Role of brain death and the dead-donor rule in the ethics of organ transplantation

Robert D. Truog, MD, FCCM; Walter M. Robinson, MD, MPH

The “dead-donor rule” requires patients to be declared dead before the removal of life-sustaining organs for transplantation. The concept of brain death was developed, in part, to allow patients with devastating neurologic injury to be declared dead before the occurrence of cardiopulmonary arrest. Brain death is essential to current practices of organ retrieval because it legitimates organ removal from bodies that continue to have circulation and respiration, thereby avoiding ischemic injury to the organs. The concept of brain death has long been recognized, however, to be plagued with serious inconsistencies and contradictions. Indeed, the concept fails to correspond to any coherent biological or philosophical understanding of death. We review the evidence and arguments that expose these problems and present an alternative ethical framework to guide the procurement of transplantable organs. This alternative is based not on brain death and the dead-donor rule, but on the ethical principles of nonmaleficence (the duty not to harm, or primum non nocere) and respect for persons. We propose that individuals who desire to donate their organs and who are either neurologically devastated or imminently dying should be allowed to donate their organs, without first being declared dead. Advantages of this approach are that (unlike the dead-donor rule) it focuses on the most salient ethical issues at stake, and (unlike the concept of brain death) it avoids conceptual confusion and inconsistencies. Finally, we point out parallel developments, both domestically and abroad, that reflect both implicit and explicit support for our proposal.

Key Words: brain death; transplantation; organ procurement; medical ethics; persistent vegetative state; anencephaly

The practice of organ transplantation has been wedded to the concept of brain death for most of its history. The bond between them has been the “dead-donor rule,” which requires that patients be declared dead before the removal of any life-sustaining organs (such as the heart, the entire liver, or both kidneys) (1). Yet the declaration of death, necessary for application of the dead-donor rule, has recently been described as an issue that is “at once well settled and persistently unresolved” (2).

The “well settled” aspect is reflected in the enormously successful and largely uncontroversial organ transplantation programs that recover organs from brain-dead patients and save the lives of those dying from organ failure on a daily basis. The “persistently unresolved” features pertain to nagging concerns that the concept of brain death is incoherent in that it fails to correspond to any biological or philosophical understanding of death.

Were no alternatives available, we believe a rational utilitarian argument could be made for ignoring these persistently unresolved issues in the interests of preserving the transplantation enterprise. We believe, however, that the ethical foundations of organ recovery need not rest on the problematic determination of death. We instead propose that the ethics of organ donation be based on the ethical principles of nonmaleficence and respect for persons rather than on brain death and the dead-donor rule. These provide a straightforward, ethically transparent, and potentially practical method for guiding the practices surrounding organ donation.

The dead-donor rule depends on a coherent definition of death, yet that definition has proved elusive. Before the development of mechanical ventilation and modern intensive care, the definition of death was relatively straightforward—patients were dead when they ceased to have evidence of circulation, respiration, and neurologic functioning (3). Typically, all three of these functions are lost over a very short period of time, with the loss of any one of them quickly leading to the loss of the other two. With the development of mechanical ventilation and cardiac support devices, however, it became possible to have the continuation of respiration and circulation in the absence of any detectable neurologic functioning. Although patients in this state are comatose (unreceptive and unresponsive), they retain most of the characteristics of living beings (Table 1); there is even a spirited debate among anesthesiologists about whether they should receive anesthesia for organ procurement procedures (4–7).

Development of the ability to sustain patients in this state has had two important consequences—it has created the possibility of procuring transplantable organs from patients while the organs are still being perfused by a beating heart, and it has made the question “when is a person dead?” much more complicated.

In an attempt to bring clarity to these issues, in 1981 a presidential commission articulated the Uniform Determination of Death Act, which states that “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 brain stem, is dead” (8, 9). This standard, or closely related variants, has become the accepted standard for determining death and suitability for organ donation throughout the United States and much of the world (10).
temporarily, the body is no longer within a short period of time, and this cardiac arrest is taken to be a manifestation of the body's disintegration.

The problem with this justification is that, even if it was once true, it clearly is no longer true. Admittedly, most patients diagnosed as brain dead do experience an imminent cardiac arrest, but this is because almost all either become organ donors or have life-support withdrawn. Imminent death for these patients thus become a self-fulfilling prophecy. But, as Shewmon (24) has clearly shown, if brain-dead patients are provided with life-support through the acute phase of their neurologic deterioration, cardiac arrest is now neither necessarily imminent nor certain. At the extreme, Shewmon has carefully documented prolonged somatic "survival" for >14 yrs in a patient with a clearly established diagnosis of brain death. These counterexamples indicate that even if a certain level of neurologic function is necessary to maintain the functioning of the organism as a whole, then brain-dead patients are not necessarily below that threshold. Indeed, the notion that complex systems require centralized organization is itself suspect—trees and other plants are but some examples of complex life forms that lack any type of brain or central organizer (25).

Furthermore, the uncertainty inherent in the diagnosis of death is fundamentally distinct from uncertainty related to other diagnoses. For all medical diagnoses except death, we believe that greater scientific knowledge will bring increasing clarity about how to make the diagnoses with ever higher levels of precision. In the case of death, however, our uncertainty is not related to the state of our scientific knowledge, but rather to different and incompatible understandings about the meaning of death. As noted above, a wide range of definitions of death have been proposed, from the permanent loss of consciousness to the loss of circulation and respiration, and each has its strengths and weaknesses depending on the medical and social context. But it is clear that we will never be able to choose between these on the basis of scientific knowledge alone.

The nature of this uncertainty means that the moment of death cannot be discovered by any scientific or logical pro-

Table 1. Comparison of living persons, brain-dead patients, and heart-dead patients in terms of features associated with living person

<table>
<thead>
<tr>
<th>Features of Living Persons</th>
<th>Living Patients</th>
<th>Brain-Dead Patients</th>
<th>Heart-Dead Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart-beating, warm, well perfused</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Breathing</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Functioning vital organs (liver, kidneys)</td>
<td>Yes</td>
<td>Yes, with ventilator</td>
<td>No</td>
</tr>
<tr>
<td>Capable of somatic growth and development</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Capable of reproducing (24)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Capacity for consciousness</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*With ventilator. Some might argue that it is the capacity to breathe spontaneously that is associated with life, yet quadriplegic patients are not regarded as any less "alive" just because their breathing is not spontaneous.

Out of these developments, brain death was created as a new medical diagnosis. But what reasons are there for believing that the constellation of clinical findings that constitutes brain death actually represents the death of the individual? Although the notion that we are dead when our brains are dead may seem almost intuitively obvious, the conclusion turns out to be surprisingly problematic when examined more closely.

To begin with, even firm supporters of the concept of whole-brain death now acknowledge that many patients currently diagnosed as brain dead do not in fact have (as required by the Uniform Determination of Death Act) "irreversible cessation of all functions of the entire brain." It is widely recognized, for example, that many of these patients retain function of the posterior pituitary and other brain functions (11–14). Although acknowledging that the concept of whole-brain death is only "an approximation" (15), supporters have insisted that these residual functions can be ignored because they are not significant. However, this begs the question of which physiologic responses are to be considered "significant": it is hard to understand why we place great emphasis on the pupillary responses are to be considered "significant"; it is hard to understand why we place great emphasis on the pupillary

One of the early reasons used to defend this particular set of clinical findings as diagnostic of death was the belief that patients with these findings inevitably had a cardiac arrest within a short period of time (usually within 1 or 2 wks), regardless of the intensity of life support that they received (16, 17). The inevitability of an imminent cardiac arrest was taken as evidence that these patients were already dead. The logical problem with this rationale is obvious—it confuses the fact that a person is dying with the claim that he or she is already dead; that is, it confuses a prognosis with a diagnosis.

Another popular justification for assuming that brain-dead patients are dead is based on the fact that these patients have become permanently unconscious. Indeed, this is true—there are no documented instances of a patient who met the criteria for brain death who ever regained any degree of consciousness (18). The problem with this rationale is not with the claim itself but with the implications that arise from this claim. Patients who are in a permanent vegetative state are also widely believed to be permanently unconscious, yet they differ from brain-dead patients in that many of them breathe adequately on their own and survive for many years, being fed through a gastrostomy tube and receiving basic nursing care (19, 20). If brain-dead patients are dead because they are permanently unconscious, then patients in a permanent vegetative state must also be dead. This conclusion is logically unavoidable, given the premise. However, the fact that few would be willing to treat these individuals as if they were dead (for example, by burying them) indicates that being permanently unconscious is not by itself a sufficient criterion for regarding a person as dead.

The most compelling justification for regarding brain-dead patients as being dead is based on the idea that death is the loss of the functioning of the organism "as a whole" (15, 21–23). The argument here is that the brain is the central organizer for the body and that when the brain can no longer provide the necessary organizational influence, the body is no longer able to oppose the entropic forces favoring disintegration. This rationale emerges from the observation noted above, that patients diagnosed as brain dead usually experience a cardiac arrest within a short period of time, and this cardiac arrest is taken to be a manifestation of the body's disintegration.

The problem with this justification is that, even if it was once true, it clearly is no longer true. Admittedly, most patients diagnosed as brain dead do experience an imminent cardiac arrest, but this is because almost all either become organ donors or have life-support withdrawn. Imminent death for these patients has thus become a self-fulfilling prophecy. But, as Shewmon (24) has clearly shown, if brain-dead patients are provided with life-support through the acute phase of their neurologic deterioration, cardiac arrest is not necessarily imminent nor certain. At the extreme, Shewmon has carefully documented prolonged somatic "survival" for >14 yrs in a patient with a clearly established diagnosis of brain death. These counterexamples indicate that even if a certain level of neurologic function is necessary to maintain the functioning of the organism as a whole, then brain-dead patients are not necessarily below that threshold. Indeed, the notion that complex systems require centralized organization is itself suspect—trees and other plants are but some examples of complex life forms that lack any type of brain or central organizer (25).

Furthermore, the uncertainty inherent in the diagnosis of death is fundamentally distinct from uncertainty related to other diagnoses. For all medical diagnoses except death, we believe that greater scientific knowledge will bring increasing clarity about how to make the diagnoses with ever higher levels of precision. In the case of death, however, our uncertainty is not related to the state of our scientific knowledge, but rather to different and incompatible understandings about the meaning of death. As noted above, a wide range of definitions of death have been proposed, from the permanent loss of consciousness to the loss of circulation and respiration, and each has its strengths and weaknesses depending on the medical and social context. But it is clear that we will never be able to choose between these on the basis of scientific knowledge alone.

The nature of this uncertainty means that the moment of death cannot be discovered by any scientific or logical pro-
cess but must be chosen by societal consensus. The constellation of signs and symptoms that constitute brain death are clearly diagnostic of severe and irreversible brain injury but diagnostic of death only by stipulation (26).

This insight has an important implication for the neurologic literature on brain death. Literally hundreds of articles have attempted to establish the usefulness of ancillary tests to confirm or rule out the diagnosis of brain death (18, 27). However, in the absence of a gold standard about what constitutes brain death, we do not know what condition or state these ancillary tests are designed to confirm. Are they seeking to confirm 1) the complete absence of brain function, 2) a uniformly fatal prognostic, 3) the absence of consciousness, or 4) something else? Indeed, the lack of clarity on this point raises the question of whether this entire literature on confirmatory testing for brain death is incoherent.

The status of brain death is, in this sense, not dissimilar from the status of “legally blind.” Both represent a point on a continuum of organ dysfunction (of the brain and of the eyes, respectively). By social convention, however, both signify a threshold with important medical, legal, and social implications. Patients who are legally blind are treated as if they are blind (even if they retain some rudimentary sight), and patients who are brain dead are treated as if they are dead (even if they retain some neurologic functioning and other characteristics of the living).

Most of the arguments advanced above have been articulated by others over the past several decades and, to our knowledge, have never been successfully refuted (12, 13, 28–32). Although they have not seriously undermined acceptance of the concept of brain death, this acceptance has nevertheless been described as representing only a “superficial and fragile consensus” (33). Indeed, some have worried that open discussion of this critique could jeopardize the important and successful program of organ procurement and transplantation, especially given the prominent role that the dead-donor rule has played in regulating the ethics of this practice (34). Such might be the case if we concluded on the basis of this critique that our practices of organ donation have been ethically flawed and that the incoherence of the concept of brain death means that our practices must be reconsidered or even suspended.

We would emphatically argue, however, that this is not the case and that our approach to organ procurement is entirely ethical—but for reasons that are radically different from those that are traditionally given.

The foundations of the ethics of the organ transplantation are the twin principles of respect for persons and nonmaleficence (the duty not to harm, or primum non nocere). As presently understood, respect for persons is operationalized through obtaining informed consent, and the duty not to harm is honored through the dead-donor rule. The concept of brain death was explicitly developed so that organs could be removed from heart-beating donors without violating the dead-donor rule.

As an alternative, we propose that sometimes the harm of dying is sufficiently small that patients should be allowed to voluntarily accept that harm if it makes organ donation possible. Using this approach, organ donation could occur in full accord with the principles of respect for persons and nonmaleficence, but without reliance on the dead-donor rule. We believe this is a more straightforward approach, because it focuses directly on the questions of harm and consent rather than focusing on the indirect question of whether a patient is dead.

Under what circumstances might the harm of dying be sufficiently small that patients could be allowed to accept this harm to donate organs? Clearly, some threshold must be set. No healthy person should be allowed to make a suicidal donation of vital organs, even if such a person were fully competent and highly motivated to save the life of a loved one. Even less extreme donations should not be permitted, such as donation of a kidney from an individual with only one kidney, even if that individual willingly accepted the consequence of chronic hemodialysis.

Nevertheless, in some circumstances we believe that the harm of dying is sufficiently small that patients or surrogates should be allowed to voluntarily accept it to be able to donate organs. For example, some might say that if they were ever diagnosed as being permanently unconscious they would accept the harm of dying if this would make it possible for them to donate their organs to others. Similarly, some patients who are imminently dying might be willing to have their life shortened by a few minutes or hours if this would make organ donation possible. Society would have to determine, through the process of public deliberation and legislation, whether “permanent unconsciousness” and “imminently dying” define thresholds sufficiently low that patients should be allowed to accept the harm of dying to make it possible for them to donate organs.

Even if society made such donations legal, this approach would respect the fact that not all patients or surrogates would choose to donate under these circumstances. These patients and surrogates would be fully empowered to refuse, just as our current system respects the rights of brain-dead patients and their surrogates to refuse to donate. But it also recognizes that many would see the opportunity to donate vital organs as an important benefit when either continued life in a state of unconsciousness or only a brief postponement of death is not deemed to be of commensurate value.

At a practical level, the clinical states of “permanently unconscious” and “imminently dying” would need to be specifically defined. The Multi-Society Task Force on PVS (persistent vegetative state) defined diagnostic criteria for persistent and permanent vegetative state and articulated several lines of evidence in support of the claim that these patients are unconscious. These have been challenged, however, by reports of a few patients who seem to have fulfilled the criteria of the Task Force yet who have regained some degree of consciousness (35). Similarly, although anencephalic infants are also widely perceived as permanently unconscious, some have argued that even the rudimentary brainstem present in anencephalic infants may be capable of a minimal degree of consciousness (36). This is in contrast to patients who meet diagnostic criteria for brain death, in which there has never been a report of recovery of consciousness and in which there is less controversy about whether these patients have any capacity for consciousness (18).

Although our view would be that patients who meet brain death criteria should therefore be considered to be permanently unconscious and allowed to donate vital organs, we are silent on whether this opportunity to donate should be extended to patients in the permanent vegetative state or newborns with anencephaly. Given the controversy, perhaps it would be prudent to use the more conservative standard defined by brain death criteria until medical research can provide greater certainty.
about the capacity for consciousness in patients with these conditions.

The category of “imminently dying” would also need to be defined for practical use. Here again, prudence would recommend a conservative approach, limiting this category to those patients completely dependent on life support, in whom death would be expected within minutes of withdrawal of that support, and in whom no treatment alternatives are available or desired. This category would therefore include, for example, patients with cervical quadriplegia who desired withdrawal of mechanical ventilation or patients on cardiac support devices who refused continuation of that support or other treatment alternatives. These are similar to the standards that are currently used to identify candidates for non–heart-beating organ donation. Patients in this category would more often be able to make the decision about donation themselves, removing any concerns about the legitimacy of surrogate decision making in cases like this.

The principle of respect for persons also requires recognition that patients and families are not the only moral agents with a stake in this process. Both society and the medical profession have legitimate claims in determining who will be allowed to be an organ donor. Clearly, patients who are otherwise healthy cannot be allowed to become organ donors as a means to committing suicide. For this reason, we have narrowly defined the categories of patients who may be organ donors. Both medical professionals and society should refuse to allow donation from patients who do not fall into one of these categories. In particular, our proposal would recognize a large gap between the category of patients permitted to have withdrawal of life support and the category of patients permitted to donate organs. American law gives patients the virtually unlimited right to refuse medical treatments, regardless of their clinical condition. Therefore, many patients would have the right to die through refusal of life-sustaining treatment while not being in a category that would permit the option of organ donation.

Proposals similar to ours have been suggested by others over the years (37–41). All involve shifting the key ethical question from “Is the patient dead?” to “Are the harms of removing life-sustaining organs sufficiently small that patients or surrogates should be allowed to consent to donation?” Although this change would have many important consequences, it would not cast doubt on the ethics of current practices of organ procurement from patients who meet brain death criteria. These practices are clearly ethical—not because the patients are dead, but rather because they have been rendered permanently unconscious from an overwhelming brain injury.

Recognizing that the central ethical commitments of organ donation are respect for persons and nonmaleficence would bring greater clarity and consistency to many facets of the organ procurement enterprise. A single ethical standard could then be applied to both “living” donations and to what we currently regard as cadaveric donations (42). When a living individual wants to donate a kidney to a relative, it is ethically necessary, but not sufficient, for them to give their consent. These patients undergo a thorough evaluation, and if it is determined that making the donation would put the donor at substantial risk (such as if the potential donor was at high risk from anesthesia), he or she is not allowed to donate. In these situations, the principle of nonmaleficence is given greater weight than the individual’s autonomous right to take risks on behalf of another. Just as we now determine when the risk of harm is too great to permit living donations, under our proposal we would decide the conditions (in terms of immence of death or degree of neurologic impairment) when the risk of harm would be minimal enough to justify allowing the donation of life-sustaining organs.

Non–heart-beating organ donation is another practice that has been muddled by the dead-donor rule. These protocols have been rapidly gaining in popularity, especially after their qualified endorsement by the Institute of Medicine (43, 44). As with our proposal, protocols for non–heart-beating organ donation address not only patients who are neurologically devastated but also those who are imminently dying. Because patients eligible for these protocols are dependent on life support but not brain dead, they are unable to donate life-sustaining organs. To comply with the dead-donor rule, therefore, these patients must undergo an orchestrated withdrawal of life support, often in the operating room, with the swift removal of the transplantable organs within 2-5 mins of the patient’s cardiac arrest (depending on the protocol).

The orchestrated death in these protocols would be unnecessary if, in abandoning the dead-donor rule, we asked whether the patient is sufficiently close to death or sufficiently neurologically impaired to justify their being a candidate for the protocol. If the answer to this question is yes, then one must ask whether it makes any sense to “make them dead” before the removal of their organs, especially because hearts and lungs are often not viable after the patient has had a cardiac arrest and because even other organs may be jeopardized by the ischemic time that is unavoidable in these protocols. Again, if the patient’s condition is such that the procurement of life-sustaining organs can be seen as a justifiable goal in itself, then why not—at the request of the patient or surrogate—remove the organs in the operating room under anesthesia and optimize both the number and the viability of the organs obtained?

Our proposal offers important safeguards not found in non–heart-beating organ donor protocols. The typical candidate for non–heart-beating organ donor is a patient who has severe brain injury and is ventilator dependent. Even though the justification for withdrawal of the ventilator in this case is usually the brain injury, the severity of brain injury that is necessary to be a candidate for the protocol is completely undefined. All that is necessary is that the patient be expected to expire quickly from respiratory failure after the withdrawal of mechanical ventilation. This respiratory failure could be due to the brain injury, to pulmonary injury, or to a combination of the two. Although we do not doubt that patients who donate organs through non–heart-beating organ donor protocols generally have severe brain injury, the criteria that would be used in our proposal have the advantage of specifying the degree of brain injury that is necessary to be a candidate for organ donation.

Recent debates in the United States and abroad have also suffered from emphasis on the dead-donor rule in thinking about the ethics of organ procurement. Several years ago, the Council on Ethical and Judicial Affairs of the American Medical Association concluded that “It is ethically permissible to consider the anencephalic as a potential organ donor, although still alive under the current definition of death,” if, among other require-
m ents, the diagnosis is certain and the parents give their permission (45). This conclusion was grounded in the Council’s judgment that organ procurement from anencephalic newborns would not be an unacceptable harm to the infants because of their extreme degree of neurologic impairment. The Council eventually reversed its view, at least in part because it was not compatible with the dead-donor rule (46).

Both the Japanese (47) and the Germans (48) have been slow to accept organ transplantation, in part because of a general unwillingness to accept that brain-dead patients are really dead. To enable the development of organ transplantation, the Japanese government recently adopted a compromise position, which essentially states that patients who meet brain death criteria may be declared dead, but only for purposes of transplantation. In this case, brain death is defined operationally, and this allows patients who want to be organ donors to be classified as dead so that organ procurement can proceed in compliance with the dead-donor rule. Here again, the dead-donor rule is serving only to obfuscate the central ethical issue, which is whether a patient who desires to donate would be unacceptably harmed by the removal of life-sustaining organs.

Transplant clinicians and the public may well object to reframing the ethical foundations of organ procurement in the way that we have proposed because if patients are not declared dead before organ procurement, then it seems there is no choice but to conclude that the patients are being killed by their doctors. Examination of the lay press would indicate that this is of much greater concern to transplant clinicians than it is to the public. Many journalistic accounts of situations involving brain death include language similar to this quote from the New York Times: “The brain dead are candidates for a donation, but the operation generally must be performed before death” (49), or this quote from the Boston Globe: “(the patient) was being kept alive so... doctors could harvest his organs for donation” (50). The frequency of this mistake in newspapers and magazines, and the lack of outraged response from the public, might indicate that the public is fundamentally confused about whether patients are declared dead before transplantable organs are procured. It is an unknown empirical question whether patients and families would be as willing to give permission for organ retrieval on the basis that the patient is in an irretrievable coma as they are on the belief that the patient is dead, but these suggestions from the lay press indicate that the question has yet to be settled.

The concern of clinicians is understandable, but may also deserve reexamination. Clinicians increasingly struggle with the emotional weight of the moral agency that they must bring to life-and-death decisions. Only a few decades ago, physicians argued strenuously that withdrawal of mechanical ventilation from a woman in a permanent vegetative state was unethical because it would mean that the physicians had killed her (52). Today, the majority of deaths that occur in intensive care units follow the withholding or withdrawing of some life-sustaining treatment, often the withdrawal of mechanical ventilation (53). The point is that physicians must often take actions that result in the imminent deaths of patients and that what was seen as unethical just a few years ago is today not only acceptable, but even ethically required. When physicians remove patients from a ventilator at the end of a terminal illness, we do not say (either descriptively or normatively) that they killed the patient; the cause of the patient’s death is attributed to the underlying disease. Parallel reasoning would apply to patients who choose to donate their organs as part of the dying process. In both ventilation withdrawal and organ procurement, the physician acts, and this act is the most proximate cause of the patient’s death. In both cases, the physician is not morally responsible for the patient’s death—the morally relevant cause of death is the patient’s disease. In both cases, the physician is acting with the patient’s consent in ways that respect the wishes of the patient and that are in pursuit of morally worthwhile ends. The present practice of defining these patients as dead before organ removal may serve to ease the concerns of the physicians involved, but it does not change the facts of the matter and only serves to perpetuate our confusion about the meaning and ethical import of brain death.

The advantage of our proposal is not that it makes the ethics of organ transplantation any easier. The difficult question “What is death?” is replaced by the equally difficult question “When are patients sufficiently close to death or sufficiently neurologically impaired that they can choose to be an organ donor?” The first question is important, but with the exception of organ transplantation, is adequately addressed by the traditional criteria of circulation and respiration. The answer to the second question would need to be determined through a process of medical, social, and legal deliberation. The advantages of our approach are that (unlike the dead-donor rule) it focuses on the most salient ethical issues at stake, and (unlike the concept of brain death) it avoids conceptual confusion and inconsistencies.

Social practices change slowly, and usually for good reason. Just as development and implementation of the concept of brain death took decades, a shift to the ethical paradigm that we propose would likely take at least as long. Such a shift would also require major changes in the current legal interpretation of causation, such that the procurement of transplantable organs before death would not be deemed to be the legal cause of death. These changes would need to ensure that the legal cause of death would be defined as the patient’s underlying disease, just as is currently the case when life support is withdrawn. Although these legal hurdles would be very significant, they would not be unprecedented, as evidenced by similar changes that have occurred in the legal view of withdrawal of life support and the definition of death.

In a larger sense, if the immunologic hurdles to xenotransplantation can be overcome, then the ethics of procuring organs from humans will become moot, and our proposal will be irrelevant. The concept of brain death will then disappear from textbooks and the medical literature, illustrating the degree to which the concept was never more than a social construction, developed to meet the
needs of the transplantation enterprise during a crucial phase of its development (54, 55).

REFERENCES