

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 6-I-10

Subject: Nonsimultaneous, Altruistic Organ Donation

Presented by: John W. McMahon, Sr., MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Daniel B. Kimball, Jr., MD, Chair)

1 Policy D-370.986, “Investigation of Non-Simultaneous, Extended, Altruistic Organ Donation”;
2 (AMA Policy Database) directs our American Medical Association (AMA) to “examine the
3 feasibility and ethical implications of unconventional organ donation variations, such as non-
4 simultaneous, extended, altruistic organ donation.” In 2005, the AMA’s House of Delegates
5 adopted a report by the Council on Ethical and Judicial Affairs (CEJA) on Transplantation of
6 Organs from Living Donors that outlined the ethical issues at stake in living organ donation.
7 Though the organ donation scenarios outlined in this report fall under the category of living
8 donation, CEJA believes that organ donation to an unknown recipient, also known as nondirected
9 donation, merits further ethical oversight. The present report outlines the ethical issues at stake in
10 nondirected organ donation arrangements including paired organ donation, domino paired
11 donation, and nonsimultaneous extended altruistic donation.

12
13 **BACKGROUND**

14
15 To increase the supply of organs available for transplantation, a variety of new options for live
16 donation have been proposed and carried out. Paired donation (also known as an organ swap or
17 living-donor exchange) is “an exchange involving two donors who are not compatible with their
18 intended recipient so that each donates to a compatible recipient.”¹ During paired donation
19 transplants blood type incompatible donor-recipient pairs Y and Z are recombined to make
20 compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y.² The transplant
21 operations are performed in the same hospital at the same time in order to prevent the second donor
22 from failing to donate.^{2,3}

23
24 A variation on paired donation known as a “domino paired donation” takes place when an
25 individual who is willing to donate an organ but who has not designated a recipient (referred to as
26 an altruistic donor or, sometimes, a nondirected donor) gives an organ to a recipient who is part of
27 an incompatible pair (i.e. an individual who needs an organ and someone who is willing to donate
28 but does not have a matching blood type). When the recipient in the incompatible pair receives an
29 organ from an altruistic donor, simultaneously the donor of the incompatible pair gives to another
30 recipient.⁴ Another variation is nonsimultaneous extended altruistic donation (“NEAD” in the
31 literature). A nonsimultaneous donation chain is initiated by an altruistic donor and each

*Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 subsequent donor only donates after the recipient in the pair has received an organ, which is like a
 2 domino paired donation except that the donor of the last pair is held in reserve and asked to donate
 3 later.⁴

4
 5 Since 2001, programs to facilitate paired donation in one variant or another have been successfully
 6 established throughout the United States, almost exclusively for kidney donation.⁵ Though it is
 7 difficult to pinpoint the total number of organs exchanged through paired, domino, or chain
 8 donation, several organizations, news media outlets, and academic journals have published results
 9 of successful transplants. One such organization is the Alliance for Paired Donation, a coalition of
 10 medical centers dedicated to facilitating kidney paired donation. The Alliance is made up of 80
 11 transplant programs in 30 states that have partnered to increase their patients' access to a large pool
 12 of potential kidney donors from incompatible pairs.⁶ Since 2007 (and as of April 2010) the
 13 Alliance has facilitated 48 transplants and launched the first U.S. kidney chain donation in 2007.
 14 Medical centers that are not a part of the Alliance for Paired Donation have participated in domino
 15 chains that have supplied kidneys to up to 14 recipients.⁷ It appears that such exchanges are on the
 16 rise: the Organ Procurement and Transplantation Network (a part of the U.S. Department of Health
 17 and Human Services Health Resources and Services Administration) is developing a national
 18 kidney paired donation system to be administered by the United Network for Organ Sharing. A
 19 pilot program will be launched in the fall of 2010.⁸

20 21 ETHICS

22
 23 Ethical issues at stake in paired organ donation include the autonomy of donors, balancing risks
 24 and benefits for both donor and recipient, privacy, allocation of organs donated through variants of
 25 paired donation as well as public acceptance of novel ways to procure and exchange organs.

26 27 *Risks and Benefits*

28
 29 There are a number of risks and benefits associated with the different designs of nondirected
 30 donation which vary for both donors and recipients. All living organ donors may experience a
 31 spectrum of emotions after donating an organ. For donors, psychological risk is feeling
 32 resentment, guilt, profound grief, or depression subsequent to the procedure.^{3,9} Benefits may
 33 include rewarding feelings of helping another, of empowerment, or of increased self-esteem; a
 34 sense of closeness to the recipient and the recipient's family, and the community; and satisfaction
 35 from having contributed to a valuable cause. Some of these benefits, however, may be contingent
 36 on factors associated with the donor's experience, including the donor's attitude toward donation
 37 and how the recipient fares.³ Feelings, both positive and negative, may be exacerbated by the fact
 38 that donors involved in a nontraditional donation likely will not know the result of their donation.⁹

39
 40 In a scenario in which the donor gives his or her organ to a stranger, the benefit to the donor may
 41 be perceived to be less than if he or she donated to a relative or friend since there is no personal
 42 relationship or connection to the recipient; the recipient may also feel burdened by a debt that can
 43 not be repaid.⁹ In nonsimultaneous donation scenarios, there is also the risk that the intended donor
 44 will renege on his or her decision to donate.²

45
 46 There may also be heightened concern about coercion for organ donors involved in paired
 47 exchanges, including domino paired donation or extended donation chains. A traditional living
 48 donor who may be reluctant to donate has the opportunity to cite—truthfully or otherwise—

1 medical criteria such as blood type or histocompatibility to explain a decision not to donate. This
2 is not possible when the donor is being matched to any third party who shares the donor's criteria.⁸
3

4 Privacy and confidentiality also may be threatened when paired donations take place. When four
5 operations are being performed simultaneously in the same hospital, as in a paired donation
6 scenario, it is challenging to prevent donors and recipients, or family or friends who are present
7 from learning the identities of the other patients and donors involved.⁹ Hospitals have dealt with
8 this issue by using different operating suites and placing patients in different units of the hospital,
9 though this may not always be possible.⁹

10
11 Public acceptance is also a concern as with any novel transplantation proposal.⁹ Any method to
12 increase the supply of organs may be met with public questioning and suspicion in transplantation
13 in general.⁹ On the other hand there may be ethical issues with commercialization, exploitation and
14 mass media.¹⁰ In the field of transplantation, there is concern that paying organ donors for organs
15 can have undue influence on decision making, inducing the prospective donor to undergo a
16 procedure with a number of risks for the sake of payment. Though both federal law and ethical
17 guidelines prohibit monetary payment to living donors (beyond compensation for medical expenses
18 and travel), in paired donation scenarios there is apprehension that the exchange of organs
19 constitutes a transfer for "valuable consideration" (i.e., donors will participate only for the
20 valuable reward of having their own intended recipient receive an organ in exchange).^{3,9} In 2007
21 the U.S. Justice Department concluded that paired exchanges of living donor transplants do not
22 count as "valuable consideration," though all fears about commercialization may not be allayed.
23 Concerns are also raised by solicitation of altruistic donors through Web sites (or other means)
24 touting benefits of donation as well as mass media coverage of nonsimultaneous donation chains
25 that supply many people with organs. The prospect of media attention may unduly influence
26 individuals to donate an organ without a designated recipient, as opposed to the ethically
27 acceptable criteria of a voluntary and independent decision free of coercion and based on altruism.²
28

29 *Further Considerations*

30
31 Some variations of paired exchange also increase the chance that some subgroups of patients on the
32 waiting list for transplantation may be at a disadvantage for increased waiting time or possibly
33 never receiving an organ.¹¹ Specifically, it is possible that patients waiting for blood group O
34 organs will experience longer waiting times than other patients, since more than two-thirds of
35 incompatible donor-recipient pairs involve a recipient of blood group O.¹¹ Arguably, it would be
36 unethical to further delay transplantation for this vulnerable group of patients (those waiting to
37 receive blood type O organs off of the traditional wait list) by allocating some type-O organs for
38 paired donation designs.^{10,11} On the other hand, it can be argued that any method to produce a net
39 gain of the number of organs in the pool is ethically acceptable.³
40

41 On the other hand, domino or chain donation systems may overcome some of the ethical concerns
42 raised by current models for allocating organs from living donors. There is no single accepted
43 model for allocating organs from altruistic donors and transplant centers variously use one of three
44 models: donor-centric, recipient-centric, and sociocentric.¹² The donor-centric model allocates
45 organs to the healthiest patients on a transplant list, who are least needy medically and who have
46 the greatest opportunity for a good outcome. The expectation of a good outcome not only helps to
47 justify asking a living donor to undergo the risks of donation, but may also give the donor a sense
48 of accomplishment.

1 The recipient-centric model allocates organs to the most vulnerable patients on a list, including
2 those who are at greatest need or those who are disadvantaged under current schemes for allocating
3 from deceased donors (e.g., children or patients who have no vascular access or can no longer
4 undergo dialysis).¹² However, the very patients recipient-centric allocation seeks to benefit are
5 those from whom transplantation is less likely to be successful.¹²

6 The sociocentric model views donated organs as a public resource to be allocated in the most
7 equitable way possible, regardless of outcome or medical need. On this model, donated organs are
8 allocated to the patient at the top of the list administered by the United Network for Organ Sharing,
9 which uses a match algorithm to rank recipients against defined criteria (e.g., HLA match and the
10 sickness of the patient). Patients at the top of the list have incurred the costs associated with a long
11 waiting period, but are likely to receive an organ from a deceased donor.

12
13 As Montgomery and colleagues note, domino or chain donation can serve the goals of all three
14 traditional allocation models and overcome their limitations. Such programs can increase the
15 likelihood of a good outcome by spreading the risk of recipient graft loss across more people.¹²
16 They can help hard to match patients who are disadvantaged by the current system by supporting
17 timelier access to a matched donor organ. Lastly, if adopted into the national system, domino or
18 chain organ donation can serve the goal of fair and equitable allocation when paired donor organs
19 are allocated to the next compatible patients on the UNOS registry.

20 21 RECOMMENDATION

22
23 The Council on Ethical and Judicial Affairs recommends that Opinion 2.15 – Transplantation of
24 Organs from Living Donors be amended as noted below and that the rest of this report be filed:

25
26 Living organ donors are exposed to surgical procedures that pose risks but offer no physical
27 benefits. The medical profession has pursued living donation because the lives and quality of
28 life of patients with end-stage organ failure depend on the availability of transplantable organs
29 and some individuals are willing to donate the needed organs. This practice is consistent with
30 the goals of the profession—treating illness and alleviating suffering—only insofar as the
31 benefits to both donor and recipient outweigh the risks to both.

32
33 (1) Because donors are initially healthy and then are exposed to potential harms, they require
34 special safeguards. Accordingly, every donor should be assigned an advocate team that
35 includes a physician. This team is primarily concerned with the well-being of the donor.
36 Though some individuals on the donor advocate team may participate in the care of the
37 recipient, this team ideally should be as independent as possible from those caring for the
38 recipient. This can help avoid actual or perceived conflicts of interest between donors and
39 recipients.

40
41 (a) To determine whether a potential living donor is an appropriate candidate, the advocate
42 team must provide a complete medical evaluation to identify any serious risk to the
43 potential donor's life or health. This includes a psychosocial evaluation of the
44 potential donor to identify disqualifying factors, address specific needs and explore
45 potential motivations to donate.

- 1 (b) Before the potential donor agrees to donate, the advocate team should provide
2 information regarding the donation procedure and its indications, as well as the risks
3 and potential complications to both donor and recipient. Informed consent for
4 donation is distinct from informed consent for the actual surgery to remove the organ.
5
6 (i) The potential donor must have decision-making capacity, and the decision to
7 donate must be free from undue pressure. The potential donor must demonstrate
8 adequate understanding of the disclosed information.
9
10 (ii) Unemancipated minors and legally incompetent adults ordinarily should not be
11 accepted as living donors because of their inability to fully understand and decide
12 voluntarily. However, in exceptional circumstances, minors with substantial
13 decision making capability who agree to serve as donors, with the informed
14 consent of their legal guardians, may be considered for donation to recipients with
15 whom they are emotionally connected. Since minors' guardians may be
16 emotionally connected to the organ recipient, when an unemancipated minor
17 agrees to donate, it may be appropriate to seek advice from another adult trusted by
18 the minor or an independent body, such as consultation with an ethics committee,
19 pastoral service, or other counseling resource. and with the informed consent of
20 their legal guardians, they may be considered for donation to recipients with whom
21 they are emotionally connected. Similarly, in exceptional circumstances and with
22 the informed consent of their legal guardians individuals without full decision-
23 making capacity may be allowed to serve as living donors to strangers as a part of
24 a paired-, domino, or chain donation that will result in an organ for someone with
25 whom they are emotionally connected.
26
27 (iii) Potential donors must be informed that they may withdraw from donation at any
28 time before undergoing the operation and that, should this occur, the health care
29 team is committed to protect the potential donor from pressures to reveal the
30 reasons for withdrawal. If the potential donor withdraws, the health care team
31 should report simply that the individual was unsuitable for donation. From the
32 outset, all involved parties must agree that the reasons why any potential donor
33 does not donate will remain confidential for the potential donor's protection. In
34 situations of paired, domino, or chain donation withdrawal must still be permitted.
35 Physicians should make special efforts to present a clear and comprehensive
36 description of the commitment being made by the donor and the implications for
37 other parties to the paired donation during the informed consent process.
38
39 (c) Living donation should never be considered if the best medical judgment indicates that
40 transplantation cannot reasonably be expected to yield the intended clinical benefit or
41 achieve agreed on goals for care for the intended recipient's condition is clinically futile.
42
43 (2) Living donors should not receive payment for any of their solid organs. However, donors
44 should be treated fairly; reimbursement for travel, lodging, meals, lost wages, and the
45 medical care associated with donation is ethically appropriate.
46
47 (3) The distribution of organs from living donors may take several different forms:

- 1 (a) It is ethically acceptable for donors to designate a recipient, whether a close relative or
2 a known, unrelated recipient.
3
- 4 (b) Designation of a stranger as the intended recipient is ethical if it produces a net gain of
5 organs in the organ pool without unreasonably disadvantaging others on the waiting
6 list. Variations involve potential donors who respond to public solicitation for organs
7 or who wish to participate in a paired donation or ~~(also known as an “organ swap”)~~—
8 (e.g., blood type incompatible donor-recipient pairs Y and Z are recombined to make
9 compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y) domino
10 paired donation, and nonsimultaneous extended altruistic donation (also known as
11 chain donation).
12 ~~Such variations require further study and ethical examination to evaluate the potential~~
13 ~~impact on the fairness of allocation.~~
- 14 (c) Organs donated by living donors who do not designate a recipient should be allocated
15 according to the algorithm that governs the distribution of deceased donor organs.
16
- 17 (4) Novel variants of living donation call for special attention to protect both donors and
18 recipients:
19
- 20 (a) Physicians must ensure utmost respect the privacy and confidentiality of donors and
21 recipients, which may be more difficult when many patients are involved and when
22 donation-transplantation cycles may be extended over time (as in domino or chain
23 donation)
24
- 25 (b) Physicians should monitor prospective donors and recipients in a proposed
26 nontraditional donation for signs of psychological distress during screening and after
27 the transplant is complete.
28
- 29 (c) Physicians must protect the donor’s right to withdraw in living paired-donations and
30 ensure that the individual is not pressured to donate.
31
- 32 (5) To enhance the safety of living organ donation through better understanding of the harms
33 and benefits associated with living organ donation, physicians should support the
34 development and maintenance of a national database of living donor outcomes, similar to
35 that of deceased donation.
36

37 The Council further recommends that Policy D-370-986 be rescinded, having been accomplished in
38 preparation of this report.

39
40 (Modify HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

REFERENCES

1. Delmonico FL. Exchanging Kidneys – Advances in Living-Donor Transplantation. *N Engl J Med.* 2004;350(18):1812-1814.
2. Rees MA, Kopke JE, Pelletier RP, Segev DL, Rutter ME, Fabrega AJ, et al. A Nonsimultaneous, Extended, Altruistic-Donor Chain. *N Engl J Med.* 2009;360(11):1096-1101.
3. Council on Ethical and Judicial Affairs. Transplantation of Organs from Living Donors. Available at <http://www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/215a.pdf> Accessed September 13, 2010.
4. Gentry GE, Segev DL, Simmerling M, Montgomery RA. Expanding Kidney Paired Donation Through Participation by Compatible Pairs. *Am J Transplantation.* 2007;7:2361-2370.
5. Johns Hopkins Medicine. Press Release: Johns Hopkins Leads First 16-Patient, Multicenter “Domino Donor” Kidney Transplant. July 7, 2009. http://www.hopkinsmedicine.org/Press_releases/2009/07_07_09.html Accessed September 13, 2010.
6. Alliance for Paired Donation. Available at <http://www.paireddonation.org/> Accessed September 13, 2010.
7. Yamura, L. Chain of transplants gives 14 kidney patients new life. *Washington Post.* June 29, 2010. <http://www.washingtonpost.com/wp-dyn/content/article/2010/06/28/AR2010062803796.html> Accessed September 13, 2010.
8. Organ Procurement and Transplantation Network. Kidney Paired Donation Pilot Program. <http://optn.transplant.hrsa.gov/resources/KPDPP.asp>. Accessed September 2, 2010.
9. Ross LF, Rubin DR, Siegler MS, Josephson MA, Thistlethwaite, JR, Woodle, ES. Ethics of a Paired-Kidney-Exchange Program. *N Engl J Med.* 1997;336(24):1752-1755.
10. Woodle ES, Daller JA, Aeder M, Shapiro R, Sandholm T, Casingal V, et al. Ethical Considerations for Participation of Nondirected Living Donors in Kidney Exchange Programs. *Am J Transplantation.* 2010;10:1460-1467.
11. Ross LF, Woodle ES. Ethical Issues in Increasing Living Kidney Donations by Expanding Kidney Paired Exchange Programs. *Transplantation.* 2000;69(8):1539-1543.
12. Montgomery RA, Gentry SE, Marks MH, Warren DS, Hiller J, Zachary AA, et al. Domino Paired Kidney Donation: A Strategy to Make Best Use of Live Non-Directed Donation. *Lancet.* 2006;368:419-421.