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THE MEDICAL, LEGAL, AND ETHICAL CONSIDERATIONS OF HUMAN ORGAN TRANSPLANTATIONS

The progress of medical science in the field of organ transplantation has had to concern itself with a three-fold problem: the actual medical difficulties involved in the surgical procedures and post-operative care; the legal issues raised when death occurs; and, the ethical considerations inherent in the decision-making process prior to the donor's death and the donee's surgery. Of utmost importance is the determination of the time of death. Medical progress has made outdated the dictionary definition of death. A new definition is needed to overcome the many problems in this area.

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In many countries of Europe, it was the custom to conduct a post-mortem examination upon the body of each patient who died while confined in an institution. That this custom still influences the thinking of many physicians practicing in those areas became evident in one of the early symposia sponsored by the Ciba Foundation, and held in London, England in 1966. After this conference, one of the participants stated: "At postmortem a doctor would have the right to remove an organ from a person who is dead unless there had been some intimation during the life of that person that he did not wish it to be so."¹ This statement was made in reply to the author's presentation of the essential points now contained in the Uniform Anatomical Gift Act which has been adopted by many jurisdictions in the United States.

At the Ciba Symposium, it was interesting to note that this group of physicians, in their discussions, endorsed the suggested statute presented by Lord Kilbrandon, the moderator of the Assembly, as follows:

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1. CIBA FOUNDATION SYMPOSIUM, ETHICS IN MEDICAL PROGRESS: WITH SPECIAL REFERENCE TO TRANSPLANTATION 160 (1966).

In any designated hospital it shall be lawful to remove from a dead person any organ required for medical or scientific purposes unless the hospital authorities have reason to believe that the deceased in his lifetime had forbidden this to be done, provided that such removal shall not disfigure the dead body.²

Lord Kilbrandon continued, "You have to realize that we will never have an act of Parliament which will define death; that is a medical question."³

The European attitude concerning the sanctity of the human body and the personal rights and privileges of a person differs remarkably from that currently held in the United States. For the most part, therefore, any discussion of the legal and ethical considerations of organ transplantation must be limited to the attitude existing in the United States. As stated above, when presented before the Ciba Symposium,⁴ the concept of the Uniform Anatomical Gift Act did not receive the full endorsement of the Symposium. The substantive content, the legal philosophy, and the intent were designed and written to satisfy the requirements of the American jurisdictions.

In the ensuing years, several symposia and meetings have considered every possible aspect of the problems involved in transplantation: the rights of the donor (living or dead), the rights of the recipient, the time of death, as well as the ethical problems involved. Recently, *Daedalus*⁵ dedicated an entire issue to the problem of the time of death, transplantation, and human experimentation. Literature is replete with articles, both legal and medical. The culmination of these investigative efforts now appears. Transplantation operations are being conducted in medical centers in many parts of the world. The technical problems involved in the surgical procedures were overcome many years ago. Indeed, it is not the technical aspects that cause concern to the medical profession but rather the complex legal, moral, and religious questions that have evolved. Most participating physicians now understand the legal and moral responsibilities placed upon them. Armed with this knowledge, they circumvent the many potential pitfalls when they participate in these operations. The public also has been exposed to the great advantages of transplantation of organs, and in most jurisdictions has participated actively in the support of legislative efforts

2. *Id.* at 213.

3. *Id.*

4. *Id.* at 102.

5. *Ethical Aspects of Experimentation with Human Subjects*, 98 *DAEDALUS* 219 (1969).

to create the legal right and procedural avenue for donation of organs which are to be removed upon death of the donor. Families too, when one of their members has died, usually are sympathetic and seldom refuse permission for removal of organs from the deceased for transplantation into a living recipient. Thus, much time and effort has been expended in discussing these non-medical problems concerning organ transplantation. In no aspect of the practice of medicine is the complete cooperation of all involved more necessary than in the performance of the transplantation of organs.

MEDICAL CONSIDERATIONS

For centuries, man has been intrigued by the concept of transplanting body parts from a healthy individual into another persons whose parts have been destroyed by disease or injury.⁶ The medical literature contains many references to legends of the middle ages which describe attempts to transfer extremities from slaves or benevolent donors to persons who had suffered the loss of such parts. In the light of present knowledge, it is not difficult to understand why, if indeed the operations were carried out, that failure ensued.

Early in the twentieth century, the techniques were developed making it possible to transplant tissue from one person to another. The transplantation of corneas and bone is now accepted surgical procedure. In recent years transplantation of kidneys, and, with some reservation, hearts, has been accomplished in the human. The transplantation of hearts is now under reassessment and reevaluation. Survival rates of recipients have been somewhat less than optimal. Moreover, the acquisition of a viable heart leads to searching questions such as exactly when did the death of the donor occur, and what are the rights of the survivor and next of kin?

One of the great medical problems still not solved is the rejection phenomenon. It has long been known that the body may reject transplanted tissues. The greater the genetic difference between the donor and the recipient, the more rapid and vigorous is the rejection reaction. Organs transplanted from an animal to a human (heterotransplantation) is seldom successful. Currently, the use of baboons is being employed in cross-circulation experiments with patients in hepatic failure. However, these experiments may be utilized only on patients who have

6. Wasmuth & Stewart, *Medical and Legal Aspects of Human Organ Transplantation*, 14 CLEV.-MAR. L. REV. 442 (1965).

both the appropriate blood and tissue type. Unfortunately, such patients constitute a very small segment of the population. Transplantation procedures involving human donors and recipients who are not related (homotransplantation) are successful under certain circumstances. In humans, blood groups (commonly referred to as ABO) are routinely determined in the laboratories. In the first instance, the recipient and donor must coincide as to ABO groups and then, with the more complicated and newer techniques further agree as to tissue types. New and highly specific techniques are now being developed. Great hope is currently being placed upon the efficacy of tissue typing, and several medical centers have been established in the United States to service all institutions participating in organ transplantation operations. In the future, tissue typing may become as commonly accepted as blood typing and cross-matching. As the tests become more exact with experimentation and tissue typing becomes readily available, organs from either living or dead donors can be more precisely matched with the recipients. Hopefully, then, use of immunosuppressive drugs will become less necessary.

It is generally accepted that the transplantation of certain tissues causes little if any rejection in the recipient. As an illustration, corneas can be removed from the eyes of a deceased person hours after death and transplanted to another person without the development of a rejection. Rejection seldom occurs when bone, obtained from one person, is used to correct a skeletal defect in another person. When considering the possibility of transplanting tissues, such as the kidney, liver, heart, and pancreas, however, the specificity of tissue typing becomes vitally important. Those tissues, unless matched accurately, are rejected actively by the recipient. Thus, physicians involved in transplantation operations are confronted not only with the legal and moral problems, but indeed medical problems that at the present cannot be fully overcome.

In transplantation of paired organs, such as kidneys, it has become an accepted medical procedure for a living person to undergo surgical removal of a kidney for transplantation into another. Under such circumstances, sufficient time exists for adequate study of the health of the donor and the compatibility of the tissues of the donor and of the recipient.

In the situation in which the donor is a recently deceased person, time is of the essence. To obtain viable tissue, the organs must be removed from the cadaver donor as soon as possible after death. Ques-

tions immediately arise: When is the person dead? Who can pronounce this person dead? Who can give consent for the removal of an organ for transplantation? Who may remove this organ? May tissue typing studies to the donor be carried out before the time of his death? These and a myriad of other questions confront the surgical team.

When death occurs, and circulation ceases, tissue death in the organs proceeds. As time passes, viability decreases. Unless prior studies have been made to determine the tissue compatibility of potential recipient and potential donor, sufficient time may not be available to do so before transplantation. If such studies have been made, then the question arises as to whether the studies were done in anticipation of death and for the possible transplantation of organs. The ante-mortem study may be construed as evidence that those in charge of the potential recipient were possibly influenced in their therapeutic endeavors for the dying patient.

Generally, in hospitals with transplantation programs, the treatment of a dying patient is under the sole and exclusive jurisdiction of the treating physician. In no event may he be a member of or participate in the transplantation procedure should his patient die and become a donor. Likewise, no member of the transplantation team may participate in the treatment of the potential donor or in the determination of the time of death. Medical ethics places this solely under the jurisdiction of the treating physician and he alone has the right to determine when the patient is dead or the moment when medical life-maintaining support may be discontinued. In most instances, the patient has contracted with the treating physician for medical treatment in his illness and therefore has placed his life in the physician's hands. It is not unusual, however, for the treating physician, in serious and terminal illnesses, to seek consultation with other physicians. Thus, the treating physician does share this responsibility and seldom makes the determination without the advice of others.

With medical progress in tissue typing and the control of rejection phenomena by immunosuppressive agents, the success rate of transplantation operations is improving. Renal transplantations, however, were first carried out successfully on patients in whom there was little or no possibility of development of the rejection phenomenon. In 1954, the kidney from a healthy twin was successfully transplanted into the body of his ailing identical twin. Surgically, the technique for transplantation had been perfected many years before. It was the rejection phenomenon that had hindered further progress. In the

case of identical twins, it is evident that their tissues must be compatible inasmuch as both twins originated from the same cell. Thus, since the tissues were genetically identical, an organ transplanted from one to the other would not be rejected.

In *Masden v. Harrison*,⁷ one twin had suffered irremediable damage to both kidneys and as a result was in renal failure. Only hemodialysis, or the use of the artificial kidney, kept that twin alive. But, while lifesaving, this treatment was palliative only. A cure was only possible if a kidney from the healthy twin could be transplanted into the ailing twin. The twins had not reached the age of majority and immediately the question of consent for the surgical procedures arose. The parents of the sick child had the right to grant permission for the implantation of the kidney, but the healthy twin, not being of age, could not give permission or contract for this operation. It became doubtful whether or not the parents could give permission for removal of a healthy organ from a healthy child. Several interesting legal questions were raised: May a person consent to the intentional or voluntary maiming of his own body? May a minor consent to an operation? May the parents of a child consent to an operation upon a healthy child which cannot possibly be of any benefit to him, and, in fact, might be to his detriment?

Before proceeding with the operations, the physicians and the institution in which the operations were to be performed, considered it necessary to have a declaratory statement from the courts. Because of the near emergency nature of the issue, application was made to the Supreme Judicial Court of Massachusetts for a declaratory decree. The court, after hearing the testimony of a highly qualified psychiatrist, stated that if the healthy twin were not permitted the opportunity to donate one of his kidneys to his brother and he died, the healthy twin would suffer a great emotional impact. This psychological trauma would be further aggravated by the realization that it had been within his power to save the life of his brother had the operation been performed. The court, therefore, decreed that "the defendant [the hospital and physicians] may operate upon the body of Leonard Masden by removing one of his kidneys and transplanting it into the body of the twin brother, Leon, without incurring any civil liability to Leonard or any criminal prosecution, if such operation is conducted in a proper manner and without negligence."⁸ Thus resolving the legal complexities

7. Equity No. 865 (Mass. Sup. Jud. Ct., June 12, 1957).

8. *Id.*

inherent in the case, the transplantation of a kidney without the fear of rejection phenomenon became possible. To the author's knowledge, both twins are alive today.

Since few patients with renal failure have an identical twin standing by, need for medical research into the rejection phenomenon and development of immunosuppressive agents remains a problem of great magnitude.

Much has been written concerning the utilization of artificial organs. Kolff and his associates at the Cleveland Clinic for many years worked on the development of artificial hearts. To date, however, Kolff's experiments at the University of Utah, and experiments of others in various medical centers have not produced an organ equal to or comparable with a heart taken from a human being. Numerous problems remain unresolved. Among these are the rejection of the heart by the host body, the durability of the driving mechanism and of the material from which the artificial heart is made, the reliability of the mechanical structure, and the effect upon the blood which flows through and is pumped by the artificial organ. There is little doubt, however, that eventually with the improvement in materials and power sources, many of the problems now existing in the use of artificial organs can be overcome. With the development of tissue cultures, however, it is perhaps possible that a new organ may be grown from cells extirpated from the specific organ in the recipient's body. This sounds like a science fiction, but with the rapid development of medical science in recent years, one may not preclude this from the realm of possibility or even probability. If it proves possible to grow such an organ, then it becomes immaterial whether or not the rejection phenomenon is solved, but legal problems may still emerge.

LEGAL CONSIDERATIONS

Probably the most complex legal questions raised in regard to organ transplantation involve the determination of the time of death and the right of physicians to experiment on human beings. The question of the time of death is of great importance to the prospective donor.

To deny that transplantation procedures were initially experimental would verge upon the ridiculous. Currently, organ transplantation still must be considered to be an experimental procedure, although it has been performed several thousand times. Irrespective of the number of times that a procedure has been performed experimentally and successfully upon animals, its application to a man must be considered

an extension of investigative or research processes.⁹ Much has been written in recent years concerning experimentation on human beings. It seems as though an attempt has been made by some to deprecate the investigative efforts of physicians interested in clinical research activities. Therefore, when discussing the aspects involving organ transplantation, the problem of experimentation does arise. Most patients undergoing such procedures are in desperate need and readily subject themselves to the procedure in order potentially to save their lives. Most would proceed regardless of the possible dangers inherent in the technique, and in most instances the patient perceives the dangers involved. Inasmuch as these procedures have been performed a limited number of times, however, all complications possible might not yet be known. According to the strict rules of an old, yet well-recognized New York case,¹⁰ a surgeon may not vary a given operative technique. To do so is tantamount to experimentation, which may be considered *prima facie* negligence. If the technique succeeds, however, the physician is exonerated. To ensure that a court will not hold him liable, a surgeon must employ the technique successfully several times, thus establishing its safety. Under such a rule, all responsibility is placed upon the physician when new techniques are employed.

The case law only requires that the physician exercise reasonable skill and care. Certain restraints, however, must be placed upon medical practitioners and investigators. The code of ethics of the medical profession is of first importance. The physician's Oath of Hippocrates is evidence of the high ideals of the practice of medicine transmitted through the ages, but recently it has become necessary to set forth basic rules to prevent the recurrence of any cruel and unscientific experimentation on man purportedly in the name of medical science. The World Medical Association adopted the Declaration of Helsinki,¹¹ which, with certain modifications, has been adopted by the House of

9. Beecher, *Experimentation in Man, Report to the Council on Drugs*, 169 J.A.M.A. 461 (1959); Schreiner, *Liability in Use of Investigational Drugs*, 185 J.A.M.A. 259 (1963); See Address by Crawford Morris, Human Testing and the Courtroom, National Academy of Sciences Conference on the Use of Human Subjects in Evaluating the Safety of Food Chemicals, in Washington, D.C., Nov. 29, 1966.

10. *Carpenter v. Blake*, 60 Barb. 488 (N.Y. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872). See also *Landon v. Humphrey*, 9 Conn. 209, 23 Am. Dec. 333 (1832); *Richy v. West*, 23 Ill. 385 (1866); *Billinger v. Craigie*, 31 Barb. 534 (N.Y. 1860).

11. See Appendices A and B *infra*.

Delegates of the American Medical Association, making it the official declaration of that association.

The intent of these declarations can be summed up in the official declaration of the American Medical Association: "The health of my patients will be my first consideration Any act or advice which could weaken the physical or mental resistance of a human being may be used only in his interest."¹²

The responsibilities of a physician who is performing a new and hazardous surgical operation or administering an agent to a patient will vary almost with the type of patient being treated. As an illustration, investigation of new drugs is often attempted on a normal subject, such as the physician himself, or on his assistants. In this instance, the normal subject is not a patient of the experimenter, but, in fact, a volunteer and may be termed the human guinea pig. He has volunteered his body for the experimentation in the spirit of the research or for monetary compensation. For example, during periods of war, conscientious objectors have volunteered for participation in medical studies, submitting themselves for investigative programs; in many studies, volunteers of penal colonies have been sought because they constitute a highly controlled population and, in certain instances, prisoners make ideal subjects for investigation.

While physicians must continue to recognize their legal responsibilities and liabilities, due consideration must be given to the patient, his welfare, and, indeed, his wishes. Patients who are suffering the ravages of complete renal shutdown or terminal heart failure are anxious to accept the risks inherent in the surgical procedure for the transplantation of an organ. It matters little to them whether it is an experimental or an investigative procedure. Even in the absence of such extenuating circumstances, however, a physician does have legal authority to institute a variation of an accepted surgical procedure without incurring liability. A somewhat similar situation was litigated in *Salgo v. Leland Stanford University*,¹³ when the dosage of a drug administered to the patient during a surgical procedure was at variance with the dosages listed in the package insert from the manufacturer. Although this case involved the use of a pharmaceutical agent, the analogy is clear. The question arose as to whether or not this variant constituted grounds for malpractice on the basis of experimentation. The court in its decision stated that because the physician departed from the custo-

12. AMERICAN MEDICAL ASSOCIATION, JUDICIAL OPINIONS AND REPORTS (1966).

13. 154 Cal. App. 2d 560, 317 P.2d 170 (Dist. Ct. App. 1957).

mary practice followed by physicians of standing in the locality did not in and of itself cause the act to be an experimentation, and therefore the permission of the patient was not necessarily required. Liberties have been assumed in attempting to draw a parallel between the use of experimental drugs and the surgeon's knife. There are few rules of law, statutory regulations, or court decisions that outline the full authority of the surgeon as to details of surgical technique, and that specifically delineate the conduct of the surgical team. As in the administration of research drugs, patients must be protected against unnecessary and unsound surgical experimentation.¹⁴ For the most part surgical investigators are usually on the staffs of large medical centers or research institutions, and such physicians are not tempted to try unfounded and unscientific experimental procedures that have not been carefully thought out and amply developed in animal experimentation. Historically, the classic advocate of the above procedure is Dr. William Beaumont, one of the great investigators, though not a surgeon, who made landmark contributions to medicine by his treatment and observations of gastric fistula, resulting from a gunshot wound, in Alexis St. Martin, now his famous patient.¹⁵

In recent years the doctrine of informed consent has been introduced into the legal literature. "Informed consent" can best be described by the words: duty to forewarn the patient. "Informed consent" denotes that the patient understands the situation probably as well as the physician or the surgeon. The duty of the physician to forewarn is the responsibility that the physician carries to warn the patient of *possible* complications in *possibly* hazardous operations. In regard to the average patient, undergoing procedures considered to be usual or standard, the physician may not wish to explain to the patient all of the *possible* complications. If this were a requirement, few patients would dare to undergo an operation, and would thereby be denied its benefit. Many complications are possible, yet seldom occur. The courts have stated that the possible courses of treatment should be explained to the patient when more than one course is available. Thus, from a practical standpoint, any legal doctrine requiring the recitation of all possible catastrophic possibilities inherent in a surgical procedure would not only be inconsiderate (because they do at least in theory exist) but

14. C. WASMUTH, LAW AND THE SURGICAL TEAM 323-32 (1969).

15. W. BEAUMONT, EXPERIMENTS AND OBSERVATIONS ON THE GASTRIC JUICE AND THE PHYSIOLOGY OF DIGESTION (Dover ed. 1959).

in fact might deny the patient the benefits of modern surgical treatment.

In the case of organ transplantation, a new, and still considered to be an experimental procedure, the doctrine of informed consent places upon the physician still another burden. In *Natanson v. Kline*,¹⁶ the Kansas Supreme Court held that the physician had a duty to explain the complications, particularly in regard to a new, experimental, and hazardous technique. In this case, it was a question of whether the patient would or would not undergo radiation therapy after undergoing mastectomy for cancer of the breast. At that time, radiation by cobalt teletherapy was a new procedure. According to the decision in the *Natanson* case, however, the physician should have explained to the patient that a surgical process for cure had been carried out; the decision to undergo additional therapy should have been left to the patient. Applying this to transplantation, all of the possible complications of the surgical procedure and the subsequent administration of the immunosuppressive agents are still considered to be in the realm of experimentation and are somewhat hazardous. The question arises then: Is the physician to assume the responsibility for these if they occur, or, does the patient assume some of the liability?

As an illustration, in recent months several reports in the medical literature referred to the appearance of fibrosarcoma, a cancerous condition of the fibrous tissue of the transplanted kidney. Whereas the neoplastic cells were not detected before transplantation, nonetheless they were present subsequent to the use of the immunosuppressive drugs and other agents. Whether or not these procedures were related to this sequence has not been determined scientifically. Forewarning the patient of this condition would have been impossible, as up to this time its occurrence was not known to medical science. Yet strictly interpreted, the duties placed upon the physician by the doctrine of informed consent require that he forewarn the patient of that possible occurrence. It is probable that even if the patient were forewarned of these dire consequences, most if not all would readily agree to undergo implantation of a kidney. The alternative is not at all attractive.

TIME OF DEATH

At this stage of development, the clinical results of transplantation of an organ from a living donor are considerably better than the re-

16. 187 Kan. 186, 354 P.2d 670 (1960).

sults obtained when the organ was removed from a cadaver donor. There are several reasons. In the case of the living donor, time is available to perform adequate tissue typing to determine whether or not the tissues of the donor will be compatible with those of the recipient. When the donor has just died, sufficient time may not be available to perform these studies adequately. In order to transplant a viable organ, it must be removed from the deceased donor as soon after death as is possible. Lack of circulation of blood results in hypoxia and acidosis within the organ, and the cells are thus damaged or killed. Such damage is usually irremediable.

Several institutions are now developing facilities for the preservation of organs.¹⁷ This will permit necessary time to carry out tissue-typing procedures so that the organ may be transplanted to a person with whom it is compatible. Once these facilities are available, then time is no longer an essential factor. At the moment of death, the organs can be removed from the donor, and with sterile precautions placed in the organ preservation unit to await the identity of the future recipient. With these facilities, the necessity will be obviated for subjecting a healthy patient to an operation to remove a healthy organ. Much of this depends upon the availability of cadaver organs.

In many jurisdictions, where the Uniform Anatomical Gift Act has been adopted, a person during his lifetime has the right to will his body or any part thereof for transplantation purposes. From a practical standpoint, however, the permission to perform this operation upon the deceased must be obtained from the survivors or next of kin. Particularly is this so, when, even though a proper consent or permission had been signed by the deceased, the surviving spouse or member of the family strenuously objects to any procedure to desecrate the deceased human body. Whether or not the statutory provisions would prevail over the case law is relatively unimportant. The invasion by the physician of the survivor's rights, particularly in situations such as organ transplantation, might be considered to be quite indiscreet. Thus, while the physician may have a valid legal right, the opposition of the family might well be the overwhelming and indeed the controlling action. The death of a relative is wrought with great emotion. The needs of a stranger who requires an organ from the deceased relative may not be persuasive to the survivors. To exercise a legal right to invade the body

17. At the Cleveland Clinic Foundation, the Organ Preservation Laboratory is equipped with highly specialized equipment to preserve kidneys extirpated from deceased donors.

of the deceased over the objection of the family might well precipitate new case law.

The entire program of transplantation is dependent upon the availability and procurability of organs, and then their preservation until transplantation. Sources of organs consist of patients who have undergone death of the brain but who still are "alive" according to the classic sense in that the heart is still beating and they are breathing or are being maintained artificially by a ventilator. In other instances, the patients are admitted to the emergency room of a hospital, the victims of automobile accidents, and are dead upon arrival. Still other sources of organs are the bodies of those who have died as the result of criminal acts.

The bodies of victims of criminal acts are, perhaps, not suitable for transplantation purposes, inasmuch as in most instances criminal litigation ensues in the prosecution of the defendant criminal. In most jurisdictions, the coroner or medical examiner takes jurisdiction over the body of the deceased. It is conceivable that if the organs involved are not all associated with, or are not directly involved in the cause of death of the victim, that such could be removed and placed in the organ preservation unit. Inasmuch as some authorities still rely upon the heartbeat as an indicator of whether or not life exists in the body, however, it is extremely difficult to explain how a heart transplanted from the victim into another in which it continues to beat and maintain life could ever have been determined to have been dead. Therefore, the defense of the criminal will be that inasmuch as the heart was still beating in the body of the recipient, the person who removed the heart for purposes of transplantation actually killed the victim of the crime. In this situation, the determination of the time of death becomes critically important.

In the event that the prospective donor is a patient who is dying, and inasmuch as the organs to be transplanted must be removed from that person as near as possible to the time of death, the determination of that moment of death is likewise critical. *Dorland's Illustrated Medical Dictionary* defines death as "[t]he apparent extinction of life, as manifested by the absence of heart beat and respiration."¹⁸ With the technological advances in medicine, it is possible to maintain by mechanical means both the heartbeat and the respiration. A cardiac pacemaker, with a self-contained power source, can be implanted under the skin of the trunk of the body and the wires connected to the

18. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 387 (24th ed. 1965).

heart muscle. By rhythmic discharge of the electric current from this pacemaker, the heart is stimulated to contract, thus maintaining circulation of the blood. In certain individuals, "life" as classically defined is extended by artificial means. Likewise, the significant advances in the ventilatory equipment now permit physicians, particularly in the intensive care units of hospitals, to maintain respiratory excursions in patients who have suffered respiratory arrest. Thus, in many instances death is thwarted by the simple expedience of supporting by mechanical means the two vital processes described in the above definition, the absence of which is defined as death. Many clinical illustrations are available that will serve as examples. It becomes patently clear that when respiratory arrest persists long enough, the patient will become asphyxiated. As a direct result of the accompanying hypoxia, the heart will stop: death then is said to occur. Likewise, should the heart stop for a long enough period, respiratory excursions also will stop.

Modern medicine, however, may not accept, to the exclusion of all others, the absence of the heartbeat and the respiration as the signs of death. Consider the person who has suffered a cardiac arrhythmia that progresses to ventricular fibrillation. Ordinarily, and in the past, this condition was fatal. In the present state of medical science, when detected soon enough (before cerebral damage has occurred) ventricular fibrillation can be stopped by the use of a defibrillator. This instrument is designed to discharge a predetermined surge of direct current through especially designed electrodes into the chest (and heart) of the patient. The heart is thus shocked into standstill and, in many instances, will revert to a normal rhythm or at least one that will support life. Most of these patients have no heartbeat or respiration. According to the dictionary definition, death has occurred, but, the condition of many patients has been reverted and they are enjoying life. The cessation of heartbeat, however, may not be detected as soon as it occurs. Not infrequently the decreasing circulation causes relative hypoxia in organs, and thus compromises viability of those tissues. When resuscitative procedures are not at once successful, and despite ventilation with oxygen-rich gases, viability of cerebral tissue may be compromised. Resuscitation of a person who has undergone severe damage of the brain will result in a person who will survive only in an unconscious vegetative state.

Many persons, other than physicians, have witnessed the condition of those who have suffered irremedial damage of the brain from massive cerebral hemorrhage, subarachnoid hemorrhage, and severe

cerebral trauma. In former years, those patients lingered until their hearts stopped or their respirations ceased due to the trauma to the brain, increase in intracranial pressure, or herniation of the brain stem. Though the patient might have been unconscious and the brain irrevocably damaged for extended periods, death was said to occur only when the respiration and heartbeat ceased. As mentioned before, with the facilities available today, physicians may utilize mechanical devices to maintain ventilation, and should the heart falter, it is possible to apply the mechanical pacemaker to assure continued heartbeat. Although these two vital processes are supported, the damaged condition of the brain is not improved. The damage to the brain, whether from physical trauma or from pressure, is permanent and the patient will remain unconscious irrespective of the fact that a heartbeat and respiration do exist. Is this patient not dead? To continue life (heartbeat and respiration) in such patients condemned to a state of coma is merely a triumph of protoplasmic resuscitation.

It is axiomatic in the law and traditional in medicine that upon the treating physician is placed the responsibility of the patient's life. In former years, this physician was most commonly the "family doctor." With the many changes occurring in the system of delivery of health care services and with the distinct tendency towards specialization, few families now rely on only one physician for medical care. Liability therefore is assumed by the physician who is treating the patient. Upon him the law places the duty to exercise reasonable skill and diligence in the treatment of the patient and according to the standards of medical practice. Upon him the law places the responsibility to treat his patient, to cure a disease, to preserve his life, and to guard his welfare. Upon him, also, is placed the responsibility to abandon treatment and life-sustaining measures when further efforts would, in his opinion, be in vain. Most treating physicians wish not to assume these responsibilities solely; in difficult cases, consultation with other physicians is sought. Upon the treating physician, though, rest the ultimate decision for treatment and the final responsibility.

When death of a patient is imminent, or when it becomes apparent that a patient will not regain consciousness because of damage to the brain, the treating physician seeks consultation with other physicians and with the patient's family. Should the consultants agree that further support would continue life, but that the cerebral damage would not be reversed, the treating physician may then advise the discontinuance of such support. Death in fact has already occurred. To stop the venti-

lator is to eliminate the artificial life-sustaining respiration. The heart will soon cease to beat. The patient then is dead cerebrally and dead according to the classic definition of death.

Many criteria have been set out for the determination of death. In his article several years ago, Doctor Hamlin set forth conditions offered for certifying brain death in association with cardiorespiratory activity artificially sustained by mechanical aids:

- (1) No spontaneous respiration for a minimum of 60 minutes.
- (2) No reflex response (superficial, deep, organic, etc.).
- (3) No change in the heart rate or ocular or carotid sinus pressure.
- (4) EEC—flat line with no rhythms in any leads for at least 60 minutes of continuous recording. No EEG response to auditory or somatic stimuli or to electrical stimulation. Longer periods of total flat recordings some hours apart may be preferred by some.
- (5) Normal basic laboratory data including electrolyte pattern.
- (6) Share responsibility for pronouncement of death with other colleagues.¹⁹

At the conclusion of his article he stated that:

if complete EEG [electroencephalogram] silence could gain acceptance as proper grounds for withholding fruitless efforts of resuscitation, some of the nobility in death would be preserved where it has frequently been forfeited through our slavish and superstitious refusal to acknowledge that St. Peter is at the gate or Sharon at the Cross. More solace thereby would be granted to relatives who under current hospital practice often have to await the grim and foregone verdict until the final beat of the dying heart has been recorded.²⁰

In summary, it is now generally accepted in the medical community that death can no longer be defined as the cessation of the heartbeat and respiration. Clinical death is evident when these processes of respiration and circulation have ceased, and as a direct result have caused other irreversible damage such as cellular death. Only when cellular death occurs in a viable organ may a physician declare such a person to be dead. Thus, at the moment when a physician determines that

19. Hamlin, *Life or Death by EEG*, 190 J.A.M.A. 112, 114 (1964).

20. *Id.* at 114.

the heart of a patient cannot be resuscitated death becomes inevitable. Further efforts to resuscitate the patient may be abandoned. Life, as we understand it, without a functioning myocardium is impossible. Likewise, respirations can be supported by the automatic ventilators. In some patients, however, the physical condition of lungs defy and prevent adequate gas exchange and perfusion. Therefore, irrespective of mechanical ventilation, asphyxia continues. It becomes evident to all concerned that these patients are beyond salvage. Sooner or later cellular death of other parts will follow. The gradual onset of cellular death proceeds with the inexorable passage of time. Cellular death does not proceed at the same rate in all tissues. Some tissues deprived of oxygen are traumatized sooner than others. It is a recognized fact that the kidneys can undergo hypoxic conditions for rather extensive periods. The brain, deprived of oxygen for only a few minutes, suffers irremedial damage.

It has been stated that it is the prerogative of the treating physician to determine the time of death. The methods used in arriving at this conclusion also are the prerogative of the treating physician. The determination of the time of death is a matter of medical judgment. The treating physician must satisfy his professional conscience and the legal requirements of reasonable medical certainty.

These are limits set by the law, and beyond this point the law should not inquire. When the physician, utilizing whatever methods are available, has determined that continued support of these vital physiological processes by artificial means becomes an agonizing and useless prolongation of a false hope of recovery, it become his responsibility to withdraw such support.

It now becomes obvious that the dictionary definition of death is anachronistic. In a recent case in which the court addressed itself to this question of the time of death, no physicians were available when the events occurred to determine the cause or the time of death. Therefore, the court was forced to receive testimony of those (not physicians) who witnessed the events. The court suggested that death is not a continuing event, but is an event that takes place at a precise time.²¹ While the facts of the case may support such a determination, the decision must not be impressed upon others where highly skilled physicians are in attendance in the scientific environment of a hospital center. The situation facing the court in which no physician was in at-

21. *Smith v. Smith*, 229 Ark. 579, 317 S.W.2d 275 (1958).

tendance, is far different from that situation in an intensive care unit where the patient is surrounded by many medical experts and the latest medical equipment. The definition of death here must be based upon medical judgment and must take into consideration many other scientific criteria. These circumstances are in vivid contrast to the situations in which lawyers are arguing the time of death in a case where none of the participants had even seen the body of the deceased, much less the circumstances causing the death.

The medical profession has set forth the criteria for the diagnosis of death based upon the present status of medical and scientific knowledge. Because of the continuing scientific advances, these criteria, from time to time may be changed. Therefore, they should not be ensconced in the immutable language of statute by legislative fiat, nor cast in bronze by the decisions of the court. The criteria for the diagnosis of the time of death may be changed, but this too must be determined by medical, not legal, judgment.

APPENDIX A*

THE DECLARATION OF HELSINKI

[The Declaration of Helsinki, consisting of recommendations guiding doctors in clinical research, was adopted by the World Medical Association in 1964 and endorsed by eight leading professional organizations including the American Medical Association. Following is the text of the declaration, followed by the AMA Ethical Guidelines for Clinical Investigation.]

Introduction

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of The World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians

* *Supra* note 1 at 216-18. (August 19, 1947).

all over the world. Doctors are not relieved from criminal, civil, and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without the therapeutic value to the person subjected to the research.

I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. Clinical Research Combined with Professional Care

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers a hope of saving life, reestablishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. Nontherapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

We, the undersigned medical organizations, endorse the ethical principles set forth in the Declaration of Helsinki by the World Medical Association concerning human experimentation. These principles supplement the principles of medical ethics to which American physicians already subscribe.

American Federation for Clinical Research
American Society for Clinical Investigation
Central Society for Clinical Research
American College of Physicians
American College of Surgeons
Society for Pediatric Research
American Academy of Pediatrics
American Medical Association

ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION

*(Adopted by House of Delegates, American Medical Association,
November 30, 1966)*

At the 1966 Annual Convention of its House of Delegates, the American Medical Association endorsed the ethical principles set forth in the 1964 *Declaration of Helsinki* of the World Medical Association concerning human experimentation. These principles conform to and express fundamental concepts already embodied in the *Principles of Medical Ethics* of the American Medical Association.

The following guidelines, enlarging on these fundamental concepts, are intended to aid physicians in fulfilling their ethical responsibilities when they engage in the clinical investigation of new drugs and procedures.

1. A physician may participate in clinical investigation only to the extent that his activities are a part of a systematic program competently de-

signed, under accepted standards of scientific research, to produce data which is scientifically valid and significant.

2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety, and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.

3. 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: (a) disclosure that the physician intends to use an investigational drug or experimental procedure, (b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits, (c) an offer to answer any inquiries concerning the drug or procedure, and (d) a disclosure of alternative drugs or procedures that may be available.

i. In exceptional circumstances and to the extent that disclosure of information concerning the nature of the drug or experimental procedure or risks would be expected to materially affect the health of the patient and would be detrimental to his best interests, such information may be withheld from the patient. In such circumstances such information shall be disclosed to a responsible relative or friend of the patient where possible.

ii. Ordinarily, consent should be in writing, except where the physician deems it necessary to rely upon consent in other than written form because of the physical or emotional state of the patient.

iii. Where emergency treatment is necessary and the patient is incapable of giving consent and no one is available who has authority to act on his behalf, consent is assumed.

4. In clinical investigation *primarily for the accumulation of scientific knowledge*—

A. Adequate safeguards must be provided for the welfare, safety, and comfort of the subject.

B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.

C. Minors or mentally incompetent persons may be used as subjects only if:

i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.

ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.

D. No person may be used as a subject against his will.

APPENDIX B*

THE NUREMBURG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the methods and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocureable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a-priori* reason to believe that death or disability or disabling injury will occur; except, perhaps in those experiments where the experimental physicians are also serving as subjects.

* *Supra* note 1 at 219-21.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiments.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experimenting at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him, that continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.