

AMA Code of Medical Ethics

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