



Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219

P.O. Box 2484, Richmond, VA 23218

tel: 804-782-4800

fax: 804-782-4817

www.unos.org

IMPORTANT NOTICE

To: Transplant Professionals

From: Brian M. Shepard
UNOS Assistant Executive Director for Contract Operations

RE: Summary of changes to the OPTN Kidney Paired Donation (KPD) Pilot Program Operational Guidelines

Date: November 30, 2011

The attached report summarizes changes the OPTN/UNOS Kidney Transplantation Committee approved at its September 2011 meeting.

This format allows you to scan the changes and quickly determine what is required of you. The notice also includes the specific changes to KPD Pilot Program Operational Guidelines.

Included as separate attachments are:

- The updated version of the OPTN KPD Pilot Program Operational Guidelines
- Updated informed consent templates, including:
 - Agreement to participate
 - Potential donor education documentation form
 - Candidate education documentation form
- An addendum to the existing potential donor education documentation form that includes only the new informed consent elements for use with potential donors who have already signed an informed consent form that includes the existing required elements of informed consent.
- Updated KPD frequently asked questions

Thank you for your careful review. If you have any questions about a particular Board action, please contact Ruthanne Hanto at (804) 836-4652 or ruthanne.hanto@unos.org or Elizabeth Sleeman at (804) 782-4616 or elizabeth.sleeman@unos.org.

Updates to OPTN KPD Pilot Program Operational Guidelines

Sponsoring Committee: Kidney Transplantation Committee

OPTN KPD Pilot Program Operational Guidelines Affected: Requirements for Participation, Prioritization Points, Donor Chains, Eligibility for A₂ and A₂B Matches

Distributed for Public Comment: No

Effective Date: September 19, 2011

Problem Statement:
The requirements for donor chains approved by the Board of Directors in November 2010 had not been incorporated into the OPTN KPD Pilot Program Operational Guidelines. Similarly, options for blood type O and B candidates to be matched to blood type A ₂ and A ₂ B donors were included in the original KPD proposal but not specifically mentioned in the Operational Guidelines previously. As a result, participants would need to refer to multiple documents to find all the requirements related to the OPTN KPD Pilot Program.
Changes:
The revisions to the OPTN KPD Pilot Program Operational Guidelines incorporate changes made as part of the donor chains proposal approved by the Board of Directors in November 2010 and codifies the titer requirements recently approved by the Kidney Transplantation Committee. Additionally, the transplant program requirements have been updated to reflect that the OPTN now has a process for approving programs that perform living donor kidney recoveries. Previously, the Operational Guidelines noted that requirement would be in effect “when applicable.” <i>Please note: These requirements were already approved by the OPTN/UNOS Board of Directors and are in effect.</i>
What You Need to Do:
Refer to the OPTN KPD Pilot Program Operational Guidelines for all rules related to the Pilot.

Affected OPTN KPD Pilot Program Operational Guidelines Language:

Requirements for Participation

1. Purpose: To outline the prerequisites that centers must meet to be eligible to participate in the Kidney Paired Donation (KPD) Pilot Program and to outline the criteria that candidates and donors must meet before they are entered in the Program by the transplant center.

2. Procedures:

a. According to the Charlie W. Norwood Living Organ Donation Act (H.R. 710),

“(4) The term ‘paired donation of human kidneys’ means the donation and receipt of human kidneys under the following circumstances:

“(A) An individual (referred to in this paragraph as the ‘first donor’) desires to make a living donation of a kidney specifically to a particular patient (referred to in this paragraph as the ‘first patient’), but such donor is biologically incompatible as a donor for such patient.

“(B) A second individual (referred to in this paragraph as the ‘second donor’) desires to make a living donation of a kidney specifically to a second particular patient (referred to in this paragraph as the ‘second patient’), but such donor is biologically incompatible as a donor for such patient.

“(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.

“(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.

“(E) All donors and patients in the group of donor-patient pairs (whether two pairs or more than two pairs) enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.

“(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to in such subparagraph.”.

b. Transplants centers:

- i. Must be Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS) approved to perform kidney transplants and living donor kidney recovery (see UNOS Bylaws, Appendix B, Attachment I, Section XIII on kidney transplant programs)
 - ~~ii. When applicable, must be OPTN approved to perform living donor kidney transplants~~
 - iii. Must have a designated contact for the KPD Pilot Program (See KPD Contact Responsibilities Operational Guideline)
 - iv. Must agree to abide by all rules set forth in the Kidney Paired Donation Pilot Program Operational Guidelines and the OPTN/UNOS Bylaws and Policies, unless explicitly stated otherwise in the KPD Pilot Program Operational Guidelines. Any potential violations of the KPD Operational Guidelines or any potential violations of policies and bylaws could be referred to the Membership and Professional Standards Committee.
- c. Candidates:
- i. Must be registered on the deceased donor kidney waiting list at the transplant center that wishes to enroll the candidate in the KPD Pilot Program
 - ii. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.
- d. Potential Living Donors:
- i. Must be at least 18 years old
 - ii. Must meet the evaluation requirements set forth in the Living Donor Evaluation Section of the Kidney Paired Donation Pilot Program Operational Guidelines
 - iii. Must be consented according to the consent process outlined in “The Resource Document for the Informed Consent of Living Donors” and in the Informed Consent Requirements Section of the KPD Pilot Program Operational Guidelines.
 - iv. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.
 - v. Must not be currently listed as a potential living donor for any other candidate registered in the KPD system

3. Records Required:

- All records below must be maintained and submitted to the OPTN contractor upon request:
 - Record of candidate's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the candidate's chart
 - Record of the potential living donor's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the potential living donor's chart
 - Record of the potential living donor's informed consent according to the consent process outlined in "The Resource Document for the Informed Consent of Living Donors" in the potential living donor's chart.

Prioritization Points

1. **Purpose:** To describe the candidate characteristics and the match characteristics that receive priority or additional points in the Kidney Paired Donation Pilot Program
2. **Procedures:**
 - a. Each match between a candidate and potential living donor receives a base of 200 points.
 - b. Zero antigen mismatches between a potential living donor and a candidate receive an additional 200 points.
 - c. Highly sensitized (e.g., probability of positive crossmatch \geq 80%) candidates receive an additional 125 points.
 - d. Candidates who are prior living organ donors receive an additional 150 points.
 - e. Pediatric (i.e., age < 18 years) candidates receive an additional 100 points.
 - f. Candidates who have participated in previous match runs but did not receive a transplant receive an additional 2 points per match run.
 - g. Matches between candidates and potential living donors who are in the same region receive 25 points in addition to the base number of points.
 - h. Matches between candidates and potential living donors who are in the same donation service area (DSA) receive 50 points in addition to the base number of points.
 - i. Matches between candidates and potential living donors who are located at the same center receive 75 points in addition to the base number of points.
 - ~~j. Matches involving three pairs receive 10 points.~~
 - k. Matches between candidates and donors who have one or more of the candidate's other antibody specificities receive -5 points.
 - l. The waiting list candidate and the non-directed donor in a donor chain will be assigned no points.

Donor Chains

1. **Purpose:** To define the requirements for how matching will occur in the context of a donor chain
2. **Procedures:**
 - a. **Definitions**
 - i. Chains start with a non-directed donor (NDD) and end with a donation to a list recipient.
 - ii. A “segment” is a part of a chain that occurs at a different time than other parts of a chain.
 - b. **Chain Size and Location**
 - i. The chain size will be limited to twenty incompatible pairs or less.
 - ii. Chains can involve multiple hospitals.
 - c. **Logistic Details**
 - i. All donor surgeries must occur at the same time within a given segment. The centers involved in the chain can decide how many segments the chain will have and where the segments will break.
 - ii. If a transplant center, pair, or potential living donor does not want to be at the end of the segment of a chain, then the segment will not end with that pair. This provision means that the potential living donor would donate on the same day that his or her intended candidate receives a transplant.
 - iii. In cases where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates.
 - iv. The scheduled time elapsed between the end of one segment of a chain and the beginning of the next segment in the chain is encouraged to be less than 1 week and must not exceed 3 weeks.
 - v. A chain will end with a donation to a candidate on the deceased donor waiting list at the center that entered the NDD that started that chain.
 - vi. If a transplant center or a pair is unwilling to participate in a chain, they will only be matched in two-way or three-way matches.

Eligibility for A₂ and A₂B Matches

1. **Purpose:** To describe in what circumstances a blood type B or blood type O candidate would be eligible to match to blood type A₂ or A₂B donors
2. **Procedures:**
 - a. In order for a blood type B candidate to be eligible to be match to a blood type A₂ or blood type A₂B donor, or for a blood type O candidate to be eligible to match to a blood type A₂ donor, all of the following conditions must be met:
 - i. The candidate must have a titer value less than 1:8.
 - ii. The candidate's titer value and date must be entered in the KPD system.
1. **Records Required:**
 - Records of the titer test and date must be maintained and submitted to the OPTN contractor upon request.

Making HLA-DP Antigen Typing Optional in the OPTN KPD Pilot Program

Sponsoring Committee: Kidney Transplantation Committee

OPTN KPD Pilot Program Operational Guidelines Affected: Histocompatibility Testing Requirements

Distributed for Public Comment: No

Effective Date: September 19, 2011

Problem Statement:
The requirement that every potential donor have HLA-DP antigen typing prevented some donors from being entered in the OPTN KPD Pilot Program.
Changes:
HLA-DP antigen typing is now optional for potential living donors in the OPTN KPD Pilot Program. <i>Please note that the Kidney Transplantation Committee temporarily suspended HLA-DP antigen typing for potential living donors in the OPTN KPD Pilot Program for six months in March 2011. Therefore, this change is already in effect, but it is now permanent.</i>
What You Need to Do:
If possible, please continue to perform HLA-DP antigen typing on potential living donors entered in the OPTN KPD Pilot Program; however, donors can be eligible for a match run without HLA-DP antigen typing entered.

Affected OPTN KPD Pilot Program Operational Guidelines Language:

Histocompatibility Testing Requirements

1. **Purpose:** To define the histocompatibility tests that must be performed on all candidates and potential living donors participating in the Kidney Paired Donation Pilot Program
2. **Procedures:**
 - a. For candidates:
 - i. HLA-A,-B,-Bw4, 6,-Cw,-DR, and -DQB as well as -DR51, 52, 53 antigen typing is required. Patients with antibodies against HLA-DQA or DPA or DPB must be typed for these specificities so that reliable non-self antibodies are identified.

- ii. Sensitized candidates may have **unacceptable** HLA-A,-B,-Cw,-DR,-DQ and DP antigens listed that include those antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens. These antigens will be considered unacceptable in all cases.
 - 1. Antibodies against HLA-DQA or non-HLA antibodies which are considered as a contraindication to transplantation at the recipient transplant center are considered unacceptable for a donor expressing the targets of these antibodies . Determination of donor compatibility in these cases will be the responsibility of the recipient center laboratory.
 - 2. Sensitization status must be validated quarterly by retesting the candidate in accordance with center protocols.
- iii. Sensitized candidates must have additional, lower level antibodies ("other antibody specificities") against HLA-A,-B, -Bw4,6, -Cw,-DR,-DQ and DP antigens listed that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens. HLA antigen targets of these antibodies will be considered when matching pairs with a minimal risk of positive crossmatch.
 - 1. Antibody specificities must be updated whenever:
 - a. Quarterly antibody screening tests indicate a change in antibody level or specificity
 - b. A potentially sensitizing event occurs (e.g. a blood transfusion)
 - c. A patient who has been inactive for more than 3 months is reactivated.
 - d. An unexplained positive crossmatch* that precludes transplantation at the recipient center occurs.
- iv. Unsensitized patients must be identified as having no detectable anti-HLA antibodies or other unacceptable histocompatibility antigens that would preclude transplantation at the candidate's center.
- v. The laboratory must verify the candidate's HLA typing, sensitization status, and low and high stringency antigens before the candidate is eligible for a match run in the KPD Pilot Program.

**Note: An unexplained positive crossmatch is one that is not due to the presence of a reported antibody and its corresponding antigen target.*

- b. For donors:
 - i. HLA-A,-B,-Bw4,6,-Cw,-DR, and -DQ and ~~-DP~~ as well as -DR51, 52, 53 antigen typing is required. HLA- DP antigen typing is optional.
 - ii. The laboratory must verify that the donor HLA type is current and correct before the donor is activated for paired exchange.
 - iii. Donor HLA typing may be repeated by the candidate laboratory for donor verification in the initial evaluation and must be repeated in the event of an unexplained positive crossmatch. Repeat testing may include additional testing for allele-level antigens, -DQA or other antigens as required to explain the positive crossmatch
- c. Exchange of materials:
 - i. Centers must agree to provide anti-coagulated donor blood to the candidate center for preliminary and final crossmatch testing. (A minimum of two, 10cc ACD tubes and a red top). The crossmatch test will be performed by the candidate center according to their test procedures.
 - ii. When requested, a candidate serum sample must be provided to the donor center.
 - iii. Recipient and donor samples should be cryopreserved and stored for future testing for two years.
- d. Methods:
 - i. HLA typing
 - 1. Each participating laboratory must be an OPTN and UNOS member laboratory and must type for HLA-A,-B,-Bw4,6, -Cw,-DR,-DQ and -DP as well as -DR51, 52, 53 antigens at the level of split resolution.
 - 2. The primary HLA typing method must be molecular.
 - ii. Antibody screening and identification
 - 1. Test sensitivity must be sufficient to reliably detect antibodies that inform the transplant process according to the written agreement between the laboratory and the candidate transplant center.
 - 2. Identification of unacceptable (low stringency) and other high stringency HLA antigens must include at least two methods, one of which must be a solid-phase single phenotypes assay or a solid-phase single-antigen test. It is strongly recommended that specificities for

broadly sensitized patients be confirmed by solid-phase single-antigen testing.

3. Patients with IgM antibodies, autoantibodies or other potentially interfering or confounding conditions that might affect the crossmatch tests must be identified and appropriate treatment included in crossmatches.

iii. Referral laboratories

1. When a candidate or donor is listed at a center whose laboratory cannot provide testing at the level specified, testing may be performed at any OPTN and UNOS member laboratory with test expertise documented by recognized external proficiency testing. Centers whose laboratories have repeated failures to perform HLA-typing at the level required or to identify unacceptable antigens that result in positive crossmatches and preclude transplantation may be required to submit their donor and recipient samples to a referral laboratory for testing in order to register candidates and donors for paired exchange.

e. Quality Assurance

- i. Laboratories must have a written agreement with their transplant center detailing criteria for histocompatibility testing of potential exchange candidates and donors that meet or exceed those described above.
- ii. The candidate center laboratory will be responsible for identifying antibodies causing an unexpected positive crossmatch and for updating the patient's unacceptable antigens to include the new information prior to reactivating the patient for a subsequent match run.
- iii. The candidate center laboratory must identify the antibody responsible for any positive crossmatch that precludes an exchange or offer within three weeks of the crossmatch test. Any additional testing of donor or recipient specimens is the responsibility of the candidate center's laboratory and must be performed using available materials. *(The antigen causing the positive crossmatch must be provided with result entry.)*
- iv. The candidate laboratory must retain the final cross match serum specimen and the specimen used for the latest solid-phase antibody assay for a minimum of two years.
- v. A joint subcommittee of the OPTN/UNOS Kidney Paired Donation Working Group and the OPTN/UNOS Histocompatibility Committee will monitor and review HLA typing discrepancies and all positive crossmatches from potential

and actual exchanges to monitor performance by participating laboratories. Laboratories which have 3 or more unexplained positive crossmatches may be required to submit serum samples from sensitized patients to a reference laboratory for parallel solid-phase antibody testing.

3. Records Required:

All records below must be maintained and submitted to the OPTN contractor upon request:

- Documentation that the laboratory has verified the candidate's HLA typing, sensitization status, and low and high stringency antigens. The documentation should be maintained at the laboratory.

What to Do When a Chain Breaks in the OPTN KPD Pilot Program

Sponsoring Committee: Kidney Transplantation Committee

OPTN KPD Pilot Program Operational Guidelines Affected: Donor Chains

Distributed for Public Comment: No

Effective Date: February 1, 2012

Problem Statement:
There was no guidance on what should happen when a chain breaks in the OPTN KPD Pilot Program.
Changes:
<p>The OPTN KPD Pilot Program Operational Guidelines now contain the following requirements:</p> <ul style="list-style-type: none">• If a non-directed donor (NDD) has a non-O blood type (A, B, AB), then the chain will proceed up to the link where it breaks regardless of the number of transplants that result.• If the NDD has a blood type of O, then<ul style="list-style-type: none">○ If the chain <i>can reach five or more transplants</i> before breaking (regardless of the total length of the chain), then the chain <i>will proceed</i> up to the link where it breaks.○ If the chain includes less than six pairs total and the chain <i>can reach 50%</i> of the transplants before breaking, then the chain <i>will proceed</i> up to link where it breaks.○ If a chain includes less than six pairs total and the chain <i>cannot reach 50%</i> of the transplants before breaking, or if a chain that is six or longer <i>cannot reach five transplants</i>, then the NDD will be given the option to donate to the shorter chain or to enter the next match run with the possibility of finding a longer chain.• If a chain breaks more than once, a NDD will not be asked to make a choice whether to enter a later match run more than two times (for a total of three months). The three months begins with the match run where a chain started by that NDD was first found. Elements were added to the informed consent that all NDDs must be informed that they may be in a position to choose to donate to a shorter chain or to wait for another match run with the possibility of finding a longer chain. <p>In the case of a broken chain, if the operating room date is not set for a chain at the time of the next match run, but the crossmatches have been performed and the donors have been approved up to the point where the chain breaks, then the final donor could be entered in the next match run to repair the chain. The donor in this situation must agree to be entered in the next match run and must be informed in advance that this situation could arise.</p>

What You Need to Do:

Transplant centers must:

- Add elements to the informed consent process informing all blood type O NDDs in the OPTN KPD Pilot Program that they may be in a position to choose to donate to a shorter chain or to wait for another match run with the possibility of finding a longer chain.
- Add elements to the informed consent process informing all donors in the OPTN KPD Pilot Program that if the operating room date is not set for a chain at the time of the next match run, but the crossmatches have been performed and the donors have been approved up to the point where the chain breaks, then the final donor could be entered in the next match run to repair the chain. In order for the final donor to be included in the next match run, the donor must agree to be in that match run.

If any of these situations arise when a chain breaks, the transplant center must inform the donor what has happened and remind them of their options so that the donor can make a decision.

Please note: The OPTN contractor will provide a supplement to the donor informed consent template for donors who have already consented to participate in the OPTN KPD Pilot Program and will update the template so that it contains these new informed consent requirements.

Affected OPTN KPD Pilot Program Operational Guidelines Language:

Donor Chains

1. **Purpose:** To define the requirements for how matching will occur in the context of a donor chain
2. **Procedures:**
 - a. **Definitions**
 - i. Chains start with a non-directed donor (NDD) and end with a donation to a list recipient.
 - ii. A “segment” is a part of a chain that occurs at a different time than other parts of a chain.
 - b. **Chain Size and Location**
 - i. The chain size will be limited to twenty incompatible pairs or less.
 - ii. Chains can involve multiple hospitals.
 - c. **Logistic Details**

- i. All donor surgeries must occur at the same time within a given segment. The centers involved in the chain can decide how many segments the chain will have and where the segments will break.
- ii. If a transplant center, pair, or potential living donor does not want to be at the end of the segment of a chain, then the segment will not end with that pair. This provision means that the potential living donor would donate on the same day that his or her intended candidate receives a transplant.
- iii. In cases where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates.
- iv. The scheduled time elapsed between the end of one segment of a chain and the beginning of the next segment in the chain is encouraged to be less than 1 week and must not exceed 3 weeks.
- v. A chain will end with a donation to a candidate on the deceased donor waiting list at the center that entered the NDD that started that chain.
- vi. If a transplant center or a pair is unwilling to participate in a chain, they will only be matched in two-way or three-way matches.

d. What to Do When a Chain Breaks

- i. If the NDD has a non-O blood type (A, B, AB), then the chain will proceed up to the link where it breaks regardless of the number of transplants that result.
- ii. If the NDD has a blood type of O, then
 - 1. If the chain *can reach 5 or more transplants* before breaking (regardless of the total length of the chain), then the chain *will proceed* up to the link where it breaks.
 - 2. If the chain includes less than 6 pairs total and the chain *can reach 50%* of the transplants before breaking, then the chain *will proceed* up to link where it breaks.
 - 3. If a chain includes less than 6 pairs total and the chain *cannot reach 50%* of the transplants before breaking, or if a chain that is 6 or longer *cannot reach 5 transplants*, then the NDD will be given the option to donate to the shorter chain or to enter the next match run with the possibility of finding a longer chain.

4. A NDD will not be asked to wait longer than three months from the match run where a chain started by that NDD was first found before donating to a chain, regardless of the length of the chain. All NDDs must be informed that they may be in a position to choose to donate to a shorter chain or to wait for another match run with the possibility of finding a longer chain.
- iii. If the operating room date is not set for a chain at the time of the next match run, but the crossmatches have been performed and the donors have been approved up to the point where the chain breaks, then the final donor could be entered in the next match run to repair the chain. The donor in this situation must agree to be entered in the next match run and must be informed in advance that this situation could arise.

Revision to the Chain Cap in the OPTN KPD Pilot Program

Sponsoring Committee: Kidney Transplantation Committee

OPTN KPD Pilot Program Operational Guidelines Affected: Donor Chains

Distributed for Public Comment: No

Effective Date: Pending Programming

Problem Statement:
With the increase in the number of pairs in the OPTN KPD Pilot Program, the optimization algorithm (the KPD matching computer program) requires more memory and time to run. It is possible that the algorithm would not run if the number of pairs continues to increase. The algorithm could run with an increased number of pairs, but it requires the removal of the chain cap.
Changes:
In order to reduce technical difficulty, there is no longer a cap on the number of pairs that can be included in the donor chain found by the optimization algorithm.
What You Need to Do:
No action necessary.

Affected OPTN KPD Pilot Program Operational Guidelines Language:

Donor Chains

- 1. Purpose:** To define the requirements for how matching will occur in the context of a donor chain
- 2. Procedures:**
 - a. Definitions**
 - i. Chains start with a non-directed donor (NDD) and end with a donation to a list recipient.
 - ii. A “segment” is a part of a chain that occurs at a different time than other parts of a chain.
 - b. Chain Size and Location**

~~i. The chain size will be limited to twenty incompatible pairs or less. There is no limit on the length of the chain.~~

ii. Chains can involve multiple hospitals.

c. Logistic Details

i. All donor surgeries must occur at the same time within a given segment. The centers involved in the chain can decide how many segments the chain will have and where the segments will break.

ii. If a transplant center, pair, or potential living donor does not want to be at the end of the segment of a chain, then the segment will not end with that pair. This provision means that the potential living donor would donate on the same day that his or her intended candidate receives a transplant.

iii. In cases where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates.

iv. The scheduled time elapsed between the end of one segment of a chain and the beginning of the next segment in the chain is encouraged to be less than 1 week and must not exceed 3 weeks.

v. A chain will end with a donation to a candidate on the deceased donor waiting list at the center that entered the NDD that started that chain.

vi. If a transplant center or a pair is unwilling to participate in a chain, they will only be matched in two-way or three-way matches.