Responses and Dialogue

Response to "From Pittsburgh to Cleveland: NHBD Controversies and Bioethics" by George J. Agich (CQ Vol 8, No 3)

60 Minutes Sets the Record Straight

Frank Koughan and Walt Bogdanich

We were not surprised by the opinion piece written for the *Cambridge Quarterly* by George J. Agich, Ph.D., who chairs the Cleveland Clinic Foundation's bioethics department. Dr. Agich uses the article to attack those who criticized his institution's proposed non-heart-beating organ donor protocol. Because we reported on this controversy for *60 Minutes* in April 1997, we wanted to set the record straight.

Cambridge Quarterly readers should be aware of the following:

• The person who contacted authorities about CCF protocol is dismissed by Dr. Agich as "a philosopher from a local university." He fails to mention that this person is a bioethicist and is in fact the director of that university's bioethics program. In an article that purports to discuss the role of bioethics in this controversy, this is a significant omission. (It is also worth noting that the university "student" who worked with the professor on this issue has well over a decade's experience in organ procurement, starting with the donation of her own child's organs 16 years ago.)

- Dr. Agich's discussion of the interaction between bioethics and the media omits a significant fact: This story did not come to our attention via this (or any other) bioethicist, nor was the professor eager to speak with us when we called. After our broadcast, the professor declined a number of interview requests from other reporters, which we believe led to some rather harsh treatment in the local Cleveland press.
- Dr. Agich implies that 60 Minutes relied solely on the bioethics professor for our information. That is untrue. 60 Minutes spent six months conducting dozens of interviews with transplant physicians, neurologists, neuropathologists, cardiac surgeons, anesthesiologists, hospital administrators, organ procurement organizations, lawyers, law enforcement officials, transplant recipients, bioethicists, and researchers, and reviewing hundreds of pages of medical literature. Just about the only people we didn't interview were representatives of Dr. Agich's institution, the Cleveland Clinic, though this was certainly not from a lack of trying. Dr. Agich does not hesitate to take the professor to task for not contacting the CCF, but he fails to note that CCF turned down our repeated requests for an on-camera interview. (And incidentally, Dr. Agich

did not speak to the professor nor anyone from *60 Minutes* before submitting his article.)

• Dr. Agich distorts the Institute of Medicine's views on the use of heparin and phentolamine (Regitine), both of which would be injected into still-living patients under the CCF's proposed protocol. Dr. Agich interprets the IOM study as finding "no evidence or compelling ethical arguments to warrant banning the use of these drugs," but he leaves out the most important part of the study's conclusion:

> It is very unlikely that heparin and phentolamine would be part of nondonor patient care in medical circumstances similar to those of NHBDs. In certain patients under certain circumstances, these drugs may actively hasten death although no specific instance of this in any donor has been reported.... In the occasional NHBD with ongoing intracranial bleeding or deficiencies in blood volume, the administration of anticoagulants or vasodilators such as heparin or phentolamine is not indicated because it could actively cause death.

- Dr. Agich also fails to note that the CCF protocol contains a blanket policy of administering 30,000 units of heparin and 10 mg of phentolamine. Yet the IOM study concluded: "a blanket policy cannot be recommended because of possible untoward effects in some donor patients."
- Dr. Agich contends that the CCF's "critics" were unaware that the CCF "was in the process of modifying the original protocol . . . precisely to accommodate a range of ethical concerns that were never addressed in the controversy." In fact, at the time of the contro-

versy, CCF's director of health affairs confirmed to the Associated Press that the protocol had been approved several months before we aired our story. That protocol, upon which we based our story, called for the use of drugs and a method of declaring death that other bioethicists and physicians found troubling. Whatever "ethical concerns" the CCF may have had at that time may well have been prompted by legal concerns, which Dr. Agich fails to mention: in the wake of investigations by the Ohio State Board of Pharmacy and the Cuyahoga County Prosecutor, the CCF had been informed that implementation of the protocol as written would be considered homicide.

- Although patients who did not die as expected would, as Dr. Agich says, be returned to the ICU, he fails to mention that the controversial drugs heparin and phentolamine would have been given to these patients before their return to the ICU.
- Dr. Agich mentions the University of Wisconsin to illustrate his point that NHBDs are a "common practice." Surely he is aware that in addition to the proposed CCF protocol our story focused extensively on the UW protocol, which called for the administration of the same potentially harmful drugs. (There was a significant difference between the two protocols, however: CCF required only half as much time between cessation of heartbeat and organ procurement as UW. CCF's proposed waiting time was also considerably less than that recommended by the IOM.)
- Dr. Agich accuses CBS News of taking a portion of a videotaped CCF grand rounds out of context

"to bolster the claim that CCF physicians intended to remove organs from living patients." In fact, the taped excerpt, used in context, illustrates the fact—which has never been subject of dispute that unlike traditional brain-dead donors, these patients are not dead when they enter the operating room. (Also, Dr. Agich is well aware that at no point in the grand rounds videotape does anyone explain to the staffers that these patients will be injected with potentially harmful drugs.)

Finally, in criticizing us and the bioethics professor we interviewed, Dr. Agich fails to note the many other prominent bioethicists who have raised concerns about protocols similar to the one proposed by CCF. Among them:

- *George Annas*, Boston University, calls non-heart-beating organ donation a "bizarre recycling scheme" which is "every bit as barbaric as" the fictional scheme in the novel *Coma*. He says that what it "asks of donors, their families, and caretakers goes so far beyond the pale of the medically decent, morally allowable and spiritually acceptable that it strains credulity."
- *Stuart Youngner*, University Hospitals, Cleveland, says "there is little scientific data to support the conclusion that [NHBDs] are certainly dead when preservation measures are begun and even when organs are taken. Thus organs will be taken from probably dead, practically dead, as good as dead, almost dead but not *certainly dead* patients. This problem not only violates the dead donor rule, but may well foment mistrust of and resistance to organ donation."
- Joanne Lynn, Center for the Evaluative Clinical Sciences, referring

to the Pittsburgh protocol's twominute wait after cessation of heartbeat (the same as in the CCF protocol) said that the protocol "might allow taking organs from persons who are not dead, depending upon some specifications of that definition. This is imprudent, to say the least."

• *Renee Fox*, University of Pennsylvania, found the Pittsburgh protocol "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." Informed by 60 *Minutes* of the details of the CCF protocol, she called it "an exquisite and terrible example of how small measures lead to real horrors."

In addition to the bioethicists who have raised concerns about NHBDs in general and the CCF protocol in particular, there is dissent within the transplant community as well:

- *Dr. Michael DeVita,* University of Pittsburgh, who played a major role in the development of the Pittsburgh protocol, told the *New York Times* that phentolamine "can certainly hasten death. . . that's specifically why we don't use it at Pittsburgh."
- *Dr. John Fung*, University of Pittsburgh's director of liver transplantation, told the *Cleveland Plain Dealer*, "The question is, do you want to hasten the heart stoppage, or let it go through the natural process? If there were no ethical issues, everyone would be using [phentolamine]." The *Plain Dealer* also reported that hospitals in Rochester and Miami "refuse to administer [phentolamine] for ethical reasons."

nttps://doi.org/10.1017/S0963180199224139 Published online by Cambridge University Press

- *Howard Nathan*, director of the Delaware Valley Transplant Authority, one of the most vocal critics of our broadcast, told us in an interview before it aired that when it comes to giving organ-preserving drugs to still-living patients, "you can't do that. That's one of the things you have to be careful about."
- *Carole Beasley*, managing director of the Partnership for Organ Donation, wrote us after our broadcast, saying that "we too have serious concerns about the pursuit of nonheart-beating donors...."
- UNOS, in their publication UNOS Update wrote that "this method of organ procurement is ethically problematic, however, because it uses nonstandard cardiac criteria in order to pronounce death quickly."

Dr. Agich would seem to prefer that this debate take place among bioethicists, far from the "media spotlight." But a survey of ethics committees published in the *Cambridge Quarterly* showed that 67% of the respondents ranked their committee members' knowledge of NHBD ethics issues as "fair" or "poor," and almost one in five did not even know if the procedure was performed in their own hospital.

Walt Bogdanich and Frank Koughan are a producer and associate producer, respectively, for CBS News' 60 Minutes. Their April 1997, report on the controversy surrounding non-heart-beating organ donation led the Institute of Medicine to study the issue.

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Say It Ain't So: 60 *Minutes* on NHBD

George J. Agich

Frank Koughan and Walt Bogdanich's response to my article, "From Pitts-

burgh to Cleveland: NHBD Controversies and Bioethics," reminds me of the Shakespearean line, "The lady protests too much, methinks." My article was not about the specifics of the 60 Minutes April 13, 1997, story on NHBD at the Cleveland Clinic Foundation (CCF), even though the story formed the basis for the reflection. I did not attack the critics, though I do believe that bioethicists are accountable for their scholarly and public pronouncements. Although I do not see why the 60 Minutes' story should be treated with deference, my article was designed to raise questions for a primarily bioethics audience about the involvement of bioethicists in media coverage of bioethics topics. I am flattered that they took notice of my piece, but think their efforts to set the record straight only obfuscate matters further.

Koughan and Bogdanich say that I "dismissed" the academic qualifications and personal and professional experience of the individuals who raised the concerns. That is an ungrounded accusation. Not mentioning the qualifications is not the same as dismissing them. Do they mean to suggest that in not listing the credentials, I meant to diminish the claims? I certainly know better than that and did not offer an ad hominum analysis of the Cleveland Clinic NHBD story. However, their pointing to the presence of credentials does not establish the truth of the claims made any more than pointing to their absence can establish the falsity of the claims. The "credentials" of the individuals were omitted mostly because they are irrelevant. I grant that if the concerns had been expressed by individuals without credibility or credentials, they would not have received the hearing that they did. That is precisely one of the questions that I raised, namely, what is the responsibility of bioethicists when given the opportunity to reach a national audience about issues and questions that they judge to be important.

For the record I want to note that in questioning the involvement of bioethics and the media, I am not defending my own involvement with the protocol. I took up my position at the Cleveland Clinic in early February 1997, by which time the development of the protocol was complete. The 60 Minutes story was broadcast on April 13, 1997. When I learned that 60 Minutes was about to report on the protocol, I conducted an independent investigation of the process whereby the protocol was reviewed and revised at CCF. I interviewed the physicians who contributed to its development, the Chair and members of the Institutional Ethics Committee, and the Chair of the IRB to ascertain their involvement with the protocol. I am an interested party in this matter to be sure, but I am far more marginal than Koughan and Bogdanich imply. I regard this case as a cautionary tale about the way that complex bioethics concerns can be distorted by the media. My article focused on a question that is increasingly unavoidable for bioethics, namely, how to conduct responsible public discussion of bioethics-related questions.

I accept Koughan and Bogdanich's report that the story did not come to their attention via any bioethicist, though I fail to see its relevance. However, their claim that the professor declined interviews is not true. After the 60 Minutes broadcast, the professor was interviewed on the syndicated Diane Rheem National Public Radio show and by Gina Kolata in a New York Times article as well by as the local media. I made no claim about the professor's motivation and do not wish to speculate whether the interviews were given with enthusiasm or reluctance. I also did not say or imply that 60 Minutes relied solely on the bioethics professor for information. However, since Koughan and Bogdanich raise the point, I will comment on the disturbing pattern behind this story which makes it appear that *60 Minutes*' efforts were directed to finding people who could deliver the kind of information that supported the story *60 Minutes* wished to present. This point was made by Hans Sollinger, M.D., Chairman of the transplantation unit at the University of Wisconsin Hospital and Clinics and, at the time of the broadcast, President of the American Society of Transplant Surgeons.¹

I believe the information 60 Minutes had came from physicians and ethicists in the Cleveland area and other places who have absolutely no experience with the drug. None of the people 60 Minutes talked to was an expert in organ donation. None of the people 60 Minutes had as a source had ever personally used Regitine or Heparin in the operating room setting, not to mention an organ donation setting. So they were coached by individuals who had absolutely no expertise or any experience. However, they failed to admit it during the segment and never appreciated that fact when I wrote several letters between the interview and the broadcast of the segment. (p. 2)

Koughan and Bogdanich are correct that CCF turned down requests for an on-camera interview, but the requests came at a time and in a context in which the Cleveland Clinic was asked to answer charges, not to discuss a protocol or issue. Dr. Sollinger, who did, unfortunately, agree to be interviewed, complained that he was misled by the producers. Dr. Sollinger said:

In my two conversations with the producer of 60 Minutes, the message was quite clear: "we want to make a piece which addresses the national shortage of donor organs and why there aren't enough organs." I specifically asked if any controversies would be discussed or if I should prepare for anything in particular for the interview with Mr. Wallace. His response again was, we should prepare for a fairly-straight-forward story on what we can do about the shortage of organ donors. (p. 1)

In their response, Koughan and Bogdanich confuse two time frames. There is the time from the point at which the Lifebanc protocol came to the Cleveland Clinic in 1995 for discussion and revision to when the charges were brought in May of 1996. Many of the ethically important modifications to the CCF protocol occurred during this time. The 60 Minutes story was broadcast on April 13, 1997. If we are to believe Koughan and Bogdanich, their investigation and "extensive interviews" began six months earlier, placing its commencement in early November 1996. I can only conclude with Dr. Sollinger that they interviewed the wrong people or selectively reported the complex clinical and ethical questions associated with NHBD. Again, Dr. Sollinger said:

I made it clear one more time that the information which he [Mike Wallace] had, which he was planning to broadcast, was scientifically incorrect. I said the sources of the information were people who had absolutely no expertise and made that clear to him verbally as well as in writing. I wrote that if the piece is damaging based on wrong information it could cost the lives of several hundred people or possibly several thousand people. (p. 2)

If Sollinger is correct, then it is understandable why Koughan and Bogdanich are so defensive.

Koughan and Bogdanich unjustifiably accuse me of distorting the Institute of Medicine's view of the use of heparin and phentolamine, when it is they who distort the point. I said that the IOM study found "no evidence or compelling ethical arguments to warrant *banning* the use of these drugs." I did not say that the IOM had no concerns about these drugs, and certainly did not imply that I have no concerns. The IOM Report² explicitly states:

Heparin and phentolamine, however, are recommended frequently during the donation process, based on clinical experience and scientific evidence that the enhanced donor organ quality and graft results usually can be safely used (D'Alessandro, 1997; Miller et al., 1974). Although prescription of these drugs during organ procurement is deemed useful and is *undoubtedly safe in the majority of instances* (Gould et al., 1980) [italics added], a blanket policy cannot be recommended because of possible untoward effects in some donor patients.

Physicians responsible for the care of individual donors should be able to make a clinical judgment on the advisability of using either heparin or phentolamine or both with hastening donor death. This report recommends that individual clinical judgment be made and also that consideration be given to involving the donor's attending physician as either the responsible prescriber or a required consultant or co-decision maker with the procurement or transplant team to improve protection, lessen conflicts of interest, and strengthen public confidence. (p. 52)

The point is even clearer in the Executive Summary³:

In most cases, careful administration is appropriate. Nevertheless, because under certain circumstances in certain patients, there is a concern that these agents might be harmful, this report recommends **case-by-case decisions on the use of anticoagulants and vasodilators** [boldface in the original], and consideration of additional safeguards such as involvement of the patient's attending physician in prescribing decisions. (p. 4)

Clearly, I have not misstated the IOM's position.

As I said in the original article, the protocol that the Cleveland Clinic had adopted included the ethically important entry requirements that limited NHBD to patients who had lost ventilatory drive precisely because of concerns similar to those raised in the IOM Report. Koughan and Bogdanich overlooked or misunderstood the significance of this point. Ironically, the Cleveland Clinic protocol conservatively limited NHBD to a narrow range of severely brain injured patients. The protocol was accepted by physicians in charge of caring for brain-injured patients in the Neurosurgical ICU only with these limiting entry conditions in place. Their goal was not to increase organ donation, but to afford families the opportunity to wring some consolation out of the death of eligible patients. That said, I repeat what I wrote in the original article, namely, that "analysis of the IOM Report is left to another time." That report is not the authoritative last word on the issues associated with NHBD; another IOM Panel is currently readdressing issues associated with NHBD.

If one followed the reasoning of Koughan and Bogdanich who critically note that the University of Wisconsin protocol also called for the administration of the "same potentially harmful drugs," we would need to ban most medications, because they are all *potentially harmful*. Every drug carries with it a risk of side effects and potential for idiosyncratic response. What Koughan and Bogdanich fail to recognize is that the potential for harm that is ethically and clinically important is patient and situation specific. The Cleveland Clinic protocol attempted to address this point by devising specific entry or eligibility criteria. Unfortunately, *60 Minutes* failed to grasp this point. In their reaction to my article, Koughan and Bogdanich seem to confuse the concept of *reasonable* or known chance of harm with a postulated risk of harm. Because they raised anew the use of the heparin and phentolamine, I welcome the opportunity to outline the use of these drugs.⁴

Heparin is routinely used in dosages three times as high as that permitted in the protocol during cardiac surgery every day to prime the pump and to anticoagulate patients. These patients do not suffer brain hemorrhage as a result of this administration. Why would one think that use of heparin in NHBD would cause fatal brain bleeding? I can only surmise that to come to this conclusion 60 Minutes wrongly assumed that the patients eligible for NHBD had a special propensity for brain hemorrhage, but this displays a shocking lack of medical sophistication.

The criticism of the administration of 10 mg of phentolamine, an alphaadrenergic blocking agent, at the time mechanical ventilation is withdrawn involves the belief that its use either directly causes death or induces a shock-like state in which life signs are not easily detectable. The rationale underlying the first view involves phentolamine's blockade of adrenaline receptors which would prevent the mechanism of autoresuscitation that might normally occur through massive release of adrenaline when blood oxygen drops after mechanical support is withdrawn. The rationale for the second view is that phentolamine would cause severe lowering of blood pressure such that carotid pulses would be undetectable. There are, however, no data to support either of these contentions; in fact what data exist suggest that phentolamine has no effect on the

Author(s)	Number of Patients	Dose of Phentolamine	Effect on Blood Pressure
Arnér ⁵	48 adults 56 children	5-15 mg 5-10 mg	"minor"
Raja et al. ⁶	18 patients	25-35 mg	Systolic \downarrow 3-4% Diastolic \downarrow 19-21%
Shir et al. ⁷	100 patients	25-75 mg	Systolic \downarrow 4 mm Diastolic \downarrow 7 mm
Dellemijn et al. ⁸	24 patients	35 mg	Systolic \uparrow 5 mm Diastolic \downarrow 12 mm

Table 1. Studies	of Phentolamine	Use in Patients	with Chronic Pain
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autoresuscitation response and does not mask the ability to detect life signs.

Four studies, published since 1990, have documented the safety of phentolamine in dosages up to 7.5 times that used in the NHBD protocol proposed by the Cleveland Clinic and used by several other institutions, most notably the University of Wisconsin. Table 1 summarizes the essential elements of the studies.

The studies summarized in Table 1 were carried out in patients suffering from chronic pain but who were otherwise healthy. They were done to establish the safety and effectiveness of phentolamine for use at the stated dosages in these populations. No ill effects were described other than some transient nasal stuffiness and/or minor tachycardia (rapid heart beat). The blood pressure effects were minimal and clinically insignificant; they peaked at 2–15 minutes and cleared rapidly over the next 15–30 minutes.

Some older studies of the safety and effectiveness of phentolamine in patients with heart failure have been reviewed by Chatterjee and Parmley who note that ". . . doses up to 2 mg/min have been administered without adverse effects."⁹ No maximum cumulative dosage has been determined. A summary of some related studies is displayed in Table 2. As Table 2 shows, even in patients with severe acute or chronic heart failure, phentolamine appears to be well tolerated in doses at least as high as those in the protocol. In all of these studies, phentolamine actually improved cardiac function by several measures. Thus, these studies provide no support for the concept that phentolamine shortens life or masks life signs as they would have been determined in the protocol.

None of this should come as a surprise. As an alpha-adrenergic blocking agent, phentolamine has no effect on the production of epinephrine, and it only blocks the *alpha* (not the *beta*) receptors for epinephrine. The interaction of epinephrine with the beta adrenergic receptors in the heart muscle stimulates cardiac function, and phentolamine has no demonstrated effect on this function. Stimulation of alpha adrenergic receptors in the heart actually weakens and slows the heart. Thus, phentolamine should not be expected to decrease the strength of the pulse, but might actually increase it by allowing the beta receptors to be stimulated without opposition by alpha adrenergic stimulation. That is the rationale for the use of this drug in the treatment of heart failure (see Notes 10-14). Even if epinephrine were the main stimulus for "autoresuscitation" -

Author(s)	Number of Patients	Dose of Phentolamine	Effect on Blood Pressure
Korewicki et al. ¹⁰	11 (severe mitral regurgitation)	15-40 mg	"Significant improvement of right atrial, pulmonary and capillary wedge pressure" Blood pressure results not given.
Kelly et al. ¹¹	11 (hypertension with acute myocardial infarction, heart failure)	7.5-15 mg	Mean arterial pressure ↓ from 130 mm Hg to 102 mm Hg.
Perret et al. ¹²	15 (acute myocardial infarction with left ventricular failure)	10 mg	Mean arterial pressure \downarrow from 112 mm Hg to 99 mm Hg.
Walinsky et al. ¹³	14 studies in 13 patients (acute myocardial infarction, 9 with heart failure)	10.9-124 mg	Mean arterial pressure ↓ from 97 mm Hg to 78 mm Hg.
Gould et al. ¹⁴	10 (acute myocardial infarction)	12 mg	Mean arterial pressure ↓ from 86 mm Hg to 76 mm Hg.

Table 2. Studies of Phentolamine Use in Patients with Heart Problems

and it is not-phentolamine would still not block this effect for the same reason. It only blocks alpha receptors, which have nothing to do with cardiopulmonary stimulation. The only patients eligible for the Cleveland Clinic protocol were patients with severe brain stem injury, a point that Koughan and Bogdanich either missed, because they relied on out-of-date information, or failed to understand. The mechanism by which the patients eligible for the Cleveland Clinic protocol would have died is the loss of brain stem functioning that enables them to breathe. Their hearts stop beating because, after discontinuation of mechanical ventilation, they do not breathe. Epinephrine has nothing to do with it. To single out this medication as a "lethal" drug is not scientifically justified as a general point, but is even more beside the point for patients who meet the eligibility standards in the CCF protocol.

Finally, Koughan and Bogdanich grossly mischaracterize my view when they say that I "prefer that this debate take place among bioethicists." I eschewed sensationalism, not responsible journalism. I eschewed uninformed authoritarian criticism, not responsible dialectical analysis. As I said in the article, bioethics is a field, not a discipline. Responsible debate over NHBD will involve not only bioethicists, but physicians and surgeons knowledgeable about the complex clinical matters involved. Had I wished to attack the 60 Minutes story, my article would have been framed very differently and directed to a more public medium than this respected journal. Koughan and Bogdanich, however, are right to feel the need to defend their reporting, but their response does not even begin to address the responsibility of public media in reporting bioethics-related issues. Even if it did, their response would miss the main question posed in my article, namely, how can bioethicists contribute to public discussion and analysis of complex issues in a medium whose attention to detail appears to be no longer than its moniker.

Notes

- 1. Warren J. Sollinger highly critical of 60 Minutes segment on Non-Heart Beating Donors, fears impact on organ donation, *Transplant News* 1997 (May 28);7;(10):1–3.
- 2. Institute of Medicine. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement. Washington, D.C.: National Academy Press, 1997.
- 3. See note 3, Institute of Medicine 1997:4.
- 4. The following analysis is taken directly from an unpublished paper written by John Clough, M.D., Cleveland Clinic Foundation, entitled "The Safety of Phentolamine." I am entirely indebted to this paper for the details of this review.
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pain relief and sensory changes following sympathetic blockade. *Brain* 1994;117:1475-87.

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