Non-Heart-Beating Organ Donation and Catholic Ethics

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The demand for organs for transplantation in the United States has reached a critical level. Improvements in transplantation techniques, new methods of preserving organs, new immunosuppressants, and a steady increase in survival rates has led more and more patients to view transplantation as a viable option. The problem is that the supply of organs is insufficient to meet the clinical needs. As of April 30, 2004, the Organ Procurement and Transplantation Network (OPTN) estimates that there are 84,931 patients on waiting lists for kidney, liver, pancreas, heart, lung, and intestine transplants. Of this total number, 57,789 patients are waiting for kidneys. It is estimated that four thousand patients die each year awaiting a lifesaving transplant.¹ This national shortage of organs for transplantation in the United States has led the United Network of Organ Sharing (UNOS) to propose a number of alternatives to meet this immediate need. One alternative being reexamined, especially for kidney transplants, is the use of the non-heart-beating donor (NHBD) criteria. Non-heart-beating donation is defined as “the surgical recovery of organs after the pro-

nouncement of death based on cessation of cardiopulmonary function.”2 Patients who meet the NHBD criteria are “either severely ill on life support, and life support can be withdrawn with proper consent, or they have suffered unexpected cardiac arrest, whether previously ill or not, and cannot be resuscitated.”3

Non-heart-beating organ donation is not a new criterion. Prior to the late 1970s and early 1980s, all organs were recovered from NHBDs. NHBDs formed the very foundation of modern clinical transplantation.4 Due to the problem of warm ischemia, kidneys are the primary organs for transplantation in NHB donation. “Kidneys can tolerate up to two hours of warm ischemia and still function similarly to those kidneys recovered from brain-dead heart-beating donors.”5 However, despite the proven clinical successes, and the long history of non-heart-beating donation, the number of NHBDs is very small.

The number of NHBDs rose from forty-two in 1993 to 167 in 2001, representing nearly 3 percent of all deceased donors in the United States in 2001. The number of OPOs [Organ Procurement Organizations] recovering organs from NHBDs rose from thirteen in 1993 to thirty-three in 2001. During that period, forty-three OPOs participated in at least one NHBD procurement. In 2001, six OPOs procured more than ten NHBDs, two OPOs procured six to ten, twenty-five OPOs procured one to five, and twenty-six OPOs procured none. For the most active OPOs procuring NHBDs in 2001, NHBDs represented an average of 10 percent of total donors; the range of NHBDs as a percentage of total deceased donors among all OPOs that procured NHBDs is 1 percent to 15 percent. Based on current data, if all fifty-nine OPOs utilized NHBDs at the same rate as the most active OPOs procuring NHBDs, as many as six hundred additional donors could be identified, yielding at least twelve hundred organs annually.6

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3Roger Herdman and John T. Potts, Institute of Medicine, Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement (Washington, D.C.: National Academy Press, 1997), 1.


5Edwards et al., “Process And Review,” 298. It should be noted that although extrarenal transplants are relatively few, there have been reports of successful use of livers, lungs, pancreata, and hearts from NHBDs. See also, Anthony D’Alessandro, “Renal and Extrarenal Transplantation from Controlled Non-Heart-Beating Donors,” UNOS Update 10 (1994): 9; and M.S. Orloff et al., “Non-Heart-Beating Cadaveric Organ Donation,” Annals of Surgery 220 (1994): 578.

6University Renal Research and Education Association and the United Network for Organ Sharing, 2002 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1992–2001 (Rockville, MD: The Department of Health and Human Services, the Health Resources and Services Administration, the Office of Special Programs, and the Division of Transplanta-
These numbers fall short of the estimates set by those who advocate for NHBDs, because of the public’s suspicion that surrounds this method of declaring death.7

As medical technology became more complex, questions concerning the criteria of death became more pronounced. Prior to the Harvard Ad Hoc Committee’s report in 1968, which established the first criteria for brain death, death was declared solely on the basis of cessation of cardiopulmonary function.8 As the acceptance of brain-death criteria increased throughout the 1970s, the **Uniform Determination of Death Act**, established in the 1980s, became the basis for brain death in the United States. It defines brain death as “irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain, including the brain stem.”9 The legal definition of brain death became the basis for determining when organs could be surgically recovered from donors. As a result, in these situations, cardiovascular tone and organ perfusion are maintained by vasopressors, fluids, and blood products, while mechanical ventilation provides oxygen to the bloodstream, keeping organs well-oxygenated.10

Organs recovered from brain-dead donors were more likely to function well because the warm-ischemia time was reduced.11 As a result, the NHBD criteria for organ donation were practically abandoned in the United States. Therefore, patients with devastating injuries who would have met the NHBD criteria are not permitted to donate their organs because they do not meet the brain-death criteria. These patients exhibit minimal brain function, enough not to meet brain-death criteria. Tragically, in these cases, families have been unable to fulfill their loved ones’ wishes for organ donation. The injury is so severe that a meaningful recovery is not possible.12

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7According to John Potts, director of research at Massachusetts General Hospital, “If the estimates are accurate, non-heart-beating donors could represent an increase of at least one thousand organ donors a year.” Associated Press, “Guidelines Are Urged in Using Organs of Heart-Dead Patients,” *New York Times*, December 21, 1997, A-38.


12Ibid.
If the NHBD criteria are reinstated in our acute-care facilities today, this protocol would allow for organ donation in these specific types of cases and would have the potential for saving more lives.

What makes this proposed solution even more controversial is widespread discomfort within the medical establishment. The major concerns among medical professionals are threefold: first, circumventing the brain-death criteria; second, the administration of anticoagulants and vasodilators that have the possibility of hastening death; and third, concern about the time requirement for the declaration of death, which ranges from two to ten minutes of asystole or electromechanical disassociation. In contrast to these concerns, patients and surrogates making end-of-life decisions of withdrawal of life-support systems due to devastating traumas or critical illnesses are requesting such donations, to comply with authorized advance directives. The shortage of organs available, especially kidneys, and the rising interest of the American public in organ transplantation have led to the reexamination of NHBDs as a potential source of organ donation. Many organ-procurement organizations have approached the institutional ethics committees (IEC) of acute-care facilities with an assortment of NHBD protocols requesting implementation. However, before acute-care facilities can agree to implement an NHBD protocol, the serious medical and ethical questions raised by both the public and medical sectors of society must be addressed. At the present time, there is no national standardized protocol for NHBDs; neither does the Ethical and Religious Directives for Catholic Health Care Services have a specific position on this issue. IECs, especially in Catholic health-care facilities, are looking for some guidance in this area. Until a protocol with standardized procedures is established at the national level and some guidance is provided from the perspective of Catholic moral tradition, the determination of death will continue to be ambiguous, and lives will be lost that might have been saved.

This article will attempt to address these fundamental medical and ethical concerns. The purpose of this article is threefold: first, to examine the medical reality of an NHBD protocol and the concerns surrounding its use today; second, to give an ethical analysis of the arguments for and against non-heart-beating donation in order to determine if such a protocol is morally justified as a solution to the shortage of organs for transplantation; third, to formulate specific recommendations for a standardized national protocol for NHBDs.

**Medical Analysis**

**NHBD Categories**

Although there are several situations which could fulfill the definition of non-heart-beating donation, it is at this moment being used for patients who have sustained a devastating neurological injury but do not meet the strict criteria for brain death.
death and whose families have chosen to withdraw life-sustaining therapy. Another essential criterion in this situation includes the determination that cessation of cardiopulmonary function most likely will occur within one hour after the withdrawal of ventilatory and hemodynamic support.\textsuperscript{14} The NHBD has been divided into four categories depending on the donor status: 1) dead on arrival; 2) unsuccessful resuscitation; 3) awaiting cardiac arrest; and 4) cardiac arrest in a brain-dead donor.\textsuperscript{15} These categories, known as the “Maastricht Categories of NHBDs,” have their own peculiarities regarding the preservation, and viability of organs, and ethical aspects. The first category, “dead on arrival,” refers to the patient who dies outside the hospital, before or while resuscitation is attempted. This situation is commonly encountered with accidents and trauma victims. It is a difficult situation from the point of view of organ donation, as the event which caused the mortality could have injured internal organs, and the dead victims may have to be transported to the nearest hospital instead of the morgue. A protocol focused on this situation will be needed to ensure the prompt retrieval of organs while keeping the warm-ischemia time to a minimum. These situations can further be complicated because of the legal and procedural requirements that need to be followed.

The second category, “unsuccessful resuscitation” is self-explanatory. The patient fails cardiopulmonary resuscitation, and the transplant team is called to consider organ donation. In certain countries which follow “presumed consent” guidelines (“opting out”), the transplant team can proceed with organ harvesting, while in countries like the United States, where one has to “opt in,” the informed consent for donation has to be obtained.\textsuperscript{16} This again creates a situation where the prompt involvement of the family may be necessary and where delays lead to poor transplant results with increased warm-ischemia time.

The third category, “awaiting cardiac arrest,” includes patients who are critically ill and on life-support, and the family has decided to withdraw life support. These patients provide a controlled situation for organ retrieval. As is apparent, this category, among the four, offers the best chance of harvesting viable organs from donors.

The last category, “cardiac arrest while brain-dead,” includes patients who suffer an unexpected cardiac arrest in the process of being diagnosed as brain-dead, or after such determination but before organ donation decisions have been made. In these patients, the loss of cardiac activity increases the warm-ischemia

\textsuperscript{14}Ibid.


\textsuperscript{16}In most European countries, the next of kin’s consent is not required, because this system presumes that potential donors would consent to organ donation, unless they had specifically objected before their deaths. For a more detailed analysis, see s.v. “Organ and Tissue Transplants,” Calvin Stiller, “Medical Overview,” in \textit{The Encyclopedia of Bioethics}, rev. ed., vol. 4, ed. Warren Reich (New York: Simon & Schuster Macmillan, 1995), 1871–1882.
time, and so, the efforts are directed toward restoring the heartbeat and improving the viability of the organs.  

Depending on the specifics of organ harvesting the process can be divided into controlled or uncontrolled categories. Controlled NHBDs are patients who are on life support and have no chance of survival, and their families have decided to withdraw life support (Maastricht Category 3). Here the situation is controlled, as the time of death depends on the time of withdrawal of life support and can be done after arranging for organ procurement. The withdrawal of life support can be done in the intensive care unit or the operating room depending on the arrangements made. The operating room is preferred in the recovery of extrarenal organs, as these organs suffer less warm-ischemia time. The controlled NHBDs have a better chance of providing viable organs, as the warm-ischemia time in these patients is minimum and the procedure starts with the decision to withdraw life support. Some institutes have protocols which do not allow the attending physician to present the option of organ donation but require the family to make the request. Some states, like Pennsylvania, have passed “routine referral legislation” which requires the hospital to notify the local procurement organization of all deaths, and the request for organ donation is made by them. If the patient has no contraindication to organ donation, the withdrawal of life support is done at the appropriate time by the treating physician, and only after he or she has been declared dead does the harvesting team take over. It is very apparent that safeguards must be in place to protect against conflicts of interest, by separating the role of the treating physician involved in the care of the patient from that of the transplant or procuring physician team.

The uncontrolled NHBDs are the patients in cardiopulmonary arrest for whom resuscitation is either not performed or fails (Maastricht Category 1 and 2). Organ procurement in uncontrolled NHBDs does pose a challenge, as the process begins with cardiac arrest. Unless the family was considering organ donation, it may not be feasible to arrange everything in a timely manner to harvest all the organs. Some organs like the kidneys, which can withstand longer warm-ischemia time, can be harvested. This will have a minimum impact on the supply of organs, unless protocols are devised for harvesting organs from categories 1 and 2. When using the Maastricht categories, G. Kootstra et al. have reported an increase of 20 percent more kidneys transplanted through the implementation of an uncontrolled NHBD

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17Ibid.

18Edwards et al., “Process and Review,” 295. It should be noted that life support may be withdrawn in different areas of the hospital depending on what has been agreed upon by the family. The operating room is the most desirable place. However, other areas include a room near the operating room such as the postanesthesia care unit, or the patient may remain in the intensive care unit until he or she dies and then is transported to the operating room. While the latter two options allow for the benefit of families to be present at the time of death, there is a resulting increase of warm-ischemic time, which may compromise the viability of the organs for successful transplantation. Ibid.

19Ibid., 296–297.
program.\textsuperscript{20} Though routine referral legislation has helped in improving the availability of these donors, current efforts are directed towards controlled NHBD.

Medications

Some NHBD protocols recommend the use of medications, like heparin and phentolamine, for the purpose of improvement of transplant results. Heparin is a parenteral anticoagulant which is used in the treatment of conditions like acute myocardial infarctions, arterial thromboembolism, deep venous thrombosis, etc., where the blood needs to be anticoagulated so that further formation of blood clots can be prevented. Chemically, it is a glycosaminoglycan composed of chains of alternating residues of D-glucosamine and uric acid and is derived from porcine or bovine tissue. It acts by accelerating the anticoagulant activity of antithrombin III.\textsuperscript{21} The usual dose in which it is used is 5,000–10,000 units (or 70–80 units/kg) intravenous bolus followed by a drip containing about 18 units/kg/hour.\textsuperscript{22} The important point regarding the metabolism of heparin is that its half-life changes from 30 minutes to 150 minutes as its dose is increased from 25 units/kg to 400 units/kg.\textsuperscript{23} That would mean that a larger dose would linger in the system for a longer time as compared to a smaller dose. The dose recommended by the sample hospital policy provided by the Gift of Life Donor Program of Delaware Valley is 300 units/kg.\textsuperscript{24} This is about four times the usual dose of 70–80 units/kg loading dose used in clinical practice. Heparin has been used in living-donor nephrectomies in a dose of 100 to 300 units/kg, and its effect is neutralized with the use of protamine sulfate after surgery is done. But a retrospective study comparing the use of heparin to nonuse of heparin in living-donor nephrectomies failed to show any difference in transplant results.\textsuperscript{25} The use of heparin is contraindicated in any patient with bleeding or coagulopathy as their condition may be adversely affected by its anticoagulant effect.\textsuperscript{26} It can have obvious detrimental effects in a patient with severe neurological trauma, by causing or increasing a bleed.

Phentolamine (regitine) is an alpha-adrenergic receptor antagonist with a short duration of action. This medication also needs to be given parenterally and has been approved for use in diagnosis of pheochromocytoma, treatment of hypertension in


\textsuperscript{22}Ibid.

\textsuperscript{23}Ibid.


\textsuperscript{26}Reents, “Heparin.”
pheochromocytoma, and prevention of tissue necrosis after norepinephrine extravasation.\textsuperscript{27} It can cause acute and prolonged hypotension, angina, and tachycardia as adverse effects.\textsuperscript{28} It is contraindicated in patients with acute myocardial infarction and coronary artery disease.\textsuperscript{29} This does raise concerns regarding the use of this medication in critically ill patients with the sole purpose of improving transplant results. The University of Wisconsin Protocol recommends the administration of heparin and phentolamine before withdrawal of life support.\textsuperscript{30}

This practice raises a number of questions regarding the hastening of death by the use of these medications which otherwise have no role in the management of these patients. The use of these medications is also not uniform in all the protocols. The University of Pittsburgh Medical Center policy explicitly forbids such interventions. It clearly states, “No interventions are to be justified by their being effective in preserving a more usable transplant or in regulating the time of death.”\textsuperscript{31} Phentolamine is used to maintain vasodilation and heparin for keeping the vessels from forming a blood clot. The practice that raises concern is the use of these medications at the time of withdrawal of life support, when the patient is still alive. The comfort measures are to be continued without any interruption. In a patient with severe brain damage who does not meet the criteria of brain death, does the use of these medications create a situation where they may hasten death? The Institute of Medicine report observes that careful administration of these medications is appropriate and recommends a case-by-case determination on the use of these medications.\textsuperscript{32}

The prediction of time of death is a difficult process, and sometimes the evaluation of the patient is done by removing him or her from the ventilator for a short period of time while their vitals and hemodynamic parameters are monitored. Rapid decreases in heart rate, blood pressure, and oxygen saturation, along with increased work of breathing, typically indicate that the patient will die in a short period of time.\textsuperscript{33} Once in the operating room, the life support is withdrawn, and the patient’s vital signs are monitored for lack of pulse pressure and heart rhythm. The patient is declared dead on the basis of cardiopulmonary criteria. If the patient does not die within one hour, then the patient is returned to the medical floor and is not a candidate for organ donation due to the prolonged warm-ischemia time.\textsuperscript{34} This is one reason why some donors or their families may opt for the use of heparin or phentolamine so that death would occur within the one-hour time frame and the opportunity to donate organs would not be lost.

\textsuperscript{27}Ibid.
\textsuperscript{28}Ibid.
\textsuperscript{29}Ibid.
\textsuperscript{31}“University of Pittsburgh Medical Center Policy and Procedure Manual,” \textit{Kennedy Institute of Ethics Journal} 3.2 (June 1993): A-5.
\textsuperscript{32}Herdman and Potts, “Medical and Ethical Issues in Procurement,” 3.
\textsuperscript{33}Edwards et al., “Process and Review,” 295.
\textsuperscript{34}See note 17 above.
Different protocols have taken different durations of time for irreversibility—the Pittsburgh protocol mandates two minutes, while the Institute of Medicine recommends not less than five minutes. The Pittsburgh protocol requires diagnosis of death by absent pulse via a femoral catheter with a zero-pulse pressure. The patient should be apneic and unresponsive to verbal stimuli and have any one of the following: 1) two minutes of ventricular fibrillation, 2) two minutes of asystole, 3) two minutes of electromechanical dissociation. It is possible that the period may have been kept brief in the Pittsburgh protocol because the use of medications like heparin and phentolamine is prohibited and a quick organ recovery will improve the chances of transplant viability. The protocol in Maastricht has recommended extending this time to ten minutes. In these ten minutes of no circulation, the brain will be dead. This warm-ischemia time of ten minutes can be tolerated by the kidneys, but not by other transplantable organs. The Institute of Medicine report recommends not less than a five-minute interval determined accurately by electronic/arterial pulse-pressure monitoring. These recommendations are for controlled NHB donation. They do not recommend any protocol for uncontrolled NHB donation. However, it should be noted that Hospital Clinico San Carlos in Madrid, Spain, has instituted a policy for NHB-donation category-1 donors. They have shown long-term results similar to those from transplantation from brain-dead donors. But their focus has been mainly on renal transplantation.

It has been estimated that the donor pool could increase by 20 to 25 percent by the use of controlled NHB donation. But still only 33 of the 59 organ procurement organizations in the United States currently recover organs using this method. The figures projected are wide and varied. A study by T. Koogler and A.T. Costarino showed that a pediatric trauma center could increase donation by 42 percent with implementation of an NHBD protocol. With such projections for improvement in organ harvesting, and more initiatives like routine referral legislation, it is expected that NHB donation is going to be a viable option in the United States for the procurement of organs for transplantation. The problem that remains is how to resolve the ethical questions that an NHBD protocol creates.

36Herdman and Potts, “Medical and Ethical Issues in Procurement,” 4.
39Herdman and Potts, “Medical and Ethical Issues in Procurement,” 4.
42See note 6 above.
Ethical Analysis

The Catholic Church has no specific ethical guidelines regarding NHBD donation. However, as a matter of charity, the Church supports organ donation; Pope John Paul II has called it “a generous gift.” The *Catechism of the Catholic Church* approves of the donation of vital organs after death has been confirmed and with explicit consent. The Church defines death as the moment of separation of the soul from the body: it has no specific medical definition of death (although the Pontifical Academy for Sciences—which lacks moral teaching authority—supports the use of brain-death criteria). To determine if an NHBD protocol is ethical, and to address the ambiguities and unresolved issues surrounding NHBDs, the traditional principle of double effect, which has its origin in Roman Catholic moral theology, will be applied to this situation.

Ethicist James F. Childress argues that the principle of double effect is applicable to the issue of NHBDs, because it has two effects, one good and the other evil. The good effect is that the donor is able to donate his or her kidney for the benefit of another. The evil effect concerns the administration of the drugs heparin.

1) “The action, considered by itself and independently of its effects, must not be morally evil.” The object of the action must be good or indifferent.
2) “The evil effect must not be the means of producing the good effect.”
3) “The evil effect is sincerely not intended, but merely tolerated.”
4) “There must be a proportionate reason for performing the action, in spite of its evil consequences.”

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44 James DuBois, “Ethical Issues in Non-Heart-Beating Organ Donation” (paper presented at the Daughters of Charity National Health System Conference, Center for Health Care Ethics, St. Louis University, St. Louis, MO, August 10, 1999), 1.
and phentolamine, which are given to the donor prior to declaring death, and may have the possibility of hastening the donor’s death. Ultimately, for Childress and other bioethicists, it is the judgment of proportionality that is indispensable to the application of this principle.

Showing that the harm caused is an indirect side effect, rather than a direct and intended effect, is not sufficient to justify the action. The agent is still morally responsible for the foreseen, even though not intended, side effects that are avoidable because the agent could have acted differently. The various effects must therefore be balanced to determine whether the action is justified.49

To determine if a NHBD protocol is ethical, this issue will be examined in light of the four conditions of the principle of double effect.

The first condition allows for NHB donation because the object of the action, in and of itself, is good. The moral object is the precise good that is freely willed in this action. The moral object of this action is for the donor (who is being removed from life-support systems because further medical treatment is futile and burdensome) to donate his or her organs to a recipient in need. The immediate goal is not to hasten the death of the donor. Rather, the direct goal is to allow a donor, who has been declared dead after a specific period of time (from two to ten minutes) of cardiac arrest, to prolong another person’s life through organ donation.

The second condition appears to allow for an NHBD protocol, because the good effect of donating an organ is not produced by means of the evil effect. The donor’s organ is transplanted to the recipient after the donor has given informed consent and has been declared legally dead. However, it is at this step that questions are raised concerning the use of heparin and phentolamine. The primary concern is whether these drugs directly (intentionally) or indirectly (unintentionally) bring about the donor’s death. The direct infliction of death on the donor is clearly a moral evil. Since there is ambiguity concerning the effects of these two drugs, there is some question as to whether they need to be administered to the patient prior to the declaration of death. If not, this would certainly eliminate the doubt of fact concerning the intentionality of the action.

The third condition is intricately tied to the second condition. The direct intention of the NHBD protocol is to donate the gift of an organ to another after the donor has been declared dead and the surrogate/family has given informed consent. Some within the medical community have questioned whether the surrogate/family can give informed consent, since there is a question about the effects of heparin and phentolamine. If the donor does not die within the prescribed time (one hour), it is true that heparin may extend the injury in patients who have had intracranial bleeding. In addition, the use of a vasodilator like phentolamine may cause a decrease in blood pressure. Both drugs may knowingly hasten the death of a donor. However, according to UNOS, the direct intention of the NHBD protocol is not to hasten the

49James F. Childress, “Non-Heart-Beating Donors of Organs: Are the Distinctions between Direct and Indirect Effects & between Killing and Letting Die Relevant and Helpful?” Kennedy Institute of Ethics Journal 3.2 (June 1993): 207.
death of the donor. The direct intention is to allow the donor to give the gift of an organ to another person after the donor has been removed from nonbeneficial life support and has been declared dead.

Finally, the argument for the ethical justification of NHBDs by the principle of double effect focuses on whether there is a proportionately grave reason for allowing the foreseen but unintended possibility that heparin and phentolamine may actively cause death. To make this determination “the probability and magnitude of the good (intended) effects will have to be balanced against the probability and magnitude of the bad (side) effects in order to determine” if there is a proportionate reason for allowing the NHBD protocol. Proportionate reason is the linchpin that holds this complex moral principle together.

Proportionate reason refers to a specific value and its relation to all elements in the action. The specific value in allowing for an NHBD protocol is to preserve human life by the provision of organs for transplantation from donors who have been declared dead and have given informed consent. The evil, which may come about by trying to achieve this value, is the foreseen but unintended possibility that heparin and phentolamine may hasten the donor’s death or may be used to control the time of death to ensure organ viability. The ethical question is whether the value of preserving the life of another at the donor’s request by allowing for medical care that will preserve organ viability for transplantation outweighs the evil of the foreseen but unintended possibility that such care may directly hasten the donor’s death and cause public mistrust which might jeopardize other donations. To determine if a proper relationship exists between the specific value and the other elements of the act, ethicist Richard McCormick, S.J., proposes three criteria for the establishment of proportionate reason:

1) The means used will not cause more harm than necessary to achieve the value.
2) No less harmful way exists to protect the value.
3) The means used to achieve the value will not undermine it.

The application of McCormick’s criteria to NHBDs may support the argument that there is a proportionate reason for allowing these protocols if certain safeguards are added.

First, scientific data is inconclusive about the effects of heparin and phentolamine on patients in these various conditions. The problem is that they are adminis-

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50Ibid.
tered prior to the withdrawal of life support at the discretion of the attending physician. The Institute of Medicine’s report on NHB donation states that

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 hasten death.53

Since the data regarding these two medications are inconclusive, and since many hospital NHBD protocols do not call for the use of phentolamine, could both drugs be eliminated from an NHBD protocol in order to ensure that the death of the donor is not hastened? If both drugs could be eliminated, then it would appear that the NHBD protocol does not cause more harm than necessary.

Second, at present, there are other alternatives being considered to increase organ donation. These include more public education, incentives for donors,54 presumed consent, use of living donors, etc. However, NHBDs could add to the number of kidneys available for transplantation. If the estimate is correct that one thousand additional kidneys could be procured each year by NHBDs, then could this be an ethically viable option with the proper safeguards established? With the proper safeguards an NHBD protocol would not only save lives but also foster patient dignity by adhering to the wishes of the donor.

Third, the present NHBD protocols do have the potentiality of undermining the value of human life if the proper safeguards are not added relative to heparin and phentolamine and if the time frame for the declaration of death is insufficient. One can argue convincingly that the intention of NHBD protocols is to save human lives. As long as there is informed consent from the surrogate/family, and health-care professionals do not compromise optimal patient care in the interest of procuring organs, the value of the donor’s life is not undermined. Childress points out that patients/surrogates have the right to define “optimal patient care” at least in terms of forgoing life-sustaining treatments and receiving comfort measures. However, he questions whether altruistic patients who want to increase the chances that their deaths will produce usable organs may choose to alter the care provided in the last few hours of their lives.


What counts as optimal patient care in these circumstances may depend on the patient’s values and choices, including his or her desire to provide viable organs. This comes down to a debate between patient/surrogate autonomy, on the one hand, and physician beneficence—what the physician views as good for the patient medically—on the other hand. Would a patient have the right not only to forgo life-sustaining treatment and certain comfort measures, but also to agree to the use of anticoagulants to increase the possibility of successful organ donation knowing it might hasten his or her death? To allow a patient/surrogate this autonomy opens the slippery slope to abuses and misuses in organ donation. This could be interpreted as direct killing of the patient, which is unethical, and could add to further public mistrust regarding organ procurement and could directly affect overall organ donation and transplantation. However, if the proper safeguards regarding optimal patient care and conflict-of-interest guidelines regarding separate medical teams for the donor and the recipient are installed, then an NHBD protocol would not undermine the value of human life.

Does the principle of double effect justify NHBD protocols? As these various protocols currently stand, without standardized safeguards regarding heparin and phentolamine, conflict of interest regarding the medical teams for the donor and the recipient, and determination of death criteria ranging from two minutes to ten minutes, NHBD protocols cannot be justified under the principle of double effect. However, if these proposed safeguards are established in a standardized national policy for NHBDs, then this protocol could be ethically justified by the principle of double effect. With the proposed safeguards, the dignity and respect of all human life, even in its last moments, would be protected, and the greater good would be promoted in spite of the potential for foreseen but unintended consequences.

**Safeguards for an NHBD Protocol**

The reexamination of the NHBD protocols and the request by organ procurement organizations to implement such protocols in acute-care facilities could lead to an increase in the supply of donor organs nationally—but at what price? Presently, the various NHBD protocols being promoted have raised serious medical and ethical questions. Without the proper safeguards, there is the potential for doing evil directly and creating a slippery-slope situation in the future. Presently, the organ procurement organizations are not directly promoting evil by advocating for these protocols. However, they may be allowing the end—helping to increase the supply of donor organs—to justify any means. This is clearly unacceptable ethically. Unless the ambiguities and inconsistencies in the numerous NHBD protocols are addressed and a standardized protocol is enacted, the present protocols should not be accepted in any Catholic health-care facility.

One way to address these ambiguities and inconsistencies is for UNOS to implement nationally a standardized protocol. For this to occur, we believe an interdisciplinary presidential commission should be convened to address these concerns and to propose ethical criteria which will eliminate the suspicion and doubt that

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55 Childress, “Are the Distinctions,” 210–211.
surround the present protocols. After careful examination of this issue, we would propose the following recommendations for a national protocol to such a commission:

- First, clear separation of responsibilities between the caregiving team and the transplant team is needed in order to reinforce safeguards regarding withdrawal decisions and appropriate timing in the determination of death. It is imperative that the transplant team not be involved in any medical decision making for the donor until death has been pronounced.

- Second, there must be the stipulation of cessation of cardiac function for at least ten minutes of EKG and arterial-pressure monitoring. Ten minutes of asystole and no blood circulation at normothermia results in irreversible damage of the brain.

- Third, there must be no administration of anticoagulants or vasodilators (e.g., heparin, phenotolamine) premortem.

- Fourth, the patient/surrogate/family must give informed consent, which entails being given all options concerning donation along with a thorough discussion of potential outcomes.

- Fifth, care and comfort measures so that patients’ pain is managed adequately and that they are treated with the utmost dignity and respect that must be accorded every human person must be administered to the donor according to each hospital’s policy.

With the implementation of these safeguards into a standardized national protocol, we believe that NHB donation could be both medically appropriate and ethically justified.

These safeguards would assure a balance between the rights of the recipient and society and the rights of the potential donor. However, without these safeguards, the public may continue to perceive NHB donation as unethical, which could result in organ donation actually decreasing. The issue of public perception is as important as the medical and ethical issues, if organ donation and transplantation are to be widely accepted, in the words of Pope John Paul II, “as a generous gift” in the future.