



Development of policies on brain death, care of the hopelessly ill, and do not resuscitate

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AMONG THE FIRST issues addressed by The Cleveland Clinic's Ethics Committee when it was established in 1984 was the importance of policies on brain death, care of the hopelessly ill, and resuscitation. The policies recently implemented (printed in their entirety in this issue of the *Cleveland Clinic Journal of Medicine*) do not fully reflect the exhaustive research and committee work that was necessary to generate concise yet workable guidelines for these aspects of patient care. The following background information summarizes some of this extensive effort and discusses the rationale for the three policies.

GROUNDWORK FOR THE ETHICS POLICIES

Besides reviewing and proposing ethical guidelines and policies, the Ethics Committee was charged with the goals of education and serving as a resource for ethics consultations on specific cases. So that new policies would further these goals, the Committee sought the opinions and perspective of many groups and individuals affected—from the Board of Governors to individual physicians, surgeons, and nurses. The Committee first appointed three subcommittees to review and propose specific institutional policies (Table 1). These subcommittees drafted the documents, entitled "Brain Death," "Do Not Resuscitate," and "Care of the Hopelessly Ill." After approval by the Ethics Committee, discussions were held with the patient care committees and the Divisions of Medicine, Surgery, Anesthesiology, and Nursing. Then, members of the physician and nursing staffs were surveyed for their comments and critiques of the policies.

BRAIN DEATH

Criteria for determining brain death

Of all the acts of physicians, a declaration of death has the most irreversible and profound consequences. Accuracy in diagnosis is of the utmost importance. The criteria that physicians use in determining that death has occurred should 1) eliminate errors in classifying a living individual as dead, 2) allow as few errors as possible in classifying a dead body as alive, 3) allow a determination of death to be made without unreasonable delay, 4) be adaptable to a variety of clinical situations, and 5) be explicit and accessible to verification.¹

The Uniform Determination of Death Act (UDDA), proposed in 1981, and its predecessor, the Uniform Brain Death Act of 1978, gave legal expression to a concept that had been developing over the previous 25 years.¹ There was a consensus that the traditional heart-lung standard for determining death was no longer adequate because circulation and respiration could be maintained by mechanical ventilators and other medical interventions despite a loss of all brain functions. It was recognized and accepted that an individual was dead whose loss of brain function was complete and irreversible. The UDDA stated: "An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brainstem, is dead. A determination of death must be made in accordance with accepted medical standards."

These guidelines for the Determination of Death stated that "the medical profession, based on carefully conducted research and extensive clinical experience,

TABLE 1
FORMATION AND COMPOSITION OF ETHICS COMMITTEE AND SUBCOMMITTEES

The Cleveland Clinic Foundation established an Ethics Committee May 23, 1984, by action of the Board of Governors, based on a proposal by James P. Orlowski, MD, George A. Kanoti, STD, and Shattuck W. Hartwell, MD.

Determination of Death Subcommittee: Michael J. Meehan, JD, Chairman; Lisa R. Rogers, DO; James P. Orlowski, MD

Do-Not-Resuscitate and Code Responses Subcommittee: George Kanoti, STD, Chairman; Brian Johnson, MD; A. Dale Gulledge, MD

Recommendation for Care and Obligations to Treat Aggressively Subcommittee: Alexander W. Kennedy, MD, Chairman; Susan M. Cancian, RN; Kathleen M. Lawry, LISW

Janicemarie K. Vinicky, MA, recording secretary

has found that death can be determined reliably by either cardiopulmonary or neurological criteria.”¹

Etiology

There are two ways in which the brain can selectively die in the absence of serious damage to other organs. One is by severe head trauma with direct and total destruction of the brain. A more common type of brain death begins with a cerebral insult that leads to a vicious cycle of cerebral edema and reduced cerebral perfusion, which mutually exacerbate each other until blood flow ceases. In the process, the brain becomes so swollen that it herniates from one cranial compartment into another or through the opening into the spinal canal, destroying itself in the process. This can happen selectively to the brain even after a systemic anoxic-ischemic insult, such as drowning or cardiac arrest, because the brain is the organ most sensitive to lack of blood flow or oxygen. If the insult is not so severe as to damage all the other organs irreparably, but severe enough to initiate this sequence of events in the brain, selective destruction of the brain can result.²

Ordinarily, as soon as the brainstem becomes affected, either directly from the initial insult or from the process of brain herniation, the person stops breathing. The resultant lack of oxygen leads quickly to cardiac arrest. However, if breathing is supported mechanically, the heart can continue beating on its own, despite total brain destruction. This condition is described as “brain death.” The remainder of the body’s cells can be kept alive for some time if ventilation, fluids, nutrition, and intensive nursing care are provided. The longest recorded time is 201 days.³ However, during this time, the dead brain tissue softens, liquefies, and eventually entirely disappears, leaving a bag of scar tissue full of watery fluid. Almost always, patients are disconnected from artificial life support long before this stage is

reached. “Respirator brain” is the pathological term used to describe the early stages of this liquefactive necrosis.²

Philosophical issues

As soon as brain death became a medical possibility with the widespread use of mechanical ventilators in the 1950s, it became a philosophical problem. Even the term “brain death” is ambiguous because it can be understood to mean either death of the brain in an otherwise live body or death of the person by virtue of death of that organ. State legislators have only confounded the situation by poor wording of brain death statutes that imply that brain death is mere legal fiction.² It is important to emphasize that brain death is true personal death (that is, the death of a person) and not merely a legal status. A person who is brain dead is dead, medically, legally, and philosophically.

The Guidelines for the Determination of Brain Death found in the Policy on Brain Death are intended to ensure that a patient who is still alive will not be misdiagnosed as brain dead. As such, the Guidelines are conservative and do not include recent diagnostic tests such as cerebral blood-flow studies, brainstem-evoked responses, and isotopic or Doppler flow studies, which have not stood the test of time and may not be readily available. However, cerebral blood-flow studies and brainstem-evoked responses can be important adjunct tests to confirm the diagnosis of brain death. The Guidelines also identify a number of clinical situations that can mimic brain death and need to be excluded before pronouncing a patient dead.

The Ethics Committee had originally considered requiring a neurology consultation for the diagnosis of brain death, but such a mandatory consultation was considered contrary to the practice patterns at The Cleveland Clinic. Nonetheless, the importance of the diagnosis mandates that the physician making the determination of brain death be familiar with the criteria and the tests for each of the requirements. Generally, critical care physicians, neurologists, or neurosurgeons are so qualified.

Diagnosis of brain death

The requirements for diagnosing brain death are relatively simple and straightforward. Only three criteria need to be fulfilled to make a diagnosis of brain death. The criteria enable an accurate determination of brain death to be made in as little as six hours and does not require an electroencephalogram (EEG). The Ethics Committee, however, recommended a confirmatory isoelectric EEG in situations when a patient is being

considered as a potential organ donor or when uncertainty exists. The three criteria for a clinical determination of brain death are: coma of established irreversible cause or exclusion of reversible causes of coma, absence of cerebral function, and absence of brainstem function.⁴

Determination of cause of coma. The first of these criteria requires either that the cause of coma be known and clearly irreversible, such as severe head trauma, brain tumor, intracerebral hemorrhage, or a gunshot wound to the brain, or that reversible causes of coma, such as drug intoxication, shock, or hypothermia, have been excluded in a patient who presents with coma of unknown etiology. In these cases, longer periods of observation, measured in days, may be required to establish irreversibility. However, in cases where the cause and irreversible nature of the coma are known, only repeated clinical assessments to confirm absence of cerebral and brainstem function over a period of six hours are needed to confirm a diagnosis of brain death and pronounce the patient dead.

Apnea testing. Apnea testing is one of the crucial steps in the assessment of brain death.^{5,6} Apnea testing evaluates the integrity of the respiratory centers in the brainstem. It is obviously important that the patient not have any residual neuromuscular blockade from paralysis agents (a check with a neuromuscular stimulator should be done if a question exists) or respiratory depressant medications that might interfere with the test results. The patient should not be significantly hypothermic (core temperature $<33^{\circ}\text{C}$), hypocarbic ($\text{PaCO}_2 <35\text{ mmHg}$) or metabolically alkalotic ($\text{pH} >7.50$) at the time of apnea testing. Arterial blood gas should be checked. The patient should be hyperoxygenated with $\text{FiO}_2 1.0$ for a minimum of 10 minutes prior to apnea testing to prevent hypoxic organ damage or cardiac arrhythmias during the test. The patient should then be removed from the ventilator and given apneic oxygenation with $\text{FiO}_2 1.0$ at 6–10 L/min flow. The patient is observed for any signs of repetitive respiratory effort and cardiovascular instability during 10 minutes of apnea.

If any repetitive respiratory movements or significant cardiovascular instability occurs during the test, the test should be terminated, arterial blood gas determined, and assisted ventilation re-established. At the end of the 10 minutes of apnea, arterial blood gas should be determined and mechanical ventilation resumed. Absence of function of the brainstem respiratory centers is confirmed by lack of respiratory efforts with an end-of-test $\text{PaCO}_2 \geq 60\text{ mmHg}$ and no significant alkalemia. In the case of significant cardiovascular instability where the test cannot be completed without the risk of injury to

potential organs for donation, the test can be performed by increasing the PaCO_2 to $>60\text{ mmHg}$ by reduced minute ventilation and documenting apnea for 30–60 seconds in the absence of significant metabolic alkalosis.

Conditions that can mimic brain death. It is also important that the clinician be familiar with conditions that can mimic brain death and that these be excluded before diagnosing brain death.^{4,7} Neuromuscular blocking drugs given during surgery, controlled mechanical ventilation, or resuscitation can cause absent motor activity, apparent coma, and apnea, all consistent with a diagnosis of brain death. In some patients, the effects of neuromuscular blocking agents can be prolonged. If doubt exists about persistence of neuromuscular blockade, testing with a nerve-muscle stimulator should be employed. Alternatively, an EEG would assess cerebral activity in the absence of motor activity and would prevent the inappropriate designation of brain death in a paralyzed patient. Sedative-hypnotic drugs in toxic levels and respiratory depressant drugs can also cause absent motor activity and apnea and are some of the important exclusions as a cause of coma.

Sedative-hypnotic drugs in toxic levels can produce an isoelectric EEG, adding further confusion in the diagnosis of brain death. An isoelectric EEG can also be produced by moderate to profound hypothermia with a core body temperature of $<33^{\circ}\text{C}$ and by shock or moderate to severe hypotension. These conditions must be excluded before a diagnosis of brain death is made.

Additional important causes of clinical signs mimicking absent brainstem function include effects of resuscitation drugs, such as atropine, epinephrine, and dopamine, causing fixed and dilated pupils and ototoxic or vestibular suppressant drugs causing the absence of oculovestibular reflexes. Pre-existing optic disease can cause fixed pupils, and pre-existing otic disease can cause absent cold-water caloric tests.

DO NOT RESUSCITATE

Cardiopulmonary resuscitation (CPR) is a unique therapeutic modality because it can be initiated without a physician's order when cardiac or respiratory arrest is recognized. In fact, not to initiate CPR requires a specific physician order. The do-not-resuscitate or DNR order refers to the suspension of the otherwise automatic initiation of CPR.

The routine application of CPR and Advanced Cardiac Life Support has given rise to serious questions regarding the appropriateness of resuscitating every patient who suffers an arrest.⁸ Nevertheless, in the ab-

sence of a properly executed DNR order, CPR must be initiated when indicated.⁹ This points up the need to discuss resuscitation status with patients who are terminally ill or likely to become so while they are still able to participate in the decision-making process. It is also appropriate to discuss resuscitation status with any patient at risk for sudden cardiac or respiratory arrest or, for that matter, any patient wishing to discuss DNR.

As stated in the policy, deceptive practices of pretending to resuscitate or only making an inadequate or partial attempt at resuscitation (commonly known as "slow" codes or "walk, don't run" codes) are unacceptable, even if the futility of the endeavor is obvious to all involved.¹⁰ A licensed physician can terminate CPR if he or she is the physician responsible for the resuscitation of the patient and determines that CPR attempts are futile.⁹ Limited CPR decisions, such as no cardiac massage, defibrillation only, or no administration of resuscitation drugs, are appropriate when agreed to in advance by patient and physician or the physician in consultation with an appropriate surrogate in the case of a comatose or incompetent patient.¹¹

DNR orders are compatible with maximal and even aggressive therapeutic care. They do not require that the patient be terminally ill or dying.¹² DNR status should be part of the discussion of treatment options and care plans with any patient with a terminal illness or any patient at risk for sudden cardiac or respiratory arrest. As stated in the policy, DNR addresses only one aspect of limiting life support and should be a springboard for discussing other medical interventions, such as intensive care, antibiotics, dialysis, pain medication, nutrition, and hydration, especially with terminally ill patients who are capable of considering these other options.

The decision makers in any discussion of DNR are the patient and his or her physician.^{13,14} In the event that the patient is comatose or incompetent, an appropriate family member or surrogate could substitute judgment for the patient.^{15,16} Important aspects of the DNR order that are specifically addressed in the guidelines include

communication of the DNR order, frequent reassessment of the appropriateness of the order, and responsibility for ongoing care of the patient.

CARE OF THE HOPELESSLY ILL

Although Cleveland Clinic policies regarding resuscitation and brain death existed prior to the formation of the Ethics Committee, there was no formal policy on the care of the hopelessly ill. A designation of "terminal care" had existed previously and was meant to convey the provision of comfort and nursing care only. Terminal care had been replaced by the DNR policy with the understanding that discussion with and concurrence of the patient or family were required, whereas terminal care had largely been a physician-only decision.

Levels of care

The policy statement on care of the hopelessly ill uses many of the concepts and procedures found in an article by Wanzer et al,¹⁷ which was formulated under the auspices of the Society for the Right to Die, entitled "The Physician's Responsibility Toward Hopelessly Ill Patients." Central to this policy is the delineation of four levels of care to be addressed and decided with each hopelessly ill patient: emergency resuscitation, advanced life support, general medical care, and supportive care. Relief of pain and suffering is also a primary consideration in the care of hopelessly ill patients, and the policy emphasizes this facet.

Importance is placed on early recognition of serious or irreversible illness so as to discuss treatment options and communicate openly with the patient, who is the person affected most directly by the prognosis and who has the primary right to participate in future treatment decisions. Early and open discussions between patient and physician avoid many ethical dilemmas and conflicts that can arise when the patient is too ill to capably participate in care decisions and the patient's wishes are unknown.¹⁸

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Policy statements: do not resuscitate, care of the hopelessly ill, and brain death

DO NOT RESUSCITATE

The Ethics Committee recognizes the diversity of patients, illnesses and therapies at The Cleveland Clinic Foundation. This diversity requires that recommendations on the Do Not Resuscitate (DNR) order be adaptable to specific circumstances. However, some issues remain constant. These constants are: the definition of DNR, both the identity of the participants in DNR decision making and the process by which a DNR order should be made, communication of the DNR decision, and reassessment of the DNR order.

A survey of The Cleveland Clinic Foundation's Patient Care Committees indicates that the DNR order may not be uniformly interpreted. The Ethics Committee's definition of DNR is "no cardiopulmonary resuscitation" (CPR). However, the options in treating a terminally ill patient are broader than CPR and also may include intensive care, antibiotic therapy, hydration and nutritional support. Therefore, discussions concerning DNR orders should include discussion of other life support systems.

THE DNR ORDER

Definitions

"Resuscitation" means a standard cardiopulmonary resuscitation procedure (CPR) with full cardiac, pharmacologic and respiratory intervention when cardiopulmonary arrest occurs. "Do Not Resuscitate" (DNR)

means no resuscitation is to be done when cardiopulmonary arrest occurs. "Slow codes," and "walk, don't run" codes are not acceptable.

Participants and process

Although the DNR order may be given only by a licensed physician, a generally accepted ethical principle acknowledges the primacy of patient autonomy. Generally speaking the person most affected by the health care decision is the patient. Ideally, the physician sensitively should discuss the DNR option with the patient and family while the patient is competent. However, not infrequently the DNR order will be considered for comatose or mentally incompetent patients with whom this discussion has not or cannot occur. In these cases, DNR should be discussed with a surrogate. A surrogate may be selected by a patient or by a patient's advanced directives such as a "living will." (Since "living will" legislation has not been enacted in Ohio, physicians who wish to follow "advanced directives" such as "living wills" do so voluntarily. The patient's medical care should be based on the physician's medical judgments as influenced by the patient's previously expressed wishes.) Frequently, a surrogate has a close relationship to the patient. In all cases, the primary physician should discuss the DNR order with the patient if possible, and the surrogate(s) if appropriate.

Communication of such decisions

The DNR order *along with the specifications and limitations of therapy* must be given by the "primary physician"