Observations of withdrawal of life-sustaining treatment from patients who became non-heart-beating organ donors

Michael A. DeVita, MD; James V. Snyder, MD, FCCM; Robert M. Arnold, MD; Laura A. Siminoff, PhD

Objective: **Non-heart-beating organ donation for transplantation is increasing despite the concern whether all the donors are dead. This concern is based on the adequacy of documentation of death and the appropriate duration that circulation and respiration should be absent before death certification. No studies have examined the documentation and deaths of patients who became non-heart-beating organ donors.**

Design: **Retrospective study of observational data.**

Patients: **All non-brain-dead patients who became non-heart-beating organ donors at the University of Pittsburgh Medical Center from January 1, 1993, to June 30, 1998, were identified. Records for 15 of 16 patients were available for review.**

Measurements and Main Results: **Adequacy of documentation, extubation time, onset of severe hypotension, duration of absent circulation before death was certified, and the time of incision for organ procurement were ascertained. Twelve of 15 records had all required clinical documentation. The mean age of patients was 46.5 ± 5.7 yrs. All 15 patients were extubated before death and had femoral arterial catheters; one had a biventricular assist device discontinued. The time of hypotension and pulselessness was not documented for one and three patients, respectively. All 12 patients with documentation had ≥2 mins of absent circulation. Time from certification to incision for procurement was 1.1 ± 2.3 mins.**

Conclusions: **In a small study of non-heart-beating organ donation, circulation never resumed after >1 min of absent circulation, suggesting that 2 mins of absent circulation is sufficient to certify death. Three of 15 patients had inadequate documentation. Gaps and inconsistencies in documentation may raise concern about the potential for abuse. (Crit Care Med 2000; 28:1709–1712)**

KEY WORDS: organ procurement; cadaver; transplantation; ethics; life support care; tissue donors; terminal care; brain death; informed consent

In 1993, the University of Pittsburgh Medical Center (UPMC) initiated a policy publicly reintroducing non-heart-beating organ donation (NHBOD) (1). Non-heart-beating cadavers are certified dead according to the following criteria: irreversible cessation of heart, lung, and brain function. In contrast, brain-dead—sometimes termed "heart-beating"—cadavers have irreversible cessation of whole brain function while the heart continues beating. Once a common source of donor organs, NHBOD largely had been abandoned since the early 1970s when brain death was accepted and organs from brain-dead donors were found to have better survival (2). Interest in NHBOD was increased because of the following: a) at the time, waiting lists for organs had increased to >30,000 individuals; b) organs from NHBOD had improved graft survival (2); and c) dying patients' families were requesting that they be allowed to donate organs (1). Although the UPMC policy was a response to patient and family requests to donate organs after terminating life-sustaining therapy, Terasaki et al. (3) hypothesized that if NHBOD were widely implemented, it would relieve the crisis in organ supply. They also hypothesized that the need for living donation could be eliminated within 10 yrs.

There are two forms of NHBOD: controlled and uncontrolled. Uncontrolled NHBOD includes nonsurvivors of cardiopulmonary resuscitation. The term *uncontrolled* refers to the emergency nature of the procurement. Controlled NHBOD, by contrast, follows the planned withdrawal of life-sustaining treatments in terminally ill patients. In these situations, procurement can be carried out in a planned and prepared manner. In both forms of NHBOD, the declaration of death precedes organ procurement. The UPMC policy, for example, requires ≥2 mins of circulatory arrest before certification of death. Incision for procurement of organs follows certification. The policy also has stringent documentation requirements to enhance the ability to audit the procedure. A special documentation form requires notation of clinical events (like extubation time) and procedural tasks (like ethics consult completed and placed on chart).

The introduction of the so-called Pittsburgh Protocol set off a national and international debate on the appropriateness of NHBOD (4). The protocol was praised for clearly identifying ethical issues, creating an auditable process, involving the lay community in development of the policy, forming rules for doctors and other professionals participating in the process, and involving an ethicist in the case before procurement occurred. Some authors criticized the

From the Departments of Anesthesiology/Critical Care Medicine (Drs. DeVita and Snyder) and Internal Medicine (Drs. Arnold and DeVita), University of Pittsburgh School of Medicine; the Institute for Quality and Medical Management, University of Pittsburgh Medical Center (Drs. DeVita and Arnold); and Case Western Reserve University (Dr. Siminoff).

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Address requests for reprints to: Michael A. DeVita, MD, C111 PUH, University of Pittsburgh Medical Center, 200 Lothrop St., Pittsburgh, PA 15213.

protocol regarding whether patients were in fact dead at the time of procurement, although the UPMC protocol had strict criteria for death determination (5). In addition, the various standards for determining death adopted by other centers that have initiated NHBOD programs have augmented concerns about the criteria used to certify death to obtain viable organs for transplant recipients (6). The Institute of Medicine recently recommended, based on expert opinion, that ≥5 mins of asystole occur before death certification. The empirical data are sparse but suggest that 2 mins, rather than 5 mins, may be sufficient to ensure irreversible cessation of cardiopulmonary function. The Institute of Medicine also recommended that all institutions adopting NHBOD policies develop an auditable process to protect patients and to increase public trust in organ donation.

To our knowledge, no data have been reported on events that follow withdrawal of support in patients who become non-heart-beating organ donors. This report is an examination of the dying process of non-heart-beating organ donors at UPMC. It is not intended to justify NHBOD.

PATIENTS AND METHODS

The identification of non-heart-beating organ donors and review of their records for research purposes were approved by the UPMC Investigational Review Board. We used two databases to identify all non-heart-beating organ donors at the UPMC. The local organ procurement organization, the Center for Organ Recovery and Education, supplied its list of non-heart-beating organ donors. This was cross-referenced against a list of the required ethics consultations done before NHBOD.

A decision to forgo life-sustaining treatments was required before the patient or the family could be approached for consent to donate organs after death. Patients became candidates for NHBOD after informed consent was obtained, the Center for Organ Recovery and Education assessed medical suitability, and a critical care medicine physician assessed the patient to determine whether the patient would likely die within a short time after withdrawal of life-sustaining treatments. The physician made this prediction by assessing respiratory drive, respiratory muscle strength, dependence on oxygen and positive end-expiratory pressure for maintaining hemoglobin oxygen saturation, and degree of pharmacologic and mechanical support of the circulation.

Patient charts were reviewed by one of the authors. Patient demographics were recorded. Records were audited for documentation of satisfying four criteria for death continuously for 2 mins: a) absence of pulse pressure recorded by central arterial catheter or absence of cardiac contraction documented by echocardiogram; b) absence of heart sounds; c) apnea; and d) unresponsiveness. Records were also audited for whether the required, standardized record to document events during withdrawal of support and certification of death was completed; the method used to document the absence of circulation (an arterial catheter or echocardiogram is required by policy); and the events that followed withdrawal of support. The specific events audited were the time of removal of the endotracheal tube, the onset of severe hypotension, the onset of absent circulation, the time of death certification, and the time of incision for organ procurement. A blood pressure of <50 mm Hg systolic was chosen for severe hypotension because some data indicate that cerebral electrical activity usually ceases below this blood pressure in adults (7).

The procedure for withdrawal of mechanical ventilation has been described elsewhere (1) and includes using sedation to relieve or prevent discomfort, rapid reduction of F_{IO_2}, and intermittent mandatory ventilation rate. Positive end-expiratory pressure is removed. Heparin was given to all patients before circulation ceased. No patients received any other medications, including phentolamine (Regitine, Novartis Pharmaceuticals, Summit, NJ).

RESULTS

Sixteen controlled NHBODs occurred at the UPMC between January 1, 1993 and June 30, 1998. One chart could not be located. For the remaining 15, the mean age was 46.5 ± 5.6 yrs (range, 23–64 yrs). Eight were male. All patients had suffered severe brain injury but were not diagnosed brain-dead because they either had some residual brain stem function or had not undergone studies to determine whether brain death was present. All patients had a required ethics consult. In all cases, the ethics consultant noted compliance with policy, which required that the decision to withdraw support be made before and separate from the decision to donate. Withdrawal of support occurred in the operating room in most cases. The preoperative holding area was used for two patients because that area was perceived to be less threatening to patients' families who wanted to remain with the patient until death occurred. All patients had a central arterial catheter. The elapsed times from extubation, onset of severe hypotension, and pulselessness until death was certified are found in Table 1. Twelve of fifteen (80%) charts reviewed had documentation of all required elements. Only two required events were always documented: time of death and time of incision for procurement. Onset of hypotension is not required but was recorded for descriptive purposes. In two cases, the documented time of incision for procurement preceded the documented time of death by 1 min and 3 mins. In each of those cases, different persons documented the times of death and incision.

DISCUSSION

Although NHBOD is increasing in this country (6), there are no accepted national standards for how death is certified or for the type of documentation required for appropriate record keeping and oversight. Reports in the lay press have portrayed ambiguity regarding procedures for death determination and have intimated that donors might not be dead. The Pittsburgh Protocol addresses most of the ethical issues; however, there are few data on the deaths of patients who become non-heart-beating organ donors. This study is the first to review the dying process in non-heart-beating organ donors. Although the number of patients described in our report is small, the patients exhibited a similar clinical pattern despite widely varying ages. All patients expired within 33 mins of extubation, and all but one did so within 22 mins. Once hypotensive to a blood pressure of 50 mm

Table 1. Latency in minutes from event until death certified

Event	No.	Mean	SD	Range
Extubation	14	15	7.3	8–33
Hypotension	14	8.1	4.3	3–18
Pulselessness	12	3.1	1.5	2–6
Death	15			
Incision	15	−1[a]	2.3	3 to −8[a]

[a]Negative number indicates minutes after death.

Hg systolic, all patients died within 18 mins. The brevity of the dying process once extubation occurs is important because of the concern that warm ischemia may damage the organs. Olson et al. (8) reported that kidneys and livers procured from non-heart-beating organ donors have function that is comparable to that of organs recovered from brain-dead organ donors. Data from Casavilla et al. (9, 10) suggest that ~45 mins of warm ischemia is the maximum tolerable for most solid abdominal organs. The rapid "trajectory" of dying and death in our patients was probably attributable to selecting only patients highly dependent on mechanical or pharmacologic support. All patients were severely brain-injured, which impaired but did not ablate their respiratory drive. Discontinuing the ventilator, reducing supplemented oxygen, and withdrawing circulatory medications and devices predictably allowed the patient to die rapidly. Patients received medication to ensure their comfort.

Two ethical issues surrounding NHBOD are impacted by our report. The first is the debate regarding whether the donors are in fact dead at the time of procurement. Lynn (5) argued that the patients might be dead at the time of procurement but have not been proven to be dead. She stated that although the heart is unlikely to restart by itself after 2 mins, there are insufficient data to prove that it will never restart. She recommended that physicians observe absent circulation for a prolonged time. This duration of observation can be reduced based on accrued experience. However, there are some data on this point. From 1900 to the present, six studies have reported 109 cases in which investigators recorded a continuous electrocardiogram to document cardiac rhythm before and after death was certified (11–16). All patients in those studies failed to regain pump function after only 1 min of mechanical asystole. Our study confirms the reported experience regarding autoresuscitation, although the small number of patients limits diagnostic certainty. None of the patients reported here resumed cardiac function after 1 min of pulselessness. After 2 mins, monitor activity was not recorded, so continuously recorded data after this time are not available. However, none of the patients had circulation at the time of procurement.

Others who claim that donors might not be dead have argued that even if circulation has collapsed, brain function may be ongoing at the time death is declared by using cardiopulmonary criteria. This argument is not consistent with data that demonstrate rapid cessation of neurologic function within seconds of circulatory collapse. A more problematic concern is that brain function can be restored if resuscitative attempts restore circulation within ~5–10 mins. Therefore, a patient who accepted resuscitative measures would not have irreversible loss of brain function until much longer than 2 mins after circulatory arrest. Consequently, some authors recommend that a longer duration should elapse before death certification. There are two responses to this contention. First, in the United States, documenting irreversible lack of cardiopulmonary function by itself is sufficient to certify death. Second, the capacity to intervene, reinstate circulation, and subsequently restore brain function is moot because the patient (or the family) has refused cardiopulmonary resuscitation. Because resuscitation will not occur, the patient is dead when circulation will not resume on its own.

The second ethical concern is whether NHBOD will destroy trust in physicians and result in fewer donated organs. Caplan (17) pointed out that donors and society implicitly trust that the physician will not harm the dying patient to obtain organs. Caplan is concerned that unless (and perhaps even if) the NHBOD process is open and accountable, trust will decrease and fewer organs will be donated. Although the UPMC policy attempts to address the issue by requiring careful documentation, nevertheless, incomplete and inaccurate documentation occurred. For example, operating room nurses twice recorded incision times that preceded the times of death certification. If true, this suggests that the two patients were not dead, and one was not even pulseless at the time of incision. When asked about the discrepancy, the critical care physicians explained that when they left the operating room after certifying the patients' deaths, the transplant surgeons were just entering and had not yet made their incisions. It seems that the critical care physicians used different timepieces than the nurses. This type of inconsistency could raise public suspicion about performing NHBOD. To prevent this error, the UPMC and the Center for Organ Recovery and Education modified their procedure so that a designated clock is used for all timekeeping. There were other documentation errors. Physicians and nurses did not always use standard NHBOD record forms, which led to incomplete record keeping. However, even when the forms were used, physicians and nurses did not always document completely. For example, the duration of absent circulation was missing for three (20%) patients. This is important, because that information proves compliance with our policy for death determination. One potential reason for poor documentation is the relative infrequency of NHBOD, which occurs on average three times per year. Physicians and nursing staff may not even remember the requirements, where the forms are located, or how to use the forms. Further educational efforts and improvements in the form were initiated.

This study describes the death sequence for patients who become non-heart-beating organ donors and the quality of documentation of the process at a major medical (and transplant) center.

CONCLUSIONS

Overall, NHBOD has increased since its reintroduction. The report by Cho et al. (18) of the favorable outcome of transplants from NHBOD may fuel attempts to further increase the use of this source of cadaver organs. However, social acceptance of NHBOD ultimately relies on delivering high-quality care to dying patients and clearly documenting the sequence of events to maintain public trust that organ procurement does not precede death. This acceptance has not yet been achieved. Despite a presumed large potential donor pool, the growth of NHBOD has been flat. Without greater support, any predictions regarding the ability of NHBOD to alleviate the organ shortage will not be met.

This study describes the death sequence for patients who become non-

heart-beating organ donors and the quality of documentation of the process at a major medical (and transplant) center. Death rapidly follows extubation, occurring in <20 mins in 80% of cases. No patient recovered a central pulse pressure after 1 min of asystole. These data are in agreement with prior studies and support the position that documentation of 2 mins of absent circulation is an appropriate criterion for death determination.

Our experience is limited to adult patients. Pediatric patients may tolerate circulatory collapse longer than adults do. Care should be taken regarding generalizing adult protocols to children.

Written documentation of compliance with the NHBOD policy was inadequate or incorrect for a minority of patients. If NHBOD is to become an accepted social policy, better compliance with instituted policy is needed. We predict that having a less explicit policy will result in even greater variability in practice and perhaps deviations from accepted practice. Vague policies may be more likely to raise public suspicion that unethical behavior might be occurring. Therefore, an explicit policy, meticulously followed, should be the national standard.

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