When Organ Donors Are Still Patients: Is Premortem Use of Heparin Ethically Acceptable?
James M. DuBois, Francis L. Delmonico and Anthony M. D’Alessandro

Am J Crit Care. 2007;16: 396-400
© 2007 American Association of Critical-Care Nurses
Published online http://www.aajconline.org

Personal use only. For copyright permission information:
http://ajcc.aacnjournals.org/cgi/external_ref?link_type=PERMISSIONDIRECT

Subscription information
http://ajcc.aacnjournals.org/subscriptions

Information for authors
http://ajcc.aacnjournals.org/misc/ifora.shtml

Submit a manuscript
http://www.editorialmanager.com/ajcc

Email alerts
http://ajcc.aacnjournals.org/subscriptions/etoc.shtml
WHEN ORGAN DONORS ARE STILL PATIENTS: IS PREMORTEM USE OF HEPARIN ETHICALLY ACCEPTABLE?

By James M. DuBois, PhD, DSc, Francis L. Delmonico, MD, and Anthony M. D’Alessandro, MD

The “dead donor rule” was established in the context of organ donation to provide a societal assurance that organ recovery would not cause the death of a potential donor. Organs may be recovered for transplantation after death is declared either by a permanent absence of circulation and respiration in the patient or by an irreversible absence of brain function that includes cortical and brainstem activity.

Donation after cardiac death (DCD) involves recovering organs from patients who have been declared dead using circulatory-respiratory (as opposed to neurological) criteria. DCD donors (also known as non–heart-beating donors) are typically ventilator-dependent patients who have suffered devastating head trauma or stroke from an intracranial hemorrhage or anoxia but are not “brain dead.” (On a side note, in 2006 an Institute of Medicine [IOM] committee proposed a change in current terminology to eliminate any implication that only the brain or the heart has died in “brain death” or “cardiac death.” The committee recommended the terms DCDD, or “donation after a circulatory determination of death,” and DNDD, or “donation after a neurological determination of death.”)

In DCD donation, the primary care physician and surrogates of the patient have decided to discontinue treatment because any further treatment would be futile for achieving meaningful recovery. The withdrawal of treatment, which usually includes discontinuation of mechanical ventilation, may occur either in the operating room or in the intensive care unit. Death may be declared between 2 and 5 minutes after an absence of circulation (asystole) and breathing (apnea) have been observed. The IOM recommends a 5-minute interval between asystole and declaration of death to verify that a patient’s circulation will not resume spontaneously. The transplant team begins the organ recovery process only after the declaration of death by a physician who is not associated with the transplant service. Kidneys, livers, pancreas, and lungs can be successfully recovered from DCD donors. Outcomes from kidney transplants from DCD donors are comparable to those achieved following brain-dead donor transplantation.

The IOM has encouraged organ procurement organizations (OPOs) and healthcare organizations to implement DCD protocols so more organs can be available for transplantation. DCD also provides families with the option of organ donation when death cannot be determined neurologically and a decision to withdraw life-sustaining treatment has been made.

A recent consensus conference reaffirmed the position of the IOM and further refined guidelines for DCD. (The National Consensus Conference on Donation after Cardiac Death was held in April 2005 in Philadelphia, Pennsylvania, and was sponsored by the United Network for Organ Sharing Foundation, Gift of Life Foundation, Division of Transplantation/Health Resources and Services Administrations, American Society of Transplant Surgeons, American Society of Transplantation, Barr Laboratories Inc, and the National Kidney Foundation.) Finally, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, now called simply “the Joint Commission”) recently...
modified its standards to require hospitals to develop a DCD policy by January 2007.9

Reviews of death records and surveys of programs that have adopted DCD protocols indicate that DCD could contribute to a 16% to 48% increase in the number of donated kidneys7,10,11 and even more when so-called “uncontrolled” DCD protocols are used.2,12 (Uncontrolled DCD involves organ recovery following unexpected cardiac arrest and unsuccessful attempted resuscitation. Although the procedure is common in Spain and the Netherlands, it has not become common in the United States. The 2006 IOM report on organ donation recommended uncontrolled DCD demonstration projects in the United States.) Although the percentage of organs transplanted via a DCD protocol in the United States is small (currently 7%), a widespread increase is anticipated as more hospitals develop DCD policies and refer suitable candidates to OPOs. Nevertheless, some OPOs in the United States already recover more than 20% of their deceased donors’ kidneys using DCD procedures.2,13

DCD protocols are controversial because some ethicists and physicians have questioned whether donors are really dead at the time organ recovery begins,14,15 because of potential conflicts between successful organ donation and the dying patient’s best interests,16,17 and because DCD protocols involve the premortem administration of medications that are allegedly risky and not intended to benefit the donor.18-20 This article aims to address only the last controversy, with a particular focus on the premortem use of heparin.

In most DCD protocols, intravenous heparin is administered after the decision is made to withdraw life support and after consent is given for organ donation, but before death is declared.1 Heparin used in DCD is intended to prevent clotting within the organs that are to be transplanted. The long-term survival of the transplanted organ may be at risk if thrombi impede circulation to the organ after reperfusion. The omission of heparin could negatively impact organ recovery and hinder the acceptance of recovered organs for transplantation. Nevertheless, its use has been controversial. Two ethical questions stand at the center of this controversy:

1. Is it ethical to administer medications before death to potential organ donors if those medications are not primarily for the patient’s benefit?
2. Does heparin pose a risk of causing or hastening the death of DCD donors that is significant enough to justify a policy of prohibiting its premortem use?

Through consideration of these 2 questions, we argue that medical facts and precedent indicate that the use of heparin is in conformity with medical ethical principles and standards of practice.

Not for the Good of the Patient

Because anesthesiology and critical care professionals have a primary duty to treat the dying patient—not the organ recipient—DCD is sometimes perceived as creating a dilemma of care when professionals are asked to provide medications that are not meant to benefit the dying patient. Some have taken the stance that professionals should not be asked to provide medications that are not primarily for the benefit of the patient.21 However, this view is ethically problematic.

First, there is clear precedence for allowing patients to receive medical interventions that do not benefit them when they are motivated to benefit another. Blood donors undertake risks and minor harm (discomfort and inconvenience) for others. More significantly, living organ donors consent to surgery and loss of an organ or part of a vital organ to benefit another through the gift of donation.22

Second, DCD protocols require informed consent for donation. They also require consent for the use of all medications and procedures involved in organ procurement, including heparinization. Given informed consent and the precedent of allowing altruistic medical procedures, the administration of heparin to DCD donors is ethically permissible.

About the Authors

James M. DuBois is the Hubert Mäder Chair of Health Care Ethics, center director, and department chair at Saint Louis University, St Louis, Missouri. Francis L. Delmonico is medical director of the New England Organ Bank and a professor of surgery at Harvard Medical School. Anthony M. D’Alessandro is professor of surgery at the University of Wisconsin School of Medicine and executive director of the UWHC Organ Procurement Organization.

Corresponding author: James M. DuBois, PhD, DSc, Center for Health Care Ethics, Saint Louis University, 221 North Grand Blvd, St Louis, MO 63103 (e-mail: duboisjm@slu.edu).

One reason donation-after-cardiac-death protocols are controversial is that they involve the premortem administration of medications [such as heparin] that are allegedly risky and not intended to benefit the donor.”
of medications meant to facilitate organ donation does not itself pose an ethical problem; in fact, it facilitates a good deed. This view is reinforced in the American College of Critical Care Medicine/Society of Critical Care Medicine guidelines on DCD, which state that “medications that do not harm the patient and are required to improve the chances of successful donation are acceptable.”

Nevertheless, these guidelines also state that the “critical care professional is first and foremost caring for the dying patient” and “therapy that is harmful to the dying patient should be avoided even if it might improve organ viability.” The guidelines do not specifically mention heparin or anticoagulants anywhere, thereby leaving it up to providers to decide whether heparin is “harmful to the dying patient” and, accordingly, whether its use is truly ethical.

**Does Heparin Risk Causing Death?**

In response to concerns expressed by some ethicists regarding the safety of heparin—specifically, the concern that heparin could cause or exacerbate intracranial bleeding—the 1997 IOM committee suggested that its use be considered on a case-by-case basis. Furthermore, heparin is ordinarily contraindicated in patients with active bleeding, which may be suspected in some potential donors with severe head trauma. Nevertheless, the actual risks of administering heparin in the context of DCD are unsubstantiated.

Heparin is an anticoagulant; it prevents thromboembolism and blood clotting and does not dissolve existing clots the way thrombolytic (fibrinolytic) agents do. Therefore, whereas heparin may prevent clotting in a patient who is actively bleeding, it is unlikely to cause bleeding in a head-injured patient who is not actively bleeding. Moreover, if (1) a patient’s bleeding remains unresponsive to treatment, (2) a decision has been made that further life-sustaining treatments are futile, and (3) the patient is expected to die shortly after ventilation is withdrawn due to cardiopulmonary arrest, then it is highly unlikely that an agent that merely prevents blood clotting could become the cause of death. Heparin remains contraindicated for patients who may recover from head trauma through aggressive critical care, but such patients are not suitable candidates for DCD.

In addition, empirical data from DCD cases do not support some of the more outlandish claims that have been made that heparin is actually hastening the death of donors. For example, good clinical indicators now exist for predicting who will and who will not die within the 60-minute period that DCD protocols typically require. Patients are likely to expire within 60 minutes following withdrawal of life support when they score high on the University of Wisconsin DCD Evaluation Tool, which examines indicators such as the use of endotracheal tube versus tracheotomy, respiratory rate and tidal volume, negative inspiratory force, use of vasopressors and isotropes, spontaneous respirations during an attempted wean, patient age, and body mass index. Those who do not score high using these clinical indicators do not normally die within 60 minutes even when heparin, regitin (phenolamine mesylate), and morphine are administered (ie, the underlying pathology, not the administration of heparin, is the reliable predictor of death, because it is reliably the cause of death). This information was not available when the IOM issued its 1997 report, which included a warning about the use of heparin, even though—as the report itself observed—there had been no reported instances of heparin causing the death of a patient in the context of DCD.

It should be noted here that others have expressed worries that even if the risks of heparin are negligible when a patient’s death is imminent, some patients do not die within the timeframe allowed by DCD protocols and eventually return to the intensive care unit. Although heparin’s pharmacologic mechanism will not cause new bleeding, these critics argue that it could impede clotting in patients with active cerebral bleeding. But the effects of heparin—which typically last 2 to 6 hours—could be reversed by administration of protamine sulfate. Because these patients are imminently dying with a comfort-measures-only order in place—even when such patients do not die within the window of time allowed by DCD protocols—it is unlikely that a physician would actually administer protamine sulfate. Nevertheless, reversing the effects of heparin might be done at least for symbolically protective reasons.

**Is the Principle of Double Effect Helpful?**

We have argued that the risks of premortem use of heparin in DCD patients have been exaggerated.
Nevertheless, David Steinberg, one of the clearest defenders of the premortem use of heparin, has argued that some unknown level of risk remains, particularly in patients with preexisting hemorrhagic lesions or active brain bleeds.22 One therefore might ask, when the use of heparin could risk hastening death in some rare cases, is its use categorically prohibited in such cases?

heparin have been based on a misunderstanding of what the principle requires and a narrow understanding of what provides benefits to donors.

Recommendations

With the consent of donors or their surrogates, heparin should routinely be administered at the time of extubation when patients have sufficient circulation to distribute the heparin throughout their vital organs.

“With the consent of donors or their surrogates, heparin should routinely be administered at the time of extubation when patients have sufficient circulation to distribute the heparin throughout their vital organs.”

In answering ethical questions of this sort, the principle of double effect is sometimes invoked. This principle asserts that an action that produces a good effect and a bad effect might be permissible if the good effect is intended and the bad effect is merely foreseen but unintended. Therefore, if heparin were used with the intent of anticoagulation to improve organ function in transplant recipients and the risk of causing or worsening hemorrhaging in donors was merely foreseen but unintended, then, under specific conditions (including a favorable risk-benefit analysis), its use might be permissible.

The 1997 IOM report and some ethics commentators have questioned whether the principle could be applied when the recipient of the beneficial effect is not the same as the person suffering the unintended bad effect.26 Because heparin presents benefits to organ recipients but risks to the donor, the IOM declined to use the principle. However, traditional applications of the principle do not require that individuals suffering the bad effect also benefit from the good effect.

For example, the first known application of the principle is found in Thomas Aquinas’s discussion of killing in self-defense, which in no way benefits the aggressor who is killed.27 Likewise, removal of a cancerous uterus from a pregnant woman does not benefit a fetus, but has been justified even within Catholic healthcare where the fetus is ascribed the full rights of personhood.28

Even more fundamentally, we must ask whether it is true that heparinization offers no benefits to donors. If it enables patients to donate organs that are viable for transplantation and enables their families to find meaning in such donation, are they or their families truly without benefit?27

In short, refusals to apply the principle of double effect to the premortem administration of heparin have been based on a misunderstanding of what the principle requires and a narrow understanding of what provides benefits to donors.

REFERENCES

28. Childress JF. Non-heart-beating donors of organs: are the distinctions between direct and indirect effects and between killing and letting die relevant and helpful? Kennedy Inst Ethics J. 1993;3(2):203-216.

To purchase electronic or print reprints, contact The InnoVision Group, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 809-2273 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.