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Informed Consent in Organ Donation and Abandonment of the Dead-Donor Rule

Matthew Phillip Mead

University of Michigan Medical School

Biography

Matthew Mead is currently a fourth year medical student at the University of Michigan Medical School. His interest in medical ethics, particularly in the ethics of organ transplantation and the various definitions of death, began as an undergraduate student at the University of Michigan-Flint where he completed a Bachelor of Science in Biology and Bachelor of Arts in Philosophy. His current research interests have broadened to include clinical research in the field of Orthopaedic Surgery, which he intends to pursue after graduation from medical school.

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Informed Consent in Organ Donation and Abandonment of the Dead-Donor Rule

Matthew Phillip Mead

Abstract

There has been considerable discussion regarding the ethics of organ transplantation and the dead-donor rule (DDR). Much of the medical and philosophical literature reveals inherent difficulties in definitions of death and the appropriate time to begin organ procurement. In this essay, an argument is presented for abandoning the DDR and switching to a practice in which donors are informed of the conditions under which their organs will be removed, rather than the current practice of requiring a declaration of death. Informed organ donation consent (IODC) would allow for greater transparency in the organ procurement process and alleviate many of the ethical concerns raised in the literature today surrounding these practices. This has the potential to improve public trust of organ procurement and increase the numbers of donors.

Keywords

Dead Donor Rule, Death, Definition/Determination of Death, Donation/Procurement of Organs/Tissues, Vital Organ Donation

In recent years, there has been considerable debate surrounding the ethics of organ transplantation in both the medical and philosophical literature. Some of this debate has been focused on organ procurement practices and the criteria used to justify the appropriate time to initiate organ procurement. Properly defining the conditions under which a donor's organs can be removed is particularly important, as it represents an important safeguard against violating individual rights. Early in this discussion, it was recognized that vulnerable donor groups needed protection, such as the poor, the elderly, prisoners, the mentally handicapped, and patients who it was unclear whether they were alive or dead. From this came one of the most fundamental principles in the protection of organ donors: the requirement that a potential donor be declared dead prior to the removal of their organs, known thereafter as the dead donor rule (DDR) (Robertson 1999). However, as will be argued, the DDR unnecessarily complicates organ procurement and fails to provide consistent conditions under which a person's organs will be removed as a result of there being multiple definitions of death. Because of this, the DDR should be abandoned and replaced with a practice in which donors are informed of the conditions under which their organs will be removed. This "informed organ donation consent" (IODC) would allow for greater transparency in the organ procurement process

and alleviate many of the ethical concerns raised in the literature today surrounding these practices.

To better understand this, it is useful to explore the reasons for abandoning the DDR. At first glance, the DDR appears to provide a simple and reliable way in which donors can be protected from abuses. However, the DDR does nothing to define what it actually means for a donor to be dead. Medical and philosophical literature reveals that death is not as clear of a concept as once thought. For example, one might wonder whether a person in an irreversible coma could be dead, or whether a person whose heart and lungs function only as a result of mechanical ventilation could actually be alive. Under the DDR, correctly answering these questions is of great importance, as it dictates whether organ procurement can begin or not.

In an effort to clarify the concept of death, three main definitions of death have been developed, each of which has been used in the DDR. The most traditional of these is the cardiopulmonary definition of death (CPD), which is usually defined as the irreversible cessation of heart and lung function (Iltis & Cherry 2010; Kerridge *et al.* 2002). This is in keeping with the customary notion of death, where breathing and pulses are signs of life and the absence of these are a sign of death. However, with the advent of mechanical ventilation and electronic defibrillation, many have concluded the CPD to be inadequate. One criticism of the CPD is that a patient who lacks brain and brainstem activity would be still be considered alive while on a mechanical respirator. Essentially, patients who would die otherwise can be kept alive under the CPD for months or even years as long as these cardiopulmonary supports are in place, even though they lack the type of brain function that many people feel is important for life.

Recognizing these inadequacies, a committee at Harvard Medical School released a report in 1968 which redefined the concept of death in humans into what is now called the brain-death definition (BDD) (Harvard 1968). According to the BDD, death is defined as the irreversible cessation of function of the brain and brainstem. This was later adopted as the primary legal definition of death by a 1981 Presidential Committee (President's Commission 1981). A variety of tests have been developed to determine whether a patient's brain and brainstem are functioning. These tests classify a patient as dead if they show a lack of awareness to external stimuli and unresponsiveness to painful stimuli, a lack of spontaneous muscular movement and respirations, and lack of key reflexes. Such findings include fixed, dilated pupils, a lack of eye movement even when the eyes are hit, moved, or stimulated by cold water in the ear (caloric reflex test), and a lack of response to noxious stimuli. This definition is useful because it helps to declare death in unclear situations, such as when a patient is on a mechanical ventilator.

Despite its strengths, several objections have been presented against the BDD. The first is that individuals can fulfill all of the diagnostic tests for determination of brain death, but still retain evidence of integrated brain function at the mid-brain and brainstem level, and in some cases may even continue to have some evidence of cortical function (Chiong 2005). For example, many different hormones (such as growth hormone, prolactin, thyroid stimulating hormone, cortisol, and vasopressin) that are regulated in the brain continue to be regulated after determination of brain death (Schrader *et al.* 1980). Additionally, a flat electroencephalogram is not always observed in patients who fulfill the diagnostic requirements for brain death. One study has found that 20% of patients who fulfill the diagnostic tests for brain death still show some level of electrical activity on an electroencephalogram (Grigg *et al.* 1987). Other clinicians have observed that patients who have fulfill the diagnostic tests for brain death often respond to pain with significant increases in both heart rate and blood pressure (Shewmon 1998; Wetzel *et al.* 1985).

While none of these are criticisms of the BDD itself (but rather criticisms of the inadequacy of the tests used to diagnose brain death), they demonstrate that despite considerable study, properly defining conditions under which the criteria for the BDD have been met remains elusive. Robert Truog, an early proponent of the abandonment of the DDR writes,

This evidence points to the conclusion that there is a significant disparity between the standard tests used to make the diagnosis of brain death and the criterion these tests are purported to fulfill. Faced with these facts, even supporters of the current statuses acknowledge that the criterion of 'whole-brain' death is only an 'approximation.'
(Truog 1997)

A third definition of death has also been proposed, known as the higher-brain function definition (HBF). The HBF definition holds that it is the potential for consciousness which differentiates between life and death. According to the HBF definition, death is the irreversible loss of personhood. If we assume consciousness is necessary for personhood, then the irreversible loss of consciousness represents the death of the person. Thus, under the HBF definition, patients in irreversible comas, newborns with anencephaly, and patients in persistent vegetative states (PVS) are all considered dead. It is with PVS patients that many find difficulty, as these patients retain complete or partial hypothalamic and brainstem functions, such as thermoregulation and the ability to swallow (Monti *et al.* 2010). They occasionally smile, cry, grunt, or moan in

response to internal stimuli. In contrast to CPD and BDD patients, irreversible coma and PVS patients do not require life-sustaining machinery (other than feeding tubes), as the areas of the brain that control respiration, hormone levels, blood pressure, heart rate, and gastrointestinal function remain intact.

Not surprisingly, a major criticism of HBF is that it classifies these PVS patients as dead. Many intuitively feel that these patients are alive, perhaps even “more” alive than patients who require mechanical respirators. Similar to a BDD patient, a PVS patient continues to grow and mature sexually. They can become ill and fight off infections. They maintain homeostatic control of hormone regulation, body temperature, and fluid balance (Schrader *et al.* 1980). Patients in PVS retain a gag reflex, exhibit evidence of normal sleep cycles, and periodically yawn. Their eyes will track light and in some cases even moan when their muscles are overly stretched. For many, it is difficult to conclude that PVS patients are dead. This stems from the difficulty in separating the biologic processes that are associated with life from the death of the person. According to the HBF definition, these patients lack the potential for consciousness and have lost personhood, and therefore are dead. Critics, such as David DeGrazia, have argued against this view on the grounds that we, as humans, are not *essentially* persons (DeGrazia 1999, 2002, 2006). In other words, there are periods in our lives in which we exist as nonpersons, such as during infancy or severe dementia. Yet during these times, we do not consider ourselves as being dead. Thus, the status of one’s personhood does not dictate whether a person is alive or dead and thus, neither would the irreversible loss of consciousness.

The purpose of this discussion has not been to promote one stance over another, but rather to show the significant disagreements among the academic community concerning the topic of death. These disagreements have resulted in numerous ethical dilemmas involving the DDR and organ procurement, where physicians must turn to one theory of death over another in order to justify the initiation of organ procurement. An excellent example of this is what has been termed donation after cardiac death (DCD). This practice, first developed at the University of Pittsburgh Medical Center in 1992, was a novel method in obtaining organs from patients who were (1) expected to die shortly, (2) demonstrated a wish to donate, and (3) who had verified do not resuscitate order on record (Pittsburg 1993). Although specific procedures have changed since its inception, the overall process remains similar. At some point in the treatment, the decision is made by family or medical personnel that it is appropriate to remove life support from these patients because they show no hope for improvement. However, prior to the removal of life support, these patients are taken to surgery and prepped for organ procurement. Additionally, prospective organ recipients and their respective surgery teams are informed

of the organs which would be available shortly. This allows adequate time for these teams to organize and prepare the prospective organ recipient for surgery as well. Then, when the time is appropriate, life-sustaining interventions are removed from the donor and these patients are allowed to “die” under CPD criteria. Following pronouncement of death, the donor is placed back on life-support to maintain adequate blood flow to the organs to be removed. These DCD procedures, allow the patient to be declared legally dead prior to organ procurement and allow for greater quality of transplantable organs by reducing the amount of ischemic damage.

There has been considerable debate over the ethics of these practices. Some have argued that DCD procedures devalue appropriate end-of-life care.¹ Others have expressed concern over the appropriateness of administering anticoagulants and vasodilator medications to these patients prior to death, as they are given to enhance the viability of the transplantable organs but can be detrimental to the prognosis of the not-yet-dead patient (Menikoff 2002). There has also been concern about the length of time patients should remain asystole. The original University of Pittsburgh protocol required patients to remain asystole for two minutes prior to declaring death. However, there have been patients that returned to cardiac rhythms after more than two minutes of asystole (Adhiyaman *et al.* 2007; Rady *et al.* 2007). To palliate this concern, some institutions have increased the asystole period from two minutes to five minutes. However, peer reviewed medical literature demonstrates some patients returning to cardiac rhythms after more than ten minutes (Adhiyaman *et al.* 2007; Hornby *et al.* 2010). The most serious criticism, however, has been over whether DCD donors could ever actually be declared dead under CPD criteria, since this requires the *irreversible cessation* of respiration and circulation. In DCD procedures, it is clearly evident that irreversibility has not been met if the goal is to restart the heart and lungs after the declaration of death.

The purpose in describing DCD procedures and their criticisms has been to demonstrate the problems that the DDR creates for organ procurement. Physicians are forced to jump through hoops in order to abide by the DDR and preserve the intentions of the donor. The easiest solution to this problem is to eliminate the DDR altogether and replace it with an organ donation process by which donors are simply informed of the conditions under which their organs will be removed, a practice I term as informed organ donation consent (IODC). These conditions would not require that a person be declared dead (although they may or may not be, depending on their specific circumstances and

1. For a short commentary on these concerns, see Rady, M.Y., J.L. Verheijde, and J. McGregor. 2006. “Organ Donation after Circulatory Death: The Forgotten Donor?” *Crit Care* 10 (5) 166: 1–3.

what definition of death you subscribe to). Highlighting the unnecessary connection between organ donation and death, Robert Truog writes,

That patients be dead before their organs are recovered is not a foundational ethical requirement. Rather, by blocking reasonable requests from patients and families to donate, the DDR both infringes donor autonomy and unnecessarily limits the number and quality of transplantable organs. (Truog *et al.* 2013)

At this point, one might ask what the criteria would be in IODC during which organ procurement could begin. In my view, the conditions could be the same clinical criteria used for defining brain death today. That is, a patient might consent to having their organs removed if they arrived at a condition in which they lacked spontaneous respirations, had fixed, dilated pupils, a lack of eye movement when their eyes were hit, moved, or stimulated by ice cold water in the ear, etc. Thus, the transition from the DDR to IODC would not require a significant change in practice. Much of the clinical criteria used today to declare death could very well be used to declare a patient suitable for organ procurement. Others could certainly argue for different clinical criteria that they find suitable. The key distinction though, is that whether or not these patients were dead from a legal or philosophical perspective would be irrelevant.

With IODC in place, organ procurement practices could be standardized or it could be up to the prospective donor. This means that patients could define the conditions on their own (similar to a living will or a DNR order) or one set of conditions (such as the BDD, CPD, or HBF criteria) could be applied universally. Importantly, the elimination of the DDR and the transition to IODC eliminates the logical problems and societal misconception about defining death. Because of this, IODC allows for greater accuracy in determining the appropriate time for procurement to begin and better protects donor autonomy.

One concern with IODC may be that in eliminating the requirement for a legal declaration of death prior to organ procurement, it is possible that the practice of organ transplantation might lose public trust and support. This would have the potential to decrease the number of available transplantable organs. However, empirical evidence supports that the DDR is not essential for public trust in organ donation. In a 2003 study, researchers at Case Western Reserve University examined factors related to families' understanding of brain death and how those factors affected decisions about organ donation (Siminoff *et al.* 2003). Their results indicated that in a sample of over four-hundred families who had family members who had been declared dead using BDD

diagnostic tests, only 28% could give a correct definition of BD. Furthermore, they found that there was no association between a willingness to donate and having an accurate understanding of brain death.

Another concern with IODC might be that the elimination of the DDR in organ procurement would lead to a slippery slope, where organs are removed from patients who have reasonable chances of survival. This problem is alleviated if patients are required to choose organ procurement conditions in which they are very close to death and show no hope of recovery. As mentioned previously, these would likely be the criteria already used to determine brain death, cardiopulmonary death, or HBF. Thus, there would be little real change in practice, other than the elimination of the need for practices such as DCD.

In conclusion, the benefits of standardizing organ donation policies, as well as freeing practitioners from relying on such problematic concepts as “legally dead” are major advantages of abandoning the DDR. IODC would provide practitioners with the opportunity to educate members of the public on the complexities of the processes of death. Patients and their family members would then be able to make truly informed decisions regarding organ donation. This has the potential to foster public support for organ donation and begin to address the severe organ shortages which greatly limit transplantation today.

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