

NEUROCRITICAL CARE THROUGH HISTORY



The History of Donation after Circulatory Death (DCD): Backlash and Boomerang

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Organs have never been readily available for the taking, and the waiting period is long and, for many patients, too long. Public support in the United States, United Kingdom, and European Union for organ donation is remarkably high. However, not everyone agrees with organ transplantation, and even physicians have raised conscientious objections about certain organ procurement methods (not the utilitarian motive) [1].

Saving a deathly ill patient with organ transplantation has been one of medicine's greatest feats. The early history of transplantation was contentious, notably for a string of major disappointments, disbelief, and cocksure surgeons who kept on trying. Their unrelenting ambition unquestionably mattered and created an important momentum, but it is only part of the much larger story. In truth, the discovery of drugs to counter the body's aggressive immune responses did more for survival than surgical techniques.

The earliest success belonged to (Nobel laureate) Joseph E. Murray, who successfully transplanted a kidney from an identical twin donor after it was understood that tissues had their own identity [2]. Although kidney transplantation (from cadavers) was successful, transplant attempts in 1963, including the first lung (James Hardy) and first liver (Thomas Starzl) transplants, failed.

Surgeons started to believe that transplantation of the heart, lung, and liver was too difficult. At that point, a major event occurred. In South Africa in 1967, Christiaan Barnard transplanted a heart from a patient in an "irrevocable coma." In a flash, the *Groote Schuur Hospital* in Cape Town leaped to the forefront of transplant surgery, even as researchers in the field regarded Barnard's work as premature and not ready for prime time. Barnard had

to confront multiple critics because he had not developed the technology needed to transplant the human heart successfully, such as extracorporeal life support. Relevant now, after the introduction of donation after cardiac death protocols, is Barnard's concern about defending himself from a wrongful death suit after excising a still-beating heart from a donor in an irreversible coma (but not technically dead). Indeed, this became the biggest concern of cardiac surgeons. To avoid legal problems, Barnard decided to wait for the heart to stop beating before he removed it, and then he fired it up again [3, 4].

These observations touched on the question of when a patient is dead. Thus, Barnard noted that if they could restart a heart in another person, why could they not restart it in its owner's chest? Critics argued that Barnard's procedure did not significantly differ from the methods of the fictional Dr. Frankenstein. Others noted even more bluntly that organ donation was the only medical procedure that required a physician to "murder" his patient.

Letting bygones be bygones, the overriding question became "Who are we to decide the exact moment that a donor is really dead?" Bioethicists and others—appropriately—raised questions about the "true" nature of death and life if the definitions depended on the premise of a beating and squeezing heart as well as the costs and benefits of such procedures.

Before establishment of the diagnosis of brain death (an unintended consequence of critical care), donation shifted to organ donation in patients with a permanently afunctional brainstem. However, it soon became apparent that brain death was very uncommon; therefore, the original avenue of obtaining organs after cardiac and circulatory standstill entered the clinical picture again. The requests of families of patients removed from life-sustaining therapy in intensive care units to have their loved ones serve as organ donors may have played a role. But DeVita and Snyder [5] formulated it as follows: "In

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the mid 1980s it was apparent that the need for organ donors exceeded those willing to donate.” The diagnosis of brain death generated significant criticism by bioethicists (and books to fill a shelf), but a momentum against it never matured.

Donation after cardiac death was different. Physicians and ethicists lived by the “dead donor rule” (DDR), which was the expression of a universally held belief that it is wrong to kill one (even moribund) person to save the life of another. This led to the conclusion that people should be dead before removal of vital organs, an act that would kill them. The DDR was neither a law nor a regulation but an ethical norm. Questions of definition of death logically came next. Barnard made decisions before there were serious ethicists in hospitals raising concerns or objections. Thirty years later, the field of bioethics did mature.

The Procedure and the Pittsburgh Protocol

Before the development of donation after circulatory death (DCD) protocols, one (rare) source of heart-beating donors was patients who died in the operating room because they could not survive the removal of cardiopulmonary bypass machine after open-heart procedures. These patients were potential sources of viable kidneys, procurable prior to discontinuing bypass. However, the danger of misunderstanding motivated the ethics communities to it out in the open for debate. This occurred in 1992 at the University of Pittsburgh, which was the leader in organ transplantation. Under the leadership of the intensivist Michael DeVita, the Ethics Committee at University of Pittsburgh Medical Center (UPMC) Center created the first policy in the United States for organ donation following cardiac death declaration (DCDD) using “traditional” circulatory–respiratory criteria. The committee also authored the nation’s first policy for research involving deceased individuals, which was a previously unregulated practice (Fig. 1).

The Pittsburgh NHBD article describes the 4-year process of developing the policy. The article shows the committees and their responsibilities (Fig. 2). The policy, which had a number of stages, was published a year later in an ethics journal rather than in a journal physicians would commonly consult [5]. They presented four illustrative cases to bolster their arguments: patients with intracerebral hemorrhage and subarachnoid hemorrhage, coma after CPR, and a fully alert patient with MS on a mechanical ventilator who wished to die and donate her organs. All had concerns: no cardiac and circulatory arrest in 60 min in two patients, one retrieval with some lingering transduced blood pressure, and one patient whose physician was called away. The UPMC Ethics Committee and administrators wanted a clear, transparent protocol.

Michael A. DeVita and James V. Snyder

Development of the University of Pittsburgh Medical Center Policy for the Care of Terminally Ill Patients Who May Become Organ Donors after Death Following the Removal of Life Support

ABSTRACT. In the mid 1980s it was apparent that the need for organ donors exceeded those willing to donate. Some University of Pittsburgh Medical Center (UPMC) physicians initiated discussion of possible new organ donor categories including individuals pronounced dead by traditional cardiac criteria. However, they reached no conclusion and dropped the discussion. In the late 1980s and the early 1990s, four cases arose in which dying patients or their families requested organ donation following the elective removal of mechanical ventilation. Controversy surrounding these cases precipitated open discussion of the use of organ donors pronounced dead on the basis of cardiac criteria. Prolonged deliberations by many committees in the absence of precedent ultimately resulted in what is, to our knowledge, the country's first policy for organ donation following elective removal of life support. The policy is intricate and conservative. Care was taken to include as many interested parties as possible in an effort to achieve representative and broad based support. This paper describes the development of the UPMC policy on non-heart-beating organ donation.

Fig. 1 Title page of the Pittsburgh donation after circulatory death protocol published in the *Kennedy Institute of Ethics Journal* (permission obtained from Johns Hopkins University Publishing)

In general, the current practice of DCD is as follows [1–5]. First, there is a decision based on the patient’s wishes or best interests to discontinue life support therapy; it is typically in situations of absolute futility or when the neurologic or medical handicap does eliminate any prospect of a quality of life. Second, the patient (or surrogate) receives an invitation to consider organ donation after death. Third, after consent, staff withdraw the patient from life support and await death in the operating room. If the circulation stops within 1 h, the patient is a DCD donor. Fourth, after 5 min of absent circulation (the death watch) and the family says their goodbyes, doctors can declare death. Fifth, the surgical team arrives at the 5-min mark and begins surgical harvest of the organs appropriate for donation. Usually, they administer medications such as heparin and phentolamine to the patient prior to absent circulation, theoretically to improve organ preservation. This orchestrated approach, “controlled DCD,” differs from “uncontrolled DCD,” which refers to donation after unexpected cardiac arrest with death pronounced after failed attempts at cardiopulmonary resuscitation. The procedure has not been greatly modified over the last decades, although the death watch time was not specified or was highly variable in the United States and Canada, where protocols were surveyed [6, 7].

TABLE 1
Membership of groups involved in writing of the UPMC policy organ donation following the elective removal of life supporting therapy.

Committee Title & Membership	Role
Health Center Wide Panel on Ethics * Physicians, ethicists, nursing, legal counsel.	Review of ethical issues; advice UPMC director.
Ethics Comminee ¹ * Physicians, nurses, administrators, lawyers, clergy, social work, patient relations, ethicists.	Review hospital policies of ethical import, review patient care issues; assist policy formulation; patient and staff education.
Ad Hoc Committee * Critical care medicine, nursing, anesthesia, neurology, ethicist.	Review, draft policy on organ donation following removal of life sustaining therapy.
Medical Executive Committee ¹ * Department Chairs, legal counsel, Administration.	Approve all hospital policy.
Joint Conference Committee ¹ * Members of the Board of Trustees, and Medical Executive Committee.	Approve all hospital policies.
Committee for the Oversight of Organ Transplantation * Local clergy, physicians, businessmen, civic leaders.	Community oversight grop for transplantation related issues

¹ MUH and PUH each have these committees. Other committees are a collaboration between the hospitals.

Fig. 2 Committees involved and their responsibilities published in the *Kennedy Institute of Ethics Journal* (permission obtained from Johns Hopkins University Publishing)

The Bioethicists Respond

The UPMC's initial experiences in implementing DCD and the views held by physicians, nurses, ethicists, lawyers, social scientists, and organ procurement coordinators about Pittsburgh's method of retrieving organs generated extensive debate. Pittsburgh's responses to these opinions and reports led to changes in the protocol about the care of patients who become non-heart-beating donors and the treatment of their families. These revisions prompted more reactions by professionals and scholars. As it became clear, there were commentaries on commentaries, criticisms of criticisms, and reports about reports. Pittsburgh's commendable decision to develop its procedures and policies as openly as possible may have triggered the controversy. However, many regarded this openness to scrutiny and willingness to clarify and change as exemplary [8–12]. But the authors may not have anticipated they would be exposed to such harsh criticism. Critical articles were published in the same issue [8, 9], producing an issue dominated by rebuttals. Fox and Christakis wrote, "We would like to propose that professional journals attach less value and priority to articles about non-heart-beating cadaver organ procurement than they have until now. We acknowledge that our suggestion raises ethical questions concerning whether journals can exercise this kind of

control over what they do and do not favor for publication without prejudicially encroaching on rights associated with academic freedom or engaging in the equivalent of censorship. But what we are advocating is restraint both in publication and in organ procurement policy" and "if our cautionary recommendation were to be taken seriously and acted upon, it would mean that the Kennedy Institute of Ethics Journal, which has been a major vehicle for articles on this subject, would be less inclined to accept such articles for publication than it has been in the past" [8]. The bioethicist Renee Fox was even more vicious and vile in another communication titled "An Ignoble Form of Cannibalism," in which she said, "the Pittsburgh protocol is the most elaborately macabre scheme for obtaining organs that I have encountered. It borders on ghoulishness. I do not consider it either medically acceptable or morally permissible. Even if it were, this proposal would be unlikely to lead to a substantial increase in non-living donors or in transplantable organs." For her, "doctors and nurses put death on an accelerated time clock and then race frantically to beat the clock" [9]. Joffe would later argue that "the UPMC protocol conspicuously fails to be compatible with ordinary understanding of the language of 'irreversible' in the statutory definition of death and with the express intent of the President's Commission when it discussed 'irreversible'" [13].

Other protocols, notably the University of Wisconsin protocol, were published [14], and in Canada, national recommendations were published [15]. DCD became an effective means of expanding the potential donor pool, and its transplantation survival is comparable to donation after brain death despite higher rates of primary nonfunction and delayed graft function. However, even a large expansion of standard DCD programs would not address the worldwide shortfall in organ availability. There were 57,681 deceased donors reported to UNOS from 1994 to 2003. Of these, 1,177 were donors without a heartbeat, and 55,206 were brain-dead donors [16].

The bioethicist Franklin Miller and pediatric anesthesiologist Robert Truog, who have been staunch advocates of "doing away" with the DDR, wrote the following in their book:

The critical issue is not whether the patient-donor is already dead, to satisfy the DDR, but whether valid decisions to bring about death of the patient by stopping life-sustaining treatments and to donate organs are valid. If such decisions are valid, no harm or wrong is done by procuring vital organs prior to death, for the patient will be dead in a short interval of time because of stopping life support regardless of whether organs are procured. The absence of harm plus appropriate consent legitimates vital organ

donation. The DDR does no genuine moral work in current practices of vital organs donation because “brain-dead” donors remain alive and donors under DCDD protocols are not known to be dead at the time of organs are procured. We should be working toward honestly facing the fact that currently we are procuring vital organs from patients who are not known to be dead and that it is ethically legitimate and desirable to do so [17].

Despite ongoing ethical debate and protest, DCD protocols progressed and expanded rapidly and now include some centers allowing donation of the heart after a clinical trial shows feasibility and safety of transplantation of hearts from circulatory death donors [18]. Surgically retrieved donor hearts enter a perfusion system (recent technology such as TransMedics Organ Care System, nicknamed “Heart in a Box”), which would have pleased Barnard to read about it. Alternatively, surgeons initiate normothermic regional perfusion after observing a certain “hands-off” period (typically 5 min) prior to the first incision. The reestablished circulation remains limited to a specific area of the body, isolated to either the abdominal area or both the abdominal and thoracic area. To keep the perfusion “regional” after performing the sternotomy and a pericardiotomy, the arch vessels, including the cerebral arteries, are clamped. (Australia, the United Kingdom, France, Italy, and Spain have more years of experience than the United States in performing this procedure.) Ethicists have decried the procedure [19], but all the words on paper and spilled ink did little to slow the DCD momentum, which was energetically promoted by organ donation agencies (and some surgeons) and until the present day [20]. One of the pioneer surgeons of New York University Langone Health dismissed the ethical problems: “You guys can sit in your offices worried about the ethics of something, but you’ve never had to walk into a room where you were facing a patient with a family who’s dying” [21].

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