

Ethical Guidelines for Organ Transplantation

It should be apparent that no stigma is attached to the performance of human experiments per se; disgrace and infamy can arise only through its misuse. The moral obligation of performing all human experiments, with due regard to the sensibility, welfare, and safety of the subject, must not be violated. As phrased by Claude Bernard in 1856, "Christian morals forbid only one thing, doing ill to one's neighbor." So, among experiments that may be tried on man, those that can only do harm are forbidden, those that are harmless are permissible, and those that may do good are obligatory.

—S. S. KETY

The medical profession, in its never-ending search for ways to save human life, relieve suffering, and improve health, has always been motivated and guided by the principles expressed in the above quotation. To achieve these goals, it has recognized that proper standards must be established and followed in clinical investigation and experimentation involving human beings.

In 1946, the American Medical Association succinctly listed three ethical guidelines to be followed in human experimentation in order to have such experimentation conform to medical ethics: (1) voluntary consent must be obtained from the person on whom the experiment is to be performed; (2) the dangers of each experiment must have been previously investigated by animal experimentation; and (3) the experiment must be performed under proper medical protection and management.

In 1964, the World Medical Association adopted the Declaration of Helsinki, which was later endorsed by the American Medical Association. The Declaration emphasizes "freely given consent" and differentiates between clinical research combined with professional care and nontherapeutic clinical research.

In 1966, the American Medical Association

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adopted a longer statement—"Ethical Guidelines for Clinical Investigation." In part, these guidelines state:

In clinical investigation primarily for treatment,

- A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.
- B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: disclosure that the physician intends to use an investigational drug or experimental procedure; a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits; an offer to answer any inquiries concerning the drug or procedure; and a disclosure of alternative drugs or procedures that may be available.

The Principles of Medical Ethics and these several statements have provided broad guidelines during the period when transplants of major body organs were first performed. In the opinion of the Judicial Council these principles continue to be valid.

Now, theologians, lawyers, and other public-spirited persons, as well as physicians, are discussing with deep concern the many new questions raised by the transplantation of vital organs. Man participates in these procedures: he is the patient in them; or he performs them. All mankind is the ultimate beneficiary of them.

A man, in the final analysis, must make a decision whether to permit or to perform a transplantation procedure. The decision must be a reasoned, intellectual decision, not an emotional decision. As medical science advances, and as technological skill increases, the ethical questions involved may become increasingly complex and difficult.

The Judicial Council, therefore, commends discussions of the moral, ethical, legal, social, and other aspects of clinical investigation, experimentation, and organ transplantation in human beings. It commends all efforts which encourage respect for

the dignity of man, and which seek to sensitize man's ethical conscience.

The Judicial Council of the AMA offers the following statement for guidance of physicians as they seek to maintain the highest level of ethical conduct in their practices.

1. In all professional relationships between a physician and his patient, the physician's primary concern must be the health of his patient. He owes the patient his 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.
2. A prospective organ transplant offers no justification for relaxation of the usual standards of medical care. The physician should provide his patient, who may be a prospective organ donor, with that care usually given others being treated for a similar injury or disease.
3. 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. In making this determination, the ethical physician will use all available, currently accepted scientific tests.
4. Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should be objective in discussing the procedure, in disclosing known risks and possible hazards, and in advising of the alterna-

tive procedures available. The physicians should not encourage expectations beyond those which the circumstances justify. The physician's interest in advancing scientific knowledge must always be secondary to his primary concern for the patient.

5. 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.
6. Transplantation of body organs should be undertaken only after careful evaluation of the availability and effectiveness of other possible therapy.
7. Medicine recognizes that organ transplants are newsworthy and that the public is entitled to be correctly informed about them. Normally, a scientific report of the procedures should first be made to the medical profession for review and evaluation. When dramatic aspects of medical advances prevent adherence to accepted procedures, objective, factual, and discreet public reports to the communications media may be made by a properly authorized physician, but should be followed as soon as possible by full scientific reports to the profession.

In organ transplantation procedures, the right of privacy of the parties to the procedures must be respected. Without their authorization to disclose their identity the physician is limited to an impersonal discussion of the procedure.

Reporting of medical and surgical procedures should always be objective and factual. Such reporting will also preserve and enhance the stature of the medical profession and its service to mankind.

ETHICS/ETIQUETTE.—For the average physician, medical ethics (of which there is no satisfactory exposition) means only medical etiquette, and actually there is usually as great a penalty attached to a transgression of one as to the other. *Medical etiquette is concerned with the conduct of physicians toward each other, and embodies the tenets of professional courtesy. Medical ethics should be concerned with the ultimate consequences of the conduct of physicians toward their individual patients and toward society as a whole, and it should include a consideration of the will and motive behind this conduct. . . .*

It is interesting that writers on medical ethics have seldom availed themselves of the philosophical analyses of the principles of ethical theory made by recognized ethical scholars. The two chief ethical positions are *idealism* which stresses the interests of humanity as a whole, and *hedonism* which emphasizes the interests of individual selves. Hedonism is usually concerned with personal pleasure; idealism, with the furtherance of the welfare of society.

The ethical basis for the professional system of etiquette is primarily hedonistic, since it is designed to promote the dignity and pecuniary advancement of the individual physician and of the profession as a whole. On the other hand, the ethical basis for the professed attitude of medicine toward the sick and toward the public is idealistic, since it presumes that every professional act of the physician is motivated by rational and sincere concern for the ultimate welfare of society. These two ethical positions are difficult to compromise.—Leake, C.D. (ed.): "Introductory Essay," in *Percival's Medical Ethics*, Baltimore: Williams & Wilkins, 1927, p23.