

## Perish and Publish: Non-Heart-Beating Organ Donation and Unduly Iterative Ethical Review

ABSTRACT. In the expanding repertoire of practices designed to increase the supply of organs for transplantation, non-heart-beating cadaver organ donation has generated an ongoing debate in the literature. The continuing stream of articles is disquieting in part because it documents a troubling “trial-and-error ethics” approach to the formulation of organ procurement policy, and because it raises serious questions about the reasons that the development of this policy is being mediated by published communication. In the light of concerns about the implicit support and credibility that professional publications give to organ procurement policies, restraint in publishing articles about non-heart-beating organ donation as well as in devising such policies is strongly advocated.

**A**T THE INCEPTION OF THE 1990s, the ungainly concept “non-heart-beating cadaver” organ recovery began to be applied to the process of obtaining organs for transplantation from persons pronounced dead according to traditional cardiopulmonary standards—the irreversible cessation of circulatory and respiratory functions. The term distinguishes it from “heart-beating cadaver” organ donation, the most frequently utilized mode of organ procurement, in which organs are taken from persons declared dead based on the irreversible stoppage of brain function (“brain death”), rather than of spontaneous breathing and heart beat.

As Bethany Spielman and Cynthia Simmons McCarthy (1995) document in their “Beyond Pittsburgh” article, which appears in this issue of the *Kennedy Institute of Ethics Journal*, during the past four years, beginning with the University of Pittsburgh Medical Center’s protocol

(UPMC Policy 1993), non-heart-beating cadaver organ procurement has spread rapidly in the United States. Underlying the deployment and diffusion of this procedure is what the transplant community describes as the “severe and steadily worsening shortage of organs” (Spital 1995, p. 504) and escalating concern about how to remedy it.

Since the 1980s, the sense of urgency in the transplant field about how to acquire more organs has greatly increased, and an expanded repertoire of means that it is hoped will enlarge the “donor pool” and “ease the shortfall” (in the language of the field) has been set into motion. Non-heart-beating cadaver donor transplantation figures prominently among the new, and the renovated older, methods for procuring more organs that have been advocated during the period from 1991 to 1995. Other methods have included espousal by the American Medical Association’s Council on Ethical and Judicial Affairs (1995) of the use of anencephalic infants as organ donors; a groundswell of renewed interest in xenotransplantation—the use of animals as organ sources, particularly baboons and pigs (Nowak 1994); and “reanimation” (proposed by Loma Linda University Medical Center), which entails “restarting the heart” of donors 10 to 15 minutes after they have been pronounced dead according to standard cardiopulmonary criteria (*UNOS Update* 1994). These methods emanate not only from awareness of all the persons waiting for organs and of the many deaths that occur before transplantable organs are found, but also from regretful recognition that “the number of organ donors is unlikely to keep pace with increased demand” and that most families still refuse to donate the organs of their dying relatives despite public drives for donors, educational campaigns about the good that can come from transplantation, legislatively mandated donor cards and “required request” policies, and the “overwhelming support for donation” consistently expressed by the U.S. public in Gallup polls (Siminoff et al. 1995).

All of these methods, non-heart-beating cadaver organ procurement included, however, have a quality of desperate determination about them and incorporate features that raise worrisome ethical questions. The drive for more organs may be leading to behaviors that are increasingly frantic and dubious.

As Spielman and McCarthy state, the chief “focal point of ethical discussions of non-heart-beating cadaver procurement in the U.S.” has been the protocol for this mode of transplantation developed by the University

of Pittsburgh Medical Center. The list of references cited by Spielman and McCarthy encompasses most, but not all, of the articles that have been published about non-heart-beating organ donation between 1993 and 1995 (see also Arnold et al. 1995). For example, they do not mention articles pertaining to the Regional Organ Bank of Illinois's protocol for transplanting kidneys from recently deceased, non-heart-beating patients who die in the emergency room, or shortly before arriving there, a protocol that has been another source and center of ethical debate (*Medical Ethics Advisor* 1995). There are also a number of articles currently in press, and still others have been submitted for publication.

The literature about the procedures and policy for non-heart-beating organ donation at the University of Pittsburgh describes the history and content of its protocol; the Medical Center's initial experiences in implementing it; the views held by physicians, nurses, ethicists, lawyers, social scientists, and organ procurement coordinators about Pittsburgh's experimentation with this method of retrieving organs; Pittsburgh's responses to these opinions; reports by Pittsburgh on changes they have made in the protocol with regard to the care of patients who become non-heart-beating donors and the treatment of their families; and reactions to these revisions by professionals and scholars. This sequence of commentaries on commentaries, criticisms of criticisms, and reports about reports has been triggered by Pittsburgh's commendable decision to develop its procedures and policy for non-heart-beating cadaver organ donation as openly as possible and to involve a wide range of professionally relevant persons in its enactment and evolution. But the continuing stream of articles that has been generated is also disquieting for at least two reasons. First, the succession of articles documents a troubling "trial-and-error ethics" approach to the formulation of organ procurement policy (Fox, "Trial-and-Error Ethics," in press). Second, it raises perturbing questions about the reasons that the formulation of this policy is being mediated by published communication.

An example taken from the Pittsburgh case will illustrate the trial-and-error process to which we refer. It concerns proper end-of-life care for the patient-donor and respectful attention to the needs of his/her family. In the original version of the Pittsburgh protocol, sedatives and analgesics were meted out to patient-donors sparingly, only after they exhibited signs of distress. Prospective donors were separated from their

families as they approached death and were transported to an operating room. There they were withdrawn from life-support systems without added comfort medication and underwent organ retrieval surgery two minutes after their hearts stopped and they were pronounced dead. The reasons given for this conduct were to limit warm ischemia and ensure the viability of organs for transplantation, to contravene any impression that the death of patients was being hastened in order to obtain their organs, and to protect both relatives and health professionals from what was assumed to be the undue stress of having the patient-donor's family present when the medical team made a rapid shift from terminal care to the preliminary steps for organ procurement. Influenced by published criticisms and by their own clinical experiences—particularly the fact that three out of the first four families they asked to donate organs refused to do so unless they could be present at the patient's bedside during withdrawal of therapy and until the pronouncement of death—Pittsburgh has altered its protocol in most of these respects and has published accounts of the changes they have made (DeVita and Snyder 1993; DeVita, in press).

The openness to scrutiny, candor about shortcomings and misconceptions, and willingness to rectify them that Pittsburgh has exhibited may be exemplary, but this high-mindedness does not dispel a troubling question: Why was it with hindsight, rather than foresight, that the health care professionals and the ethics committee members involved in formulating the Center's policy for non-heart-beating cadaver organ transplantation realized that they should not isolate dying patient-donors from their families, ship them to an operating room before their death occurred, and tightly restrict their pain medication? This question is compounded by the fact that Pittsburgh publications give the impression that the post hoc revisions the Medical Center has made have stemmed more from pragmatic and prudential conclusions, incrementally reached, about what could and could not be done without creating "community backlash against organ transplantation" than from enlightenment about what was medically inhumane and morally wrong about the initial procedures.

The story surrounding the protocol for non-heart-beating organ donation drawn up by the Regional Organ Bank of Illinois (ROBI), an organ procurement organization located in Chicago, is a more convoluted and disturbing one. It involved a pilot plan, launched in 1993, to explore the feasibility of transplanting organs from fatally ill or injured

patients who die en route to (or in) the emergency room of a hospital and are pronounced dead on the basis of cardiopulmonary criteria. Peritoneal cooling and vascular perfusion, which entail making small femoral and abdominal incisions in the body to insert cannulas and catheters, were used to preserve the non-heart-beating cadaver donor's kidneys. This protocol did not require the consent of a prospective donor's next of kin before beginning the perfusion procedures, although if the family did not give permission for organ donation, the perfusion lines were subsequently withdrawn (sometimes with, and sometimes without, the knowledge of the family).

The protocol was introduced to the institutional review board (IRB) of Loyola University Medical Center by a trauma surgeon on the Center's staff who agreed to act as the principal investigator. The IRB decided to approve the study, but only if prospective informed consent for starting the procedure to preserve the kidneys was obtained along with permission to use them for transplantation. Through the intermediary of the principal investigator, ROBI substituted another version of the protocol that made it unnecessary to have family consent to initiate cold perfusion of the kidneys. Nine pairs of kidneys were procured from non-heart-beating cadaver donors and transplanted without family permission for the cold perfusion part of the process before Loyola discovered the situation and called an immediate halt to acquiring organs under those conditions. ROBI subsequently ended that way of proceeding, too. Their protocol now requires family consent for the insertion of perfusion lines as well as for organ donation. With post facto piety, ROBI stated that the change reflected the belief that ethical concerns outweigh the benefits of a "presumed consent approach" (*Medical Ethics Advisor* 1995, p. 50; Fox, "Afterthoughts," forthcoming 1996).

Publications about ROBI's non-heart-beating cadaver organ transplant venture have not been as numerous or as extensive as those that deal with the Pittsburgh experience. They have been largely confined to periodicals like *UNOS Update* and *Medical Ethics Advisor*. And, as indicated, the circumstances surrounding the trials of this type of organ procurement that were conducted under the protocol of the Regional Organ Bank of Illinois have not been characterized by the integrity and openness displayed by Pittsburgh. These important differences notwithstanding, the University of Pittsburgh Medical Center and the Regional Organ Bank of Illinois share a strong commitment to finding additional

sources of organs, engagement in “try-it-and-see-what-happens” efforts to move ethical boundaries for this purpose, and a tendency to determine the ethical limits of their efforts to obtain organs more on the basis of concern about jeopardizing public trust in transplantation, than of abiding moral principles.

In our opinion, the amount of respectful attention that non-heart-beating cadaver organ procurement in general and the Pittsburgh protocol in particular have received through publications is problematic for another set of reasons. The great interest that professional journals have shown in publishing articles about non-heart-beating organ donation and its concomitants has created “secondary gain” advantages for the authors who have written multiple articles on the subject, by adding numerous items to their *vitae*. Although there is nothing inherently dishonorable about this, it does create tension between two motives: conviction about the importance of perfecting ethical conduct, on the one hand, and the desire to advance one’s professional career through published commentary, on the other.

The outpouring of articles delineating successive ethical revisions to the same protocol also inflates the importance of this mode of organ procurement, gives too much credit to those who are pursuing it, and confers an unwarranted degree of legitimacy on a method of organ procurement that has subjected dying patients and their families to ethically unacceptable conditions. To be sure, some of the most objectionable conditions have been corrected in anticipation of, or in response to, publication. But the corrections have been done in an after-the-fact-way, without clear insight into why they were ethically wrong in the first place. Further, despite the changes that Pittsburgh has introduced into its protocol, families are still being rushed away from the patient-donor’s bedside as soon as death has been declared, and death continues to be pronounced only two minutes after a potential donor’s circulatory and respiratory functions cease. What is more, the revised Pittsburgh protocol contains provisions that permit the insertion of femoral artery lines and the administration of heparin in dying donors to monitor blood pressure and to keep blood clots from forming. In so doing, it sets a precedent for introducing interventions to maintain organs in an optimal state for transplantation to patients who are recipients—interventions that at the same time are incompatible with the most humane care of the patients who are donors.

The Pittsburgh protocol shares another profoundly disturbing characteristic with other non-heart-beating cadaver protocols: an objectification of the nearly dead or newly dead patient that accelerates the transformation of a person from “patient” to “donor.” Objectification may help the professionals involved in the procurement and transplantation of organs to handle the feelings that this process evokes, but it is also a source for some of the ethically problematic features we have been considering. The Regional Organ Bank of Illinois’s variant of non-heart-beating organ recovery, for example, initially skirted family consent for major interventions such as peritoneal cooling and vascular perfusion of a candidate-donor’s kidneys, in no small measure, we believe, because of this objectification combined with an unrestrained attitude toward obtaining organs.

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. Enthusiasm about submissions on this topic should be tempered with more judicious awareness of what is being implicitly supported by the voluminous flow of publications devoted to non-heart-beating cadaver organ recovery. 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—including, we recognize, this one.

#### REFERENCES

- Arnold, Robert M.; Younger, Stuart J.; Schapiro, Renie; and Spicer, Carol Mason, eds. 1995. *Procuring Organs for Transplant: The Debate over Non-Heart-Beating Cadaver Protocols*. Baltimore: Johns Hopkins University Press.

- Council on Ethical and Judicial Affairs, American Medical Association. 1995. The Use of Anencephalic Neonates as Organ Donors. *Journal of the American Medical Association* 273: 1614-18.
- DeVita, Michael A. Reflections on Non-Heart-Beating Organ Donation: How Three Years' Experience Affected the University of Pittsburgh's Ethics Committee's Action. *Cambridge Quarterly*, in press.
- and Snyder, James V. 1993. 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. *Kennedy Institute of Ethics Journal* 3: 131-43.
- Fox, Renée C. Afterthoughts: Continuing Reflections on Organ Transplantation. In *Meanings and Realities of Organ Transplantation*, ed. Stuart J. Younger, Renée C. Fox, and Laurence J. O'Connell. Madison: University of Wisconsin Press, forthcoming 1996.
- . Trial-and-Error Ethics: Experimenting with Non-Heart-Beating Cadaver Organ Donation. *Cambridge Quarterly*, in press. (Response to: DeVita, Michael A. Reflections on Non-Heart-Beating Organ Donation: How Three Years' Experience Affected the University of Pittsburgh's Ethics Committee's Action. *Cambridge Quarterly*, in press.)
- Medical Ethics Advisor*. 1995. Racing the Clock for Organ Recovery: Time Constraints and Presumed Consent. (April): 49-50.
- Nowak, Rachel. 1994. Xenotransplants Set to Resume. *Science* 266: 1148-51.
- Siminoff, Laura A.; Arnold, Robert M.; Caplan, Arthur L.; et al. 1995. Public Policy Governing Organ and Tissue Procurement in the United States: Results from the National Organ and Tissue Procurement Study. *American College of Physicians* 123 (1 July): 10-17.
- Spielman, Bethany, and McCarthy, Cynthia Simmons. 1995. Beyond Pittsburgh: Protocols for Non-Heart-Beating Cadaver Organ Recovery. *Kennedy Institute of Ethics Journal* 5: 323-33.
- Spital, Aaron. 1995. Mandated Choice: A Plan to Increase Public Commitment to Organ Donation. *Journal of the American Medical Association* 273: 504-6.
- UNOS Update*. 1994. Reanimation May Play Role in Increasing Donor Supply. (November): 11-12.
- UPMC Policy. 1993. UPMC Policy for the Management of Terminally Ill Patients Who May Become Organ Donors After Death. University of Pittsburgh Medical Center, 18 May 1992. Reprinted in *Kennedy Institute of Ethics Journal* 3 (2): A-1-A-15.