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CONSEQUENCES OF THE DEAD DONOR RULE

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Introduction

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The Case of the Rejected Heart Donor

Terry Sklavin is 49-years-old and was a successful investment banker before he sustained a severe head injury in an automobile accident. A week after the accident, the patient is ventilator-dependent in the intensive care unit. Dr. P.V. Staat, the consulting neurologist, determines that only minimal brainstem function is present, and estimates that Mr. Sklavin's chance of recovery is negligible. The patient's wife has produced her husband's living will and durable power of attorney for health care; she is his health care agent. Both documents specify that if he were ever in an incapacitated condition from which he is unlikely to recover substantially, he does not want to be kept alive but wants to donate any organs that are medically suitable for transplantation. His hand-written instruction emphasizes that his heart especially should be used if at all possible.

The patient and his wife have had several conversations about end-of-life preferences, and she says that he felt very strongly about his clearly documented wishes. Dr. Staat informs her that organ donation might be feasible under the hospital's donation after cardiac death protocol, but even if DCD were successful, it's highly unlikely that the heart could be used. Mrs. Sklavin says that her husband is as good as dead, will die soon, and can't understand why all of his medically suitable organs won't be used, particularly why his heart will most likely be buried with him. She wants his heart and other organs to be recovered while they're still in good condition for transplantation.

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Dr. Staat explains that the dead donor rule does not permit recovery of organs until the patient has been declared dead after withdrawal of life support. He's aware of recent challenges to the current concepts of death and organ donation, and wonders whether it's time to replace the dead donor rule with one that permits donation by persons who are not dead but are facing inevitable imminent death.

Heart Donation without the Dead Donor Rule

Franklin G. Miller, PhD

Donation of vital organs is currently governed by the “dead donor rule” (DDR). Donors must be determined to be dead according to established legal criteria and medical standards prior to procurement of vital organs for transplantation. Most donors are determined to be dead on neurological criteria: the irreversible cessation of all functions of the entire brain. In response to a shortage of “brain dead” donors, vital organs increasingly have been procured from donors declared dead according to circulatory criteria following withdrawal of life-sustaining treatment (LST). Protocols for donation after circulatory death (DCD) typically involve patients on mechanical ventilation with severe neurological damage short of “brain death,” as in the case of Mr. Sklavin. After withdrawal of life support and cessation of circulation, a waiting period of usually 2-5 minutes is required before organs are retrieved. Hearts rarely have been procured under DCD protocols, although hearts of infants have been transplanted successfully in some controversial cases.[1]

Rethinking the ethics of vital organ donation is imperative because there are compelling reasons for calling into question compliance of current practices of transplantation with the DDR. The first criterion for determining death under the Uniform Determination of Death Act—the operative law in most states in the U.S.—is “irreversible cessation of circulatory and respiratory functions.” Can we be confident that these functions are *irreversible* a very short interval after cessation of heart beat? The fact that circulation has ceased 2-5 minutes (or even less in some cases) does not mean that the cessation of circulation is irreversible. To satisfy the criterion of “irreversibility” in its ordinary meaning, it must be impossible to restore circulation with available means of medical intervention. Although decisions have been made not to undertake cardiopulmonary resuscitation (CPR) following withdrawal of LST in DCD cases, the use of CPR might be successful in restoring circulation if it were initiated. Hence, donors under DCD protocols are not known to be dead at the time of organ procurement. Some commentators have contended that the permanent cessation of circulation is sufficient to satisfy the DDR.[2] However, “permanent” does not mean the same as “irreversible.” If cessation of circulation is irreversible, then it also is permanent; but the converse is not necessarily true.[3]

There are even more compelling reasons to argue that the DDR is routinely being violated in the case of “brain dead” donors. With mechanical ventilation, “brain dead” individuals maintain a wide array of biological functions, including circulation, respiration, wound healing, infection fighting, temperature regulation, secretion of neurohormones, and even gestation of a fetus for up to three months. They are not dead according to the established biological conception of death.[4] While detailed examination of the status of “brain dead”

donors lies outside the scope of this essay, it is mentioned here to indicate that compliance with the DDR is systemically problematic—the problem is not limited to the practice of transplantation under DCD protocols.

What is the upshot if vital organ donors under DCD protocols (and “brain dead donors) are not really dead, or not known to be dead, at the time of organ procurement? Strict compliance with the DDR would dictate that we stop transplanting vital organs from these donors. However, this would lead to many desperately ill patients failing to receive life-saving, or life-enhancing, organ transplantations—a drastic outcome that few people would endorse. To be sure, it is possible to sustain the status quo by muddling through, relying on the fiction, which is not officially acknowledged, that vital organ donors are dead at the time of organ procurement. Instead of relying on a legal and moral fiction, however, we can seek an ethically sound justification for vital organ transplantation from donors who are not known to be dead. Space limitations permit only a sketch of the argument, which has been developed in detail elsewhere.[4]

The key to justifying vital organ donation without the DDR is to acknowledge the causal force of withdrawing LST, particularly mechanical ventilation. The conventional view is that withdrawing mechanical ventilation, or other means of life support, merely allows the patient to die, but does not cause the patient's death. Rather, the patient's underlying medical condition causes death. This view, however, is not credible and fails to withstand critical scrutiny.

Consider the following case. Debbie, aged 50 years, was thrown from her horse in a horse-show event. She sustained a high level spinal cord injury. The accident left her quadriplegic and ventilator-dependent. Two years later, following rehabilitation and return home, she decided that her life was no longer worth living. She arranged to be admitted to the intensive care unit of an academic medical center for the purpose of withdrawing her ventilator. Thirty minutes after being sedated and extubated, Debbie died.[5] What caused Debbie's death? Was it the spinal cord injury? Despite her spinal cord injury, Debbie likely could have lived for many years with continued mechanical ventilation and personal care. Withdrawing the ventilator set in motion the causal chain leading to her death, given her inability to breathe spontaneously due to the spinal cord injury. In other words, the treatment withdrawal was the proximate cause of Debbie's death. Based on our common-sense understanding of causation, withdrawing mechanical ventilation causes death in patients unable to breathe spontaneously.

The same causal account pertains to patients on mechanical ventilation with a much more grim prognosis than that of Debbie, as in the case of Mr. Sklavin. According to his advance directive and conversations with his wife, it is clear that Mr. Sklavin would not want to live with no hope of recovery from profound neurological injury and would want to donate his heart, along with his other vital organs. Successful heart donation is considered highly unlikely for him under a DCD protocol. Would there be anything wrong from an ethical perspective in procuring Mr. Sklavin's heart and other vital organs prior to stopping mechanical ventilation? Through Mrs. Sklavin's surrogate decision-making, in light of Mr. Sklavin's prior expressed preferences, valid decisions have been made to stop life support

and donate organs. Moreover, Mr. Sklavin would be dead following withdrawal of LST regardless of whether his organs are procured. Accordingly, no harm or wrong would be done to Mr. Sklavin by procuring his heart and other organs under anesthesia *prior* to withdrawing the ventilator. In this set of circumstances, absence of harm to the donor and valid consent to donation justify organ procurement prior to stopping life support. This not only would make possible a life-saving heart transplantation that otherwise would not occur; it also would provide greater assurance of viability for his other organs, which would be continuously perfused until they were retrieved.

Once we see that withdrawing LST, in service of patient self-determination and relief of suffering, causes the death of patients, there is no sound ethical reason for concern about procuring vital organs prior to treatment withdrawal. The patient is on a planned trajectory, with death as the imminent outcome. Procuring vital organs with valid consent before treatment withdrawal does not change this trajectory; nor does it wrong the patient, who soon will be dead whether or not the organs are procured.

It might be objected that withdrawing mechanical ventilation does not necessarily cause death. While this is true, the possibility of surviving withdrawal of life support does not reflect the medical conditions of current candidates for DCD. In two recent prospective multi-centered studies of potential DCD donors in the Netherlands and the U.K., including 402 cases, all the patients died after treatment withdrawal.[6-7] The median times to death were 20-36 minutes, and the longest times to death were less than four days. Viable organs could not be retrieved in 17 percent of the potential donors in one of the studies, and 38 percent in the other. However, under the approach recommended here, vital organs could have been donated from all of these potential donors with procurement prior to withdrawing LST, and heart donation likely would have been possible in many of the cases.

The scope and limits of vital organ donation from still-living patients should be carefully defined. Limiting this practice to patients with valid decisions to stop LST and to donate organs would assure that the interests of patients are not being sacrificed in order to save the lives of others.

Unbiased examination of the practice of withdrawing LST, which causes the death of patients, underwrites a rethinking of the ethics of vital organ donation. From an ethical perspective, we do not need to uphold the DDR. Abandoning the DDR and procuring organs prior to withdrawing LST will potentially lead to many more lives saved from transplantation and greater respect for the donation preferences of individuals like Mr. Sklavin. Realizing this potential, however, will require policy changes predicated on honestly facing up to the realities of withdrawing LST and vital organ donation.

Commentary

Robert M. Sade, MD

A person who has irreversibly lost function of the entire brain, including the brain stem, is dead. The concept of brain death seems simple enough, but there is a great deal of confusion about it. For example, two out of three people think that someone who is brain dead is not

legally dead, and more than half think that a patient in coma is brain dead.[8] Both beliefs are wrong. Because of these misunderstandings, controversy has been ongoing for many years about the relation between declaration of death and organ donation.

As the field of organ transplantation grew, demand mounted for increasing numbers of organs, especially from the recently deceased, producing a paradox: “the need for both a living body and a dead donor.”[9] To resolve this paradox, the Uniform Determination of Death Act (UDDA) was promulgated in 1981 and was subsequently adopted by all the states:

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. A determination of death must be made in accordance with accepted medical standards.

Although death is unitary, the law allows its determination in two different ways. Legally, an individual who is brain dead and is warm and pink with intact circulation and ventilation is just as dead as a cadaver that has turned cold and stiff after permanent circulatory arrest.

The “Dead Donor Rule” (DDR) lies at the heart of current organ procurement policy.[10] It is not a legal statute; rather, it reflects the widely held belief that it is wrong to kill one person to save the life of another. On those grounds, an organ donor must already be dead before vital organs are removed. The DDR is therefore an ethical norm: vital organs may be removed only after the organ donor is dead. The UDDA assures patients, families, physicians, and other health professionals that a patient who is brain dead is in fact dead, so the combination with the DDR makes removal of organs for life-saving transplantation legally and ethically acceptable.

Brain death under the UDDA undoubtedly increased the supply of organs for transplantation, but the demand has grown much faster than the supply. Because of the growing waiting list and annual deaths, there has been increasing emphasis on donation after cardiac death (DCD) over the last 20 years. A protocol for DCD allows organ donation by patients who are near death and are ventilator-dependent but will not progress to brain death. [11] After a valid decision is made to discontinue life support, the option of organ donation may be offered. If the patient expressed a wish to be a donor or if the family agrees to donation, DCD may be carried out. The patient is brought to the operating room, the ventilator is removed so ventilation stops, circulation stops within 60 minutes, and when there has been no circulation for 2-5 minutes, the patient is pronounced dead and organs are rapidly removed. Kidneys and liver can often be used for transplantation, but because of the ischemic time, the heart is seldom transplanted. If circulation does not stop within 60 minutes, the organs are deemed to be too damaged for transplant and the patient dies without donating organs.

A problem that arises from the DDR is that it may frustrate the express wishes of an individual to be an organ donor. An example is Terry Sklavin, the patient in our scenario. He wants to donate his heart as well as other organs, but he cannot because of the DDR. He is near death and will certainly be dead very soon. The DCD protocol requires up to 60

minutes of diminishing circulation, several minutes of no circulation, and the additional time it takes to open the body cavities, administer tissue preservation fluids, and remove the organs. This extended period of ischemia means that his heart will almost certainly not be used for transplant, although his kidneys and liver probably will be used, as they are less sensitive to ischemic damage than the heart. In cases in which the time requirements are not met, all organs are lost.

Although the DDR is well-established in transplantation policy and practice, it has been challenged in recent years as an unnecessary fiction that results in lost lives.[12,13,14,15] According to this position, without the DDR, Mr. Sklavin's heart as well as other organs could have been donated without violating basic ethical and legal principles, as Dr. Miller explains in the accompanying paper.

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