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MEDICAL-LEGAL RAMIFICATIONS OF HUMAN TISSUE TRANSPLANTATION

CYRIL H. WECHT* AND MICHAEL J. ARANSON†

INTRODUCTION

It was in December of 1967 in Capetown, South Africa that Doctor Christian Barnard and his colleagues accomplished the first cardiac homotransplantation in man. In the year that followed, more than one hundred heart transplantations were attempted, with forty-three of the recipients still surviving. Fifty-three transplants were accomplished in the United States alone; Canada followed with thirteen and France with nine. It is expected, and indeed it is anticipated, that heart transplant operations ultimately will become as commonplace as transplants of eyes and kidneys. It is noted, in view of the one hundred worldwide heart transplants, that as of late such operations do not even make front page news, while at one time these miracles called for headline treatment. Society tends to reduce the importance of a discovery or new technique when it is no longer new and unusual, and this precedent is continuing through public reaction to heart transplantation.

On the other hand, as each heart transplant is accomplished, complex legal and medical problems develop, which the layman not only fails to realize but fails even to recognize or acknowledge. The basic problem can be summed up as follows: The donor of an eye or a kidney need not necessarily be dead in order to make his contribution; on the other hand, there can be no heart transplant until the donor has achieved a total state of death. Thus, the medical problems come quickly to the fore. Naturally, the most important question to consider is, “Is the donor dead?” If the donor is, in fact, dead, it appears that medicine is removing a useless molecular structure from a cadaver and replacing

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it where it can do obvious and life-saving good. If the prospective donor is not dead, then medicine commits murder. This problem immediately leads us to others: What is death? How is death defined? What is the difference between legal death and medical death? Exactly when does death occur so that a donation may be made?

The medical problems, as discussed above, are obvious. At one time or another, certainly everyone, layman or professional, must consider them. On the other hand, the legal technicalities involved are perhaps more subtle. Who has the right to determine whose heart will be used for a transplant? Can a prospective donor determine the use of his organs before he dies? If so, how long in advance of death need this decision be made? Can a surviving spouse or heirs of a decedent make this decision? What happens in the event that the decedent and his survivors have different ideas about what should be done with his remains? Who owns the cadaver?

It is the purpose of this article to review all of the above mentioned problems in relation to heart transplant operations. The problem will be analyzed, and both legal and medical solutions will be offered. Great emphasis will be placed on the Uniform Anatomical Gift Act which has been proposed and approved by the National Conference of Commissioners on Uniform State Laws.1 It is submitted that the Uniform Anatomical Gift Act, if properly adopted, interpreted and supplemented, will provide the ultimate solution in codified form for all problems presently existing in the area of heart transplantation, as well as providing for solution and interpretation of difficulties that are sure to arise as the art of heart transplantation gradually develops into a science.

THE PROBLEM OF DEATH

Webster's New Collegiate Dictionary defines death as the act or fact of dying; the state of being dead; cessation or privation, as of function, existence, capacity for development.2 The word die is defined as: to cease to live; to become dead; or decease.3 Black's Law Dictionary defines death as the cessation of life; ceasing to exist; defined by phy-

1 The complete text of the Uniform Anatomical Gift Act is reproduced in the appendix of Wheeler, Anatomical Gifts in Illinois, page 485 of this issue.
2 Webster's New Collegiate Dictionary 214 (2d ed. 1953).
3 Id.
Physicians as a total stoppage of the circulation of the blood, and the cessation of the animal and vital functions consequent thereon, such as respiration and pulsation. Although these definitions have served the community and legal profession for years, modern medical technology has made them obsolete. Doctors are faced with a dilemma as to whether a person should be kept alive artificially or allowed to die. Is a doctor justified in taking a patient off a resuscitator before the patient's heart stops beating, when an encephalogram indicates that there are no brain waves? To restate the problem, should a donor's heart, even if still beating, be removed for transplantation, if the brain is irreversibly dead and falling blood pressure shows cardiac failure?

Does a surgeon have the right to remove a still-beating heart? In addition to the dictionary definitions of death, various criteria for death have been used in the past, and new and more modern methods are constantly being suggested. A discussion of the various methods follows.

In the common law states, a person is legally dead when his attending physician declares him to be dead, based upon a criterion of irreversible cessation of respiration and circulation. There have been cries for statutory codification of rules relating to the question of when death takes place, but the legal community continues to feel that the question of death is a medical and not a legal problem and has thus far not attempted to enact any statutory definition.

In August of 1968, the Twenty-Second World Medical Assembly met at Sydney, Australia and unanimously resolved the following declaration on death, to be known as The Declaration of Sydney:

The determination of the time of death is in most countries the legal responsibility of the physician and should remain as so. Usually he will be able without special assistance to decide that a person is dead, employing the classical criteria known to all physicians. Two modern practices in medicine, however, have made it necessary to study the question of the time of death further: (1) The ability to maintain by artificial means the circulation of oxygenated blood through tissues of the body which may have been irreversibly injured, and (2) the use of cadaver...
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organs such as heart or kidneys for transplantation. A complication is that death is a gradual process at the cellular level with tissues varying in their ability to withstand deprivation of oxygen. The clinical interest lies not in the state of preservation of isolated cells, but in the fate of a person. Here the point of death of the different cells and organs is not so important as the certainty that the process has become irreversible by whatever techniques of resuscitation that may be employed. This determination will be based on clinical judgment supplemented if necessary by a number of diagnostic aids of which the electroencephalograph is currently the most helpful. However, no single technological criterion is entirely satisfactory in the present state of medicine nor can any one technological procedure be substituted for the overall judgment of the physician. If transplantation of an organ is involved, the decision that death exists should be made by two or more physicians, and the physicians determining the moment of death should be in no way immediately concerned with the performance of the transplantation. Determination of the point of death of the person makes it ethically permissible to cease attempts at resuscitation and in countries where the law permits, to remove organs from the cadaver provided that prevailing requirements of consent have been fulfilled.

The Council for International Organization of Medical Science, meeting in Geneva in June of 1968 under the auspices of the World Health Organization, stated that death consists of a total and irreversible cessation of brain function. This is determined according to the Council by five criteria: loss of all response to the environment, complete disappearance of reflexes and loss of muscle tone, stopping of spontaneous respiration, an abrupt fall in arterial blood pressure, and an absolutely flat (isoelectric) electroencephalographic tracing which measures the brain waves. Of these tests, the first four are in a sense subjective, as they depend on the doctor’s interpretation; the last is objective and absolute, as it is made by a machine.

In a recent case in Israel, however, a fifteen year old boy, who had fallen into a deep cavern, appeared to be dead according to these five criteria. However, in view of his youth, the doctors went on battling for his life and kept him in a respirator and on drugs for two weeks. At the end of this time he recovered completely. As a result of this medical experience, Dr. Mordechai Shalit, one of the team of neurosurgeons attending the boy, has suggested a sixth criterion for death—measurement of the oxygen consumed by the brain. This can be done by administering an inert gas, such as nitrous oxide, to the patient in a state of coma, and then by drawing blood from the jugular vein. Oxygen readings will give the physician a picture of what activity, if any, is going on in the brain of the comatose patient. By the use of this procedure, Dr. Shalit submits that there can be absolute certainty that death has taken place, without having to wait for a long period of
time, during which vital organs may become unsuitable for transplant.

There are some experts desirous of establishing a definition of death based upon neurological criteria. The following guidelines have been suggested: (1) No reflexes, spontaneous breathing, or muscle activity; (2) No clinical or electroencephalographic response to noise or pinch; (3) Repetition of conditions one and two at twenty-four or forty-eight hour periods. Further, it must be demonstrated that the patient is not under the influence of hypothermia or anesthetic drugs capable of depressing the central nervous system.  

Perhaps the most publicized of all attempts to determine when death takes place is the report of the Ad Hoc Committee of the Harvard Medical School to examine the definition of brain death. The primary purpose of that report was to establish irreversible coma as a new criterion for death. Basically, the object was to define a permanently nonfunctioning brain, and four requirements were proposed: (1) nonreceptivity and unresponsiveness to externally applied stimuli and inner need; (2) no movement or breathing; (3) no reflexes; (4) a flat electroencephalograph reading. All four are to be repeated at least twenty-four hours later if no change was first indicated. The Harvard Committee further concluded that the decision that irreversible coma has occurred be made only by a physician. Before such a decision is reached, the physician in charge should, if possible, consult with one or more other physicians who had been on the case. But this decision should not be shared by a physician involved in later efforts to transplant organs or tissue from the deceased.  

Not in full accord with the completeness of the conclusions reached by the Harvard Ad Hoc Committee, an Ad Hoc Committee on Human Tissue Transplantation was formed in Pittsburgh, Pennsylvania in September of 1968 under the aegis of the Institute of Forensic Sciences at the Duquesne University School of Law. This was believed to be the first such local committee formed in the country and was composed of twenty members.  

9 Supra note 5.
10 Of the twenty members, fourteen were medical specialists (surgeons, internists, psychiatrists, neurologists, a pathologist, an anesthesiologist, the Allegheny County Coroner, and the President of the Allegheny Medical Association); three were theologians (one of whom also was an attorney); one was a County Judge, one a law school Dean, and one a County Bar Association President.
Historically, the determination of the time of death is the responsibility of the physician. There is no "legal" definition of death in the United States today, and all informed sources, including those of the religious community, concur that the determination of the time of death must remain a matter of medical judgment and knowledge.

The traditional means of determining death—absence of heartbeat, pulse and respiration—continue to be sufficient and adequate for most situations.

Two recent developments in modern medicine, however, have made it necessary to further evaluate the criteria for determining death: (1) the ability to maintain the circulation of oxygenated blood through tissues which may have been irreversibly injured, and (2) the use of cadaver organs for transplantation.

According to the Declaration of Sydney adopted by the Twenty-Second World Medical Assembly in August 1968, "... death is a gradual process at the cellular level with tissues varying in their ability to withstand deprivation of oxygen. But clinical interest lies not in the state of preservation of isolated cells but in the fate of a person. Here the point of death of the different cells and organs is not so important as the certainty that the process has become irreversible by whatever techniques of resuscitation that may be employed.

"Determination of the point of death of the person makes it ethically permissible to cease attempts at resuscitation and, in countries where the law permits, to remove organs from the cadaver provided that prevailing legal requirements of consent have been fulfilled."

It is estimated that more sophisticated criteria for determination of death are necessary in less than two per cent of terminal situations: those patients beyond hope of survival who are being maintained by supportive apparatus and drugs in intensive care units, and those also kept alive by supportive apparatus and drugs who are being considered as organ donors (after all legal and consent requirements have been met).

At the present time in Pennsylvania the consent for an organ transplant must be obtained from the next-of-kin. The Uniform Anatomical Gift Act, pending in the current session of the legislature, would spell out additional and more comprehensive avenues of consent.

Members of the Ad Hoc Committee are unanimous in their support of the UAGA, and have pledged to work toward its adoption by the legislature.

Another area of legal ramifications occurs in cases where the Coroner’s Office has assumed jurisdiction, or logically might be considered to assume jurisdiction, based on the circumstances of the case.

As ultimately defined by the Ad Hoc Committee after much deliberation, the "Determination of Death" is as follows:

I. Documentation of Death
   A. Lack of responsiveness to internal and external environment.
   B. Absence of spontaneous breathing movements for three minutes, in absence of hypocarbia and while breathing room air.
   C. No muscular movements with generalized flaccidity and no evidence of postural activity or shivering.
   D. Reflexes and Responses
      1. Pupils fixed and dilated, non-reactive to strong light stimuli.
      2. Corneal reflexes absent.
      3. Supraorbital or other pressure response absent (both pain response and decerebrate posturing).
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5. No reflex response to upper airway stimulation.
6. No reflex response to lower airway stimulation.
7. No ocular response to ice water stimulation of inner ear.
8. No deep tendon reflexes.
9. No superficial reflexes.
10. No plantar responses.

E. Falling arterial pressure without support by drugs or other means.
F. Isoelectric electroencephalogram (in absence of hypothermia, anesthetic agents and drug intoxication) recorded spontaneously and during auditory and tactile stimulation. Multiple recordings totalling at least thirty minutes, using a standard number of diagnostic electrodes with maximum allowable interelectrode distances. Part of recording at full gain. External artifacts and EKG ruled out by use of right hand electrode.

G. A note detailing these observations should be made in chart at time of first determination of irreversible coma.

II. Certification of Death
A. Criteria A through F should be present for at least two hours before death is certified.
B. Death should be certified and recorded in the patient’s chart by two physicians other than the physicians of a potential organ recipient.

This determination is submitted and recommended by the Ad Hoc Committee for the guidance and use of any physician with occasion to need criteria beyond the traditional cessation of vital signs.

The Committee believes that these criteria are realistic in light of today’s medical knowledge since no one has ever been reported to have regained consciousness and brain wave activity after one hour’s isoelectric EEG, with the noted exceptions of hypothermia, anesthetics, and certain central nervous system depressant drugs. However, medical science is changing so rapidly that these criteria may well be too rigid in a few years time.

The recommendations represent the consensus of medical, legal and theological representation on the Committee, including the belief that extraordinary measures to support life need not be continued indefinitely, and that there is a time when death should be unopposed.

It is the Committee’s hope that this “Determination of Death” will provide additional guidelines and standards of safety and caution for the physician and the patient in those situations where traditional criteria are inadequate.

It is suggested that the Pittsburgh Ad Hoc Committee’s criteria for determination of death is the most comprehensive of the various suggestions made thus far for the determination of death. It incorporates the Declaration of Sydney by name specifically; it takes into account the conclusions reached by the Ad Hoc Committee at Harvard; and it also touches upon virtually all of the individual suggestions that have been discussed above. It is further submitted that all of the problems suggested with relation to death in the introduction to this article can be solved adequately by a study of the report of the Pittsburgh Ad Hoc Committee. And it is finally submitted that statutory codification of the results of the Pittsburgh Ad Hoc Committee can result in the solu-
tion of a medical problem through legal means, whereby the medical community acting in good faith along the guidelines suggested can avoid virtually all criminal and civil liability for acts with respect to the determination of when death has occurred.

THE LEGAL PROBLEMS INVOLVED

In addition to the medico-legal problems surrounding the "time of death" which have been discussed in the preceding section, we must now turn our attention to the legal problems dealing with who can give away the various parts of a cadaver and in what manner is this desire to make anatomical gifts to be legally manifested?

Throughout the Commonwealth of England, there was a well recognized doctrine that there were no property rights in the body of a deceased person. The rule was that a person could not direct what was to become of his remains because the body, not being in the nature of property, was not includable in the decedent's estate. This rule found its way into American law, although there evolved various rights that allowed a decedent by will to direct the disposition of his remains for burial purposes, and/or to authorize autopsies. Those rights are now virtually commonplace in all American jurisdictions.

The question as to whether or not a person could direct that his remains be used for medical and scientific purposes evolved slowly, as is evidenced by the dearth of reported cases on this issue. In Re Johnston's Estate concerned a decedent who by codicil had donated her body for medical research. The New York Court upheld this bequest, but it should be noted that an existing New York statute specifically authorized such a gift and that the court was not faced with a contesting next of kin. A more recent case arose in New Hampshire where a decedent had directed that her remains be used for the purposes of experimentation in the interest of science. The surviving spouse and children objected to the nature of the bequest, and the court upheld their objections, but perhaps, only because both of the medical institutions to which the decedent bequeathed her body refused to accept it. Had either medical institution desired to accept the cadaver, the rights

of the surviving spouse and children to the body might not have prevailed over the claims of the institutions.

The question of whose wishes are to prevail, the decedent's or the next of kin's, comes to the fore. There are lines of decisions in both directions, and precedent in this area is not really clear-cut, but it appears that the courts will determine each case unto itself, looking only to the individual facts and circumstances in the particular case, and making their decision in a manner most equitable to the parties. Another anomaly in the picture is the legal duty imposed on the next of kin by statutes in most jurisdictions requiring that the next of kin provide a proper burial for the decedent. Thus, these statutory provisions seem to give weight to the proposition that those responsible for the burial of the decedent have some sort of right of disposal of the body for medical-scientific purposes. There are several states which specifically authorize a body donation by next of kin, while none specifically prohibit the next of kin from exercising this right.

Of the fifty separate sovereign jurisdictions within the United States, there is little uniformity of rules with respect to the methods and ways of disposition of dead bodies or parts thereof for medical purposes. Thirty states grant authority to any person of legal age and sound mind to donate all or part of his body, changing the common law in those states. Four of the remaining twenty states allow such donation but for the eyes only. Sixteen jurisdictions permit the next of kin to donate all or parts of their ancestor's body, while eighteen jurisdictions provide that the wishes of the testator shall outweigh the desires of the next of kin. In other words, if the decedent provides for a gift of his remains, and the next of kin objects, the gift will prevail. On the other hand, if the decedent directs a place and manner of burial, which would appear inconsistent with the idea of the donation of any of the parts of his body, and the next of kin desire to make such a gift, the decedent's wishes will prevail.

Fifteen jurisdictions have comprehensive provisions for donees specifying who such donees are to be, what the obligations of the donees are, and what is to be done with the remains afterwards. Thirty-three states make some sort of provision for the purposes for which donations can be made, but most of them are quite vague. Twenty-five jurisdictions allow these gifts to be made by will, but in many of these states the highly technical and procedural rules relating to the validity of wills and testamentary capacity are a hindrance and in many cases
serve to invalidate the gift. In thirty-eight states, however, the situation has been improved by allowing a gift to be made in written instruments other than a will, thus avoiding some of the legal technicalities that arise. Only three states allow a prospective donor to carry a card that will uphold the validity of such a gift, and only two states permit revocation which can be reasonably accomplished. Twenty-eight states provide that if the medical practitioners have acted in accordance with statutory rules, they cannot be civilly or criminally liable for their actions. Only one state builds a conflict of laws provision into its statute. And a conflicts question may often arise, particularly in the event that a resident of one state dies in another, and makes a gift to an institution in a third. Conflicts problems will cause needless uncertainty and probably invalidate a great many gifts. Finally, only two states have attempted to define what exactly is the time of death. Thus, the problems relating to time of death, as discussed in the preceding section of this article, are called greatly into play, but seem only to introduce an element of greater uncertainty into the situation.\textsuperscript{14}

Being acutely aware first of the problems created by the great numbers of organ transplants that have occurred in the last year and of the incongruity of applicable states' laws, the National Conference of Commissioners on Uniform State Laws promulgated the \textit{Uniform Anatomical Gift Act}, which was approved by the Conference on July 30, 1968. Efforts are now underway to have this Act adopted by all fifty jurisdictions within the United States.

The Act provides that any individual of sound mind over the age of eighteen may give all or any part of his body for any purposes specified in the Act, the gift to take effect upon death. This completely eliminates all of the common law rules and prohibitions dealing with property rights in dead bodies and realizes the common sense fact that the primary person to make a gift of his body is ultimately the decedent himself. The Act goes on to say that the wishes of the decedent shall be conclusive, but in the event of non-specification by the decedent, the following may give all or any part of the decedent's body for any purpose specified in the Act: (1) the spouse; (2) an adult son or daughter; (3) either parent; (4) an adult brother or sister; (5) a guardian of the person of the decedent at the time of his death; (6) any other person authorized or under obligation to dispose of the body. The Act

\textsuperscript{14} The legal statistics contained in the text may be found in Sadler & Sadler, \textit{Transplantation and the Law: The Need for Organized Sensitivity}, 57 Geo. L.J. 5 (1968).
further provides that the decision shall be made by the person who is in the lowest numbered class, and that the only opposition which will be recognized to such decision may come from a member of the same class, and that such opposition will prevent the donation from being achieved. In other words, if there is no spouse or adult son or daughter or parents left, an adult brother or sister can make the decision, and that decision will be binding and unimpeachable except by someone in the same class, to wit, another adult brother or sister. The Act further specifies that such a gift may be made by the person authorized immediately after death or immediately before the death of the decedent.

The Act goes on to distinguish exactly who may become donees and the purposes for which such gifts shall be made. Generally, these provisions are all encompassing, allowing gifts to virtually any hospital, surgeon or physician, or any specified individual. It is doubtful that any anatomical gift made will fail under the standards and provisions of this section of the Act. The Act allows a gift to be made by will which becomes effective upon the death of the decedent before any probate proceedings, and if the will should later be declared invalid but the gift was acted upon in good faith, it is nevertheless valid and effective.

It is also provided that a gift may be made by a document other than a will. One such document may be a card carried upon the person of the donor which has been signed by him in the presence of two witnesses who must also sign the card. If the donor cannot sign, the instrument may be signed at his direction and in his presence. It is not necessary that such a card be delivered during the donor's lifetime. A caveat is employed in this section of the Act which prohibits a physician who becomes a donee under the Act from participating in the procedures for removing or transplanting the heart or part of the body. A further liberalization allows a donor to make this gift by telegram or recorded telephone message.

The Act also provides for simple methods of revocation of the gift by the execution and delivery to the donee of a signed statement, or an oral statement made in the presence of two witnesses and communicated to the donee, or a statement made during a terminal illness to an attending physician and communicated to the donee, or a signed card or document found on his person or in his effects. Further, the donor can cancel or destroy or mutilate the document which originally
designated the gift, which act will serve as revocation of the gift. Also, any gift made by will may be revoked in the same manner in which wills are to be revoked, whether by new will, codicil, or other writing to the contrary.

An important provision of the Act provides that the time of death shall be determined by a physician who attends the donor at his death or, if none, the physician who certifies the death. This physician shall not participate in the procedures for removing or transplanting the part of the body. The Act further states that a person who acts in good faith in accord with the terms of this Act or under the anatomical gift laws of another state or foreign country will not be civilly or criminally liable for his actions. The last stated proposition is also a conflict of laws rule, providing that if an act is done in a state other than one which has adopted the Uniform Act and if the procedures were legal in the state where performed, they will be considered legal in an UAGA jurisdiction.

Generally, satisfaction is to be found in this Act, as it alleviates a great many of the new problems that currently exist. It is submitted, however, that the Commissioners should have taken greater steps in defining death, and opposition is taken to their statement that the decision requires the judgment of medical personnel in each instance and is not a matter for codification into law. It is hoped that as the reports of the various Ad Hoc Committees on determination of death are made known, such as that suggested by the Pittsburgh Ad Hoc Committee, such reports will be incorporated into the Uniform Act so that the goal of the Act, that is, complete uniformity, can be achieved. It is rather an anomaly to have complete and total uniformity in all items relating to organ transplantation, yet leave the most important facet, the definition of death, without some sort of legislative guidelines. This deficiency, however, should not be considered a barrier to the adoption of the Act, for it is better to resolve nineteen problems and leave one unsolved, than to attempt unsuccessfully to resolve twenty issues, and upon discovery that this cannot be feasibly accomplished, resolve none of them.

Medical technology will always move forward. Law, unfortunately, will always be a step behind. If the gap can be kept at one mere step, then the law will be valuable in the evolutionary process of technology. We must be careful not to create an insurmountable gap that will prohibit the medical profession from knowing where they legally stand as
new techniques are developed. The rapid adoption of the Uniform Anato-
mical Gift Act is a necessity for both law and medicine. Before medi-
cine takes another giant step forward as was done in December of 1967 in 
Capetown, it must know exactly where it stands at the present. In 
this respect, the law must move quickly in order not to hinder the 
growth of medical development and to be certain that opportunities for 
progress in medicine will not be abandoned for fear of legal ramifica-
tions. The law has the capacity to encourage or discourage procedures 
which may tend to save countless thousands of lives in the future, and 
it should act with due diligence upon this responsibility.