CHAPTER 6: OPINIONS ON ORGAN PROCUREMENT & TRANSPLANTATION

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

6.1 Organ Procurement

6.1.1 Transplantation of Organs from Living Donors
6.1.2 Organ Donation after Cardiac Death
6.1.3 Studying Financial Incentives for Cadaveric Organ Donation
6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors
6.1.5 Umbilical Cord Blood Banking
6.1.6 Anencephalic Newborns as Organ Donors

6.2 Organ Transplantation

6.2.1 Guidelines for Organ Transplantation
6.2.2 Directed Donation of Organs for Transplantation

6.3 Special Issues in Organ Procurement & Transplantation

6.3.1 Xenotransplantation

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

6.1.2 Organ Donation after Cardiac Death

Increasing the supply of organs available for transplant serves the interests of patients and the public and is in keeping with physicians' ethical obligation to contribute to the health of the public and to support access to medical care. Physicians should support innovative approaches to increasing the supply of organs for transplantation, but must balance this obligation with their duty to protect the interests of their individual patients.

Organ donation after cardiac death is one approach being undertaken to make greater numbers of transplantable organs available. In what is known as "controlled" donation after cardiac death, a patient who has decided to forgo life-sustaining treatment (or the patient's authorized surrogate when the patient lacks decision-making capacity) may be offered the opportunity to discontinue life support under conditions that would permit the patient to become an organ donor by allowing organs to be removed promptly after death is pronounced. Organ retrieval under this protocol thus differs from usual procedures for cadaveric donation when the patient has died as a result of catastrophic illness or injury.

Donation after cardiac death raises a number of special ethical concerns, including how and when death is declared, potential conflicts of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation, and the use of a surrogate decision maker.

In light of these concerns, physicians who participate in retrieving organs under a protocol of donation after cardiac death should observe the following safeguards:

(a) Promote the development of and adhere to clinical criteria for identifying prospective donors whose organs are reasonably likely to be suitable for transplantation.

(b) Promote the development of and adhere to clear and specific institutional policies governing donation after cardiac death.

(c) Avoid actual or perceived conflicts of interest by:

  (i) ensuring that the health care professionals who provide care at the end of life are distinct from those who will participate in retrieving organs for transplant;

(ii) ensuring that no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.

(d) Ensure that the decision to withdraw life-sustaining treatment is made prior to and independent of any offer of opportunity to donate organs (unless organ donation is spontaneously broached by the patient or surrogate).

(e) Obtain informed consent for organ donation from the patient (or surrogate), including consent specifically to the use of interventions intended not to benefit the patient but to preserve organs in order to improve the opportunity for successful transplantation.

(f) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing the decision to withdraw a life-sustaining intervention.

AMA Principles of Medical Ethics: I,III,V

6.1.3 Studying Financial Incentives for Cadaveric Organ Donation

Physicians' ethical obligations to contribute to the health of the public and to support access to medical care extend to participating in efforts to increase the supply of organs for transplantation. However, offering financial incentives for donation raises ethical concerns about potential coercion, the voluntariness of decisions to donate, and possible adverse consequences, including reducing the rate of altruistic organ donation and unduly encouraging perception of the human body as a source of profit.

These concerns merit further study to determine whether, overall, the benefits of financial incentives for organ donation outweigh their potential harms. It would be appropriate to carry out pilot studies among limited populations to investigate the effects of such financial incentives for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Physicians who develop or participate in pilot studies of financial incentives to increase donation of cadaveric organs should ensure that the study:

(a) Is strictly limited to circumstances of voluntary cadaveric donation with an explicit prohibition of the selling of organs.

(b) Is scientifically well designed and clearly defines measurable outcomes and time frames in a written protocol.

(c) Has been developed in consultation with the population among whom it is to be carried out.

(d) Has been reviewed and approved by an appropriate oversight body, such as an institutional review board, and is carried out in keeping with guidelines for ethical research.

(e) Offers incentives of only modest value and at the lowest level that can reasonably be expected to increase organ donation.

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

6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors

Organ transplantation offers hope for patients suffering end-stage organ failure. However, the supply of organs for transplantation is inadequate to meet the clinical need. Proposals to increase donation have included studying possible financial incentives for donation and changing the approach to consent for cadaveric donation through "presumed consent" and "mandated choice."

Both presumed consent and mandated choice models contrast with the prevailing traditional model of voluntary consent to donation, in which prospective donors indicate their preferences, but the models raise distinct ethical concerns. Under presumed consent, deceased individuals are presumed to be organ donors unless they have indicated their refusal to donate. Donations under presumed consent would be ethically appropriate only if it could be determined that individuals were aware of the presumption that they were willing to donate organs and if effective and easily accessible mechanisms for documenting and honoring refusals to donate had been established. Physicians could proceed with organ procurement based on presumed consent only after verifying that there was no documented prior refusal and that the family was not aware of any objection to donation by the deceased.

Under mandated choice, individuals are required to express their preferences regarding donation at the time they execute a state-regulated task. Donations under mandated choice would be ethically appropriate only if an individual's choice was made on the basis of a meaningful exchange of information about organ donation in keeping with the principles of informed consent. Physicians could proceed with organ procurement based on mandated choice only after verifying that the individual's consent to donate was documented.

These models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh ethical concerns.

Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:

(a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.

(b) Has been developed in consultation with the population among whom it is to be carried out.

(c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.

Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

AMA Principles of Medical Ethics: I,III,V

6.1.5 Umbilical Cord Blood Banking

Transplants of umbilical cord blood have been recommended or performed to treat a variety of conditions. Cord blood is also a potential source of stem and progenitor cells with possible therapeutic applications. Nonetheless, collection and storage of cord blood raise ethical concerns with regard to patient safety,

autonomy, and potential for conflict of interest. In addition, storage of umbilical cord blood in private as opposed to public banks can raise concerns about access to cord blood for transplantation.

Physicians who provide obstetrical care should be prepared to inform pregnant women of the various options regarding cord blood donation or storage and the potential uses of donated samples.

Physicians who participate in collecting umbilical cord blood for storage should:

(a) Ensure that collection procedures do not interfere with standard delivery practices or the safety of a newborn or the mother.

(b) Obtain informed consent for the collection of umbilical cord blood stem cells before the onset of labor whenever feasible. Physicians should disclose their ties to cord blood banks, public or private, as part of the informed consent process.

(c) Decline financial or other inducements for providing samples to cord blood banks.

(d) Encourage women who wish to donate umbilical cord blood to donate to a public bank if one is available when there is low risk of predisposition to a condition for which umbilical cord blood cells are therapeutically indicated:

    (i) in view of the cost of private banking and limited likelihood of use;

    (ii) to help increase availability of stem cells for transplantation.

(e) Discuss the option of private banking of umbilical cord blood when there is a family predisposition to a condition for which umbilical cord stem cells are therapeutically indicated.

(f) Continue to monitor ongoing research into the safety and effectiveness of various methods of cord blood collection and use.

AMA Principles of Medical Ethics: I,V

6.1.6 Anencephalic Newborns as Organ Donors

Permitting parents of an anencephalic newborn to donate their child's organs has been proposed as a way to increase the organ supply for pediatric transplantation.

However, organ donation in these circumstances also raises concerns, particularly about the accuracy of diagnosis and the potential implications for other vulnerable individuals who lack decision-making capacity and are not able to participate in decisions to donate their organs, although anencephalic newborns are thought to be unique among other brain- damaged beings because they lack past consciousness and have no potential for future consciousness.

In the context of prospective organ donation from an anencephalic newborn, physicians may ethically:

(a) Provide 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.

(b) Retrieve and transplant the organs of an anencephalic newborn only after such determination of death, and in accordance with ethics guidance for transplantation and for medical decisions for minors.

AMA Principles of Medical Ethics: I,III,V

6.2.1 Guidelines for Organ Transplantation from Deceased Donors

Transplantation offers hope to patients with organ failure. As in all patient-physician relationships, the physician's primary concern must be the well-being of the patient. However, organ transplantation is also unique in that it involves two patients, donor and recipient, both of whose interests must be protected. Concern for the patient should always take precedence over advancing scientific knowledge.

Physicians who participate in transplantation of organs from deceased donors should:

(a) Avoid actual or perceived conflicts of interest by ensuring that:

(i) to the greatest extent possible that the health care professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor. Physicians should encourage health care institutions to distinguish the roles of health care professionals who solicit or coordinate organ transplantation from those who provide care at the time of death;

(ii) no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.

(b) Ensure that death is determined by a physician not associated with the transplant team and in accordance with accepted clinical and ethical standards.

(c) Ensure that transplant procedures are undertaken only by physicians who have the requisite medical knowledge and expertise and are carried out in adequately equipped medical facilities.

(d) Ensure that the prospective recipient (or the recipient's authorized surrogate if the individual lacks decision-making capacity) is fully informed about the procedure and has given voluntary consent in keeping with ethics guidance.

(e) Except in situations of directed donation, ensure that organs for transplantation are allocated to recipients on the basis of ethically sound criteria, including but not limited to likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in certain cases, amount of resources required for successful treatment.

(f) Ensure that organs for transplantation are treated as a national, rather than a local or regional, resource.

(g) Refrain from placing transplant candidates on the waiting lists of multiple local transplant centers, but rather place candidates on a single waiting list for each type of organ.

AMA Principles of Medical Ethics: I,III,V

6.2.2 Directed Donation of Organs for Transplantation

Efforts to increase the supply of organs available for transplant can serve the interests of individual patients and the public and are in keeping with physicians' obligations to promote the welfare of their patients and to support access to care. Although public solicitations for directed donation—that is, for donation to a specific patient—may benefit individual patients, such solicitations have the potential to adversely affect the equitable distribution of organs among patients in need, the efficacy of the transplant system, and trust in the overall system.

Donation of needed organs to specified recipients has long been permitted in organ transplantation. However, solicitation of organs from potential donors who have no pre-existing relationship with the intended recipient remains controversial. Directed donation policies that produce a net gain of organs for transplantation and do not unreasonably disadvantage other transplant candidates are ethically acceptable.

Physicians who participate in soliciting directed donation of organs for transplantation on behalf of their patients should:

(a) Support ongoing collection of empirical data to monitor the effects of solicitation of directed donations on the availability of organs for transplantation.

(b) Support the development of evidence-based policies for solicitation of directed donation.

(c) Ensure that solicitations do not include potentially coercive inducements. Donors should receive no payment beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.

(d) Ensure that prospective donors are fully evaluated for medical and psychosocial suitability by health care professionals who are not part of the transplant team, regardless of any relationship, or lack of relationship, between prospective donor and transplant candidate.

(e) Refuse to participate in any transplant that he or she believes to be ethically improper and respect the decisions of other health care professionals should they choose not to participate on ethical or moral grounds.

AMA Principles of Medical Ethics: VII,VIII,IX

6.3.1 Xenotransplantation

Physicians have an obligation to participate in efforts to increase the supply of organs available for transplantation. In fulfilling that obligation, they must also be mindful of their obligations to protect the interests of patients and the welfare of the public. Xenotransplantation, i.e., using organs or tissues from nonhuman animal species for transplantation into human patients, is a possible novel means of addressing the shortage of transplantable organs that can pose distinctive ethical challenges with respect to patient safety and public health.

Some forms of transplantation, implantation, or infusion into a human recipient of organs or tissues from a nonhuman animal source have a significant history in clinical practice—for example the use of porcine heart valves. Other proposed procedures are more controversial and are restricted to research protocols

Physicians who choose to participate in clinical research that involves transplantation of organs or tissues from nonhuman sources should:

(a) Encourage education and public discussion of xenotransplantation in light of the unique risks such procedures pose to individual patients and the public.

(b) Ensure that research in which they participate is well designed and adheres to institutional review board requirements, applicable national guidelines, and ethical standards for research with human participants.

(c) Ensure that research in which they participate is adequately funded to assure lifelong surveillance of xenotransplant recipients and treatment of medical complications related to transplantation.

(d) Ensure that recruitment is restricted to patients with serious or life-threatening conditions for whom no adequately safe and effective alternative therapies are available unless there is documented, very high assurance of safety.

(e) Ensure that if participation by individuals who lack decision-making capacity is contemplated, appropriate measures are taken to safeguard their interests. In exceptional circumstances, minors with substantial decision-making capacity may, with the informed consent of their legal guardians, be considered as recipients in xenotransplantation. When an unemancipated minor proposes to participate in xenotransplantation, it may be appropriate to seek advice from another adult trusted by the minor or to seek consultation with an independent body, such as an ethics committee, pastoral service, or other counseling resource.

(f) Ensure that participants are informed about and consent to the unique risks and burdens posed by xenotransplantation, including:

  (i) novel infectious diseases (zoonoses);

  (ii) potential psychological concerns arising from receiving an organ or tissue from a nonhuman animal;

  (iii) the need for lifelong surveillance and ongoing clinical and laboratory monitoring, with archiving of biological samples when appropriate;

  (iv) the need to inform intimate contacts of potential risk to their health;

  (v) the need for an autopsy when appropriate.

(g) Ensure that high standards of care and humane treatment of all animals used in research are upheld.

AMA Principles of Medical Ethics: IV,VII