The Dead Donor Rule and Organ Transplantation

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ince its inception, organ transplantation has been guided by the overarching ethical requirement known as the dead donor rule, which simply states that patients must be declared dead before the removal of any vital organs for transplantation. Before the development of modern critical care, the diagnosis of death was relatively straightforward: patients were dead when they were cold, blue, and stiff. Unfortunately, organs from these traditional cadavers cannot be used for transplantation. Forty years ago, an ad hoc committee at Harvard Medical School, chaired by Henry Beecher, suggested revising the definition of death in a way that would make some patients with devastating neurologic injury suitable for organ transplantation under the dead donor rule.1

The concept of brain death has served us well and has been the ethical and legal justification for thousands of lifesaving donations and transplantations. Even so, there have been persistent questions about whether patients with massive brain injury, apnea, and loss of brain-stem reflexes are really dead. After all, when the injury is entirely intracranial, these patients look very much alive: they are warm and pink; they digest and metabolize food, excrete waste, undergo sexual maturation, and can even reproduce. To a casual observer, they look just like patients who are receiving longterm artificial ventilation and are asleep.

The arguments about why these patients should be considered dead

have never been fully convincing. The definition of brain death requires the complete absence of all functions of the entire brain, yet many of these patients retain essential neurologic function, such as the regulated secretion of hypothalamic hormones.2 Some have argued that these patients are dead because they are permanently unconscious (which is true), but if this is the justification, then patients in a permanent vegetative state, who breathe spontaneously, should also be diagnosed as dead, a characterization that most regard as implausible. Others have claimed that "brain-dead" patients are dead because their brain damage has led to the "permanent cessation of functioning of the organism as a whole."3 Yet evidence shows that if these patients are supported beyond the acute phase of their illness (which is rarely done), they can survive for many years.4 The uncomfortable conclusion to be drawn from this literature is that although it may be perfectly ethical to remove vital organs for transplantation from patients who satisfy the diagnostic criteria of brain death, the reason it is ethical cannot be that we are convinced they are really dead.

Over the past few years, our reliance on the dead donor rule has again been challenged, this time by the emergence of donation after cardiac death as a pathway for organ donation. Under protocols for this type of donation, patients who are not brain-dead but who are undergoing an orchestrated withdrawal of life support are monitored for the onset of cardiac

arrest. In typical protocols, patients are pronounced dead 2 to 5 minutes after the onset of asystole (on the basis of cardiac criteria), and their organs are expeditiously removed for transplantation. Although everyone agrees that many patients could be resuscitated after an interval of 2 to 5 minutes, advocates of this approach to donation say that these patients can be regarded as dead because a decision has been made not to attempt resuscitation.

This understanding of death is problematic at several levels. The cardiac definition of death requires the irreversible cessation of cardiac function. Whereas the common understanding of "irreversible" is "impossible to reverse," in this context irreversibility is interpreted as the result of a choice not to reverse. This interpretation creates the paradox that the hearts of patients who have been declared dead on the basis of the irreversible loss of cardiac function have in fact been transplanted and have successfully functioned in the chest of another. Again, although it may be ethical to remove vital organs from these patients, we believe that the reason it is ethical cannot convincingly be that the donors are dead.

At the dawn of organ transplantation, the dead donor rule was accepted as an ethical premise that did not require reflection or justification, presumably because it appeared to be necessary as a safeguard against the unethical removal of vital organs from vulnerable patients. In retrospect, however, it appears that reliance on the dead donor rule has greater potential to undermine trust in the transplantation enterprise than to preserve it. At worst, this ongoing reliance suggests that the medical profession has been gerrymandering the definition of death to carefully conform with conditions that are most favorable for transplantation. At best, the rule has provided misleading ethical cover that cannot withstand careful scrutiny. A better approach to procuring vital organs while protecting vulnerable patients against abuse would be to emphasize the importance of obtaining valid informed consent for organ donation from patients or surrogates before the withdrawal of life-sustaining treatment in situations of devastating and irreversible neurologic injury.5

What has been the cost of our continued dependence on the dead donor rule? In addition to fostering conceptual confusion about the ethical requirements of organ donation, it has compromised the goals of transplantation for donors and recipients alike. By requiring organ donors to meet flawed definitions of death before organ procurement, we deny patients and their families the opportunity to donate organs if the patients have devastating, irreversible neurologic injuries that do not meet the technical requirements of brain death. In the case of donation after cardiac death, the ischemia time inherent in the

donation process necessarily diminishes the value of the transplants by reducing both the quantity and the quality of the organs that can be procured.

Many will object that transplantation surgeons cannot legally or ethically remove vital organs from patients before death, since doing so will cause their death. However, if the critiques of the current methods of diagnosing death are correct, then such actions are already taking place on a routine basis. Moreover, in modern intensive care units, ethically justified decisions and actions of physicians are already the proximate cause of death for many patients - for instance, when mechanical ventilation is withdrawn. Whether death occurs as the result of ventilator withdrawal or organ procurement, the ethically relevant precondition is valid consent by the patient or surrogate. With such consent, there is no harm or wrong done in retrieving vital organs before death, provided that anesthesia is administered. With proper safeguards, no patient will die from vital organ donation who would not otherwise die as a result of the withdrawal of life support. Finally, surveys suggest that issues related to respect for valid consent and the degree of neurologic injury may be more important to the public than concerns about whether the patient is already dead at the time the organs are removed.

In sum, as an ethical requirement for organ donation, the dead donor rule has required unnecessarv and unsupportable revisions of the definition of death. Characterizing the ethical requirements of organ donation in terms of valid informed consent under the limited conditions of devastating neurologic injury is ethically sound, optimally respects the desires of those who wish to donate organs, and has the potential to maximize the number and quality of organs available to those in need.

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