Medical Intelligence

Criteria for the Determination of Death

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Background

Two rapidly developing areas of medical knowledge are forcing a re-evaluation of ethical behavior in care of the dying. The first of these is the development of techniques for prolonged maintenance of ventilation, circulation, alimentation and excretion by artificial means, making possible the creation of a macabre situation in which the body lives while the brain is dead. The immense expense in terms of loss of human dignity, mental anguish of loved ones, financial costs and misappropriation of medical manpower and facilities is at once apparent.

The second area is the development of organ transplant techniques. Kidney transplantation is now an accepted procedure, and heart, liver and lung transplant may soon become common. By the end of 1971, 5,127 kidney transplants had been reported from 104 institutions in the United States.1 Use of cadaver donors has become increasingly common,2 and 604 cadaver kidneys were harvested during 1970 in 66 institutions in the United States and Canada.3 At present, 60 per cent of transplanted kidneys are harvested from cadaver donors, and it is expected that this ratio will continue.4 While procedures for collecting information about organ transplantation do not provide a detailed description of donor status, certainly many of these cadaver donors were patients having brain death without cessation of heartbeat. Thus, the patients mentioned above, with death of the brain and no hope for survival, have become a major source of organs for transplant patients.

after the harvest of organs is frequently the responsibility of the anesthesiologist, he must have full knowledge of the historic developments that have put him in such a position, and he must understand the criteria for determining death so that he need feel no moral compunction.

Since the final act of turning off the ventilator

The Definition of Death

The legal definition of death has evolved through the judicial process. Over many years, through court case precedent, it has become an element of common law. "Death is the cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc."

In March 1970, the state of Kansas enacted legislation establishing for the first time in history a statutory "definition of death." It states, "A person will be considered medically and legally dead if, in the opinion of a physician, based on ordinary standards of medical practice, there is the absence of spontaneous brain function; and if based on ordinary standards of medical practice, during reasonable attempts to either maintain or restore spontaneous circulatory or respiratory function in the absence of aforesaid brain function, it appears that further attempts at resuscitation or supportive maintenance will not succeed, . . death will have occurred at the time when these conditions first coincide. Death is to be pronounced before artificial means of supporting respiratory and circulatory functions are terminated and before any vital organ is removed for purposes of transplantation." In 1972 the state of Maryland enacted similar legislation, and bills are presently pending in Florida, Illinois and Wisconsin.7

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Criticisms of the Kansas and Maryland statutory "definitions of death" have centered on the fact that rules for determination of death involve important basic human rights and might well be ruled unconstitutional if seriously challenged in the courts. ^{7,8}

Many lawyers feel that gradual change within the framework of common law is a more desirable approach to the awesome problems raised by transplantation. However, in the one case to date in which a judicial reformulation of the "definition of death" has been requested, the judge refused. "Application for such a radical change in the law should be made not to the courts but to the legislature wherein the basic concepts of our society relating to the preservation and extension of life could be examined and, if necessary, re-evaluated."9

In practice, determination of death remains a matter of judgment on the part of the physician. This determination is generally accepted in law as a matter of fact, not requiring proof. ¹⁰ However, in many legal cases regarding rights of survivorship and inheritance the judicial definition of death specifying cessation of all vital functions including heart beat has been invoked. ^{5,6,10,11,12} Louisell and others ^{10,13} have expressed concern that the courts might deny the legality of a physician's judgmental determination of death not based upon "total cessation of vital functions."

Public opinion is uncertain. In one survey¹⁴ only 10 per cent of those interviewed thought of cerebral death as a certain index of status mori.

Criteria for Determination of Death by the Physician

Clearly, the determination of death will continue to be based upon the professional judgments of physicians. What appear to be challenged by recent technologic advances are the criteria or operational tests employed by physicians to identify death. Beecher believes that any statutory definition of criteria for the determination of death would be premature at this time and certain to present unacceptable limitation requiring revisions in the future. Yet, judgment must be based upon some criteria, however diffusely specified. It will be necessary for physicians to agree on some

recognized criteria for the pronouncement of death prior to cessation of heart beat.

In fact, a number of sets of diagnostic criteria for determination of death have been recommended. Most prominent of these in the United States is the 1968 report of the Harvard Medical School Ad Hoc Committee to Examine the Definition of Brain Death. ¹⁶ The following criteria were presented: 1) unreceptivity and unresponsiveness; 2) no movement or breathing; 3) no reflexes, usually including spinal reflexes; 4) electroencephalogram (EEG) isoelectric at gain of $5 \,\mu$ v/mm; 5) all of the above repeated after 24 hours; 6) the patient not to be hypothermic or under the influence of central nervous system depressants.

The Harvard criteria are based upon experience with terminally ill patients without consideration of organ transplantation. They evolved in answer to the basic question, "When may the ventilator be turned off?" There was no urgency to obtain viable organs. Thus a 24-hour delay for re-evaluation propounded no problem.

Other sets of diagnostic criteria have evolved from experience with problems of organ transplantation. The first of these, given by G.P.J. Alexandre of Belgium in 1966, included: 1) complete mydriasis; 2) complete absence of reflexes; 3) complete absence of spontaneous ventilation during five minutes without ventilatory support: 4) falling blood pressure necessitating increasing amounts of vasopressors; 5) flat electroencephalogram.17 Revilliard suggested two additional criteria: 1) interruption of blood flow to the brain as determined by angiography and 2) absence of tachycardia in response to atropine. For patients fulfilling these criteria, the French Surgical Society has introduced the term "coma de passé," literally, beyond coma.18

Criteria such as those of Alexandre and Revilliard generally omit the delay of 24 hours because some potential donors cannot be maintained for that period. 19-20 Craaford of Stockholm, 21 Ewing of Melbourne, 22 Hamburger of Paris 22 and Schuster of Mainz 24 have all reported criteria similar to those of Alexandre and Revilliard.

In 1968 the Institute of Forensic Sciences at the Duquesne University School of Law formed the Allegheny Ad Hoc Committee on Tissue Transplantation. In 1969 this group of clergymen, lawyers, and physicians formulated a protocol for the determination of death which requires 1) absence of all brain and spinal reflexes, 2) isoelectric EEG; 3) falling blood pressure without support of drugs or other means, and 4) all to have been present for at least two hours. Death is to be certified by two physicians other than the physician of a potential recipient.²⁵ The Allegheny Committee effectively combined the Harvard criteria with those of the transplant groups.

The 22nd World Medical Assembly adopted the Declaration of Sidney: a Statement on Death, in August 1968. "Death is a gradual process at a cellular level. The point of death of the different cells and organs is not so important as the certainty that the process has become irreversible this determination will be based on clinical judgment supplemented, if necessary, by a number of diagnostic aids of which the electroencephalograph is most helpful 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 in no way be immediately concerned with the performance of the transplantation."26

In June 1968 the A.M.A. House of Delegates approved a similar set of Ethical Guidelines for Organ Transplantation. "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. In making this determination, the ethical physician will use all available, currently accepted scientific tests."²⁷

In both the latter declarations, clinical judgment is stressed. Both would require determination of death by at least one physician with no vested interest in the transplantation. An essentially identical statement was presented in 1968 by the National Academy of Sciences Board of Medicine.²⁶

Most American surgeons initially were reluctant to consider organ harvest from the patient with cerebral death prior to cessation of heart beat. In 1968 Starzl stated that he had doubts whether his transplant group would remove organs under these conditions.²³ Jude expressed similar feelings at a symposium in Stockholm in 1968.²⁹ Moore felt that prior to

organ removal, there must be grossly evident damage of the brain together with usual electrical and neurologic signs.³⁰

However, the general trend in recent years has been to accept the fact of "coma de passé." Indeed, some transplant groups have abandoned attempted organ harvest after terminal circulatory arrest. The International Society of Transplantation has recently stated: "We recognize that the definition of death of an individual is that of brain death rather than cardiac death." 33

Objective Indices of Brain Death

ELECTROENCEPHALOGRAM

Since the electroencephalogram (EEG) records bioelectric potentials characteristically generated by a living brain, it should be helpful in determination of brain death. Use of the EEG as an aid in determining death was first suggested by Fishgold and Mathis in 1959.34 Dr. Hannibal Hamlin suggested in 196435 that "The electroencephalographer should promote the acceptance of his instrument and diagnostic skill for legal certification of status mori the sanctity of human life is not generated by cardiac signs." Rosoff and Schwab34 have reported their experience over a ten-year period including more than 100 cases. Their suggested criteria for EEG determination of cerebral death formed the basis of the Harvard Committee recommendations.

In 1970 the Ad Hoc Committee of the American Electroencephalographic Society on E.E.G. Criteria for the Determination of Cerebral Death described a retrospective study of 2,642 patients reported to have isoelectric EEG recordings. To Only three survived. Two had barbiturate-induced coma and one had coma due to overdose of meprobamate. In about a third of the reported incidences of electrocerebral silence surveyed, the EEG was a factor in determining death. Twenty-five of these cases involved organ transplantation. No medicolegal difficulty was encountered by any respondent.

The American Electroencephalographic Society Committee recommended stringent attention to technical details in EEG recording, as follows: A) a minimum of ten scalp electrodes and ear reference electrodes; B) interelectrode resistance less than 10,000 ohms; C) deliberate creation of electrode artifact by manipulation to test the apparatus and check connections; D) recording with an EKG and other monitoring devices to detect extracerebral potentials if necessary; E) use of the longest time constant of the instrument during part of the recording; F) gains increased during part of the recording from 7 μ v/mm to 3.5 μ v/mm and 2.5 μ v/mm; G) tests for reactivity; H) inclusion of ear referential runs and long-distance scalp-to-scalp linkages; 1) a 30-minute recording time.

The question of how long electrocerebral silence must persist prior to declaration of death was not finally answered; however, 24 hours was usually accepted. The EEG was only a single item of evidence in determining death and did not stand alone, and most respondents felt that determination of death was the responsibility of the attending physician. The committee emphasizes that "flat EEG" may not be electrocerebral silence. Absence of any potential greater than 2µv constitutes electrical silence. The EEG societies of France³⁷ and Holland³⁸ have criteria similar to those described by the American Society.

While these conclusions are generally supported in the literature,³⁹⁻⁴⁵ there have been reports of survival following isoelectric EEC's in drug overdosage^{36,43,46,47} and in patients having hydrocephalus.⁴⁵ Another group of patients has survived following isoelectric EEC's for various periods with catastrophic brain damage.^{53,48,49,50} One of these⁴⁸ survived two years as an akinetic mute and still had no EEC activity with gain at 1.5 μv/mm. Another⁵³ survived for 1 1/2 years in a vegetative state following attempted suicide by hanging.

There can be neocortical death without brainstem death. In this circumstance, the patient can maintain spontaneous respiration and have functioning cranial nerve reflexes. Two cases of prolonged (5 months) survival with flat EEG's and absence of evoked potentials exemplify this. ⁵¹ Corneal, pupillary and laryngeal reflexes were present and respirations were spontaneous. In each case autopsy examination revealed nearly total neocortical destruction.

There have been recent reports of brain death in the absence of electrocerebral silence.^{22,23,63,25} Two of these ^{10,19,22,32} described autorsy findings of brainstem necrosis.

The EEG thus provides some small amount of false-positive information as well as a considerable amount of false-negative information. Thus, other objective indices have been sought.

BRAINSTEM AND SPINAL REFLEXES

Near-total destruction of vital brainstem areas, as evidenced by absence of all cranial nerve reflexes including vestibular and carinal reflexes, tonic neck reflexes, and spinociliary reflexes, for longer than 12 hours, has been adopted by the group at the University of Minnesota as the major criterion for determining brain death. This criterion appears to measure potential for continued survival, and thus to be more demanding than the EEG.^{20,22,23}

INDICES OF CEREBRAL METABOLIC STATE

Walker and co-workers suggest that prolonged absence of cerebral metabolic activity indicates brain death. ³² Shalit⁵³ believes that a reduction of cerebral metabolic rate to a third of normal indicates brain death. Bes and co-workers ³⁷ found cerebral blood flow and cerebral metabolic rate reduced approximately 20 per cent in apoplectic coma and 90 per cent in "coma de passé."

OTHER INDICES OF BRAIN DEATH

Walkers2 has suggested measurement of the EEG by thalamic depth electrodes and brain biopsy as possible additional measurements. The list of tests that might be used could be expanded almost endlessly. The wisdom of the A.M.A. Ethical Guidelines for Organ Transplantation becomes clear27 . . . "the ethical physician will use all available currently accepted scientific tests. . . ."

Synthesis and Conclusions

Whatever criteria may be used to determine brain death, the chief determinant for cessation of therapy must clearly be a certainty of hopelessness. However elaborate the clinical tests involved in arriving at this determination of hopelessness may become, some element of human judgment must inevitably remain.

In our opinion, the most important criteria are those determining impossibility for independent survival apart from therapeutic heroism. These are not simply indices of cortical function. Rather, these are also indices of viability of vital brainstem centers whose function is essential to cardiovascular and respiratory independence. We cannot agree with Sir Peter Medawar that one must be able to "Rise up and litigate to be alive." ¹⁵

On the other hand, the condition of hopelessness which must be the final determinant in termination of therapy is not met simply because continued mechanical ventilatory support is needed or because pharmacologic cardiovascular support is required. This is exemplified by the poliomyelitis victim with bulbar damage.

It is clear, therefore, that complete criteria of death must define both neocortical and brainstem death. This would require an isoelectric EEG as defined by the American Society of Electroencephalography to determine neocortical death. The best available evidence 40,41,43,44 would indicate that persistence of an isoelectric EEG for six to 12 hours in the absence of drug overdosage or hypothermia is sufficient. Absence of spontaneous respiratory effort determined according to the Harvard criteria16 and absence of cranial nerve reflexes determined according to the Minnesota recommendations 19 appear to be adequate means of determining brainstem death

A decision to cease resuscitation efforts must be totally independent of any thought of harvesting of organs. Set Only when the physician primarily responsible for the patient's care has finally decided to cease therapy and to permit the completion of death processes can organ donation be considered.

In no instance will the anesthesiologist member of the transplantation team be

responsible for determining death. He must, however, in all cases be morally satisfied with the certainty of this determination. Furthermore, anesthesiologists involved in care of severely ill patients outside of the operating room may frequently be personally responsible for determining when heroic therapy should be terminated. In this setting, the recommendations here included should serve him well.

A committee of physicians at the University of Pennsylvania has developed the following set of recommendations for the determination of death in this hospital.

1. Consciousness

The patient is totally unresponsive to painful stimulation. In exceptional cases one or more limbs may withdraw in response to painful stimulation, or deep tendon reflexes may be present in the extremities as manifestations of an intact spinal cord. The decision whether such movements represent voluntary or reflex activity is made by the neurologist or neurosurgeon examining the patient. The patient does not have postural movements (decerebration, decortication) in response to stimulation.

2. Respirations

Cessation of all respiratory movements is demonstrated by removing the respirator for a minimum of 3 minutes. Arterial blood-gas measurements are made prior to removing the respirator to be certain that the patient is not hypocapnic. The patient who is subsequently determined to be an organ donor is maintained on the respirator until the organ is removed.

3. Brainstem Reflexes

The pupils are dilated and unresponsive to light stimulation, and the following reflexes are absent: corneal and lid reflexes, oculocephalic reflexes to head movement and caloric stimulation, and the pharyngeal reflex.

4. The Electroencephalogram

The EEG is recorded on two occasions, during a 24-hour period. Minimal techniques for recording include the following:

a. A minimum of 16 scalp electrodes and

ear reference electrodes

- Interelectrode resistance between 100 and 10,000 ohms
- c. Deliberate creation of electrode artifact by manipulation to test the apparatus and to check connections
- d. Two electrodes on the dorsum of the hand or a similar location on an extremity to detect extracerebral potentials due to muscular activity
- The use of the longest time constant of the instrument during part of the recording
- Gains increased progressively to a maximum gain which must be equal to or greater than 2.5 μv/mm
- g. Sound or pain stimulation to determine whether there is any effect on the EEG or heart rate.
- Electrode mountings] to include ear referential runs and long-distance scalp-to-scalp linkages.
- A 30-minute total recording time per session.

The Committee recommends the following additional procedures for management of the patient who is a potential organ donor:

- 1. The team of physicians responsible for the transplantation procedures will have no responsibility in establishing brain death.
- 2. The discussion with the patient's family regarding transplantation should be initiated by the physician primarily responsible for the patient's care. After this has been done, the surgeon who will carry out the transplantation should explain the procedures to the family. As a general rule, when the clinical criteria of brain death are present, prior to EEG confirmation, discussion of transplantation with the family can begin.
- 3. The final pronouncement of brain death must be made by a neurologist or neurosurgeon and one other physician responsible for the patient's care. They then sign a typed statement which becomes a permanent part of the patient's chart.

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