor/candidate pairs [can maximize] the quantity and/or quality of [matches] according to the priorities assigned…Some mechanism for choosing among these combinations of potential matches is needed. Whereas a local program with relatively few donor/candidate pairs may be able to perform this function using a medical review group or similar entity, basing their decisions upon collective medical judgment, this practice would not be feasible on a national level. Instead, an automated, objective solution is needed.1

[...]
The Work Group considered several other factors that may be appropriate in prioritizing among combinations of potential matches. In each case, they are factors included based upon expected improvement of the graft following transplant and/or issues of access to transplantation due to candidate biologic or other reasons. They include the following:
- Zero antigen mismatch between donor and candidate: 200 points

1 An automated, objective solution removes human judgment from the matching process. The removal of human judgment, combined with the transparency of the matching system achieved by codifying the priority points in policy, ensure the matching system is fair.
Highly sensitized (e.g., probability of positive crossmatch≥80%) candidate: 125 points
Prior living donor status of candidate: 150 points
Pediatric (i.e., age < 18 years) candidate: 100 points
Waiting time accumulated within the KPD Pilot Program: 50 points per cycle
Geographic proximity (i.e., transplant center, local, regional): 75, 50, 25 points

There was considerable discussion that benefit to the candidate in terms of improved kidney graft survival is apparent now based upon donor age and degree of HLA similarity between the potential donor and recipient. Others suggested that these findings have not yet been demonstrated for living donor transplantation through objective data. This opinion was supported by a preliminary study evaluated by the Kidney Transplantation Committee during the initial phase of the Committee’s work on this program...and is confirmed by later studies. Moreover, the system will allow candidates to select acceptable age ranges based upon the experience and advice of their physicians. Particularly in the absence of available evidence to support restrictions in this regard, this approach appears to be the better option. The highest level of match between donor and candidate (i.e., zero antigen mismatch) was included based upon the consensus of opinion that a transplant with a zero antigen mismatched kidney, whether from a living or deceased donor, continues to be valued and improves opportunities for matching for sensitized candidates.

The March 2012 proposal included slight modifications to the way in which candidates are prioritized based on time waiting in the KPDPP. Appearing in a match run requires the candidate to be eligible, which includes setting the KPD status to active for that candidate. Previously, two points were awarded to a candidate for every match run in which that candidate was included. Since the match run was initially executed once every month, a candidate in KPD would receive two waiting time points per month of waiting, provided the candidate was eligible and entered into prior match runs.

To increase the number of matches found, the match run schedule shifted from monthly to biweekly (and ultimately, weekly) later in 2012. In anticipation of this change, the March 2012 proposal replaced “2 points per match run” with 0.07 points per day waiting in the KPDPP. This modified approach equates to approximately 2 points per month, irrespective of the KPD match run schedule. A candidate’s KPD waiting time starts on the date the candidate is added to the KPDPP, rather than being based on the number of previous match runs in which the candidate was eligible. Doing so achieves a fairer system in two important ways: (1) waiting time points are not dependent on changes in the match run schedule; and (2) candidates continue to accrue waiting time even if they are ineligible for a match run. Continuing to award waiting time points while a candidate is in a pending exchange avoids penalizing the candidate for being actively involved in a match that does not proceed to transplant.

In response to public comment feedback, the Kidney Committee ultimately withheld a number of sections from proceeding to the OPTN/UNOS Board of Directors for approval in November 2012, including the prioritization points section. Since then, the KPDPP match system has been programmed to use the prioritization points that were proposed in the March 2012 public comment proposal, as they are currently included in the KPDPP Operational Guidelines. (Exhibit A). The number of matches identified, transplants performed, and characteristics of candidates that are benefitting from the current optimization system are described in great detail in the State of KPD Report, which is also currently before the Board of Directors.
Supporting Evidence and/or Modeling:

The 2008 Proposal for a National Kidney Paired Donation (KPD) Pilot Program describes the historical studies and simulations performed to support the selection of the priority points in the KPDPP:

Simulations have been run to approximate results from the KPD Pilot Program assuming various priority assignments using the factors noted above and projecting numbers of donor/candidate pairs in the match run ranging from 50 to 350. The simulated patients were estimated from the OPTN/UNOS 2003 Wait List and other sources (Figure 1).

**Figure 1: Data Sources for Simulation Models**

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<thead>
<tr>
<th></th>
<th>% of all</th>
<th>Source of Data</th>
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</thead>
<tbody>
<tr>
<td>Pediatric</td>
<td>3.07%</td>
<td>UNOS WL Additions 2003</td>
</tr>
<tr>
<td>Prior Living Donor</td>
<td>0.052%</td>
<td>UNOS WL Additions 2003</td>
</tr>
<tr>
<td>Center</td>
<td>Of 242 centers</td>
<td>UNOS WL Additions 2003</td>
</tr>
<tr>
<td>Race</td>
<td>(exclude other)</td>
<td>UNOS WL Additions 2003</td>
</tr>
<tr>
<td>Caucasian</td>
<td>52.55%</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>30.45%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>17.00%</td>
<td></td>
</tr>
<tr>
<td>PRA Range</td>
<td></td>
<td>UNOS WL Additions 2003</td>
</tr>
<tr>
<td>0-9</td>
<td>71.31%</td>
<td></td>
</tr>
<tr>
<td>9-80</td>
<td>18.66%</td>
<td></td>
</tr>
<tr>
<td>80-100</td>
<td>10.02%</td>
<td></td>
</tr>
<tr>
<td>Predicted Positive Crossmatch Rate</td>
<td></td>
<td>Assumed from definition of PRA, no data available</td>
</tr>
<tr>
<td>PRA 0-9</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>PRA 9-80</td>
<td>45%</td>
<td></td>
</tr>
<tr>
<td>PRA 80-100</td>
<td>90%</td>
<td></td>
</tr>
</tbody>
</table>

In the simulation models, the probability of [a] positive crossmatch [for which a candidate’s unacceptable antigens have not been entered] is assumed to be: 90% for high PRA candidates, 45% for mid-level PRA candidates, and 5% for low PRA candidates. These assumptions are consistent with those reported in the peer-reviewed literature [and the basis of PRA assignment]. Blood groups for the recipients and donors in the simulated pool were chosen by a decision tree model that incorporates both genetic inheritance of these traits within families (who are likely donors to a given recipient) and the blood-group-linked probability of having an incompatible donor. It takes into account the fact that mothers are often sensitized against their children and spouses.²

Outputs from the simulations are …summarized below for several [different scenarios]. In this...model, each transplant equals 200 points plus any priority points assigned to a candidate (e.g., pediatric, sensitized, prior living donor), or to the match (zero mismatch, geographic proximity).

---

Figure 2: Output simulation model 1

<table>
<thead>
<tr>
<th>Average % Candidates Receiving TXs</th>
<th>100 Pairs in Match Run</th>
<th>350 Pairs in Match Run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>33.4%</td>
<td>33.4%</td>
</tr>
<tr>
<td>Priority</td>
<td>% TXed</td>
<td>Priority</td>
</tr>
<tr>
<td>Pediatrict Priority*</td>
<td>0 34.2%</td>
<td>100 52.4%</td>
</tr>
<tr>
<td>Prior Living Donor Priority*</td>
<td>0 50.0%</td>
<td>150 80.0%</td>
</tr>
<tr>
<td>Sensitized Priority*</td>
<td>0 6.3%</td>
<td>125 7.7%</td>
</tr>
<tr>
<td>Same Center Priority†</td>
<td>0 0.6%</td>
<td>75 4.5%</td>
</tr>
<tr>
<td>Same State Priority†</td>
<td>0 4.8%</td>
<td>50 13.5%</td>
</tr>
<tr>
<td>Same Region Priority†</td>
<td>0 5.1%</td>
<td>25 13.7%</td>
</tr>
<tr>
<td>Zero Antigen MM Priority*</td>
<td>0 0.0%</td>
<td>200 0.0%</td>
</tr>
</tbody>
</table>

* “0/34.2” is 0 priority points results in 34.2% of the simulated number of pediatric candidates being matched in this run.

† For geographic locations, 0/0.6% translates to: with 0 priority points, 0.6% of the donors can stay at the same center as the candidate (if they have elected that they would travel if necessary). The larger areas do not include the smaller areas, so the total percentage of donors who would not need to travel beyond their region (even if they agree to travel as far as necessary), would be the summation of the “same center + same state + same region”.

Figure 3: Output simulation model 2

<table>
<thead>
<tr>
<th>Average % Candidates Receiving TXs</th>
<th>350 Pairs in Match Run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>43.2%</td>
</tr>
<tr>
<td>Priority</td>
<td>% TXed</td>
</tr>
<tr>
<td>Pediatrict Priority*</td>
<td>0 42.0%</td>
</tr>
<tr>
<td>Prior Living Donor Priority*</td>
<td>0 50.0%</td>
</tr>
<tr>
<td>Sensitized Priority*</td>
<td>0 17.9%</td>
</tr>
<tr>
<td>Same Center Priority†</td>
<td>0 1%</td>
</tr>
<tr>
<td>Same State Priority†</td>
<td>0 5.3%</td>
</tr>
<tr>
<td>Same Region Priority†</td>
<td>0 5.9%</td>
</tr>
<tr>
<td>Zero Antigen MM Priority*</td>
<td>0 0.026%</td>
</tr>
</tbody>
</table>

Modifying the priorities does allow opportunity for a greater number of transplants for those assigned priority while only minimally impacting the total number of expected transplants. The larger impact upon the total number of expected transplants results from the number of pairs in the match run, with a greater number of pairs contributing to a greater overall percentage of pairs matched and an expected increase in transplants for most priority assignments. After an initial evaluation of the simulations shown above, the following priority points are suggested to start the KPD Pilot Program with further adjustment of points to be recommended by the Kidney Transplantation Committee based upon continual evaluation of the KPD Pilot Program.
Discussions following the meeting of and recommendations from the Kidney Transplantation Committee have indicated concern regarding including zero antigen mismatch as a priority in the system. This concern is due to lack of data supporting any significant impact upon transplant outcomes based upon this factor. The simulations show few matches or transplants would be modified by including even a relatively high priority value for this variable. Therefore, neither including nor removing it as a priority should alter results substantially.

Evidence demonstrating the success of the prioritization points as currently written and programmed can be found in the State of the OPTN/UNOS KPDPP Report, currently before the Board of Directors. Transplanting highly sensitized patients remains a key goal of the KPDPP, and this report highlights that 26% (n=28) of candidates transplanted through the program have had CPRA of 80% or higher, including 15 candidates with CPRA of 95% or higher.
Expected Impact on Living Donors or Living Donation

This proposal clearly outlines the matching protocol for the KPDPP. As a result, living donors will have access to more information about the KPDPP.

Expected Impact on Specific Patient Populations

This proposal affects all KPDPP candidates, including specific patient populations. Highly sensitized candidates (46% of all KPDPP candidates) and pediatrics (2%) receive additional points. Since the priority points are not being changed, it is expected that the types of matches found by the optimization algorithm will be similar in terms of candidate characteristics (e.g., CPRA, age, days waiting in KPDPP) as to the distributions shown in the most recently distributed State of the OPTN/UNOS KPDPP report and CMR.

Expected Impact on OPTN Key Goals:

This proposal meets the OPTN Key Goal to “increase the number of transplants” by “increasing the number of organ donors” by “resolving the OPTN’s role in operating a KPD system” and “facilitating matching of willing donor and recipient pairs among different transplant centers.” By including the prioritization points in OPTN/UNOS policy, the KPDPP adheres to its principles of transparency and public participation.

Plan for Evaluating the Proposal:

- **What questions or hypotheses are guiding the evaluation of the proposal?**
  - Is the overall number of matches identified increasing?
  - Is the overall number of transplants increasing?
  - Are match success rates (the probability that a match offer is accepted and leads to a transplant) increasing?
  - Is the OPTN KPDPP continuing to find matches and transplants for highly sensitized patients?
  - How frequently are zero-ABDR mismatches being identified, and are they resulting in transplants?
  - How frequently are pediatrics candidates being entered into match runs, and are these candidates receiving match offers and transplants?
  - How frequently are candidates being identified as prior living donors, and are these candidates receiving match offers and transplants?
  - How frequently are match offers and transplants being found for candidates and matched donors at the same center, same DSA, and same OPTN region?

- **Policy Performance Measures:**

  These questions will continue to be evaluated using updated versions of the ongoing KPD Cumulative Match Report (CMR), particularly the table that shows match rates for candidates by candidate characteristic. Since the priority points are not being changed, the committee expects matches found by optimization algorithm remain similar after this policy change goes into effect. This proposal is not expected to affect match success rate.

- **Time Line for Evaluation:**

  [Exhibit A]
The CMR will continue to be updated at least twice per calendar year. The committee is also actively engaged in evaluating potential future changes to the way matches are prioritized in the KPDPP, through the use of simulation modeling and sensitivity studies.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

If this proposal is approved by the Board of Directors, the policy language will be effective September 1, 2014. On September 1, 2014, the Prioritization Points section of the KPDPP Operational Guidelines will no longer be in effect. This proposal will not require additional programming. Transplant programs seeking waiting time reinstatement for candidates in the KPDPP will follow the waiting time reinstatement process for deceased donor kidney transplant recipients.

**Communication and Education Plan:**

This guidelines to policy effort will continue to be monitored for possible instructional opportunities, in order to give members and professionals an avenue to ask questions and implement processes, if necessary.

Communication & Education Activities

- Policy notice
- E-newsletter/member archive article
- Articles/Guidance

**Compliance Monitoring:**

This proposal will not affect monitoring of OPTN members.
Policy or Bylaw Proposal:

At a meeting of the OPTN/UNOS Board of Directors convened on June 23-24, 2014 in Richmond, Virginia, the following resolution is offered.

A resolution to convert the prioritization points in the KPDPP Operational Guidelines into OPTN/UNOS policy.

Sponsoring Committee: Kidney Transplantation Committee

RESOLVED, that Policy 13.7.E (Prioritization Points) is modified as set forth below, effective September, 1, 2014.

13.7.E OPTN KPD Prioritization Points

Reserved

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

<table>
<thead>
<tr>
<th>If the:</th>
<th>Then the match will receive:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candidate is a 0-ABDR mismatch with the potential donor</td>
<td>200 points</td>
</tr>
<tr>
<td>Candidate has a CPRA greater than or equal to 80%</td>
<td>125 points</td>
</tr>
<tr>
<td>Candidate is a prior living organ donor</td>
<td>150 points</td>
</tr>
<tr>
<td>Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program</td>
<td>100 points</td>
</tr>
<tr>
<td>Candidate and potential donor are registered for the OPTN KPD program in the same region</td>
<td>25 points</td>
</tr>
<tr>
<td>Candidate and potential donor are registered for the OPTN KPD program in the same DSA</td>
<td>25 points</td>
</tr>
<tr>
<td>Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same</td>
<td>25 points</td>
</tr>
<tr>
<td>If the:</td>
<td>Then the match will receive:</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Potential donor has at least one of the other antibody</td>
<td>- 5 points</td>
</tr>
<tr>
<td>specificities reported for the candidate</td>
<td></td>
</tr>
</tbody>
</table>

**13.7.F 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.
Public Comment Responses:
1. Public Comment Distribution
   Date of distribution: 03/16/2012
   Public comment end date: 06/15/2012

<table>
<thead>
<tr>
<th>Public Comment Response Tally</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Response</strong></td>
</tr>
<tr>
<td>Individual</td>
</tr>
<tr>
<td>Regional</td>
</tr>
<tr>
<td>Committee</td>
</tr>
</tbody>
</table>

The voting results displayed above reflect responses to the entire public comment proposal that was distributed in March 2012, and therefore may be misleading. Any comments received during the public comment period pertaining directly to the prioritization points section (13.6.4) of the March 2012 proposal are included below. Refer to the November 2012 Proposal to Establish Kidney Paired Donation (KPD) Policy for complete documentation of public comment feedback. The specific responses to each Region or individual comment are also copied from the November 2012 Proposal to Establish Kidney Paired Donation (KPD) Policy.

2. Regional Public Comment Responses

<table>
<thead>
<tr>
<th>Region</th>
<th>Meeting Date</th>
<th>Motion to Approve as Written</th>
<th>Approved as Amended (see below)</th>
<th>Meeting Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3/26/2012</td>
<td>15 yes, 0 no, 0 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>2</td>
<td>3/30/2012</td>
<td>1 yes, 25 no, 0 abstentions</td>
<td>29 yes, 0 no, 0 abstentions</td>
<td>In Person</td>
</tr>
<tr>
<td>3</td>
<td>5/11/2012</td>
<td>18 yes, 0 no, 0 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>4</td>
<td>5/11/2012</td>
<td>0 yes, 21 no, 0 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>5</td>
<td>5/10/2012</td>
<td>18 yes, 1 no, 0 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>6</td>
<td>5/4/2012</td>
<td>44 yes, 0 no, 0 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>7</td>
<td>6/15/2012</td>
<td>0 yes, 15 no, 1 abstention</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>8</td>
<td>5/11/2012</td>
<td>2 yes, 18 no, 2 abstentions</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>9</td>
<td>5/2/2012</td>
<td>15 yes, 1 no, 1 abstention</td>
<td></td>
<td>In Person</td>
</tr>
<tr>
<td>10</td>
<td>5/4/2012</td>
<td>19 yes, 0 no, 0</td>
<td></td>
<td>In Person</td>
</tr>
</tbody>
</table>
Region 4:
The region did not support this proposal for the following reasons:

Policy 13.6.4 Prioritization Points: Potential donor has at least one of the candidate’s other antibody specificities. -5 Points. Policy 13.10 defines “other antibody specificities” as antigens that may result in a positive or negative crossmatch.

- If this is considered, the effects of multiple weak antibodies should be considered differently from that of only a single weak antibody. This would be complicated programming and could delay implementation of the KPD program. This should be deleted – a specificity is either a contraindication to transplant or not based on the transplant center’s criteria and no software program can be configured for that – it would have to be a transplant center decision based on the actual type of the potential donor. The transplant center should have the option to decide without having points deducted first.
- The region does not believe that the point system should be based off the deceased donor system. The point system for KPD seems arbitrary and doesn’t meet the goals of KPD. For example, the highest number of points given is to zero mismatch candidates. KPD is available to assist candidates who are disadvantaged by the kidney allocation system. If the point system is not redesigned, then the region believes it should be deleted.

Committee Response (in 2012):
In order to maintain flexibility in determining program rules; provide increased efficiency and accurately understand the how prioritization affects program results, the KPD Workgroup recommends Section 13.6.4 Prioritization Points be removed in its entirety from the KPD Policy Proposal; the current prioritization points should remain in guideline format with the following statement added to the guidelines:

The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.

Region 8:
Region 8 did not support moving the OPTN KPD program from a pilot program into policy. The region agreed that prior to creating policy, the pilot program needs to mature and use biology and not points when running a match. In addition, the region agreed that if these policies are implemented it would create another situation where CMS and the OPTN will have different regulations with which centers have to comply.

Committee Response (in 2012):
Committee Response to concerns regarding prioritization points section 13.6.4
In order to maintain flexibility in determining program rules; provide increased efficiency and accurately understand the how prioritization affects program results, the KPD Workgroup
recommends Section 13.6.4 Prioritization Points be removed in its entirety from the KPD Policy Proposal; the current prioritization points should remain in guideline format with the following statement added to the guidelines:

The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.

3. Committee Public Comment Responses

The Committees did not respond with any comments relevant to the Prioritization Points section in the March 2012 proposal.

4. Individual Public Comment Responses

Comment 5:
vote: Oppose
Date Posted: 06/25/2012

ASTS is concerned that it is premature to formulate policy on this magnitude, including MPSC punitive action, given the limited history of this program. We suggest that any final decisions regarding OPTN KPD policy should be postponed until the consensus document from the March 29-30, 2012 KPD conference held in Herndon, VA is released. Additionally, ASTS would support a full formal assessment of the program to date.

OPTN specifically asked for comments to the following questions regarding this proposal:

Is the process for matching participants in the OPTN KPD Program transparent?
There is a table delineating the prioritization points but the policy proposal fails to provide rationale for the variables considered and the point valuation for each characteristic.

Committee Response

Committee Response to concerns regarding prioritization points section 13.6.4
In order to maintain flexibility in determining program rules; provide increased efficiency and accurately understand the how prioritization affects program results, the KPD Workgroup recommends Section 13.6.4 Prioritization Points be removed in its entirety from the KPD Policy Proposal; the current prioritization points should remain in guideline format with the following statement added to the guidelines:

The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.

Comment 6:
vote: Oppose
Date Posted: 06/15/2012

AST Comments:
Is the process for matching participants in the OPTN KPD Program transparent?
While the process for matching is delineated, the AST did not think that the rationale for specifics of the prioritization point assignments were clear and transparent. There is insufficient explanation as to either the characteristics considered (although many are intuitive) or the specific valuation of each characteristic.

Committee Response:
Committee Response to concerns regarding prioritization points section 13.6.4
In order to maintain flexibility in determining program rules; provide increased efficiency and accurately understand the how prioritization affects program results, the KPD Workgroup recommends Section 13.6.4 Prioritization Points be removed in its entirety from the KPD Policy Proposal; the current prioritization points should remain in guideline format with the following statement added to the guidelines:

The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.

Comment 9:
vote: Support
Date Posted: 06/11/2012

Proposal to Establish Kidney Paired Donation (KPD) Policy, (Kidney Transplant Committee)
Response: I agree in principal with the goal of converting the existing OPTN Kidney Paired Donation Pilot Program rules into OPTN policy. However, there are several concerns that must be addressed before these rules become policy…Section 13.6.4, Table 13-2: This table states that if the potential donor has at least one of the candidates other antibody specificities, then 5 points will be deducted from the match. From 13.10 definitions, other antibody specificities is defined as antigens that may result in a positive or negative crossmatch. If this is considered, the effects of multiple weak antibodies should be considered differently from that of only a single weak antibody.

Additionally, an antibody specificity is either a contraindication to transplant or not based on the transplant programs criteria. The candidate transplant program should be able to decide if a donor is acceptable based on the actual type of the donor without having points deducted first. The justifications for the actual numbers of the priority points for each consideration in this table are not included in the proposal. The points should be removed unless justified.

Committee Response:
Committee Response to concerns regarding prioritization points section 13.6.4
In order to maintain flexibility in determining program rules; provide increased efficiency and accurately understand the how prioritization affects program results, the KPD Workgroup recommends Section 13.6.4 Prioritization Points be removed in its entirety from the KPD Policy Proposal; the current prioritization points should remain in guideline format with the following statement added to the guidelines:

The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.
Comment 12:
vote: Support
Date Posted: 06/15/2012
I am a living kidney donor, non-directed, and a physician. I support the proposal. My support is, however, qualified for three reasons. FIRST QUALIFICATION. It is unclear how well this proposal is coordinated with another component in UNOS policy -- specifically, the proposed KPD Policy. How does this proposed OPTN KPD Policy fit in with another proposed OPTN Policy on the priority status of living organ donors (LODs) who develop ESRD and need a kidney transplant? In KPD, every match receives 100 base points, plus additional points awarded for special categories. The points for four categories range from 100 to 200 points, and for three other categories from 25 to 75 points. In the great majority of circumstances, the 4 LOD-points will be swamped by the proposed KPD points, meaning that LODs will have only an insignificant priority regarding KPD matches. I did not see how either proposal coordinated with the other proposal.

Committee Response:
There is currently only one KPD policy proposed and one policy proposed to allow the use of bridge donor in KPD. The deceased door waitlist and the KPD program are two separate and independent programs. The points allotted to prior living donors on the deceased donor waitlist are separate from and will not be affected by prioritization in KPD. KPD priority points only refer to KPD match runs. Kidney transplant candidates can be on both the deceased donor waitlist and in the KPD program (if they have a paired donor).

Comment 15:
vote: Support
Date Posted: 06/14/2012
Response: ASHI agrees in principal with the goal of converting the existing OPTN Kidney Paired Donation Pilot Program rules into OPTN policy. However, there are several concerns that we have identified which we feel must be addressed before these rules become policy. Section 13.6.4, Table 13-2: This table states that if the potential donor has at least one of the candidates other antibody specificities, then 5 points will be deducted from the match. From 13.10 definitions, other antibody specificities is defined as antigens that may result in a positive or negative crossmatch. If this is considered, the effects of multiple weak antibodies should be considered differently from that of only a single weak antibody. Additionally, an antibody specificity is either a contraindication to transplant or not based on the transplant programs criteria. The candidate transplant program should be able to decide if a donor is acceptable based on the actual type of the donor without having points deducted first. The justifications for the actual numbers of the priority points for each consideration in this table are not included in the proposal. The points should be removed unless justified.

Committee Response:
Committee Response to concerns regarding histocompatibility requirements in Sections 13.5 and 13.6
The recommended histocompatibility changes to policy language would have significant impact on auditable requirements for transplant centers and histocompatibility labs. The KPD Workgroup and Kidney Committee have reviewed the feedback and will make policy language revisions for a future public comment cycle so that the entire community will have the opportunity to review the changes and provide feedback prior to implementing new requirements. In the meantime, UNOS will recommend that transplant centers follow the
Histocompatibility guidelines developed at the KPD Consensus Conference in March 2012, once they are available.

Post Public Comment Consideration:

In response to public comment, the Kidney Committee stated “The KPD Workgroup and Kidney Transplantation Committee will evaluate, in real time, the current prioritization point system, as well as investigate and test alternative algorithms and matching methods for improving the matching of pairs. Adjustments to the system will be recommended based on the results of testing and evaluation.” After the public comment period ended, two significant events occurred: (1) the KPD Consensus Conference published its meeting report and findings; and (2) the KPD Workgroup formed the Design and Optimization Algorithm Subcommittee (DOAS).

Findings of the KPD Consensus Conference

During the spring 2012 public comment period, a KPD Consensus Conference convened “to address the dynamic challenges and complexities of KPD that inhibit optimal implementation.” The KPD Consensus Conference did not arrive at a unified recommendation regarding the preferred method for matching candidates in any KPD program, stating “as yet, there is no consensus regarding the ‘best’ KPD matching strategy.” The Consensus Conference noted that in optimization systems, such as the one utilized by the KPDPP, “points values should not be arbitrarily assigned but reflect true biological effects…priorities for reducing distance between centers and prioritizing same center matches could be incorporated but should be deemphasized…”

DOAS

Since 2012, the KPD Workgroup and DOAS have met regularly to determine the type of prioritization system that should be used for the KPDPP matching system. The mission statement for DOAS is “to explore refinements to the design of and optimization algorithms used in the OPTN KPDPP to incentivize maximal participation, reduce match failure rates, promote fairness, and increase the overall effectiveness of the Program.”

DOAS hopes to identify ways of improving the KPDPP match run process by providing incentives to transplant centers to participate while decreasing the rate of declined match offers. Part of this work includes reviewing the current prioritization points to determine whether and how to improve them. Members of DOAS are performing simulation studies that may ultimately lead to an entire revamping of the current matching system, including both the priority points as well as the optimization algorithm. For example, the committee is evaluating the benefits of moving to a more “dynamic” approach to optimization that takes into account the anticipated future size and composition of the candidate and donor pool instead of myopically maximizing the number and/or quality of matches in just the current match run.

DOAS’s work is not yet complete. Even though work is underway to refine or replace the current point system, converting the existing points to policy in the interim will fill a gap in OPTN KPD policy, which is currently silent with respect to prioritizing matches. Filling this gap, and eventually transitioning completely from operational guidelines to OPTN policies, will align the KPDPP with the OPTN’s commitment to transparency, public involvement, and stability; future changes will require the policy development process including committee deliberation, public comment, and Board approval.

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KPD Work Group and Kidney Committee Proposal

The KPDWG evaluated the priority points as they were proposed in March 2012 and determined that they should be incorporated into OPTN policy as written, acknowledging that changes are needed and work should continue to develop a proposal for improving the way matches are prioritized. The current proposed policy language is already programmed in the KPD system, so no additional UNOS IT resources are required because of this proposal. Further, this proposal more clearly states the policy for waiting time accrual and reinstatement in KPDPP compared to the current operational guidelines.

In response to the suggestion from Region 4 to consider “the effects of multiple weak antibodies” differently from single weak antibodies, the KPDWG and DOAS are actively evaluating potential changes to the prioritization point schedule and matching algorithm, including eliminating the -5 points when one or more “other antibody specificities” are listed. In addition, since the March 2012 public comment period, a donor pre-select tool has been developed and implemented, with the primary goal of allowing centers to review the HLA antigen profile of donors that could potentially match with their candidates and either pre-accept or pre-refuse the donor.

Other changes actively being investigated by the KPDWG and DOAS for potential inclusion in a future proposal include, but are not limited to, the following:

- Awarding CPRA points in a way more aligned with the biology of allosensitization, where difficulty in finding a compatible donor increases substantially and nonlinearly as CPRA approaches 100%. A sliding scale similar in concept to the one adopted for deceased kidney allocation has been proposed and will be evaluated.
- Removing or reducing points for 0-ABDR mismatches
- Changing or removing points for geographic proximity (changing points for same center matches while removing points for same DSA and regional matches, as donor organs are predominately shipped between transplant centers)
- Awarding points based on candidate and/or paired donor’s blood type
- Awarding points based on combination of candidate and paired donor blood types
- Awarding priority to candidates whose donor previously donated but who did not receive a kidney in return due to a transportation failure or other reason
- Changing the optimization algorithm to consider future matching potential instead of solely optimizing with respect to the current pool of candidates and donors
- Changing the optimization algorithm such that it takes into account the likelihood of each match being accepted, having a negative crossmatch, and resulting in a transplant

This proposal also brings to the attention of the Board of Directors a minor, inconsequential discrepancy between this proposed policy language and the priority points currently in KPDPP Operational Guidelines. The Operational Guidelines state that every candidate/donor match receives 200 base points, while the March 2012 proposal prescribes 100 base points for each match. Currently, the KPDPP system is programmed to use 100 points. Since awarding 100 versus 200 points for each match is immaterial as it will not affect results of the optimization, the current proposal gives each match 100 base points, in agreement with current programming.

The proposal also changes the phrasing in the March 2012 proposal and Operational Guidelines from “zero antigen mismatch” to “0-ABDR mismatch.” Zero-ABDR mismatch more accurately reflects how the system currently operates, since only the A, B, and DR loci are considered when determining whether a match is eligible for the 200 points due to HLA matching.
This proposal also clarifies how points are assigned due to geographic proximity. While the March 2012 proposal and the Operational Guidelines both state that 75 points are awarded for same-center matches, 50 for same DSA, and 25 for same region, expressing the priorities in this way led to ambiguity, since a same-center match is also same-DSA and same-region. It was unclear to members whether a same-center match should get 75 points (correct) or 75 + 50 + 25=150 points (incorrect). As with the other priority points in Table 13.2, in which the same match can be awarded multiple point values (e.g., 200 for 0-ABDR mismatch + 125 for CPRA>=80% candidate), one, two, or all three geographic proximity points (25 points each) can be awarded to a single match, if applicable. For example, a match is awarded 75 points if the candidate and matched donor were registered at the same center: 25 for being in the same region, 25 for being in the same DSA, and 25 for being at the same center.

The KPDWG voted on March 25, 2014 to recommend to the Kidney Committee to put the prioritization points and waiting time reinstatement proposal into policy. (9 approved; 0 opposed; 0 abstained). The Kidney Committee voted on April 7, 2014 to recommend to the Board of Directors to put the priority points into policy (20 approved; 0 opposed; 0 abstained).
Exhibit A

KP DPP Operational Guidelines (version 6.0, effective December 12, 2013)

Prioritization Points

1. Purpose: To describe the candidate characteristics and the match characteristics that receive priority or additional points in the Kidney Paired Donation Pilot Program

2. Procedures:
   a. Each match between a candidate and potential living donor receives a base of 200 points.
   b. Zero antigen mismatches between a potential living donor and a candidate receive an additional 200 points.
   c. Highly sensitized (e.g., probability of positive crossmatch ≥ 80%) candidates receive an additional 125 points.
   d. Candidates who are prior living organ donors receive an additional 150 points.
   e. Pediatric (i.e., age < 18 years) candidates receive an additional 100 points.
   f. Candidates entered in the OPTN KPD Pilot Program receive 0.07 points per day beginning on the day the candidate is added to the OPTN KPD Pilot Program.
   g. Matches between candidates and potential living donors who are in the same region receive 25 points in addition to the base number of points.
   h. Matches between candidates and potential living donors who are in the same donation service area (DSA) receive 50 points in addition to the base number of points.
   i. Matches between candidates and potential living donors who are located at the same center receive 75 points in addition to the base number of points.
   j. Matches between candidates and donors who have one or more of the candidate’s other antibody specificities receive -5 points.
   k. The waiting list candidate and the non-directed donor in a donor chain will be assigned no points.
Appendix A

Priority Points Proposal from March 2012 Proposal to Establish Kidney Paired Donation (KPD) Policy

13.6.4 Prioritization Points
The OPTN Contractor will identify all possible matches and exchanges from the list of potential donors and candidates, assign points to each match according to Table 13-2, and select the set of exchanges with the highest point values.

All OPTN KPD Program matches receive 100 base points. Matches will receive additional points as described in Table 13-2.

Table 13-2: KPD Points

<table>
<thead>
<tr>
<th>If the:</th>
<th>Then, the match will receive:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candidate is a zero antigen mismatch with a potential donor</td>
<td>200 points</td>
</tr>
<tr>
<td>Candidate is highly sensitized</td>
<td>125 points</td>
</tr>
<tr>
<td>Candidate is a prior living organ donor</td>
<td>150 points</td>
</tr>
<tr>
<td>Candidate is aged less than 18 years</td>
<td>100 points</td>
</tr>
<tr>
<td>Candidate is entered in the OPTN KPD Program at the time of the match run</td>
<td>0.07 points per day in the OPTN KPD program</td>
</tr>
<tr>
<td>Candidate and potential donor are in the same region</td>
<td>25 points</td>
</tr>
<tr>
<td>Candidate and potential donor are in the same local unit</td>
<td>50 points</td>
</tr>
<tr>
<td>Candidate and potential donor are registered at the same Transplant Hospital</td>
<td>75 points</td>
</tr>
<tr>
<td>Potential donor has at least one of the candidate’s other antibody specificities</td>
<td>- 5 points</td>
</tr>
</tbody>
</table>

KPD waiting time begins on the day the candidate’s Transplant Hospital enters the candidate in the OPTN KPD Program. A candidate will accrue KPD waiting at both an active and an inactive status in the OPTN KPD Program.

The OPTN Contractor will reinstate KPD waiting time, without interruption, to KPD candidates when immediate and permanent non-function of the kidney occurs within 90 days of any kidney transplant, as evidenced by one of the following:

- The removal of the organ
- Dialysis treatment 90 days after transplant
- Creatinine clearance (CrCl) or calculated Glomerular filtration rate (GFR) less than or equal to 20 ml/min 90 days after transplant.

The OPTN Contractor will reinstate KPD waiting time after receiving a completed KPD waiting time reinstatement form and will notify the candidate’s Transplant Hospital of the candidate’s KPD waiting time reinstatement.
KPD Program Permanency
May 16, 2014

We are pleased to present this report to the OPTN/UNOS Board of Directors. The Board is asked to approve the removal of the “pilot” label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP), based on the progress of the program since its first match run in October, 2010 as described below.

The vision of the program is that every kidney transplant candidate with an incompatible but willing and approved living donor receives a living donor kidney transplant. To that end, the first match run was conducted in late 2010. Through March 31, 2014, 88 patients received a life-saving kidney transplant through the program. In 2013 alone, 52 patients were transplanted, a 246% increase over the previous high of 15 in 2011.

![Figure 1. OPTN/UNOS KPDPP Transplants per Year](image)

It is particularly encouraging to see that the KPDPP increased transplant opportunities for candidates who tend to have difficulty finding a match on the deceased donor waiting list. More than a quarter of the candidates who received a kidney through the program had a calculated panel reactive antibody (CPRA) of 80% or higher (Figure 9), including 15 recipients with a CPRA of at least 95%. In addition, nearly 300 minority candidates have participated in KPDPP match runs, and minorities comprise one third of KPDPP transplant recipients (Figure 8).

We appreciate the dedicated transplant teams at 138 kidney programs (61% of the U.S. living donor kidney programs) who agreed to participate in the KPDPP (Figure 2). We especially appreciate the hundreds of individuals who contributed their expertise, time and attention to improving the program by serving on committees, finding solutions to problems, and providing valuable feedback in surveys. Most importantly, we owe a debt of gratitude to the living donors who are willing to donate a kidney to a loved one, friend, or someone they don’t even know, through our program or any other. They are the heroes that save lives.

During the past three years, we developed an increasingly user-friendly, online KPD system that is integrated with UNet™, the computer system that manages the deceased donor waiting list. Candidate and donor data are shared among transplant programs to facilitate kidney exchanges, allowing users to view and respond to match offers and to see the donor information in one place. We continue to solicit and respond to user recommendations to make further system improvements.
The program was originally governed solely by operational guidelines. The first KPDPP policies were approved by the OPTN Board of Directors in November 2012 and implemented in February 2013. At that time, many of the operational guidelines were converted to policy. The KPD Work Group, under the OPTN Kidney Transplantation Committee, continues this conversion, with several policy proposals planned for 2014 and 2015. The program will be governed by both policy and operational guidelines until the transition is complete.

Several subcommittees have worked to improve KPDPP processes:

- The Finance Subcommittee developed financial tools to help transplant hospitals work through billing and paying for a KPD kidney that is recovered at one institution and transplanted at another. The tools include financial recommendations, a template contract and a financial checklist.
- The Histocompatibility Advisory Subcommittee developed KPD histocompatibility policies to improve the KPD system by decreasing the match offer decline rate related to unacceptable antigens. They routinely review the decline reasons related to HLA antibodies and continuously evaluate the policies to promote process improvement.
- The Design and Optimization Algorithm Subcommittee is evaluating alternative matching algorithms to optimize match pair efficiencies in order to increase the number of transplants. The subcommittee also ensures that both easy and difficult-to-match patients have access to matching opportunities.

To assist the potential donors and candidates who are considering KPD as an option, we are creating an educational video and expanding online resources for patients, donors, and transplant professionals.

We welcome the remaining living donor kidney transplant hospitals to participate in the KPDPP and to suggest system improvements to optimize all aspects of the program. We look forward to continuing to help transplant candidates receive the gift of life through kidney paired donation.

Sincerely on behalf of the OPTN/UNOS KPD Work Group,

Mark Aeder, M.D.
Chair
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Participating Transplant Programs

Of the 228\(^1\) active U.S. kidney programs approved to perform living donor transplants in the U.S., 138 (61%) agreed to participate in the KPDPP, and 98 programs entered at least one donor/candidate pair into a match run (Figure 2). In early 2010, an initial wave of 69 transplant programs agreed to participate by way of four coordinating programs, central hubs that provided data directly to UNOS to operate the program. Fifteen “early adopter” programs provided data on a total of 43 pairs that were included in the very first match run on October 28, 2010, leading to matching opportunities for seven patients. By mid-2011, a “critical mass” of 45 programs had entered match run-eligible pairs into the system, resulting in a pool of well over 100 donors and candidates in each match run. Since then the number of candidates entered has steadily increased.

Figure 2: Trends in Participation
As of March 21, 2014

\(^1\) Includes all kidney transplant programs with active OPTN membership status, active living donor program status, and active deceased kidney program status, as of March 21, 2014.
The number of candidates entered into the system varies greatly among participating hospitals. Since 2010, one program entered 85 match run-eligible candidates (along with their paired donors), or 9% of the total of 904 match run-eligible candidates. The eight most actively participating programs account for 39% of the total number of candidates entered, while half of participating programs entered at least six candidates (Figure 3).

As the OPTN continues to encourage additional living kidney donor programs to join the pilot program, it also seeks ways to incentivize programs to enter all of their candidate/donor pairs, not just hard-to-match pairs, to create more matching opportunities for all participants.

Figure 3: Number of Match Run-Eligible\(^2\) Candidates per Program
As of March 21, 2014

\(^2\) A candidate can be entered into the KPDPP without being match run eligible. To be match run-eligible, a candidate must have all required data elements entered and be set to “active” status in the KPD system.
Candidates and Donors Added to the KPD System

On average, 25.2 candidates were added to the program each month since October 2010. In the first quarter of 2014, there were an average monthly addition of over 28, reflecting the continued growth of the KPDPP. In total, 1,046 candidates were added as of March 31, 2014. A total of 1,135 donors were added, including 52 non-directed donors (NDDs). An NDD is a donor who enters the program without a paired candidate, with the intent of starting an NDD chain.

Figure 4: Number of Candidates Added, by Month
Through March 31, 2014

While most candidates entered the program with one paired donor, some candidates had more than one donor. 

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3 While most candidates entered the program with one paired donor, some candidates had more than one donor.
Match Run Participation

Coinciding with the steady growth in participating programs, the number of candidate-donor pairs eligible for each match run increased dramatically since KPDPP initiation (Figure 5). In late 2010, the candidate-donor pool consisted of less than 50 pairs available for matching. By 2013, more than 200 candidates and donors were consistently entered into each weekly match run. In the first quarter of 2014, the numbers had grown to average 247 donors and 235 candidates per match run, and recently a record 270 donors and 256 candidates were included in the match run on April 21, 2014.

Despite the overall increasing trends, the number of non-directed donors (NDDs) eligible for match runs declined in recent months. NDD chains are an especially powerful way to uncover matching opportunities for a large number of patients because chains operate in one direction, without requiring a match to be found to “close the loop,” as in two-way and three-way exchanges. The KPD Work Group continues to explore ways to encourage programs to enter NDDs into the system, including providing the option of bridge donation. In bridge donation, a paired donor at the end of a chain can opt to become a non-directed donor in a future match run, turning a short chain into a potentially much longer chain that will result in more patients receiving transplants (Figure 5).

Figure 5: Average Number of Eligible Candidates and Donors per Match Run

Trends in Matching Opportunities

A growing pool of candidates and donors eligible for match runs (Figure 5), the introduction of non-directed donor (NDD) chains, and the switch in 2012 from monthly to weekly match runs have led to substantial increases in the number of donor-candidate matches found over time (Figure 6). In March

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4 To be match run eligible, a candidate must have all required data elements entered and be set to “active” status in the KPD system.
2014, 47 matches were identified. Through the first quarter of 2014, an average of 44 match offers were sent per month, a 22% increase over 2013. Since 2010, over 1,000 match offers were sent to participating transplant programs.

Figure 6: Matches Found per Month

Relatively few (10%) of the matches found in the KPDPP have been from two-way exchanges, while three-way exchanges (45%) and NDD chains (45%) have together accounted for the majority of matches (Figure 7).

Figure 7: Matches Found, by Exchange Type
Characteristics of Candidates and Transplant Recipients

Nearly 70% of the 904 total KPDPP candidates were white, 15% black, 10% Hispanic, and 5% Asian. The race/ethnicity distribution of the 88 KPDPP transplant recipients is fairly similar to that of candidates entered into the program, with 65% of recipients having been white (Figure 8).

While nearly 60% of candidates had blood type O, only 31% of recipients had this most difficult to match blood type. Blood type O candidates tend to be more difficult to match since they are generally only compatible with other blood type O donors. Blood type B candidates are also often difficult to match. However, while blood type B candidates represented only 15% of candidates, they accounted for 24% of the transplants facilitated thus far through the KPDPP (Figure 8).

Figure 8: Characteristics of Match Run-Eligible Candidates and Recipients (Blood Type, Race/Ethnicity)
Through March 31, 2014
Transplant programs representing all 11 OPTN regions had candidates participate in OPTN KPDPP match runs. Programs in Region 2 contributed the most candidates (27%), followed by Region 7 (14%) and Region 1 (12%). At least one of the 88 transplants performed thus far through the KPDPP occurred in each region. (Figure 9)

The average age\(^5\) of the 904 participating candidates was 47.3 years, with 37.4% in the 50-64 age group. Only 2% of the candidates were pediatric. The age distribution of patients transplanted through the program is fairly similar to the age distribution of participating candidates, although a moderately higher percentage of the recipients (19.3%) compared to candidates (11.7%) have been age 65 or older.

Only 30% of KPDPP candidates had a CPRA\(^6\) of zero, whereas 46.2% had CPRA of 80% or greater. Over a quarter of candidates were extremely sensitized, having a CPRA of at least 98%. Though these patients are more difficult to match, 32% (n=28) of the transplants facilitated thus far were for CPRA ≥ 80% patients and 17.1% (n=15) of recipients had a CPRA of 98% or higher. Finding transplants for difficult-to-match patients has been one of the goals of the KPDPP and we are encouraged by these successes.

On average, candidates waited 507 days (about 1 year and 4 months) on the deceased donor waitlist\(^7\) before entering the KPDPP. The distribution of time on the deceased donor waitlist is fairly similar for candidates and recipients.

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\(^5\) Candidate age as of first KPDPP match run; recipient age as of transplant date.
\(^6\) Candidate CPRA as of first KPDPP match run; recipient CPRA as of the match run that led to transplant or at time of waiting list removal for chain-closing waiting list recipients.
\(^7\) Candidate and recipient time on waiting list = date candidate added to KPDPP minus date candidate added to waiting list; chain-closing recipient time on waiting list = transplant date minus date candidate added to waiting list.
Figure 9: Characteristics of Match Run-Eligible Candidates and Recipients (Region, Age, CPRA, Time on Deceased Donor Waitlist) Through March 31, 2014
KPDPP Participation by OPTN Region

More than one kidney transplant program from each of the 11 OPTN regions signed the agreement to participate in the KPDPP. In Region 8, all 11 programs have signed up, and 14 out of 15 in Region 1. Region 2 entered 245 match run-eligible candidates into the system, more than any other region and over a quarter of the total number of candidates entered.

KPDPP transplants occurred in all 11 OPTN regions. Programs in Region 2 performed the most transplants (N=19, 22% of KPDPP transplants) followed by Region 1 (N=18, 20%). More than 75% of the 88 total transplants resulted from interregional exchanges.

Figure 10: Participating Programs, Match Run-Eligible Candidates, and Transplants by OPTN Region
Through March 31, 2014

Figure 7 Key
# programs participating in KPDPP (of 228 total active living kidney donor programs)
# KPDPP candidates (% of total 904 KPDPP candidates)
# KPDPP transplants (% of total 88 KPDPP transplants)
Characteristics of Participating vs. Actual Donors

The race/ethnicity distribution of match run-eligible donors participating in the KPDPP (Figure 11) is very similar to the distribution of candidates (shown previously in Figure 8). About 70% of participating donors were white, and about 30% were minorities. While 11% of the participating donors were black, 18% of the donors that actually donated through the KPDPP were black.

Blood types of participating donors (Figure 11) are notably different from those of participating candidates (Figure 8). While nearly 60% of candidates had blood type O, only 34% of donors had blood type O. In general, blood type O candidates are the most difficult to match, since they are only compatible with type O donors. Type O donors are the easiest to match, since they are compatible with all blood types. However, despite the disproportion in blood type O donors and candidates, as well as the high percentage of candidates having a CPRA of 98% or above (Figure 9), the KDPPP still finds more than 40 matches per month (Figure 6) due to a steadily growing participant pool (Figure 5).

Though only 17% of participating donors are blood type B donors, they accounted for nearly a quarter of the donations. Of the 435 participating blood type A donors, only two have been reported as having a non-A1 (e.g., “A2”) subtype. Though non-A1 donors are compatible with blood group B and O candidates, so far few such candidates have been reported as both willing and medically eligible to receive non-A1 subtype-compatible match offers.

Figure 11: Characteristics of Participating vs. Actual Donors
Through March 31, 2014
Transplants by Year

The annual number of transplants facilitated by the KPDPP surged to 52 in 2013 from 10 the prior year and a previous high of 15 in 2011 (Figure 12). Through the first three months of 2014, an additional 9 transplants occurred, bringing the total since inception to 88.

Several factors contributed to the dramatic increase in 2013, including more matches found (Figure 6), coupled with an improved match success rate. The match success rate - the percentage of match offers resulting in a transplant – was less than 3% for much of 2012 but jumped to 12% in 2013. To increase match success rates, an online tool that allows participating programs to “pre-accept” or “pre-refuse” donors that could potentially match to their candidates was implemented in early 2013.

Common reasons for matches not resulting in a transplant include unacceptable donor antigens, unexpected positive cross-matches, and the candidate being involved in an exchange through another KPD program. The KPD Work Group and its Histocompatibility Advisory Subcommittee continue to evaluate interventions that can increase the likelihood of matches becoming transplants.

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Figure 12: Transplants in the KPDPP

*Through March 31, 2014*

Total: 88 transplants

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8 Based on KPDPP match runs from January 1, 2013 - December 2, 2013.
**Time to Transplant after Entering KPDPP**

**Figure 13** shows outcomes for match run-eligible candidates from 0 to 540 days after being added to the KPDPP. The cumulative percentage of candidates reaching each possible outcome by 12 and 18 months is highlighted.

By 18 months, 53% received a transplant in one of four different ways: through the KPDPP (10%); through another KPD program (21%); from a non-KPD living donor transplant (11%); or from a deceased donor transplant (11%).

Less than 1% of patients were removed due to death, 11% were removed from the KPDPP for another reason, and 35% of candidates were still waiting for a transplant after 18 months.

**Figure 13: Time to Transplant (or Other Outcome\(^9\)) for Candidates Added to the KPDPP**

*Includes Match Run-Eligible Patients Added to the KPDPP\(^10\) from Jan 1, 2012 - Nov 22, 2013*

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\(^9\) Cumulative incidence curves shown in Figure 13 were derived using competing risks methodology for time-to-event data.

\(^10\) Based on OPTN KPDPP data as of November 30, 2013.
Time to Transplant for Recipients

Candidates receiving a kidney transplant through the KPDPP waited a median of 185 days\textsuperscript{11} in the system before the transplant. Figure 14 illustrates that the waiting times among recipients varied greatly from patient to patient. Although a few recipients waited nearly three years before their KPDPP transplant, 42\% were transplanted after waiting for less than six months.

Thirteen (14.8\%) recipients benefited from the KPDPP by receiving a transplant without having been entered into the program. These transplants, which are shown as zeroes in Figure 14, happened as a result of chains that began with a non-directed donor (NDD) and ended with a patient on the deceased donor waitlist at the transplant hospital that entered the NDD.

\textbf{Figure 14: Time Waiting in the KPDPP System for Transplant Recipients Through March 31, 2014}

\textsuperscript{11} This “median waiting time” estimate must be interpreted carefully since it only includes those KPDPP candidates that actually received a transplant through the program. Figure 14 is intended to be interpreted in conjunction with the results shown in Figure 13.
Time between Match Run and Transplant Surgery

For the 88 recipients transplanted through the KPDPP, the median time between finding the match and performing the transplant was 71 days. This time lag was primarily due to logistics, such as sending samples for testing, performing cross-matches, financial complexities, and scheduling OR dates, but it was also affected by acute changes in a candidate’s or a donor’s health. The lag time decreased from 91 days in the first few years of the KPDPP to just 65 days in 2014 (Figure 15). The maximum number of days between finding a match and proceeding to transplant also sharply declined.

The KPD Work Group continues to pursue ways to further reduce the time lag from match offer to transplant. The KPDPP operational guidelines were recently updated to include required timelines for responding to match offers, providing matched donor information, sending test kits and running cross-matches.

Figure 15: Time from Match Run to Transplant
Through March 31, 2014
Kidney Function after Transplant

Of the 83 KPDPP transplants with available data, only two recipients (2.4%) experienced delayed graft function (DGF), defined as requiring dialysis within a week of the transplant. By comparison, 3.1% of other living donor transplant recipients and nearly 25% of deceased donor recipients experienced DGF during this same time period (October 2010 through February 2014).

So far, only one graft failure within six months of the transplant was reported. Figure 16 shows that the estimated six-month graft survival rate for KPDPP transplants is 98.8%, compared to 98.1% for all other living donor kidney transplants and 95.1% for deceased donor kidney transplants. The graft survival curve for KPDPP transplants is statistically no different from other living donor transplants (p=0.58), despite a median cold ischemic time of eight hours in the KPDPP (primarily due to shipping donor kidneys to the recipient center) compared to just one hour for all other living donor transplants.13

Figure 16: Six-Month Kidney Graft Survival Rate14 Comparison
Includes Kidney Transplants Performed October 2010 – February 2013

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12 Difference in DGF rates for KPDPP vs. other living donor transplants is not statistically significant (p-value=0.69, per likelihood ratio chi-squared test).

13 P-value for difference in graft survival curves is based on the log-rank test.

14 Kaplan-Meier graft survival curves estimated using kidney transplants with a validated Transplant Recipient Registration (TRR) form. Thus, some transplant recipients in this cohort had less than six months of follow-up, yet this graft survival time can still contribute to the Kaplan-Meier survival estimates. Patient death, as well as graft failure without patient death, were both considered to be a graft failure. Multi-organ transplants were excluded from deceased donor transplant analysis.
Automated Solution

The KPDPP automated solution rolled out in three phases, with the first release December 2011 and the final release February 2014. Features of the system include:

- User friendly, intuitive data entry system
- Ability of transplant programs to manage their pairs and create reports
- Ability for transplant programs to view and respond to match offers in UNet\textsuperscript{SM}
- Automated match offer emails sent to primary contacts at transplant programs
- Center-specific dashboards
- Donor pre-selection

The KPD Work Group is in the process of prioritizing future enhancements to the KPD system, such as a message board to help facilitate inter-hospital communication. Future enhancements will be prioritized individually in the overall OPTN/UNOS IT queue, and will follow the process for programming changes required for other applications in UNet\textsuperscript{SM} (Waitlist\textsuperscript{SM}, DonorNet®, TIEDI®).
Costs

Staff from many departments at UNOS, including Research, IT, Communications, Instructional Innovations, and Policy, dedicate time to KPD. Some of these staff were involved in operating the manual KPD solution. Now that an automated solution has been implemented, the level of staffing needed from these departments has decreased. There is no plan to increase the time allocated to KPD from these departments.

One full time equivalent (FTE) program manager was hired in July 2011 and another half-time KPD coordinator has recently been added. The KPD coordinator operates within the Organ Center and assists the program manager with the daily operations of facilitating KPD match offers. These staffing levels are sufficient for the near future given the current levels of KPD transplants. As the number of match offers and transplants increases, it will be necessary to reevaluate the level of staffing necessary to coordinate the match offers and transplants.

Resolution

The Board is asked to approve the removal of the “pilot” label from the OPTN/UNOS Kidney Paired Donation Pilot Program, based on the progress of the program since its first match run in October, 2010 as described in this State of KPD report. Removal of the pilot label reflects the stability and success of the OPTN/UNOS KPD program, and symbolizes the OPTN’s commitment to continue to meet the demand for kidney transplants by providing another method of identifying and matching kidney transplant candidates with donors.

RESOLVED, that the pilot label is removed from the OPTN/UNOS Kidney Paired Donation Pilot Program, and the program is a permanent function of the OPTN, effective pending HRSA’s approval.
Informed Consent for Participants in Kidney Paired Donation
Recommended Policy from the AST/ASTS/NATCO/UNOS Joint Societies Working Group

Introduction

In March, 2012, the Kidney Transplantation Committee distributed the OPTN/UNOS Kidney Paired Donation (KPD) Policy proposal for public comment. The informed consent sections of the policy proposal, 13.3 (Informed Consent for Candidates) and 13.4 (Informed Consent for Potential Donors), were removed from the proposal before it was presented to and approved by the OPTN/UNOS Board of Directors in November 2012. In December, 2012, the Joint Society Policy Steering Group formed a Joint Societies Policy Working Group (JSWG) to review the informed consent elements removed from the KPD proposal, and to provide recommendations for KPD informed consent policy. The individuals appointed to represent the societies and the OPTN/UNOS Kidney Transplantation Committee are:

1) AST: Elisa Gordon, PhD, MPH; Eric Gibney, MD; and Steven Katznelson, MD
2) ASTS: Stuart Flechner, MD FACS; Lloyd Ratner, MD; and Peter Abt, MD
3) NATCO: Patricia McDonough, RN, CCTC, CPTC; and Marian Charlton, RN, CCTC
4) OPTN/UNOS: Matthew Cooper, MD; Mary Amanda Dew, PhD; and Janet Hiller, RN, MSN

The charge of the JSWG was to “provide recommendations to OPTN/UNOS regarding the development of informed consent policies for paired donors, candidates and non-directed donors entering the OPTN/UNOS KPD program. The KPD JSWG should provide recommendations regarding the risks and benefits of participating in the KPD program, the KPD matching process, and confidentiality and sharing of protected health information. The KPD informed consent policies are being developed in addition to existing informed consent policies that already apply to all candidates and living donors.”

During its initial teleconference, the JSWG elected Dr. Stuart Flechner as the Chair. The JSWG carried out its charge over a series of teleconferences spanning from January, 2013 to October, 2013. HRSA representatives were invited to participate on every teleconference. The JSWG used the proposed policy language that was distributed for public comment in March, 2012 as the starting point. The structure and content of the March, 2012 proposed language remains largely the same, with some notable modifications:

1) The JSWG recommends expanding the scope of informed consent policy to apply to all KPD programs
2) The JSWG recommends each KPD program prioritizes candidates if they do not receive a kidney from their matched donor due to certain unforeseen circumstances
3) The JSWG recommends removing the requirement that a bridge donor must verbally consent to continue as a bridge donor every three months, and instead suggests permitting the bridge donor to assert the amount of time he or she is willing to wait
4) The JSWG recommends requiring the recovery hospital to provide non-directed donors (NDDs) with the matched recipient’s hospital’s national and program-specific recipient outcomes upon identification of the matched recipient
5) The JSWG recommends advising both the KPD donor and recipient of the inherent risks in "shipping" kidneys between transplant centers

The JSWG’s recommended informed consent policies are included below in the “Recommended Policy” section. Specific policy numbers align with the version of OPTN/UNOS
policy current as of October 9, 2013. Please note, Policy 12 is current, Board-approved policy, so proposed changes to Policy 12 are underlined. Policies 13.3 and 13.4 are entirely proposed language, as none of it has been approved by the Board. Rationale explaining significant changes to the original proposal is included below in the “Discussion” section.
### 12.2 Informed Consent of Living Kidney Donors.

**Living Kidney Donor Consent**

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

<table>
<thead>
<tr>
<th>If the recovery hospital and the recipient hospital...</th>
<th>Then...</th>
<th>Including all the following information...</th>
</tr>
</thead>
</table>
| Are the same                                           | The recovery hospital must provide the potential donor with both national and that hospital’s program-specific transplant recipient outcomes from the most recent SRTR center-specific reports. | 1. National 1-year patient graft survival  
2. The hospital’s 1-year patient and graft survival  
3. Notification about all CMS outcome requirements not being met by the transplant hospital |
| Will not be the same and the recipient hospital is known | The recovery hospital must provide the potential donor with both national and the recipient hospital’s program-specific transplant recipient outcomes from the most recent SRTR center-specific reports. | 1. National 1-year patient and graft survival  
2. The recipient hospital’s 1-year patient and graft survival  
3. Notification about all CMS outcome requirements not being met by the recipient hospital |
| Will not be the same, and the recipient hospital is not known | Upon identification of the matched recipient, the recovery hospital must provide the potential donor with both the national and the recipient hospital’s program-specific transplant recipient outcomes from the most recent SRTR center-specific reports. | 1. National 1-year patient and graft survival  
2. The recipient hospital’s 1-year patient and graft survival  
3. Notification about all CMS outcome requirements not being met by the recipient hospital |
13.3 Informed Consent for Candidates

13.3.1 Release of Protected Health Information

The recipient transplant hospital must obtain written consent from the KPD candidate to share protected health information (PHI) with other members participating in KPD. The written consent must allow the KPD program to share the candidate’s PHI with the recovery hospital of the candidate’s matched potential donor. The recipient transplant hospital must maintain documentation of this consent in the candidate’s medical record.

13.3.2 Consent to Participate

The recipient transplant hospital must obtain written consent from the candidate to participate in KPD, and must maintain documentation of this consent in the candidate’s medical record.

13.3.3 Agreement to Accept a Shipped Kidney

The recipient transplant hospital must obtain written consent from the candidate to receive a shipped kidney for the candidate.

The recipient transplant hospital must maintain documentation in the candidate’s medical record that the candidate has been informed that the donor’s kidney could be lost in transport, and that greater ischemic time could create a greater incidence of delayed graft function or need for dialysis.

13.3.4 Prioritization of Candidates with a Failed Kidney Exchange

If a candidate’s paired donor donates, but the candidate is not transplanted for the following reasons:

- Problems in organ recovery
- Problems in organ transportation
- The KPD matched donor has opted out

Then the candidate will receive high priority within that KPD program to receive a kidney from the first available non-directed donor or donor chain, until a suitable donor is found.

13.4 Informed Consent for Potential Donors

13.4.1 General Potential Donor Informed Consent

For any KPD exchange, the transplant hospital registering the potential KPD donor is responsible for obtaining and documenting informed consent from the potential KPD donor as required in Policy 12.2 (Informed Consent of Living Kidney Donors). If a different transplant hospital performs the organ recovery, the recovery hospital must also comply with Policy 12.2.

13.4.2 Release of Protected Health Information (PHI)
The transplant hospital registering the potential KPD donor must obtain written consent from the potential KPD donor to share PHI with other members participating in KPD. The release must allow the KPD program to share the potential donor’s PHI with the recipient transplant hospital. The transplant hospital registering the potential KPD donor must maintain documentation of this consent in the potential donor’s medical record.

13.4.3 Agreement to Participate

The transplant hospital registering the potential KPD donor must obtain written consent from the potential KPD donor to participate in KPD, and must maintain documentation of this consent in the potential KPD donor’s medical record.

13.4.4 KPD-Specific Elements

For any KPD exchange, the transplant hospital registering the potential KPD donor must maintain documentation in the potential KPD donor’s medical record it has informed the potential KPD donor of all of the following:

- The possibility of helping more than one candidate receive a transplant
- The possibility that the potential KPD donor may have to wait to find a match
- The possibility that the potential KPD donor might have to wait longer to donate after a match has been identified because of logistical complexities
- The possibility that a candidate might not receive a transplant because of an unexpected issue with a potential KPD donor’s kidney found during or after surgery
- The possibility that the potential KPD donor’s kidney might not be transplanted or the potential KPD donor’s intended candidate might not receive a transplant because of unexpected events
- The possibility that the matched candidate’s insurance might not cover travel costs if the potential KPD donor travels to the matched recipient transplant hospital
- The possibility that the potential KPD donor’s paired recipient and the potential KPD donor’s matched recipient might not have equal outcomes
- The possibility of the potential KPD donor’s name appearing on the matched recipient’s insurance estimation of benefits
- The potential risks of transporting a living donor kidney, including, but not limited to:
  - The possibility that the donor’s kidney could be lost in transport
  - That greater ischemic time could create a greater possibility of delayed graft function or need for dialysis
- That the potential KPD donor may require additional testing, including multiple blood draws for crossmatching

For any KPD exchange, the transplant hospital registering the potential KPD donor must inform the potential KPD donor of the right to withdraw from participation at any time, for any reason.

13.4.5 Additional Elements for Non-Directed Donors (NDD)
For any KPD exchange, the transplant hospital registering the potential NDD in KPD must maintain documentation in the potential NDD’s medical record that it has informed the potential NDD of all the following options:

1. Participating in KPD
2. Donating directly to the local deceased donor list
3. Any other options available in the potential NDD’s donation service area

### 13.4.6 Additional Elements for Bridge Donors

The transplant hospital registering a potential KPD donor must maintain documentation of the potential KPD donor’s consent to be a bridge donor in the potential KPD donor’s medical record. Written consent to be a bridge donor must be obtained before reporting the potential KPD donor is willing to be a bridge donor. The transplant hospital registering the potential bridge donor must maintain documentation in the potential bridge donor’s medical record that it has informed the potential bridge donor of all the following:

- The potential bridge donor may need to have another medical evaluation at a future time
- The potential bridge donor may need to be available to provide blood on multiple occasions for cross matching.
- The KPD program’s process for determining whether a chain ends with a bridge donor
- An estimated amount of time for which the potential bridge donor can expect to wait before undergoing surgery to recover the potential bridge donor’s kidney, based on the experience of the transplant hospital registering the potential bridge donor. The potential bridge donor will have the option to revise the estimated amount of time the potential KPD donor is willing to be a bridge donor. The transplant hospital registering the potential KPD donor will maintain documentation of the amount of time the potential KPD donor is willing to be a bridge donor in the potential KPD donor’s medical record.

Verbal consent by the potential KPD donor to remain a bridge donor must be obtained when a match has been identified.

### 13.4.7 KPD Program Process Consents

The transplant hospital registering the potential KPD donor must maintain written documentation in the potential KPD donor’s medical record that it has informed the potential KPD donor of the following elements of the KPD program:

- Potential KPD donors do not choose their match
- A potential KPD donor or a candidate may decline a match after it has been found
- The KPD program’s matching requirements
- The KPD program’s rules for when members may facilitate meetings between KPD donors and recipients
Discussion

Policy 12.2 Informed Consent of Living Kidney Donors – Living Kidney Donor Consent

There is currently a gap in policy regarding providing center-specific outcomes to living donors when the recovery hospital and the recipient hospital are not the same, but the recipient hospital center is unknown. Before the Board of Directors approved the living donor policy (Policy 12) a requirement to inform the donor about center-specific outcomes for unknown recipient hospitals was removed. The JSWG considered the following options regarding when to provide the potential donor with information about the recipient hospital, and what information should be provided:

- **Option 1**
  - The recovery hospital informs the donor of the “national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports” including “national 1-year patient and graft survival.”
  - When the recipient center becomes known, the recovery hospital must inform the donor of “the recipient hospital’s program-specific transplant recipient outcomes from the most recent SRTR center-specific reports,” including “the recipient hospital’s 1-year patient and graft survival” and “notification about all CMS outcome requirements not being met by the recipient hospital.”

- **Option 2**
  - The recovery hospital does not provide any information about outcomes until the matched recipient is identified.
  - Upon identification of the matched recipient, the recovery hospital informs the donor of the “national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports” including “national 1-year patient and graft survival,” as well as the “recipient hospital’s program-specific transplant recipient outcomes from the most recent SRTR center-specific reports,” including “the recipient hospital’s 1-year patient and graft survival” and “notification about all CMS outcome requirements not being met by the recipient hospital.”

- **Option 3**
  - The recovery hospital informs the donor of the “national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports” including “national 1-year patient and graft survival.”
  - Transplant hospitals that are not in good standing (either defined by bylaws or defined by policy) are not permitted to participate in KPD

The JSWG ultimately agreed upon Option 2. It noted that the donor should not bear the burden of asking for information on the matched recipient’s hospital. Option 3 would have placed that onus on the potential donor. The JSWG was also concerned that hospitals “not in good standing” with OPTN/UNOS are permitted to perform transplants in some situations. Option 3 would have included a proposal to change OPTN bylaws or include in policy that a transplant hospital cannot participate in KPD unless the center is in good standing. That way, the donor can be assured that the recipient hospital is in “good standing” criteria without requiring the recovery hospital to provide the donor with statistics about the recipient center once the recipient center becomes known.

The JSWG noted that Option 2 aligns most closely with current CMS requirements, making the informed consent process more streamlined for the recovery hospital. Additionally, Option 2 permits the recovery hospital to complete the requirement in one step, rather than requiring the
hospital to provide information to the potential donor at two separate times, as required by Option 1.

Policy 13.3 and Policy 13.4 – Application to Any KPD Exchange

The March, 2012 proposal included some policies that applied to all KPD exchanges, and some policies that applied only to the OPTN KPD program:

<table>
<thead>
<tr>
<th>Policy</th>
<th>Scope</th>
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</thead>
<tbody>
<tr>
<td><strong>13.3 Informed Consent for Candidates</strong></td>
<td></td>
</tr>
<tr>
<td>13.3.1 Release of Protected Health Information</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td>13.3 Informed Consent for Candidates</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td>13.3.2 Agreement to Participate</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td>13.3.3 Agreement to Accept a Shipped Kidney</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td><strong>13.4 Informed Consent for Potential Donors</strong></td>
<td></td>
</tr>
<tr>
<td>13.4.1 General Potential Donor Informed Consent</td>
<td>All KPD Exchanges</td>
</tr>
<tr>
<td>13.4.2 KPD-Specific Elements</td>
<td>All KPD Exchanges</td>
</tr>
<tr>
<td>13.4.3 Additional Elements for Non-Directed Donors</td>
<td>All KPD Exchanges</td>
</tr>
<tr>
<td>13.4.4 OPTN KPD Program Process Consents</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td>13.4.5 Consent to Ship a Kidney</td>
<td>All KPD Exchanges</td>
</tr>
<tr>
<td>13.4.6 Release of Protected Health Information</td>
<td>OPTN KPD Only</td>
</tr>
<tr>
<td>13.4.7 Agreement to Participate</td>
<td>OPTN KPD Only</td>
</tr>
</tbody>
</table>

The JWSG held numerous discussions regarding the scope of KPD informed consent policies. OPTN/UNOS Policy 12 (Living Donation) applies to all living donors. The JSWG members conceive of Policy 13 (Kidney Paired Donation) as a supplement to Policy 12, and therefore propose that Policy 13.3 and 13.4 apply to all KPD exchanges in order to achieve consistency within OPTN/UNOS policies.

Policy 13.3.3 Agreement to Accept a Shipped Kidney

The original proposal only required transplant hospitals to obtain written consent from the candidate to accept a shipped kidney. During discussion, some JSWG members felt this requirement was extraneous, noting such consent is implicit for recipients, as well as the lack of data on loss of living kidneys due to shipping. However, an OPTN/UNOS Committee member noted that there is a 1-2% loss of shipping of deceased donor kidneys, and it is expected that loss
of kidneys from living kidney donation will increase. Thus, the JSWG ultimately agreed that candidates should consent to receive a shipped kidney.

In addition to obtaining written consent to accept a ship kidney, the JSWG also recommends requiring the transplant hospital to inform the candidate about potential consequences of shipping a kidney. Therefore, the JSWG included in the proposal the requirement to inform the candidate of the potential for the donor kidney to be lost in transport, and that greater ischemic time could create a greater incidence of delayed graft function or need for dialysis.

**Policy 13.3.4 Prioritization of Candidates with a Failed Kidney Exchange**

The JSWG recommends requiring the transplant hospital to inform the candidate of the potential outcomes if the candidate’s pair donates, but the candidate is not transplanted due to problems in recovery, problems in transportation, or if the KDP matched donor opts out. Currently, prioritization on a KPD match differs by KPD program. However, the JSWG believes that a candidate who is not transplanted for one of the reasons above should receive prioritization in the KPD program’s match. The JSWG used language that could broadly apply to all programs. They did not specify a precise prioritization for the candidate in any program, only that the candidate be prioritized in some way.

The JSWG is aware that this recommendation may be beyond the scope of the JSWG’s charge. If so, the JSWG strongly recommends the OPTN/UNOS Kidney Committee, and all other KPD programs, adopt this policy and apply it to candidates within their programs.

**Policy 13.4.6 Additional Elements for Bridge Donors**

The original proposal required donors that agreed to be bridge donors to consent on multiple occasions: before the transplant hospital reported that the donor was willing to be a bridge donor; every three months after the match run in which a potential donor has been identified as a bridge donor until the potential donor donates, declines to be a bridge donor, or declines to donate; and upon identification of a matched recipient. The JSWG engaged in many discussions regarding whether consent on multiple occasions is necessary for bridge donors. Some members believed that a donor’s initial consent to be a bridge donor served as their consent.

However, some members believed that obtaining informed consent on various occasions helped protect the donor’s freedom to opt out of the donation process, and prevent the donor from being “on call” for an indefinite period of time to donate. These members argued that verbal consent provided the donor the ability to opt out of donation in a non-pressured situation, and that failing to require the transplant hospital to continue to obtain consent could be coercive to the donor. The bridge donors should either have a limited timeframe in which to donate, or they should provide verbal consent at various time points, allowing them to opt out of the donation process.

The JSWG considered three options for informed consent for bridge donors:

- **Option 1:**
  - No separate consent for a bridge donor at all (the donor already implicitly opted to be a bridge donor when he or she agreed to be a living donor)
- **Option 2:**
  - The transplant hospital obtains consent from the donor twice. The first consent is obtained when the donor initially agrees to be a bridge donor. The donor would be informed how the chain ends, and provided an estimated amount of time for
when the chain would be complete, so the bridge donor would not be “on call” for an indefinite amount of time. The second consent is obtained upon identification of a match.

- **Option 3:**
  - The transplant hospital obtains informed consent when the donor initially agrees to be a bridge donor, and subsequently at different intervals while the hospital is looking for a match for the bridge donor. The intervals would be different than the originally proposed three month intervals, and the chain could therefore remain open without giving the bridge donor an expected timeframe.

Ultimately, the JSWG agreed to recommend Option 2, as it strikes the appropriate balance between properly informing the donor without the risk of coercing the donor to continue to be a bridge donor longer than he or she truly feels comfortable.
Proposal: Add Deadlines for Preliminary Response, Performing Crossmatch, and Reporting Final Acceptance

**Problem:** Guidelines and policies do not specify a timeframe for transplant programs involved in a potential exchange to respond to offers and crossmatches. Candidates and donors in a pending exchange are not eligible to appear in subsequent match runs. If a KPD donor transplant hospital or KPD candidate transplant hospital is not performing its responsibilities in a timely manner, potential donors and candidates may miss other KPD matching opportunities.

**Proposal:** Incorporate set timelines for transplant programs involved in an exchange for:

1. Preliminary responses to exchange offers
2. Performing a crossmatch and reporting the results in the KPD system
3. Indicating refusals after preliminary acceptance
   a. Requirement for donor transplant hospitals to transfer all required records to candidate transplant hospital in a certain amount of time
   b. Requirement for candidate transplant hospitals to review the donor records in a certain amount of time and to indicate their final acceptance/rejection in KPD system

If the transplant programs fail to adhere to the deadlines, the exchange will be terminated on the day of the deadline and all candidates and donors will appear in the next match run.

Because there may be legitimate reasons that a transplant hospital is unable to meet the deadlines in proposal items 2 and 3, the transplant programs will be allowed to request exceptions to these deadlines. If all other transplant programs involved in the exchange agree to allow an extension, the exchange will not be terminated if the policy deadline is exceeded. A new deadline must be presented at the time the extension is requested.

**Proposed Guidelines Change:**

*Proposed additions are indicate with an underline, and proposed deletions are struck through.*

KPD Contact Responsibilities

1. Purpose: To define the duties of the KPD contact
2. Procedures:
   a. Each transplant center must designate a primary KPD Contact and an alternate to fulfill the duties described below. (Note: For the purposes of the KPD Contact Responsibilities Operational Guideline, KPD Contact refers to both the primary KPD Contact and the alternate.)
   b. The KPD contact’s site administrator must make sure that his/her contact information (phone number, e-mail address, and mailing address) are up-to-date in the UNOS membership database. Additionally, the KPD Contact must
keep the address for the lab or the transplant center where the potential living
donor blood sample should be sent for crossmatch updated in the system.
c. The primary and/or alternate KPD contact or their proxy must participate in
regular conference calls to discuss operations of the KPD Pilot Program.
(Attendance at every call is not required, but the contact must attend some calls
and will be responsible for obtaining any information communicated during a
missed meeting.)
d. If the KPD contact is not available for any period of time, the contact may
designate a proxy from the same center. The proxy will be responsible for all
of the normal duties of the KPD contact during this time frame.
e. The KPD contact is responsible for making sure all data is entered for
candidates and potential living donors. The KPD contact will receive an e-
mail before each match run is generated with information on which potential
living donors and candidates are not eligible to be entered in the match run
because of lack of required data. The KPD contact and the alternate will receive
an e-mail notification when each match run results are available of match offers
via email. The KPD contact is responsible for forwarding this information to
anyone else at the transplant center who needs to know this information.
f. The KPD contact’s information (both primary and alternate) will be given
provided on the Exchange Report to the KPD contacts (both primary and
alternate) for any candidate/donor pair that has matched to a candidate/donor
pair at that center for all matches in an exchange. The primary KPD contact
must make sure that someone at the center is in charge of communicating
with the matched candidate’s or donor’s center for each case.
g. The KPD contact is responsible for coordinating the crossmatch process by
making sure the potential living donor blood sample is sent to the matched
candidate’s center and by providing an address for where the matched potential
living donor’s blood sample should be sent.
h. The KPD contact is responsible for making sure acceptances and refusals for
matches are entered into the system within the specified time frame listed
below: (match run time line will be provided before each match run).
i. For any KPD exchange, each of the transplant hospitals receiving the match
offer must report a preliminary response to the OPTN Contractor within 2 days
business days of receiving the offer or the exchange will be automatically
terminated.
   i. The KPD matched donor transplant hospital must provide the matched
candidate’s transplant hospital the name and location of where the
crossmatch kit is to be sent within 1 business day of receiving the
notification of exchange acceptance. If this information is not provided to
the matched candidate’s transplant hospital within 1 business day of
receiving notification of exchange acceptance, the exchange will be terminated.

ii. The KPD candidate’s transplant hospital must perform a crossmatch and report the results of the crossmatch to the OPTN Contractor and the matched donor’s transplant hospital within 13 days of receiving notification of the exchange acceptance. If the results of the crossmatch are not reported to the OPTN Contractor within 13 days of notification of exchange acceptance, the exchange will be terminated.

iii. The transplant hospital registering the potential donor in KPD must make all of the donor records accessible to the matched candidate’s transplant hospital within 2 days of receiving the notification of exchange acceptance. If the donor records are not made available within 2 days of receiving the notification of exchange acceptance, the exchange will be terminated. The donor records must include any updated serology and NAT testing results, and must indicate whether the donor is increased risk according to the PHS Guidelines.

iv. The matched candidate’s transplant hospital must review the donor records and report a final acceptance or refusal to the OPTN Contractor within 13 days of notification of exchange acceptance. If the matched candidate’s transplant hospital does not report an acceptance or refusal to the OPTN contractor within the timeframe, the exchange will be terminated.

The deadlines can be postponed for Guidelines h.iii, h.iv and h.v if all transplant hospitals in the exchange consent. The transplant hospital requesting the extension must submit the request in writing to the OPTN Contractor explaining the reason for the request and providing an updated date by which the transplant hospital will perform. The OPTN Contractor will notify all of the transplant hospitals in the exchange of the request.

Upon receipt of the request for extension, the transplant hospitals in the exchange will have 1 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 day of receiving the request, the request will not be granted. If the extension request is submitted before the deadline defined by the guidelines, the exchange will not terminate until the resolution of the extension request.