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Another Matter of Life and Death

What Every Anesthesiologist Should Know about the Ethical, Legal, and Policy Implications of the Non–Heart-beating Cadaver Organ Donor

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A COMMUNITY hospital agrees to participate in organ harvest from non–heart-beating cadaveric donors (NHBCDs). Members of the anesthesiology department are informed that patients requiring life support will be transferred to the operating room, where an anesthesiologist will monitor them during preparation and draping for organ harvest. The anesthesiologist will discontinue life support and administer medications to keep the patient comfortable while he or she dies. Three minutes after asystole ensues, the anesthesiologist will pronounce the patient dead, and organ harvest will immediately begin.

The anesthesiologists question the ethics of stopping life support and then harvesting vital organs. Some believe it is acceptable to discontinue life support and administer medications to stop respirations and hasten death. Many are resentful that an unpleasant task is being thrust onto them by other physicians in a manner reminiscent of "orders to nurses." Most express bewilderment that the duties of discontinuing life support, caring for the dying patient, and diagnosing and pronouncing death should fall to an anesthesiologist.†

Many anesthesiologists are uneasy about allowing organ harvest from a patient after withdrawal of life support. Anxiety stems from poor understanding or nonacceptance of ethical principles supporting vital organ donation and justifiable concerns regarding potential conflicts of interest that may arise during such donations. The above case demonstrates issues that are problematic with regard to end-of-life care. Some of the proposed actions are illegal or unethical.

The purpose of this article is threefold: (1) to present legal and ethical issues concerning NHBCDs, (2) to discuss important aspects of NHBCD protocols, and (3) to assert that only physicians trained and experienced in caring for dying patients and withdrawing life support should participate in the care of an NHBCD.

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Background

On August 9, 2002, the United Organ Sharing Network reported that 52,923 patients were awaiting kidney transplants, and 17,459 were awaiting liver transplants in the United States. The total number of kidney and liver transplants performed in the year 2000 was approximately 19,000. The number of patients awaiting kidney transplants has almost tripled, and the number of those awaiting livers has increased 10-fold since 1990, while kidney and liver donations have less than doubled.‡

Lack of public awareness does not explain the shortage of donations—surveys demonstrate that public awareness of the organ shortage is actually high.[1] Incomplete acceptance of the concept of brain death and worries that physicians will place the needs of dying patients secondary to those of recipients are known to be significant impediments to donation. Efforts to increase donations, through required request, mandated choice, and presumed consent laws, have been resisted or have had minimal effect.[2–5]

One way to increase the organ supply is to rapidly harvest organs from patients who have undergone irreversible cardiopulmonary arrest.[6] Because organs are removed after circulatory arrest, these donors are referred to as "non–heart-beating cadaver donors," distinguishing them from donors who are brain dead but whose hearts continue to beat. Some authors estimate that NHBCDs would increase available organs by 20–50%.[6–8] Others question these numbers because in a retrospective review, only 3 of 209 potential NHBCDs met criteria for medical suitability for organ donation prior to the decision to withdraw life support.[9] Currently, only approximately 1% of all cadaver donors are NHBCDs.[10]

There is evidence that the public is reluctant to accept the use of NHBCDs, and that the concept may even negatively impact donations. More than 65.7% of people in one study were willing to become organ donors if

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†A summary of discussions between 1996 and 2000 in one anesthesiology department, for which the author was present. Written communication to the author from Steven Jackson, M.D. (Chair, Ethics Committee of the American Society of Anesthesiologists), in February 2002 confirms similar discussions in other departments.

‡United Network of Sharing. UNOS Transplant Patient Data Source. Available at: http://www.unos.org. August 9, 2002.

declared brain dead, and up to 72.5% were willing to donate the organs of a loved one if they knew that the loved one favored donation. Far fewer were willing to donate as an NHBCD— 47.3% for themselves, and 51.3% for loved ones. Reasons they gave included loss of a chance of recovery, the possibility that an error could be committed, and that it sounded like murder or suicide.[11]

The concept of NHBCDs is not new: Before establishment of brain death criteria, NHBCDs and living related donors were the only sources of transplantable organs; kidneys, for example, were usually harvested from cadavers after "uncontrolled" cardiopulmonary deaths. Development of brain death criteria made the procurement of organs from ventilated, heart-beating donors possible, and the use of NHBCDs fell into disfavor except in a few countries, such as Japan, where brain death criteria did not achieve social or legal acceptance until recently.[2,6,12]

NHBCDs were all but abandoned due to problems minimizing the interval between declaration of death and the removal, cooling, and preserving of organs—the "warm ischemia time."[12,13] Renewed interest in NHBCDs lead to strategies to reduce warm ischemia time, such as preservation of organs *in situ* immediately following uncontrolled death or harvesting organs from NHBCDs at a time and place where death is "controlled."[2] Studies demonstrate that such organs have similar viability to those procured from brain-dead donors.[14–17]

In Situ Preservation in Uncontrolled Death

With *in situ* preservation, organs are preserved in the body immediately following uncontrolled death. A catheter is inserted *via* the femoral artery into the abdominal aorta, and an occluding balloon is inflated. Catheters may also be inserted through the abdominal wall. After death, the organs are immediately cooled by infusion of cold preservative solution into the abdominal aorta and peritoneal cavity. The body is then transferred to an operating room for organ harvest.[2,12]

In situ preservation must occur rapidly after cardiopulmonary arrest to be effective. It ideally involves advance consent from the patient or family for the insertion of cannulae under local anesthesia *prior to death*. However, many potential donors arrive in critical condition, unable to give consent. Physicians at the Regional Organ Bank of Illinois, after being refused permission in 35 cases, undertook preservative infusion without family consent, reasoning that it was nondeforming, was nonmutilating, and did not require consent. They then approached the families about organ donation, and six of seven consented.[2,13] The ethics of performing invasive procedures in dying patients without consent are questionable because even the moral acceptability of performing invasive procedures *on dead bodies* without obtaining consent of the patient before death or consent of surrogates after death is doubtful—it may be disrespectful, potentially ignores family desires, and may foster undesirable attitudes among medical professionals toward dead and dying patients.[2,18–20] In a 1994 survey, 71% of people opposed allowing physicians to undertake preservative infusion without family consent.[11] Nevertheless, Florida, Virginia, and Washington, DC, legislators passed laws allowing *in situ* preservation without consent.[21–23] This practice, even where legalized, still presents serious ethical questions regarding rights and wishes of donors and their spokespersons.

Harvesting Organs after "Controlled" Death

The second strategy of controlling the time and place of death allows patients and families to consider organ donation after deciding to withdraw life-sustaining treatment and before death has occurred.[2] This has several advantages. The decision to donate organs before death allows time for discussion, reflection, and informed consent. In addition, the time and place of death are "controlled," and organ preservation and harvest can be planned to minimize warm ischemia time. Often, this involves withdrawing life-sustaining therapy from a patient in an operating room and harvesting organs immediately after death occurs. One of the earliest protocols for organ harvest after "controlled death" was developed at the University of Pittsburgh and is commonly referred to as the "Pittsburgh Protocol."

Is Removal of Organs from a Patient after Withdrawal of Life Support Legal?

Legal developments in the United States over the past 50 yr permit the harvesting of organs after death from patients who wish to terminate life-sustaining medical treatments. These include (1) the Uniform Anatomic Gift Act of 1968, (2) development of new criteria for death and clarification of the rights of permanently unconscious patients, (3) development of the Uniform Determination of Death Act in 1981, and (4) precedents in case law allowing withdrawal of life-sustaining treatment.

Organ Donation and Criteria for Death

In 1968, the Uniform Anatomic Gift Act allowed patients over age 18 to designate that their organs be transplanted after they are legally dead. Next of kin were also given authority to permit or refuse donation.[24] During the same year, the Ad Hoc Committee at Harvard Medical School, lead by Henry Beecher, M.D., Professor of Anesthesiology, developed criteria for brain death. The committee accepted two different criteria for de-

claring death: (1) irreversible cessation in cardiopulmonary function and (2) irreversible cessation of all brain function, including the cortex and brainstem.[25] In 1981, the Uniform Determination of Death Act recognized both criteria for declaring death described by the Harvard Committee,[26,27] and all states have laws or precedents recognizing both criteria. Therefore, once an NHBCD meets either cardiopulmonary or neurologic criteria for death, he or she can legally be used as a vital organ donor.

The Right to Forgo Life-sustaining Treatment

The right to forgo life-sustaining treatments has been well recognized in the courts. Examples include the cases of Karen Ann Quinlan, Claire Conroy, and Nancy Cruzan.[26,28,29]

In 1976, the New Jersey State Supreme Court determined that Karen Ann Quinlan, a permanently unconscious woman, had the right to refuse life-sustaining medical therapy and that her rights could be implemented through surrogate decision-makers. In 1985, in the case of Claire Conroy, a woman with severe dementia, the New Jersey State Supreme Court determined that nutrition and hydration could be withdrawn from an incompetent patient (1) if it is clear that the patient would have refused the treatments under the circumstances involved, (2) if there is at least some evidence that the patient would have refused the treatment and the burdens clearly outweigh the benefits, or (3) if the net burdens markedly outweigh the benefits and continued treatment would be inhumane. In the case of Nancy Cruzan in 1990, the United States Supreme Court concluded that a constitutional right to refuse treatment exists and extends to a surrogate's interpretation of those wishes.[26,28–30] All states now have laws recognizing the rights of patients to refuse life-sustaining treatment and allowing such wishes to be implemented through Durable Powers of Attorney, living wills, and surrogate decision-makers.[29,30]

Ethical Principles Supporting the Use of NHBCDs

Ethical arguments supporting the use of NHBCDs are straightforward, citing principles of respect for patient autonomy and beneficence.

Respect for Autonomy

The principle of respect for patient autonomy recognizes that competent patients have the right to make informed and unencumbered choices regarding their bodies and lives. The principle is essential to ethical medical care of patients and is uniformly supported in the courts.[31] Patients have the right to forgo medical therapy under most circumstances, even if that therapy would be life saving. They also have the right to offer their organs for transplantation, irrespective of the circumstances of their death.

The need to make serious medical decisions frequently arises at times when patients are not capable of exercising autonomy because of illness, alterations in mental status, or unconsciousness. Surrogate decision-makers or legal instruments, such as durable powers of attorney and living wills, are means through which patients can record their wishes during a time of lucidity for use when they can no longer speak for themselves. When an unconscious patient has expressed a desire to forgo or terminate life-sustaining treatment and to donate organs through a surrogate decision-maker or legal document, that decision carries the same moral and legal authority as the patient's own words would, if he or she could express them.[30,32,33]

Beneficence

Beneficence is the principle "doing good" for this particular patient and, secondarily, for society as a whole.

Life-sustaining treatment can cause unbearable burdens, such as prolonged physical, emotional, and psychological suffering; social and physical isolation; loss of sense of self; loss of dignity and independence; and financial impoverishment. Patients may decide to forgo medical treatments, feeling that the "benefit" of prolonging life is outweighed by these other burdens. The ethical principles of beneficence and nonmaleficence ("do no harm") support withdrawal of life-sustaining treatment in accordance with patient wishes in such circumstances, provided that patient suffering is avoided and patient dignity is preserved as much as possible. Withdrawal of life-sustaining treatment is never to be construed as an excuse not to "care" for the patient. Relief of suffering and preservation of the dignity of dying patients requires extraordinary effort and expertise on the part of healthcare providers.[34,35]

Donating vital organs at the time of death may benefit the patient and his or her loved ones through feelings of altruism, a sense of community, belief that the quality of life of others will be improved, and mitigation of grief. The donation of vital organs also benefits society by providing a scarce and valuable resource and promoting values of generosity and community participation.

Ethical Arguments against the Use of NHBCDs

Ethical arguments against the use of NHBCDs are complex. They include the principle of nonmaleficence, preservation of values such as patient–doctor trust, re-

spect for human dignity and professionalism, "slippery-slope" concerns, and the presence of conflicts of interest.

Nonmaleficience

The flip side of the coin of beneficence ("do good") is nonmaleficence ("do no harm"). Some physicians believe that withdrawal of life support constitutes an overriding harm because it deprives the patient of life. Public sentiment and most medical ethicists disagree.[36] It is widely accepted that withdrawal of life-sustaining treatments under appropriate circumstances is ethical, appropriate, and even kind. If extreme care is not taken, however, the principle of nonmaleficence can be violated during withdrawal of life-sustaining treatment, death, and organ harvest. The very decision to forgo life support may be biased by the prejudices of the physicians involved. As Shaw states: "If the person in need of organ transplantation is younger, more attractive, or in some way seems more deserving than another critically ill patient, then the conclusion that one patient's condition is hopeless can be tainted by an understanding of the tremendous hope organ availability holds for another."[37]

Physical suffering can potentially be increased by preparations for organ harvest, such as placement of catheters prior to death for *in situ* organ preservation or transfer of the patient from the intensive care unit (ICU) to an operating room. Preparations for organ harvest could deny the patient the presence and support of loved ones during death. Families may be denied the benefits of being able to provide support and comfort to a loved one while he or she dies.[7]

Care of the dying patient can be manipulated and potentially compromised if the transplant team's concerns about organ viability take precedence. Physicians can cause increased patient suffering by inappropriately withholding sedative or analgesic medication to avoid the appearance of euthanasia. Alternatively, some physicians may be tempted to use those same medications unethically to hasten death when a patient does not die promptly after withdrawal of life support.[38] Administration of medications in anticipation of or to relieve patient suffering, *i.e.*, the administration of sedatives or narcotics to relieve symptoms of anxiety, dyspnea, or pain, is acceptable and required, even if a side effect of the treatment is death instead. However, administering such medications *in the absence of patient suffering*, such as administering a narcotic to stop respirations in an unconscious patient, is active euthanasia—a practice that is illegal in the United States and considered unethical.[29,39]

Some NHBCD protocols allow the administration of medications to donors prior to death, such as heparin and phentolamine, to enhance organ viability,[27,37,40] even though it does not benefit the donor and could potentially hasten death. Patients with elevated intracranial pressure or intracranial hemorrhage might experience lethal increases in pressure or bleeding, for example.[27]

According to the principle of "double effect," acts intended to produce morally "good" effects, such as analgesia, are permissible even if they produce morally "bad" effects, such as causing death, but only if the good effect is *the only one that is intended*. Hastening death in the process of obtaining vital organs is considered by most to be maleficent to the patient, harmful to the doctor–patient relationship, and potentially detrimental to organ transplant programs.[41] It harms the patient by placing his or her needs second to the discomfort or impatience of the medical team and the needs of the organ recipient. It harms the doctor–patient relationship by violating trust; patients increasingly doubt that doctors will do what is best for them and not place the interests of someone else first.[38] It harms transplant programs by justifying concerns that the needs of dying patients will take back seat to the economic and professional pressures on physicians and hospitals to perform transplantations.

There is risk of loss of dignity to the dying patient if the focus of the healthcare team is shifted from them to the transplantation process and the recipients. This trivializes the dying process and transforms the patient from a person with his or her own intrinsic value into a mere commodity through which other patients can be treated.[20,42]

Finally, there is risk of harm to the professional image of doctors, who must avoid being perceived as hovering over dying patients, ready to snatch kidneys and livers, literally before the corpses have grown cold.

Slippery Slopes

Changes in medical practice involving ethical issues are inevitably contested with slippery-slope arguments. I will review two major types of slippery-slope arguments, the conceptual (or logical) and the pragmatic (or psychological–sociological) slippery slopes[31,43,44] and then discuss examples of how psychological–sociological slippery-slope arguments in particular are applied to NHBCDs.

In the logical slippery-slope argument, morally acceptable action A is not logically distinguishable from morally questionable action B. Allowing A must lead to logical acceptance of B, and therefore, A should not be allowed. Arguments against allowing withdrawing of life-sustaining medical therapy, for example, are often based on a logical slippery-slope argument that "letting die" is no different from active euthanasia, and allowing the former

must also permit the latter. The fact that withdrawal of life support and active euthanasia share some characteristics seems to lend credence to the argument. Not only is the actual outcome (death) indistinguishable in each case, but the *intended outcome* is also indistinguishable. In addition, neither active euthanasia nor withdrawal of life-sustaining treatments occurs by chance or accident—both require deliberate action. Acceptance of active euthanasia, as the argument goes, would be an undesirable *and a logically unavoidable* consequence of permitting withdrawal of life support. Logical slippery-slope arguments are nearly always weak, however, because they rely on an underlying and usually erroneous assertion that no significant distinction exists to justify A and not B. Distinctions usually *can* be drawn between two similar actions such that one can be prohibited while another is allowed. For example, the concept of "letting die" encompasses ideas involving the avoidance of interventions that prevent natural death, while active euthanasia encompasses ideas involving making interventions that directly cause a patient's death. United Stated courts cite this particular distinction and accordingly have legalized withdrawal of life support but thus far have not permitted active euthanasia.[27,31]

The pragmatic slippery-slope argument recognizes that, while rules of law may be useful in preventing unwanted human behavior, human beings have a demonstrated capacity both collectively and individually to allow inertia, habituation, thoughtlessness, and self-interest carry them down the road to unanticipated, undesired, and unethical results.[43] We can draw lines and make distinctions, but rational discriminations might not withstand powerful social, economic, and psychological pressures.[44,45] Under the right social or psychological pressure, committing the morally justifiable A prepares us psychologically to *accept* the morally questionable B, even if it is logically distinct from A. Accepting A may also condition us to *redraw the lines and rewrite the laws* to conform to that acceptance.[45–47]

NHBCDs present many potential pragmatic slippery-slope issues, such as the manipulation of the timing of death, the definition of when cardiopulmonary arrest is "irreversible," the question of who might be used as an NHBCD, and the economic pressures of end-of-life care and transplantation.

Manipulation of the Timing of Death

When we manipulate the timing and place of withdrawal of life support to facilitate organ retrieval, our underlying purpose is to manipulate the time of death. If the dying process is unexpectedly prolonged after withdrawal of life-sustaining treatment, will it some day be acceptable to administer drugs to hasten an "inevitable" death and facilitate organ retrieval? How is this different from withdrawing treatment and waiting for death to ensue?

When Is Cardiopulmonary Arrest "Irreversible"?

Ethically and legally, one person must not be killed to provide organs for another, and organ retrieval cannot begin until after the donor has been declared dead—the "dead donor" rule[48–50]—but when can we be confident that either neurologic or cardiopulmonary criteria for death has been met and that neurologic or cardiopulmonary function has been "irreversibly lost"?[2,27,50] In the process of dying, there are stages in which loss of cardiopulmonary or neurologic function is probably reversible, probably not reversible, and certainly irreversible. How do we define "irreversible"? Is cardiac arrest "irreversible" if circulation could be restored but no resuscitation efforts are going to occur? Or is cardiac arrest only "irreversible" when circulatory function cannot be restored, even if resuscitation efforts are undertaken?[27,50] Ironically, in a few cases in which cardiac transplantation has been achieved using NHBCDs, the heart has resumed function in a recipient after cessation of function in a donor has been deemed "irreversible."

The Pittsburgh Protocol requires a 2-min wait after cardiopulmonary arrest before organ harvest, arguing that a 2-min period precludes spontaneous resumption of circulatory and/or respiratory function after arrest. Because artificial resuscitation will not be attempted, even if circulation *could* be restored, *it will not be*. Thus, the arrest is deemed "irreversible."[3,51] Scientific validity of the 2-min interval has been questioned because the phenomenon of "autoresuscitation" has not been prospectively studied and because the proposed interval was based on only 108 case observations.[52] Some authors assert that enough time should pass following cardiac arrest not only to preclude any resuscitation, but to assure irreversible loss of brain function as well.[53,54]

Other proposed intervals have equally tenuous underpinnings. The 1981 President's Commission set 10 min of cardiopulmonary arrest as a reasonable time frame for declaring death,[55] and this interval has also been endorsed by the First International Workshop on Non-Heart Beating Donors.[56] But cardiopulmonary function has been restored after 15 min or more of circulatory arrest, suggesting that 10 min is arbitrary.[52] The Institute of Medicine settled on 5 min as a minimum interval to wait but did not cite supporting data.[10,40,50] Some authors have accused the transplant community of drawing the line between life and death wherever it maximizes chances for organ procurement,[36,50] and the issue remains one of heated debate.[10,27,49,50,57–59]

Who Can Become an NHBCD?

Candidates for non–heart-beating donation may be neurologically intact or neurologically impaired and may require life-sustaining medical treatments as diverse as left ventricular assist devices, mechanical ventilation, intraaortic balloon pumps, and vasopressor therapy. Are we psychologically predisposed to use certain types of candidates as NHBCDs? Without careful safeguards, the dignity and autonomy of vulnerable persons could potentially be systematically compromised to procure organs for transplantation.[41,50]

Bias has been demonstrated on the part of medical professionals toward patients who are perceived as handicapped or are otherwise stigmatized. Studies have shown that, when evaluating the quality of life of severely handicapped patients, physicians consistently apply much poorer ratings than do the patients themselves. Moreover, it has been shown that 17% of physicians, 28% of nurses, and 34% of emergency technicians *would act on their prejudices when it comes to life-sustaining interventions*, and deny emergency life support to patients with severely handicapping injuries, even if patient wishes were unknown.[60,61] Would prejudice about vulnerable patients, such as the handicapped, lead medical professionals to approach such individuals and families for non–heart-beating organ donations more than others with higher "quality-of-life" ratings?[62] Should we be willing to accept surrogate permission for profoundly mentally handicapped or senile patients to donate organs, even though their individual wishes about organ donation are not and perhaps never were known? Some physicians have proposed actively euthanizing permanently unconscious patients to obtain organs for transplantation.[63] Vulnerable populations may be at risk that a future shift in our sensibilities will allow us to justify withdrawing expensive medical treatments and using them as organ donors without their express consent.

The Economics of End-of-life Care and Transplantation

Economic considerations are powerful disincentives to make rational distinctions that might otherwise keep us off of slippery slopes concerning NHBCDs.[2,38,64] The NHBCD requires expensive life-sustaining support, often in the setting of end-of-life care. End-of-life care consumes up to 10–12% of all healthcare expenditures and 27% of all Medicare expenditures.[65,66] Forty-six percent of all Medicare charges in the last year of life are spent in the final 60 days.[67] The costs of palliative therapy are also high.[35] Emanuel[65] points out that hospice care might result in savings of only 0–10% in the last year of life.

Contrast the economics of end-of-life-care with those of transplantation. The profitability of kidney transplantation is hard to glean from the literature, but Stratta *et al.*[68] reported that while one center charged approximately $42,000 for kidney transplants, during the same period, another reported average costs (not charges) of approximately $30,000. For simultaneous kidney–pancreas transplants, costs (not charges) were reported by one center as approximately $46,000, and charges by other centers during the same period were between $68,000 and $110,000 exclusive of professional fees—roughly 1.5–2.4 times the cost. NHBCD programs hypothetically provide a way to cut costs of end-of-life care by promoting withdrawal of life-sustaining treatments to allow organ donation and simultaneously support a profitable enterprise in organ transplantation. With such powerful inducements, will we one day set aside important ethical distinctions and accept what we today agree would be morally questionable actions?

Concerns about medical treatment of the handicapped and rising economic pressures regarding end-of-life care are certainly not unique to NHBCDs, but NHBCDs magnify these issues and the ways in which they might affect attitudes and medical decision-making in difficult end-of-life situations. As we contemplate changes in medical practice, slippery slopes are not by themselves reasons to reject significant medical advances. Rather, slippery-slope concerns are cautionary signs in the road to change.[43,46,47] We need to ask: What benefits are we trying to achieve? What harms can we predict and prevent? Will we be able to make important distinctions and set limits that are clear enough and strong enough to protect the persons and values we must protect?

Protocols to Address the Use of NHBCDs

Ethical questions about NHBCDs are far from resolved, but transplantation practices have outraced the debate, and we are left in the uncomfortable position of regulating through protocols a practice that still raises serious ethical doubts. In 1992, the University of Pittsburgh approved its first protocol for procuring organs from cadavers certified dead using cardiopulmonary criteria.[69] Three years later, they reviewed their experience and instituted changes to their protocol.[70] The Pittsburgh Protocol has been praised in ensuing discussions as "an ethically and legally acceptable program for increasing the organ supply," and decried as "ethics by trial-and-error."[71] Nevertheless, most institutions that have NHBCD protocols follow some version of the Pittsburgh Protocol, a current summary of which is provided in Appendix I.

A 1995 study examining how some centers have handled NHBCDs is profoundly disturbing: Of 12 organ procurement organizations studied, several were conducting procurement without any protocol at all or without policies that addressed key features such as the timing of death, but all authorities on NHBCDs agree that

specific protocols and policies are mandatory for appropriate medical, ethical, and legal management of NHBCDs. Many centers allowed a single procurement coordinator to act on behalf of both the donor and the recipient, a conflict of interest. Many organ procurement organizations collaborated with doctors on the use of medications for patient suffering, another conflict of interest. Most did not designate a minimum interval after cardiac arrest to declare death. All but three did not allow families to be present at the time of death. Four centers studied had no provisions for situations in which donor death did not occur as expected after termination of life support. More than half did not use ethics committees or consultants during protocol development.[72]

In April 1997, a report on the television program "60 Minutes" (CBS) suggested that organs were being removed from some people before they were actually dead. One month later, the Department of Health and Human Services requested a review of the ethics and practices of non–heart-beating organ donation from the Institute of Medicine (IOM), an organization established by the National Academy of Sciences to serve as an advisory body to the government on matters of public health. Reviews by the IOM in 1997 and 2000 strongly supported the use of NHBCDs but criticized national organ procurement organizations for using incomplete and inconsistent protocols. The IOM emphasized the need for written, standardized protocols as well as continued study to improve existing protocols using NHBCDs. Other issues of concern to the IOM were the interval of cardiopulmonary arrest necessary to declare death and whether medications intended to preserve organ viability could ethically be administered to the donor before death.[40,73]

Expertise and experience in end-of-life care is requisite to appropriate management of all dying patients, including the NHBCD, and no center should undertake an NHBCD program until it has separate policies and procedures that address palliative care and withdrawal of life-sustaining treatments. Given the complexity of the medical, social, and legal contexts of NHBCD protocols, involvement of an ethics committee or ethics consultation service is critical to protocol development, implementation, and review, a position strongly endorsed by the IOM. No center should undertake organ harvest from NHBCDs without a protocol that addresses certain key issues.[7,56]

NHBCD protocols must address concerns such as donor eligibility and criteria for declaring death. They must acknowledge relevant conflicts of interest and set preventative safeguards. Finally, they should include steps for dealing with unanticipated conflicts of interest as well as provisions for continuing evaluation of the NHBCD program and protocol. Important aspects of NHBCD protocols and their rationales are summarized below.

How Are Discussions about Organ Donation Initiated?

The decision to withdraw life support should be made before consideration of organ donation. It represents an obvious conflict of interest for medical professionals caring for potential organ recipients to be involved in discussions with or in the direct care of potential donors.[3,7] The original Pittsburgh Protocol required that discussions of organ donation only be initiated by the patient or his or her family, not by medical personnel. This proved to be impractical and may even have denied some patients the opportunity to donate organs through lack of information. The protocol was revised to prohibit discussion of organ donation until after the decision to forgo life-sustaining therapy but allow medical personnel to initiate the discussion.[69,70]

Which Patients Can Be NHBCDs?

Potential donors must be dependent on life-sustaining treatment, such that stopping therapy will lead *predictably and quickly* to death.[2] Appropriate care of patients who experience a protracted death may be compromised if withdrawal of life-sustaining therapy is planned in an operating room rather than in an ICU or palliative care setting. Even modestly prolonged cardiopulmonary compromise after withdrawal of treatment in a patient whose physiologic reserve is unknown could compromise the viability of transplantable organs, rendering the donation process irrelevant.

There should be policies in place protecting the interests of vulnerable patients, such as the mentally handicapped, whose wishes regarding withdrawal of life-sustaining therapy and organ donation may never have been known.

Informed Consent

Decisions regarding organ donation must include a fully informed consent process.[7,54] This must include information about the process of removing life-sustaining therapy, the process of declaring death and organ procurement, the possibility of a protracted death that disqualifies the patient from donating organs, and any procedures that might be performed prior to death. The consent process must also include clear agreements that consent can be withdrawn at any time without cost to the patient and without endangering the quality of his or her subsequent care.

Care of the Dying Patient

The interest of procuring organs must not interfere with optimal patient management during the dying process.[2,54] It is a clear conflict of interest for members of the transplantation team or organ procurement organization to be involved in the decision-making during care of the dying patient.[3] The protocol should designate—or describe a credentialing process for—those profession-

als who may withdraw life support. Caregivers must have appropriate training, competence, and experience. The protocol should outline a humane process for withdrawing physiologic supports, such as infusions, left ventricular assist devices, and ventilators. The titration of drugs for justifiable comfort measures should be consistent with their use in palliative end-of-life care for other patients. The prohibition of the administering of drugs for the purpose of intentionally hastening death should be emphasized.[9] Therapies to maximize organ preservation that do not benefit the dying patient, such as administration of heparin and phentolamine, should be viewed skeptically or avoided altogether since they have the potential to hasten death.[37] Steps should be outlined for cases in which the dying process is unexpectedly prolonged. The length of the waiting period for asystole to occur after withdrawal of treatment should be specified. A process should be described for canceling organ procurement and transferring the patient back to the ICU or terminal care ward when dying is prolonged.[37] Finally, family support at the time of death should not be denied to patients to facilitate organ retrieval.[3,9] Provisions should be made for family members to be present at the time of death if they so desire.

Definition and Declaration of Death

Organ harvest must not begin until after the donor's death, and death cannot be declared unless the patient meets medical and legal criteria for cardiopulmonary death.[7,48] When designating how long circulatory function must be absent in order to declare death, the protocol should state the empirical and philosophical grounds for the designation.[2]

Documentation, Discussion, and Review

All discussions with patients or families or among healthcare providers should be rigorously documented, including the rationales for decisions, the clinical course of events, timing and dosages of any medications required, and time of death. It is desirable for an ethics committee to review any decision to forgo life-sustaining therapy in the setting of organ donation and submit a summary of that review for the medical record. A process for periodic external review should be designated.[7,70]

Should Anesthesiologists Be Involved in NHBCD Organ Harvest?

In many cases, anesthesiologists first learn about NHBCDs because someone involved in protocol development decides that, since withdrawal of life support will occur in an operating room, an anesthesiologist should supervise it. For NHBCDs, however, the presence of an operating room anesthesiologist is both unnecessary and potentially harmful. The NHBCD does not need anesthesia; organ harvest does not occur until after death. Further, the involvement of an anesthesiologist could create the mistaken and harmful impression that the donor is actually *not* dead and therefore might suffer during organ harvest.

There may be legitimate reasons for withdrawing life support in an operating room, but in such cases, last-minute transfer of complex end-of-life care to an unfamiliar medical team is inappropriate and potentially harmful. Care of the patient should remain with the primary medical team. While the role of end-of-life care provider does sometimes appropriately involve subspecialty anesthesiologists with intensive care or palliative care expertise, it does not fall under the customary practice of the operating room anesthesiologist.

Withdrawal of life-sustaining therapy is a complex and solemn undertaking requiring special physician knowledge and training.[28,74] Competence in withdrawal of life support includes the ability to support and counsel patients and families, respect for the patient's autonomy and religious and cultural beliefs, knowledge about the pharmacology and physiology of end-of-life care, ability to meet the nonphysical needs of patients, ability to work in a complex team, ability to communicate, and empathy.[34,75–77] Physicians with inadequate knowledge of palliative medicine may fail to adequately treat patient suffering.[34] Further, physicians who are not experienced in end-of-life care may mishandle important legal, social, and psychological issues concerning the dying patient and cause undue suffering of families and loved ones.[30,74,78]

The specialties of internal medicine, family medicine, and intensive care medicine have designated core curricula, including specific training in end-of-life care, terminal weaning of ventilator support, palliative care, and legal and ethical dimensions of decisions and procedures during withdrawal of life-sustaining therapies.[79–81] The Joint Commission on Accreditation of Healthcare Organizations has also published standards for the palliative care of dying patients and withdrawal of life-supporting therapies.[82] In 2001, the Ethics Committee for the Society of Critical Care Medicine published recommendations for end-of-life care in the ICU, including protocols for withdrawal of life-sustaining treatments and appropriate use of sedatives and analgesics.[83] Anesthesiology residency and anesthesiology critical care medicine specialty training do not require core curriculum competency in end-of-life issues or withdrawal of life-sustaining therapy,[84,85] and it cannot be assumed that most anesthesiologists have the education or experience to withdraw life-sustaining therapies from dying patients. For this reason, only those anesthesiologists who have specialty training and/or significant practice experience in end-of-life care should ever be involved in withdrawing life-sustaining treatment from patients who will become NHBCDs.

Summary

It remains to be seen whether the use of NHBCDs will significantly increase the number of organs available for transplantation. Organ retrieval from such donors may be ethical, provided that conflicts of interest among healthcare providers are defined and prevented, the exploitation of vulnerable persons is avoided, the withdrawal of care is in accordance with accepted and appropriate medical standards, the inadvertent harvesting of vital organs from living patients does not occur, and the humane treatment of dying patients and their families is safeguarded. Further, the process must not be implemented in ways that cause distrust among dying patients that their medical and social needs will be put secondary to those of patients needing transplantable organs. It is arguable whether any existing protocol completely addresses all of these issues.

Any anesthesiologist involved with either policies or care of patients who will become NHBCDs should be educated about the legal, ethical, and medical issues involved and should not undertake such duties without adequate knowledge and training. Even when withdrawal of care is anticipated in an operating room setting, only physicians with appropriate knowledge, training, and experience in the withdrawal of life support and comfort care of the dying patient should be involved with the NHBCD. Such specialty expertise is not within the customary training and practice of most anesthesiologists. The physician withdrawing life support should be someone who has been involved with the patient and family throughout the decision-making process, so that death does not become, as Renee Fox described it, a "desolate, profanely 'high-tech' death that the patient dies, beneath operating room lights, amid masked, gowned, and gloved strangers."[20]

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Appendix I: Summary of the Pittsburgh Protocol for Non-Heartbeating Organ Donation

This only a summary of the protocol, which contains more discussion and detail.

(Updated February 7, 2001)

I. Policy

UPMC Presbyterian strives to provide an ethically justifiable and auditable policy respecting the rights of patients to have life support removed and to donate organs if they wish to do so.

II. Management of Terminally Ill Patients Who May Become Organ Donors after Death

A. Principles

1. Decisions concerning treatment of patients must be made separately from and prior to discussion about organ donation. Decisions about and consent for organ donation should be made independent of any decision to remove life-sustaining treatment.

2. The healthcare team's primary responsibility is to optimize patient care. Removal of life support shall be done primarily to promote patient comfort and respect for patient autonomy. The interest in procuring organs should not interfere with optimal patient management.

3. Appropriate candidates for organ donation are limited to patients on life-sustaining therapy in whom withdrawal of treatment is likely to result in death within 1 h.

4. Interventions intended to preserve organ function but which may cause discomfort to the patient or hasten death are prohibited.

5. Any intervention whose primary intention is to shorten the patient's life is prohibited.

6. Protection of the dignity and rights of donors is of utmost importance.

7. Healthcare professionals shall not be required to participate in the procedures described below if it is against their personal, ethical, or religious beliefs.

8. Surrogate decision-maker is defined in accordance with UPMCP policy.

B. Procedures

1. Detailed discussion of organ donation is deferred until after the decision to withdraw life support. Patient is assigned the status of "comfort measures only." Discussions with the patient or surrogate must be appropriately documented in the medical record.

2. After it has been decided to withdraw life support, if the patient or surrogate has not initiated discussion of organ donation, the healthcare representative consults with the organ procurement agency to determine organ suitability. Drawing blood for testing to determine medical eligibility for organ donation may occur either after the decision to withdraw support or after consent for organ donation.

3. Organ procurement may proceed only if the patient or surrogate agrees and signs the appropriate consent form. Consent can be withdrawn at any time. No pressure or coercion shall be used to maintain a consent.

4. Organ procurement may proceed only if, prior to signing consent, the patient or surrogate has met with a member of the Ethics Consultation Service. The Ethics consultant will review the decisions and write a summary of the discussion with the patient or surrogate in the medical record.

5. If any member of the healthcare team perceives an ethical problem, he or she is encouraged to notify the ethics consultant.

6. The administrator on duty will be notified that organ procurement from an NHBCD is contemplated.

7. Appropriate support will be provided for the patient, surrogate, or family by healthcare professionals. Discussion should take place regarding whether the family wishes to be present at the moment of the patient's death and whether the family wishes to see the patient after organs have been removed. Pastoral care of the patient, surrogate, or family shall be provided by clergy if requested.

8. The patient's attending physicians must agree with the proposed procedure and so note it in the chart.

9. The responsible anesthesiologist will be informed of the plans.

10. The responsibilities of the ICU physician withdrawing support include the following:

a. Informed Consent: The following must be discussed with the patient or surrogate:

- UPMCP's policies regarding patients for whom the goal of care is comfort measures only
- The process of removal of life support
- The process of organ procurement
- That withdrawal of life support may be completed in the OR or OR holding area
- That a femoral artery catheter or echocardiogram is required
- That removal of life support may not always lead to death in a very short period of time
- That organs will not be procured until after the patient is declared dead
- That organs may not be procured if certain problems occur
- That death will be certified in accordance with law
- That consent can be withdrawn at any time without cost or prejudice

b. Deciding when to transfer the patient to the OR

c. Managing the patient's care with an ICU nurse in the OR

d. Informing the surgeon when it is acceptable to start surgical preparation of the patient's skin

e. Certifying death—the physician certifying death must not be involved in either procuring organs or the care of transplant recipients

f. Filling out and signing the NHBCD record

11. The following criteria shall be used for selecting the supervising ICU staff physicians:

a. the physician must attend in the ICU

b. the physician must have familiarity with guidelines on life sustaining treatment and the policy for removal of life support for NHBCDs

c. the physician must have personal experience with termination of life support

d. the physician shall have no current clinical responsibilities on the transplant service or caring for potential recipients of organs from the NHBCD

e. The physician shall be designated by the Chief of service, or UPMCP credentialing committee

f. ICU physicians who have other basis for conflicts of interest in individual cases shall decline or not be asked to participate

12. The surgical staff responsible for organ procurement shall not participate in the donor's care.

13. Anesthesiologists who might later be involved in the management of recipients of the donated organs shall not participate in the donor's care.

14. Narcotics and sedatives must be titrated to the patient's comfort needs.

15. Interventions intended to preserve organ function but which may cause discomfort or hasten death are prohibited. Medications which do not harm the patient and are necessary for NHBC donation are acceptable, *e.g.*, heparin.

16. If organ ischemia is prolonged, the organ procurement may be cancelled by the responsible transplantation surgeon. The ICU physician may return the patient to the ICU.

17. No organs will be procured until death is certified. All other appropriate preparations for procurement may take place prior to death but never before the patient is unconscious and unresponsive to noxious or painful stimuli. Skin preparation and draping may occur with approval of the ICU physician.

18. Certification of death: Continuous EKG and pulse oximetry monitoring are required. Diagnosis of death requires absence of circulation documented either by absent pulse pressure *via* a femoral arterial catheter or by echocardiogram. The patient must be apneic. The patient must be unresponsive to verbal and tactile stimuli. All criteria must be present for a minimum of 2 min.

19. Immediately after certification of death, organ procurement is to proceed.

20. The procedure for organ procurement, cleaning of the body, and transfer to the morgue is to be conducted with respect and sensitivity to the deceased and their surrogates.

21. Procured organs will be distributed in accordance with current UPMCP policies and UNOS requirements.

22. Donors will not be charged for the cost of procurement.

23. Cases will be reviewed by the chairperson of the Ethics Committee, or designee,

- to assure that the above principles are adhered to
- to assure that the above procedures are complied with
- to identify problems and complications, potential or actual, and recommend changes
- to protect the interests of the donor, recipients, UPMCP, and involved healthcare workers
- to assess the effect of these procedures on the family's grief process and determine whether changes could be made to improve the