Non–Heart-Beating Organ Donation

Designing an Ethically Acceptable Protocol

BY JAMES M. DUBOIS, PhD, DSc

Dr. DuBois, an associate professor of health care ethics, Saint Louis University, St. Louis, is a member of the United Network for Organ Sharing's Region 8 Liver Review Board and Mid-America Transplant Services' Non–Heart-Beating Organ Donation Lay Committee.

Organ donation after death is considered a generous gift, a gift of life. In harmony with many religious traditions, the Catholic Church teaches that organ donation can be a concrete gesture of "solidarity and self-giving love"[1] and "meritorious."[2] Yet many people cannot donate organs because of the circumstances of their death. Aside from living donation (most typically of a single kidney), solid organ donation requires that the organs be procured after the donor has died but before the transplantable organs have themselves died.

Most organ donors are declared dead after a traumatic head injury. Such circumstances permit attending physicians to use neurological (or brain death) criteria to declare the donors dead, even while the donors' circulation and respiration are being maintained artificially.[3] However, this pool of organ donors has always been inadequate to meet need. Moreover, most people do not die from traumatic injury and thus cannot donate organs after death even though they might have wanted to do so.

Non–heart-beating organ donation (NHBD) provides an alternative for some patients. In this article I will focus only on "controlled" NHBD, in which patients or their proxies decide to withdraw life support because life support is futile or excessively burdensome. NHBD protocols use circulatory-respiratory (CR) criteria to determine death. The unusual twist to NHBD protocols is that death must be declared within a few minutes after CR functions are lost; otherwise solid organs are severely damaged by warm ischemia (lack of oxygenation at body temperature). NHBD protocols give rise to many ethical questions. Nevertheless, the use of a well-designed NHBD protocol is ethically acceptable. With this article, I hope to help hospitals identify the major ethical issues so that they may design an acceptable protocol while providing an adequate ethical rationale to the public.

Protecting Donor Interests

Using a person merely as a means to an end is wrong. Put otherwise, acting against one person's dignity for the sake of another is wrong. In the context of organ donation, this principle requires that the organ donor always be shown respect. The benefit to the organ recipient, great as that may be, does not justify harming the donor—even in the last minutes of life. With these thoughts in mind, I will briefly touch on the most important donor safeguards that NHBD protocols should include.

How Can One Be Sure That Dead Donors Are Really Dead?

The transplant community frequently speaks of the "dead donor rule." Laws and norms against homicide require that donors of vital organs not be killed in the process of procuring their organs. Some commentators claim that this is *all* the rule entails.[4] In practice, the dead donor rule is usually understood to entail that vital organs not be procured until after death has been determined (even though, in some scenarios, organ procurement might not be the cause of death).[5]

The U.S. Uniform Determination of Death Act of 1983 (UDDA) says death may be declared when a person sustains "either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem."[6] Although the presidential commission report on which the UDDA was based permits two different kinds of criteria to be used in determining death, it maintains that death is a unified phenomenon: the loss of integrative unity. Some commentators argue that NHBD patients are not dead because one must wait at least 9 or 10 minutes after cardiac

arrest to establish that the donor's brain has incurred damage severe enough to meet brain death criteria.[7] But this approach is mistaken. NHBD protocols use CR criteria, not neurological criteria, to determine death. This approach is consistent with defining death as a unified phenomenon: With the loss of CR functions, integrative unity is lost, the brain stops functioning, and consciousness is lost. Moreover, assuming that CR functions are *irreversibly* lost, all other functions (including brain functions) are irreversibly lost as well.[8]

> NHBD presents potential conflicts of interest, which must be avoided.

Controversy also exists over competing interpretations of the UDDA requirement that functional losses be irreversible. NHBD protocols vary across the nation, but many state that death can be declared just two minutes after the patient's CR functions have ceased.[9] We know, however, that aggressive cardiopulmonary resuscitation can often restore CR functions, even after two minutes of arrest. How can NHBD protocols then satisfy the legal requirements for irreversibility? Well-designed protocols do this by noting two facts:

- Available medical evidence suggests that no patient can revive without help (auto-resuscitate) two minutes or more following the cessation of CR functions.[10]
- NHBD becomes an option only after a decision has been made to withdraw life support. Therefore, applying resuscitative measures would violate the patient's wishes as expressed in a valid do-not-resuscitate order.

The loss of CR function is both *naturally* and *morally* irreversible in such cases. If nature is allowed to take its course (and we are obliged to let it do so), function will not return. In waiting out a two-minute absence of pulse and breath, physicians are ensuring that the donor, being dead, will not be harmed by procurement.

Should Heparin Be Administered before Death Is Declared?

NHBD protocols frequently instruct physicians to administer a large dose of the drug heparin after life support has begun to be withdrawn but before death is declared. Heparin is an anticoagulant used to ensure a proper "flush" of newly procured organs so that they may be preserved for transplantation. Some ethicists argue that heparin should not be administered routinely. Many patients who donate using NHBD protocols have head injuries. In such cases, an anticoagulant could cause massive brain hemorrhaging and death.

Is the premortem use of heparin unethical? Or can the principle of double effect be invoked? Certainly this scenario meets most of the requirements for the correct application of the double-effect principle. The physician's intention—thinning blood to ensure organ viability for transplant—is legitimate. The intention is not to hasten or cause the donor's death. Nor is the risk of death a means of achieving the good that is sought. Because, moreover, the patient has withdrawn life support and is in the process of dying, the good at stake is proportionate to any risk.

The objection some ethicists have to invoking the double-effect principle in such cases is this: Ordinarily the person who suffers the potential harm is also the beneficiary of the intended resulting good. These ethicists claim that since the organ recipient is the sole beneficiary of the use of heparin, the principle of double effect cannot be invoked. However, it is also possible to argue that, if the organ donor truly wanted to donate organs for the sake of another, enabling him or her to realize this wish is a good for the donor. If this rationale is accepted, then the uniform use of heparin before death may be justified.

Of course, the principle of double effect also requires that the action be necessary to bring about the good. Some transplant teams, having questioned the uniform use of heparin before death is determined, are exploring other options: administering heparin immediately after death is declared, for example, or using a cold perfusion technique as an alternative.[11] The Institute of Medicine (IOM) wisely recommends making such decisions on a case-by-case basis. It also urges transplant teams to obtain informed consent for the use of any medication that does not directly benefit the donor.

Avoiding Conflicts of Interest

NHBD, like all forms of organ donation, presents potential conflicts of interest that must be avoided to protect the interests of donors and their families. NHBD protocols should address at least four possible conflicts of interest.

The Decision to Discontinue Treatment Must Come First The issue of donation should not be raised until the potential donor or his or her family has decided to discontinue treatment. In the early years of NHBD, some protocols prohibited medical personnel from raising the issue of donation; NHBD protocols were to be used only if the family raised the donation issue. Naturally great sensitivity must be shown to families when broaching the subject of organ donation, but NHBD presents no unique obstacles to making the request. One should simply wait until after a decision has been made to withdraw life support, thereby avoiding conflicts of interest.

Medical Treatment and Organ Procurement Must Be Kept Separate The physician who makes the determination of death cannot be a member of the transplant team.

Donation Costs Must Not Fall on the Donor Family The family should incur no expenses related to the donation process. NHBD protocols typically state that, should the potential donor not die within 30 to 60 minutes after withdrawing life support, he or she will be returned to the intensive care unit and the family will resume responsibility for expenses incurred thereafter.

Donors Must Receive Standard-of-Care Treatment In the well-publicized University of Pittsburgh NHBD protocol, donors were not given morphine or comfort care unless they visibly showed signs of distress. This practice was an effort to avoid the impression that morphine was used to hasten death. Ironically, it may have sacrificed patient interests in an effort to avoid giving the impression of doing so; as a result, the University of Pittsburgh team has since changed the practice. If patients at a given hospital routinely receive comfort care during the process of withdrawing life support, then this same standard should be adopted in the NHBD protocol.

Obligations to Organ Recipients

Although ethical discussions about organ transplantation tend to focus on organ donors, we have ethical obligations to organ recipients as well. Above all, we need to guarantee these patients that we will do everything we reasonably can to make their transplant a success. To do that, we must ensure that the transplantable organ is sufficiently healthy.

The 1997 IOM report cites evidence that success rates with organs procured from NHBD donors and brain-dead donors are comparable. However, they are comparable because certain safeguards are standard. For example, if potential NHBD donors do not die within 30 to 60 minutes after the removal of life support, they are declared ineligible as donors. This is done largely because, although such patients' circulation may not have ceased entirely, their organs are in most cases poorly perfused during withdrawal of life support and have begun to die. Similarly, future data may show that NHBD requires the use of heparin or cannulation (the insertion of tubes for cold perfusion) before death.

Obligations to Donor Families

Cadaveric organ donation occurs at times that are already stressful and emotionally painful for donors' families, and NHBD presents some unique challenges for them.

Family members frequently want to be with their dying loved one. They want to be present when death is declared. Yet NHBD requires that organ procurement begin minutes after death is declared. In such cases, life support is therefore often withdrawn in the operating room (OR), after the body has been prepped for surgery. Most people would not choose this environment for a loved one to die in. Medical personnel need to be sensitive to this fact.

NHBD protocols frequently permit families to remain in the OR until the moment the donor dies. Family members are informed well in advance why they need to leave the OR quickly after the determination of death. There is no perfect way to deal with this challenge. But some hospitals are creative: When their floor layouts permit it, they allow the family to wait with the patient in a room near the OR until the declaration of death is made, thereby accommodating family wishes.

As noted, donor families should be protected from incurring financial expenses of the organ donation process. Their exemption from such responsibility should be explicitly stated in the consent process and in the NHBD protocol.

Developing Protocols

NHBD protocols are typically crafted by and for *local communities. Most NHBD protocol com*mittees include lay persons, religious leaders or clergy, ethicists, and sometimes members of the local media. This approach gives protocol committees an opportunity to gain community input, approval, and oversight.

However, the approach has disadvantages. Lay people are, for example, not experts on many of the medical and ethical issues involved in NHBD. A committee that recruits members who lack authority to make decisions may create a false appearance of oversight and consensus; but a committee that gives each of its members—even the inexpert—equal authority may be acting irresponsibly. Moreover, the current habit of basing protocols on local practice guarantees that the protocols will vary in significant respects: Some allow the use of heparin, for example, whereas

others do not; some require a wait of five minutes or more after CR function loss, whereas others require only that CR functions cease. Because such disparities have the potential to create scandal, they certainly do not reflect a strong commitment to ethical or medical best practice.

The IOM, in both its 1997 and 2000 reports, urges transplant committees to follow certain standard guidelines. Although not all legally binding, these guidelines provide committees with certain advantages:

- They reflect the consensus of panels of experts involved in NHBD.
- Should NHBD cause ethical concern in a particular community, the fact that local committees are following IOM-sanctioned guidelines may help allay that concern.[12]

Fear and Public Opinion

We have a duty not to damage the reputation of organ donation by offending members of the public. In drafting protocols, NHBD committees should ask themselves not only, "Is this ethical and humane?" but also "Will it be *perceived* as ethical and humane?" Committees generally understand that even if administering heparin (for example) is not intrinsically wrong, it will become wrong if the scandal it creates hurts organ donation rates. This insight is basically sound.

However, like many other ethical norms, those concerning NHBD must be balanced. Protocol committees need to build an ethical rationale into certain aspects of their protocol. NHBD protocols should be public documents, and they should provide accounts of prescribed actions. But once we have constructed a solid ethical rationale, we should refuse to allow fear to drive our actions and interfere with medical best practice. □

NOTES

1. John Paul II, "Address of the Holy Father to the Participants of the Society for Organ Sharing, June 20, 1991," *Transplant Proceedings*, 23, pp. xvii-xviii.
2. *Catechism of the Catholic Church*, Libreria Editrice Vaticana, Rome, 1994. See 2301. The Catholic Church's commitment to organ donation finds concrete expression in the *Ethical and Religious Directives for Catholic Health Care Services*, U.S. Catholic Conference, Washington, DC, 1995. See Directive 63: "Catholic health care institutions should encourage and provide the means whereby those who wish to do so may arrange for the donation of their organs and body tissue, for ethically legitimate purposes, so that they may be used for donation and research after death."
3. The Pontifical Academy of Science has twice addressed the issue of brain death and has approved the use of brain death criteria to determine death. See C. Chagas, *On the Artificial Prolongation of Life and the Determination of the Exact Moment of Death*, Pontifica Academia Scientiarum, Rome, 1986, and R. J. White, et al., *The Determination of Brain Death and Its Relationship to Human Death*, Pontifica Academia Scientiarum, Rome, 1989. On August 29, 2000, Pope John Paul II, in his "Address to the International Congress on Transplants," voiced support for the use of brain death criteria: "the complete and irreversible cessation of all brain activity in the cerebrum, cerebellum, and brain stem." The address's full text is available at www.zenit.org (text # ZE00082924).
4. J. A. Robertson, "The Dead Donor Rule," *Hastings Center Report*, November-December, 1999, pp. 6-13.
5. See, however, R. D. Truog, "Is It Time to Abandon the Dead Donor Rule?" *Hastings Center Report*, January-February 1997, pp. 29-37; L. L. Emanuel, "Reexamining Death: The Asymptotic Model and a Bounded Zone Definition," *Hastings Center Report*, July-August 1995, pp. 27-35; and R. M. Arnold and S. J. Youngner, "The Dead Donor Rule: Should We Stretch It, Bend It, or Abandon It?" *Kennedy Institute of Ethics Journal*, June 1993, pp. 263-278. Such writers would allow organ procurement itself to be the cause of death, provided that consent for it has been given and the donor is either permanently unconscious or removed from life support. In contrast, the norms of the Catholic Church would uphold the dead donor rule. See Directive 64 of the *Ethical and Religious Directives for Catholic Health Care Services* and the address by John Paul II cited above. Although the Catholic Church currently insists that donors be dead before their organs are procured, one commentator argues that in some cases procuring organs before death does not itself cause death. See D. A. Shewmon, "Brainstem Death, Brain Death, and Death: A Critical Re-evaluation of the Purported Equivalence," *Issues in Law and Medicine*, no. 14, 1998, pp. 125-145. Because the Catholic Church's reasons for using the dead donor rule have to do with not killing the donor, Shewmon's argument may contradict only the letter of Catholic theology, not necessarily its spirit.
6. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal, and Ethical Issues in the Determination of Death*, Washington, DC, 1981, p. 73.
7. J. Lynn, "Are the Patients Who Become Organ Donors Under the Pittsburgh Protocol for 'Non-Heart-Beating Donors' Really Dead?" *Kennedy Institute of Ethics Journal*, no. 3, 1993, pp. 167-178.
8. J. M. DuBois, "Non-Heart-Beating Organ Donation: A Defense of the Required Determination of Death," *Journal of Law, Medicine & Ethics*, no. 27, 1999, pp. 126-136.
9. Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, National Academy Press, Washington, DC, 1997. The institute, having documented the diversity of protocol standards, urged the transplant community to work toward standard criteria.
10. Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academy Press, Washington, DC, 2000, table 2.1.
11. Cold perfusion is "a method for preserving organs in the body (in situ) before they are removed but after death has occurred. Cold preservative solution is infused into the large vessels and blood is drained out." Institute of Medicine, 2000, p. xv.
12. See Institute of Medicine, 2000, pp. 112-156, for sample protocols. A committee seeking to develop or revise its own protocol might find guidance in these documents.

JOURNAL OF THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES www.chausa.org

HEALTH PROGRESS®

Reprinted from *Health Progress*, January-February 2001