

From Pittsburgh to Cleveland: NHBD Controversies and Bioethics

GEORGE J. AGICH

In March 1997, *60 Minutes*, a nationally syndicated news magazine program, featured a story in which it was claimed that The Cleveland Clinic Foundation (CCF) had in place a non-heart-beating donor (NHBD) protocol that involved killing patients for their organs. These charges were brought by a philosopher from a local university. A student who worked at LifeBanc, the northeastern Ohio organ procurement agency where the organ donation protocol originated, was given the protocol by LifeBanc with the understanding that it was to be used in class; the student and professor charged that the protocol involved killing patients for their organs. These claims were advanced without noting that the protocol was a draft that was being reviewed and revised and had not been implemented.

The widely reported charges directly challenged the integrity of organ procurement practices in the United States. They were taken so seriously that the Secretary of the Department of Health and Human Services requested the prestigious Institute of Medicine of the National Academy of Sciences to conduct a study and offer recommendations on the issues associated with non-heart-beating organ transplantation.¹ I leave the analysis and discussion of this report for other occasions; instead, at the gracious invitation of the editors of *CQ*, I reflect on the role of bioethics in the media maelstrom that surrounded the CCF protocol.

Questions about NHBD are hardly new in bioethics. Several books, journal issues, and many articles have dealt with various aspects of NHBD.² This literature first focused on the so-called Pittsburgh protocol, a protocol developed at the University of Pittsburgh involving a return to the practice of using asystolic organ donors.³ Occurring only five years apart, the controversy surrounding the Pittsburgh protocol and the LifeBanc proposed protocol illustrates some important lessons about the contribution of bioethical analysis and discussion to the evolving practice of medicine as well as some of the perils involved in conducting a bioethics inquiry in the mainstream media.

The *60 Minutes* story was the culmination of a series of questions, none of which, remarkably, was ever brought directly to the attention of physicians, administrators, or bioethicists at CCF. In spring 1996 the philosopher went to the Cuyahoga County Prosecutor (Cleveland is in the county of Cuyahoga, Ohio) alleging that CCF had a protocol in which patients were to be killed in order to take their organs. This claim was reportedly based on the belief that the use of the drugs heparin and regitine either caused death or obscured the accurate determination of death.⁴ Even though similar protocols have been used in at least a third of the regional organ procurement organizations⁵ and

the protocol was openly provided to the student for classroom use, the LifeBanc protocol was treated as the product of a conspiracy. In response to rumors circulated in spring 1996 that CCF was under investigation, concerned CCF officials queried the Assistant County Prosecutor, who confirmed that an investigation into organ procurement practices at CCF was being conducted. CCF informed the County Prosecutor's office that the protocol in question was under open discussion internally. During its consideration at CCF, the LifeBanc protocol was, in fact, modified with involvement of neurosurgical intensive care physicians and the CCF Ethics Committee.⁶

Although the professor had received assistance from the CCF Department of Bioethics a few years earlier in recruiting students and CCF had provided meeting space for the professor's course, CCF colleagues were not approached. The professor explained why CCF was not approached in the following way: "If you have reason to believe that someone plans to violate the law, you report them to the authorities. You don't sit down for a nice chit-chat. What purpose would such consultation serve? To inform them of facts they already knew, or had a professional duty to know?"⁷ The idea that a distant assessment might not be thoroughly accurate apparently was not seriously considered.

These events are recounted because they raise important and seldom-discussed questions about the responsibility of bioethicists who claim expertise on clinical, medical, or scientific questions in interaction with public officials and the media. In the first generation of bioethics issues, bioethicists could be cast as privileged observers and disinterested commentators. Though not without its critics, bioethics has been allied with patient and family rights, yet accepted in medical institutions.⁸ Clinical bioethics and ethics committees owe their acceptance to everyday yeoman's work on myriad issues plaguing the practice of medicine. If bioethics is relevant, it is not because the media have made it so, though media coverage has certainly helped to promote the field.⁹

Bioethicists have earned their place as thoughtful collaborators in academic medical centers through their daily work on institutional committees, in clinical education, and in bioethics research. Even in the midst of contentious and emotionally charged issues such as abortion, healthcare reform, and physician-assisted suicide, or in the face of emotion-ridden conflicts over patient care decisionmaking, academic and clinical bioethicists alike have generally been able to conduct themselves as responsible and respectful colleagues whose fundamental role is to promote rational discourse and discussion. As a result, bioethics has emerged as a practice that aims for the resolution of conflicts or conundrums. Although the media might sensationalize bioethics topics, bioethicists have generally sought the path of responsible, rational inquiry and argument. They have chosen to focus their energies academically. Perhaps the rub occurs here.

Bioethics is a multidisciplinary endeavor, not a single discipline in which one can claim competence or expertise based on position or title. Teaching bioethics or practicing clinical bioethics may confer face validity, but not authoritative expertise. What might serve as good teaching cases in academic bioethics courses are often greatly oversimplified in order to illustrate theoretical distinctions and points. What serves these disciplinary purposes, however, may be quite remote from the complex issues and processes involved in clinical settings. It is not enough for bioethicists to think abstractly about an issue or problem, they

must practically understand the problem in the actual context of the care of patients. Bioethics needs a firm linkage to clinical practice and the biomedical sciences. Cooperation and collegiality, often optional in traditional academic contexts, are indispensable in bioethics.

Had these points been heeded, the critics would have learned that CCF was in the process of modifying the original protocol. In discussions with the ethics committee, the protocol was revised precisely to accommodate a range of ethical concerns that were never addressed in the controversy. All patients had to meet strict criteria. The only patients eligible for inclusion were patients who had suffered a documented, devastating brain stem injury. They also had to meet strict criteria demonstrating that they were avventilatory, i.e., that they lacked respiratory drive as assessed by neurointensivists highly skilled in prognosis. The protocol was rewritten to require caregivers to stay focused on the patient's and the family's interests and not be distracted by organ donation. Importantly, the family would have had to ask independently about organ donation. Indeed, the prospect of NHBD would never have been offered by a member of the healthcare team, transplant team, or the regional organ donation agency until two conditions were met. *Only if* a family made an independent decision to withdraw life-support based on patient and family values in light of the prognosis and consistent with ethical and legal standards regarding withdrawal of life-support *and* independently raised the possibility of organ donation would the patient be eligible for NHBD. An additional consent requirement was also included, namely, the patient would have had to previously indicate a desire to donate organs, a condition imposed so as to respect autonomy and further eliminate conflict of interest.

When these conditions were met and life-support was to be withdrawn, the patient would be taken to the operating room on monitors accompanied by the ICU physician who would withdraw life-support. After life-support was withdrawn, if the patient did not die as expected within one hour, the patient would be returned to the ICU for continued end-of-life care. The family making the decision to withdraw life-support and donate organs would have been fully informed of all of these conditions. The protocol also included a provision for the presence of a member of the clergy in the operating room who could perform appropriate religious rituals at the time of death. These conditions were so strict that only a very small number of patients would ever have met the selection criteria. As a protocol intended to "take" organs, this protocol would have been inefficient; as a protocol to assist individual families fulfill their desire to donate organs of a family member who suffered a catastrophic brain stem injury, the protocol might have been a qualified success. To be sure, the protocol did include the use of the drugs heparin and regitine to ensure organ quality, but as the IOM study concluded, there is no evidence or compelling ethical arguments to warrant banning the use of these drugs. The IOM properly advised that sound medical judgment is needed to determine when the use of these medications is contraindicated, for example, in patients with known intracranial bleeds. The CCF protocol did not encourage clinically or ethically unjustified administration of these medications.

Two features of the CCF protocol are especially worth stressing. First, the consent requirements were designed to avoid conflicts of interest and to ensure that patient autonomy and family rights were respected. Before a patient was eligible for consideration in this protocol and before the organ procurement

officer was to be notified, there had to be some prior indication of the patient's own intent to donate organs as evidenced by family reports or a signed donor card. The family must have separately raised the possibility of organ donation for the patient, and a decision had to be made based on the patient's own wishes or advance directive in light of a highly specialized neurological assessment that the patient would not survive and that care should be withdrawn. The neurological assessment was based on the rigorous application of a subset of Apache III data. Patients would be eligible for this protocol based on this assessment only if they failed an apnea challenge on two occasions. Ironically, the CCF protocol conservatively limited NHBD to patients who were as proximate to death as can be reliably determined.

It is ironic that The Cleveland Clinic Foundation's NHBD protocol came under such fire. It is a remarkably conservative protocol designed to ensure that patient autonomy and family decisionmaking were protected, that legal requirements for withdrawing life-support were scrupulously observed, and that conflicts of interest were minimized—all points subsequently recommended in the IOM study. The protocol was conceived as a patient care protocol, one that offered the families of a select group of patients who have suffered devastating neurological injury the opportunity to donate organs that would not have been otherwise available. Such donation has been widely reported to provide consolation and comfort to families, who see a meaning in the loss of a loved one. The protocol was not designed or intended to *take* organs, but rather, under an extremely limited set of circumstances, to *make possible* donation.

Organ donation in the CCF protocol was limited because the bioethics discussion since the initiation of the Pittsburgh protocol had rightly raised a set of questions about consent, determination of death, and conflict of interest that were actively addressed in the revision process. Saying this certainly does not mean that the protocol is beyond criticism or scrutiny. Bioethics rightly does not accept authoritarian claims, but bioethical analysis and criticism itself must be responsible and academically sound. Feeding the media appetite for sensationalistic stories does little to contribute to the ethical improvement of health-care. Public trust is critical to the organ donation enterprise, and sensationalistic stories can all too easily erode a trust that is difficult to rebuild. The IOM report strongly urged public discussion and disclosure of NHBD protocols, but such discussion needs to be informed. It is ironic that the public criticism of a protocol that was in process of development stirred this controversy. The CCF protocol was not made public, but was also not a secret. It was circulated widely in the institution and efforts were made to involve all relevant parties in its discussion and development. This very process of openness, albeit within the institution, seems to have provided fodder for some of the more outlandish charges made.¹⁰

Clearly, the call for openness and public discussion is a tricky matter. Openness itself requires trust and trust requires communication that is open. Critics, too, must be open and share their concerns in ways that contribute to the improvement of the product. The unwillingness of critics to bring their concerns to the institution in a collaborative fashion promotes a distrust that bioethics should work to avoid. The adage "if you're not part of the solution, then you are part of the problem" seems apt. Media attention is ephemeral. Today's sensationalist story is quickly forgotten, but the perennial problems

that occupy bioethics, such as the shocking shortage of organs available for transplantation, remain.

Bioethicists *do* solve problems; we can make a constructive difference. But bioethics can also create problems when it succumbs to the media machine. As a practice, bioethics, too, must have an ethics. The deep story and issue in this affair is the “Ethics of Media Bioethics,” as I have previously discussed¹¹ and the media sensationalization of a common practice of NHBD in various sites for two decades.¹² Is bioethical analysis and discussion responsibly carried out by such sensationalism?

No bioethicist can reasonably expect to confine discussion and debate to academic journals; responsible bioethics will always be communal. Medicine exists within society and there is no compelling reason, save confidentiality of medical records, to confine discussion of important bioethics topics within healthcare institutions. An informed public is a democratic ideal that bioethicists should support. Bioethicists do not have a privileged perch just because they teach the subject. Media attention can blind any one of us to the fact that bioethics is less a discipline in which each of us can reliably claim full competence than it is a field of endeavor composed of a diversity of issues in which none of us is completely expert. As a practice, bioethics is conducted in a socially shared space; we learn from and with others. That is one reason the field of bioethics is so vibrant. We are concerned with the subject matter, the issues, and problems arising both in the daily practice of medicine and at the edge of the biomedical sciences. We share no single discipline, only a commitment to the complex process of understanding and enhancing the place of value in medicine. For this reason, what we say and when and how we speak matters, because the media’s interest in bioethics stories often ends as soon as the shock subsides.

In the midst of this controversy, patients awaiting transplantation at The Cleveland Clinic Foundation hospital requested a meeting to brief them on the controversy and to answer their questions. This meeting portrayed a side of the controversy that was less dramatic, a side that the media was not interested in examining, yet underscores the human cost underlying the shortage of organs for transplantation. The media also ignored the situation of families of patients with devastating brain stem injuries. Being able to respond affirmatively to the requests of a few of these families to donate organs motivated the discussion of the protocol at CCF. Unfortunately, the anxiety and suffering of patients awaiting transplantation or the emotional needs and altruistic concerns of families struggling to cope with a loved one’s devastating injury are apparently not inflammatory enough to elicit much attention. Rather than feeding the media’s addiction to the unusual and controversial, bioethics needs to find ways to help the media to articulate the usual, everyday ethical realities involved with complex issues like organ donation and transplantation. The future of bioethics may be not in the media spotlight, but in shadows where the quality of everyday patient care is enhanced.

Notes

1. Institute of Medicine. *Non-heart-beating organ transplantation: medical and ethical issues in procurement*. National Academy Press, 1997.

2. Arnold RM. Procuring organs for transplant: the debate over non-heart-beating cadaver protocols. Baltimore: Johns Hopkins University Press, 1995; [special issue]. *Kennedy Institute of Ethics Journal* 1993;3(2); Spielman B, ed. *Organ and Tissue Donation: Ethical, Legal, and Policy Issues*. Carbondale, Ill.: Southern Illinois University Press, 1996.
3. The Pittsburgh NHBD protocol was adopted in May 1992. See DeVita MA, Snyder JV. 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* 1993;3(2):131-43. The wider history of asystolic organ donors is also reviewed in DeVita MA, Snyder JV, Grenvik A. History of organ donation by patients with cardiac death. *Kennedy Institute of Ethics Journal* 1993;3(2):113-29.
4. A corollary criticism, repeatedly made by the professor, was that the draft protocol contained a reference to ascertaining death by "carotid pulse" upon disconnection from life-support. This was taken as evidence that the physicians would rely on this clinical method when the use of regitine, a drug that lowers blood pressure, would obfuscate the determination of irreversible asystole. This belief persisted despite the fact the CCF protocol required that the patient be transported to the operating room with life-support and monitoring in place. Anyone with clinical experience would have realized that the patient would have to be taken to the operating room on monitored life-support. Checking the carotid pulse after withdrawal of life-support is a direct, hands-on corroboration that the asystole detected by cardiac monitoring was not a monitoring error. It is routinely, perhaps even symbolically, used to validate that a patient has died per the discontinuation of life-support. It did not represent a regression from more accurate and reliable electronic monitoring, as was suggested, to one that was ethically problematic, but rather represented a humane and symbolic addition to electronic instrumentation.
5. Spielman B, Verhulst S. Non-heart-beating cadaver procurement and the work of ethics committees. *Cambridge Quarterly of Healthcare Ethics* 1997;6:282-7.
6. Although the protocol was designed as a clinical, not a research protocol, it was also sent to the CCF IRB, which concurred that formal approval was not required since it did not involve research.
7. Letter to the Editor. Blowing the whistle on transplant protocol. *Cleveland Plain Dealer* 1997; May 21.
8. Rothman DJ. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books, 1991.
9. Bioethics is listed in Smith-Maxey LR. Twenty-five hottest careers for women. *Working Woman* 1996; July.
10. One of the more outlandish was the use by CBS News in a promotion of the *60 Minutes* story of an excerpt from a CCF videotape of a meeting with operating room personnel to discuss the protocol and to answer questions. The excerpt was taken totally out of context, which was an educational meeting that was videotaped for OR personnel who were not able to attend. The excerpt has the director of the neurosurgical ICU saying that the patient would not be dead when taken from the neurosurgical ICU. CBS used the excerpt to bolster the claim that CCF physicians intended to remove organs from living patients. However, the preceding and subsequent portions of the videotape show that the director of the neurosurgical ICU was explaining the process for complying with the family's request to withdraw life-support consistent with hospital ethics policy and state law. Although common enough in ICUs and other hospital settings, withdrawal of support is obviously unusual in operating rooms. The attempt to educate operating room personnel about the ethics and practice of withdrawal of life-support at the family's request was used to imply a sinister plan to callously take organs from vulnerable patients.
11. Agich GJ. The ethics of media bioethics. Bioethics Summer Retreat, Hilton Head, South Carolina, 11 June 1997.
12. The University of Wisconsin at Madison, for example, has always had an active NHBD program.

Editor's note: The producers of 60 Minutes have expressed a desire to respond to the issues in this article. Their response will appear in a future issue.