

**FAQ's ABOUT THE ORGAN PROCUREMENT AND
TRANSPLANTATION NETWORK (OPTN)
KIDNEY PAIRED DONATION PILOT PROGRAM**

What is Kidney Paired Donation?

Kidney paired donation (KPD) helps donors who are medically able, but cannot donate a kidney to a loved one because they are incompatible (i.e., poorly matched). For example, Mary wants to donate her kidney to her husband, Carlos. Amir wants to donate his kidney to his coworker, Shauna. Unfortunately, Mary can't donate to Carlos because she is blood type A and Carlos is blood type B. Amir can't donate to Shauna because he is blood type B and Shauna is blood type A. Fortunately, Mary is a match for Shauna and Amir is a match for Carlos. See Diagram 1. The Organ Procurement and Transplantation Network (OPTN) KPD Pilot Program, discussed below, supports people in this situation by helping recipient/donor pairs who are incompatible with each other find another recipient/donor pair(s) with whom they are compatible so that transplants can proceed. Typically, an exchange transplant involves 2 recipient/donor pairs; however, on occasion, an exchange could involve more than 2 recipient/donor pairs and/or a non-directed donor.

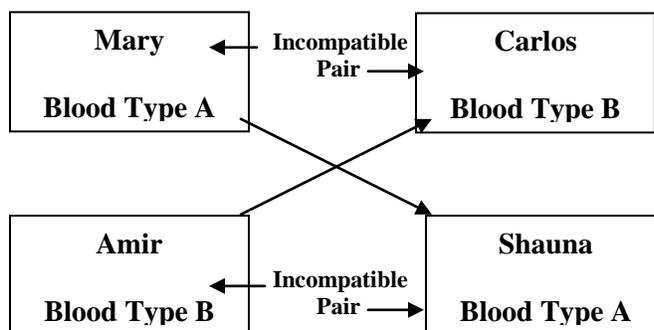


Diagram 1

What is the OPTN KPD Pilot Program?

The KPD Pilot Program is part of the OPTN. The OPTN is managed by the United Network for Organ Sharing (UNOS) through a contract with the Health Resources and Services Administration (HRSA). The OPTN registers and tracks everyone who registers in the Pilot Program. If you decide to join the OPTN KPD Pilot Program, a member of your transplant team will enter your medical information into a computerized system that works with transplant centers and organ recovery agencies throughout the United States to search for cases where the donor in each pair is compatible with the recipient in another pair (or multiple pairs). By exchanging the donors, a compatible match for both recipients can be found.

Why is a Pilot Program needed?

There are KPD programs that exist and operate regionally. With its ability to locate incompatible living donors and recipients across the country, the KPD Pilot Program will test the benefits of having a national program, where matches can take place across the country. The goal is to find as many compatible pairs of potential donors and recipients as possible, while considering the needs of special populations (including children and highly sensitized recipients). By pilot testing this program, the OPTN will be able to use the information gained to correct any problems and improve the system. The OPTN can also make sure that the transplant centers understand and meet the program requirements and then use this information to develop national policy. The Pilot Program follows OPTN Operational Guidelines and the OPTN will continue to evaluate the Pilot Program until it determines the best way to run the KPD system. When a final policy is developed by the OPTN from information gained, the OPTN KPD Pilot Program will become permanent. You can find the OPTN KPD Pilot Program Briefing Paper and Operational Guidelines at <http://optn.transplant.hrsa.gov/resources/KPDPP.asp>.

Who can participate in the OPTN KPD Pilot Program?

If you are eligible for a kidney transplant, are on the deceased donor waiting list, and are receiving care at an OPTN-approved transplant center in the United States, then you can join the Pilot Program. You do not have to be on dialysis to join. Potential living donors must follow the evaluation and consent requirements found in the OPTN KPD Pilot Program Operational Guidelines (see <http://optn.transplant.hrsa.gov/resources/KPDPP.asp>), and be willing to take part in an exchange. Pairs usually join because the potential living donor and recipient have incompatible blood or tissue types. However, non-directed donors may also participate in the Pilot Program.

What is a Good Samaritan or Non-directed Donor?

People who wish to donate a kidney to a person they do not know are referred to as non-directed donors (also known as altruistic or Good Samaritan donors). A non-directed donor may help to match incompatible pairs that could not otherwise be matched. This way, the non-directed donor can allow multiple patients to receive a kidney transplant as a result of their one gift.

What is a donor chain?

If an exchange is started from a non-directed donor, then an “extra” kidney is brought into the system of recipient/donor pairs. As such, the last recipient will have a living donor(s) who has not donated. This donor will donate to a candidate on the deceased donor waiting list. This situation is referred to as a donor chain.

What are the medical requirements to join the OPTN KPD Pilot Program?

The medical criteria to join are based on the KPD Pilot Program Operational Guidelines (see internet address above). Each transplant center may have additional medical requirements, so it is important for potential donors and recipients to talk with the transplant center about the medical requirements. Some general requirements are listed below:

All recipients must:

- Be eligible to receive a kidney transplant,
- Be registered on the deceased donor waiting list,
- Have a willing living donor who is medically suitable, but unable to donate because of an incompatible blood type or positive crossmatch test, and
- Consent to participate in writing (he or she may decline to participate at any time).

All potential living donors must:

- Be at least 18 years old;
- Be willing to donate to a friend or relative, but cannot because of an incompatible blood type or positive crossmatch test or, in the case of a non-directed donor, be willing to donate a kidney to a recipient identified through the OPTN KPD Pilot Program;
- Complete a series of medical and psychosocial evaluations to determine if he or she is eligible to donate a kidney;
- Not be currently listed as a donor for anyone other than the potential recipient in the OPTN KPD Pilot Program (the donor may be listed in other paired exchanges);
- Be able to consent to participate in writing (he or she may decline to participate at any time);
- Expect to be contacted by the transplant center regarding his or her health status for 2 years post-donation; and
- Agree to commit to postoperative follow-up testing, which is coordinated by the actual recipient's transplant center for 2 years.

What are the possible risks and benefits of participating in a kidney paired donation program?

Both the risks and benefits of KPD will be discussed with the potential living donor and recipient in detail by the assigned transplant center as part of the consent process. Some of the possible risks and benefits are provided below. Please note, however, that there is no guarantee that a recipient or a potential living donor will receive any benefit from participating in the OPTN KPD Pilot Program. This document is *not* a surgical consent form.

Possible risks for recipients and donors include (not limited to):

- Surgery is major and requires anesthesia; thus, there are possible medical complications including injury and death – discuss these risks in detail with the transplant center.
- The organ may not function after being transplanted into or may be rejected by recipient.
- Scars, pain, fatigue.
- Negative psychological symptoms (such as anxiety, depression, etc.) are possible after donation.
- Possible impact on lifestyle.
- Potential financial effects.
- Possible risk of breach of confidential information if all safeguards are not followed (please discuss with the transplant center).
- It is possible for something to happen in the operating room that makes it necessary to stop a donor procedure. In this case, one recipient would not receive a kidney. Also, if it

is necessary to stop a recipient surgery, a kidney would still be available for someone else. This kidney would then be offered to another recipient on the OPTN waiting list – following OPTN distribution policies.

Possible benefits for recipients and donors include (not limited to):

- The recipient may receive the benefit of a compatible living donor kidney transplant by participating in the program.
- Kidneys that come from a living donor last longer, on average, than kidneys that come from a deceased donor.
- The recipient may also require less immunosuppressant drug therapy after a transplant from a living donor.
- Transplant recipients may wait less time for a transplant.
- Transplant recipients may spend less time on dialysis.
- Transplant recipients may receive a transplant before they begin dialysis.
- Potential donors are assigned an Independent Donor Advocate (IDA), who will advocate for and promote their best interests.
- It can be a rewarding experience for the donor as more families are helped by their donation.

What costs or payments are involved in joining the OPTN KPD Pilot Program?

There is no cost for registering. Potential donors or recipients will not receive payments or compensation of any kind if they participate. Potential donors need to discuss the financial risks of participating in the OPTN KPD Pilot Program and the resources that may be available with the transplant center. There are national and possible local resources available, such as the National Living Donor Assistance Center, which may be able to assist those who qualify (see end of document for list). In certain cases, for example, qualifying donors may be reimbursed for limited travel and subsistence expenses.

Do potential living donors or recipients have to sign a contract promising they won't change their minds in order to participate in the OPTN KPD Pilot Program?

No, potential living donors and recipients have the right to change their minds and end the process at any time. There is no penalty for doing so and the decision remains confidential; an explanation of the donor's decision not to continue with the donation is only disclosed if the donor agrees.

As mentioned previously, every potential living donor who participates in the Pilot Program is assigned an IDA. The IDA promotes the best interests of the potential living donors and advocates for their rights.

What are the alternatives to participating in the OPTN KPD Pilot Program?

The transplant center will discuss with potential living donors and recipients the alternatives to KPD, including deceased donation. Participants may decline to participate at any time without any penalties.

How are recipient/donor pairs matched-up?

Every potential living donor and recipient who is interested in exchanging kidneys is entered into the OPTN KPD database along with their tissue type and blood type. A transplant coordinator will also enter other factors, including where a potential living donor is willing to travel to donate; the maximum age of a donor that a recipient is willing to accept; etc. Approximately every 4 weeks, the computer system identifies potential matches (or exchange pairs). If a potential exchange pair is identified, transplant surgeon, physicians, and transplant center program staff will review the match. All individuals involved have the option to decline identified potential exchange pairs.

How are recipient/donor pairs informed of possible identified matching pairs?

The transplant center will contact the recipient/donor pair if the program identifies a potential pair that matches. At that point, the center will arrange for both the potential recipient and the potential living donor to receive crossmatch tests to confirm compatibility to the matched donor or recipient. The transplant center will notify the donor/recipient pair with the results of the crossmatch tests.

Recipient/donor pairs should discuss when they will be contacted about potential matches and what type of information the transplant center will share with them.

How does a recipient know that a matched donor will be a medically acceptable donor?

Each potential living donor must go through medical and psychosocial evaluations before being accepted into the program. Every potential living donor is evaluated according to standard medical practice. The recipient's transplant center will enter screening criteria for the recipient in the OPTN KPD database indicating the minimum medical requirements for a donor for the potential recipient. The recipient's transplant center will determine if the donor kidney offered is appropriate for their recipient.

How are the recipient and donor involved in evaluating the suitability of a match?

The OPTN KPD Operational Guidelines state that once a match has been found, the recipient's transplant center will receive the matched donor's center name and the de-identified medical data regarding the matched potential living donor. The potential living donor's center will be told the name of the center treating the matched recipient. Any additional information would be shared only by mutual agreement of the centers involved. Recipients and living donors should discuss with their transplant center:

- what information will be shared with them,
- how the center will decide what additional information is necessary,
- whether they will be involved in deciding what additional information will be shared,
- what additional consent may be necessary to share this information, and
- how they will be involved in determining whether the match is suitable.

What information will a donor receive about a matched recipient?

The potential living donor's center will be told the name of the center treating the matched recipient. Confidentiality in medicine is heavily regulated. Any additional information would be shared only by mutual agreement of the centers. Transplant centers will not share information that would violate any person's confidentiality. Potential living donors should discuss with their transplant center:

- what information will be shared with them,
- how the center will decide what additional information is necessary,
- whether they will be involved in deciding what additional information will be shared,
- what additional consent may be necessary to share this information, and
- how they will be involved in determining whether the match is suitable.

The potential living donor should be aware that they may not know any medical information about the matched recipient, other than the fact that the recipient's physician has determined that a transplant is a medically suitable treatment for the potential recipient. The risk of organ failure will be different for every patient. It is not possible to inform the donor of the likely risk of organ failure for a given recipient.

What is the chance of finding a match? How long does it take to find an exchange pair that matches?

Different factors affect the chances of finding a match. It can take anywhere from 1 month to several years to find an exchange pair that matches. Whether or not a match is found and the length of time it takes to find a match depends on many factors, including:

- The number of potential living donors each potential recipient brings into the program: A potential recipient who has more than one willing potential living donor, only one of whom will eventually donate, has a greater chance of finding a match and a greater chance of finding a match in a shorter time frame.
- Blood Types of potential living donors and recipients: People with common blood types will have a greater chance of finding a match and a greater chance of finding a match in a shorter time frame.
- Potential recipient's sensitization level: Those with low sensitization will have a greater chance of finding a match. If a recipient has been exposed to another person's tissue through a pregnancy, blood transfusion, or a previous transplant, they can develop very specific antibodies to that person's tissue (antigens). If they were to receive another transplant that contained those same antigens, it could cause a severe reaction (rejection of the kidney). The greater number of antibodies a recipient has, the harder it is to find a match.
- The number of participants registered in the OPTN KPD Pilot Program: The greater the number of pairs in the system, the more likely a possible recipient/donor match will be found and the more likely a match can be found quickly.
- Recipients who previously donated an organ will receive some priority in matching (discuss with the transplant center).

How many pairs are involved in a KPD exchange?

There could be as few as 2 pairs involved or as many as 3 pairs involved, depending on the results of the match run and choices of the recipients and transplant centers. As stated above, non-directed donors may also participate in the OPTN KPD Pilot Program. In a donor chain, up to 20 pairs can be involved.

Can the pairs meet?

Yes, if everyone involved in the KPD process agrees to the meeting. The transplant center will discuss the program's protocols and make the arrangements.

Where would the transplant take place?

Transplant recipients will generally have their surgery at the transplant center where they currently receive care or at a center where he/she is multi-listed. However, a potential recipient may travel to another transplant center if the donor is unable or unwilling to travel. The information initially entered in the database indicates whether the potential recipients are willing to travel and if they are willing to accept a shipped kidney (with informed consent of the risks by the transplant center).

In both two-pair and three-pair exchanges, the donor surgeries begin at the same time. The recipient surgeries start after the donor surgeries. In a donor chain where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates.

Would the donors have to travel to the matched recipient's center for their donation?

A transplant coordinator will enter into the OPTN KPD database whether the potential donor is able and willing to travel for surgery. This information is considered in the process of matching potential donors with potential recipients. However, some transplant centers will ask the donor to travel and the decision to do so is made by the donor and transplant center, together. If a donor is asked to travel for surgery, a team including a transplant coordinator, a surgeon, and a nephrologist will work to meet the traveling donor's needs.

In some cases, the donor has surgery at the center where he/she was first evaluated and the kidney may be shipped to the matched recipient's transplant center. There are increased risks associated with the transport of organs. (These risks will be explained in detail by the transplant team.) Thus, having the donor travel to the recipient's transplant center decreases the risk involved in moving the donated kidney to a different transplant center. Donors and recipients should talk about the best options with the transplant center. As stated above, there are national and possible local resources available that may be able to assist those who qualify with travel expenses (these are listed at the end of this document). Those who need help with travel or who will need financial assistance should discuss their options and needs with the transplant center

Who decides whether a kidney will be shipped?

Both transplant centers and potential living donors have a role in deciding whether a kidney will be shipped. Some transplant centers choose not to participate in exchanges where a kidney will be shipped because they do not want to take on any risk involved with the potential for loss or damage of a shipped kidney. Also, there are some cases where the reimbursement through insurance does not adequately cover the cost of shipping the organ. Similarly, potential living donors have the option to not allow their kidney to be shipped. If a living donor is willing to have his or her kidney shipped, the transplant center must explain any risks of loss or damage of the organ involved with transporting the kidney, and the living donor must specifically consent to having his or her kidney shipped. If the transplant center or living donor chooses not to have a kidney shipped, there are several alternatives:

- The living donor may travel to the matched recipient's center.
- The matched recipient may travel to the living donor's center.
- The living donor may be matched in a situation that does not require shipment of the kidney or travel.

These preferences are stored in the OPTN KPD database along with the medical information about the potential living donor. For the match to occur, all medical information as well as the donor's shipping and traveling preferences must be consistent.

What are the risks of participating in a kidney paired donation when the kidney is shipped to the recipient transplant center?

The living donor kidney will be shipped by ground and/or air transportation to the recipient transplant center. This form of transportation has the risk of courier delay, flight cancellation, or flight delay which would extend the cold ischemic time of the kidney. Cold ischemic time is the amount of time an organ spends being preserved after recovery from the donor. Too much cold ischemic time can affect the quality of the organ for transplant. With clear-cut, organized plans, this risk is decreased. There is the potential risk of problems outside of the transplant center's control such as a plane crash, terrorist activity, and natural disaster. There is a risk of damage to the kidney during transport which would be discovered when the kidney is being inspected at the recipient's transplant center.

Is it possible that the recipient outcomes may not be equal or that recipients will not have the same results in an exchange situation?

Yes. As with any transplant, recipient outcomes depend on a variety of factors, which will be shared by the transplant center. Potential donors should be aware that their matched recipient may do better than their planned recipient.

What information will be entered into the OPTN KPD database and how will this information be used?

For recipients: Recipients entered in the KPDPP must be on the OPTN deceased donor waiting list. Therefore, all information entered for a recipient on the OPTN deceased donor waiting list will be available for use in the KPDPP. Additional information, such as any tissue markers

(antigens) that need to be avoided in the donor in order for a compatible match to be made and recipient matching preferences, will be entered in the OPTN KPD database specifically for use in the KPDPP. Both data entered on the deceased donor waiting list and in the OPTN KPD database are considered OPTN data.

For donors: Information entered into the OPTN KPD database includes, but is not limited to: name, date of birth, relationship between potential living donor and incompatible recipient, blood type, current medications, genetic tissue type, and other health information. The personal information entered into the database will be used to identify other potential recipient/donor pairs. Potential living donor data will be shared with the surgeons, physicians, and transplant team at the potential recipient's transplant center. Personal data will be stored indefinitely.

How will information remain confidential?

Prior to locating a possible match, a potential living donor's or recipient's information will not be shared with anyone outside of the OPTN KPD Pilot Program or the participating transplant centers without the participant's clear permission. Access to the OPTN KPD database will be through a secure, password protected system. After a potential match is identified, the recipient's transplant center will review the matched donor's transplant center and the de-identified medical data. Likewise, the donor's transplant center will review the center of the matched recipient. All other information may be shared outside of the KPD system by the transplant centers on a case-by-case basis. The potential donor's health insurance may provide the matched recipient with the name of the actual matched donor on an Estimate of Benefits form that is sent to the recipient before surgery. This means that recipients may learn of their actual matched donor's identity. Otherwise, the participants' medical information will remain confidential to the extent required by law (discuss this with the transplant center).

Transplant centers maintain records of potential donor and recipient's written informed consents and living donor evaluations. Laboratories maintain documentation of verification of recipient's HLA typing, sensitization status, and low and high stringency antigens. This information is available to the OPTN contractor upon request. The transplant center must report certain medical conditions to governmental authorities.

Once potential living donors and recipients are entered into the database, what else do they have to do to stay active?

Potential living donors and recipients will remain active in the OPTN KPD database until they receive a transplant, donate, ask to be withdrawn from the program or are unable to participate because of a new medical condition. **It is extremely important for potential living donors and recipients to notify their transplant center if they have any medical or psychological changes or if anything happens that will affect their ability to donate or receive a kidney (for example: if he or she started a new or different medication, have an increase or decrease in weight or any other change in medical status).**

Who will provide medical care following surgery?

For recipients, the transplant center that performed the transplant will provide care following transplant. For donors, the transplant center that removed the kidney is responsible for submitting living donor follow-up forms to the OPTN for two years after donation. However, the follow-up evaluation may be provided at that transplant center or by another medical professional, depending on circumstances. Discuss the plan for follow-up care, including who will provide the follow-up care with the transplant center before donation.

How will medical care for donors following surgery be paid for?

Follow-up care coverage for donors varies by transplant center and insurance type. Discuss the plan for follow up care payment with the transplant center before donation.

How do recipient/donor pairs and non-directed donors join the OPTN KPD Pilot Program?

All interested pairs should contact the transplant center where the potential recipient is being cared for to discuss the Pilot Program. There is a list of transplant centers at <http://optn.transplant.hrsa.gov/resources/KPDPP.asp>.

Want more information?

All interested parties should contact the transplant center or local organ procurement organization to ask about the OPTN KPD Pilot Program.

Resources:

Below is a list of agencies that may be able to help donors with travel expenses and lodging needs. Additional funding may be available from other sources - please ask the transplant center.

National Living Donor Assistance Center (NLDAC)

- Administered by the University of Michigan in partnership with the American Society of Transplant Surgeons
- Website: <http://www.livingdonorassistance.org>
- Provides assistance with travel and meals
- For more information, contact:
NLDAC
2461 S. Clark Street, Suite 640
Arlington, VA 22202
Phone: 703.414.1600
Fax: 703.414.7874
Email: NLDAC@livingdonorassistance.org

AOTA (American Organ Transplant Association)

- For more information call or write:
P.O. Box 667566
Houston, TX 77266-7566
713-344-2402
- Or visit their website at www.aotaonline.org

American Kidney Fund

- Can assist with costs relating to the donation of a kidney (ie. transportation to transplant center) and living expenses during the recuperation period, based on financial need. 800-638-8299.
 - National Transplant Assistance Fund: 800-642-8399 or www.transplantfund.org
 - National Foundation for Transplants: 800-489-3863 or www.transplants.org
(Both are geared more to recipients, but have been willing to offer help to donors in dire circumstances as well.)

Airline Flights

Southwest Airlines

- Free flight (large budget for charitable giving)
- 14 days notice prior to flight
- Limited to 1 round trip ticket for a patient and 1 round trip ticket for a support person if needed per year (may ask for an exception for two tickets)
- Forms for patient and physician to fill out
- To apply call 214-792-6178 for forms and more details

Delta Airlines - SkyWish Program

- Free flight using Donated Frequent Flyer Miles
- 30 days notice prior to flight
- Demonstrate financial need
- To apply go to www.unitedwayatlanta.org
 - Click on programs
 - Click Delta SkyWish
 - 4th paragraph on left side of screen click application download

United Airlines

Supports TRIO members

The TRIO/United Airlines Travel Program is a cooperative arrangement between TRIO and the United Airlines Charity Miles Program. This program allows TRIO members and family members to fly free on transplant-related trips.

TRIO is an independent, not-for-profit, international organization committed to improving the quality of life of transplant candidates, recipients, their families and the families of organ and tissue donors.

Eligibility for use of the Travel Program is based upon financial need and must be for one of the following purposes:

- Medical treatment or consultation prescribed by the physician of an organ transplant recipient or candidate, or
- Travel by an organ donor for the purpose of donation or for medical consultation or treatment which is needed before donation, or
- One person traveling with a transplant recipient or candidate who must travel and is unable to travel alone, or
- Donor family member(s), on a case-by-case basis.

For more information about eligibility and applying to the program, please call TRIO at 1-800-TRIO-386 or (202) 293-0980. **To donate miles**, please call United at 800-421-4655.

Mercy Medical Airlift

- Free flight using money donated for tickets to purchase
- One week notice prior to flight
- To apply call 888-675-1405

Angel Flight North East

- Free flight using private and corporate donations; pilots donate time and fuel
- 4-6 seat airplanes
- 3-5 business days notice prior to flight
- Fly within 300 miles from home patient plus one support person
- Requires birthdates; weight; and medical waiver from physician
- To apply call 800-549-9980 or email to angelflight@angelflightne.org, Internet: <http://www.angelflight.com>

Hotels

ITM Hospitality Fund

- Provides free hotel rooms for patients and their families traveling to New York City for medical treatment
- 4 free nights stay; discount for anything over 4 nights
- Must apply through participating organization.