

**OPTN/UNOS Kidney Transplantation Committee  
Report to the Board of Directors  
November 12-13, 2012  
Saint Louis, Missouri**

**Summary**

**I. Action Items for Board Consideration**

- Living donor proposal (Item 1, Page 2)
- Kidney Paired Donation Policy Language Proposal (Item 2, Page 4)
- Kidney Paired Donation Bridge Donors Proposal (Item 3, Page 16)

**II. Other Significant Items**

- Progress to revise the National Kidney allocation system (Item 4, Page 21)
- Review of Situations Involving Kidney Payback Accounting System (Item 5, Page 23)
- Update on the Kidney Donor Profile Index (KDPI) (Item 6, Page 24)
- Review of Member Request to Require Consultation with Referring Nephrologists (Item 7, Page 24)
- Review of Proposal to Grandfather Waiting Time (Item 8, Page 24)
- Review of Intended Candidate Committee Sponsored System (Item 9, Page 24)

**OPTN/UNOS Kidney Transplantation Committee  
Report to the Board of Directors  
November 12-13, 2012  
Saint Louis, Missouri**

**John J. Friedewald, MD, Chair  
Richard N. Formica, Jr., MD, Vice Chair**

This report summarizes the discussions had and decisions made by the Kidney Transplantation Committee during its in person meeting on August 27, 2012, teleconference on October 15, 2012, and developments following the release of its public comment proposal to substantially revise the kidney allocation system (circulation date: September 21, 2012).

## **1. Living Donor Policy Proposal**

The Committee reviewed comments received on its proposal to clarify the allocation priority assigned to prior living organ donors who later require a kidney transplant (Exhibit A). Current policy is unclear as to whether the priority is to be assigned in the event that a prior living donor requires a second or third transplant. This proposal would clarify that the priority is to be assigned with each kidney transplant registration for prior living organ donors. The proposal was supported by all regions and strongly supported from those who submitted public comment feedback. The Committee voted to send the proposal to the Board of Directors for consideration during its November 2012 meeting with the following resolution which was supported with 23 committee members in favor, none opposed, and non abstaining.

**\*\*RESOLVED that the proposed revisions to Policies 3.5.11.6 (Prior Living Organ Donors) and 12.9.3 (Priority on the Waiting List) set forth below are hereby approved, effective February 1, 2013.**

### **3.5.11.6 Prior Living Organ Donors**

A candidate will receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
  - Kidney
  - Liver segment
  - Lung segment
  - Partial pancreas
  - Small bowel segment.
2. The candidate's physician provides all of the following information to the OPTN Contractor:
  - The name of the recipient of the donated organ or organ segment
  - The name of the recipient's Transplant Program
  - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

### **12.9.3 Priority on the Waiting List**

A candidate will receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
  - Kidney
  - Liver segment
  - Lung segment
  - Partial pancreas
  - Small bowel segment.
2. The candidate's physician provides all of the following information to the OPTN Contractor:
  - The name of the recipient of the donated organ or organ segment
  - The names of the recipient's Transplant Program
  - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

~~**3.5.11.6 Donation Status.** A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.~~

~~**12.9.3 Priority on the Waitlist.** A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be~~

submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.

## 2. Proposal to Institute Formal Policies for the KPD Pilot Program

Richard N. Formica, MD, presented to the Committee the work of the KPD Work Group to finalize the KPD policy language proposal (Exhibit B). The proposal was circulated for public comment in the spring of 2012. Based on the feedback received, the Work Group modified the proposal to remove the sections pertaining to priority points and informed consent. The Work Group was concerned that by codifying the priority points into formal policy, it would be unable to easily make modifications as the field advances. The Work Group also heard from the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) that those two professional groups would like for the informed consent portion of the policy proposal to be discussed by the Joint Societies Working Group.

The Committee thanked the Work Group for its recommendations and decided to send the language below with a vote of 17 in favor, 0 opposed, 0 abstentions, to the Board of Directors to consider during its November 2012 meeting:

**\*\*RESOLVED: Policy 13 (Kidney Paired Donation) and Bylaws Appendix E are modified as set forth below, effective February 1, 2013 for the sections that do not require programming, and effective pending programming and notice to the OPTN membership for the remaining sections:**

The proposed policy language is organized into two sections: policy additions that will not require programming and policy changes that will require programming.

*For recommended changes in policy language based on public comment feedback added language is double underlined (example) and deleted language is double strikethrough (~~example~~).*

### 13 KIDNEY PAIRED DONATION

#### 13.1 Scope of Policy

Unless otherwise stated, references to potential donors and donors within this policy are specific to KPD potential donors and donors and references to candidates and recipients are specific to KPD candidates and recipients.

#### 13.2 Requirements for Participation in the OPTN KPD Program

##### 13.2.1 Candidates

In order to participate in the OPTN KPD program, candidates must be registered on the deceased donor kidney waiting list at the Transplant Hospital that wishes to enroll the candidate in the OPTN KPD Program.

### **13.2.2 Potential Donors**

In order to participate in OPTN KPD Program, potential donors must comply with *all* of the following requirements:

1. Be aged at least 18 years old
2. Not be currently listed as a potential donor for any other candidate registered in the OPTN KPD Program

### **13.3 Informed Consent for Candidates**

*Reserved*

### **13.4 Informed Consent for Potential Donors**

*Reserved*

### **13.5 Histocompatibility Testing**

In the OPTN KPD Program, the candidate's Transplant Hospital is responsible for performing HLA-A, -B, -Bw4, -Bw6, and, -DR ~~antigen~~ typing on the candidate. If the candidate has antibodies against HLA-DQA or -DPA or -DPB, the candidate's Transplant Hospital is responsible for performing HLA-DQA, -DPA, or -DPB ~~antigen~~ typing on the candidate.

In the OPTN KPD Program, the ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD is responsible for performing HLA-A, -B, -Bw4, -Bw6, -Cw, -DR, -DR51, -DR52, -DR53, and, -DQ ~~antigen~~ typing on the potential donor.

In the OPTN KPD Program, HLA typing must be performed at the level of split resolution. The primary HLA typing method must be molecular.

### **13.6 Matching Within the OPTN KPD Program**

#### **13.6.1 Requirements for Match Run Eligibility for Candidates**

The OPTN KPD Program will only match candidates that comply with *all* of the following requirements:

1. The candidate's Transplant Hospital must comply with Policy 3.1.2
2. The candidate's Transplant Hospital must complete the informed consent process in Policy 13.2
3. The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor
  - a. Candidate Details

- Last name
  - First name
  - SSN
  - Date of birth
  - Gender
  - Ethnicity/Race
  - ABO
  - Whether the candidate has signed an agreement to participate in the OPTN KPD Program
  - Whether the candidate has signed a release of protected health information
  - Whether the candidate is a prior living donor
  - KPD status
- b. Candidate Choices
- Whether the candidate would be willing to travel, and, if so, the Transplant Hospitals to which a candidate would be willing to travel
  - Whether the candidate is willing to accept a shipped kidney, and, if so, from which Transplant Hospitals the candidate would be willing to accept a shipped kidney
  - Minimum and maximum acceptable donor age
  - Minimum acceptable donor creatinine clearance
  - Maximum acceptable donor BMI
  - Maximum acceptable systolic and diastolic blood pressure
  - Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor
  - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
- c. HLA
- HLA-A antigen typing
  - HLA-B antigen typing
  - HLA-Bw4 antigen typing
  - HLA-Bw6 antigen typing
  - HLA-DR antigen typing
4. The candidate must be in an active status in the OPTN KPD Program
  5. The candidate must have at least one and no more than two active and eligible potential donor registered in 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

### 13.6.2 Requirements for Match Run Eligibility for Potential Donors

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

1. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications
  - a. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must report the potential donor's actual blood type to the OPTN Contractor
  - b. Someone, other than the person who reported the potential donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential donor's actual blood type to the OPTN Contractor
  - c. The potential donor is not eligible for a KPD match run until the Transplant Hospital reports two identical blood types
2. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must complete the informed consent process per KPD Operational Guidelines
3. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must complete the medical evaluation process per KPD Operational Guidelines
4. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must submit the required fields below to the OPTN Contractor
  - a. Donor Details
    - Last name
    - First name
    - SSN
    - Date of birth
    - Gender
    - Ethnicity/Race
    - ABO
    - Height and weight
    - Whether the potential donor is a non-directed donor;
    - If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate
    - Whether the potential donor has signed an agreement to participate in the OPTN KPD Program
    - Whether the potential donor has signed a release of protected health information
    - Whether the potential donor has signed an informed consent as required in policy

- Whether the potential donor has undergone a medical evaluation as required in policy
  - Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society
  - KPD status
- b. Clinical Information
- The number of anti-hypertensive medications the donor is on
  - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
  - Creatinine clearance, date, and method
  - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
- c. Donor Choices
- Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel
  - Whether the potential donor is willing to ship a kidney
  - Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney
  - Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain
- d. HLA
- HLA-A ~~antigen~~ typing
  - HLA-B ~~antigen~~ typing
  - HLA-Bw4 and –Bw6 ~~antigen~~ typing
  - HLA-Cw ~~antigen~~ typing
  - HLA-DR antigen typing
  - HLA-DR51, -DR52, and –DR53 ~~antigen~~ typing
  - HLA-DQ ~~antigen~~ typing
5. The potential donor must be in an active status in the OPTN KPD Program
  6. The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program
  7. The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD must submit a response for all previous match offers for the potential donor in the OPTN KPD Program
  8. The potential donor must not be in a pending exchange in the OPTN KPD Program.

### 13.6.3 Screening Criteria

#### 13.6.3.1 Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in Table 13-1. Fields with a “●” indicate identical blood type matches. Fields with a “◐” indicate permissible blood type matches. Fields with a “◑” indicate permissible blood type matches providing the candidates meets the requirements in Policy 13.6.3.2. Fields with a “○” indicate impermissible blood type matches.

		Candidate's Blood Type			
		O	A or A1 or A2	B	AB or A1B or A2B
Donor's Blood Type	O	●	◐	◐	◐
	A	○	●	○	◐
	A1	○	●	○	◐
	A2	◑*	●	◑*	◐
	B	○	○	●	◐
	AB	○	○	○	●
	A1B	○	○	○	●
	A2B	○	○	◑*	●

**Table 13-1: Blood Typing for KPD**

### 13.6.3.2 A<sub>2</sub> and A<sub>2</sub>B Matching

In order for a blood type B candidate to be eligible to be matched to a blood type A<sub>2</sub> or A<sub>2</sub>B potential donor, or for a blood type O candidate to be eligible to match to a blood type A<sub>2</sub> potential donor in the OPTN KPD Program, *all* of the following conditions must be met:

1. The candidate must have an IgG antibody titer value less than 1:8
2. The candidate's Transplant Hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

### 13.6.3.3 Unacceptable Antigens

A Transplant Hospital may specify any unacceptable antigens it will not accept for its candidates. The OPTN Contractor will not match the

candidate with any potential who has one of the candidate's unacceptable antigens entered as an HLA value.

#### **13.6.3.4 Candidate and Potential Donor Choices**

A Transplant Hospital may specify criteria it will not accept for any of its candidates as outlined in Policy 13.6.1-3(b) or potential donors as outlined in Policy 13.6.2-6(c). The OPTN Contractor will not match the candidates with potential donors who fall outside the specified criteria or potential donors with candidates who fall outside the specified criteria.

#### **13.6.4 Prioritization Points**

*Reserved*

#### **13.6.5 Two and Three Way Matches**

##### **13.6.5.1 Match Size**

The OPTN Contractor will match donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor as outlined in Policy 13.6.6.

##### **13.6.5.2 Logistical Requirements**

In two-way or three-way exchanges in the OPTN KPD Program, all donor surgeries involved in the exchange must begin on the same day and only after all donor surgeons involved in the exchange agree to proceed.

#### **13.6.6 Donor Chains**

##### **13.6.6.1 Chain Size**

In the OPTN KPD Program, donor chains will be limited to 20 donor-candidate pairs.

##### **13.6.6.2 Logistical Requirements**

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain.

### 13.6.6.3 What to Do When a Chain Breaks

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may be entered in the next match run to repair the donor chain if *all* of the following conditions are met:

1. The operating room dates are not set for a chain at the time of the next match run
2. The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match
3. The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.

## 13.7 Crossmatching Protocol

The candidate's Transplant Hospital must perform a preliminary crossmatch for candidates in the OPTN KPD Program before the matched donor's recovery procedure.

The ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD is responsible for shipping the potential donor's blood sample to the matched candidate's Transplant Hospital or the laboratory specified by the matched candidate's Transplant Hospital.

The candidate's Transplant Hospital is responsible for running the crossmatch and reporting the results to the OPTN Contractor and the matched donor's Transplant Hospital.

## 13.8 Transportation of Kidneys

For any KPD exchange, the recovery Transplant Hospital is responsible for packaging, labeling, and transporting kidneys from donors as provided in Policy 12.7.

In the OPTN KPD Program, the recipient's Transplant Hospital must specify the location where the recovery Transplant Hospital must deliver the kidney. The recovery Transplant Hospital must then document the name and telephone number of every person or company who will package, label, or transport the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the recipient's Transplant Hospital along with the date and time that the name is documented. The recovery Transplant Hospital must complete this documentation before the potential donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's ~~chart~~ medical record.

### 13.9 Rules for When Donors and Recipients Can Meet

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

Members can facilitate a meeting between donors and recipients that participated in an OPTN KPD Program exchange only if *all* of the follow conditions are met:

1. All the donors and recipients participating in the meeting agree to meet
2. The meeting occurs after the transplant concludes
3. The Transplant Hospital establishes a written protocol for when donors and recipients can meet. This protocol must include, at a minimum, the timing of the meeting and what staff must attend the meeting.
4. Transplant Hospital complies with their written protocol for when donors and recipients can meet. The Transplant Hospital must maintain documentation of compliance in the donor's or recipient's ~~chart~~ medical record.

### 13.10 Definitions

- *Chain* – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.
- *Exchange* – a set of matches that form a chain, a two-way exchange, or a three-way exchange.
- *Match* – a donor and his matched candidate
- *Match Run* – procedure used to generate a set of exchanges
- *Matched candidate* – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney
- *Matched donor* – a donor identified by a KPD match run as a potential donor for a candidate
- *Matched recipient* – a matched candidate that has received a transplant
- *Non-Directed Donor (NDD)* - a donor that enters KPD without a paired candidate
- *Other antibody specificities*- antigens 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.
- *Pair* – a donor and his paired candidate
- *Paired candidate* – the candidate to whom a donor intended to donate his organ before entering into KPD
- *Paired Donation of Human Kidneys (KPD)* – the donation and receipt of human kidneys under the following circumstances:
  - An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.

- A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
- 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.
- If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
- All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
- Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.
- *Paired donor* –a donor who intended to donate his organ, before entering into KPD, to his paired candidate
- *Paired Recipient*- a paired candidate that has received a transplant
- ~~potential donor's~~ Transplant Hospital registering the potential donor in KPD - the Transplant Hospital that enters the potential donor in a KPD program
- *Three-way exchange*- a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.
- *Two-way exchange* – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.
- *Unacceptable antigens*- 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.

*For original OPTN Bylaws, Appendix E, proposed language is underlined (example) and deleted language is struck through (example). For recommended changes in policy language based on public comment feedback added language is double underlined (example) and deleted language is double strikethrough (example).*

## **OPTN Bylaws, Appendix E**

### **E.5. Kidney Transplant Programs that Perform Living Donor Recovery**

#### **~~F. Kidney Paired Donation~~**

~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

## **F. Kidney Paired Donation (KPD)**

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

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the Transplant Hospital decides to participate in the OPTN KPD program. A Transplant Hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary and alternate kidney paired donation contact that is a member of the Hospital's staff.

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

*For original Policies 13.6.1, 13.6.4, and 13.6.6, proposed language is underlined (example) and deleted language is struck through (example). For these sections, language that is proposed or deleted is in reference to the above proposal but would require programming before implementation. The only recommended changes in policy language based on public comment feedback is the removal of Section 13.6.4 Prioritization Points.*

### **Pending implementation:**

#### **13.6.1 Requirements for Match Run Eligibility for Candidates**

The OPTN KPD Program will only match candidates that comply with *all* of the following requirements:

1. The candidate's Transplant Hospital must comply with Policy 3.1.2
2. The candidate's Transplant Hospital must complete the informed consent process in Policy 13.2
3. The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor
  - a. Candidate Details
    - Last name
    - First name
    - SSN
    - Date of birth
    - Gender
    - Ethnicity/Race
    - ABO
    - Whether the candidate has signed an agreement to participate in the OPTN KPD Program

- Whether the candidate has signed a release of protected health information
  - Whether the candidate is a prior living donor
  - KPD status
- b. Candidate Choices
- Whether the candidate would be willing to travel, and, if so, the Transplant Hospitals to which a candidate would be willing to travel
  - Whether the candidate is willing to accept a shipped kidney, and, if so, from which Transplant Hospitals the candidate would be willing to accept a shipped kidney
  - Minimum and maximum acceptable donor age
  - Minimum acceptable donor creatinine clearance
  - Maximum acceptable donor BMI
  - Maximum acceptable systolic and diastolic blood pressure
  - Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor
  - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
- c. HLA
- HLA-A antigen typing
  - HLA-B antigen typing
  - HLA-Bw4 antigen typing
  - HLA-Bw6 antigen typing
  - HLA-DR antigen typing
4. The candidate must be in an active status in the OPTN KPD Program
  5. The candidate must have at least one ~~and no more than two~~ active and eligible potential donor registered in 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

#### 13.6.4 Prioritization Points

*Reserved*

#### 13.6.6 Donor Chains

### 13.6.6.1 Chain Size

In the OPTN KPD Program, ~~donor chains will be limited to 20 donor-candidate pairs.~~ there is no limit on the length of the donor chains.

## 3. Proposal to Include Bridge Donors in the KPD Pilot Program

Richard N. Formica, Jr., MD, Chair of the KPD Working Group updated the Committee on the Group's progress to advance a proposal to increase matching opportunities in the OPTN KPD Program by allowing bridge donors (a donor who does not have a match identified during the same match run as his paired candidate) (Exhibit C). Currently, the OPTN KPD Pilot Program requires that donor chains end with a donation to a candidate on the deceased donor waiting list. As a result, donor chains could end when there may be the potential to extend the chain and transplant more candidates. Additionally, many transplant hospitals have expressed a desire for the OPTN KPD Program to include bridge donors. A secondary goal of this proposal is to increase participation in the OPTN KPD Program by providing more options for participating transplant hospitals. These policies are being proposed as new policies in the Proposal to Establish KPD Policy, which is also out for public comment in Spring 2012. The proposed changes would allow potential donors who are not matched in the same match run as their paired candidates to enter a later match run to find a KPD match rather than donating to the deceased donor waiting list. Public comment support for this proposal was reported to be strong. The Committee voted to send the proposal to the Board of Directors for consideration during its November 2012 meeting (24 in favor, 0 opposed, 0 abstentions). Additionally, the Committee voted to charge the Working Group with finalizing the proposal (23 in favor, 0 opposed, 0 abstentions).

**\*\*RESOLVED, Policy 13 (Kidney Paired Donation) set forth below, is modified as set forth below, effective pending programming and notice to OPTN membership:**

For the convenience of the reader, proposed policy language is underlined (example) and deleted language is struck through (~~example~~). Policy language that is proposed or deleted is in reference to a separate 2012 public comment proposal that creates Policy 13 and has not yet been adopted by the OPTN Board of Directors.

### 13.4.4 OPTN KPD Program Process Consents

The potential donor's Transplant Hospital must inform potential donors of the following elements of the OPTN KPD Program:

1. Potential donors do not choose with whom they match. A potential donor or a candidate may decline a match after it has been found.
2. Matching requirements in Policy 13.6.5 and Policy 13.6.6
3. Rules for when Members may facilitate meetings between donors and recipients in the OPTN KPD Program in Policy 13.9

The potential donor's Transplant Hospital must maintain documentation in the potential donor's chart that the potential donor has been informed of each element.

If the potential donor is willing to be a bridge donor, then the potential donor's Transplant Hospital must receive consent to be a bridge donor from the potential donor at each of the following times:

- Before the potential donor's Transplant Hospital reports to the OPTN Contractor that the potential donor is willing to be a bridge donor
- When a match has been identified in which the potential donor is a bridge donor and before the potential donor's matched candidate receives a transplant as part of the exchange in which the potential donor is a bridge donor
- Every three months after the match run in which a potential donor has been identified as a bridge donor until the potential donor donates, declines to be a bridge donor, or declines to donate

At each time, the potential donor's Transplant Hospital must inform the bridge donor that they may continue to be a bridge donor, donate to the waiting list, or decline to donate. The potential donor's Transplant Hospital must maintain documentation of these consents in the potential donor's chart.

Before the potential donor's Transplant Hospital reports to the OPTN Contractor that the potential donor is willing to be a bridge donor, the potential donor's Transplant Hospital must inform the potential donor:

- That the potential donor may need to have another medical evaluation at a future time
- Of the process for determining whether a chain ends with a bridge donor as defined in Policy 13.6.6.2

The potential donor's Transplant Hospital must maintain documentation in the potential donor's chart that it provided this information.

### **13.6.2 Requirements for Match Run Eligibility for Potential Donors**

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

9. The potential donor's Transplant Hospital must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications
  - a. The potential donor's Transplant Hospital must report the potential donor's actual blood type to the OPTN Contractor
  - b. Someone, other than the person who reported the potential donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential donor's actual blood type to the OPTN Contractor
  - c. The potential donor is not eligible for a KPD match run until the Transplant Hospital reports two identical blood types
10. The potential donor's Transplant Hospital must complete the informed consent process per KPD Operational Guidelines

11. The potential donor's Transplant Hospital must complete the medical evaluation process per KPD Operational Guidelines.
12. The potential donor's Transplant Hospital must submit the required fields below to the OPTN Contractor
  - a. Donor Details
    - Last name
    - First name
    - SSN
    - Date of birth
    - Gender
    - Ethnicity/Race
    - ABO
    - Height and weight
    - Whether the potential donor is a non-directed donor;
    - If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate
    - Whether the potential donor has signed an agreement to participate in the OPTN KPD Program
    - Whether the potential donor has signed a release of protected health information
    - Whether the potential donor has provided informed consent as required in policy
    - Whether the potential donor has undergone a medical evaluation as required in policy
    - Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society
    - KPD status
  - b. Clinical Information
    - The number of anti-hypertensive medications the potential donor is on
    - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
    - Creatinine clearance, date, and method
    - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
  - c. Donor Choices
    - Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel
    - Whether the potential donor is willing to ship a kidney
    - Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney

- Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential donor and the Transplant Hospital are willing for the potential donor to be a bridge donor

d. HLA

- HLA-A antigen typing
  - HLA-B antigen typing
  - HLA-Bw4 and –Bw6 antigen typing
  - HLA-Cw antigen typing
  - HLA-DR antigen typing
  - HLA-DR51, -DR52, and –DR53 antigen typing
  - HLA-DQ antigen typing
  - HLA-DR51, -DR52, and –DR53 antigen typing
13. The potential donor must be in an active status in the OPTN KPD Program
  14. The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program
  15. The potential donor's Transplant Hospital must submit a response for all previous match offers for the potential donor in the OPTN KPD Program
  16. The potential donor must not be in a pending exchange in the OPTN KPD Program.

### 13.6.6 Donor Chains

#### 13.6.6 Chain Size

In the OPTN KPD Program, donor chains will be limited to 20 donor-candidate pairs.

#### 13.6.7 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his or her paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain or with a bridge donor who will be included in a later match run. The Transplant Hospital that enters the NDD can choose whether the chain can end with a bridge donor or whether the chain must end with a donation to a candidate on the waiting list at that Transplant Hospital. In order for a potential donor to be a bridge donor, the potential donor's Transplant Hospital must receive consent from the donor to be a potential bridge donor as defined in Policy

13.4.4. The potential donor's Transplant Hospital may refuse to allow the potential donor to serve as a bridge donor at any point in the process.

### **13.6.8 What to Do When a Chain Breaks**

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in Policy 13.6.6.2. ~~may be entered in the next match run to repair the donor chain if all of the following conditions are met:~~

- ~~4. The operating room dates are not set for a chain at the time of the next match run~~
- ~~5. The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match~~
- ~~6. The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.~~

### **13.10 Definitions**

- Bridge donor- a donor who does not have a match identified during the same match run as his paired candidate.
- *Chain* – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.
- *Exchange* – a set of matches that form a chain, a two-way exchange, or a three-way exchange.
- *Match* – a donor and his matched candidate
- *Match Run* – procedure used to generate a set of exchanges
- *Matched candidate* – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney
- *Matched donor* – a donor identified by a KPD match run as a potential donor for a candidate
- *Matched recipient* – a matched candidate that has received a transplant
- *Non-Directed Donor (NDD)* - a donor that enters KPD without a paired candidate
- *Other antibody specificities*- antigens 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.
- *Pair* – a donor and his paired candidate
- *Paired candidate* – the candidate to whom a donor intended to donate his organ before entering into KPD

- *Paired Donation of Human Kidneys (KPD)* – the donation and receipt of human kidneys under the following circumstances:
  - An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.
  - A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
  - 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.
  - If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
  - All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
  - Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.
- *Paired donor* – a donor who intended to donate his organ, before entering into KPD, to his paired candidate.
- *Paired Recipient* – a paired candidate that has received a transplant.
- *Three-way exchange* – a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.
- *Two-way exchange* – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.
- *Unacceptable antigens* – 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.

#### **4. Progress to Develop a Revised National Kidney Allocation System**

John Friedewald, MD, Committee Chair, reviewed recent progress with the Committee regarding its work to propose a revised national kidney allocation system. The Committee voted in May 2012 to circulate for public comment those allocation rules from the Kidney Pancreas Simulated Allocation Model (KPSAM) run N4. UNOS staff had prepared a written proposal based on the allocation rules simulated by the Scientific Registry of Transplant Recipients (SRTR) (Exhibit D). The Committee also reviewed a draft of the presentation to be given at upcoming regional meetings (Exhibit E) and provided feedback.

Mark Aeder, MD, chair of the variance subcommittee, reviewed the transition plans received from LifeGift in Texas and from Region 1. The plans met the transition plan requirements that the Committee developed in February 2012 by proposing a single step that would end with the implementation of a new kidney allocation system. The Committee voted to circulate the

transition plans as part of the public comment proposal for the kidney allocation system (25 in favor, 0 opposed, 0 abstentions).

The Committee then reviewed a presentation delivered by Lainie Freedman Ross, MD, and colleagues. Dr. Ross presented a paper detailing a theoretical method for allocating kidneys entitled equal opportunity for fair innings (EOFI). In this approach, kidneys would be allocated based on candidate age. A pre-set number of donated kidneys would be allocated to each age group of candidates. The goal of the system would be to provide an equal chance of getting a kidney for all candidates. Members of the Committee expressed reservations about the approach which did not take into account other factors affecting equality such as access challenges due to geography, blood type, or degree of sensitization.

On September 21, 2012, the Committee released its proposal for public comment and implemented a detailed communications strategy which included a media webinar, tailored presentations for both professional and lay audiences, and documents to address frequently asked questions. Since the release of the proposal, several articles have been published in major newspapers including the Chicago Tribune and the New York Times as well as broadcast on National Public Radio (Exhibit F).

In October, Dr. Friedewald, reviewed the feedback that had been received since the proposal to substantially revise the kidney allocation system had been released. Since its release, two regions met and reviewed the proposal. The Region 10 Representative reported that while the proposal did not pass in his region, the concerns with the system were largely related to the elimination of the kidney payback system and not to other major elements of the proposal. Members of the Committee remarked that the feedback on elimination of the kidney payback system was mixed due to it being a system of credits and debts.

A member who presented the proposal to the OPO Committee shared that the main concerns raised in that forum related to inefficiency in sharing for the highest CPRA candidates. Several OPO personnel expressed a lack of confidence in virtual crossmatching and fear that high quality kidneys will be accepted based on the donor's characteristics but then need to be transplanted into back-up candidates. Since there is not expected to be a kidney payback provision in the new system, these individuals feared that there would be little incentive for determining compatibility early on in the organ acceptance process. While the proposal requires that each highly sensitized candidate's physician and the HLA laboratory director sign off on listed unacceptable antigens, members of the Kidney Transplantation Committee remarked that there will need to be additional accountability built into the system including HLA-DP typing. Nancy Reinsmoen, PhD, shared that the Histocompatibility Committee is developing tools that can be used by transplant programs to determine proficiency in identifying and reporting unacceptable antigens based on rates of unexpected positive crossmatches. Additionally, a member remarked that the proposal should encourage listing of all unacceptable antigens because it offers increasing points based on an increasing CPRA score (unlike the current system which only offers 4 points starting at a CPRA of 80%). The Committee determined that it will continue to monitor this aspect of the proposal to determine if additional opportunities for improving efficiency could be built into the final proposal.

In October, Darren Stewart, MS, biostatistician with UNOS Research, presented an analysis requested by the Committee during its August 2012 meeting (Exhibit G). At that time, the Committee wanted to better understand the types of Estimated Post Transplant Survival (EPTS) scores that candidates with different characteristics may have. To answer these questions, the analysis provided 22 vignettes for candidates across the EPTS spectrum. Mr. Stewart reviewed

the findings with the Committee. The vast majority of pediatric candidates and nearly 97% of adults with age between 18 and 25 had EPTS scores <20%. Among candidates age 26-35, 80.6% were in the EPTS Top 20%, with some having EPTS as low as 1% and others as high as 67%. Over 10% of candidates between ages 46 and 55 were in the Top 20%, with EPTS ranging from 12% to 98%. The candidates in the Top 20% range in age from 0 to 54, with a median age of 35, whereas candidates outside of the Top 20% ranged in age from 1 to 91, with a median age of 58.

It is noteworthy that the EPTS formula is influenced substantially by factors other than age. Though younger candidates are more likely to be in the Top 20%, a 50-year old not on dialysis, without diabetes, and without prior transplants would have an EPTS of 18%. Conversely, it is possible for a 25 year old, for example one who is diabetic, to be outside the Top 20%. However, a 25 year old who has been on dialysis for two years and had a prior transplant has an EPTS of just 7%, well inside the Top 20%.

The Committee thanked Mr. Stewart for his presentation. A member asked whether high CPRA patients were as likely as candidates with lower CPRA scores to have EPTS scores in the Top 20%. Mr. Stewart reported that prior transplant was a modest factor in the model. Candidates who have had a prior transplant are more likely to be sensitized than candidates who have not had a prior transplant. The Committee also asked why the EPTS calculation compounded the negative effect of being both diabetic and having a prior transplant. Nicholas Salkowski, and Ajay Israni, MD, both from the Scientific Registry of Transplant Recipients (SRTR) explained that selection bias may be a factor. Specifically, candidates who have diabetes and were transplanted previously are otherwise generally healthier than diabetic candidates who have not yet received a transplant. Therefore, a candidate with diabetes and a prior transplant is thought to have better survival than a candidate who only has one factor of the two factors.

The Committee reviewed the portion of the analysis that addressed missing data. EPTS relies on four factors, candidate age, prior transplant, diabetes status, and time on dialysis. Currently, dialysis start date is collected on the Waitlist, but it was not collected prior to July 6, 2000. Consequently, some candidates that are still on the list have missing dialysis start dates. The vast majority of kidney candidates on the waitlist with missing dialysis start dates were added to the list on 7/5/2000 or prior, as expected. In total, 473 candidates (including 172 active candidates) had missing dialysis start dates as of May 31, 2012. The Committee reiterated that it will need to spend time prior to implementation of a new system helping centers fill in missing data and validate existing data. A member suggested that CMS Form 2728 could be used to validate existing dialysis start date information. An implementation subcommittee will begin reviewing these issues and recommending strategies for assisting transplant programs.

##### **5. Review of Issues with the Kidney Payback System**

OPTN Policy requires a kidney to be paid back if the kidney is shared and transplanted as a zero-antigen mismatch or kidney/extra-renal transplant. In two separate reported cases, a standard criteria donor (SCD) kidney was shipped and then later discarded, resulting in no payback credit to the shipping OPO. The Committee reviewed the documentation provided and asked the liaison to obtain additional information from the receiving transplant program to determine why a local candidate was not pre-selected to serve as a backup and to prevent discard.

**6. Update on the Kidney Donor Profile Index**

UNOS Biostatistician Darren Stewart, MS, provided the Committee with an update on the Kidney Donor Profile Index (KDPI) (Exhibit H). This metric was made available with every organ offer in Donor Net on March 26, 2012. It is a mathematical formula calculated from the following ten donor characteristics: age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, HCV status, and DCD status. Mr. Stewart reviewed the resources made available to members to assist with the interpretation of KDPI. These included a KDPI calculator, available on line, a guide to calculating and interpreting KDPI, a KDRI to KDPI mapping table, and interactive documentation in DonorNet. Mr. Stewart reported that feedback so far on KDPI has been mixed, with some transplant professionals reporting that additional education is needed to learn how to incorporate this value into clinical decision making. Later this year, the Committee will review an analysis of kidney utilization during the first six months of KDPI versus the six months prior to KDPI implementation.

**7. Review of Member Request to Require Notification of Referring Nephrologist**

Current OPTN Policy requires that the transplant surgeon and/or physician responsible for the patient's care make the final decision whether to accept and transplant an organ. A nephrologist requested that the policy be amended to require both the surgeon and the physician make these decisions. The Committee evaluated the current policy to determine if a modification was warranted. Members of the Committee remarked that they encourage communication between referring physicians and transplant surgeons. However, requiring this communication through policy is impractical. For example, some members reported that they have difficulty reaching referring nephrologists. In these cases, if the policy requires that the referring nephrologist be consulted, additional and unnecessary cold ischemic time could result while the nephrologist is located. The Committee declined to undertake a policy change to address this matter. Instead, the Committee recommends that referring nephrologists and transplant centers work out communication expectations on a more individualized basis.

**8. Review of Proposal to Grandfather Waiting Time**

The Committee reviewed a proposal from UNOS Information Technology to adjust waiting time for candidates who had been listed in inactive status when this time was not counted towards a candidate's waiting time. Prior to November 5, 2003, "KIPA" candidates at an inactive medical urgency status could accrue 30 days time while inactive, and then ceased to accrue time for kidney, pancreas, kidney/pancreas, and pancreas islets. Since then, policy was changed to allow candidates to accrue unlimited amounts of time in inactive status. A total of 547 candidates were found to be affected, of these 155 were presently listed in active status. The proposal was to stop deducting grandfathered inactive time accrued prior to the policy change in 2003. The benefits of this proposal were to reduce programming cost and complexity for the revised waiting list. The proposed changes would result in minimal impact to the other candidates on the waiting list. Since all affected candidates have at least eight years of waiting time, they are all likely near the top of their local lists. The Committee agreed with the proposal and shared its agreement with the Executive Committee during its August 28, 2012, meeting.

**9. Review of Intended Candidate Committee Sponsored System**

In 2006, the Board of Directors passed a committee-sponsored alternative allocation system for intended candidates. Essentially, any OPO could decide to participate in this system. In

participating OPOs, an incompatible donor could donate to a candidate on the deceased donor waiting list and the intended candidate could receive the next suitable deceased donor kidney.

Four OPOs currently operate this system (MOMA, NYAP, NYWN, and UTOP). Since the system was implemented in 2006, 89 transplants of intended candidates have resulted.

When the Kidney Committee was making decisions about continuing or discontinuing variances at the February meeting, it chose to discontinue this variance with the implementation of a new kidney allocation system. The Committee was asked to determine whether to have this committee-sponsored system programmed into Chrysalis (the new waitlist software). The Committee discussed the benefits of maintaining this variance for the time period between the implementation of Chrysalis and the implementation of a new system. It determined that the resources required to program the system for this short time period would be better spent on other projects. Therefore, the Committee decided that the Committee-sponsored alternative allocation system for intended candidates, currently operated by MOMA, NYAP, NYWN, and UTOP should be discontinued upon the implementation of Chrysalis (12 in favor, 0 opposed, 0 abstentions).