Reconsidering the Dead Donor Rule: Is it Important That Organ Donors Be Dead?

ABSTRACT. The “dead donor rule” is increasingly under attack for several reasons. First, there has long been disagreement about whether there is a correct or coherent definition of “death.” Second, it has long been clear that the concept and ascertaining of “brain death” is medically flawed. Third, the requirement stands in the way of improving organ supply by prohibiting organ removal from patients who have little to lose—e.g., infants with anencephaly—and from patients who ardently want to donate while still alive—e.g., patients in a permanent vegetative state. One argument against abandoning the dead donor rule has been that the rule is important to the general public. There is now data suggesting that this assumption also may be flawed. These findings add additional weight to proposals to abandon the dead donor rule so that organ supply can be expanded in a way that is consistent with traditional notions of ethics, law, public policy, and public opinion.

In 1968, an ad hoc committee at the Harvard Medical School (Harvard Medical School Ad Hoc Committee 1968) published a report with the explicit utilitarian intent of improving the supply of organs for transplantation (Pernick 1999). To achieve this goal, the committee reported its conclusions on a strictly medical matter and then made a policy proposal. The medical conclusion was that they had identified criteria for reliably ascertaining when all brain functions had irreversibly ceased and a patient could be considered to be irreversibly comatose. This condition they called “brain death.” The policy proposal was that this medical condition—death of the brain—be accepted as constituting death of the person and that laws be enacted to acknowledge this.

Implicit in the report was the assumption that—for reasons of ethics, law, and public acceptance—a patient should be dead before vital organs were removed. This assumption has come to be known as “the dead do-
nor rule” (Robertson 1998). Since the traditional definition of death, based on irreversible loss of cardiorespiratory function, had been undermined by the development of machines that could replace these functions, a new definition of death was needed.

“Brain death” is now generally accepted as a sufficient reason for declaring a patient dead and, with appropriate attention to the prevailing rules regarding consent, for removing organs for transplantation. But there is increasing criticism (Arnold and Younger 1993; Brennan and Delgado 1981; Dworkin 1973; Emanuel 1995; Fost 1983; 1999; Halevy and Brody 1999; Koppelman 2003) of all three assumptions of the Harvard committee: (1) that patients who meet so-called “Harvard criteria” in fact have lost all brain function; (2) that patients who have lost all brain function are in fact dead; and (3) that death is a necessary condition for removing vital organs.

PROBLEMS WITH THE BASIC ASSUMPTIONS

Problems with the medical definition and ascertainment of “brain death” have long been evident. Many patients determined to have lost all brain function still maintain hypothalamic function sufficient to regulate water balance (Lynn and Cranford 1999), so the “whole brain” in fact has not ceased to function. Cells continue to function, evidenced by recovery of stem cells which can be propagated in vitro. And in the real world of clinical practice, even those who are called upon to make the determination of when a patient is dead according to these criteria have a high rate of misunderstanding, confusion, and error. For example, only 35 percent of physicians and nurses likely to be involved in organ procurement at a major academic health center correctly identified the legal and medical criteria for determining death. Nineteen percent of these clinicians “had a concept of death that was consistent with . . . (classifying) . . . anencephalics and patients in a persistent vegetative state as dead” (Youngner et al. 1989).

These observations do not necessarily imply that there is any serious ethical problem in removing organs from such patients, with appropriate consent. But they lead to two other observations. First, if “whole-brain death,” using various modifications of the Harvard criteria, is the basis for declaring death, many thousands of patients have had organs removed who are not dead by the widely accepted criteria. That is, the premise that these patients have been “brain dead,” or dead by legal standards, is false. Second, Since these medical observations are widely acknowledged and organ retrieval continues from patients who are still alive—i.e., still have
some residual brain function—without apparent objection, they suggest that it is not morally or legally essential that all brain activity cease before organs can be removed. If that is the case, then discussion should focus on other clinical situations that may be morally similar. What is it about these patients who are almost “brain dead” that makes it acceptable to remove organs? One candidate answer is that the patient has suffered irreversible loss of all higher brain functions, and there is extremely low (but not zero) likelihood of this prognosis being in error. The same also could be said about other patients—e.g., patients in a permanent vegetative state of known etiology or infants with anencephaly—and it therefore should be appropriate to discuss a policy that permits organ removal from such patients.

The other conclusion of the Harvard report—i.e., that patients who are “brain dead” are in fact dead—also has been subject to increasing criticism for two reasons. First, on epistemological grounds, there are many competing proposals for what constitutes “death,” and there is no objective way of identifying which is the “right” or “correct” definition (Arnold and Younger 1993; Emanuel 1995; Halevy and Brody 1999). Second, the concept of “brain death” as equivalent to death of the person is not coherent to substantial numbers of ordinary citizens. For some, the standard is too high, as they believe a loved one has died long before the whole brain has ceased to function. For some, the standard is too low, as it is difficult to accept that a patient is dead when he appears to be sedated but otherwise normal, with good color and all other organs functioning normally, and indistinguishable from many others in the intensive care unit whose status as “alive” is not in question.

In summary, there has been increasing questioning of the long-standing assumption that a patient must be dead before organs may be removed for transplantation (Brennan and Delgado 1981; Dworkin 1973; Fost 1999; Truog and Fletcher 1989). According to these critics, whether a patient is dead oversimplifies the central question, which is, “under what circumstances can organs be removed in a way that is morally defensible, legally acceptable, and within the mainstream of public opinion?” (The discussion is limited here to the United States.)

LIMITS TO THE DEAD DONOR RULE

As noted, the dead donor rule has been undermined by increasing realization that it is conceptually and medically flawed. But its importance has been overrated for more basic reasons.
First, it never really has been a rule, but rather a guideline. Obviously, many living persons have donated solid organs. In fact, live donors are now more common than dead donors (Organ Procurement and Transplantation Network 2003). The increasing acceptance of living donation has extended to unrelated donors, children (Fost 1977; Ross 1993, 1994), and now even strangers (DeWolf 2003; National Kidney Foundation 2002; Radcliffe-Richards et al. 1998; Spital 2001). Although the incidence of serious complications from live donation is low, they indeed can be very serious, including death related to the procedure (Cronin, Millis, and Spiegler 2001). The increasing acceptance of live donation is consistent with the central role of respect for autonomy in American law and bioethics, and in the case of minors, that it is acceptable to invade an incompetent person’s body when it is in his interests to do so, or when it is clear that, if competent, he would want such an invasion to occur.

Second, the expanding categories of live donation (children, unrelated friends, and strangers) shows that professional and public views are not fixed. A stranger offering to donate a kidney was once considered to be prima facie mentally ill (Spital 2001). Transplant centers now recognize a duty to rule out mental illness, but increasingly accept such offers after appropriate medical and psychiatric screening (University of Wisconsin 2001). Even the long-standing taboo against payment for organs increasingly is being questioned (Arnold et al. 2002; Matas 2002). The American Medical Association (2002) has supported a proposal for more research on public acceptance of alternative proposals to create a market for organs.

Third, underlying the dead donor rule is the premise that it is wrong to invade a person’s body without the informed consent of the patient or an appropriate representative, or, if consent is not possible, unless it is clearly in the patient’s interest. Resistance to organ removal from unconscious dying patients, while still alive, is based partly on the perception that it involves a bodily invasion that is not in the interests of the patient. Although it would not serve any direct medical interests of such a patient, the respect for living wills, as well as traditional wills, reflects the widely shared belief that competent patients do have interests in what happens to their bodies after they become incompetent, whether living or dead, and these interests generally should be respected.

A patient, while still competent, may choose to have organs removed prior to death, through an advance directive. This is simply an extension of the right of competent patients to make live donations, or to submit to other nontherapeutic procedures, as occurs in clinical research. Given the
general agreement that competent patients should be able to control their
own medical care, even when it will result in premature death, it would
be odd to hold that competent persons can make decisions in advance
that will result in their own deaths, but should be prohibited from mak-
ing decisions that are of far less risk, such as removal of a kidney.

This suggestion that competent patients might want organs removed
before they die, but at a time when they would be incompetent to con-
sent, is not just a theoretical proposition. In a survey of adult patients
with cystic fibrosis, we asked if they would be interested in donating their
kidneys, prior to death, if they were admitted to the hospital for terminal
care. About one-third said yes, and another one-third expressed interest
in learning more about it (Fost, unpublished data).

Finally, the dead donor rule never was necessary for ethically and le-
gally acceptable organ retrieval (Arnold and Younger 1993; Brennan and
Delgado 1981; Dworkin 1973; Emanuel 1995; Fost 1983; Halevy and
Brody 1999; Kopelman, Irons, and Kopelman 1998; Truog and Fletcher
1989). For many years kidneys were removed from many patients in states
that did not recognize brain-based criteria for declaring death, with no
evidence of public or legal disapproval or concern (Fost 1999). Nor is
there evidence that statutes redefining death played a critical role in im-
proving organ donation rates (Fost 1999).

In summary, the dead donor rule oversimplifies general practice and is
not consistent with widely shared views of ethically acceptable interven-
tions on incompetent and dying patients. Public attitudes on these issues
are fluid. Sometimes they are ahead of medical opinion and practice; some-
times they are more tolerant of change than is realized.

PUBLIC ACCEPTANCE OF A CHANGE IN POLICY AND PRACTICE

Given the growing disparity between organ supply and patient needs,
it is understandable that policies and practices involving organ retrieval
have undergone continuous change. The current debate is whether it should
be permissible to expand the eligible donor pool to include incompetent
patients who are imminently dying and about whom there is unanimity—
among family and providers—that discontinuing treatment and allowing
death to occur is in the patient’s interest. The paradigm case is the patient
in a permanent vegetative state. The strongest case for allowing organ
retrieval from such a patient would include a requirement that the patient
had consented to such a donation while still competent. As noted earlier,
a donation of this sort would be consistent with current accepted prin-
principles and practices in other areas. Many who support such donations have reservations on utilitarian grounds; namely, that the public might be so offended by such a policy that there would be adverse effects on organ donation overall, or that other restrictions would be placed on organ transplantation.

Good ethics starts with good facts. Like many disputes in bioethics, this one is primarily about empirical questions: what, in fact, does “the public” think about these matters; how would they respond if there were a change in practice; and what effect, if any, would public attitudes have on transplantation in general? In this light, the study by Laura Siminoff, Christopher Burant, and Stuart Youngher (2004) is on point and provides the best data yet available on this topic.

As Daniel Hausman (2004) points out, there are unavoidable difficulties in defining public attitudes on complex issues, and the moral relevance of such surveys is, at best, questionable. A clear majority of “the people” have been morally wrong on major ethical questions, such as the acceptability of holding slaves. The existence of clear laws and court opinions on such issues does not weaken these moral judgments—i.e., we have little difficulty in concluding today that the Dred Scott decision was based on a faulty moral premise. We may understand why such errors were made, and even be sympathetic to those who had to make judgments in a different time, but we still can be confident that these judgments were based on faulty moral reasoning (Buchanan 1996).

Nonetheless, public opinion has an important effect on policy and practice—witness the reluctance of many transplant surgeons even to discuss in public the possibility of challenging the dead donor rule. If there are strong ethical arguments for abandoning or modifying the dead donor rule, then documenting public support, if it exists, or campaigning for public support can be important, if only for strategic reasons.

DEFINING “PUBLIC ACCEPTABILITY”

“Public acceptability” is, of course, an ambiguous phrase. What the public does or will accept may be reflected in statutes, surveys, or even the absence of complaints, lawsuits, or criminal charges. These indicators of public attitudes may give conflicting information.

The Public May Be Apathetic

As a case in point, consider an “exposé” on 60 Minutes (CBS 1997) on the donation after cardiac death (DCD) program at the University of
Wisconsin. The major implication of the segment was that the transplant surgeons were killing patients through the lethal injection of a drug to enhance organ supply and organ survival and that the hospital had adopted a definition of death inconsistent with state law and standard practice. In anticipation of an avalanche of enquiries by the press and public, a panel of physicians, knowledgeable in the medical, ethical, and legal aspects of the DCD program, were prepared to respond to the anticipated outcry. Not a single call was received.

A similar experience followed an article in the New York Times, stimulated by the publication of a book detailing the controversies surrounding DCD (Arnold, Youngner, Schapiro, and Spicer 1995). There were few letters or other reactions. Whether the millions of people who saw or read these accounts were confused, unconcerned, or supportive is unknown, but the absence of almost any response suggests that the public is not greatly concerned about these issues.

“Illegal” Does Not Mean Publicly Unacceptable

Some have argued that abandoning the dead donor rule—for example, by allowing removal of organs from a patient in permanent vegetative state before death—would require a change in the law (Veatch 2003). A variant claim is that it would be important to document prospectively public support for such a change through the statutory or judicial process.

The law, of course, is an imperfect guide to the ethical acceptability of practice, and to public opinion. Polls consistently show, for example, that a majority of Americans have long supported gun control laws far more restrictive than those enacted by the state or federal legislatures (ABC News 2000). The infamous Jack Kevorkian repeatedly violated a state statute prohibiting assisted suicide and active euthanasia, including a statute crafted specifically to stop his precise protocol, and three times juries refused to find him guilty. He was convicted at his fourth trial, apparently because he offended the public by sending a videotape of his latest case to 60 Minutes. Active euthanasia, according to several surveys, is commonly practiced, despite explicit statutory prohibition, but prosecutions are extraordinarily rare, and convictions are virtually unknown in the U.S. This tolerance of clearly illegal behavior by prosecutors and juries suggests either that the law does not reflect public opinion, or that the public likes it the way it is: having the law as a “caution” sign, with extremely broad tolerance for violations when they involve sympathetic cases (Quill 1991).
As noted earlier, Wisconsin, among other states, removed organs from “brain-dead” patients before any authorizing statute or state court opinion, without objection. DCD programs have thrived in Wisconsin and elsewhere, notwithstanding claims by 60 Minutes and others (Funk 1997) that they violate homicide laws.

PUBLIC OPINION MAY FOLLOW PRACTICE

Those who advocate statutory change or judicial support for new approaches to organ retrieval reflect a traditional “top down” approach to public policy. But many legal changes occur after practices are established, from the “bottom up,” particularly in medicine, and particularly in transplantation (Burt 1979). This is not to attack or defend such an approach to policy, but only to say that controversial practices sometimes become standard practice with broad social support, despite initial opposition, without prospective legal guidance.

This “bottom up” development of policy is particularly common with regard to new biomedical technologies. Assisted reproductive technologies, such as in vitro fertilization, for example, although initially upsetting to a majority of the public (Gallup Organization 2003), have become common and generally accepted with little legal oversight or social control (Press Association 2003). The even more controversial practice of conceiving a child primarily for the purpose of creating a bone marrow donor for a dying sibling, universally condemned when the first case was widely publicized (Graham 1990), is now common practice in many centers.

As noted above, changes in practice in transplantation commonly have preceded formal social approval. Removal of organs from “brain-dead” patients occurred regularly without objection in the absence of statutes or court opinions, and donation after “cardiac death” developed and expanded without explicit legal or political authorization.

IMPLICATIONS OF THE OHIO SURVEY

Siminoff, Burant, and Youngner (2004) have reported the findings of an extensive survey of Ohio residents on attitudes regarding organ retrieval from patients with various degrees of brain injury. The methodology, as noted by the authors, limits the generalizability of their findings, and responses to a survey may not reflect how these respondents would feel if they or others actually were involved in the removal of organs in the described clinical situations. Nonetheless, the results will be surpris-
ing to those who believe the public would be opposed generally to changes of the sort described earlier in this paper.

Scenario 2 describes a patient who has suffered profound brain injury, with no prospect of recovery, and who is ventilator dependent, but not in a persistent vegetative state. No transplant center would remove a kidney for transplantation from a patient in this condition, but 75 percent of the respondents supported organ procurement in this case. Indeed, 55 percent believed this patient should be considered dead, reflecting the enormous gap between the statutory definitions of death and public opinion. These data suggest that present policies are far more restrictive than what many ordinary citizens would support.

One cannot determine from this study whether the respondents were stating how they would like to be treated; whether they were stating how they believe others should be treated; or merely expressing support or tolerance for a practice that they personally might oppose. At the least, the hypothesis that a majority of general public would be alarmed if organs were removed from a living patient with profound brain damage is not supported by these data.

CONCLUSION

“Public opinion” is difficult to define. Its relevance to judgments about the ethical justification for actions is limited. It often follows changes in practice, rather than precedes such changes. It is malleable, susceptible to information, argument, and evolving evidence of benefits and risks. In the field of organ transplantation, it seems to be more pragmatic than conceptual. There seems to be widespread confusion in the public about the definition of death, as that term is understood by clinicians and scholars, but there is a sense that many patients are “as good as dead,” and that it should therefore be permissible to remove organs from them with appropriate safeguards.

When or whether a patient is dead is a topic of seemingly endless fascination to ethicists and other scholars (Arnold, Youngner, Schapiro, and Spicer 1995). Some have argued that, with regard to transplantation policy, whether a potential donor is dead is not of critical importance (Fost 1999). The survey by Siminoff and colleagues suggests that a majority of the public either supports the latter view—it really doesn’t matter—or is willing to use the word “dead” in such a broad way as to lead to the same practical conclusion.

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