Subject: Nonsimultaneous, Altruistic Organ Donation

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

BACKGROUND

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

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

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

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

ETHICS

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

\textit{Risks and Benefits}

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

In a scenario in which the donor gives his or her organ to a stranger, the benefit to the donor may
be perceived to be less than if he or she donated to a relative or friend since there is no personal
relationship or connection to the recipient; the recipient may also feel burdened by a debt that can
not be repaid.\textsuperscript{9} In nonsimultaneous donation scenarios, there is also the risk that the intended donor
will renge on his or her decision to donate.\textsuperscript{5}

There may also be heightened concern about coercion for organ donors involved in paired
exchanges, including domino paired donation or extended donation chains. A traditional living
donor who may be reluctant to donate has the opportunity to cite—truthfully or otherwise—
medical criteria such as blood type or histocompatibility to explain a decision not to donate. This is not possible when the donor is being matched to any third party who shares the donor’s criteria.8

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

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

Further Considerations

Some variations of paired exchange also increase the chance that some subgroups of patients on the waiting list for transplantation may be at a disadvantage for increased waiting time or possibly never receiving an organ.11 Specifically, it is possible that patients waiting for blood group O organs will experience longer waiting times than other patients, since more than two-thirds of incompatible donor-recipient pairs involve a recipient of blood group O.11 Arguably, it would be unethical to further delay transplantation for this vulnerable group of patients (those waiting to receive blood type O organs off of the traditional wait list) by allocating some type-O organs for paired donation designs.10,11 On the other hand, it can be argued that any method to produce a net gain of the number of organs in the pool is ethically acceptable.9

On the other hand, domino or chain donation systems may overcome some of the ethical concerns raised by current models for allocating organs from living donors. There is no single accepted model for allocating organs from altruistic donors and transplant centers variously use one of three models: donor-centric, recipient-centric, and sociocentric.12 The donor-centric model allocates organs to the healthiest patients on a transplant list, who are least needy medically and who have the greatest opportunity for a good outcome. The expectation of a good outcome not only helps to justify asking a living donor to undergo the risks of donation, but may also give the donor a sense of accomplishment.
The recipient-centric model allocates organs to the most vulnerable patients on a list, including those who are at greatest need or those who are disadvantaged under current schemes for allocating from deceased donors (e.g., children or patients who have no vascular access or can no longer undergo dialysis). However, the very patients recipient-centric allocation seeks to benefit are those from whom transplantation is less likely to be successful. The sociocentric model views donated organs as a public resource to be allocated in the most equitable way possible, regardless of outcome or medical need. On this model, donated organs are allocated to the patient at the top of the list administered by the United Network for Organ Sharing, which uses a match algorithm to rank recipients against defined criteria (e.g., HLA match and the sickness of the patient). Patients at the top of the list have incurred the costs associated with a long waiting period, but are likely to receive an organ from a deceased donor.

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

RECOMMENDATION

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

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

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

(a) To determine whether a potential living donor is an appropriate candidate, the advocate team must provide a complete medical evaluation to identify any serious risk to the potential donor’s life or health. This includes a psychosocial evaluation of the potential donor to identify disqualifying factors, address specific needs and explore potential motivations to donate.
(b) Before the potential donor agrees to donate, the advocate team should provide information regarding the donation procedure and its indications, as well as the risks and potential complications to both donor and recipient. Informed consent for donation is distinct from informed consent for the actual surgery to remove the organ.

(i) The potential donor must have decision-making capacity, and the decision to donate must be free from undue pressure. The potential donor must demonstrate adequate understanding of the disclosed information.

(ii) Unemancipated minors and legally incompetent adults ordinarily should not be accepted as living donors because of their inability to fully understand and decide voluntarily. However, in exceptional circumstances, minors with substantial decision making capability who agree to serve as donors, with the informed consent of their legal guardians, may be considered for donation to recipients with whom they are emotionally connected. Since minors' guardians may be emotionally connected to the organ recipient, when an unemancipated minor agrees to donate, it may be appropriate to seek advice from another adult trusted by the minor or an independent body, such as consultation with an ethics committee, pastoral service, or other counseling resource, and with the informed consent of their legal guardians, they may be considered for donation to recipients with whom they are emotionally connected. Similarly, in exceptional circumstances and with the informed consent of their legal guardians individuals without full decision-making capacity may be allowed to serve as living donors to strangers as a part of a paired-, domino, or chain donation that will result in an organ for someone with whom they are emotionally connected.

(iii) Potential donors must be informed that they may withdraw from donation at any time before undergoing the operation and that, should this occur, the health care team is committed to protect the potential donor from pressures to reveal the reasons for withdrawal. If the potential donor withdraws, the health care team should report simply that the individual was unsuitable for donation. From the outset, all involved parties must agree that the reasons why any potential donor does not donate will remain confidential for the potential donor’s protection. In situations of paired, domino, or chain donation withdrawal must still be permitted. Physicians should make special efforts to present a clear and comprehensive description of the commitment being made by the donor and the implications for other parties to the paired donation during the informed consent process.

(c) Living donation should never be considered if the best medical judgment indicates that transplantation cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for care for the intended recipient’s condition is clinically futile.

(2) Living donors should not receive payment for any of their solid organs. However, donors should be treated fairly; reimbursement for travel, lodging, meals, lost wages, and the medical care associated with donation is ethically appropriate.

(3) The distribution of organs from living donors may take several different forms:
(a) It is ethically acceptable for donors to designate a recipient, whether a close relative or a known, unrelated recipient.

(b) Designation of a stranger as the intended recipient is ethical if it produces a net gain of organs in the organ pool without unreasonably disadvantaging others on the waiting list. Variations involve potential donors who respond to public solicitation for organs or who wish to participate in a paired donation or (also known as an “organ swap”)—(e.g., blood type incompatible donor-recipient pairs Y and Z are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y)—domino paired donation, and nonsimultaneous extended altruistic donation (also known as chain donation).

Such variations require further study and ethical examination to evaluate the potential impact on the fairness of allocation.

(c) Organs donated by living donors who do not designate a recipient should be allocated according to the algorithm that governs the distribution of deceased donor organs.

(4) Novel variants of living donation call for special attention to protect both donors and recipients:

(a) Physicians must ensure utmost respect the privacy and confidentiality of donors and recipients, which may be more difficult when many patients are involved and when donation-transplantation cycles may be extended over time (as in domino or chain donation).

(b) Physicians should monitor prospective donors and recipients in a proposed nontraditional donation for signs of psychological distress during screening and after the transplant is complete.

(c) Physicians must protect the donor’s right to withdraw in living paired-donations and ensure that the individual is not pressured to donate.

(5) To enhance the safety of living organ donation through better understanding of the harms and benefits associated with living organ donation, physicians should support the development and maintenance of a national database of living donor outcomes, similar to that of deceased donation.

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

(Modify HOD/CEJA Policy)

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