



# Kidney Paired Donation

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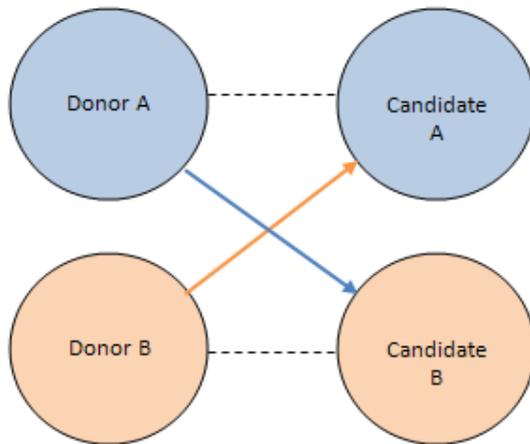
Healthcare Systems Bureau

Health Resources and Services Administration

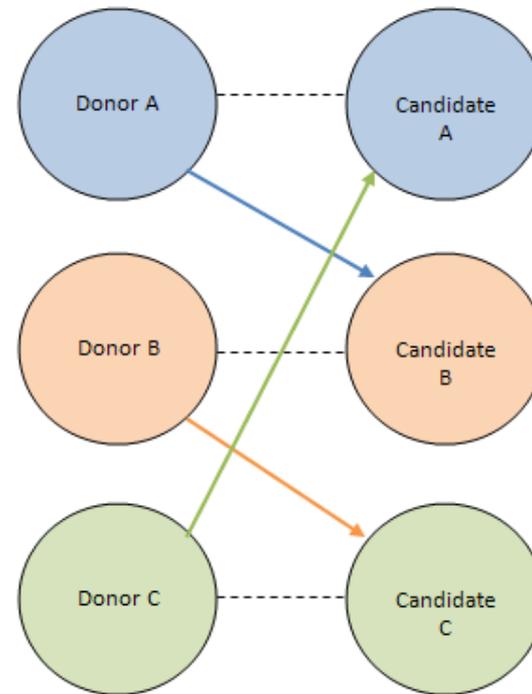
Department of Health and Human Services

# Background: KPD exchanges

Two-Way Exchange



Three-Way Exchange



# Background: Historical

- First performed in U.S. in 2000
- KPD and non-directed donation provides 12% of all living donor kidneys
- Evolution of original 2-way and 3-way simple exchanges (simultaneous operations):
  - now includes incompatible pairs due to blood type and also highly sensitized candidates
  - multiple paired exchanges (sequential operations)
  - chains initiated by altruistic living donors

# Background: KPD Structure

- Single center programs
- Multicenter Consortium with central coordination
  - one transplant center as coordinating center
  - separate organization as coordinating center
  - OPTN/UNOS KDP Pilot Program

# Legal Framework

- National Organ Transplantation Act of 1984 as amended (NOTA)
  - Prohibits transfer of organs for valuable consideration (section 301)
- Organ Procurement and Transplantation Network (OPTN) shall:
  - establish... a national list of individuals who need organs
  - establish... a national system... to match organs and individuals...
  - establish... medical criteria for allocating organs...
- Charlie W Norwood Living Organ Donation Act (2008) amended NOTA
  - excludes KPD from criminalization of valuable consideration (section 301)

# Legal Framework (continued)

- OPTN final rule: “Directed donation. Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.” 42 CFR 121.8(h)
- Federal Register Notice (June 16, 2006): Under the authority of 42 CFR 121.4(a)(6), the Secretary directed the OPTN to develop “policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the OPTN final rule.”
- OPTN final rule: OPTN Board of Directors shall develop “policies on such other matters as the Secretary directs”

# ACOT Recommendation 57

## (September 4, 2013)

- KPD plays an emerging role in the United States, now comprising more than 10% of live donor kidney transplants.
- Current decentralized organization of KPD programs is not optimal in terms of equity of access, broad participation by centers and patients, donor safety, and transparency.
- Providing a nationally accessible KPD system with incentives to participation in this system rather than in smaller, decentralized programs would improve equity of access and facilitate participation by centers and patients.
- Implementation of a standardized reimbursement model (such as a standard acquisition charge) would improve donor safety by ensuring medical care for donors, in addition to providing an equitable framework for reimbursement of KPD transplants.
- Evaluation of all KPD programs by a centralized group would improve transparency.

# ACOT Recommendation 57

- To address these issues, we recommend that the Secretary identify a national KPD contractor responsible for implementing a nationally accessible KPD system, identifying optimal matching strategies, and encouraging participation by all transplant centers.
- The contractor would also be responsible for
  - (1) administering a standardized reimbursement model for KPD costs, donor workups, and post-donation medical care that would be available to centers fully participating in the system;
  - (2) evaluation of KPD programs and transplant centers that choose to perform KPD outside of the national registry;
  - (3) balancing the needs of current and future patients;
  - (4) striving towards equity in patient access to kidneys;
  - (5) ensuring quality through frequent and critical assessment of equity and efficacy; and
  - (6) recommending process and/or policy changes as appropriate.

# Recent Developments on KPD

- The OPTN Pilot Project KPD Program (began Fall 2010) represents “a nationally accessible KPD system” with other KPD systems continuing to operate.
- OPTN KPD Finance Work Group and others have worked closely with CMS and third party payers to identify common elements and barriers for “a standardized reimbursement model”, with ongoing discussions
- All KPD transplant centers must comply with OPTN policies regarding data reporting and living donors (donor evaluation, informed consent, and follow up) and are subject to evaluation of living donor recipient outcomes by OPTN
- Other KPD programs facilitating exchanges among multiple transplant centers are not members of OPTN and not subject to direct oversight by OPTN

# Questions for the Committee

- How can the transplant community best approach a balance between innovation and patient safety and outcomes given KPD is evolving field?
- What are the advantages and disadvantages (and vulnerabilities) of:
  - Regional KPD systems?
  - Single center KPD systems?
  - A single national KPD system?