

**OPTN/UNOS Kidney Transplantation Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Richard Formica, Jr, MD, Chair
Mark Aeder, MD, Vice Chair**

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

Action Items

1. Kidney Paired Donation Histocompatibility Testing Requirements

Public Comment: March 14 – June 13, 2014

This proposal includes requirements for histocompatibility testing on donors and recipients in the OPTN KPD Program. It includes required methods for HLA typing, antibody screenings, and crossmatching; a list of HLA types that must be reported for donors and candidates; and processes that must be followed for identifying unacceptable antigens and in the event of unacceptable positive crossmatches.

The Board is asked to approve new histocompatibility testing requirements for candidates and donors in the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP).

RESOLVED, that additions and modifications to Policies 13: (Kidney Paired Donation (KPD)); 13.5 (Histocompatibility Testing); 13.6 (Matching within the OPTN KPD Program); 13.7 (KPD Screening Criteria); and 13.10 (Crossmatching Protocol), as set forth in Exhibit A, are hereby approved, effective pending programming and notice to the OPTN membership.

Committee Projects

2. Simultaneous Liver Kidney (SLK) Allocation

Public Comment: August, 2015 (Estimated)

Board Review: December 2015 (Estimated)

The Committee has formed a working group with representatives from the Kidney, Liver, OPO, Ethics, Minority Affairs, and Operations and Safety Committees. In August, the working group held an introductory conference call to discuss background on the project and come to consensus on a problem statement. The Kidney Committee had previously submitted a problem statement for the group to consider:

Data suggests that a portion of kidneys are allocated to liver candidates who may have regained their kidney function following a liver alone transplant. Recent data show almost half of SLK recipients received a kidney with a KDPI less than 35% (a category of kidneys that is prioritized highly for pediatric candidates). The lack of allocation rules is counter to Final Rule principles regarding the best use of organs and allocation policies being based on medical urgency.

Some of the members of the working group did not agree with the first part of this problem statement, asserting that it is very much still up for debate whether the data show who is

likely to regain kidney function after a liver transplant. The group agreed that there should be well defined rules around SLK allocation and that the lack of rules and consistency is counter to the OPTN Final Rule. The working group agreed to the following amended problem statement:

The OPTN Final Rule specifies that organ allocation policies must be based on sound medical judgment, contain standardized criteria for allocating each organ type and combination of organ types, and must seek to achieve the best use of organs, avoid wasting organs and futile transplants, and promote efficient management of organ placement.

There are minimal rules for SLK allocation. When a liver-kidney candidate and the donor are in the same DSA, OPTN policy specifies that the kidney must be allocated with the liver. However, there are no standardized medical criteria that allocation is based on. When a liver-kidney candidate and the donor are in different DSAs, there are no policies defining rules for how the organs will be allocated. The OPO can opt to allocate the kidney with the liver or to allocate both organs separately. The policy does not provide for a consistent set of allocation rules that is based on patient need. The lack of consistent local and non-local allocation rules for SLK is counter to these Final Rule principles.

As background, UNOS staff presented the working group with the elements of a 2009 public comment proposal establishing rules around SLK allocation. Several members of the group indicated support for the overall elements of the 2009 proposal, which created candidate eligibility criteria for allocating a kidney with the liver and prioritized liver recipients with continued kidney failure on the deceased donor kidney waiting list. The working group is scheduled to discuss the 2009 public comment proposal elements in greater detail in October and November to determine which of the proposed changes are still relevant and whether changes need to be made.

In September, the working group reviewed a summary of the data previously presented to the Kidney Committee and several articles published on the topic. The group agreed that kidney graft outcomes, recipient outcomes (patient survival) as well as waiting list mortality data for different groups of patients need to be taken into account when making recommendations on policy changes. However, many in the group have expressed the view that additional data is not likely to help in determining what patients may regain kidney function after liver transplant. Because of the lack of data, it may be difficult to develop an allocation policy around eligibility criteria that is based on OPTN data.

The working group has also discussed the possibility of broadening the scope of this project to include new rules for simultaneous heart kidney and simultaneous lung kidney allocation, since the problem identified applies to allocation of these combined organ types as well. As the working group finalizes the recommended rules for SLK allocation, the working group chair will reach out to the Thoracic Transplantation Committee leadership to get feedback on this effort.

3. Addressing Geographic Disparities in Deceased Donor Kidney Allocation

Public Comment: August, 2016 (Estimated)

Board Review: December 2016 (Estimated)

The Committee is focusing the majority of its resources on KAS implementation and the SLK project at this time. In April 2015, the Committee will resume work on defining a metric to

assess geographic disparities in deceased donor kidney allocation. The Committee is following the liver redistribution project to assess lessons learned from the feedback.

4. **Marking Kidney Laterality**

Public Comment: N/A

Board Review: June, 2015 (Estimated)

The incorrect reporting of kidney laterality was the third highest ranking failure on the Failure Modes Effects and Analysis (FMEA) conducted by Northwestern University as part of the Electronic Tracking and Transport Project. A total of 21 cases of switched kidney laterality have been self-reported to UNOS since 2012. In 5 of these cases, one or both of the switched kidneys was not transplanted due (at least in part) to the laterality switch. Anecdotal feedback from OPOs and transplant programs suggest that the number of kidneys with incorrect laterality reported may be much higher. In February 2015, the Committee was tasked with making recommendations on whether there should be uniform guidance or policy on marking kidney laterality.

In August, a working group comprised of representatives from the Kidney, Operations and Safety, and OPO Committees held a conference call to discuss the issue. The group agreed that switched laterality is a problem that results in discards and should be addressed.

Prior to the workgroup call, the chair of the subcommittee reached out to a number of OPOs to ask about their practice for marking kidney laterality. She presented the responses to the Committee. A number of OPOs reported having a practice for marking laterality due to an incident at their organization. The method of marking laterality was different among the OPOs, although the majority (5 out of 6) reported doing it *in situ*.

The workgroup discussed solutions to the problem, particularly whether policy changes or guidance may be needed for marking kidney laterality. The majority of the workgroup did not feel that policy changes are needed at this time. However, they did agree that guidance on the issue may be appropriate.

They also discussed the possibility of requiring reporting of switched laterality in addition to issuing guidance on the issue (otherwise it would be difficult to know whether the guidance had the intended effect). However, the majority of the workgroup did not agree that it was appropriate to move forward with recommending a reporting requirement at this time. Members of the group wanted to issue guidance first and then assess whether the number of self-reported and complaints of switched laterality decrease as a result. They requested feedback from the OPO Committee before moving forward with official guidance.

In September, the chair of the working group presented the recommendations to the OPO Committee. The OPO Committee indicated support for moving forward with a guidance document on marking kidney laterality. Many of the OPO Committee members reported that their institutions began this practice after having a switched laterality incident. However, some members said their efforts to enact a protocol in their institution was not supported.

The OPO Committee suggested that the guidance put forth the following as the best practice:

- OPOs should work with their surgeons to develop a policy for marking laterality.
- OPOs should indicate laterality by marking the *left* kidney *in situ* (but leaving it up to the OPO as exactly what they use to mark it)

The Committee will draft a guidance document for the Board of Directors to consider at the June 1, 2015 Board meeting.

5. KPD Informed Consent Guidelines to Policy

Public Comment: [September 29, 2014 – December 5, 2014](#)

Board Consideration: *June, 2015 (Estimated)*

In April 2014, the KPD Work Group recommended that the Kidney Committee distribute for public comment the *Proposal for Informed Consent for Kidney Paired Donation*. The Kidney Committee approved the recommended proposal for public comment with slight modifications on August 4, 2014 (10 support; 0 oppose; 0 abstentions).

During the discussions surrounding this proposal, it became apparent that the KPD Work Group and Kidney Committee may need to make future policy changes. For example, the proposal requires transplant programs registering donors and candidates in any paired donation program to advise the donors and candidates of the paired donation program's remedy in the event of a failed exchange. If there is no explicit remedy, the donors and candidates should be advised of the same. This requirement led the KPD Work Group to realize it should develop a "failed exchange" policy for the OPTN/UNOS KPD Paired Donation Pilot Program (KPDPP).

For more information, see the public comment proposal and the Kidney Committee meeting summary from August 4, 2014.

6. Converting KPD Operational Guidelines to OPTN Policies and Bylaws

Public Comment: [September 29, 2014 – December 5, 2014](#)

Board Consideration: *June, 2015 (Estimated)*

In June 2014, the Board of Directors voted to remove the "pilot" label from the KPDPP. As part of the transition to permanence, the KPD Work Group and Kidney Committee are moving the requirements for the KPDPP, which in part currently reside in Operational Guidelines, to OPTN/UNOS policies and bylaws. Doing so exemplifies the OPTN's commitment to the continued success of the KPDPP, and also adheres to the OPTN's values of transparency and responsiveness to the transplant community. Once the guidelines become policy, they can only be modified through the tradition OPTN/UNOS public comment process.

On August 4, 2014, the Kidney Committee adopted the KPD Work Group's recommendations to distribute for public comment the *Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy* (10 support; 0 oppose; 0 abstentions). The goal of KPD Contact Responsibilities and Donor Pre-Select Requirements is to improve the efficiency of the KPDPP by ensuring that transplant programs perform their KPD match-related duties in a timely manner, and contribute to increase match success rates by pre-selecting and pre-refusing potential paired donors for their candidates.

For more information, see the public comment proposal and the Kidney Committee meeting summary from August 4, 2014.

7. Revising KPD Priority Points

Public Comment: *August, 2015 (Estimated)*

Board Consideration: *November, 2015 (Estimated)*

The KPD Work Group continues to analyze the current matching algorithm to determine whether and how to modify it. The goals of the project are to increase transplant program participation and increase the number of KPD transplants performed. The KPD Work Group

is developing a project plan to approach the project methodically; it is likely the improvements to the priority points and matching algorithm will be completed in phases. This project will be a top priority for the KPD Work Group for the 2014-2015 term, and the majority of the work will be completed by the Design and Optimization Algorithm Subcommittee and the KPD Work Group's technical advisors.

8. Membership Requirements for KPD Programs

Public Comment: *January, 2016 (Estimated)*

Board Consideration: *June, 2016 (Estimated)*

This is projected to be the last section of Operational Guidelines that will need to transition to OPTN policies and bylaws. Current guidelines require transplant programs participating in the KPDPP to be approved kidney transplant programs and approved living donor recovery programs. The potential policy solution will likely include minor changes to the criteria for participating in the KPDPP, to permit transplant programs to transplant KPD candidates even if they are not approved living donor recovery center. The modification is likely to benefit pediatric transplant programs that are not living donor recovery centers, but nevertheless want to register a pediatric candidate in the KPDPP.

The transition is likely to have a minimal impact on transplant programs participating or that wish to participate in the KPDPP, but it is likely to require a programming change to link the KPD system in UNetSM with the OPTN's membership database.

9. Allowing Deceased Donor Chains in the KPDPP

Public Comment: *To be determined*

Board Consideration: *To be determined*

The KPD Workgroup may explore the potential for initiating a chain in the KPDPP with a deceased donor. The goal of the project would be to increase the number of kidney transplants overall, without decreasing the number of deceased donors. The KPD Work Group will not begin work on this project without input from the Health Resources Services Administration (HRSA).

Committee Projects Pending Implementation

10. Revised Kidney Allocation System (KAS)

Public Comment: *September 21 – December 14, 2012*

Board Approval: *June, 2013*

Implementation: *December 4, 2014.*

On May 27, 2014, a number of programming changes were released in UNetSM that allowed programs to add or 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 were also programmed in the system to help ease the data and compliance burden for kidney programs. Programs now have the ability to upload and update data in bulk or within each individual candidate record. The system also provides kidney programs with reports that flag missing or unconfirmed data on their candidates. With regard to donor acceptance criteria, the system updated 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 UNetSM system. If a current candidate has consented to accept an ECD kidney, UNetSM set the candidate's maximum KDPI to 100%. If a current candidate has not consented to accept an ECD kidney, UNetSM set the KDPI maximum at 85%. On December 4, UNetSM will once again assign these values automatically for any candidates with a missing maximum KDPI value. Programs have the ability to select different maximum KDPI scores and differentiate between maximum KDPI criteria for local v. non-local offers, as well as zero mismatch v. non-zero mismatch offers.

The system now displays 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., UNetSM 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 are also new tools that allow kidney programs to assess how the new allocation system changes will affect prioritization for candidates on their list prior to implementation. Programs can access a 'Priority Points Report' in the system that displays 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 gives 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.

As of September 23, 2014, over 50% of kidney candidates have had their EPTS data entered and verified. 73 programs have verified EPTS data for 100% of the candidates on their waiting list. Among those 73 kidney programs, are programs with very large waiting lists (more than 700 candidates). Eighteen kidney programs have not verified data for any candidates. UNOS staff continues to perform outreach to programs that have not verified any data.

The Committee continues to work with UNOS staff to release a number of educational offerings and resources to help transplant programs, OPOs, and histocompatibility laboratories prepare for implementation of the new system. Below is a list of new resources that have been added to [the KAS toolkit that is posted on the OPTN website](#):

- Draft OPTN evaluation plan
- New KAS policy language
- Updated FAQ document (now listed with a Table of Contents and hyperlinks by subject matter)
- Patient e-learning module
- Patient brochure
- Updated resources for interpreting and talking to patients about KDPI

In addition, several members of the Committee will join UNOS staff for a virtual town hall on October 23, 2014. This event will allow members of the community to participate online and ask a panel of experts any remaining questions about the new system. UNOS staff will release a UNetSM system training on November 17, 2014.

The Committee has collaborated with a number of other OPTN/UNOS committees as part of these educational efforts, including the Transplant Administrators, Transplant Coordinators, OPO, Minority Affairs, Pediatric and Patient Affairs Committees. Since June 2014, the Committee leadership and members have presented basic KAS preparation information at the World Transplant Congress (WTC), the NATCO annual meeting, the Polycystic Kidney Disease (PKD) Conference, the Texas Transplant meeting, and as part of grand rounds at kidney programs across the country. There will also be a presentation at the American Society for Histocompatibility and Immunogenetics (ASHI) annual meeting in October.

Upon implementation on December 4, all variances will be eliminated along with the current payback system.

Implemented Committee Projects

11. KPD Priority Points Guidelines to Policy

Public Comment: March 16 – June 25, 2012

Board Approval: June, 2014

Implementation Date: September 1, 2014

In June 2014, the Board of Directors approved the transition of the priority points section of KPDPP Operational Guidelines to OPTN/UNOS policy. The policy language became effective on September 1, 2014. The transition did not change the way in which priority points are assigned in the KPDPP, so the impact on members participating in the KPDPP was negligible, and will not affect the way in which the KPD Work Group is analyzing the priority points as part of the Revising KPD Priority Points project.

Review of Public Comment Proposals

12. None

Other Committee Work

13. Increasing Utilization of Double Kidney Allocation

Though dual kidney transplantation has been shown to provide a substantial survival advantage over single kidney transplantation, in particular from deceased donors with high KDPI values. Currently only about 1% (approximately 100 per year) of kidney transplants are duals. With discard rates for high KDPI kidneys at or exceeding 50%, expanding the prevalence of dual kidney transplantation may be a way to increase the number of kidney transplants by reducing the number of discards.

In September, the Committee reviewed the current policy criteria for allocating dual kidneys and the programming for dual allocation that will be in place with the new kidney allocation system on December 4. Some members expressed concern that the current policy and programming are suboptimal and need revision in order to expand the use of dual kidney transplantation.

The Committee will continue to review and discuss proposed changes beginning in January 2015 (after the implementation of the new kidney allocation system).

14. Priority for Medically Urgent Kidney Candidates

In August, the Membership and Professional Standards Committee (MPSC) sent a memo to the Committee leadership requesting review of OPTN policy pertaining to medically urgent kidney candidates. The MPSC recently reviewed a case where an OPO bypassed a number

of national 0-ABDR mismatch and local pediatric candidates for a medically urgent local candidate in the DSA.

In September, the Committee reviewed the policy language around medical urgency that will take effect with the new KAS. The Committee agreed that the policy should be clarified to define medical urgency. There was some support for specifying that a kidney candidate is medically urgent when they are on their last vascular access for dialysis, but the Committee could not come to consensus during this first conversation. The Committee will continue to discuss what clarifications may be needed to this policy, including how medically urgent candidates should be prioritized if they meet the definition.

15. Kidney Graft Failure and Non-Function Definitions

In September, the Committee reviewed the Pancreas Transplantation Committee's proposal to create a separate definition of pancreas graft failure. The Committee reviewed the general definition of graft failure in OPTN policy (used for assessing kidney program performance), along with the definition of 'immediate and permanent non-function' (used for reinstating waiting time for kidney candidates). There are some differences in these definitions, and the Committee discussed whether the differences are appropriate for each definitions use in OPTN policy.

The Committee offered the feedback that the current definition of graft failure is sufficient and appropriate for assessing kidney program performance. They did, however, request to further discuss the definition of immediate and permanent non-function of a transplanted kidney, due to the fact that interpretation of the current policy means that programs must report a graft failure in order to reinstate a candidate's waiting time. The Committee will continue to discuss what clarifications may be needed to this policy, including whether candidates who request waiting time reinstatement based on GFR/CrCl values at or below 20 ml/min within 90 days of a transplant should be granted reinstatement without the program reporting the transplant to the OPTN as a graft failure.

Meeting Summaries

The Committee held meetings on the following dates:

- August 4, 2014
- September 29, 2014
- October 20, 2014

Meetings summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=89>

Kidney Paired Donation (KPD) Histocompatibility Testing Requirements
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Title: Kidney Paired Donation Histocompatibility Testing Requirements**Sponsoring Committee: Kidney Transplantation Committee****Summary and Goals of the Proposal:**

The OPTN/UNOS Kidney Transplantation Committee (“the Committee”) recommends this proposal with the goal of promoting efficiency and transplant safety in the OPTN KPD Pilot Program (“OPTN KPD program”). The proposal includes the changes below. Some of the changes are already required through programming or in the OPTN KPD pilot program guidelines required to participate in the program, and this change simply moves those requirements into OPTN/UNOS policies. Items that are new are followed by “(new)” in the below list.

- HLA typing is required for donors and candidates in order to be eligible for match runs in the OPTN KPD Program
- The potential donor’s hospital is responsible for all HLA reporting requirements on the donor
- The transplant hospital registering the candidate in the OPTN KPD program is responsible for all HLA reporting requirements on the candidate
- HLA typing for donors and candidates must be performed using molecular methods (New)
- The following HLA types are required to be reported for potential donors in the OPTN KPD program: HLA-A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, DPB (DQA and DPB are new)
- The following types are required to be reported for candidates in the OPTN KPD program: HLA-A, B, Bw4, Bw6, and DR
- If a candidate has unacceptable antigens listed for the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB (New)
- The candidate’s transplant hospital is responsible for retyping a matched donor to confirm the donor’s HLA information (New)
- The candidate’s transplant hospital is responsible for testing the candidate for antibodies at all of the following times: 1) every 90 days (+/- 20 days), 2) when a potentially sensitizing event occurs, 3) if the candidate has been reactivated after being inactive for more than 90 days, and 4) if an unacceptable positive crossmatch occurs that precludes transplantation (New)
- Candidates must be screened for antibodies using a method at least as sensitive as the crossmatch method and using a solid phase assay (New)
- The candidate’s physician or surgeon (or designee) and the affiliated histocompatibility laboratory director (or designee) must review and confirm the unacceptable antigens reported for a candidate before the candidate appears on the first KPD match run (New)
- The candidate’s transplant hospital is responsible for performing a physical crossmatch before the donor’s nephrectomy is scheduled and a final crossmatch prior to the transplant. The candidate’s transplant hospital must report crossmatch results to the matched donor’s hospital and the OPTN Contractor (New)
- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the OPTN Contractor will make the candidate ineligible for subsequent match run until the candidate’s hospital confirms that the physician or surgeon and the histocompatibility laboratory director have reviewed the candidate’s unacceptable antigens. (New)

- The candidate's hospital must report to the OPTN Contractor a reason for an unacceptable positive crossmatch within 7 days of the date that the crossmatch results were received by the candidate's transplant hospital. (New)

Background and Significance of the Proposal:

Since becoming operational in 2010, the OPTN KPD pilot program has largely been governed by a set of rules called Operational Guidelines. The Operational Guidelines are requirements for transplant programs who wish to participate in the OPTN KPD pilot program. In March 2012, the Kidney Committee released a public comment proposal converting several sections of the Operational Guidelines into policy in an effort to move toward making the OPTN KPD program permanent. Among these sections were proposed policies governing histocompatibility testing in the OPTN KPD program. The majority of the March 2012 proposal received support, but there were a number of opposing comments pertaining to the histocompatibility policy sections. For this reason, the Kidney Committee opted to recommend reserving these sections for further deliberation as other sections of the OPTN KPD polices went forward. The Kidney Committee and KPD Workgroup formed a Histocompatibility Advisory Committee (HAC) to discuss the feedback received and make recommendations for how the policy proposal should be amended.

Around the same time that the Kidney Committee distributed the original public comment proposal, a number of professional transplant societies convened a KPD consensus conference. This consensus conference brought together physicians, histocompatibility experts, allied health professionals, transplant administrators, representatives from current KPD programs, insurers, and patients to address dynamic challenges and complexities in KPD.

The recommendations in this proposal incorporate comments and recommendations from:

- comments received during the spring 2012 public comment period
- the 2012 KPD consensus conference findings related to histocompatibility testing
- the OPTN/UNOS Histocompatibility Committee
- the KPD Workgroup and the HAC

The Kidney Committee has incorporated the following recommendations in this proposal:

Expanding the list of HLA types required to be reported for OPTN KPD donors: The 2012 public comment proposal did not include a requirement to report HLA-DQA and HLA-DPB for KPD donors. Many of the public comments expressed concern that this would result in unexpected positive crossmatches. The requirement also aligns with the recommendations in the KPD consensus conference findings. Therefore, this proposal now includes an expanded list of donor HLA types that the donor's transplant hospital must report to be eligible for OPTN KPD match runs.

Expanding the list of HLA types required to be reported for OPTN KPD candidates: The 2012 public comment proposal did not include a requirement for reporting HLA-C, -DR51, -DR52, or -DR53 for candidates. Many of the public comments suggested that these types are important in cases where the candidate has HLA antibodies to these types. Therefore, this proposal now includes a requirement for these types to be reported on the candidate in instances where unacceptable antigens are reported by the candidate's transplant hospital. HLA-DQA and HLA-DPB were included in the list of types to be reported in the original proposal and remain as required in the current proposal if the candidate has unacceptable antigens reported.

Molecular typing required for donors and candidates: In the 2012 public comment proposal, molecular typing was the primary method required for both donors and candidates. Some public comments expressed concern about the need for molecular typing on all candidates, and they suggested that molecular typing should be required only for further interpretation of a positive crossmatch or where a candidate has anti-HLA antibodies. During the post-public comment discussion, members of the KPD Workgroup and Kidney Committee also expressed concern that requiring molecular typing for all candidates will add unnecessary expense with little benefit. Members of the HAC responded to these concerns, asserting that molecular typing, a superior form of typing, is important when comparing the patient's HLA with the potential donor's HLA, especially when the patient is making anti-HLA antibodies. The KPD consensus conference findings also recommend that all HLA typing be done by molecular methods. Therefore, the Committee is recommending that molecular typing be performed on both donors and candidates.

Confirming HLA type of the donor: The 2012 public comment proposal did not include a requirement for the candidate's transplant hospital to confirm the donor's HLA type. Several of the public comments received raised concern that this should be a requirement in order to ensure patient safety. The HAC agreed that this additional typing is needed in the KPD program in order to detect HLA typing discrepancies and prevent incompatible transplants and unexpected positive crossmatches. Therefore, the Committee is proposal that the candidate's hospital be required to confirm the donor's HLA type.

Antibody Screenings—methods and frequency: The 2012 public comment proposal did not include specific requirements for antibody identification. The American Society for Histocompatibility and Immunogenetics (ASHI) recommended that policy state that the antibody screening method be at least as sensitive as the crossmatch method. In addition, the KPD consensus conference recommended quarterly antibody screenings with a solid phase immunoassay. Some members of the KPD Workgroup and the Committee voiced concern that requiring antibody screenings on *all* candidates quarterly will be expensive and burdensome to participating programs. Members of the HAC responded that quarterly screenings are common practice and are especially important in the KPD program to detect antibodies if any sensitizing events have occurred. The majority of the Kidney Committee members agreed that all of these recommendations are important, and therefore, the proposal contains all of these new requirements for antibody screenings. However, the Committee has added a +/- 20 day window to this requirement to allow for some flexibility for transplant programs.

Review of unacceptable antigens: The 2012 public comment proposal did not contain a requirement for a joint review (between the candidate's physician or surgeon and the affiliated histocompatibility director) of the unacceptable antigens entered for a candidate. However, the KPD consensus conference strongly recommended regular communication between the candidate's transplant hospital and the histocompatibility laboratory. Members of the HAC expressed the view that this communication is most important for review and determination of unacceptable antigens. In addition, a joint review of unacceptable antigens will be required with implementation of the new deceased donor kidney allocation system when a candidate's CPRA score is greater than 98% (candidates in this category will receive additional allocation priority if the joint review and approval occurs).

Given the large number of sensitized patients in the OPTN KPD program and the risk that comes with breaking a chain with an unexpected positive crossmatch, the HAC recommended that this joint review be required in OPTN policy. The Kidney Committee has amended the proposal to require this review before the candidate appears on their first KPD match run, when the candidate's program is declining a match offer due to unacceptable antigens, and when an

unacceptable positive crossmatch occurs between a candidate and their matched donor that precludes transplant.

Crossmatching protocol: The 2012 public comment proposal required the candidate's hospital to perform a preliminary crossmatch prior to the matched donor's recovery procedure. Several public comments pointed out that federal regulations require histocompatibility laboratories to perform a final crossmatch and have the results available prior to transplant for kidney transplants and multi-organ transplants involving a kidney. The current proposal specifies that the candidate's transplant hospital is responsible for performing a physical crossmatch before the donor's nephrectomy is scheduled and a final crossmatch prior to transplant. The candidate's hospital must report the results to the OPTN Contractor and the matched donor's transplant hospital.

Candidate eligibility in cases of unacceptable positive crossmatches: The 2012 public comment proposal did not specify any new requirements with regard to addressing positive crossmatches that occur between a candidate and matched donor that preclude transplantation and break a chain. The HAC regularly reviews reported reasons for positive crossmatches. In response to these reports, the HAC recommended that transplant hospitals inactivate a candidate within two days of the positive crossmatch and report the reason to the OPTN Contractor within seven days of the positive crossmatch. Some members of the KPD Workgroup and the Kidney Committee expressed concern with this measure, stating that it seemed punitive to candidates and would be burdensome for transplant hospitals participating in the OPTN KPD program. The HAC responded that unexpected positive crossmatches have the ability to affect many candidates and donors in a chain and create deficiencies in the overall paired exchange program.

The Committee members discussed whether the OPTN Contractor should automatically make a candidate ineligible after an unacceptable positive crossmatch occurs, alleviating some burden from the individual programs. Some members thought that allowing the transplant hospital to inactivate the candidate gives transplant hospitals *more* flexibility in the process.

In response to public comment feedback, the Committee is recommending that UNOS make a candidate ineligible for subsequent match runs when the candidate's program reports that an unacceptable positive crossmatch has occurred with a matched donor. UNetSM will alert the program that the candidate is ineligible and the candidate will remain ineligible until the program confirms that the candidate's physician or surgeon and the histocompatibility laboratory director have reviewed the unacceptable antigens. For more information on the post-public comment discussion, see 'Primary Public Comment Concerns/Questions and Post Public Comment Considerations' below.

Supporting Evidence and/or Modeling:

The match success rate is defined as the percentage of candidate/donor match offers in the OPTN KPD program that end up resulting in a transplant. The sharp increase in the number of transplants facilitated through the OPTN KPD program in 2013 is attributable to a rise in match offers in conjunction with an increase in the match success rate. Though the rate has gone up, it still remains at approximately 10%, which implies that 90% of match offers currently do not result in a transplant.

Increasing match success rates, a challenge reportedly faced not just by the OPTN KPD program but by other KPD programs as well, is vital to increasing the number of patients that receive transplants and remains a key goal of the KPD Workgroup and the Committee. In a survey about barriers to KPD participation sent to living donor transplant programs in 2013, when asked what could be done to improve the OPTN KPD program, several respondents submitted responses

such as “match success rates,” “more transplants,” “(reduce) potential matches falling through,” and “better matching of highly sensitized patients.”

Due to the interdependencies among matches within the same 2-way, 3-way, or chain exchange, the consequence of one match failure is that all of the matches in the exchange do not result in a transplant. If match failures occur more than a week after initially being accepted, candidates and donors end up missing out on subsequent match runs and additional matching opportunities. This interdependency between matches, coupled with the relatively low match success rate, led the Kidney Committee’s KPD Workgroup in 2012 to remove long chains from the program in favor of chains of length 4 or less. Prior to this switch, long chains of as many as 16 links were repeatedly falling apart, leading to a large number of unrealized transplant opportunities.

Matches can fail for a variety of reasons. According to the “OPTN KPD Pilot Program Cumulative Match Report (CMR), for KPD Match Runs Oct 27, 2010 – Apr 15, 2013,” 52% of failed matches were not actually refused, but could not have proceeded to transplant due to refusals of other matches in the same exchange. Of the matches that were refused, 30% were refused due to either “positive crossmatch” or “unacceptable antigens.” An analysis of OPTN KPD program data through September 30, 2013 showed that crossmatch or antibody-related issue continue to account for approximately 30% of refusal reasons. Of the crossmatch-related refusals, about 1/3 were due to an actual positive crossmatch, while 2/3 were due to unacceptable antigens.

In match runs through June 3, 2013, 61 transplant programs had accepted at least one match offer for which the entire exchange subsequently fell through. Some programs had more than 20 such futile acceptances. Seven programs receiving at least 10 offers had refused more than half of them. The report indicates that one program refused 19 matches due to crossmatch-related reasons (“positive crossmatch” or “unacceptable antigens”). For one other program, 4 of 5 (80%) refusals were due to crossmatch-related reasons. However, though some programs may have had a disproportionate number of crossmatch-related refusals, the report also reveals that the problem is not isolated to a few institutions: 39 programs refused at least one match offer due to a crossmatch related reason.

On August 8, 2012, the HAC started requesting information from centers that refused match offers due to a virtual (unacceptable antigens) or actual positive crossmatch to identify underlying causes and possible solutions to prevent similar match failures in the future. Given the transplant center’s ability in the KPD system to prevent unwanted offers by entering unacceptable antigens as well as using the donor pre-refusal tool, understanding whether these match failures could have been avoided is paramount in determining whether education, system enhancements, policy changes, or other solutions are needed.

Additional information discovered about refusals due to actual positive crossmatches included the following:

- Donor DPB antigens not listed
- Typo in donor’s HLA-DQ (had no effect on crossmatch prediction)
- Candidate had newly identified antibodies and increased MFI for existing antibodies
- Cumulative strength of multiple moderate-level antibodies
- Donor has DPB 16, but no bead to detect DPB antibody and no way to report it to UNOS
- No sample sent in last quarter to retest patient for unacceptable antigens

Additional information discovered about virtual positive crossmatches refusals (unacceptable antigens) included the following:

- DQ5 antibodies too high
- Patient had allele-level antibodies to DPB
- Two moderately high unacceptable antigens
- Education issue: center did not realize that unacceptable antigen updates in Waitlist did not carry over to the KPD system
- No data entry field for DPB unacceptable antigen
- Inadvertent omission of flow-level unacceptable antigens in candidate's KPD record

At the inception of the OPTN KPD program, entry of DPB antigens was required for all donors. However, to reduce the burden on transplant centers, the KPD Workgroup decided to make entry of DPB antigens optional in April 2011. Subsequent to relaxing the requirement to enter DPB antigens, the percentage of donors for whom DPB antigens were entered dropped from 100% to just over 80% within just 3 months. Table 6 of the most recent Cumulative Match Report (CMR) shows that (in aggregate for all match runs from Oct 27, 2010 through Apr 15, 2013) DPB antigens were not reported for about 27% of donors entered into match runs.

Expected Impact on Living Donors or Living Donation:

This proposal requires additional histocompatibility testing on living donors in the OPTN KPD program.

Expected Impact on Specific Patient Populations:

This proposal will impact all candidates and potential donors in the OPTN KPD program. However, it will be especially beneficial to sensitized patients listed in the program. As of January 6, 2014, 61% of the patients listed in the OPTN KPD program (236 out of 390) were highly sensitized (had CPRA scores \geq 80%).

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal is intended to further the OPTN strategic goal of promoting transplant safety by preventing negative graft outcomes through more effective donor screening and quality testing for donor and recipient histocompatibility.

Plan for Evaluating the Proposal:

The Kidney Committee will evaluate the effect of this proposal 1 and 2 years post-implementation.

This proposal is intended to promote efficiency and transplant safety in the OPTN KPD pilot program through more effective donor screening and quality testing for donor and recipient histocompatibility. The Committee's hypothesis is that following implementation of this proposal, offer refusals and match failure rates due to positive crossmatch and unacceptable antigens will decrease. Since external factors and other changes in transplant policy can have an influence on the post-implementation period, interpreting the apparent impact of the additional optional fields based on "before vs. after" analysis must be done with caution.

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

- Has the number and the percentage of KPD match offers refused due to a positive crossmatch or unacceptable antigens decreased?

- Has the match failure rate due to positive crossmatch or unacceptable antigens decreased?

The following performance metrics, and any others subsequently requested by the Committee, will be compared against the data before and after implementation to evaluate the proposal:

- The number and percentage of KPD match offers refused due to a positive crossmatch or unacceptable antigens.
- Match failure rate due to positive crossmatch or unacceptable antigens.

The committee will also evaluate the effect of the policy on specific patient populations (e.g. pediatric, minority, and sensitized candidates).

Additional Data Collection:

Additional data collection will be required as part of this proposal:

- Transplant programs entering a potential donor in the OPTN KPD pilot program will be newly required to report HLA-DQA and HLA-DPB as part of this proposal.
- If a candidate has unacceptable antigens listed to the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB.
- Transplant programs will be required to report candidates with no antibodies or unacceptable antigens as unsensitized.
- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the OPTN Contractor will make the candidate ineligible for subsequent match runs until the candidate's transplant program reports to the OPTN Contractor that the candidate's physician or surgeon and the histocompatibility laboratory director have reviewed the unacceptable antigens listed for the candidate.
- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the candidate's transplant hospital must report a reason for the unacceptable crossmatch to the OPTN Contractor within 7 days of the date that the crossmatch results were received by the candidate's transplant hospital.

These new requirements are proposed to ensure that members are complying with the histocompatibility testing requirements for candidates and donors in the OPTN KPD program.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the Board of Directors in November 2014 and, if approved will be effective pending programming and notice to the OPTN membership.

Communication and Education Plan:

Instruction for this effort may coincide with programming. The proposal is being monitored for possible content instruction and systems training.

Compliance Monitoring:

During its compliance reviews of transplant hospitals, UNOS may request and review KPD candidate records to verify documentation showing compliance with the policy requirements listed pertaining to candidate antibody screening, required reporting to the OPTN contractor, required process and documentation of verification of data entry, candidate antibody retesting when

indicated, documentation of antibody screening results in the candidate record, and placement of the candidate on inactive status when indicated.

UNOS may request and review donor records to verify documentation showing compliance with policy requirements pertaining to required reporting to the OPTN contractor, documentation of the required joint review prior to declining a KPD match offer due to unacceptable antigens, submission of explanation to the OPTN contractor if declining due to either a positive crossmatch or unacceptable antigens, and performance and verification of HLA type of the matched donor prior to transplant.

Policy or Bylaw Proposal:

1
2 **RESOLVED**, that additions and modifications to Policies 13: (Kidney Paired Donation
3 (KPD)); 13.5 (Histocompatibility Testing); 13.6 (Matching within the OPTN KPD Program);
4 13.7 (KPD Screening Criteria); and 13.10 (Crossmatching Protocol), as set forth below,
5 are hereby approved, effective pending programming and notice to the OPTN
6 membership.

7
8 **Policy 1: Administrative Rules and Definitions**

9
10 **1.2 Definitions**

11 ~~Potential Paired donor's transplant hospital~~

12 The transplant hospital that enters the ~~potential living-paired~~ donor in a KPD program.

13
14 **Policy 13: Kidney Paired Donation (KPD)**

15
16 **13.5 OPTN KPD Histocompatibility Testing**

17
18 *Reserved*

19
20 13.5.A HLA Typing Requirements for OPTN KPD Candidates

21
22 Before a candidate can appear on an OPTN KPD match run, the paired candidate's transplant
23 hospital is responsible for reporting to the OPTN Contractor serological split level molecular
24 typing results for all of the following:

- 25 • HLA-A
- 26 • HLA-B
- 27 • HLA-Bw4
- 28 • HLA-Bw6
- 29 • HLA-DR

30
31 If the candidate has unacceptable antigens listed for any of the following HLA types, then the
32 paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor
33 serological split level molecular typing results for the corresponding HLA type before the
34 candidate can appear on an OPTN KPD match run:

- 35 • HLA-C
- 36 • HLA-DR51
- 37 • HLA-DR52
- 38 • HLA-DR53
- 39 • HLA-DPB
- 40 • HLA-DQA
- 41 • HLA-DQB

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43 13.5.B Antibody Screening Requirements for OPTN KPD Candidates

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45 The paired candidate's transplant hospital must complete antibody screening tests and report to
46 the OPTN Contractor as follows:

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1. Use an antibody testing method that is at least as sensitive as the crossmatch method. If antibodies are detected, then identify unacceptable antigens using a solid-phase single phenotype or solid-phase single-antigen test.
 2. If no HLA antibodies or unacceptable antigens are detected, then report the paired candidate as unsensitized.
 3. Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.
 4. Before candidates can appear on their first OPTN KPD match run, each paired candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee must review and sign a written approval of the unacceptable antigens listed for the paired candidate. The paired candidate's transplant hospital must document this review in the paired candidate's medical record.
 5. Retest active candidates for antibodies according to #1 above at all of the following times:
 - At least once every 90 days (+/- 20 days) from the date of the first antibody test
 - When any potentially sensitizing event occurs
 - When a paired candidate who has been inactive for more than 90 days has been reactivated
 - When an unacceptable and positive physical crossmatch occurs that precludes transplantation of the matched candidate

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If any new unacceptable antigens are identified, then the paired candidate's transplant hospital must report these antigens using the process outlined in #3 and #4 above. If no new unacceptable antigens are identified, the paired candidate's transplant hospital must document the antibody screening results in the paired candidate's medical record.

75 13.5.CHLA Typing Requirements for OPTN KPD Donors

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Before a paired donor can appear on an OPTN KPD match run, the paired donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

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- HLA-A
 - HLA-B
 - HLA-Bw4
 - HLA-Bw6
 - HLA-C
 - HLA-DR
 - HLA-DR51
 - HLA-DR52
 - HLA-DR53
 - HLA-DQA
 - HLA-DQB
 - HLA-DPB

94 13.5.DResponding to OPTN KPD Match Offers

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1. Before declining an OPTN KPD match offer due to unacceptable antigens, the matched candidate's physician or surgeon or their designee must review the matched donor's antigens and their matched candidate's unacceptable antigens with the histocompatibility laboratory director or the director's designee. This joint review must be documented in the matched candidate's medical record.

- 101 2. When an OPTN KPD match offer is declined due to either a positive crossmatch or
 102 unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must
 103 submit a written explanation to the OPTN Contractor within 7 days after declining the offer.
 104 3. The matched candidate's transplant hospital is responsible for performing HLA typing on the
 105 matched donor and verifying the HLA information reported prior to transplant.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

106
 107
 108
 109 The OPTN KPD program will only match candidates who comply with *all* of the
 110 following requirements:

- 111
 112
 113
 114 1. The candidate's transplant hospital must comply with Policies 5.5.A: *Receiving and*
 115 *Reviewing Organ Offers* and 5.5.D: *Blood Type Verification upon Receipt*
 116 2. The candidate's transplant hospital must complete the informed consent process according to
 117 KPD Operational Guidelines
 118 3. The candidate's transplant hospital must submit all the information for these required fields to
 119 the OPTN Contractor:
 120
 121 a. Candidate details, including all of the following:
 122 • Last name
 123 • First name
 124 • SSN
 125 • Date of birth
 126 • Gender
 127 • Ethnicity/Race
 128 • ABO
 129 • Whether the candidate has signed an agreement to participate in the OPTN KPD
 130 program
 131 • Whether the candidate has signed a release of protected health information
 132 • Whether the candidate is a prior living donor
 133 • KPD status
 134 b. Candidate choices, including all of the following:
 135 • Whether the candidate would be willing to travel, and, if so, the transplant hospitals to
 136 which a candidate would be willing to travel
 137 • Whether the candidate is willing to accept a shipped kidney, and, if so, from which
 138 transplant hospitals the candidate would be willing to accept a shipped kidney
 139 • Minimum and maximum acceptable donor age
 140 • Minimum acceptable donor creatinine clearance or GFR
 141 • Maximum acceptable donor BMI
 142 • Maximum acceptable systolic and diastolic blood pressure
 143 • Whether the candidate is willing to accept a hepatitis B core antibody positive KPD
 144 donor, a CMV positive KPD donor, and an EBV positive KPD donor
 145 • Whether the candidate would be willing to accept a left kidney, right kidney, or either
 146 kidney
 147 c. Candidate HLA as defined in Policy 13.5.A: *Histocompatibility Requirements for KPD*
 148 *Candidates*
 149
 150 4. The candidate must have current active status in the OPTN KPD program
 151 5. The candidate must have at least one active and eligible potential KPD donor registered in
 152 the OPTN KPD program

6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program
7. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

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

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by Policy 14.4.A: Living Donor Blood type Determination with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to KPD Operational Guidelines
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:
 - a. Donor details, including all of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Height and weight
 - Whether the potential KPD donor is a non-directed donor or a paired donor
 - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
 - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
 - Whether the potential KPD donor has signed a release of protected health information
 - Whether the potential KPD donor has signed an informed consent as required in policy
 - Whether the potential KPD donor has undergone a medical evaluation as required in Policy 14: Living Donation
 - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status: active, inactive or removed
 - b. Clinical information, including all of the following:

- 206 • The number of anti-hypertensive medications the potential KPD donor is currently
207 taking
- 208 • Systolic and diastolic blood pressure with date (either 24-hour monitoring or two
209 measurements)
- 210 • Creatinine clearance, date, and method
- 211 • Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
- 212
- 213 c. Donor choices, including all of the following:
- 214 • Whether the potential KPD donor would be willing to travel, and, if so, the transplant
215 hospitals to which the potential KPD donor would be willing to travel
- 216 • Whether the potential KPD donor is willing to ship a kidney
- 217 • Whether the potential KPD donor is willing to donate a left kidney, right kidney, or
218 either kidney
- 219 • Whether the KPD candidate-donor pair and the transplant hospital are willing to
220 participate in a three-way exchange or a donor chain
- 221 • Whether the potential KPD donor and the transplant hospital are willing for the
222 potential KPD donor to be a bridge donor
- 223
- 224 d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD*
225 *Donors*
- 226
- 227 5. The potential KPD donor must have current active status in the OPTN KPD program
- 228 6. The potential KPD donor must be paired to an active and eligible candidate registered in the
229 OPTN KPD program
- 230 7. The transplant hospital registering the potential KPD donor must submit a response for all
231 previous match offers for the potential KPD donor in the OPTN KPD program
- 232 8. The potential KPD donor must not be in a pending exchange in the OPTN KPD program.
- 233

234 **1. 13.7 OPTN KPD Screening Criteria**

235 13.7.C Unacceptable Antigens

236

237 A transplant hospital ~~may~~ must specify any unacceptable antigens it will not accept for its paired
238 candidates using the process outlined in *Policy 13.5.B: Antibody Screening Requirements for*
239 *OPTN KPD Candidates*. The OPTN Contractor will not match the paired candidate with any
240 potential KPD donor who has one of the candidate's unacceptable antigens entered as a human
241 leukocyte antigen (HLA) value.

242

243 **2. 13.10 OPTN KPD Crossmatching Protocol**

244

245 The matched candidate's transplant hospital must do all of the following:

246

- 247 1. Perform a physical crossmatch between the matched candidate and the matched donor
248 before the matched donor's recovery is scheduled.
- 249 2. Perform a final crossmatch prior to transplant.
- 250 3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant
251 hospital.
- 252

253 If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable
254 positive crossmatch between the candidate and the matched donor, then the matched candidate is
255 ineligible for subsequent match runs. The candidate will remain ineligible until all of the following are
256 completed:

257

- 258 1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory

259 director or the director's designee review the unacceptable antigens reported for the candidate.
260 2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has
261 occurred.

262
263 ~~The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the~~
264 ~~OPTN KPD program before the matched KPD donor's recovery procedure.~~

265
266 The paired donor's transplant hospital ~~registering the potential KPD donor~~ is responsible for arranging
267 shipment of the paired potential KPD donor's blood sample to the matched candidate's transplant hospital
268 or the laboratory specified by the matched candidate's transplant hospital.

269
270 ~~The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the~~
271 ~~results to the OPTN Contractor and the matched KPD donor's transplant hospital.~~

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Public Comment Responses

1. Public Comment Distribution

Date of distribution: March 14, 2014

Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	47	43 (91%)	0 (0%)	2 (4.2%)	2 (4.2%)
Regional	11	11 (100%)	0 (0%)	0 (0%)	0 (0%)
Committee	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)

2. Primary Public Comment Concerns, Questions, and Post-Public Comment Considerations

There were three major themes among the comments received.

1. Verifying accuracy of unacceptable antigens

The comments submitted on behalf of ASHI raised a concern that section 13.5.B only specified that one of two reviewers be from the histocompatibility laboratory and recommended that the other reviewer must be the physician or surgeon or their designee. When presented with this comment, the members of the KPD Workgroup's Histocompatibility Advisory Committee responded that this requirement was *not* about a joint review, but intended to require someone from the histocompatibility laboratory verify accuracy in the unacceptable antigen data before it is entered. Their assumption is that some of the HLA data errors that occur are due to coordinators who are not knowledgeable about HLA entering the data.

Members of the KPD Workgroup and the Committee expressed concerns about requiring the histocompatibility laboratory staff to verify these data, because the policy also requires the candidate's transplant program to document the verification. There were concerns that this would be very burdensome for programs to comply with, especially when unacceptable antigens can fluctuate frequently for some candidates. The Committee weighed this concern against the need for unacceptable antigens to be entered accurately, because accuracy is key to increasing the successful match rate in the KPD program. As a result, the final proposal includes a requirement for the candidate's physician or surgeon (or their designee) and the histocompatibility laboratory director (or their designee) to review the unacceptable antigens before the candidate can appear on their first KPD match run. Members of the Committee felt that this was in keeping with the KPD Consensus Conference recommendations that the transplant program and the laboratory collaborate and communicate on KPD transplants, while also minimizing the burden for transplant program compliance.

2. Frequency of Antibody Screenings

During the public comment period, the Committee specifically requested feedback on the proposed requirement that all candidates in the OPTN KPD program be screened for antibodies every 90 days. Some members of the KPD Workgroup and the Committee had previously expressed concern that requiring antibody screenings on *all* candidates quarterly will be expensive and burdensome to participating programs, but they wanted to seek feedback from the community before removing this requirement. The majority of the regional, individual, and professional societies feedback indicated that 90 days is a reasonable timeframe and specifying a frequency is appropriate in the KPD program, where HLA antibody issues are the causes of a significant number of match failures. In order to ease the compliance burden on transplant programs, the Committee has added a +/- 20 day window to the 90 day requirement.

3. Candidate Eligibility in Cases of Unacceptable Positive Crossmatch

During the public comment period, the Committee requested specific feedback on a section of proposed policy 13.10 which would require the candidate’s transplant program to inactivate a candidate prior to the next KPD match run if there was an unacceptable positive crossmatch that precluded transplant with a matched donor (and, therefore, broke the entire chain). The Committee solicited feedback on whether the OPTN Contractor should automatically make a candidate ineligible after an unacceptable positive crossmatch occurs, alleviating some burden from the individual programs. Some members thought that allowing the transplant hospital to inactivate the candidate gives transplant hospitals *more* flexibility in the process.

The majority of regional, individual, and professional society comments recommended that the OPTN Contractor be responsible for making the candidate ineligible. In response to these comments, the Committee is recommending that UNOS make a candidate ineligible for subsequent match runs when the candidate’s program reports that an unacceptable positive crossmatch has occurred with a matched donor. UNetSM will alert the program that the candidate is ineligible and the candidate will remain ineligible until the program confirms that the candidate’s physician or surgeon and the histocompatibility laboratory director have reviewed the unacceptable antigens.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	11 yes, 0 no, 3 abstentions		In person
2	03/28/2014	27 yes, 0 no, 1 abstention		In person
3	5/30/2014	14 yes, 0 no, 1 abstention		In person
4	5/9/2014	24 yes, 0 no, 0 abstentions		In person
5	6/12/2014	24 yes, 4 no, 0 abstentions		In person
6	5/16/2014	51 yes, 0 no, 0 abstentions		In person
7	5/9/2014	20 yes, 0 no, 0 abstentions		In person

8	4/4/2014	17 yes, 0 no, 1 abstention	In person
9	5/21/2014	9 yes, 0 no, 0 abstentions	In person
10	5/15/2014	22 yes, 0 no, 0 abstentions	In person
11	5/30/2014	22 yes, 0 no, 0 abstentions	In person

Region 1:

The region supports typing the donor at the donor's transplant hospital. Retyping the donor at the candidate's hospital is burdensome and unnecessary.

Committee Response:

The proposal places the requirement on the candidate's hospital to ensure a second and separate typing verifies the donor HLA type.

Region 2: The region did not have any comments about the proposal, but responded to the request for feedback. In cases where an unacceptable positive crossmatch breaks a chain, there was support for having UNOS automatically inactivate a candidate and automatically reactivate them once the review is complete. There was also consensus that screening every 90 days for all candidates was reasonable.

Committee Response:

The proposal now reflects both of the region's recommendations.

Region 3:

No comments

Region 4:

DPA should be added to the donor and candidate HLA typing requirements. The region responded to the committee's questions as follows:

- Please inactivate candidates automatically in the KPD program if an unacceptable positive crossmatch occurs.
- There should be a longer timeframe between antibody screenings for non-sensitized candidates. The suggestion of 180 days seems reasonable.

Committee Response:

The Committee did not amend the proposal to add HLA-DPA to the list of types required to be reported on donors because this would be an additional requirement on transplant programs and was not discussed as part of the public comment process. The Committee has discussed the possibility of adding this requirement as part of a future public comment proposal.

Region 5:

- Regional members felt that re-testing for low risk candidates should only be required at max every 180 day but felt that annual was sufficient. They agreed those candidates at higher risk for positive crossmatch should be tested more frequently.
- Several members asked if UNOS had data to track how quickly certain level of sensitized candidates were being transplanted in the national system. They felt that at some point, this data should be used to determine how often candidates should be re-tested. The

ultimate goal is to have a current snapshot of a candidate's sensitivity. Without knowing what the average time to transplant is, this is hard to predict the optimal testing timeframe.

Committee Response:

The majority of the regional, individual, and professional societies' feedback indicated that 90 days is a reasonable timeframe and specifying a frequency is appropriate in the KPD program, where HLA antibody issues are the causes of a significant number of match failures. Therefore, the Committee decided not to amend the proposal to allow for a more relaxed frequency for non-sensitized candidates. However, in order to ease the compliance burden on transplant programs, the Committee has added a +/- 20 day window to the 90 day requirement.

For candidates added to the OPTN KPD pilot program between January 1, 2012 and November 22, 2013, about half of patients were still waiting for a transplant after 12 months and 35% were still waiting at 18 months. For those that were transplanted through the OPTN KPD pilot program, the median time to transplant has been approximately 185 days¹. Since high-CPRA patients have accounted for disproportionately fewer transplants compared to lower-CPRA patients, the median time-to-transplant for highly sensitized patients is likely to be higher. Once larger sample sizes are available, reliable estimation of time-to-transplant for various groups of patients, including by level of sensitization, will become more feasible.

Region 6:

The region requested clarification of policy section 13.5.A, 2. to indicate that if a candidate had antibody to on one HLA type, for example HLA C, they would only need to be typed for HLA C not DR, DPB etc. The group did not come to consensus about screening all candidates every 90 days. The transplant programs thought this was not necessary and the Histo labs thought it was a good idea because they would not be aware of a sensitizing event. There was no comment on having the candidate inactivated automatically by UNOS versus having the center inactivate.

Committee Response:

The Committee amended the proposal to make clear that the candidate's transplant program is only required to report the corresponding candidate HLA type if the candidate reports unacceptable antigen. The Committee appreciates your question and attention to detail.

Region 7:

The committee asked for specific feedback on the following questions:

- Should UNOS inactive or should the center? The centers should inactivate the candidates since they control the testing timeline and UNOS does not inactivate candidates for any other reasons.
- Should candidates be tested every 90 days? Members felt that the regional standard of practice was to perform the testing anywhere from 90-120 days. They felt that 90 was reasonable.

Committee Response:

The majority of regional, individual, and professional society comments recommended that the OPTN Contractor be responsible for making the candidate ineligible. In response to these comments, the Committee is recommending that UNOS make a candidate ineligible for subsequent match runs when the candidate's program reports that an unacceptable positive crossmatch has occurred with a matched donor. UNetSM will alert the program that the candidate is ineligible and the candidate will remain ineligible until the program confirms that the candidate's

¹ The State of the OPTN/UNOS KPD Pilot Program.
http://optn.transplant.hrsa.gov/ContentDocuments/KPD_Report.pdf

physician or surgeon and the histocompatibility laboratory director have reviewed the unacceptable antigens.

Region 8:

The region had no opinion on who should inactivate/activate candidates who have unacceptable positive crossmatches. There was general support for screening all candidates every 90 days.

Region 9:

The region didn't reach consensus as to whether UNOS or the transplant hospital should inactivate the candidate. Several members were concerned about how/if UNOS will notify them when inactivating candidates.

Requiring antibody screenings every 90 days seemed reasonable to the region.

Committee Response:

UNetSM will alert the program that the candidate is ineligible and the candidate will remain ineligible until the program confirms that the candidate's physician or surgeon and the histocompatibility laboratory director have reviewed the unacceptable antigens.

Region 10:

Members expressed frustration that UNOS is not moving towards requiring universal participation in the national system. It is in the best interest of all KPD candidates to have access to the most robust list possible – which would be a national system.

Committee Response:

Thank you for your comment, but this is out of scope for this proposal.

Region 11:

No comments

4. Committee Public Comment Responses

Histocompatibility Committee:

The Histocompatibility Committee reviewed this proposal on August 12, 2014. Below are the comments from the Committee.

Crossmatching

There were some questions about the crossmatching requirements and, in particular, the timing of the crossmatch. The proposal would require the crossmatch to be performed before the donor's nephrectomy is scheduled. The Committee recommends requiring a review between the physician/surgeon and the HLA laboratory director (to discuss sensitization history, the possible need for additional screening or crossmatch) if the transplant doesn't occur within 60 days of the original crossmatch.

Frequency of Antibody Screenings

In response to the specific request for feedback regarding the requirement to perform antibody screenings on all candidates every 90 days, the members of the committee were somewhat split in opinion. Half of the committee indicated support for leaving the requirement as is. This half of the committee did not agree that there should be a longer timeframe for candidates who are/were

unsensitized on previous screenings, because a longer timeframe (180 days was used, for example) could mean that they would proceed to transplant on what they considered to be very old test results (100 days or more).

The other half thought that it would be more productive to require the collection of sera every 30 days (monthly) instead of specifying the frequency for antibody screenings. This half of the committee said that having a recent sample to perform the tests is the most important key in this instance and that the frequency of screenings should be left as a center specific practice. Some members of the committee did not agree that this should be left to the center to decide as a protocol, reasoning that many programs are involved in the same exchange and they are just as dependent on the outcome of the match run as other centers, so consistency is key for KPD.

Inactivation Due to Unacceptable Positive Crossmatch

In response to the specific request for feedback, the Committee did not specify a particular option as to whether UNOS or the transplant program should be responsible for inactivating the candidate. They did, however, express the hope that the review/reporting turnaround time would be quick so that the candidate is not disadvantaged by not being eligible for match runs for significant periods of time. This is especially because there will be many instances where the crossmatch is unacceptable because of low level antibodies and the unacceptable antigens are not going to change with the review between the surgeon/physician and the HLA laboratory director.

Members of the Committee did suggest that the Kidney Committee consider requiring the program to pre-refuse that particular donor for the candidate for subsequent match runs.

Kidney Committee Response:

Thank you for your comments. The proposal contains a requirement for a final crossmatch to be performed prior to transplant, as this is in compliance with federal regulations. The Committee did not make the changes suggested as alternatives around the frequency of antibody screenings and the unacceptable positive crossmatches, because these would require additional, more burdensome actions from transplant programs and were not discussed as part of the public comment process.

5. Individual Public Comment Responses

Comment 1:

Vote: Oppose

Date Posted: 06/11/2014

I oppose the proposal unless it is modified in the following ways: First, there should be no requirement that candidates have to be typed by molecular methods. Although most laboratories use molecular methods for their routine HLA typing, there is no requirement that typing candidates for deceased donor transplants have to use molecular methods and there is no reason why KPD candidate typing should be different. Specifically, there is no way any possible error in candidate typing would affect cross-match results since those depend completely on candidate antibodies and those are the only critical results for KPD exchanges. It would be unduly burdensome to require all labs to have to retype candidates who were previously typed by serological methods or to require them to have different protocols to participate in the KPD Program from what they already do for deceased donor transplant candidates. Second, while it would be good clinical

practice for transplant hospitals to ensure that the HLA-C, HLA-DR51/52/53, DQB1, DQA1 and DPB1 specificities they list as unacceptable for individual KPD candidates are actually not the patients own types, there is no requirement for doing that for candidates for deceased donors and there is no reason why any errors in excess unacceptable antigen assignments would cause any delays in the KPD allocation process. Candidates may have too many unacceptable antigens but that is a problem for that Transplant Center. Meanwhile, this requirement would serve mainly to increase the cost to all centers for their participation in the KPD Program. Third, one of the stated goals of the proposal was to require joint review of the assignment of unacceptable antigens by both a candidate's surgeon/physician or their delegate and the HLA Laboratory Director. However, the actual proposal only requires that for cases when an offer is declined. I would strongly object to the idea that joint review would be required every time an unacceptable antigen is assigned; the process for assigning unacceptable antigens often requires testing with several different methods and it would be very impractical to have to involve a nephrologist, surgeon or their designee in every such decision. Finally, I believe that there is little or no incentive for transplant centers to comply with the new requirement to inactivate candidates after an offer is refused until they investigate why it happened. Instead, I would suggest that such candidates be placed on KPD inactive status by the OPTN/UNOS until the transplant hospital either updates the unacceptable antigens or otherwise offers a plausible explanation for the decline (perhaps with expedited review by a subcommittee of the Histocompatibility Committee).

Response 1: Both the requirement to perform molecular typing on candidates and the additional reporting of candidate HLA types is designed to allow for more information in the donor acceptance process when the candidate has HLA antibodies. These recommendations were requested by the KPD Workgroup's Histocompatibility Advisory Committee and the OPTN/UNOS Histocompatibility Committee. The KPD Consensus Conference findings also include the recommendation that molecular typing be required.

Under the final proposal, the joint review of unacceptable antigens will be required 1)before the candidate appears on their first KPD match run; 2)before the program declines based on unacceptable antigens; and 3)when there is an unacceptable positive crossmatch that precludes transplant with a matched donor. This collaboration between the candidate's physician and the histocompatibility laboratory staff is a recommendation from the KPD Consensus Conference and is intended to decrease the likelihood of future match failures.

Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for information on changes related to candidate eligibility in response to an unacceptable positive crossmatch.

Comment 2:

Vote: Oppose

Date Posted: 06/12/2014

Section 13.5.3 Documentation of unacceptables should be programmed into UNET so whoever is updating them can document within the screen that this was done. It poses too much of a burden for the outside lab to communicate with the transplant center everytime the unacceptables are updated on recipients. This bound to cause confusion and missed documentation. If it is programmed into the screen you could also consider automatically inactivating recipient if they do not have updated unacceptables. THE rationale is that data that is not kept up to date has a much higher risk of cxm failure. NKR does program this type of 'lab maintenance' directly in their website which proves very convenient and they are aware of outdated data. 13.10.2 It should be left to

the discretion of the recipient transplant center if they want a final crossmatch based on when the initial cxm was completed and factors related to recipient.

Response 2: Under the final proposal, the joint review of unacceptable antigens will be required 1)before the candidate appears on their first KPD match run; 2)before the program declines based on unacceptable antigens; and 3)when there is an unacceptable positive crossmatch that precludes transplant with a matched donor. This collaboration between the candidate's physician and the histocompatibility laboratory staff is a recommendation from the KPD Consensus Conference and is intended to decrease the likelihood of future match failures. UNetSM will be programmed to have a reporting mechanism for the joint review in cases of an unacceptable positive crossmatch. However, all other reviews will require documentation in the candidate's medical record.

The proposal contains a requirement for a final crossmatch to be performed prior to transplant, as this is in compliance with federal CLIA regulations.

Comment 3:

Vote: Support

Date Posted: 06/09/2014

The College of American Pathologists (CAP), the Histocompatibility/Identity Testing Committee of the CAP, and the CAP Laboratory Accreditation Program agree with the American Society for Histocompatibility and Immunogenetics (ASHI) position of support for the UNOS Proposal 1: Kidney Transplantation Committee: Kidney Paired Donation (KPD) Histocompatibility Testing Policies. The CAP supports the recommendation for Proposal 1 to modify section 13.5.B.3 to specify the second individual for reviewing and verifying unacceptable antigens be specified as a physician, surgeon or designee. The CAP supports the suggested wording change for 13.5.D.3 to "The matched candidate's transplant hospital is responsible for performing HLA typing on the matched donor at an appropriate level to verify the HLA information reported and to confirm the identity of the original sample prior to transplant." The CAP also supports the recommendation that the OPTN Contractor automatically inactivate the KPD candidate before the next match run after an unacceptable positive crossmatch.

Response 3: Thank you for your comment. Many of your recommendations have been incorporated into the final proposal. Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for more details.

Comment 4:

Vote: Support

Date Posted: 06/04/2014

ASHI supports this proposal. It is much improved over the former version and it is clear that the Kidney Committee took into consideration the opinions of the OPTN/UNOS Histocompatibility Committee, the KPD Consensus Conference, and ASHI. However, we would like to make a few comments: Under the summary and goals of the proposal, it states that the candidates physician or surgeon (or designee) and the affiliated histocompatibility laboratory director (or designee) must review and confirm the unacceptable antigens reported for a candidate. We support the intent of this requirement. However, in the actual policy, it would appear that this communication between the physician/surgeon and laboratory director is only a requirement when declining an offer (13.5.D.1). For reviewing and verifying entry of a candidates unacceptable antigens, the requirement is for two separate individuals, one of whom must be the laboratory director or

directors designee (13.5.B.3). However, in this case, there is no requirement for the second individual to be a physician or surgeon or their designee. We suggest that the second individual in 13.5.B.3 be specified as a physician, surgeon or designee. Section 13.5.D.3 states that the matched candidates transplant hospital is responsible for performing HLA typing on the matched donor and verifying the HLA information reported prior to transplant. ASHI supports the idea that verification typing to confirm the identity of the original sample needs to be performed, but the proposed wording is vague and could imply that all the same loci need to be typed again at the same resolution as the original typing. We suggest that the policy be reworded to: The matched candidates transplant hospital is responsible for performing HLA typing on the matched donor at an appropriate level to verify the HLA information reported and to confirm the identity of the original sample prior to transplant. Section 13.5.B.5 requires the transplant program to inactivate the candidate before the next match run after an unacceptable positive crossmatch. While some members of the Kidney Committee might feel that this gives the transplant programs more flexibility in the process, we are concerned that there might be less than total compliance with this requirement and it will be difficult to monitor. A better solution may be to have the OPTN Contractor automatically inactivate the candidate and require the program to update the unacceptable antigens or to otherwise offer a plausible explanation to reactivate the candidate. It should also be specified in the policy that this inactivation is only for KPD runs and not for deceased donor offers, if that is indeed the case.

Response 4: Thank you for your comment. Many of your recommendations have been incorporated into the final proposal. Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for more details.

Comment 5:

Vote: Support

Date Posted: 06/17/2014

ASTS supports this proposal regarding requirements for histocompatibility testing on donors and recipients in the OPTN KPD program. ASTS is pleased that the committee considered recommendations from the March 29-30, 2012 KPD consensus conference in Herndon, VA in formulating this policy proposal.

Comment 6:

Vote: Support

Date Posted: 05/11/2014

I have been an organ donor on my driver's licence for years. I feel if someone can benefit from the use of my organs, I am more than happy to let them have the organ(s) needed. I do really believe in the three r's. Reduce, reuse and recycle. I am glad to be able to do that for someone.

Comment 7:

Vote: Support

Date Posted: 05/29/2014

I support overall proposal except, I oppose the requirement that both the lab director and the surgeon or physician must review the unacceptable antigens. I feel that two people from the Histocompatibility lab must review the unacceptables and one of them should be the director in contrast to the physician or surgeon + histo lab director. Alternatively, the two reviewers may be a transplant coordinator and the lab director or designee.

Response 7: The final proposal allows for the candidate's physician or surgeon and the histocompatibility laboratory director to select a designee for the review of unacceptable antigens.

Comment 8:

Vote: Support

Date Posted: 05/12/2014

I think everyone should have the same chance at getting donated organs.

Comment 9:

Vote: Support

Date Posted: 05/12/2014

If the organs are good give them to the kids first please!

Comment 10:

Vote: Support

Date Posted: 06/13/2014

NATCO supports this proposal as written.

Comment 11:

Vote: Support

Date Posted: 05/12/2014

Passage of this proposal will ensure that kids have access to a larger donor pool. With the alternative being death in most if not all cases, what is there to lose?

Comment 12:

Vote: Support

Date Posted: 06/05/2014

Please accept ASHI recommendations

Comment 13:

Vote: Support

Date Posted: 06/11/2014

Section 13.5.B.5 requires the transplant program to inactivate the candidate before the next match run after an unacceptable positive crossmatch. There is a concern that some centers might not be totally compliant with this requirement and it will be difficult to monitor. Therefore, centers with recurrent unacceptable positive crossmatches should be penalized since the impact of these crossmatch failures can be huge.

Response 13: Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for more details.

Comment 14:

Vote: Support

Date Posted: 06/06/2014

Section 13.5.D.3 requires that the matched candidates transplant hospital confirm the donor typing. This would suggest that the typing is to be repeated for all loci. This would not be time or cost efficient if the purpose is to confirm the identity of the tissue received for testing. Typing at a level sufficient to verify the identity of the tissue is more appropriate. Section 13.5.B.5. I support comments from ASHI that the OPTN Contractor inactive a patient with an unexpected positive crossmatch. I also support ASHI's recommendation that the physician or surgeon should be added as additional verifier of data entered in section 13.5.B.3

Response 14: The policy does not specify a method for retyping the donor. Programs will be required to confirm the HLA typing data reported by the donor's laboratory. Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for more details about eligibility in cases of unacceptable positive crossmatches.

Comment 15:

Vote: Support

Date Posted: 06/13/2014

This proposal makes GOOD SENSE. The one concern that I have is in regard to frequency of antibody screening. This is a center specific practice. I think that rather than prescribing the frequency (or the medical practice), the proposal should be worded in such a way that the center must have on hand at all times a screened current serum adequate to perform the preliminary crossmatch without having to acquire a new serum sample producing a delay in the construction of the final chain.

Response 15: Please see above section, "Primary Public Comment Concerns/Questions and Post-Public Comment Considerations" for more details about the frequency of antibody screenings.

Comment 16:

Vote: Support

Date Posted: 06/06/2014

This proposal provides better protection of the patient and reduces the chance of an unexpected positive crossmatch.

Comment 17:

Vote: Support

Date Posted: 06/16/2014

We find the proposal strong and well written. The AST supports the proposal. We believe the changes will increase efficiency in arranging compatible matches and facilitate transplants for candidates enrolled in KPD.

Comment 18:

Vote: Support

Date Posted: 06/08/2014

Willing to donate any organs needed any just tired of hurting and knowing theirs kids out there that haven't had a chance to live

Comment 19:

Vote: No Opinion

Date Posted: 05/10/2014

I was a living kidney donor who was not INFORMED that I was a 0 HLA with the man that I had asked to be tested for. I was never told that I was a 0 match. I was deceived and I resent this to this day. I was never told about the paired kidney donation program or offered to participate. The surgeon used my 0 matched kidney without my knowledge that I was 0 match. The kidney failed within 6 months and I was used for a transplant that had very little chance of success to begin with. I did not consent to this. I was never informed. The surgeon even went so far as to say that I did not NEED to know that I was a 0 HLA match. This is a system that preys upon kind compassionate trusting people to harvest organs for a transplant. No one cares what the transplant industry did to me. My life does not matter. All they wanted was my organ. I am not upset that the transplant failed. I am outraged that I was deceived and that a transplant that had little chance of success was ALLOWED to go forward. Placing my life and the life of the recipient at risk. All I hear about is the great need there is for more organs and mine was thrown in the garbage and wasted on a transplant that was destined to fail from the beginning. I CAN NOT ever support living donation again after this was allowed to happen and go unpunished. I am left with complications that have effected my quality of life all for a lie. Living donors deserve to know the FULL truth and be fully informed before ever proceeding.