

Virtual Mentor

American Medical Association Journal of Ethics
March 2012, Volume 14, Number 3: 204-214.

THE CODE SAYS

AMA Code of Medical Ethics' Opinions on Organ Transplantation

Opinion 2.16 - Organ Transplantation Guidelines

The following statement is offered for guidance of physicians as they seek to maintain the highest level of ethical conduct in the transplanting of human organs.

- (1) In all professional relationships between a physician and a patient, the physician's primary concern must be the health of the patient. The physician owes the patient primary allegiance. This concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected. A prospective organ transplant offers no justification for a relaxation of the usual standard of medical care for the potential donor.
- (2) When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician, who should rely on currently accepted and available scientific tests.
- (3) Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should ensure that consent to the procedure is fully informed and voluntary, in accordance with the Council's guidelines on informed consent. The physician's interest in advancing scientific knowledge must always be secondary to his or her concern for the patient.
- (4) Transplant procedures of body organs should be undertaken
 - (a) only by physicians who possess special medical knowledge and technical competence developed through special training, study, and laboratory experience and practice, and
 - (b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.
- (5) Recipients of organs for transplantation should be determined in accordance with the Council's guidelines on the allocation of limited medical resources.

(6) Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.

(7) Patients should not be placed on the waiting lists of multiple local transplant centers, but rather on a single waiting list for each type of organ.

Issued prior to April 1977; updated June 1994 based on the report adopted June 1993.

Opinion 2.15 - Transplantation of Organs from Living Donors

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.

(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.

(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 "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).

(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 for 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.

Issued November 2005 based on the report "[Transplantation of Organs from Living Donors](#)," adopted June 2005; updated June 2011 based on the report "[Nonsimultaneous, Altruistic Organ Donation](#)," adopted November 2010.

Opinion 2.157 - Organ Donation After Cardiac Death

Given the increasing need for donor organs, protocols for donation after cardiac death (DCD) have been developed. Controlled DCD allows patients who have agreed to be taken off of life support or their surrogate decision makers the opportunity to donate the patients' organs once death has been declared. In these cases, life support is discontinued in or near the operating room so that organs can be removed promptly after death is pronounced. DCD also may be considered from patients who suffer unexpected cardiac death (uncontrolled DCD). It requires that they be cannulated and perfused with cold preservation fluid (in situ preservation) within minutes after death to maintain the viability of organs. Both of these methods may be ethically permissible, with attention to certain safeguards.

(1) Hospital policies should specify important details of the DCD process, such as the required time delay before death can be pronounced after cardiac arrest.

(2) In all instances, it is critical to avoid perceived or actual conflicts of interest in the health care team with respect to caring for the patient versus facilitating organ donation. The health care professionals providing care at the end of life should be distinct from those participating on the transplant team. No member of the transplant team may have any role in the decision to withdraw life support or in the process leading to pronouncement of death.

(3) Clear clinical criteria should be in place to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under these protocols.

(4) Palliative care for DCD candidates should continue after removal of life support until death is declared.

(5) In controlled DCD, the decision to withdraw life support should be made by the patient or the patient's surrogate decision maker before any mention of organ

donation (unless the patient or surrogate spontaneously broaches the subject). This is meant to ensure that withdrawal of life support is not influenced by the prospect of organ donation.

The informed consent for controlled DCD should include specific discussion of pre-mortem interventions aimed at organ preservation, to improve the opportunity for successful transplantation, rather than to benefit the patient. Interventions that are likely to hasten death must not be used.

(6) In cases of uncontrolled DCD, prior consent of the decedent or consent of the decedent's surrogate decision maker is ethically required. Perfusion without consent to organ donation violates requirements of informed consent for medical procedures and is not permissible.

Issued June 1996 based on the reports "[Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol](#)" and "[Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs](#)," adopted December 1994; updated November 2005 based on the report "[Organ Procurement Following Cardiac Death, Amendment](#)," adopted June 2005.

Opinion 2.151 - Cadaveric Organ Donation: Encouraging the Study of Motivation

Physicians have an obligation to hold their patients' interests paramount and to support access to medical care. To discharge these obligations, physicians should participate in efforts to increase organ donation including promotion of voluntary donation. Beyond educational programs, however, physicians should support innovative approaches to encourage organ donation. Such efforts may include encouragement of and, if appropriate, participation in the conduct of ethically designed research studies of financial incentives.

Because the potential benefits and harms of financial incentives for cadaveric organ donation are unknown, physicians have an obligation to study financial incentives. Whether or not they are ethical depends upon the balance of benefits and harms that result from them. Physicians should encourage and support pilot studies, limited to relatively small populations, that investigate the effects of financial incentives for cadaveric organ donation for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Pilot studies of the effects of financial incentives for cadaveric organ donation should be implemented only after certain considerations have been met, including:

(1) Consultation and advice is sought from the population within which the pilot study is to take place.

(2) Objectives and strategies as well as sound scientific design, measurable outcomes and set time frames are clearly defined in written protocols that are publicly available and approved by appropriate oversight bodies, such as Institutional Review Boards.

(3) Incentives are of moderate value and at the lowest level that can be reasonably expected to increase organ donation.

(4) Payment for an organ from a living donor is not a part of any study.

(5) Financial incentives apply to cadaveric donation only, and must not lead to the purchase of donated organs; the distribution of organs for transplantation should continue to be governed by United Network for Organ Sharing (UNOS), based on ethically appropriate criteria related to medical need.

Issued December 2002 based on the report “[Cadaveric Organ Donation: Encouraging the Study of Motivation](#),” adopted June 2002.

Opinion 2.152 - Solicitation of the Public for Directed Donation of Organs for Transplantation

The obligation of physicians to hold their patients’ interests paramount and to support access to medical care requires that maximizing the number of medically suitable solid organs for transplantation by ethical means should remain a priority of the medical profession. Donation of organs to specified recipients has been permitted since the beginning of organ transplantation. Although directed donation is permitted under current national policy, solicitation of organs from potential donors who have no preexisting relationship with the recipient is controversial. The following guidelines regarding solicitation of organ donors are offered:

(1) Solicitation of the public for organ donation has unknown effects on the organ supply and on transplant waiting lists. Policies should be based, as far as possible, on facts rather than assumptions, so physicians should support study of the current system and development of policy based on the results of such studies.

(2) Directed donation policies that produce a net gain of organs in the organ pool and do not unreasonably disadvantage others on the waiting list are ethically acceptable, as long as donors receive no payment beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.

(3) The health care team must fully evaluate the medical and psychosocial suitability of all potential donors, regardless of the nature of the relationship between the potential donor and transplant candidate. A physician should resist pressure to participate in a transplant that he or she believes to be ethically improper and should not pressure others to participate if they refuse on ethical or moral grounds.

Issued November 2006 based on the report “[Solicitation of the Public for Directed Donation of Organs for Transplantation](#),” adopted June 2006.

Opinion 2.155 - Presumed Consent and Mandated Choice for Organs from Deceased Donors

The supply of organs for transplantation to treat end-stage organ failure is inadequate to meet the clinical need. Therefore, physicians should support the development of policies that will increase the number of organ donors. Two prominent proposals aimed at increasing organ donation would change the approach to consent for deceased donation: mandated choice and presumed consent.

Under a presumed consent model, deceased individuals are presumed to be organ donors unless they indicate their refusal to donate. Such donations would be ethically appropriate only if it could be determined that individuals were aware of the presumption and if effective and easily accessible mechanisms for documenting and honoring refusals to donate were established. Moreover, physicians could proceed with organ procurement only after verifying that there was no documented prior refusal by the decedent and that the family was unaware of any objection to donation by the decedent.

Under a mandated choice model, individuals are required to express their preferences regarding organ donation at the time of performing a state-regulated task. This contrasts with the widespread model of voluntary organ donation under which individuals are afforded an opportunity to indicate their preferences. A mandated choice model would be ethically appropriate only if an individual's choice were made in accordance with the principles of informed consent, which would require a meaningful exchange of information. Physicians could proceed with organ procurement only after verifying that an individual's consent to donation was documented. It is not known whether implementation of ethically appropriate models of presumed consent or mandated choice for deceased donation would positively or negatively affect the number of organs transplanted. Therefore, physicians should encourage and support properly designed pilot studies, in relatively small populations, that investigate the effects of these policies. Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for deceased donation should be widely implemented.

In all models, education of individuals to facilitate informed consent is requisite. Issued November 2005 based on the report "[Presumed Consent for Organ Donation](#)," adopted June 2005.

Opinion 2.161 - Medical Applications of Fetal Tissue Transplantation

The principal ethical concern in the use of human fetal tissue for transplantation is the degree to which the decision to have an abortion might be influenced by the decision to donate the fetal tissue. In the application of fetal tissue transplantation the following safeguards should apply:

- (1) The Council on Ethical and Judicial Affairs' guidelines on clinical investigation and organ transplantation are followed, as they pertain to the recipient of the fetal tissue transplant;
- (2) a final decision regarding abortion is made before initiating a discussion of the transplantation use of fetal tissue;
- (3) decisions regarding the technique used to induce abortion, as well as the timing of the abortion in relation to the gestational age of the fetus, are based on concern for the safety of the pregnant woman;
- (4) fetal tissue is not provided in exchange for financial remuneration above that which is necessary to cover reasonable expenses;
- (5) the recipient of the tissue is not designated by the donor;
- (6) health care personnel involved in the termination of a particular pregnancy do not participate in or receive any benefit from the transplantation of tissue from the abortus of the same pregnancy; and
- (7) informed consent on behalf of both the donor and the recipient is obtained in accordance with applicable law.

Issued March 1992 based on the report "[Medical Applications of Fetal Tissue Transplantation](#)," adopted June 1989; updated June 1996.

Opinion 2.162 - Anencephalic Neonates as Organ Donors

Anencephaly is a congenital absence of major portion of the brain, skull, and scalp. Anencephalic neonates are thought to be unique from other brain-damaged beings because of a lack of past consciousness with no potential for future consciousness.

Physicians may provide anencephalic neonates with ventilator assistance and other medical therapies that are necessary to sustain organ perfusion and viability until such time as a determination of death can be made in accordance with accepted medical standards, relevant law, and regional organ procurement organization policy. Retrieval and transplantation of the organs of anencephalic infants are ethically permissible only after such determination of death is made, and only in accordance with the Council's guidelines for transplantation.

Issued March 1992 based on the report "[Anencephalic Infants as Organ Donors](#)," adopted December 1988; updated June 1994; updated December 1994 based on the report "The Use of Anencephalic Neonates as Organ Donors," adopted December 1994; and updated June 1996 based on the report "Anencephalic Infants as Organ Donors - Reconsideration," adopted December 1995.

Opinion 2.145 - Pre-embryo Splitting

The technique of splitting in vitro fertilized pre-embryos may result in multiple genetically identical siblings.

The procedure of pre-embryo splitting should be available so long as both gamete providers agree. This procedure may greatly increase the chances of conception for an infertile couple or for a couple whose future reproductive capacity will likely be diminished. Pre-embryo splitting also can reduce the number of invasive procedures necessary for egg retrieval and the necessity for hormonal stimulants to generate multiple eggs. The use and disposition of any pre-embryos that are frozen for future use should be consistent with the Council's opinion on frozen pre-embryos.

The use of frozen pre-embryo identical siblings many years after one child has been born raises new ethical issues. Couples might wait until they can discover the mental and physical characteristics of a child before transferring a genetically identical sibling for implantation, they might sell their frozen pre-embryos based upon the outcome of a genetically identical child, or they might decide to transplant a genetically identical sibling based on the need to harvest the child's tissue.

The Council does not find that these considerations are sufficient to prohibit pre-embryo splitting for the following reasons:

- (1) It would take many years to determine the outcome of a child and most families want to complete their childbearing within a shorter time.
- (2) The sale of pre-embryos can and should be prohibited.
- (3) The small number of couples who might bear identical siblings solely for purposes of harvesting their tissue does not outweigh the benefits which might be derived from pre-embryo splitting. Additionally, it is not evident that a sibling would have negative psychological or emotional consequences from having acted as an organ or tissue donor. Indeed, the child may derive psychological benefits from having saved the life of a sibling.

To the extent possible, discussion of these issues should be had with gamete providers prior to pre-embryo splitting and freezing so as to inform the prospective parents of possible future ethical dilemmas.

Issued [June 1994](#).

Opinion 2.169 - The Ethical Implications of Xenotransplantation

Xenotransplantation includes any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. Although xenotransplantation offers a potential source of tissue and organs for medical procedures, research in this area may uncover physical and

psychological conditions that require medical attention. As such, physicians need to be involved in developing and implementing guidelines for continued research. Therefore, the following guidelines are offered for the medical and scientific communities:

- (1) Physicians should encourage education and public discussion of xenotransplantation because of the potential unique risks such procedures pose to individual patients and the public.
- (2) The medical and scientific communities should support oversight for the development of clinical trial protocols and of ongoing xenotransplantation research.
- (3) Given the uncertain risk xenotransplantation poses to society, participants in early clinical trials may have to agree to (a) postoperative measures such as life-long surveillance, disclosure of sexual contacts, autopsy; and (b) a waiver of the traditional right to withdraw from a clinical trial until the risk of late xenozoonoses is reasonably known not to exist. These requirements may continue even if the transplanted tissue is rejected or removed. The informed consent process should include a discussion of the above issues as well as potential risks to third parties and psychological concerns associated with receiving an organ or tissue graft from an animal. Careful attention must be paid to both the content of the consent disclosure and the manner in which consent is obtained.
- (4) It would be ethical to include children and incompetent adults in xenotransplantation research protocols only when the patients are terminally ill and alternative treatments are not available.
- (5) Allocation protocols must be fair and in accordance with Council Opinion 2.03, "Allocation of Limited Medical Resources," which recommends that decisions regarding the allocation of medical resources among patients be based only on ethically appropriate criteria relating to medical need. These criteria include, but are not limited to, the likelihood of benefit, the urgency of need, the change in quality of life, the duration of benefit, and, in some cases, the amount of resources required for treatment.
- (6) Sponsors of xenotransplantation research should assure that adequate funding exists for life-long surveillance and treatment of complications arising from xenotransplantation procedures on research subjects.
- (7) At a minimum, all on-going research should adhere to the Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation, FDA guidelines relating to xenotransplantation, Council Opinion 2.07 "Clinical Research," and any additional precautionary measures believed to minimize potential risks to the public or to patients. It is inappropriate to participate in xenograft procedures outside federal guidelines.

(8) All xenotransplantation research should continue to promote high standards of care and humane treatment of all animals used in research and to apply these standards to the care and treatment of animals used as sources of transplantation material.

Issued June 2001 based on the report “[The Ethical Implications of Xenotransplantation](#),” adopted December 2000.

Related in VM

[Severe Brain Injury and Organ Solicitation: A Call for Temperance](#), March 2012

[Should a Nonadherent Adolescent Receive a Second Kidney?](#) March 2012

[Contemporary Debates Over the Acceptability of Kidneys for Donation](#), March 2012

[Rationing Livers: The Persistence of Geographic Inequity in Organ Allocation](#),
March 2012

[Liver Transplantation: The Illusion of Choice](#), March 2012

Copyright 2012 American Medical Association. All rights reserved.