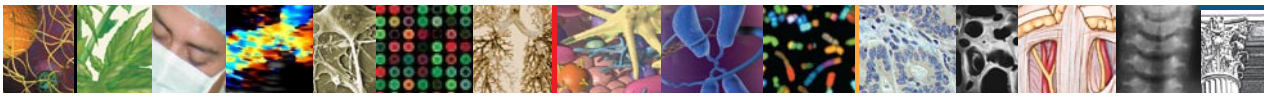

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Perspective

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Organ Donation after Cardiac Death

In this issue of the Journal, *Boucek et al. (pages 709–714) report on three cases of heart transplantation from infants who were pronounced dead on the basis of cardiac criteria. The three Perspective articles below and a video roundtable discussion at www.nejm.org address key ethical aspects of organ donation after cardiac death. Bernat and Veatch comment on the cases described by Boucek et al.; Truog and Miller raise a fundamental question about the dead donor rule. In a related Perspective Roundtable, moderator Atul Gawande, of Harvard Medical School, is joined by George Annas, of the Boston University School of Public Health; Arthur Caplan, of the University of Pennsylvania; and Robert Truog.* Watch the Roundtable online at www.nejm.org.

The Boundaries of Organ Donation after Circulatory Death

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Related article, p. 709

Organ donation after circulatory (or cardiac) death has become an accepted medical practice over the past 15 years.[1] Programs permitting such donations satisfy two needs: they provide organs in addition to those procured after brain death, and they fulfill the wish of family members that relatives with severe brain injuries serve as organ donors after cessation of life-sustaining therapy and subsequent death. The proliferation of protocols for donation after circulatory death has been spurred by the publication of three reports by the Institute of Medicine (IOM), support by the Department of Health and Human Services, and the establishment of criteria for such donation by the Joint Commission, which accredits U.S. hospitals. A 2005 national conference on the topic identified areas of consensus in an effort to standardize practice.[2]

Now that donation after circulatory death has become mainstream, researchers have begun to design innovative protocols that aim to improve the function of transplants and expand the donor pool. These protocols test the con-

Principles Governing Organ Transplantation Involving Deceased Donors.

Principle	Donation after Brain Death	Donation after Cardiac Death
Respect the dead donor rule	Yes	Yes
Determine death using accepted tests and procedures	Yes, using brain-death tests	Yes, using circulatory-death tests
Separate death-determination team from organ-procurement team	Yes	Yes
Separate decision to refuse life-sustaining therapy from decision to donate	Not applicable	Yes
Obtain surrogate consent for withdrawal of life-sustaining therapy	No	Yes
Obtain surrogate consent for organ donation	Yes	Yes
Provide palliative care during dying	No	Yes
Provide end-of-life family support	Yes	Yes
Properly design and scrupulously follow protocol; document findings	Yes	Yes

ceptual limits of donation after circulatory death — by permitting invasive intervention in living organ donors or by altering the tests required to determine death. In this issue of the *Journal*, Boucek et al. (pages 709–714) report their success with a research protocol for the donation of infant hearts after circulatory death, in which they shortened the duration of asystole required for the determination of death to less than that in prevailing standards of practice. To determine whether such protocols should be incorporated into standards of practice, we must analyze them within the context of accepted principles of organ transplantation from deceased donors (see table) and test them against the conceptual basis for death determination.

The decision of a patient (or a surrogate) to have life-sustaining therapy withheld should precede and remain independent of the decision to donate organs. The strict separation of these two decisions ensures that society's need or a physician's request for organs does not drive the decision to withdraw treatment — a possibility that may be even more of a concern when the patient and potential organ donor is a child.[3] In most cases, the inherent conflict may be mitigated (but not eliminated) by having a representative from the local organ-procurement organization, rather than physicians in the intensive care unit (ICU), speak to families about donation.

The physician team determining death must be strictly separated from the procurement team to prevent organ-procurement considerations from influencing the death determination. This separation of roles is even more critical in donation after circulatory death than in donation after brain death, because the former requires the withdrawal of life-sustaining therapy, which should be done by the donor's ICU physician. The recent allegations against Dr. Hootan Roozrokh in San Luis Obispo, California, demonstrates the serious problems that may result from the conflict created when a transplantation surgeon manages the terminal care of a potential organ donor.

The process of withdrawing life-sustaining therapy and providing appropriate palliative care for a dying patient should be the same, irrespective of the patient's donor status. The situation becomes complicated, however, when a protocol permits intervention in the living donor through the administration of intravenous heparin or vasodilators, not to benefit the donor patient but only to improve the function of transplantable organs. Protocols instituting extracorporeal membrane oxygenation (ECMO) in the donor after the declaration of death permit much more invasive intervention, including the insertion of arterial catheters before death. Advocates assert that surrogate consent sufficiently justifies these interventions, because they are minimally harmful to the patient and they benefit the organ recipient. Opponents argue that respect for the dying patient is being compromised.

The dead donor rule states that the donor must be dead before vital organs are procured. Death statutes require the irreversible cessation of circulation and respiration or the irreversible cessation of brain functions; the former constitutes an adequate criterion for death because, in the absence of cardiopulmonary resuscitation (CPR) or autoresuscitation, it inevitably leads to the fulfillment of the brain criterion.[4]

What duration of asystole proves irreversibility? The IOM has recommended that after the withdrawal of life-sustaining therapy, physicians wait 5 minutes after the onset of asystole to be certain that a heart rhythm sufficient to gen-

erate a pulse does not resume spontaneously. In such circumstances, autoresuscitation has never been reported after 65 seconds of asystole. Physicians can confidently declare the donor dead after 5 minutes of asystole and apnea, because without autoresuscitation or CPR, the cessation of circulatory and respiratory functions is permanent (will not return), and it inevitably and rapidly becomes irreversible (cannot return).[4]

In their investigational protocol, Boucek et al. shortened the interval of required asystole to 75 seconds on the grounds that 60 seconds was the longest reported duration of asystole that had been followed by autoresuscitation and that the sooner death can be declared after asystole, the less damage from warm ischemia will occur in the organs. What minimum duration of asystole ensures that autoresuscitation will not occur is an empirical question that can be answered conclusively only after observing many hundreds of patients. The recommended duration of asystole required for donation after circulatory death should be determined by scientific and public policy considerations. The IOM and the Canadian Council for Donation and Transplantation purposely chose a conservative duration of 5 minutes, which has been adopted by most donation programs, but a few protocols use as short a span as 2 minutes. In 2005, participants in a national conference on donation after circulatory death agreed with the recommendation by the Society of Critical Care Medicine to wait at least 2 minutes and at most 5 minutes.[2]

An unanswered question is whether cardiac transplantation from a donor declared dead according to a circulatory criterion retroactively negates the determination of death. Does the fact that a donor's heart is restarted in another patient prove that circulatory cessation was not irreversible? Or should the requirement of irreversibility be restricted to circulation within the donor?

Another unconventional protocol used by several hospitals for donation after circulatory death involves providing ECMO to the donor immediately after death is declared. If ECMO adequately provided circulation and oxygenation to the donor's entire body, it would retroactively negate the death determination by preventing the loss of circulation and respiration from becoming permanent or irreversible, potentially "reanimating" the heart and preventing the progression to brain destruction on which the circulatory criterion of death is predicated.

A University of Michigan ECMO protocol for procuring abdominal organs apparently avoids this problem.[5] During ECMO, an intraaortic occlusion balloon blocks all blood flow above the diaphragm so that only the abdominal organs are perfused with oxygenated blood. The thoracic organs and brain are isolated from this perfusion circuit and are destroyed by ischemic infarction. If blood flow above the diaphragm is successfully blocked, this protocol does not negate the previous determination of death. Ex vivo ECMO, in which the procured organ is temporarily perfused and preserved after removal from the donor's body, is another technique that is under investigation.

These investigational protocols test the permissible societal boundaries of donation after circulatory death. To what extent should society permit manipulation of an organ donor or alteration of the determination of human death for the good of organ recipients? A consensus-driven oversight process should determine whether investigational protocols reflect appropriate medical treatment and whether their translation into accepted clinical practice is sound public policy. Leaders of the critical care, neurology, and transplantation communities need to jointly draft practice guidelines for organ donation after circulatory death that establish acceptable boundaries of practice. These boundaries should be based on scientific data and accepted principles and should be demarcated conservatively to maintain public confidence in the integrity of the transplantation enterprise. I predict that when prudent boundaries are created, they will exclude whole-body ECMO of the donor and death determinations at 75 seconds of asystole.

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