6.1.1 Transplantation of Organs from Living Donors

Donation of nonvital organs and tissue from living donors can increase the supply of organs available for transplantation, to the benefit of patients with end-stage organ failure. Enabling individuals to donate nonvital organs is in keeping with the goals of treating illness and relieving suffering so long as the benefits to both donor and recipient outweigh the risks to both.

Living donors expose themselves to harm to benefit others; novel variants of living organ donation call for special safeguards for both donors and recipients.

Physicians who participate in donation of nonvital organs and tissues by a living individual should:

(a) Ensure that the prospective donor is assigned an advocacy team, including a physician, dedicated to protecting the donor's well-being.

(b) Avoid conflicts of interest by ensuring that the health care team treating the prospective donor is as independent as possible from the health care team treating the prospective transplant recipient.

(c) Carefully evaluate prospective donors to identify serious risks to the individual's life or health, including psychosocial factors that would disqualify the individual from donating; address the individual's specific needs; and explore the individual's motivations to donate.

(d) Secure agreement from all parties to the prospective donation in advance so that, should the donor withdraw, his or her reasons for doing so will be kept confidential.

(e) Determine that the prospective living donor has decision-making capacity and adequately understands the implications of donating a nonvital organ, and that the decision to donate is voluntary.

(f) In general, decline proposed living organ donations from unemancipated minors or legally incompetent adults, who are not able to understand the implications of a living donation or give voluntary consent to donation.

(g) In exceptional circumstances, enable donation of a nonvital organ or tissue from a minor who has substantial decision-making capacity when:

    (i) the minor agrees to the donation;

    (ii) the minor's legal guardians consent to the donation;

    (iii) the intended recipient is someone to whom the minor has an emotional connection.

(h) Seek advice from another adult trusted by the prospective minor donor when circumstances warrant, or from an independent body such as an ethics committee, pastoral service, or other institutional resource.

(i) Inform the prospective donor:

    (i) about the donation procedure and possible risks and complications for the donor;

    (ii) about the possible risks and complications for the transplant recipient;

    (iii) about the nature of the commitment the donor is making and the implications for other parties;

    (iv) that the prospective donor may withdraw at any time before undergoing the intervention to remove the organ or collect tissue, whether the context is paired, domino, or chain donation; and

(v) that if the donor withdraws, the health care team will report simply that the individual was not a suitable candidate for donation.

(j) Obtain the prospective donor's separate consent for donation and for the specific intervention(s) to remove the organ or collect tissue.

(k) Ensure that living donors do not receive payment of any kind for any of their solid organs. Donors should be compensated fairly for the expenses of travel, lodging, meals, lost wages, and medical care associated with the donation only.

(l) Permit living donors to designate a recipient, whether related to the donor or not.

(m) Decline to facilitate a living donation to a known recipient if the transplantation cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for the intended recipient.

(n) Permit living donors to designate a stranger as the intended recipient if doing so produces a net gain in the organ pool without unreasonably disadvantaging others on the waiting list. Variations on donation to a stranger include:

(i) prospective donors who respond to public solicitations for organs or who wish to participate in a paired donation ("organ swap," as when donor-recipient pairs Y and Z with incompatible blood types are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y);

(ii) domino paired donation;

(iii) nonsimultaneous extended altruistic donation ("chain donation").

(o) When the living donor does not designate a recipient, allocate organs according to the algorithm that governs the distribution of deceased donor organs.

(p) Protect the privacy and confidentiality of donors and recipients, which may be difficult in novel donation arrangements that involve many patients and in which donation-transplant cycles may be extended over time (as in domino or chain donation).

(q) Monitor prospective donors and recipients in proposed nontraditional donation arrangements for signs of psychological distress during screening and after the transplant is complete.

(r) Support the development and maintenance of a national database of living donor outcomes to support better understanding of associated harms and benefits and enhance the safety of living donation.

AMA Principles of Medical Ethics: I,V,VII,VIII

Background report(s):

CEJA Report 6-I-10 Nonsimultaneous, altruistic organ donation

CEJA Report 5-A-05 Transplantation of organs from living donors

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)

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 organ 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 know 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."[1] 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.[2] The transplant operations are performed in the same hospital at the same time in order to prevent the second donor from failing to donate.[2,3]

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.[4] Another variation is nonsimultaneous extended altruistic donation ("NEAD" in the literature). A nonsimultaneous donation chain is initiated by an altruistic donor and each subsequent donor only donates after the recipient in the pair has received an organ, which is like a

*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.

domino paired donation except that the donor of the last pair is held in reserve and asked to donate later.[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.[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.[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.[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.[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.

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.[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.[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.[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.[9] In nonsimultaneous donation scenarios, there is also the risk that the intended donor will renege on his or her decision to donate.[2]

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 participates 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.[3]

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).[12] However, the very patients recipient-centric allocation seeks to benefit are those from whom transplantation is less likely to be successful.[12]

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.[12] 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

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.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 5 - A-05

Subject: Transplantation of Organs from Living Donors

Presented by: Michael S. Goldrich, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Art L. Klawitter, MD, Chair)

INTRODUCTION

Continuing scientific discoveries and innovation in the field of organ transplantation have increased the types of organs that can be transplanted and the range of individuals who can donate or receive an organ. This in part explains a constantly increasing number of potential recipients waiting for organs, which has grown at a faster rate than organs have become available. The result has been a persistent shortage of organs for transplantation.

Many initiatives have endeavored to increase the number of organs available for transplantation. Some have focused on gaining a better understanding of what motivates individuals to consider organ donation.[1] Others have focused on identifying new sources of organs, such as donation after cardiac death.[2, 3, 4] For the two decades following the first successful organ transplant operation in 1954, kidneys were donated primarily by living donors related to the recipients. Subsequently, organs from deceased donors largely replaced organs from living donors. However, efforts in the last decade to increase living donation are once again transforming the field.[5] In the past ten years, the number of living donors has more than doubled, surpassing that of deceased donors in 2001-2003.[6] Today, living donors can donate not only kidneys, but also liver segments, lung lobes, and parts of other organs.

Living donors usually derive no physical benefit from a surgical procedure that presents the usual risks of surgery, including infection or death during or after surgery and temporary or permanent disability.[7] The probability and magnitude of risk varies with the organ being donated. The risks to a kidney donor, for example, are fairly well understood, have a relatively low incidence, and are considered minimal beyond the regular risks of surgery;[8] the risks to liver donor are more significant, which helps account for why the procedure is less common.[9, 10]

Because living donors are initially healthy and voluntarily place themselves in harm's way, they require special protection. The purpose of this report is to examine living donation in the context

---

* 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.

of the goals of medicine and to provide guidelines for physicians who are involved in the transplantation of organs from living donors.

LIVING DONATION AND THE GOALS OF THE MEDICAL PROFESSION

Principle VIII of the American Medical Association's (AMA's) *Principles of Medical Ethics* states that: "A physician shall, while caring for a patient, regard responsibility to the patient as paramount."[11] An initial question that arises is whether physician participation in the transplantation of organs from living donors is consistent with this Principle. The procedure presents risks, but no physical benefits to the living donor, so some argue that physician participation in the procedure is antithetical to the professional obligation to do no harm.[12] At the very least, they maintain that living donors should be used only as a last resort for individuals who need a transplant, but have been unable to obtain one from a deceased donor through the national waiting list. However, the medical profession has performed living donation because the lives of some patients with end-stage organ failure depend on the availability of donated vital organs, a resource that is in very short supply. Some healthy individuals are willing to donate an organ to save or improve the lives of these patients, usually the living donors' relatives.

Collaboration of this kind between the public and physicians is almost without parallel. The context, however, is similar to the participation of physicians in enrolling human subjects in phase 1 and 2 clinical trials, which usually do not offer direct benefits to participants.[13] Under these circumstances, physicians facilitate a process that entails risks but no physical benefit to willing participants for the benefit of others.

Risks/Benefits Assessment

Living donation provides an alternative for individuals awaiting transplantation and effectively increases the organ supply.[14] In addition to reducing waiting time, organs from living donors provide other benefits to recipients: time to search for a well-matched organ, control over the operation's timing, and often a higher-quality organ, thus improving the chance of short- and long-term survival of both the organ and its recipient.[15]

Several kinds of benefits may accrue to the donor. The thorough medical evaluation may uncover previously unknown current or potential problems that can then be treated appropriately. Psychological benefits may include rewarding feelings of helping another, of empowerment, or of increased self-esteem; a sense of closeness to the recipient, 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. Donors also can experience feelings of resentment, guilt, profound grief, or depression subsequent to the procedure.[16]

The relationship between donor and recipient also may have an impact on the donor's experience. Donors who are emotionally connected to recipients may receive considerable psychological and emotional benefits because they have a bond with a relative, friend or colleague who is suffering and in need.[17] Benefits to Good Samaritan donors – donors without a designated recipient – have

not been measured, however, so it cannot be determined conclusively whether one type of living donor benefits from donation more than the other.[18]

The risk-benefit balance of living organ donation cannot be calculated directly, but some relevant criteria can guide physicians through this process. Certain baseline standards should be met to justify the procedure. An offer to donate should not be accepted if the donation process presents a serious risk to the potential donor's life, health, or well-being or if the recipient is unlikely to fare well with a transplant, as this would place an unreasonable burden on the potential donor.

Another baseline standard has been proposed: physicians should facilitate living donation only for potential recipients who would be eligible for an organ transplant from a deceased donor. A healthy individual should not be exposed to the risks that donation entails for a potential recipient who does not meet medical criteria to receive a transplant from a deceased donor. Others, however, believe such an exclusion would be inappropriate for a potential recipient with an acceptable prognosis for survival with a transplant and a suitable, willing donor. At the very least, living donation should never be considered in clinically futile circumstances.

APPROPRIATE SAFEGUARDS FOR POTENTIAL LIVING DONORS

Nationally, transplant centers have established policies for the protection of potential living donors, but the comprehensiveness and stringency of these policies are highly variable. It seems reasonable that health care professionals in this country be guided by the same baseline standards. The Council suggests such standards in this report.

Transplantation of organs from living donors should occur only when appropriate safeguards are pre-established. It is already a matter of AMA policy that physicians may assume responsibility in organ transplantation only if the rights of both donor and recipient are equally protected.[19] Toward this end, each potential donor should be assigned an advocate team that includes a physician. 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. Such a team, the primary concern of which is the donor's well being, will help avoid actual or perceived conflicts of interest. This is essential, because a major responsibility of the potential donor's team is to determine whether the individual is an appropriate candidate.

Some transplant centers have found it helpful to make additional support available to the potential donor. The third parties who fill this role usually are separate from the advocate team and the transplant center, though they may be affiliated with the same institution.

Informed Consent

The advocate team is responsible for helping a candidate make an informed decision regarding living donation. The process requires that the potential donor have decision-making capacity, demonstrate understanding of the information disclosed, and make a voluntary decision.

Because living donation affects not only the donor but also the donor's family, potential candidates should be encouraged to involve family members in the decision-making process. In fact, some

centers have required that potential candidates' immediate family be notified when donation is being considered.

Before any interviews of potential donors, all concerned parties should be informed that the reasons why any potential donor does not donate will be kept strictly confidential from everyone but the potential donor and the potential donor's health care team.

Comprehensive disclosure extends beyond reviewing relevant risks and benefits associated with living donation. Physicians, in partnership with potential donors and assisted by appropriate members of the health care team, should evaluate how donation might affect a patient's overall mental or emotional well-being, personal relationships with the recipient, family and friends, and lifestyle and activities over time. Financial matters also should receive consideration, including the potential impact of donation on health insurance coverage, on employment status, and on dependents in case of a bad outcome for the donor.

In addition, complete disclosure requires that the potential donor receive information regarding the risks and benefits associated with the recipient's transplantation: possible loss of the transplanted organ, potential death of the recipient, and alternative treatment available to the recipient.[20,21] This information may be relevant to the level of risk the potential donor is willing to accept.

The context in which potential donors who are emotionally connected to potential recipients must reach a decision often is highly charged: the life of the intended recipient may be in jeopardy. Real or imagined pressure to donate from the potential recipient and other members of the family may be difficult to resist. A candidate who has been identified as a good match for a family member, but who is reluctant to proceed, may be driven to donate by feelings such as guilt. The health care team cannot prevent these situations from arising, but can strive to ensure that donation goes forward only when it is truly voluntary and free from undue pressure.

The motivations and pressures underlying a Good Samaritan donor's decision to donate are likely to be significantly different[22] and must be thoroughly assessed to establish the voluntary nature of the decision. These donors may be acting out of a profound sense of altruism, but also may be trying to compensate for negative feelings such as inadequacy and loneliness, or acting on the basis of underlying psychopathology.[23] Evaluations to identify these psychological states must be thorough, as some would preclude donation.

As part of the consent process, potential donors should be informed explicitly that they can withdraw from donation at any time before undergoing the operation.[24] If a potential donor decides to decline or withdraw, the health care team should be available to help protect the donor from pressures to reveal the reasons. Some transplant centers provide potential donors with a medical excuse to shield them from undue family pressures and from the need to justify the decision to decline or to withdraw. This approach risks compromising trust in the physicians and in the profession. Instead, it is ethically acceptable for the health care team to report simply that the individual was unsuitable for donation.

Potential Donors without Full Decision-Making Capacity

Unemancipated minors and legally incompetent adults lack the capacity to decide whether or not to donate an organ. Whether their legal guardians can consent to living donation on their behalf is questionable. On one hand, total prohibition maximizes the protection of such individuals. On the other hand, organ donation might be ethically justifiable in rare situations.[25] For example, if the potential donor has a strong emotional attachment to the potential recipient and if there is good reason to believe that the potential donor would suffer greater psychological harm from the death of the potential recipient than medical harm from the removal of an organ for transplantation, it may be appropriate to proceed. Under no circumstance should individuals without full decision-making capacity be allowed to serve as donors for strangers.

Financial issues

Some financial issues are ethically relevant to living donation. Living donors may suffer considerable financial losses if they bear the expenses of travel, lodging, meals, lost wages, and the medical care associated with donation. In order to protect the donor from undue burden, reimbursement for these costs should be permitted within reasonable limits – perhaps based on a flat rate considering that wages, for example, can vary considerably. In addition, a donor may be at risk for uninsurability or increased cost of insurance if loss of a vital organ is considered to be a preexisting condition.[26, 27]

Whether financial incentives for living donors should be allowed is a distinct matter that is the source of some controversy. In support of their position, advocates of such incentives cite saving lives by increasing rates of organ donation and respect for personal autonomy, while opponents cite fear of exploiting the poor and aversion to treating human body parts as commodities. As in the case of motivations for organ donation from deceased persons (Policy E-2.151, AMA Policy Database),[28] pilot studies could establish the facts of donation numbers, exploitation, and commodification. At present, however, such incentives are illegal and are considered to be unethical (E-2.15).[29]

ALLOCATION OF ORGANS FROM LIVING DONORS

Unlike the process of deceased donation, no uniform process currently governs how transplant centers should allocate organs donated by Good Samaritan donors. As a result, there are variations between centers regarding how organs from living donors are distributed, some of which are ethically questionable. Some transplant centers systematically give preferred access to patients on the center's list. However, according to some commentators, these organs constitute a unique national resource,[30] and recipients should be selected according to the same allocation principles used for distribution of deceased donor organs[20] and good medical judgment.[19, 31] This relieves individual physicians of the need to make allocation decisions, a function that may conflict with their primary role as patient advocates.[31]

Other allocation schemes arise at institutions that permit paired exchanges (also known as organ swaps), which are intended to increase the overall supply of transplantable organs. One model is direct paired exchanges, in which 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.[32, 33, 34, 35] Such organ exchanges have been carried out with more than two donor-recipient pairs. Another model is a list-paired exchange: a patient waiting for a transplant receives priority status for a deceased donor organ in exchange for someone donating on his or her behalf into the general organ pool.[34,35] Some of these variations may place people with certain blood types at a disadvantage, so further study and ethical examination is warranted.[36] Ultimately, only variations that produce a net gain of organs in the organ pool and do not unreasonably disadvantage others on the waiting list are ethically acceptable.

THE NEED TO GATHER INFORMATION SYSTEMATICALLY AND CENTRALLY

A registry of living donors is maintained by the United Network for Organ Sharing (UNOS), which collects demographic information and outcome data on all such donors up to a year after donation. In order to better understand living organ donation and to refine relevant standards, guidelines, and best practices, a more complete database with longer follow-up is needed.[9, 15, 20] This would allow extensive analysis of relevant risks and benefits associated with living organ donation, and provide a solid basis for developing evidence-based standards for living donation.[37] Donor motivation and adequacy of the informed consent process also deserve further study.

Lack of uniformity and of systematic information illustrates the need for more oversight of the field. As transplantation of organs from living donors becomes more common and as transplant centers across the country gather more information in this domain, increased consistency in basic policies may result.[38]

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder 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, which 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 and with the informed consent of their legal guardians, they may be considered for donation to recipients with whom they are emotionally connected. Under no circumstance should individuals without full decision-making capacity be allowed to serve as living donors to strangers.

(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.

(c) Living donation should never be considered if 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 appropriate for donors to designate a recipient, whether a close relative or a known, unrelated recipient.

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 that have received recent attention involve potential donors who respond to public solicitation for organs or who wish to participate in a paired

donation (also known as organ swaps)—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.

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

(b) 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) 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. (New HOD/CEJA Policy)

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

ACKNOWLEDGMENTS

The Council gratefully acknowledges the following individuals and organizations for their contributions to this Report:

The American Society of Transplantation (comments submitted by Jay A Fishman, MD, President, and Jeffrey S. Crippin, MD, Secretary-Treasurer, Public Policy Committee Chair); The American Society of Transplant Surgeons Ethics Committee (comments submitted by Douglas W. Hanto, MD, PhD, Chair); Peter Angelos, MD, PhD, Associate Professor of Surgery, Northwestern University; The Northwestern/ Northwestern Memorial Hospital Organ Transplantation Ethics Group; David J. Conti, MD, Professor of Surgery, Director of Transplantation, Head/Division of General Surgery, Albany Medical College, Chair, New York State Transplant Council's Committee on Quality Improvement in Living Liver Donation; Francis L. Delmonico, MD, Professor of Surgery, Harvard Medical School, Visiting Surgeon, Transplantation Unit, Massachusetts General Hospital, Medical Director, New England Organ Bank; Catharine Kim, Student, Harvard University; Timothy Murphy, PhD; Professor of Philosophy in the Biomedical Sciences, University of Illinois College of Medicine; Lainie Friedman Ross, MD, PhD, Associate Professor, Department of Pediatrics, Assistant Director, MacLean Center for Clinical Medical Ethics, University of Chicago; Mary Simmerling, MA, University of Chicago, Social Sciences Division; University of Illinois at Chicago, Department of Philosophy.

REFERENCES

[1] Taub S. et al. for the Council on Ethical and Judicial Affairs of the American Medical Association, "Cadaveric Organ Donation: Encouraging the Study of Motivation," *Transplantation* 2003; 76(4): 748-751.
[2] Council on Ethical and Judicial Affairs Report 3 – I-94, "Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs," American Medical Association, House of Delegates Meeting, December 2004, Honolulu, Hawaii.
[3] Council on Ethical and Judicial Affairs Report 4 – I-94, "Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol," American Medical Association, House of Delegates Meeting, December 2004, Honolulu, Hawaii.
[4] Committee on Non-Heart-Beating Transplantation II, Institute of Medicine, "Non Heart-Beating Organ Transplantation: Practice and Protocols," (Washington, DC; National Academy Press, 2000).
[5] Caplan AL, "Organ and Tissue Transplants, III. Ethical and Legal Issues" in: Reich WT, Ed., *Encyclopedia of Bioethics*, Revised Edition, (New York, NY: Simon & Schuster MacMillan, 1995) pages 1888-1894.
[6] National Data Report, "Donors Recovered in the U.S. by Donor Type." The Organ Procurement and Transplantation Network. Available at http://www.optn.org/latestData/rptData.asp. Last accessed March 21, 2005.
[7] "American Society of Transplant Surgeons' Position Paper on Adult-to-Adult Living Donor Liver Transplantation." American Society of Transplant Surgeons. Available at http://www.asts.org/positionpaper1.cfm. Last accessed October 25, 2004.
[8] Matas A, Leichtman A, Bartlett S, Delmonico F, "Morbidity and mortality after living kidney donation, 1999-2001: Survey of United States transplant centers," *Am J Transplant* 2003; 3(7): 830-4.
[9] Surman O, "The ethics of partial-liver donation," *NEJM* 2002; 346(14): 1038.
[10] Brown BS et al., "A survey of liver transplantation from living adult donors in the United States," *NEJM* 2003; 348(9): 818-825.
[11] American Medical Association, Principles of Medical Ethics in: Council on Ethical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions with Annotation* (Chicago, IL: AMA Press; 2004).

[12] Potts M, "Role of living liver donation: Surgery violates principles of beneficence and autonomy," *BMJ* 2003; 327: 1287.
[13] Simmerling M et al., "Do gifts create moral obligations for recipients?" *American Journal of Bioethics* 2004; 4(4): 20-22.
[14] The Organ Procurement and Transplantation Network, "Donation & Transplantation – About donation: Living donation." Available at http://www.optn.org/about/donation/livingDonation.asp. Last accessed: October 25, 2004.
[15] Trotter JF et al., "Medical progress: Adult-to-adult transplantation of the right hepatic lobe from a living donor," *NEJM* 2002; 346(14): 1074-1082.
[16] Wright L, Daar AS, "Ethical aspects of living donor kidney transplantation and recipient adherence to treatment," *Prog. Transplant.* 2003; 13(2): 105-9.
[17] Simmons RG, Marine SK, Simmons RL, "Living related donors: Costs and gains," in *Gift of Life: The Effect of Organ Transplantation on Individual, Family, and Societal Dynamics* (New Brunswick, Canada: Transaction Books; 1987).
[18] Dixon DJ, Abbey SE, "Religious altruism and organ donation," *Psychosomatics* 2000; 41:407-411.
[19] "Opinion E-2.16, Organ Transplantation Guidelines," in: Council on Ethical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions with Annotation* (Chicago, IL: AMA Press; 2004). See also: McQuarrie B, Gordon D, "Separate, dedicated care teams for living organ donors," *Prog. Transplant* 2003; 13(2): 90-3.
[20] The Authors for the Living organ donor Consensus Group, "Consensus Statement on the Living organ donor," *JAMA*. 2000;284: 2919-2926.
[21] U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation, Recommendations, Nov 2002. Available at www.organdonor.gov/acotrecs.html. Last Accessed October 25, 2004.
[22] Gohh RY, Morrissey P, Madras P, Monaco A. Controversies in organ donation: the altruistic living donor. Nephrology Dialysis Transplantation. 2001;16: 619-621.
[23] Khajedhehi P, "Living non-related versus related renal transplantation – its relationship to the social status, age and gender of recipients and donors," *Nephrol. Dial. Transplant.* 1999; 14(11): 2621-4.
[24] New York State Committee on Quality Improvement in Living Liver Donation, "A Report to: New York State Transplant Council and New York State Department of Health," December 2002.
[25] Strunk v. Strunk, 445 SW.2d 145 (Ky. 1969).
[26] Jacobs C, Thomas C, "Financial considerations in living organ donation," *Prog Transplant.* 2003; 13(2): 130-6.
[27] Joint Commission on Accreditation of Healthcare Organizations, white paper on "Health care at the Crossroads: Strategies for narrowing the organ donation gap and protecting patients," June 2004. Available at http://www.jcaho.org/about+us/public+policy+initiatives/organ+donation+white+paper.pdf. Last accessed on March 25, 2005.
[28] "Opinion E-2.151, Cadaveric Organ Donation: Encouraging the Study of Motivation," in: Council on IEthical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions with Annotation* (Chicago, IL: AMA Press; 2004).
[29] "Opinion E-2.15, Financial Incentives to Living Donors," in: Council on Ethical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions with Annotation* (Chicago, IL: AMA Press; 2004).
[30] OPTN/UNOS Ethics Committee, informational white paper on "Allocation of Organs from Non-Directed Living Donors," June 2002. Available at http://www.unos.org/resources/bioethics.asp?index=9. Last accessed on October 25, 2004.
[31] "Opinion E-2.03, Allocation of Medical Resources" in: Council on Ethical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions with Annotation* (Chicago, IL: AMA Press; 2004).

[32] Menikoff J, "Organ swapping," *Hastings Cent Rep*. 1999 Nov-Dec; 29(6):28-33.
[33] Delmonico FL, "Exchanging kidneys – Advances in living-donor transplantation," *NEJM* 2004; 350 (18): 1812-1814.
[34] Delmonico FL et al., "Donor kidney exchanges," *American Journal of Transplantation* 2004; 4: 1628-1634.
[35] Ross LF, Zenios S, "Practical and ethical challenges to paired exchanged programs," *American Journal of Transplantation* 2004; 4: 1553-1554.
[36] Ross LF, Zenios S, "Restricting living-donor-cadaver-donor exchanges to ensure that standards blood type O wait-list candidates benefit," *Transplantation* 2004; 78(5): 641-6.
[37] American Society of Transplantation. "Living Organ Donation." Available at http://www.a-s-t.org/public_policy/pdf/LivingOrganDonationFinal.pdf. Last Accessed October 25, 2004.
[38] Cronin D et al., "Transplantation of liver grafts from living donors into adults: Too much, too soon," *NEJM* 2001; 334: 1633-1637.